


# Fidelity and adherence in self-management interventions for an ageing population

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Ultimately none of this would have been possible without my number one supporter in life, my husband, Christopher. This is also for you since you have lived and breathed this work over the years. Thank you just doesn't seem enough!

## Statement on authorship

I am first author on four of the included ten publications, senior author on one publication and a contributing author on five publications.

For the Lifestyle Matters trial I had an active role as the Trial Manager in the design, delivery, analysis and reporting of this trial. I also co-designed the fidelity assessment framework and process evaluation, including fidelity checklists, interview schedules and supporting documents. I conducted the semi-structured interviews, undertook observations, scored fidelity checklists and analysed all the data. I was lead author for the protocol and fidelity assessment publications and co-author for the trial results and qualitative findings publications.

I was also the Trial Manager for the Journeying through Dementia feasibility study in which I had an active role in the design, delivery, analysis and reporting of this study. I am the first author on the results publication. For the Journeying through Dementia trial, I was a co-applicant and lead for the fidelity assessment and qualitative sub-study. I therefore had an active role in the design, delivery, analysis and reporting of the trial. I also designed the fidelity assessment framework and process evaluation, including fidelity checklists, interview schedules and supporting documents. I conducted the semi-structured interviews, undertook observations, scored fidelity checklists and analysed all the data. I am lead author for the fidelity assessment and qualitative findings publications and co-author for the trial protocol, results, Patient and Public Involvement (PPI) and implementation publications.

A summary of these publications can be found in Chapter 3, Table 2 and full copies are presented in Chapter 4. All author contributions are available in Appendix 3. During my time working on the Lifestyle Matters programme of work, including delivery and reporting of the Journeying through Dementia feasibility study, I moved from Sheffield Clinical Trials Research Unit (CTRU) to Nottingham Clinical Trials Unit (NCTU). During this time, I was promoted from Trial Manager to Senior Trial Manager. During my time working on the Journeying through Dementia trial I was further promoted from Senior Trial Manager to Assistant Professor of Clinical Trials within the NCTU.

## Glossary

| | |
|---|---|
| ADLs | Activities of Daily Living |
| BCW | Behaviour Change Wheel |
| BRS | Brief Resilience Scale |
| CRLW | Community Research Link Worker |
| CTRU | Clinical Trials Research Unit |
| DEMQoL | Dementia Quality of Life measure |
| EQ-5D-5L | EuroQol 5 Dimension questionnaire |
| GAD-7 | General anxiety disorder scale |
| GP | General Practitioner |
| GSE | General self-efficacy scale |
| HTA | Health Technology Assessment |
| IADL | Instrumental activities of daily living |
| JtD | Journeying through Dementia |
| LM | Lifestyle Matters |
| MRC | Medical Research Council |
| NCTU | Nottingham Clinical trials Unit |
| NHS | National Health Service |
| NICE | National Institute for Health and Care Excellence |
| NIHR | National Institute for Health and Care Research |
| PEO | Person-environment Occupational Model |
| PHQ-9 | Patient Health Questionnaire (depression scale) |
| PPI | Patient and Public Involvement |
| PSMS | Physical self-maintenance scale |
| QALY | Quality-adjusted life years |
| RCT | Randomised Controlled Trial |
| SCT | Social Cognitive Theory |
| SF-36 | 36 item Short-Form Health Questionnaire |
| SMA | Self-Management Ability scale |
| SPLW | Social Prescribing Link Workers |
| SROI | Social Return on Investment |
| SSCQ | Short Sense of Competence Questionnaire |
| TDF | Theoretical Domains Framework |
| UK | United Kingdom |
| US | United States |
| WHO | World Health Organisation |
| WOOP | Well-being of Older People measure |

# Extended abstract

**Background:** Living longer has made ageing well a health and research priority and key global challenge for policy makers, with a national and international focus on self-management interventions. Conducting research in this area has many challenges. These include population level benefits, modelling consistent interventions, as well as access to adequate frameworks and tools to measure effectiveness, adherence and implementation; so further insights are needed. In this thesis two self-management intervention trials (Lifestyle Matters and Journeying through Dementia) and one feasibility study (Journeying through Dementia) are presented. The interventions are designed to support independence, increase self-efficacy and improve resilience to age well in the community.

**Aim:** To explore issues of fidelity, adherence, and adaptation in the implementation of complex self-management interventions for older adults at risk of age-related decline, including people living with early-stage dementia within the context of clinical trials.

**Methods:** Three studies were evaluated for this thesis, consisting of two multi-centre pragmatic parallel group randomised controlled trials (RCTs) and one single site feasibility study. A mixed methods process evaluation was conducted in both trials in line with Medical Research Council (MRC) guidance on the development and evaluation of complex interventions. This included fidelity assessment using an intervention fidelity framework and an embedded qualitative study consisting of semi structured interviews with participants, supporters, facilitators and supervisors. The feasibility study included a qualitative study with facilitators and participants.

**Results:**

Lifestyle Matters

Publication 1: Lifestyle Matters RCT of 288 randomised participants. Analysis showed no change in the SF-36 mental wellbeing dimension or quality of life at a population level. There was significant reduction in loneliness at 24 months suggesting the intervention could have influenced a reappraisal of relationships and social networks. A lack of adherence to the overall intervention (poor attendance at individual sessions of 32%) and failing to recruit those most at risk of age-related decline may have eroded receipt of benefit.

Publication 2: Fidelity assessment findings for the Lifestyle Matters trial demonstrated good fidelity to several intervention components: facilitator training and the group sessions. However, it was not possible to observe either the individual sessions or out of venue components of the intervention due to ethical and practical challenges e.g. maintaining

participant confidentiality. Future research should explore methods of assessing fidelity in trials of complex community-based interventions to overcome these challenges.

Publication 3: Qualitative findings from the Lifestyle Matters trial (13 participants). Behavioural changes identified by participants were mapped onto the intervention theory; namely practising decision-making and taking the lead, sharing and enacting activities, and positively managing age-related illness and disability. Thereby demonstrating the potential of the intervention and the self-management model for this population. Those deriving most benefit had experienced a significant life event and recognised the need for lifestyle change. How to identify and recruit adults entering age-related decline to participate in trials of self-management interventions requires further exploration.

Publication 4: Qualitative findings from 13 participants on the long-term effect on health and well-being of the Lifestyle Matters intervention at 24 months post randomisation. Sustained benefits and increases in self-efficacy were reported but were overall not perceived as significantly improving health and well-being. The intervention was found to boost self-efficacy through performance accomplishment and modelling influences. Those who experienced significant life changing events appeared to get most benefit, suggesting that the intervention maybe most effective at the time when lifestyle change must be reconsidered.

Journeying through Dementia

Publication 5: Journeying through Dementia feasibility study of 10 participants. Findings suggest the intervention design and mode of delivery was acceptable although capacity to participate in the intervention was influenced by memory. Reported benefits included increased confidence and self-efficacy, engagement in new or lapsed activities and re-engagement in fun and friendships. Appropriate outcomes were not available at the time to measure all aspects of reported benefit such as social support and social networks. Identification of participants through memory services maximised recruitment.

Publication 6: Journeying through Dementia trial of 480 participants. The study found no improvement in self-reported quality of life. There were indications of improved psychological wellbeing in those who received the intervention, but other secondary outcomes selected to address other important aspects showed no differences. The quality of life (DEMQoL) scores replicated those in other trials, from which we deduced the DEMQoL may not be sensitive enough to detect changes attributed to these types of intervention. The secondary outcomes had not been validated in dementia populations but were selected due to the paucity of suitable validated measures.

Publication 7: Fidelity assessment findings from the Journeying through Dementia trial replicated those of the Lifestyle Matters intervention. There was good fidelity for the facilitator training and delivery of the group sessions components. More data were collected on the out of venue and individual session components compared to Lifestyle Matters, but using limited and inherently biased methodology (facilitator self-report only). The question remains how to assess fidelity in community-based complex interventions without impacting upon the integrity of the intervention whilst maintaining participant confidentiality.

Publication 8: Qualitative findings from 25 Participants in Journeying through Dementia. This study identified four factors that could moderate delivery and receipt of the intervention: context and environment; readiness, training, skills and competencies of the workforce; identifying meaningful participation and relationships. Benefits of the intervention were nuanced to each participant in line with the personalised approach. Mechanisms of behaviour change were influenced by a range of individual social and contextual factors. Future research should consider how best to identify and measure the multifaceted interplay of mechanisms of change in self-management interventions.

Publication 9: Reflections on experiences of Patient and Public Involvement (PPI) in dementia research through the Journeying through Dementia Trial. Involving people with lived experience of dementia improved the accessibility and relevance of the research for participants. The successful engagement of people living with early-stage dementia and their supporters was associated with staff skills and engagement techniques to scaffold meaningful involvement, recognising participants' memory and cognitive capacity. Meaningful engagement was influenced by diminishing cognitive abilities and the resilience of the individual. Further consideration is needed in relation to the lifespan of a trial (typically 4 years +) and ongoing activities such as presentations and publications that typically occur beyond the end of the trial which can be affected by timing of conferences and administrative inefficiency.

Publication 10: A review of strategies to run a successful pragmatic trial of a self-management complex intervention for people living with early diagnosis dementia reflecting on the Journeying through Dementia Trial. Recommendations for future research include recruiting additional staff to deliver the intervention; having clear protocols in place for managing staff absences; utilising supervision to problem solve intervention delivery challenges; ensuring ring-fenced time to deliver the intervention and engage in supervision; and regular monitoring and feedback in relation to fidelity to delivery of the intervention.

**Discussion:** Self-management interventions have emerged as an attractive solution to policy makers seeking to address the challenges posed by an ageing population in conjunction with a resource diminished health service. However, translating this into effective, evidence-based practice requires careful consideration of how such interventions are delivered and evaluated in real-world settings. This body of work contributes to our understanding of the challenges and considerations surrounding fidelity, adherence, and adaptation in the implementation of complex self-management interventions for older adults at risk of age-related decline, including those living with early-stage dementia. It situates these issues within the broader context of intervention development and trial design drawing on the strengths of the presented studies, that of robust trial methodology, applied fidelity frameworks and multi-method process evaluations.

Evidence from the Lifestyle Matters and Journeying through Dementia trials indicates that older adults at risk of age-related decline, including those with early-stage dementia, can engage with and benefit from self-management interventions when these are appropriately supported and delivered at the right stage in life. However, these findings are drawn largely from predominantly homogeneous participant groups, which limits their wider generalisability and raises important questions about the cultural relevance, acceptability, and accessibility of such interventions for more diverse populations. Across both trials, fidelity to facilitator training and group-based components of the intervention was strong, but major challenges arose in monitoring the more flexible, individualised components due to ethical, practical, and confidentiality constraints. Poor adherence, particularly to individual sessions, combined with difficulty recruiting those most likely to benefit, likely diluted intervention effects. The selected outcome measures often lacked sensitivity to detect the nuanced, personalised changes reported qualitatively in this population. Fidelity was also shaped by contextual and workforce-related factors, including facilitator skill, supervision, and organisational pressures. Together, these findings highlight a core limitation of current fidelity methods in their design and application to complex, community-based self-management interventions for older adults, especially those at risk of age-related decline or living with early dementia.

Despite this, there remains a clear need for more targeted, adequately resourced, and effective interventions that reach those most likely to benefit and can be rigorously evaluated for implementation fidelity. Future research should therefore establish acceptable mechanisms for identifying and engaging those most likely to benefit and prioritise the development of fidelity frameworks and assessment methods that are more acceptable, unobtrusive, and both context and culturally appropriate.

# Chapter 1 – Introduction

## 1.1 Why are new health and well-being interventions needed?

In 2022 there were approximately 12.7 million people, or 19% of the population, living in the UK aged 65 years or older[1], and this age group had the highest level of growth[2]. By 2032 its expected that 13 million people, or 22% of the population will be aged 65 years or older[3]. Such population changes can have a significant impact on health and social care services in terms of provision, particularly in this age group who tend to have more complex needs. National data on ageing indicates a healthy later life is becoming increasingly unlikely and that more people will become at risk of age-related decline[3]. Reasons cited include poor physical and mental health and fewer people living with the traditional family structure for support, thereby increasing pressure on already overburdened health and social care services.

One result of living longer is an increase in people living with a diagnosis of dementia, a very common and disabling condition that affects all aspects of daily living (ADLs). It is currently estimated in the UK, that 944,000 people are living with dementia and this is expected to rise to more than 1 million by 2030[4]. Although not an inevitable outcome of ageing, age is the biggest risk factor for dementia[5]. The risk of developing dementia rises from 2 in 100 for people aged 69, to 33 in 100 over the age of 90[6].

This fundamental shift in the numbers of people living to old age, makes ageing well a health and research priority, and key challenge for policy makers. The traditional medical model of patient/provider presenting with a problem that can be treated within a service, is no longer adequate to meet this challenge. Current policy and guidance in the UK[7] and globally[8] acknowledge that current health and social care is under-resourced to meet the needs of a growing ageing population. Therefore, interventions are imperative that enable people living longer to maintain their independence and their physical and mental health whilst continuing to live and be supported in the community. This has been recognised in the core principles of the UK government's concept of 'productive healthy ageing' which refers to the need for interventions that offer a holistic approach to healthy ageing[1] and services that promote and empower positive lifestyle changes[9].

This thesis concentrates on an emerging model to support healthy ageing, that of self-management. With a focus on fidelity, adherence, and adaptation in the evaluation and implementation of such interventions for older people at risk of age-related decline

[1] For clarity the term 'healthy ageing' used in this thesis is defined by the World Health Organisation (WHO) as 'the process of developing and maintaining the functional ability that enables well-being in older age'.

including people living with early-stage dementia. The remainder of this chapter provides an overview of the body of research presented and summarises the aims and plan for the rest of the thesis.

## 1.2 Summary of included publications

This thesis includes 10 peer reviewed publications evaluating two self-management interventions; Lifestyle Matters and Journeying through Dementia, see Table 1. The detailed findings from each publication can be found in Chapter 4, however a brief summary is provided below.

### 1.2.1 Publications 1-4 – Lifestyle Matters trial

Publications 1-3 present the results, fidelity assessment and qualitative study findings from the Lifestyle Matters RCT that compared the Lifestyle Matters intervention to a usual care control. The primary outcome was mental well-being at 6 months on the Short Form-36. A fidelity assessment and qualitative sub-study were embedded to evaluate delivery according to protocol, acceptability, experiences and impact of the Lifestyle Matters intervention on participants and facilitators in context of the trial findings. Publication 4 further explores qualitatively the sustainability of intervention effects 24 months post intervention. Although the intervention was found to have no benefit *[Publication 1]*, participation for some people, was found to moderate and in some instances overcome the consequences of age-related illness, disability, and social isolation and make lifestyle changes *[Publications 3, 4]*. Benefits, relating to meeting new people, creating new friendships and sustaining lifestyle change following intervention cessation were only partially fulfilled and engagement in individual sessions was limited. The full extent of sustained behavioural change that the intervention might encourage was unlikely to be achieved due to incomplete delivery of the overall program *[Publication 2]*. Small numbers of participants who reported deriving significant benefit were those who had also experienced life-changing events and could consequently recognise the need to make changes *[Publications 3, 4]*. Findings from the interviews demonstrated, participants may have required more assistance than was available to them to benefit fully from the intervention and sustain any gains that they may have obtained [Publications 3, 4]. Ethical considerations and the need to maintain participant confidentiality limited our ability to observe all intervention components in practice *[Publication 2]*. Poor adherence to the individual sessions and challenges recruiting those most at risk of age-related decline may have eroded benefit of the intervention *[Publications 3, 4]*.

**Table 1: Thesis publications**

| Publication | Title | Focus |
|---|---|---|
| 1 | Mountain G, Windle G, Hind D, Walters S, Keertharuth A, Chatters R, Sprange K, et al. A preventative lifestyle intervention for older adults (lifestyle matters): a randomised controlled trial. Age Ageing. 2017 Jul 1;46(4):627-634. https://doi.org/10.1093/ageing/afx021. | Trial results |
| 2 | Sprange K, Mountain G, Craig C. Evaluation of intervention fidelity of a complex psychosocial intervention Lifestyle Matters: a randomised controlled trial *BMJ Open* 2021;11:e043478. doi: 10.1136/bmjopen-2020-043478 https://bmjopen.bmj.com/content/11/4/e043478b | Fidelity |
| 3 | Mountain G, Sprange K, Chatters R. Lifestyle Matters Randomized Controlled Trial of a Preventive Health Intervention for Older People: Qualitative Sub Study with Participants and Intervention Facilitators. Clin Interv Aging. 2020;15:239-253 https://doi.org/10.2147/CIA.S232108 | Qualitative |
| 4 | Chatters R, Roberts J, Mountain G, Cook S, Windle G, Craig C, Sprange K. The long-term (24-month) effect on health and well-being of the Lifestyle Matters community-based intervention in people aged 65 years and over: a qualitative study. BMJ Open. 2017 Sep 24;7(9):e016711 DOI: 10.1136/bmjopen-2017-016711 | Qualitative |
| 5 | Sprange K, Mountain GA, Shortland K. *et al.* Journeying through Dementia, a community-based self-management intervention for people aged 65 years and over: a feasibility study to inform a future trial. *Pilot Feasibility Stud* 1, 42 (2015). https://doi.org/10.1186/s40814-015-0039-6 | Feasibility results |
| 6 | Mountain GA, Cooper CL, Wright J, Walters SJ, Lee E, Craig C, Berry K, Sprange K et al. The Journeying through Dementia psychosocial intervention versus usual care study: a single-blind, parallel group, phase 3 trial. Lancet Healthy Longevity. 2022 Apr;3(4):e276-e285. 10.1016/S2666-7568(22)00059-9 | Trial results |
| 7 | Sprange K, Beresford-Dent J, Mountain G et al. Assessing fidelity of a community based psychosocial intervention for people with mild dementia within a large randomised controlled trial. BMC Geriatr 21, 119 (2021). https://doi.org/10.1186/s12877-021-02070-8 | Fidelity |
| 8 | Sprange K, Beresford-Dent J, Mountain G, Thomas B, Wright J, Mason C, Cooper CL. Journeying through Dementia Randomised Controlled Trial of a Psychosocial Intervention for People Living with Early Dementia: Embedded Qualitative Study with Participants, Carers and Interventionists. Clin Interv Aging. 2021 Feb 4;16:231-244. doi: 10.2147/CIA.S293921 | Qualitative |
| 9 | Beresford-Dent J, Sprange K, Mountain G, et al. Embedding patient and public involvement in dementia research: Reflections from experiences during the 'Journeying through Dementia' randomised controlled trial. *Dementia*. 2022;21(6):1987-2003. doi:10.1177/14713012221106816 | PPI |
| 10 | Berry K, Wright J, Sprange K, Cooper C, Courtney-Walker R, Mountain G. The implementation of Journeying through Dementia: Strategies to run a successful pragmatic multicenter trial of a complex intervention. Brain Behav. 2021 Dec;11(12):e2436. doi: 10.1002/brb3.2436. https://doi.org/10.1002/brb3.2436 | Implementation |

### 1.2.2 Publication 5 – Journeying through Dementia feasibility study

Part of the Lifestyle Matters programme of work was to establish whether the intervention could be adapted for other populations, in this instance community living people diagnosed with early-stage dementia. Publication 5 presents the findings from the Journeying through Dementia feasibility study to determine the feasibility of conducting a future population-based trial. An embedded qualitative study evaluated acceptability and experiences of participants, carers and the intervention facilitators. Findings suggested the intervention was acceptable to participants, carers and facilitators and guided future eligibility criteria regarding capacity requirements to engage. Other key findings included identification of participants through services was essential to recruit those most likely to benefit, and highlighted the paucity of validated meaningful outcomes, particularly in social support and networks, at the time of the study.

### 1.2.3 Publications 6-10 – Journeying through Dementia trial

Following on from the successful feasibility study, publications 6-8 present the results, fidelity assessment and qualitative sub-study work from the Journeying through Dementia Trial. The primary outcome was the DEMQol at 8 months, a quality-of-life outcome specifically designed for people living with dementia. The fidelity assessment and qualitative sub-study evaluated acceptability, experiences and impact of the Journeying through Dementia intervention on participants, carers and facilitators. Like Lifestyle Matters, the Journeying through Dementia intervention also found no change in the primary outcome, nor the secondary outcomes except psychological wellbeing *[Publication 6]*. Possible explanations were that the primary outcome was not sensitive enough to detect small changes attributed to the intervention [*Publication 8*]; and, that secondary outcomes, although used in older adult population research, had not been validated in dementia populations. The paucity of suitable validated outcome measures was previously identified during feasibility work *[Publication 5]*. Again, findings from the fidelity assessment replicated those from Lifestyle Matters. Good fidelity was found for intervention components that could be directly observed. However, for those that could not be observed whilst maintaining integrity for the intervention and ethical boundaries, assessing fidelity was problematic *[Publication 7]*. Qualitatively we found that intervention benefits maybe nuanced to each individual including social and contextual factors *[Publication 8]*. Thereby supporting the theory that current outcome measures may not be adequate.

Publication 9 reflects on our experiences of Patient and Public Involvement (PPI) in dementia research through the Journeying through Dementia Trial. The successful engagement of people living with early-stage dementia and their supporters was associated with staff skills and engagement techniques to scaffold meaningful involvement although

engagement was influenced by diminishing cognitive abilities and the individual's resilience. The inclusion of people with lived experience of dementia is essential to ensure relevance of research to those it serves.

Publication 10 shares our experiences of implementing the Journeying through Dementia trial resulting in a number of recommendations for future research including recruiting additional staff to deliver the intervention; having clear protocols in place for managing staff absences; utilising supervision to problem solve intervention delivery challenges; ensuring ring-fenced time to deliver the intervention and engage in supervision; and regular monitoring and feedback in relation to fidelity to delivery of the intervention.

The protocol publications for both the Lifestyle Matters trial and the Journeying through Dementia trial have been included in appendix 1 for reference.

## 1.3 Aim of this thesis

The aim of this thesis is to explore issues of fidelity, adherence, and adaptation in the evaluation and implementation of complex self-management interventions for older adults at risk of age-related decline, including people living with early-stage dementia within the context of clinical trials. It also seeks to explore wider issues relevant to the development, uptake and effectiveness of such self-management interventions to inform future implementation in practice.

The thesis plan is as follows. Chapter 2 provides a narrative overview of the literature relevant to the themes explored in the publications presented in this thesis. More specifically, reflecting on the challenges to adequately evaluate fidelity and adherence in complex self-management interventions to support healthy ageing. Chapter 3 then introduces the Lifestyle Matters and Journeying through Dementia trials; two self-management interventions for older adults living with age-related decline (Lifestyle Matters) including early-stage dementia (Journeying through Dementia). Chapter 4 comprises the 10 selected publications presented in full. Chapter 5 collates and discusses the main findings from the body of work as a whole. Chapters 6 and 7 explore these findings in relation to the wider literature on fidelity and adherence in self-management interventions as well as the broader impact on current policy, service delivery and research conduct.

# Chapter 2 - Background literature

## 2.1 What is fidelity in a clinical trial and why does it matter?

In the context of clinical trials, fidelity refers to the integrity and quality with which an intervention is implemented. It encompasses not only whether an intervention was delivered as planned (adherence), but also how well it was delivered, including the competence of those delivering it and the level of participant engagement[10]. High fidelity strengthens a trial's internal validity by demonstrating that outcomes are a true reflection of the intervention rather than variation in how it was delivered or received. Conversely, low fidelity introduces uncertainty about whether observed outcomes are attributable to the intervention itself or to inconsistencies in implementation[11]. Within evidence-based practice, establishing fidelity is therefore essential. It provides the foundation for assessing not only whether an intervention works, but whether it can be reliably and feasibly implemented in routine clinical or community settings. This underlines the importance of systematic approaches to fidelity assessment in both the development and evaluation of complex health interventions. The following section will now explore some of the core theoretical frameworks available for assessing fidelity within self-management interventions.

## 2.2 How can we assess fidelity of self-management interventions?

Self-management interventions are by design complex comprising multiple interdependent components that integrate a personalised patient approach. Person-centred care being an approach to services that places the individual at the heart of their own care, making them an active partner in decisions about their needs, goals, and preferences. These complexities are further amplified in community-based settings where interventions must be delivered flexibly and responsively to individual needs. Such characteristics pose significant methodological challenges for assessing fidelity where real-world variability can affect both delivery and engagement[12].

Current evaluation of complex interventions often relies on established fidelity assessment frameworks most notably the Medical Research Council (MRC) framework for complex interventions[13]. This framework provides structured guidance for developing, evaluating, and implementing interventions that involve multiple interacting components, such as those commonly used in self-management interventions. The framework recognises that complex interventions require a systematic, theory-informed, and iterative approach to ensure they are both effective and implementable in practice. Thereby encouraging researchers to move beyond simple cause-and-effect testing toward a holistic understanding of how and why interventions work (or fail) in practice, strengthening the evidence base for policy and health service decision-making.

Owing to its widespread adoption, the MRC Framework has undergone multiple revisions to address key limitations, some of which have been incorporated in the most recent 2021 update[13]. The latest guidance progressed from a linear model of development, piloting, evaluation, and implementation, stages which often overlap in practice[14], towards emphasising a more flexible approach that addresses the dynamic and multi-dimensional nature of complex interventions. While the revised framework now encourages researchers to develop and refine a programme theory of change, it does not mandate the use of any specific theoretical approach. This flexibility, while allowing adaptation to diverse interventions, can result in subjective theoretical choices, potentially reducing consistency and reproducibility in understanding intervention mechanisms. Furthermore, as with many frameworks that attempt to integrate theory and practice, the MRC guidance remains resource intensive and time consuming. These demands may limit uptake, slow the translation of evidence into practice, and pose practical challenges for research teams, particularly when interventions target complex, community-based populations such as older adults at risk of age-related decline.

To address these limitations, theory-informed approaches have been developed to work alongside the MRC Framework. Two key frameworks are that of the Behaviour Change Wheel (BCW)[15] and Theoretical Domains Framework (TDF)[16]. The BCW offers a systematic structure for intervention design, beginning with behavioural diagnosis through the COM-B model (Capability, Opportunity, Motivation–Behaviour)[17] and progressing to the selection of appropriate intervention functions (e.g., education, training, enablement) and policy categories (e.g., guidelines, regulation). Similarly, the TDF consolidates multiple psychological and organisational theories into a single framework of domains such as knowledge, skills, social influences, and beliefs about capabilities, allowing researchers to identify the key determinants, barriers, and facilitators of target behaviours. When applied alongside the MRC Framework their use can strengthen the theoretical grounding of behaviour change interventions, as well as enhance replicability and the accuracy of fidelity assessments which are critical for interpreting intervention effectiveness within clinical trials.

Despite these advantages, the BCW and TDF also have limitations. As with the MRC Framework, they can be time and resource intensive posing significant barriers in clinical trials which operate under strict constraints of time, funding, and staffing. Their complexity may also pose practical challenges for research teams unfamiliar with behavioural theory resulting in difficulties operationalising the frameworks or requirements for additional expertise on trial teams[18]. Despite these challenges, their use is increasing, and they are

contributing to greater rigour, transparency, and interpretability in the design, implementation, and evaluation of behaviour change interventions.

Well-designed fidelity assessment is particularly important for self-management interventions, given their inherent complexity, multi-component structure, community setting and need for personalised delivery. By providing a crucial link between intervention theory and implementation, fidelity assessment helps explain variations in participant outcomes and identifies which components are essential for achieving meaningful change. The following section will now examine the methods and tools available for assessing fidelity in self-management interventions. This includes practical approaches for measuring adherence, facilitator competence, and participant engagement, as well as wider discussion on strategies for balancing fidelity with necessary adaptation across diverse community and clinical contexts.

## 2.3 What methods and tools are used to monitor fidelity?

Although there is agreement that assessment of fidelity of self-management interventions should be systematic[12] there is currently no standardised methodology or tools to support this. Consequently, researchers have adopted a range of complementary methods and tools to capture the different dimensions of fidelity and competency of delivery which are often combined as per MRC guidance[13], to provide the most comprehensive understanding of intervention fidelity.

A common method employed in the assessment of self-management interventions is that of direct and/or non-direct participant observations. Direct observation involves the researcher being present during the intervention, allowing for real-time data collection on behaviours, interactions, and contextual factors[19]. This can be particularly valuable in populations living with age related and/or cognitive decline, where subtle communication cues, functional limitations, or fluctuating cognitive engagement may influence how an intervention is delivered and received. However, direct observation may heighten self-consciousness or alter natural behaviour (Hawthorne effect) of those being observed, potentially impacting ecological validity[20]. Such effects can be especially pronounced among older adults, particularly those living with dementia, who may already feel scrutinised or anxious about their performance. Whereas non-direct methods, including audio or video recordings, reduce the influence of researcher presence and allow repeated review, supporting more reliable coding and assessment. Yet they may fail to capture contextual nuances such as vision or hearing challenges, home environment constraints, or spontaneous peer interactions that are often critical to understanding fidelity and engagement in home and community-based interventions. Both approaches are resource

intensive, requiring considerable time, training, and logistical planning, particularly in multi-site or community-based studies. They also raise ethical considerations around privacy, consent, and data security, particularly when involving vulnerable populations and when conducted in community settings[21]. Selecting between direct and non-direct observation requires careful consideration of research objectives, participant characteristics, resource availability, and the balance between depth of insight and methodological rigour.

Checklists are one of the most widely used tools for assessing fidelity observations, offering a structured and quantifiable way to determine whether key intervention components are delivered as intended[22]. Typically completed by trained observers or facilitators, they support consistent assessment across sessions and sites. However, this standardisation can limit sensitivity to interpersonal, cultural, and contextual factors that shape engagement in ageing populations such as sensory decline, mobility limitations, or variable confidence. Checklists also struggle to capture necessary adaptations common in community-based self-management interventions, where flexibility is often essential[23]. Moreover, behavioural interventions depend heavily on facilitator competence and participant responsiveness, elements that may require subjective judgement[24]. Reliability can be further affected by observer bias, when a researcher's expectations, beliefs, or prejudices influence the recording of data, underscoring the need for rigorous training and, where possible, inter-rater checks. Crucially, checklists alone offer limited insight into mechanisms of change or the link between fidelity and participant outcomes. Combining checklists with qualitative methods and self-report tools therefore provides a more comprehensive understanding of delivery quality. While efficient and widely used, their limitations highlight the need for multi-method fidelity assessment approaches in complex self-management interventions for older adults.

In addition to observational methods, self-report approaches are frequently employed as a means of assessing fidelity in self-management interventions. They offer a practical and low-resource complement to observation, enabling facilitators to record session content and adaptations, and allowing participants to reflect on their understanding and use of self-management strategies. Among older adults, these reports can reveal valuable insights into perceived relevance, comprehension, and real-world enactment. However, self-report accuracy may be affected by cognitive impairment recall difficulties, social desirability, or reluctance to disclose challenges particularly in interventions targeting independence, where participants may fear judgement[25]. These limitations necessitate careful design of self-report tools and appropriate timing relative to intervention activities. When combined with other measures, self-report tools can contribute valuable information, enhancing the

overall robustness and interpretability of fidelity assessment in complex self-management interventions[12].

Other commonly used fidelity assessment tools are records and logs, including session attendance sheets, supervision logs, and training records which can provide an inexpensive, practical and structured means of assessing fidelity in self-management interventions. Attendance logs offer insight into participants' exposure to the intervention (or dose), although they cannot capture the quality of engagement or understanding. Supervision and training records can also document facilitator performance, protocol deviations or adaptations, and ongoing quality assurance through competency monitoring[26]. These tools are particularly valuable for ensuring consistency across facilitators and sites and, in ageing populations, can help identify patterns in attrition or barriers to participation such as health fluctuations or transport difficulties as well as adaptations made in response to age-related needs[23]. However, their usefulness depends on the accuracy, completeness, and consistency of documentation[10], and they provide limited insight into contextual or interpersonal aspects of delivery. When used alongside complementary fidelity methods, records and logs can contribute to a more transparent and auditable account of intervention implementation.

Finally, participant and facilitator interviews offer a rich qualitative approach to assessing fidelity, particularly in relation to receipt and enactment of intervention components. For older adults, interviews can illuminate how they understood, internalised, and applied self-management strategies in everyday life, as well as how age-related challenges or personal contexts shaped their engagement [19]. This approach allows researchers to capture the nuances of participant engagement, such as personal motivations and contextual barriers which may not be evident through structured observations or checklists. Facilitator interviews can also provide insight into the fidelity of delivery from the perspective of those implementing the intervention, highlighting challenges, adaptations, and perceived effectiveness. While these methods rely on self-report and retrospective interpretation, introducing potential bias, they uniquely reveal subjective experiences, variations in implementation, and the complex interplay between intervention content and individual behaviour. When integrated with quantitative measures, interviews can contribute a more comprehensive understanding of fidelity, helping to explain why interventions succeed or fail.

Combining these approaches can provide a more comprehensive understanding of implementation quality in self-management interventions for older adults[12]. This multi-method approach not only strengthens the internal validity of the trial but also informs

future scalability and adaptation of interventions in pragmatic healthcare settings. However, self-management interventions for older adults are highly heterogeneous, often tailored to individual needs and delivered across diverse community contexts. As a result, bespoke fidelity tools are frequently created for each intervention, limiting opportunities for validation, cross-trial comparison, or accumulation of shared learning[19]. This presents a particular challenge given the multi-component nature of these interventions. Failure to adhere to even a single component may diminish potential benefits, and such risks may be heightened in community-based delivery where variability is greater. Consequently, our understanding of how well existing monitoring methods capture fidelity in complex, community-led self-management programmes for older adults experiencing age-related decline remains limited. This raises the question, how can we best assess fidelity in complex, multi-component self-management interventions for older adults while preserving both participant safety and the integrity of the intervention?

Understanding how to assess fidelity effectively is only one part of ensuring that complex interventions achieve their intended outcomes; it is equally important to understand the theoretical foundation of the interventions themselves. To evaluate fidelity meaningfully, we must also clarify what is being delivered, why it is expected to work, and how its core components interact to produce change. In this context, the self-management model, underpinning the two trials included in this thesis, provides a critical conceptual basis. The next section therefore examines the principles of the self-management model, situating it within contemporary healthcare policy and exploring its impact on the design and fidelity of interventions aimed at supporting ageing well.

## 2.4 What is the self-management model?

The concept of self-management has evolved over the last 40 years from the Corbin and Strauss tripartite model of medical, behavioural and emotional management[27], to more disease specific models. Common attributes of self-management models include problem solving, decision-making, resource management, relationships, managing symptoms and disability, maintaining diet and exercise, and psychological and social (lifestyle) adjustments[28-30]. Self-management interventions have also been found to have a positive effect on health outcomes, in particular quality of life[31]. In addition to being a contemporary health management tool, self-management interventions are increasingly recognised as a key component of preventive care[32]. Preventative interventions being designed to promote independence and delay deterioration of a person's health and/or wellbeing. Indeed the UK NHS Long term plan[33] currently advocates the design and implementation of self-management interventions for healthy ageing.

An example of a self-management programme from the UK is the Expert Patient Programme for people living with chronic illness which placed the patient as expert in managing their illness[34]. The programme used a whole systems approach providing a structured tool to enable individuals to cope with multiple dynamic physical and social changes. This was achieved working in partnership with professionals to enhance the existing skills of the individual in managing their own health and wellbeing. Some of the benefits identified included enhanced quality of life, reduced reliance on health services and greater empowerment. Thereby implying there could also be the added benefit of reducing burden on healthcare resources[35]. However, there were also challenges around how to incorporate self-management approaches into people's everyday lives and how to integrate them into people's existing coping strategies[34].

In line with the self-management model is the current move towards a personalised medicine approach in which treatments and interventions are tailored to an individual's unique characteristics including environments, and lifestyles. This is on the understanding that an intervention that can be tailored to an individual's needs is likely to be more impactful. This potential has also been recognised in the UK, in which personalised medicine has been integrated through initiatives like the NHS Long-Term Plan[33], which envisions expanding personalised medicine across various conditions.

In addition to this, evidence is also emerging that patients with co-morbidities could benefit from self-management care coordination strategies, including a combination of clinical or social care input (case management) and education[36], and that such strategies are gaining prominence in research into healthy ageing[37,38]. Such multimorbidity self-management models would be most appropriate for adaptation for an ageing population due to their heterogeneous nature in terms of recognising disease severity, functional status, or prognosis. Thereby channelling a personalised medicine approach.

It is worth noting however, a number of barriers to engagement with self-management interventions have been identified by patients. For example, a significant factor is lack of motivation when living with multimorbidity, which has been found to be confusing for some patients and overwhelming for providers due to a heterogeneous population[39]. Self-management is therefore seen as adding to this burden resulting in disengagement especially if the programme is felt to be unrealistic leading to lack of progress[40]. Other barriers to participation in self-management interventions include physical and mental health decline, lack of education on medical conditions; and socioeconomic status[41]. To support engagement, any self-management programme should adopt a patient-centred approach. The approach should align with the perspectives of those participating

incorporating an understanding of the effects of physical and psychological multimorbidity. As a whole systems approach incorporating health and social care, family, carers and the community, the self-management model is well placed to support healthy ageing.

## 2.5 How can the self-management model support ageing well?

### 2.5.1 Re-valuing and re-empowering ageing

As we age, we may experience significant health and personal care challenges including multimorbidity, polypharmacy, reduced activities of daily living, frailty, social isolation, and cognitive decline which can reinforce negative stereotypes and perceptions of dependence [42]. To define older adults in such a way however strips individuals of their identity, disempowers them and undervalues the contribution they can make to society as an individual and as part of a community. In contrast, self-management interventions promote successful ageing by supporting physical and mental wellbeing, resilience and independence through re-skilling and lifelong learning [42].

Research has shown that self-management interventions are feasible for older adults at risk of age-related decline, including those living with early-stage dementia enabling engagement, learning, and active participation in healthcare[43,44]. Research has also demonstrated that such populations can engage with and learn new information, particularly when associated with positive feelings and emotions[45,46]. As a model for care they enable and empower older adults at risk of age-related decline to take an active role in their healthcare, with group-based interventions delivering better outcomes[47]. They could therefore offer a way to tackle the experience of stigma thereby improving outcomes. However they may be less effective for those with advanced decline due to reduced capacity for engagement[48] highlighting the importance of early implementation post diagnosis[45].

### 2.5.2 Offsetting decline and stigmatisation

People living with dementia have additional cognitive challenges that can exacerbate stigma and limit engagement. The stigma of a dementia diagnosis alone can lead to increased isolation and poor management of the condition through impact on identity or sense of self and reduced self-efficacy[48]. Kitwood and Bredin (1992) proposed ageing, and dementia does not progress along a linear path, instead it varies resulting in the need for care that affirms what they termed 'personhood'. This includes recognition, respect, trust, and dignity in a way that supports that person's sense of self[49]. The concept of personhood is now generally used as a lens to understand the relationship and impact of cognitive decline on a person's identity, or their sense of self. Jaggers et al (2022) later proposed that personhood in older

people should be a process of identity maintenance as opposed to re-constructing of the self and identity over time thereby creating coherence across the life experience[50]. Personhood therefore recognises the individual and their agency including the right to make decisions about one's life. Self-management interventions may help offset decline and stigmatisation associated with ageing, by providing a structure in which maintenance of personhood could be propagated with support of caregivers, health services and wider social networks.

### 2.5.3 Retaining independence

Independence is fundamental to healthy ageing, encompassing social participation, autonomy, and quality of life[51]. Ageing is known to impact independent functioning at a physical, personal, societal, and environmental level[52,53]; and the concept of independence and promoting aging in place (i.e. in the community) is related to a person's quality of life[54]. To support continued independence, it is essential that individuals are empowered by health and social care providers to remain autonomous for as long as possible, whilst maintaining dignity and privacy[54]. The self-management model offers individuals and their carers a way to participate in their own healthcare, including decision making, thereby maintaining a level of independence important for quality of life whilst reducing dependence on current care pathways[48].

With an ageing population, greater responsibility for care provision is falling to the community including family and friends. According to Age UK, there are approx. 10.6 million people who provide unpaid care in the UK, with 30% of those carers providing over 50 hours of care per week[55]. A significant amount of this care is also provided by older carers who are themselves living with a long-term illness or disability. Data from Alzheimer's Research UK, show that the burden of unpaid care is even greater for the families of people living with dementia. For example 36% of family carers of people living with dementia will spend 100 hours a week or more in their caring role[56]. Self-management should not be seen as a replacement for health care services but as an adjunct to support quality independent living in the community for as long as possible. Self-management interventions need to include participation by family and health care services which have been associated with better outcomes[57]and greater adherence[58]. So, it is important to design interventions to incorporate these wide-ranging relationships.

### 2.5.4 Improving self-efficacy

Low self-efficacy undermines motivation and health management in older adults with multimorbidity[59]. Self-management interventions have shown potential to increase self-efficacy in older adults helping maintain independence and improving general health

through skill development that is transferable within different contexts and across evolving life circumstances[60,61]. So, there is a beneficial relationship between self-efficacy, motivation and overall health and wellbeing in older adults[62,63]. Greater self-efficacy can lead to effective problem solving, increase in positive emotions, prevent decline, and ultimately improve life satisfaction[64,65]. This was supported by Cramm, Twisk et al, in which they proposed self-management interventions should be implemented early in community dwelling older-adults to delay the onset of frailty and loss of self-efficacy[66], though interventions should complement, not replace, professional care[67].

### 2.5.5 Maintaining social connectivity

Social connectivity plays a significant role in maintaining mental and physical health [68] as well as wellbeing and independence [69]; with poor social engagement and contribution associated with poor health and well-being outcomes[70]. Therefore, the concept of 'ageing in place', [71] that is based in a person's community and social network, is of particular interest. The growing pressures on healthcare services to support an ageing population is unsustainable therefore we need to find other ways to provide that support, in which families and the community could play a significant role. Self-management interventions embedded within integrated health and social care frameworks could strengthen social participation, mitigate isolation, and support sustainable community-based care[72].

Having established the conceptual foundations of the self-management model and its relevance to designing and implementing complex interventions, the next step is to consider how success is defined and measured. Understanding fidelity alone is not sufficient if the outcomes used to evaluate effectiveness fail to capture what truly matters to participants. In self-management interventions, particularly for older adults and those living with early-stage dementia, meaningful evaluation depends on aligning how interventions are delivered with how their impact is experienced. This connection between fidelity and outcomes is critical for determining not only whether an intervention works as intended, but also whether it delivers genuine value to those it aims to support. The following section therefore explores how meaningful outcomes can be identified and measured in the context of self-management interventions for older adults experiencing age-related decline.

## 2.6 How can we measure meaningful outcomes in self-management interventions?

Fidelity assessment determines whether interventions are delivered as intended, while outcome measures indicate whether they achieve their goals. However, when outcomes fail to reflect participants' priorities, such as social participation, identity maintenance, or emotional wellbeing, interventions may appear ineffective despite high fidelity[73]. This is particularly salient for older adults and people living with dementia, where cognitive,

cultural, and social factors influence both engagement and how benefit is experienced or expressed. Aligning fidelity frameworks with person-centred and context-sensitive outcomes[74] will therefore strengthen the validity and interpretability of trial findings, ensuring that assessments of "what works" truly reflect meaningful change for participants.

Although there are health outcome sets for older adults specifically developed for practical use by healthcare providers in services[75], there remains limited focus on outcomes addressing emotional, social, and existential needs. Recent reviews indicate that existing measures often prioritise clinician-defined outcomes, such as morbidity and mortality, rather than outcomes that are meaningful to the individuals themselves, who may value quality of life, autonomy, and social engagement more highly[36,76].

We already know that many outcome assessments rely on retrospective judgement which can be challenging for individuals with episodic memory deficits, who may prefer to provide contemporary reports[77]. Identifying ways of minimising requirement for recall could improve data credibility when using measures in populations with existing or declining cognitive function[38]. The COTiD-UK trial, evaluating an occupation based intervention to promote independence and quality of life in people with dementia, proposed that outcomes could focus on maintenance rather than improvement as a more realistic and achievable measure of effectiveness for self-management interventions designed for people living with dementia[38]. This would be in line with Jagger et al's proposed maintenance of identity in older age as important to personhood[50]. There is a push to develop more sensitive outcome measures for both people living with early-stage dementia and their carers, but this is still in its infancy and new measures would require validation as part of trials[78,79].

Social participation is a key example of a meaningful, modifiable outcome that supports well-being and independence in older adults. Social participation fosters well-being, combats isolation and loneliness, and promotes active and healthy aging by offering opportunities for social interaction, engagement, and maintaining or establishing supportive relationships. There are a number of outcomes that explore social participation for example the Ageing Well Participation Questionnaire[80] and Lubben Social Network Scale[81]. However, a review of social participation assessments for older adults in 2021 found that some standard measures had not been fully assessed in older adult populations limiting their utility and interpretability in this context[82].

This highlights a broader issue in evaluating self-management interventions. If outcome measures do not capture what is meaningful to participants, assessments of effectiveness may be misleading. In interventions targeting older adults at risk of age-related decline, it is

therefore critical to ensure that the outcomes selected are both relevant to participants' priorities and sensitive to change. Without appropriately tailored and validated measures, linking intervention fidelity to meaningful outcomes and demonstrating true effectiveness remains challenging.

## 2.7 Summary

This chapter has examined fidelity and outcome measures as essential components of clinical trial integrity and critical determinants of intervention effectiveness. Within the context of complex, community-based self-management interventions, fidelity extends beyond adherence to encompass the quality of delivery, facilitator competence, participant engagement, and consistency across implementation sites. Existing frameworks provide valuable structures for conceptualising and assessing fidelity, however their application in real-world settings remains challenging due to the dynamic, context-dependent nature of complex interventions. A comprehensive approach to fidelity assessment, integrating both objective and subjective methods, can enhance methodological rigour and deepen understanding of how interventions achieve their effects. Nonetheless, significant gaps persist in adapting fidelity assessment tools to the personalised and multi-component design of self-management interventions. Effective fidelity assessment therefore depends not only on robust methodological frameworks but also on clear theoretical foundations and mechanisms underpinning the intervention.

Although national and international policies emphasise the development and implementation of self-management interventions, translation into effective, sustainable practice to support healthy ageing remains limited. Understanding why these interventions often fail to deliver their intended impact despite their potential to empower an ageing population to live independently and well within their communities requires further exploration. As populations age and health systems face increasing pressures, it is imperative to identify interventions that can support individuals, carers, and communities in bridging the widening gap between need and service capacity. Conducting research in this area presents substantial challenges, including demonstrating population-level benefits, modelling consistent delivery, and developing fidelity frameworks capable of capturing both effectiveness and implementation quality. Addressing these challenges necessitates critical reflection on previous trials to understand what works, for whom, and under what circumstances thereby informing the development of more responsive, contextually grounded approaches to self-management intervention design and evaluation. The following chapter therefore presents detailed descriptions of the two trials included in this thesis, Lifestyle Matters and Journeying through Dementia, highlighting their design, population, intervention components, and approaches to fidelity assessment.

# Chapter 3 – Methodology

Chapter 3 describes the Lifestyle Matters and Journeying through Dementia interventions and trial designs.

A detailed description of the trial methods is provided in each individual publication; however, a summary of the trial designs is provided in table 2 and a summary of the methodological approach used for the process evaluation and fidelity assessments can be found in table 3. The two trials were multi-centre pragmatic parallel group randomised controlled trials. The feasibility study was a single site study. A mixed methods process evaluation was conducted in both trials in line with Medical Research Council (MRC) guidance on the development and evaluation of complex interventions. This included a fidelity assessment using an intervention fidelity framework and an embedded qualitative study consisting of semi-structured interviews with participants, supporters, facilitators and supervisors. The feasibility study included a qualitative study.

## 3.1 Why an occupational approach to self-management

It has been suggested that healthy ageing should not be defined in relation to ill health or disability[83] but in promotion of a meaningful life[84] and remaining living independently (or supported) in the community [85]. This philosophy is at the core of occupational therapy which encourages meaningful occupation, supports managing health and reduces the frequency and need for care services[86]. There is also evidence to suggest a relationship between well-being and occupation for older people, more specifically variation and independence in undertaking activities and having agency[87]. The need to understand the role of Occupational therapy within self-management interventions is also supported by the James Lind Alliance Priority Setting Partnership in which Priority 7 questions "What is the role of occupational therapy in supporting self-management"[88]. Occupational therapy within the self-management model could offer a meaningful approach to 'productive healthy aging' and has already been explored, for example in the Expert Patient Programme[34].

Further evidence from a systematic review in 2008 confirmed that a US occupational therapy based intervention called Lifestyle Redesign® promoted good health and wellbeing in older people[89]. More specifically it enhanced physical and mental health, occupational functioning and life satisfaction of community-living older adults[90] with good sustained therapeutic gain at 6 months[91]. In addition, it was also found to be cost effective as defined by NICE[92]. How such an intervention could be adapted to the UK setting and whether effectiveness could replicated needed to be determined[93]. The outcome being the development of the Lifestyle Matters Intervention[94,95], resulting in the MRC funded Lifestyle Matters programme of work, which included sub-population studies for people living with depression and people living

with early-stage dementia. The work on depression is not covered as part of this thesis but the work on early-stage dementia is included with the Journeying through Dementia feasibility study and follow-on pragmatic trial.

## 3.2 The intervention model

Lifestyle Matters and Journeying through Dementia use the same underpinning theory; Bandura's (1977) social cognitive theory (SCT) [96] and Laws (1996) person-environment occupational model (PEO)[97]. The PEO model is a framework used by occupational therapists to assess how a person's environment and circumstances affect their ability to perform daily activities and therefore how to personalise care to meet individual needs. SCT posits that learning is achieved through dynamic and reciprocal relationships including social influences and reinforcement. Thus, people's life experiences influence their future behaviour and decision making. The emphasis on the dynamic relationship between the individual and their environment has meant SCT has been widely applied in health care and health promotion interventions. The PEO model focuses on these dynamic relationships shaping occupational performance through the three interdependent domains, the person, environment and occupation. The PEO model further factors in life changes which forms the foundation for the Lifestyle Matters and Journeying through Dementia interventions as shown in the logic model presented in figure 1.

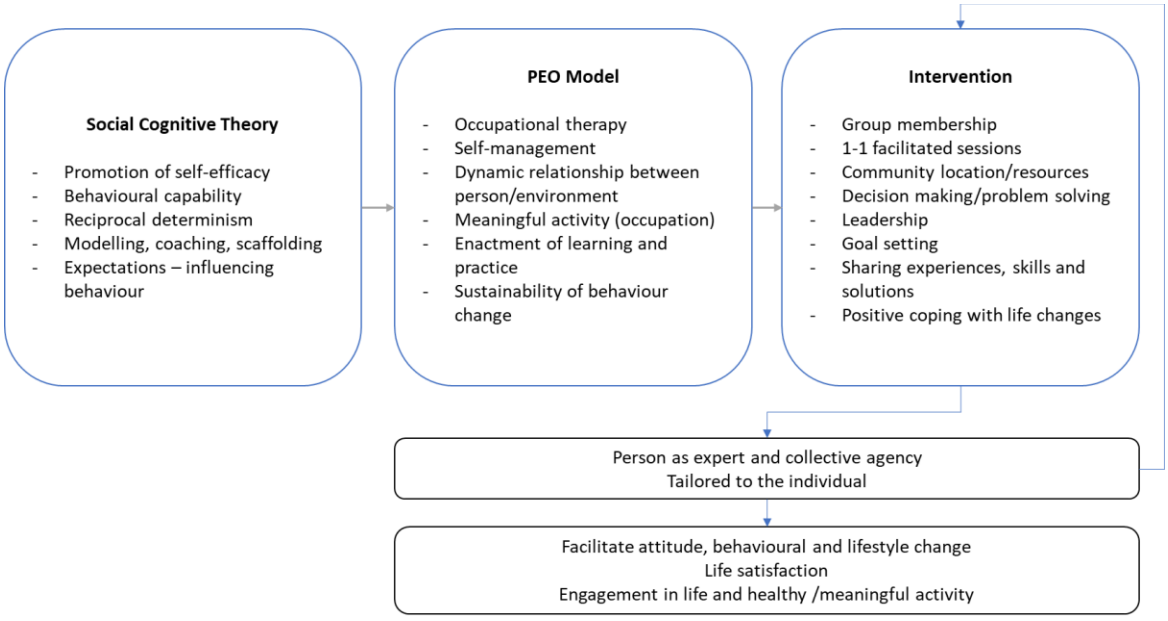


**Figure 1: Intervention model for Lifestyle Matters and Journeying through Dementia interventions**

**Table 2: Summary of included trials**

| | MRC Programme Grant (G1001406)<br>Evaluate occupational self-management interventions for older adults | | NIHR HTA Grant (14/140/80)<br>Evaluate occupational self-management interventions for older adults with dementia |
|---|---|---|---|
| **Trial/Study** | **Lifestyle Matters (Publications 1-4)** | **JtD Feasibility (Publication 5)** | **JtD Trial (Publications 6-10)** |
| **Trial design** | Multi-centre pragmatic individually randomised parallel group RCT (n=288) | Single site feasibility study (n=10) | Multi-centre pragmatic individually randomised parallel group RCT (n=480) |
| **Setting** | Community | NHS and the community | NHS and the community |
| **Primary outcome** | SF-36 Mental Health dimension at 6 months post randomisation | | DEMQOL at 8 months post randomisation |
| **Secondary outcomes** | Other SF-36 dimensions; EQ-5D; Brief Resilience Scale (BRS); General Self Efficacy (GSE) Scale; PHQ-9 depression scale; de Jong Gierveld Loneliness Scale; Health and Social Care Resource Use; Wellbeing Question of the Integrated Household Survey 2011. | Participants: DEMQol; EQ-5D-5L; PHQ-9 depression scale; GAD-7 anxiety scale; General Self-Efficacy scale (GSE); Physical Self-Maintenance Scale Self-rated Version (PSMS); Instrumental Activities of Daily Living (IADL); Health and Social Care Resource Use questionnaire.<br>Participating supporters: EQ-5D-5L; PHQ-9; Sense of Competence Questionnaire (SSCQ); Zarit Burden Interview; Health and Social Care Resource Use questionnaire. | Participants: EQ-5D-5L; PHQ-9 depression scale; GAD-7 anxiety scale; General Self-Efficacy scale (GSE); Diener's Flourishing Scale; Self-Management Ability scale (SMA); Instrumental Activities of Daily Living (IADL); Health and Social Care Resource Use questionnaire.<br><br>Participating supporters: PHQ-9; EQ-5D-5L; Sense of Competency questionnaire (SCQ). |
| **Sample size** | 268 participants or couples<br>134 per arm assuming a 20% loss to follow-up<br>90% power to detect a 10-point difference in the SF-36 Mental Health scores 6 months post randomisation. | n/a | 486 participants<br>243 per arm assuming a 20% loss to follow-up<br>90% power to detect a 4-point difference in the DEMQOL at 8 months post randomisation. |
| **Analyses** | All outcomes measured at baseline, 6 and 24 months. Analyses compared the two arms on an intention-to-treat basis. Primary analyses compared the mean SF-36 Mental Health dimension scores at 6 months.<br>Secondary outcomes were compared at 6 and 24 months post randomisation.<br>A cost effectiveness analysis was undertaken of the incremental cost per Quality Adjusted Life Years (QALYs). | Analyses were mainly descriptive to ascertain participants and carers ability to complete the measures and the time taken to do so. Validity of scores was considered to determine their use in a future trial. | All outcomes measured 8 months post randomisation. Some measures repeated at 12 months post randomisation. Primary analyses compared the mean DEMQOL scores at 8 months between the two arms.<br>Secondary outcomes were compared at 8 months and 12 months post randomisation.<br>A cost-effectiveness analysis was undertaken of the incremental cost per Quality Adjusted Life Years (QALYs). |

Both Lifestyle Matters and Journeying through Dementia interventions, were purposely designed not to include carers directly. This was for several reasons, firstly to empower the participant in taking control and responsibility for their participation in line with the self-management model, and secondly to ensure carers did not overbear those participating or make decisions on their behalf.

## 3.3 The Lifestyle Matters intervention

Lifestyle Matters is a complex manualised intervention (based on the Lifestyle Re-Design® principle[92]) designed to promote physical and mental health, occupational functioning and life satisfaction in older adults living in the community[98,99]. It aims to improve and/or maintain independence; and increase self-efficacy using the self-management approach. The intervention, although facilitated, is designed so those participating are in control of the content of the programme and is therefore personalised on two levels – at the point of the group and again during the individual sessions. The main aim is to enable individuals to develop skills, techniques and strategies to continue self-managing beyond the intervention either as a group or on their own with support from their personal network.

Participants attend 16 facilitated consecutive weekly group meetings of up to 12 people over 4 months at a local community venue or as an 'out-of-venue' activity. Examples of out-of-venue activities are visits to local libraries, garden centres or historical properties. The latter are designed to allow those participating to practice and enact learning from the group sessions, for example learning how to use public transport if they are no longer able to drive. Group session topics are either chosen from the manualised programme or identified and agreed by the group based on their priorities[100]. Facilitators are provided with training on the manualised intervention and how to work with the participants to explore the selected topic through discussion, activities and community enactment. In addition, facilitators receive regular professional supervision by qualified occupational therapists. The first three group sessions are mandatory topics designed to introduce the intervention to the group, develop group bonding and cover core topics. The remaining topics are free for the group to select or to identify their own priority topics. Participants also engage in four monthly individual sessions with a facilitator to explore personal goals.

## 3.4 Journeying through Dementia intervention

The Journeying through Dementia intervention was developed based on Lifestyle Matters with adaptation for people living with early-stage dementia and with low levels of independence and wellbeing, but with sufficient cognitive capacity to participate[101,102]. The aim of the intervention is to promote independence and continued engagement in meaningful activities through equipping individuals with the necessary knowledge, skills and understanding of ways to

continue to do the things they enjoy for as long as possible. This may be through adapting the way an activity is performed, making adjustments to the wider environment, using compensatory techniques, recognising and drawing on existing skills or developing new ones and drawing on broader resources. Through building self-efficacy, the person is supported to continue to use these strategies, to address the challenges that living with early-stage dementia brings in order to maximise participation in everyday meaningful activity and promote continued well-being.

The content is not designed for carers. Carers can attend up to three group meetings as an observer to promote awareness and encourage support for the person participating.

Like Lifestyle Matters, the Journeying through Dementia intervention comprises a menu of topics. Groups are empowered by the facilitator to select topics from the programme menu which form the basis of group discussion and planned activities during weekly meetings and/or as part of individual sessions with the facilitator. In addition, the intervention allows groups to identify their own priority topics, enabling discussion of areas that may not be represented within the manualised menu. Facilitators are trained to judge the extent of assistance each group requires to identify topics to work on and support individual engagement.

Participants attend 12 facilitated consecutive weekly group meetings with a maximum of 12 people living with early-stage dementia. Group sessions are held in accessible community venues and at least three of these sessions are out-of-venue sessions to enable participants to put learning into practice with both peer and facilitator support. Each group session is designed with the same structure to support engagement:

1) welcome and sharing of aims
2) information giving (to set the context)
3) group discussion to build shared understanding, drawing upon participant strengths
4) a practical activity for active experimentation (out-of-venue sessions)
5) a summary of key messages and an opportunity to plan for the next session.

In addition, each participant receives four individual sessions with a trained facilitator, with the first session being before commencement of the group sessions to bond with the facilitator and develop trust. As far as possible the same facilitator conducts all four individual sessions with a participant for continuity. The nature and content of the individual sessions is guided by the participant's expressed needs, interests, and aspirations. These sessions may involve some discussion and enactment of activities in the home and the community, depending upon the participant's goals. Examples of individual goals taken forward during the feasibility study[103]

included introducing methods to read and cook recipes, maintain a diary, attend a community group, engage in physical activities, and preparing resources to take to forthcoming group sessions.

As with the Lifestyle Matters intervention, the main aim is to enable individuals to develop skills, techniques and strategies to continue self-managing beyond the intervention.

## 3.5 Fidelity assessment methods

A comprehensive fidelity assessment framework specific for each intervention was developed prior to intervention delivery based on the Behaviour Change Consortium (BCC) recommendations and National Institute of for Health and Care Excellence guidance on behaviour change[104,105]. See *Publications 2 and 7* for a full description of the fidelity methods and table 3 for a summary. Fidelity assessment and quality assurance parameters centred on the five BCC recommended criteria: intervention design, training, delivery, receipt and enactment. For each criterion, programme objectives based on the manualised intervention and training were discussed and agreed by two senior researchers. A description for each standard was then developed and methods to demonstrate fidelity to each standard identified. As both Lifestyle Matters and Journeying through Dementia are both complex tailored interventions a mixed methods approach was used in line with MRC recommendations for complex interventions[106], including attendance registers, observation checklists and interview schedules which were all piloted before application. A convenience sample of sites delivering the interventions were approached and consented to participate in the fidelity assessment.

## 3.6 Interview study methods

Each trial incorporated an embedded qualitative sub-study to evaluate the impact of the intervention upon participants health and wellbeing and to identify factors which may mediate or moderate effectiveness of the intervention. See *Publications 3, 4 and 8* for a full description of the interview study methods and table 3 for a summary. This included evaluating the implementation of the intervention and eliciting participants' experiences of the intervention. Semi-structured interviews were undertaken where relevant with participants, carers, facilitators and supervisors. Interview themes included:

- How participants experienced the programme and its delivery.
- What issues promoted the effectiveness of intervention facilitation.
- The skills and competencies required to facilitate the programme.
- The barriers and facilitators to its uptake and continued use.

Interviews were conducted with a purposive sample, using a sample frame, to elicit a range of experiences of the interventions and perceived barriers and enablers. Transcripts were managed in NVivo and analysed using Framework Analysis by multiple researchers.

### 3.7 Changes to design and delivery – implementation of learning between trials

It is worth noting that the same research team worked across both Lifestyle Matters and Journeying through Dementia trials meaning we were able to build on learning from Lifestyle Matters which could be applied in Journeying through Dementia. This knowledge enabled us to revise and improve several aspects of the Journeying through Dementia trial design and intervention delivery. Firstly, we were able to better target our recruitment strategy and applied tighter eligibility criteria to better identify people entering decline. Secondly, we adapted and increased facilitator training to improve adherence to the individual session component. This allowed us to improve our fidelity to delivery of the intervention and therefore our ability to see any intervention effect. Lastly, we revised the fidelity assessment framework to include data collection via self-report from facilitators on the individual sessions and out-of-venue activities which were previously excluded. Thereby we were better able to understand implementation of the intervention.

The following chapter comprises the 10 full text publications for the Lifestyle Matters and Journeying through Dementia trials. The main findings are presented in Chapter 5 and further discussed in context in Chapter 6.

**Table 3: Summary of included trial process evaluation and fidelity assessment methods**

| Trial/Study | Lifestyle Matters (Publications 1-4) | JtD Feasibility (Publication 5) | Journeying through Dementia (Publications 6-10) |
|---|---|---|---|
| **Trial design** | Multi-centre pragmatic individually randomised parallel group RCT (n=288) | Single site feasibility study (n=10) | Multi-centre pragmatic individually randomised parallel group RCT (n=480) |
| **Process evaluation** | • Deductive framework analysis of semi-structured interviews using NVivo<br>• Purposive sampling<br>• Topic guides<br>• Respondent validation<br>n=13 participants and n= 4 facilitators | • Framework analysis of semi-structured interviews<br>• Semi structured interviews with participants and carers<br>• Focus group with facilitators<br>• Topic guides<br>n=10 participants, n=7 carers | • Deductive and inductive framework analysis of semi-structured interviews using NVivo<br>• Convenience sampling<br>• Topic guides<br>n=15 participants, n=10 carers and n= 10 facilitators and n=4 supervisors |
| **Fidelity assessment** | Conceptual framework* including intervention/trial design, training, delivery, receipt, enactment<br>• 2-day training – one session, delivered by intervention author<br>• Four intervention groups video recorded at two time points (8 observations total)<br>• Inter-rater reliability – kappa | N/A | Conceptual framework* including intervention/trial design, training, delivery, receipt, enactment<br>• 2-day training – multiple sessions delivered by same trainer (intervention author), assisted by different staff<br>• Four intervention groups observed in person by two researchers at two time points (8 observations total)<br>• 1-1 observation checklists – completed by facilitators<br>• Inter-rater reliability – kappa |
| **Fidelity data collection tools** | • Intervention (group and 1-1) attendance registers completed by facilitators<br>• Facilitator training observation checklist completed by participant researchers<br>• Intervention group meeting observation checklist completed by researchers<br>• Participant goal setting records | N/A | • Intervention (group and 1-1) attendance registers<br>• Supervision attendance registers<br>• Training observation checklist completed by non-participant researchers and by attending facilitators<br>• Intervention group meeting observation checklist completed by researchers/facilitators<br>• 1-1 session observation checklist completed by facilitators<br>• Supervision checklists completed by supervisors/ facilitators<br>• Participant goal setting records |

* Full copies of the conceptual frameworks can be found in the two fidelity publications, see chapter 4, publications 2 and 7.

# Chapter 4 - Included publications

Confirmation of contribution to publications is provided in Appendix 2.

## Publication 1 (Trial Results): A preventative lifestyle intervention for older adults (Lifestyle Matters): a randomised controlled trial

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# A preventative lifestyle intervention for older adults (lifestyle matters): a randomised controlled trial

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## Abstract

**Objectives:** to test whether an occupation-based lifestyle intervention can sustain and improve the mental well-being of adults aged 65 years or over compared to usual care, using an individually randomised controlled trial.
**Participants:** 288 independently living adults aged 65 years or over, with normal cognition, were recruited from two UK sites between December 2011 and November 2015.
**Interventions:** lifestyle Matters is a National Institute for Health and Care Excellence recommended multi-component preventive intervention designed to improve the mental well-being of community living older people at risk of decline. It involves weekly group sessions over 4 months and one to one sessions.
**Main outcome measures:** the primary outcome was mental well-being at 6 months (mental health (MH) dimension of the SF-36). Secondary outcomes included physical health dimensions of the SF-36, extent of depression (PHQ-9), quality of life (EQ-5D) and loneliness (de Jong Gierveld Loneliness Scale), assessed at 6 and 24 months.
**Results:** data on 262 (intervention = 136; usual care = 126) participants were analysed using intention to treat analysis. Mean SF-36 MH scores at 6 months differed by 2.3 points (95 CI: −1.3 to 5.9; $P = 0.209$) after adjustments.
**Conclusions:** analysis shows little evidence of clinical or cost-effectiveness in the recruited population with analysis of the primary outcome revealing that the study participants were mentally well at baseline. The results pose questions regarding how preventive interventions to promote well-being in older adults can be effectively targeted in the absence of proactive mechanisms to identify those who at risk of decline.
**Trial Registration:** ISRCTN67209155.

**Keywords:** *Older people, occupational health, randomised controlled trial, mental health*

## Introduction

Current national guidance advocates the implementation of health promoting interventions for older people with the aim of compressing morbidity in the later stages of the life course and promoting quality of life and well-being [1, 2]. The guidance is informed by evidence, which demonstrates the relationship between extent of social activity and morbidity and mortality in the extended lifespan [3] and the importance of participation in meaningful activities for mental well-being [4, 5].

An occupation-based intervention designed in the United States to promote continued participation and

engagement (Lifestyle Redesign) was shown to be effective in improving the mental well-being of older adults through two randomised controlled trials [4, 6]. The aim of the study reported in this paper was to test whether an intervention modelled on Lifestyle Redesign and adapted for a UK population (Lifestyle Matters) could also demonstrate clinical and cost-effectiveness.

## Methods

### Study design

A pragmatic, multicentre randomised controlled trial was conducted in two contrasting UK sites (rural North Wales and a large urban city in Northern England) between December 2011 and November 2015. The study protocol was published [5]. A Trial Steering Group (TSC) and independent Data Monitoring Committee (DMC) were appointed to monitor the quality and conduct of the study.

### Participants

A variety of recruitment methods were used to attract community living people aged 65 years and over with reasonable cognitive ability to participate. The feasibility study had highlighted the value of using local communities to identify those who might benefit [7]. Therefore, considerable effort was invested in informing community health and social care practitioners and groups for older people through face to face meetings and media advertisements. However, the time constraints of undertaking a randomised controlled trial necessitated an additional recruitment strategy via general practicioner (GP) mail outs in the areas where intervention delivery was planned. The original intention was that mail outs would support achievement of recruitment targets within the required time frame [8].

### The intervention

Based on an occupational approach to healthy ageing, the manualised Lifestyle Matters intervention was designed to assist participants to improve their well-being and avoid the decline associated with social isolation and poor mental health (MH). Participants met in a weekly group of up to 12 people over 4 months at a local venue. Participants were also asked to engage in monthly individual sessions with a facilitator. Session topics were either chosen from the manualised programme or new topics identified [9]. The facilitators worked with the participants to explore the selected topic through discussion, activities and community enactment. The emphasis throughout was upon the identification of participants' goals, empowerment through sharing strengths and skills and providing support to enable them to practice new or neglected activities independently, particularly in the community [10, 11]. The facilitators were paid National Health Service (NHS) or social care staff who were provided with training and supervised by qualified occupational therapists throughout.

### Study procedures

Eligible participants were enroled, screened for cognition and consented by a research assistant (RA) and randomised to one of two study arms (intervention or usual care) via a remote web-based randomisation service. The randomisation sequence was computer generated in advance by the trial statistician and stratified by site. Random permuted blocks of variable size were used to ensure that sufficient participants were allocated in a 50:50 ratio to each arm of the trial at each study site. When a couple in the same household both consented to take part, the pair was randomised as a couple.

The principal investigator (PI), TSC, study statisticians, health economists and RAs collecting outcome data at 6 and 24 months were blinded to treatment allocation but the Trial Manager, clerical team and participants were not blinded. RAs who undertook follow-up appointments asked participants to avoid revealing which arm they were allocated to.

All study participants were asked to participate in study data collection at baseline and follow-up.

Adherence to the manualised intervention was assessed [5, 9]. Facilitator fidelity to the group intervention was determined by two independent researchers evaluating video recordings of four groups (two at each site) during weeks 4 and 10 of delivery using a checklist which rated six domains: goals and needs, resources, personal qualities, enabling, group work skills and content. 'Group member performance' was also assessed using a checklist to determine a participant's uptake of the intervention and their understanding of it. Participant attendance at group and individual sessions was monitored through registers.

### Outcomes

All participants were assessed at baseline and followed up at 6 and 24 months post-randomisation using validated questionnaires, completed either face to face or over the telephone by an RA.

The primary outcome was mental well-being measured by the 36 Item Short Form Health Survey (SF-36) MH dimension score at 6 months [12], measured on a 0 (poor) to 100 (good health) scale. Secondary outcomes were other dimensions of the SF-36, Patient Health Questionnaire (PHQ) [13], EQ-5D-3 L [14], de Jong Gierveld Loneliness Scale [15], General Self-Efficacy Scale (GSE) [16] and Office for National Statistics (ONS) well-being at 6 and 24 months post-randomisation [17]. Serious adverse events (SAEs) were assessed at 6 and 24 months; these were assessed by the PI for relatedness to the intervention. Economic evaluation involved collection of all health and social care use over the previous 3 months at each data collection point through application of a bespoke health and social care resource use questionnaire.

### Statistical analysis

Sample size was derived from the mean SF-36 MH dimension score of a general health survey (68.3 with a standard

deviation (SD) of 19.9) [18]. Assuming a mean difference in SF-36 MH scores of 8 or more is of a clinical or practical importance, and a SD of 20 points, to have an 80% power of detecting this difference, significant at the 5% (two-sided) level, with cluster sizes of 10 subjects per Lifestyle Matters group, an intra cluster correlation of 0.01 and with 20% lost to follow-up at 6 months, the study needed to recruit 268 participants (134 per arm). Primary and secondary outcomes were analysed using a linear mixed effects model with independent correlation and two levels of nested clustering. The lower level of clustering treats each couple as a cluster of size two, or each individual, if not in a couple, as a cluster of size one. The higher level of clustering regards participants in the same Lifestyle Matters intervention group as a cluster. Participants allocated to either arm who withdrew from intervention before being allocated a group were treated as a cluster of size one, or of size two if they were in a couple. An adjusted analysis was performed alongside this unadjusted analysis, which included potential baseline prognostic covariates of age, sex and baseline SF-36 MH dimension score and whether the participant lived alone in a mixed effects model. Analysis of secondary outcomes at 6 and 24 months post-randomisation was performed in a similar manner.

In calculating the cost-effectiveness of the intervention, a cost perspective of the NHS and social care was adopted. Intervention costs (cost of facilitators and their supervision, venue hire and related costs of delivering the intervention), drugs, inpatient stay, general practitioner visits, outpatient appointments, visits to the emergency department and day care services were included. Costs were obtained from NHS reference costs 2013–14 and other published sources [19, 20]. There was less than 5% missing data for costs and as a result no imputation was necessary. Costs and benefits had not been discounted. Utilities were calculated using SF-6D derived from SF-36 collected at baseline, 6 and 24 months. Quality-Adjusted Life Years (QALYs) were estimated using a total of 30 imputations and were calculated using the area under the curve method.

Cost-effectiveness was analysed using seemingly unrelated regression, a multivariate technique that takes into consideration potential correlation between costs and QALYs [21]. An incremental analysis was conducted by dividing mean incremental QALYs to produce an incremental cost-effectiveness ratio (ICER) by comparing participants in the intervention and control groups. Uncertainty in the decision is assessed from cost-effectiveness acceptability curve, which plots the probability that the intervention is cost-effective for a range of thresholds that the NHS would be willing to spend per QALY.

This work was supported by the Medical Research Council [grant number G1001406], who had no input into the design, execution, analysis and interpretation of data, or writing of the study.

## Results

The trial randomised 288 participants between 14 August 2012 and 19 April 2013 (18 couples and 252 individuals); 145 and 143 were allocated to the intervention and control groups, respectively (Figure 1). Twenty six participants either withdrew, were lost to follow-up, or had missing primary outcome data at 6 months, leaving 262 (91%) participants in the primary analysis (136 intervention; 126 control). Baseline characteristics of the participants are displayed in Table 1.

Intention to Treat (ITT) analysis found no difference in the primary outcome (SF-36 MH) between randomised groups (Table 2, adjusted mean difference 2.3, 95% CI: −1.3 to 5.9, $P = 0.209$). Fifty-two percent (71/136) of participants allocated to the intervention received a therapeutic dose of group sessions in that they attended 12 or more of the 16 weekly groups before 6-month follow-up. A sensitivity (per-protocol) analysis of the 71 participants who received a therapeutic dose of the group found similar results to the ITT analysis. Other sensitivity analyses, of the imputing missing data, gave consistent estimates of treatment difference (see Supplementary data, Table Appendix 1, available at *Age and ageing* online). There was no evidence of difference between those the intervention and usual care groups on any secondary outcomes at 6 months. However at 24 months, scores on two subscales (de Jong Gierveld Emotional Loneliness and de Jong Gierveld Social Loneliness) were significantly improved in the intervention compared to the usual care group (Table 2), although the relevance of this finding is questionable due to a lack of evidence to support a minimal clinically important difference [15]. Assessment of fidelity to the group component was satisfactory in seven out of eight video recordings for both group member and facilitator performance, indicating that the group component had been delivered as intended. The mean number of group sessions attended per participant was 9.2 (SD = 5.8). Out of the 123 participants who attended at least one group session, 93 (75.6%) were offered four individual sessions as per-protocol but only five (4.1%) accepted and received all four sessions. The number of participants that experienced a SAE was similar across the trial arms (46% (63/136) of the intervention and 53% (67/126) of the treatment as usual group). The majority of the SAEs reported persistent or significant disability/incapacity over the time scale since last assessment, which accounted for 71% of the total. All SAEs reported by intervention group participants were assessed as either unrelated or unlikely to be related to the intervention. RAs were unblinded to group allocation in 13.7% ($n = 109$) of follow-up appointments.

The cost of Lifestyle Matters was estimated at £430 and £575 (£1 = $1.51) per person in the North England and North Wales sites, respectively. From the regression analysis, the ICER was found to be £7,621 (see Supplementary

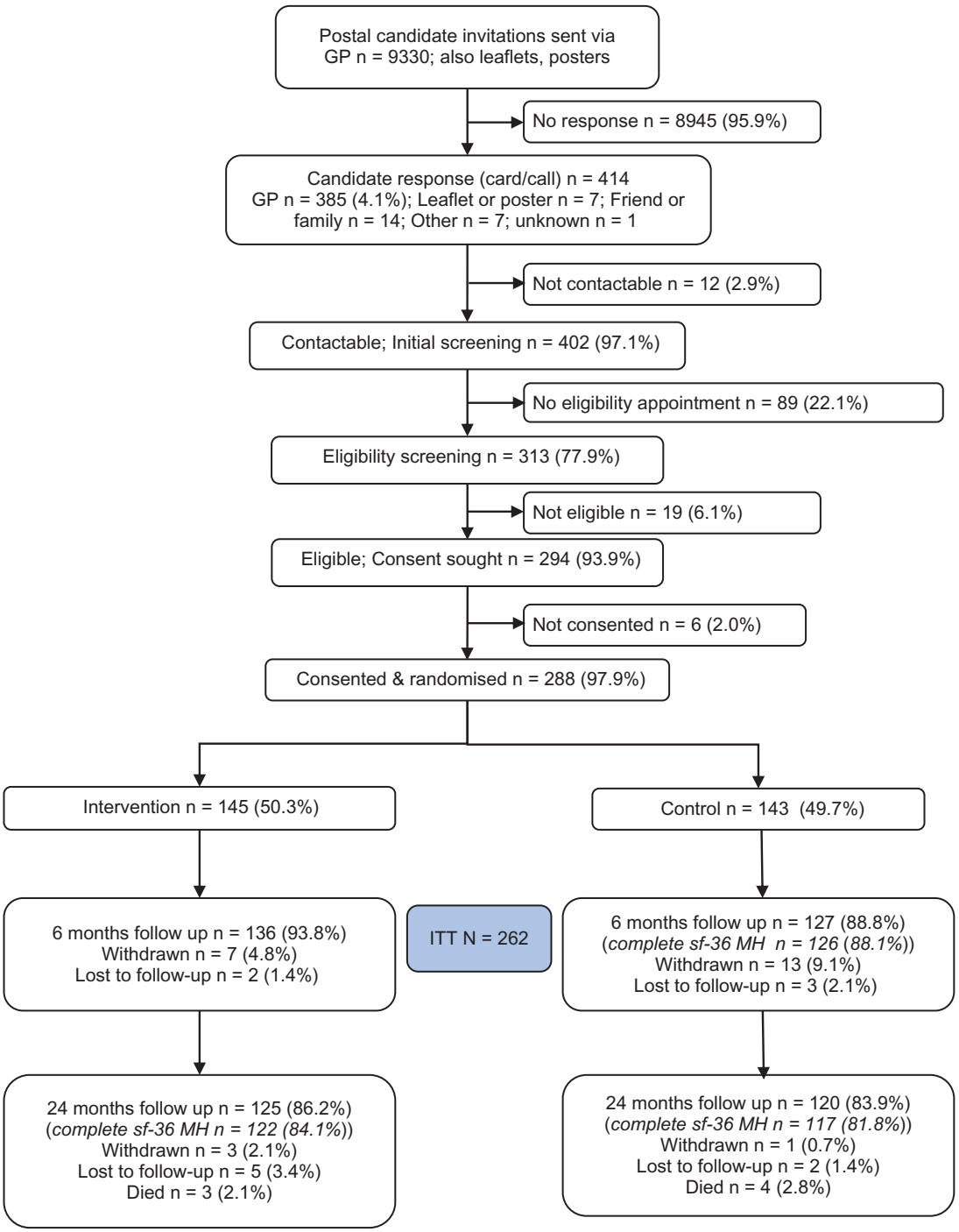


**Figure 1.** Trial profile.

data, Table Appendix 2, avaliable at *Age and Ageing* online) but this lies in the third quadrant of the cost-effectiveness plane implying that the intervention is less costly but less effective. At a threshold of £20,000, commonly used within the NHS, there was a probability of 30% that Lifestyle Matters would be cost-effective. Utilities generated from EQ-5D to generate QALYs were used as sensitivity analysis. The incremental cost-effectiveness ratio was £7,861 but remained less costly and less effective.

## Discussion

This trial was undertaken to a high standard including blinding of outcome assessors, concealed randomisation techniques and recruitment to sample size. Follow-up was successful at 6 and 24 months post-randomisation (85% retention at 24 months). Limitations were that targeted recruitment through service providers and the community (recommended from the feasibility study) was unsuccessful,

Table 1. Baseline characteristics by randomised group for participants in the ITT population

| Characteristic | Intervention ($n$ = 145) | Control ($n$ = 143) | All ($n$ = 288) |
|---|---|---|---|
| Sex, *n* (%) | | | |
| Male | 44 (30.3%) | 48 (33.6%) | 92 (31.9%) |
| Female | 101 (69.7%) | 95 (66.4%) | 196 (68.1%) |
| Age | | | |
| Mean (range) | 72.9 (65-92) | 71.3 (65-90) | 72.1 (65-92) |
| Ethnic group, *n* (%) | | | |
| English/Welsh/Scottish/Northern Irish/British | 142 (97.9%) | 141 (98.6%) | 283 (98.3%) |
| Irish | 1 (0.7%) | 1 (0.7%) | 2 (0.7%) |
| European | 1 (0.7%) | 1 (0.7%) | 2 (0.7%) |
| Prefer not to say | 1 (0.7%) | 0 (0.0%) | 1 (0.3%) |
| Lives alone, *n* (%) | 86 (59.3%) | 71 (49.7%) | 157 (54.5%) |
| Lives with, *n* (%) | | | |
| Spouse/partner | 48 (33.1%) | 61 (42.7%) | 109 (37.8%) |
| Child/children | 3 (2.1%) | 4 (2.8%) | 7 (2.4%) |
| Both partner and children | 5 (3.4%) | 6 (4.2%) | 11 (3.8%) |
| Other | 3 (2.1%) | 1 (0.7%) | 4 (1.4%) |
| Main activity/occupation, *n* (%) | | | |
| Employed or self employed | 6 (4.1%) | 6 (4.2%) | 12 (4.2%) |
| Retired | 133 (91.7%) | 134 (93.7%) | 267 (92.7%) |
| Looking after home/family | 4 (2.8%) | 2 (1.4%) | 6 (2.1%) |
| Other | 2 (1.4%) | 1 (0.7%) | 3 (1.0%) |
| If employed or retired; occupation type, *n* (%) | | | |
| Professional | 27 (18.6%) | 20 (14.0%) | 47 (16.3%) |
| Managerial/technical | 34 (23.4%) | 33 (23.1%) | 67 (23.3%) |
| Skilled (non-manual) | 36 (24.8%) | 39 (27.3%) | 75 (26.0%) |
| Skilled (manual) | 12 (8.3%) | 24 (16.8%) | 36 (12.5%) |
| Partly skilled | 11 (7.6%) | 10 (7.0%) | 21 (7.3%) |
| Unskilled | 18 (12.4%) | 14 (9.8%) | 32 (11.1%) |
| Age on leaving full time education | | | |
| *N* (%) | 143 (98.6%) | 141 (98.6%) | 284 (98.6%) |
| Mean (SD) | 16.4 (2.8) | 16.2 (2.3) | 16.3 (2.5) |

A level, Advanced level; AS level, Advanced Subsidiary level; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education; max., maximum; min., minimum; NVQ4, National Vocational Qualification level 4; O level, Ordinary level.

despite sustained effort [7]. To recruit the required numbers of participants meeting study eligibility criteria within the allocated time frame almost all were recruited through GP mail outs, resulting in a self-selecting sample.

The findings do not support the hypothesis that an intervention modelled on Lifestyle Redesign and adapted for a UK population (Lifestyle Matters) is effective at improving the well-being of older adults. The change in the primary outcome (MH dimension of the SF-36) over a 6-month period was not significantly different between the usual care and intervention groups [12]. Compared to the second US Lifestyle Redesign study, where recruited participants had a mean baseline SF-36 Mental component summary (MCS) score of 41, participants in our study were mentally well with mean baseline SF-36 MCS score scores of 52 [4] (MCS scores are standardised to have mean of 50 and SD of 10 the same as the reference population). Participants in the US studies were independently residing in retirement communities and private homes; those in private homes visited senior community centres. In our trial, older adults were also independently living but were recruited from the community and did not necessarily have any involvement in community centres. It can be deduced that participants recruited to Lifestyle Matters were not at a stage of their life when then would benefit most from such an intervention, nor were they activity seeking support when recruited. The US studies suggest that recruiting from an existing support group enabled recruitment of those with lowered mental well-being [4].

At 24 months there were significant decreases in aspects of emotional loneliness (e.g. 'I often feel rejected'; 'I miss having people around me') for those who had participated in the Lifestyle Matters intervention. This suggests that the groups could have influenced a reappraisal of relationships and social networks, a potential area for further study. A small proportion of individuals (4.1%) took up all four offers of a one to one session with a facilitator. Fostering increased uptake of these sessions, which focussed on goal setting, may aid individuals gain quality of life in future evaluations.

Identifying older people at risk of mental decline and in particular those not known to services is challenging and has only recently been identified as a priority for UK health, social care and other agencies [2]. Consensus is required as to the responsibility of clinicians—especially GPs—for

**Table 2.** ITT repeated measures analysis at baseline, 6 and 24 months post-randomisation.

| Outcome | Baseline | | | | 6 months | | | | | | | 24 months | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Intervention | | Control | | Intervention | | Control | | Adjusted mean difference[a] | 95% CI | *P*-value[b] | Intervention | | Control | | Adjusted mean difference[a] | 95% CI | *P*-value[b] |
| | *n* | Mean (SD) | *n* | Mean (SD) | *n* | Mean (SD) | *n* | Mean (SD) | | | | *n* | Mean (SD) | *n* | Mean (SD) | | | |
| SF-36 MH | 145 | 75.5 (18.3) | 143 | 77.0 (18.2) | 136 | 77.3 (18.2) | 126 | 75.9 (18.7) | 2.3 | −1.3 to 5.9 | 0.209 | 122 | 78.0 (17.1) | 117 | 75.4 (17.8) | 2.2 | −1.4 to 5.8 | 0.233 |
| SF-36 Physical function | 145 | 67.5 (25.3) | 143 | 71.7 (26.4) | 136 | 66.0 (28.4) | 126 | 70.7 (27.3) | 1 | −2.1 to 4.1 | 0.535 | 123 | 65.0 (27.8) | 118 | 66.3 (29.5) | 3 | −0.7 to 6.8 | 0.116 |
| SF-36 Role physical | 145 | 72.4 (27.6) | 143 | 76.8 (25.5) | 136 | 69.9 (29.9) | 126 | 73.9 (26.4) | 0.9 | −4.2 to 5.9 | 0.728 | 123 | 69.7 (27.5) | 117 | 72.5 (27.7) | 0.5 | −5.1 to 6.1 | 0.855 |
| SF-36 Bodily pain | 145 | 61.2 (25.6) | 143 | 64.7 (26.5) | 136 | 60.5 (28.0) | 126 | 61.6 (27.4) | 1.9 | −3.1 to 7.0 | 0.453 | 123 | 56.0 (25.6) | 117 | 59.9 (26.1) | −1.1 | −6.0 to 3.8 | 0.656 |
| SF-36 General health | 145 | 63.6 (20.4) | 143 | 68.8 (20.4) | 136 | 61.9 (22.7) | 126 | 64.8 (21.1) | 2.8 | −0.6 to 6.2 | 0.103 | 123 | 64.3 (20.7) | 117 | 64.0 (20.7) | 3.4 | −1.0 to 7.9 | 0.132 |
| SF-36 Vitality | 145 | 58.4 (21.4) | 143 | 60.3 (20.9) | 136 | 56.4 (22.2) | 126 | 58.0 (21.7) | −0.2 | −4.0 to 3.7 | 0.929 | 122 | 57.1 (21.6) | 117 | 57.3 (19.5) | 0.2 | −3.7 to 4.2 | 0.902 |
| SF-36 Social function | 144 | 82.9 (22.0) | 142 | 82.0 (26.4) | 136 | 77.8 (28.2) | 126 | 81.3 (26.0) | −3.7 | −9.4 to 2.0 | 0.205 | 122 | 80.7 (25.4) | 117 | 79.2 (25.2) | 1.4 | −4.3 to 7.1 | 0.63 |
| SF-36 Role emotional | 145 | 82.7 (23.4) | 143 | 84.5 (21.5) | 136 | 82.7 (23.2) | 125 | 86.7 (19.4) | −2.4 | −7.1 to 2.3 | 0.325 | 121 | 87.2 (20.2) | 117 | 85.3 (22.9) | 1.8 | −3.1 to 6.7 | 0.466 |
| SF-36 Physical component summary | 144 | 44.1 (11.0) | 142 | 45.9 (10.6) | 136 | 42.8 (12.0) | 125 | 44.4 (11.3) | 1 | −0.6 to 2.5 | 0.21 | 121 | 42.1 (11.5) | 117 | 43.5 (11.6) | 0.7 | −1.2 to 2.5 | 0.487 |
| SF-36 MCS | 144 | 51.5 (10.4) | 142 | 51.8 (10.0) | 136 | 51.5 (9.7) | 125 | 51.9 (10.1) | −0.3 | −2.2 to 1.6 | 0.763 | 121 | 53.3 (9.9) | 117 | 51.6 (10.0) | 0.9 | −1.1 to 2.9 | 0.384 |
| EQ-5D-3L | 142 | 0.73 (0.25) | 143 | 0.77 (0.24) | 133 | 0.71 (0.25) | 126 | 0.76 (0.23) | −0.01 | −0.05 to 0.03 | 0.742 | 121 | 0.73 (0.24) | 116 | 0.71 (0.28) | 0.05 | −0.00 to 0.10 | 0.065 |
| EQ-5D your health state today | 145 | 73.0 (19.2) | 142 | 77.7 (17.6) | 135 | 72.6 (18.3) | 126 | 77.3 (17.0) | −1.6 | −5.0 to 1.9 | 0.37 | 121 | 74.7 (16.9) | 118 | 75.3 (16.4) | 0.9 | −4.0 to 5.8 | 0.726 |
| Brief Resilience Scale | 143 | 3.6 (0.8) | 140 | 3.6 (0.8) | 132 | 3.7 (0.7) | 123 | 3.7 (0.8) | 0.1 | −0.2 to 0.3 | 0.625 | 122 | 3.5 (0.8) | 115 | 3.6 (0.8) | 0 | −0.2 to 0.2 | 0.872 |
| de Jong Gierveld Emotional Loneliness | 138 | 2.3 (2.1) | 138 | 2.4 (2.0) | 130 | 1.9 (2.0) | 122 | 2.0 (2.1) | −0.2 | −0.6 to 0.2 | 0.254 | 117 | 1.9 (2.1) | 116 | 2.3 (2.2) | −0.5 | −0.9 to −0.0 | 0.042 |
| de Jong Gierveld Loneliness | 142 | 4.1 (3.5) | 142 | 4.6 (3.6) | 134 | 3.5 (3.2) | 124 | 4.1 (3.4) | −0.4 | −0.9 to 0.2 | 0.201 | 121 | 3.7 (3.4) | 117 | 4.8 (3.6) | −0.7 | −1.4 to −0.1 | 0.026 |
| de Jong Gierveld Social Loneliness | 140 | 1.8 (1.8) | 141 | 2.2 (1.9) | 133 | 1.6 (1.8) | 123 | 2.0 (1.9) | −0.1 | −0.4 to 0.2 | 0.51 | 122 | 1.8 (1.8) | 117 | 2.4 (1.9) | −0.2 | −0.6 to 0.1 | 0.223 |
| PHQ-9 | 143 | 4.1 (4.1) | 135 | 3.3 (4.1) | 133 | 3.8 (4.2) | 122 | 3.4 (4.3) | −0.1 | −0.9 to 0.6 | 0.762 | 122 | 3.8 (4.6) | 114 | 4.0 (4.8) | −0.7 | −1.6 to 0.2 | 0.122 |
| GSE | 144 | 31.7 (5.1) | 143 | 31.9 (4.8) | 135 | 31.9 (5.0) | 124 | 31.6 (5.0) | 0.5 | −0.5 to 1.6 | 0.336 | 121 | 32.3 (5.1) | 118 | 31.6 (5.4) | 0.7 | −0.4 to 1.9 | 0.213 |
| ONS well-being | 145 | 7.3 (2.2) | 141 | 7.3 (2.2) | 136 | 7.2 (2.4) | 124 | 7.3 (2.3) | 0 | −0.4 to 0.4 | 0.911 | 120 | 7.4 (1.7) | 115 | 7.3 (2.0) | 0.1 | −0.3 to 0.5 | 0.595 |

The Short Form (36) Health Instrument (SF-36) Dimensions are scored on a 0 (poor) to 100 (good) health scale, except for the Physical and MCS scores which are standardised to have a mean of 50 and SD of 10. The EuroQol 5-Dimension (EQ-5D) utility score is measured on a −0.56 to 1.00 (good health) scale. The EQ-5D visual analogue scale is measured on a 0 (worst imaginable health state) to 100 (best imaginable health state). The brief resilience scale is scored on a scale of 1–5 with higher scores indicating more resilience. The emotional loneliness scale of the De Jong is scored on a 0–6 scale with higher scores indicating more loneliness. The social loneliness scale of the De Jong is scored on a 0–5 scale with higher scores indicating more loneliness. The total loneliness scale of the De Jong is scored on a 0–11 scale with higher scores indicating more loneliness. The PHQ−9 is measured on a 0–27 scale with higher scores indicating more severe depressive symptoms. GSE Scale is scored on a 10–40 scale with higher scores indicating more perceived self-efficacy. The ONS instrument measures subjective well-being on a 0–40 scale, with higher scores indicating high subjective well-being.

For the SF-36, EQ-5D, Brief Resilience Scale, GSE, ONS a positive mean difference indicates the invention group has the better QoL. For the de Jong Gierveld and PHQ-9 a negative mean difference indicates the Intervention group has the better QoL.

[a]Adjusted for lifestyle matters intervention group, couple, age, sex, baseline score and if lives alone for.

[b]*P*-value for adjusted mean difference between treatment and control conditions.

identifying such individuals, and the exact methods by which isolated older adults can be identified.

Identifying older people when they are beginning to decline and taking action at that point is crucial to the success of preventive interventions. Proactive recognition and signposting strategies are required, which were not in evidence during this study; the benefits of which were strongly indicated in our feasibility study [7]. Unlike the feasibility study, the randomised controlled trial methodology did not provide the time required to seek those in most need. We therefore do not know if those who are experiencing mental or physical decline would actually participate in and benefit from such an intervention. Identification of those in potential need remains an elusive challenge.

## Key points

- Social participation and involvement in meaningful activities can prevent mental ill-health in older adults.
- Two US studies found that an occupation-based lifestyle intervention improved the mental well-being of older adults.
- We adapted the US lifestyle intervention for a UK population and assessed it's effectiveness in comparison to usual care.
- We were unable to recruit those with lowered mental well-being, which contributed to the intervention not showing effectiveness.
- Findings highlight the need for strategies to identify those who are on the cusp of decline.

## Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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## Authors' contributions

G.M., G.W., J.B., D.H., S.W., A.K., K.S., C.C., S.C. and B.W. designed the study and obtained funding. A.K. undertook the health economic analysis with input from J.B. S.W. designed the statistical plan and E.L. conducted the analyses with input from S.W. L.N., J.R., L.P. and K.T. collected data. T.C. processed and cleaned the data. All authors had input into the set-up and running of the study. All authors reviewed the manuscript and gave final approval to submit to the journal. G.M. had full access to all the data in the study and had final responsibility for the decision to submit for publication.

## Conflicts of interest

G.M. and C.C. are the original authors of the published Lifestyle Matters manualised programme. No other authors have any competing interests.

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## Ethical approval

Ethics approval was obtained from the South Yorkshire Research Ethics Committee (12/YH/0101).

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Publication 2 (Fidelity assessment): Evaluation of intervention fidelity of a complex psychosocial intervention Lifestyle Matters: a randomised controlled trial

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# Evaluation of intervention fidelity of a complex psychosocial intervention Lifestyle Matters: a randomised controlled trial

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## ABSTRACT

**Objectives** Robust research of complex interventions designed to promote mental well-being in later life is required to inform service development. An essential component is ensuring that such interventions are delivered as intended. We present a detailed description of the design and implementation of a fidelity assessment within a trial of one such intervention (Lifestyle Matters). The findings help to explain the trial results and also inform the design of embedded fidelity assessments within future evaluations of complex interventions.

**Design** We conducted a mixed-method fidelity assessment embedded as part of a multicentre pragmatic randomised controlled trial. A conceptual fidelity framework was developed from the Behaviour Change Consortium framework. From this the fidelity assessment was designed. The resulting instrument assessed the following parameters: intervention design, training, supervision; and delivery, receipt and enactment of the intervention.

**Intervention** The Lifestyle Matters intervention was designed to assist older people to improve and sustain mental well-being through participation in meaningful activity. The aim is to enable participants to engage in both new and neglected activities through a mix of facilitated group meetings and individual sessions.

**Results** The fidelity assessment demonstrated that the intervention was delivered as per protocol for the group component and was tailored to meet individual needs. There was substantial inter-rater agreement for training; and group member performance 0.72; and moderate agreement for facilitator performance 0.55. It was not possible to determine whether small declines seen in facilitator performance were due to facilitator drift or moderating factors such as group dynamics or participant characteristics.

**Conclusions** The assessment methods adequately measured criteria identified as being significant indicators of fidelity. Adherence during training, delivery and supervision was good. The subjective nature of identification and rating observed behaviours was the main challenge. Future research should explore alternative methods of assessing fidelity in trials of complex interventions.

**Trial registration number** ISRCTN67209155.

## Strengths and limitations of this study

- ► This study demonstrated that it is feasible to design a fidelity assessment framework and develop bespoke assessment tools to evaluate a complex multicomponent psychosocial intervention.
- ► The extent of the assessment was limited by the methods used, for example it was not appropriate or even ethical to undertake observations of activities in the community.
- ► The validity of the findings is reliant on whether bespoke assessment tools are sensitive enough to identify the complex constructs within this type of intervention.

## BACKGROUND

An increase in long-term conditions within the global population combined with increased longevity has led to interest in how tailored psychosocial interventions might enable individuals to retain physical and mental well-being in the extended life span.[1 2] UK guidance has identified the need for multicomponent, tailored individual and group-based preventative interventions which promote health and well-being through occupation and physical activity.[3] The benefits of social networking and group interventions involving activity targeting social isolation and loneliness has also been identified[4] but there is a limited range of recommended interventions. The challenges of associated research include intervention development and evaluation of intervention acceptability, followed by robust testing to determine intervention effectiveness.[3] Robust testing should include an assessment of intervention fidelity to assess the extent to which the intervention is delivered as intended.

Fidelity assessment and maintenance of fidelity[5] enables researchers to demonstrate with greater confidence that study results were due to the intervention and not

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to other confounding factors. It is acknowledged that using multiple methods as part of a fidelity assessment can enhance validity and reliability of complex interventions.[6] Development and application of such multimethod fidelity assessments in complex multicomponent interventions have been demonstrated as feasible.[7–9]

A pragmatic randomised controlled trial (RCT) with an embedded fidelity assessment was conducted to evaluate a complex manualised intervention, Lifestyle Matters, which was created to promote the mental well-being of community living older people.[10] Lifestyle Matters was developed for the UK setting from a US intervention, Lifestyle Redesign which was found to promote physical and mental health and well-being, occupational functioning and life satisfaction in older adults.[11 12] As reported in Mountain *et al*[10] the trial fully adhered to Consort guidelines. There is some debate about the benefits or otherwise of the manualisation of complex interventions but one argument suggests that manualisation can reduce variance in intervention delivery thereby enhancing fidelity.[13]

Fidelity assessment for the Lifestyle Matters study included an evaluation of facilitator training and intervention delivery against predetermined criteria; and a complementary qualitative exploration of the views of facilitators regarding how lifestyle change might be supported or not through the intervention and their views of how they had been able to deliver this goal.[14]

Medical Research Council (MRC) guidance recommends that complex intervention design and associated fidelity assessment frameworks are developed from the underlying intervention theory.[15] Lifestyle Matters is underpinned by social cognitive theory. There is a focus on promotion of self-management by participants,[16] and in particular on developing and sustaining self-efficacy as this is known to be a protective factor in improving motivation and emotional well-being.[17] Intervention theory is located in the promotion of self-efficacy[18] as well as a model that proposes that the transactional relationships between the person, environment and activities influence occupational performance. Occupation in this context refers to meaningful activity and active participation in life.[19] The intervention guides participants to identify their own personal goals and work towards them. They are encouraged to use peer support through the group and support from facilitators in both group and individual sessions to actively overcome barriers to meaningful participation within their communities.

Interventions like Lifestyle Matters will have core components such as number of group and individual sessions and structured manual topics. However adapting a complex intervention to meet the needs of individual participants is important.[15 20] The Lifestyle Matters intervention provides a content and delivery structure, which is both flexible and readily tailored to the needs of participants. Therefore, a range of methods and tools to assess and evaluate the fidelity of this tailored intervention was required. This was important as the application of measures to assess intervention adaptation can improve our understanding of how different components can impact on delivery and receipt in context.[5 21]

This paper describes the fidelity assessment conducted for the Lifestyle Matters study and presents the findings from analysis of facilitator training and supervision, intervention delivery and receipt. The findings are then discussed in the context of intervention implementation.

## Trial design

The study was a pragmatic, two-arm, parallel group, individually RCT designed to determine the population benefit of an occupation-based intervention for people aged 65 years or older.[10] A total of 288 participants was randomised between 14 August 2012 and 19 April 2013 (18 couples and 252 individuals); 145 and 143 were allocated to the intervention and control groups, respectively. The intervention was delivered in one city in the north of England and in North Wales. Participants were eligible if they had reasonable cognitive function to participate in the intervention as evidenced by a score of 0 to 7 on the Six Item Cognitive Impairment Test.[22] They were also living independently or in sheltered accommodation, alone or with others and were able to converse in English or Welsh. An associated fidelity assessment and qualitative substudy were conducted to evaluate facilitator training and supervision; intervention delivery; and intended changes to lifestyle by participants. The latter are reported elsewhere.[14 23]

## The Lifestyle Matters intervention

The intervention involves volunteers taking part in 16 facilitated sequential weekly group meetings with up to 15 others and in four individual sessions with one of the facilitators to pursue individual goals.[10 24] During group meetings participants are encouraged to think about and engage in discussion and activities to explore the relationship between occupation and health, selecting from a menu of potential topics. A crucial element is going into the community to try out new or neglected skills with support from each other and from the facilitators; at least four sessions should involve such activities.

Group meetings are approximately 2 hours in duration at a convenient community venue. The first group sessions are structured to cover key topics from the manualised intervention. This provides a foundation for facilitators to maintain adherence to the intervention and for both facilitators and participants to work together on future sessions using the same model. Short breaks of no more than 2 weeks can be included to accommodate statutory holidays.

Individual sessions are an important intervention component and are specifically directed by the individual's goals and preferences. The first session concentrates on the participant-facilitator relationship. The remaining three sessions are built around the participant and what they want to achieve, using the intervention to assist them to execute this.



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### Facilitators and facilitation

Facilitators with the necessary skill set and qualities were recruited to deliver the intervention as intended.[25] A job description was produced which detailed core requirements, deemed to be essential for understanding the intervention and enabling successful delivery. These included prior experience of working with groups and with older people in community settings and specifically the planning and delivery of group and individual sessions. A requirement of intervention delivery is for two facilitators to be present during each group and to share working with participants during individual sessions. Facilitators could be involved in the delivery of up to three intervention groups of 8–16 participants at any one time (including associated individual sessions).

### Facilitator supervision

Supervision was provided by appropriately experienced Occupational Therapists who also attended facilitator training alongside the facilitators. A protocol was created to enable provision of consistent and appropriate supervision across and within sites. Regular one-to-one supervision was recommended on a weekly basis at a mutually convenient time and place, preferably face-to-face but with distance supervision being an option if appropriate. Joint supervision was also deemed acceptable if the individual supervisory needs of facilitators had been met.

### Training

A 2-day intensive training course was delivered jointly to all facilitators and supervisors before intervention delivery commenced, thereby ensuring that everyone received the same information and training experience to equip them to deliver the intervention and improve fidelity.[26]

Training content included presenting the rationale and theory behind the intervention and intervention components.[25] The training then mirrored delivery of the Lifestyle Matters intervention and manual,[27] in that it involved;

- Understanding the importance of taking a personalised and tailored approach towards participants at all times.[28]
- Didactic sessions to explain the programme and its ethos.
- Peer sharing; providing the opportunity to share narratives, explore experience and attitudes, and reflect on the relationship that can develop between participants and between facilitators and participants and between supervisor and facilitators.
- Undertaking active experimentation, thereby testing out ideas and concepts.
- Exploring communication skills through role playing, vignettes and group discussions.

The 2-day training was video recorded to give facilitators an idea of how they and their participants might experience this for fidelity assessment and smooth out any challenges with using the recording equipment.

All facilitators and supervisors received a copy of the manual and an accompanying CD-ROM with downloadable resources for intervention delivery.[27]

## MATERIALS AND METHODS

### Fidelity assessment framework

A comprehensive fidelity assessment framework specific to the intervention was developed prior to intervention delivery (see table 1) based on the Behaviour Change Consortium (BCC) recommendations and National Institute of forHealth and Care Excellence guidance on behaviour change.[29 30] Fidelity assessment and quality assurance parameters centred on the five BCC recommended criteria: intervention design, training, delivery, receipt and enactment. For each criterion, programme objectives based on the Lifestyle Matters manualised intervention and training were discussed and agreed by two senior researchers. A description for each standard was then developed and methods to demonstrate fidelity to each standard identified (see table 1).

### Assessment tools

The underlying ethos of Lifestyle Matters and the tailored approach to delivery make fidelity assessment complex as many of the identified criteria are subjective. A range of quantitative and qualitative tools was therefore used in line with MRC recommendations for complex interventions,[15] including attendance registers, observation checklists and interview schedules which were all piloted before application.

### Intervention attendance registers

Registers were used to routinely record both group and individual session attendance. Using pilot study findings it was estimated that participants would need to attend at least half (eight) group meetings, to benefit from the intervention.[31] The number of individual sessions required to derive benefit was not set.

### Development of observation checklists

Observation checklists were developed by two senior researchers who identified domains comprising the core skills and key criteria identified in the Lifestyle Matters manual, worksheets and training materials (see online supplemental additional file 1). Criteria described the components and behaviours expected to be present during intervention delivery. Domains were divided into those associated with ‘Trainer or Trainee performance’ and those associated with ‘Facilitator or Group member performance’.

A scoring system was devised. Several criteria were rated on a binary ‘Yes’ or ‘No’ scale for presence or absence. For the purpose of analysis if a criterion was present this was converted to a score of 3. If the criterion was not present this was converted to a score of 0.



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**Table 1** Lifestyle Matters fidelity assessment framework and results

| Element | Fidelity criteria | Fidelity standard | Standard met | Evidence |
|---|---|---|---|---|
| Trial design | | | | |
| Comparable treatment | All participants received the same programme tailored to the needs of the group/setting. | ► Sixteen weekly meetings offered to all participants<br>► Attendance recorded | Yes | ► Trial documentation, for example, information sheet<br>► 176 (11×16) weekly registers recorded |
| | | ► Four individual sessions offered to all participants<br>► Attendance recorded<br>► Four out-of-venue sessions offered to all participants<br>► Attendance recorded | Yes | ► Trial documentation, for example, information sheet<br>► 443 individual sessions offered, 143 taken up (32%)<br>► On average participants took part in four out-of-venue activities across the 16 weeks |
| Risk to implementation | Plan for potential issues that could affect the delivery of the Lifestyle Matters programme | ► A range of recruitment strategies will be implemented | Yes | ► Methods used included GP mail-outs, direct referrers and posters/leaflets |
| | | ► A range of days and times for meetings offered, from which participants can choose | Yes | ► Facilitators worked flexibly<br>► Groups took place on various days of the week and times of day (AM/PM) |
| | | ► Undertake three recruitment cycles in three geographical areas, to prevent saturation | Yes | ► Recruitment conducted in multiple areas at each site |
| Monitoring provider training | | | | |
| Standardised training and facilitator skill acquisition | All facilitators receive the same training tailored to the group/setting and engage with the training in a similar way | ► Completion of training exercise by facilitators | Yes | ► Observation by researchers of participants completing role playing exercises and group work |
| | | ► Training delivered by the same trainer | Yes | ► Same trainer delivered all training |
| | | ► Manual/CD-ROM provided to all trainees | Yes | ► Manual (or copy) and CD provided to all trainees |
| | | ► Observation of the training session by two researchers using a content checklist | Yes | ► Observation by two researchers of skill transference using content checklist<br>► Checklist coding developed to observe 'All' participants |
| Monitoring intervention delivery | | | | |

Continued



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**Table 1** Continued

| Element | Fidelity criteria | Fidelity standard | Standard met | Evidence |
|---|---|---|---|---|
| Standardised delivery | All facilitators using the same techniques and content from the programme | ► Observation using a content checklist by two researchers | Yes | ► Observation completed by two researchers |
| | | ► 75% of opportunities for completing goal setting are recorded (for individual and group) | No | ► Participants found concept of 'goal setting' difficult to understand. 'Goal setting' sheets provided in programme rarely used. Discussion of 'Planning' and 'Wishes' preferred |
| | | ► Range of materials from the Lifestyle Matters programme received by all participants | Yes | ► Use of materials discussed by participants during qualitative interviews<br>► Observation of manual materials used during recorded group meetings |
| | | ► Facilitators maintain reflective diaries | Yes | ► Used as part of supervision sessions, confirmed by facilitators and supervisors |
| | | ► Registers completed for weekly meetings and individual sessions | Yes | ► Registers completed and recorded on the trial database |
| | | ► Participant and facilitator semistructured interview topic guide | Yes | ► Interviews conducted with all facilitators at the end of cycle 1 and cycle 3 Interviews conducted with 10% sample of participants at the end of their programme attendance |
| | | ► All participants receive certificate of attendance/achievement | Yes | ► Copies of certificates given to all participants across both sites |
| | | ► Facilitators meet the National Health Service Band 4 equivalent job description | Yes | ► Facilitators selected for interview based on meeting essential criteria of job description. |
| Minimise drift in skills/delivery | Adherence to training content and delivery over the three cycles of the intervention | ► Observation using a content checklist by two researchers | Yes | ► Observation by two observers |
| | | ► OT supervisor protocol | Yes | ► Protocol written and provided to supervisors and facilitators prior to the programme start |
| | | ► Each facilitator will attend between 8 and 16 supervision sessions in total of which half should be delivered face to face | Yes | ► Interviews: Reported face-to-face contact recorded for one facilitator for 12 months. Three facilitators' supervision started as face to face moving to a combination with telephone contact<br>► Supervisor attendance records provided for two facilitators (consent obtained) |
| Monitoring receipt of intervention | | | | |

Continued



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Table 1 Continued

| Element | Fidelity criteria | Fidelity standard | Standard met | Evidence |
|---|---|---|---|---|
| Participant attendance and engagement | Recording participants' weekly attendance<br>All participants taking part in the meetings and activities<br>Impact of intervention on participant in terms of well-being | ▲ Registers completed by facilitator for weekly meetings and individual sessions where arranged<br>▲ 75% of opportunities for completing goal setting are recorded (individual and group)<br>▲ Participant and facilitator semistructured interview topic guide<br>▲ PROMS | Yes<br>No<br>Yes<br>Awaiting results | ▲ Interviews demonstrated that most participants took part in the programme, although not all joined every activity mainly due to health or mobility issues<br>▲ All registers completed and recorded<br>▲ Concept of 'goal setting' difficult to understand by participants. 'Planning' or 'Wishes' preferred<br>▲ 10% sample of participants interviewed<br>▲ Participant behaviours observed during videoed sessions<br>▲ All facilitators interviewed at cycle 1 and cycle 3<br>▲ Completed PROMS recorded on trial database |

Adapted from Bellg *et al*.[29]
GP, General Practitioner; OT, Occupational Therapist; PROMS, Patient Reported Outcome Measures.

Fidelity scores were calculated based on agreement of a final score between the two coders and the total was given a percentage score as follows. The scoring system was adapted from the principle set out in Borrelli, that 80%–100% constitutes high fidelity:[25]

- 60% Unsatisfactory.
- 61%–70% Satisfactory.
- 71%–80% Good.
- 81%–90% Very good.
- 91%–100% Excellent.

To ensure consistency the same two researchers completed fidelity assessment activities and coding. The patient and public contributor for the project also contributed to the fidelity assessment analysis including reviewing and piloting observation checklists (as described below), as well as participant observation during training.

### Assessment of the fidelity of training delivery

Participant observation, in which the researcher not only observes, but takes an active role in the setting,[32] was selected to assess the fidelity of training delivery. The researchers therefore attended the training as delegates. This decision was taken as participant observation allows the observer to not only have the same experience as those taking part, as an insider, but also enables them to understand the more subtle aspects of delivery such as group dynamics as an outsider.[33] However, this can also result in loss of perspective and objectivity to some extent.

During the training, sessions were independently rated by the two researchers. There were also discussions between the trainer and researchers at the beginning and end of each day to review content and feedback from attendees. All scores were then shared and reviewed for reliability of interpretation and coding against checklist criteria.

### Assessment of the fidelity of intervention delivery

A purposive sample of eight video recordings was taken of 4 of the 11 Lifestyle Matters groups to monitor implementation and adherence to the intervention and identify any facilitator drift over time. To reduce bias the same number of groups and group meetings from both sites were selected for assessment. Written consent to conduct video recordings was obtained from each participant and facilitators recorded the group meetings using simple compact video recorders.

One video of each of the four selected groups was recorded at approximately week 4 and again at around week 10 of intervention delivery although some flexibility in session choice was necessary to avoid out-of-venue activities (see table 2). Observing two meetings per group, one at the beginning and one near the end, enabled us to examine any learning effects and identify any facilitator drift.[34]

Video content was then rated using the predetermined checklist and findings analysed to determine delivery and receipt of the intervention and any change over time.



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Table 2 Sample of video-recorded group meetings

| Site | Wave | Lifestyle Matters group | Programme week (1–16) videoed | No of facilitators present | Participants attending/registered |
|---|---|---|---|---|---|
| North England | 1 | 1 | 6 | 2 | 10/13 (77%) |
| | | | 10 | 2 | 11/13 (85%) |
| North Wales | 1 | 1 | 4 | 2 | 7/10 (70%) |
| | | | 10 | 2 | 7/9* (78%) |
| North England | 3 | 6† | 7 | 2 | 6/8 (75%) |
| | | | 15 | 2 | 7/8 (88%) |
| North Wales | 3 | 5† | 4 | 2 | 8/9 (89%) |
| | | | 10 | 2 | 7/9 (78%) |

*Participant withdrew.
†North England site completed six Lifestyle Matters groups and North Wales completed five.

During piloting of the intervention fidelity checklist, it became apparent that several of the assessment criteria could not be observed during the weekly group meetings. For example, receipt and enactment of the intervention would occur in the participant's everyday life away from the group. It was deemed that either the criterion could not be present during every weekly meeting or it would be necessary to observe several meetings consecutively which was not planned. Further observations using the checklist to test the assumption found this to be consistent. The criteria deemed to be immeasurable were therefore excluded from the final analysis.

Due to practicalities, only the groups held within the meeting venue were observed. Given the importance of enactment of activities in the community this was a limitation.

We did not undertake observations of the individual sessions as these were deemed a safe space for participants to work with their facilitator on individual goals. These sessions could also involve activities in the community where it would be impractical and unethical for researchers to observe sessions.

### Inter-rater reliability

Inter-rater reliability demonstrates whether available data accurately represent the variables being measured and the extent to which coders attribute the same score to the same variable.[35] Inter-rater reliability was calculated by two researchers independently coding video recordings and by scores being compared using the Kappa statistic, with a value of 0.61 and above indicating good inter-rater agreement.

- <0.20 Poor.
- 0.21–0.40 Fair.
- 0.41–0.60 Moderate.
- 0.61–0.80 Good.
- 0.81–1.00 Very good.

### Semistructured interviews

Semistructured interviews were undertaken with all facilitators to explore views on what enables effective intervention facilitation, and the skills and competencies required to deliver the intervention and enable participants to act on it.[14 23] Interviews took place at the end of the first and third (final) waves of intervention delivery to identify any changes in experiences of delivery over time.

An interview topic guide was developed informed by the content of the training materials and intervention manual as well as knowledge gained from prior feasibility work.[31]

A purposeful sample of 10% of participants was interviewed, selected from both sites and from each of the three waves of intervention delivery to elicit the range and nature of issues that influenced their experiences of the intervention. The sample was considered adequate to reach data saturation within resource limitations.[36]

All transcripts were read for familiarisation and annotated for themes by the same two researchers (fidelity lead and second researcher) using framework analysis in NVivo.[37 38] For the purposes of the fidelity assessment, data from the interviews were used to identify cross-cutting themes and explanatory factors for fidelity outcomes.

### Patient and public involvement

Patients and members of the public were involved at all stages from the development of the intervention during feasibility testing through to trial design and conduct. We received input from older adults on the design of the trial materials and in the oversight of the delivery of the study through PPI representation on trial oversight groups. The main trial results were disseminated to participants using materials suitable for a non-specialist audience and shared with the wider public, clinical and academic colleagues through events and publications.

## RESULTS

The 'Fidelity Assessment Framework' including evidence for fidelity is presented in table 1.



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### Facilitators

All four facilitators remained the same throughout the trial at both sites. They were all female, younger than the youngest participant (65 years) and from a healthcare or social care professional background.

### Intervention attendance

Eleven Lifestyle Matters interventions were delivered, six in one city in Northern England and five in North Wales. Four groups were selected for the fidelity assessment as previously described. Overall attendance at the observed group sessions was 70% or above (see table 2). The average number of out-of-venue activities conducted as a part of the group aspect of the intervention across all groups was four.

### Training delivery

The 2-day training was attended by all four facilitators (two from each site) and the two supervisors (one from each site).

Excellent fidelity was demonstrated for trainer performance with a score of 100% across all four domains.

Good fidelity was identified through a criterion score of 75.4% across eight domains for trainees. Overall training fidelity was very good with a total agreed criterion score for 'trainer performance' and 'trainee performance' of 83.9%.

### Intervention delivery

#### Facilitator performance

Excellent or very good fidelity was achieved in four out of the eight recorded groups (see table 3). Only one observed group (Wave 1, Site A, Video 2) demonstrated unsatisfactory fidelity (52%). The other three groups all showed either an increase or maintenance in fidelity scores.

Excellent or very good fidelity was demonstrated in three of the six assessment domains. Only one domain 'Goals and Needs' was rated as being unsatisfactory. This required evidence of programme tailoring and how facilitators helped participants to select achievable activities with appropriate levels of challenge.

The decline in fidelity seen at Site A during Wave 1 (77% to 52%), could be explained by the facilitators arranging for two external speakers to deliver sessions on relaxation and physical health. During the meeting the facilitators largely left facilitation to the external speakers who used a didactic style, which did not invite discussion or tailoring to the needs of group members. It was deemed by both coders that the facilitators could have coached external speakers on how to deliver a session in accordance with the Lifestyle Matters ethos and could have interjected during the sessions. An outcome from this session was to provide facilitators with further guidance on when and how to engage external speakers. This was delivered as an email to all facilitators ensuring they received consistent information.

A difference was also noted between the first and last waves at Site B where the assessed fidelity dropped from 87.5% to 70.8% but was still within the boundary set for satisfactory fidelity. Based on findings from the qualitative interviews, reasons for the reduction in scores could be explained by difficulties in time management to undertake planning and delivery of multiple consecutive groups as well as the challenges presented by the dynamics within groups.

#### Group member performance

Excellent or very good fidelity was demonstrated for four out of the eight recorded groups (see table 4). Only one group (Wave 1, Site A) was rated as being unsatisfactory (41%) with this being related to the same issue described earlier for 'Facilitator performance'.

Excellent or very good fidelity was demonstrated for three out of eight identified domains with unsatisfactory evidence for only one, 'Confidence and hope'. However, it became evident that ability to score some criteria was affected by the nature of the activities participants engaged in.

### Inter-rater reliability

Kappa scores were calculated using linear weights.[35]

For the assessment of training fidelity, the inter-rater reliability between coders was Kappa=0.72 (p<0.0.001), 95% CI 0.478 to 0.964.

Inter-rater reliability for overall fidelity to intervention delivery across sites was Kappa=0.63 (p<0.001), 95% CI 0.543 to 0.719.

Inter-rater reliability for facilitator domains across both sites was Kappa=0.55 (p<0.001), 95% CI 0.432 to 0.678.

**Table 3** Fidelity scores for 'facilitator performance'

| | Facilitator score/out of 48 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Rater 1 | Rater 2 | Agreed score | % | Rater 1 | Rater 2 | Agreed score | % |
| Wave 1 | (Site A) Group 1 | | | | (Site B) Group 1 | | | |
| Video 1 | 38 | 33 | 37/48 | 77.0% | 38 | 39 | 39/48 | 81.2% |
| Video 2 | 22 | 28 | 25/48 | 52.0% | 44 | 44 | 42/48 | 87.5% |
| Wave 3 | (Site A) Group 6 | | | | (Site B) Group 5 | | | |
| Video 1 | 44 | 44 | 44/48 | 91.6% | 30 | 34 | 30/48 | 62.5% |
| Video 2 | 46 | 45 | 44/48 | 91.6% | 33 | 35 | 34/48 | 70.8% |



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Table 4 Fidelity scores for 'group members'

| | Group member score/out of 39 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Rater 1 | Rater 2 | Agreed score | % | Rater 1 | Rater 2 | Agreed score | % |
| Wave 1 | (Site A) Group 1 | | | | (Site B) Group 1 | | | |
| Video 1 | 34 | 33 | 33/39 | 84.6% | 37 | 35 | 38/39 | 97.4% |
| Video 2 | 11 | 18 | 16/39 | 41.0% | 30 | 29 | 29/39 | 74.3% |
| Wave 3 | (Site A) Group 6 | | | | (Site B) Group 5 | | | |
| Video 1 | 33 | 31 | 33/39 | 84.6% | 23 | 28 | 24/39 | 61.5% |
| Video 2 | 36 | 36 | 36/39 | 92.3% | 26 | 26 | 26/39 | 66.6% |

For group members inter-rater reliability was Kappa=0.72 (p<0.001), 95% CI 0.598 to 0.844.

## Qualitative findings

The following themes relevant to intervention fidelity were identified from analysis of the qualitative interviews conducted with facilitators following cessation of delivery. Other qualitative findings including those derived from interviews with participants are reported elsewhere.[14 23]

### Theme 1: Experience as an enabler of intervention delivery

Analysis of facilitator interviews revealed that they all considered that they had become more confident, skilled and flexible over time. Also, that their commitment to the ethos of the programme was maintained:

> We've actually grown in confidence…it feels a very different place to where we were at the beginning… far more skilled… allowing for that flexibility and spontaneity (Facilitator D).

### Theme 2: Views of how skills acquisition for intervention delivery could have been enhanced

Further training opportunities such as booster sessions or shadowing experienced facilitators were suggested to help consolidate knowledge of the intervention and improve fidelity further.

> …it would have been useful just to have…a follow-up session just to see what kinds of things were coming up for people and have that, that kind of discussion (Facilitator B).

Regular self-review, using a group observation checklist was proposed by facilitators as a tool to enable them to reflect on delivery style and decision-making processes. (Facilitators were aware of the checklist as part of the fidelity work but did not have sight of the checklist.)

> it may be more useful in future, if the facilitators could peer review themselves every 3 weeks against the checklist…scoring themselves and detailing an action against those that need to be achieved (Facilitator A).

### Theme 3: Need for more training to support greater understanding of group dynamics

One facilitator suggested that additional content in the training on how to avoid dependency relationships when facilitating using concrete examples case studies and written guidance would have been helpful.

> …what might breed relationships of dependency, what are the little things we (facilitators) don't realise we're doing, I think that might be something that could be added to the training (Facilitator A).

The same facilitator thought that fostering and enabling independence was also important for the intervention and more time dedicated in the training was needed.

> …to process and assimilate all that… (Facilitator A).

Another facilitator suggested that training should incorporate more on managing group dynamics and handling difficult people, and how to adapt sessions spontaneously when needed.

> …few trouble-shooting scenarios… (Facilitator D).

### Theme 4: Tailoring intervention components

One facilitator described modifying their approach to goal setting within the individual sessions where they felt participants had found the concept too formal or difficult to understand. Rather than talking about conscious goals they would integrate it subtly into the intervention.

> Interestingly you'd be approaching that same subject in a very subtle way over the weeks and weaving it into natural conversation, that was received a lot better… (Facilitator A).

### Theme 5: Anxiety as a consequence of researcher observations

Two facilitators reported levels of performance anxiety due to the session being recorded, which they felt may have hindered their delivery of the intervention.

> I think it is fair to say that being recorded has significantly affected the performance of the facilitators due to nerves of being recorded. As such I don't think the recordings reflect what has actually taken place within the groups over time. We tick many of the boxes on the checklist, but the recordings I feel won't pick a lot of this up (Facilitator D).



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## DISCUSSION

### The framework

The fidelity assessment framework designed for this study provided a satisfactory structure for monitoring and evaluating adherence to the intervention over time. We were able to demonstrate good fidelity to training as well as delivery of the group component of the intervention but were unable to observe all intervention components including the individual sessions and the out of venue activities. It was significant, however, that participant adherence to the individual sessions was poor (32% of available sessions). As these sessions were deemed to be an essential component of the overall intervention, the reasons require further exploration. We were aware from the qualitative interview data that goal setting as part of the individual sessions proved problematic for facilitators to deliver. This was attributed to the significant tailoring needed to meet the needs of individual participants.

There were however several shortcomings to the framework approach[29] for this type of intervention. Assessment frameworks are designed to rate set criteria, which by definition should be the same for all observations. This is not necessarily true of complex interventions such as Lifestyle Matters that have tailoring as an underlying mechanism. To accommodate this, the underpinning ethos of the intervention along with the manual and training content provided the basis of the observation checklists.[39] This allowed for a range of observed behaviours to be considered in relation to set criteria instead of only one behaviour signifying presence.

### Fidelity assessment methodology and adaptation

We recognised the adaptive nature of the intervention and the resultant complexity for fidelity assessment at the time of delivering this study. Current debate is indeed questioning whether fidelity and adaptation can coexist.[40] Being able to determine the difference between intervention ineffectiveness or alternatively failure to deliver as intended can significantly impact the implementation outcome.[41] This intervention includes a number of interlinked adaptations, namely, selection of different components from a menu of possibilities; the context, the characteristics and needs of the participant and the group they are a member of; and the characteristics and abilities of facilitators. Whether it is possible to measure a range of adaptions for such tailored interventions, and how this would be achieved requires further consideration.

### Coding

Coding performance can raise concerns. Expectations of both the facilitators and those rating performances must be considered and moderated. All those involved should try to avoid preoccupation with fidelity assessment at the cost of intervention delivery.[42] Coders were not independent of the study, having attended the training as participant observers. Having the same knowledge and learning experience as those expected to deliver the intervention could enhance coder observations through greater understanding of observed behaviours and processes. Alternatively, using independent coders would reduce bias of unknown factors arising from personal knowledge of facilitators and increase the rigour of fidelity assessment. Overall we deduce that when the intervention is complex, ability to interpret what is occurring is required if accurate observations are to be recorded.[43] Using researchers with knowledge or experience of the intervention as coders may therefore be preferable.

### Training and competence

One of the main challenges to fidelity was the delivery of high-quality in-depth training for a complex psychosocial intervention in just 2 days to a range of staff. Chances of variation in intervention delivery were deemed to lie in facilitator background and experience which are related to fidelity.[6] Evidence from the qualitative interviews also indicated that coverage of several core principles of the intervention including managing individual and group dynamics could have been improved during training. In this trial it was not possible for facilitators to give feedback on the training they had received but in real world implementation we would recommend including this. To scaffold fidelity we employed senior members of staff with experience working with older people and behaviour change interventions to supervise facilitators in the delivery of the intervention.[44] Due to the novelty of the intervention, it was not possible to identify staff with existing experience of delivering it or anything similar. Therefore, a recommendation for future research would be to include evaluation of fidelity to supervision in more detail including competence and content. This has since been explored in another trial, Journeying through Dementia.[8]

The Lifestyle Matters manual and training are founded in 'occupational therapy' theory and practice and the facilitators were supervised by trained Occupational Therapists. However, in pursuance of evidence that the intervention might be delivered by a range of staff, the recruited facilitators came from a variety of professional backgrounds including social work and mental health advocacy as well occupational therapy. Further customisation of training may be required to meet the needs of a wider range of health and social care staff.

Some deterioration of skills, or drift, is common post training.[25] Although no additional training or booster sessions were provided during this study, facilitators received regular supervision and occasionally received emailed 'study updates'. These communications (approved by the Trial Management Group) clarified details on intervention delivery to help reduce potential facilitator drift. Any emergent ethical concerns would have been immediately acted on if identified during the fidelity assessment. Although fidelity to group intervention delivery was generally found to be good, further training opportunities such as booster sessions or shadowing experienced facilitators might be incorporated in future studies to test whether additional training



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consolidates knowledge of the intervention and further improves fidelity. In addition the group observation checklist used to assess adherence and competence[13 45] to deliver the intervention could be used by facilitators as a tool to self-regulate and thereby enhance fidelity.[46]

### Facilitators and supervisors

It has been suggested that due to the key role of facilitators they should be cognisant of the impact of fidelity.[6] The importance and nature of the planned fidelity assessment was explained to the facilitators during the 2-day preparatory training before they took part in the assessment. This was beneficial in providing reassurance about the process including the observations.

Even though facilitators were from a range of backgrounds and had different experiences of working with older people in the community, this did not appear to negatively impact on intervention delivery.[34] The facilitator job description and person specification provided a priori level of credentials required to provide some consistency across facilitators. However, the previous point about responsiveness to needs for training and support by those running the study should be maintained. This also applies to supervisors who are not experienced in delivering the programme.

A 'Good fit' between providers and participants can be key to successful intervention delivery.[25] All facilitators in this trial were female and younger than the youngest participant but this did not appear to impact on delivery. The supervisors were generally older and more experienced in delivering occupational therapy-based interventions, which could be drawn on during supervision sessions.

### Receipt of intervention

Fidelity to the intervention increased between waves for Site A, but gradually decreased for Site B. This could have been due to the dynamics of the groups that were recorded; challenges with the methods used to assess fidelity or may have been indicative of facilitator drift over time. The only factor that could be identified to explain facilitator drift at site B was the time pressure they expressed in trying to prepare and deliver the group sessions as well as trying to organise and conduct individual sessions. This explanation is commensurate with the slight decline seen in 'Facilitator performance' and suggests that additional training may have been beneficial.

Fidelity was also influenced by receipt of the intervention. For example, we expected to observe group and individual goal-setting opportunities in intervention sessions. However, from the qualitative interviews it was evident that the majority of participants struggled to engage with the concept of 'goal setting' and facilitators were required to make significant changes to their own understanding and how they presented the concept to participants.[14] Low fidelity therefore may not necessarily be associated with poor fidelity to delivery but may highlight a problem with the original intervention requirements, the nature of associated training and supervision, and subsequent criteria identified to evidence fidelity. Detailed analysis of feasibility study findings is therefore essential to establish clear baselines for behavioural interventions. Good design and piloting of tools is also important.

### Practicalities and ethical considerations

The assessment only involved the video recording of a small number of weekly meetings out of the total provided and therefore it is inevitable that some facilitator and participant behaviours that may have affected intervention delivery were not observed. The assessment process also did not include observations of facilitators arranging and conducting individual sessions or out-of-venue activities which would have enhanced our understanding of the underlying intervention mechanisms. As previously described there were ethical considerations around participant confidentiality when assessing fidelity in a community setting.[47] Consideration should therefore be given to how fidelity assessment can be undertaken within any given setting without interfering with the intervention.[48] How many, when and what type of sessions to record should be dependent on the complexity of the trial and availability of resources. For example, it may be prudent to monitor consecutive sessions to capture more information regarding participant receipt and enactment. Behaviour change may be more evident if an activity undertaken during one session can then be followed through to the next.

Psychosocial interventions are not designed to be passive; participants and facilitators bring their life experience, beliefs and expectations.[34 49] When determining intervention fidelity it is therefore important to consider how group dynamics and also environmental factors[50] impact not only on group composition but also group behaviour, especially when external factors to the intervention may be outside the control of those facilitating.[49]

The findings obtained from assessment of intervention fidelity within this RCT were important, given the neutral results obtained from analysis of outcome data.[10] The fidelity assessment enabled identification of the aspects of intervention delivery that were delivered as per protocol as well as those aspects that were compromised such as delivery of the individual sessions and specifically ability to facilitate goal setting with participants. These issues help inform our understanding and interpretation of the trial results as well as indicate the challenges that future implementation would involve.

## Conclusions

The outcomes from this fidelity assessment add to the growing literature on the use of fidelity assessment in trials and other studies of complex interventions. Psychosocial interventions that are flexible and offer a tailored approach in delivery may make fidelity assessment difficult, but not impossible. Paradoxically the importance of undertaking thorough fidelity assessment is enhanced for complex interventions, which have a number of



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components. Despite the challenges, this study has demonstrated that by testing methods identified in a replicable framework, fidelity assessment can be carried out successfully.

Further research should explore the potential of different observational methods for monitoring fidelity in psychosocial community-based complex trials and the impact of these methods on intervention delivery.

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**Competing interests** GM and CC are the original authors of the published Lifestyle Matters manualised programme. No other authors have any competing interests.

**Patient consent for publication** Not required.

**Ethics approval** The study was approved by the South Yorkshire Research Ethics Committee 12/YH/0101, the National Institute for Social Care and Health Research (NISCHR) Permissions Co-ordinating Unit in Wales, Betsi Cadwaladr University Health Board. Written informed consent was obtained from all participants.

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Publication 3 (Qualitative study): Lifestyle Matters Randomised Controlled Trial of a Preventive Health Intervention for Older People: Qualitative Sub Study with Participants and Intervention Facilitators

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ORIGINAL RESEARCH

# Lifestyle Matters Randomized Controlled Trial of a Preventive Health Intervention for Older People: Qualitative Sub Study with Participants and Intervention Facilitators

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**Objective:** This qualitative study embedded within a randomized controlled trial was conducted to explore the acceptability, experiences of, and short-term impact of a preventive health intervention (Lifestyle Matters) from the perspectives of those who took part, and to uncover any evidence for the theorised mechanisms of action (improved participation and self efficacy) underpinning the intervention. It was also conducted to help explain the quantitative trial results.

**Methods:** A purposive sample of 13 trial participants who had been randomized to receive the Lifestyle Matters intervention (approximately 10%) were individually qualitatively interviewed immediately following their involvement. All four intervention facilitators were also individually interviewed.

**Results:** Evidence of the hypothesized behavioural changes could be identified within the interview data, demonstrating the potential of this intervention. However, lack of adherence to the overall intervention eroded receipt of benefit. This finding complements the quantitative trial results which found that the study had failed to recruit those who considered themselves to be at risk of age-related decline.

**Conclusion:** This form of preventive health intervention requires proactive identification of those who recognise the need to make lifestyle changes. This is difficult if reactive health and social care systems are the main referral routes. The methodological approaches taken towards the study of complex interventions requires reconsideration if potential benefits are to be accurately assessed.

**Clinical Trial Registration:** ISRCTN67209155

**Keywords:** preventive health intervention, older people, qualitative study, randomized controlled trial

## Background

Preventive health interventions to promote health and well-being in the extended lifespan are a priority across the globe.[1] The Lifestyle Redesign™ intervention improved the health and wellbeing of older adults who were living in sheltered accommodation and at risk of health disparities in one US study,[2] and that of older adults attending some form of community provision in a second.[3] The Lifestyle Matters intervention was inspired by Lifestyle Redesign™ and adapted to the UK context.[4] Similar to the US intervention, Lifestyle Matters sought to improve health and well-being of older people at risk of decline, using the principles of occupational therapy and occupational science.[5] Based on the findings from the US

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studies[2,3] and UK feasibility study,[6] multi-component preventive interventions such as those provided through Lifestyle Matters are recommended in UK guidance,[7] with the guidance having a specific emphasis upon the benefits of social connectedness.

The Lifestyle Matters randomized controlled trial (RCT) measured intervention clinical and cost-effectiveness[8] with 288 people aged 65 years and over. Participants living in one city in the north of England and in rural North Wales were recruited between August 2012 and April 2013 via General Practitioner (GP) mail outs to those who met the age criteria for involvement. Other recruitment methods included community engagement and health-care professional referrals, but these were in the minority. The recruitment process had to be pragmatic to reach the target number of participants within the trial timeline. Participants were randomly allocated to receive either the intervention or usual care, in couples (if both consented to participate) or individually.

Those randomized to the intervention were invited to take part over 16 consecutive weeks,[8] which involved attendance at weekly, facilitated groups at local community venues with up to 12 others. Participants were encouraged to explore and enact activities of relevance to them from a menu of different topics, with community engagement being a crucial component. Examples of topics that participants could select from included the importance of activity for health, maintaining physical and mental well-being and safety in the home and community.[4] The group could also suggest other topics not included in the manualized intervention. Additionally, monthly 1:1 sessions were included to enable participants to identify and work towards individual lifestyle goals, supported by a facilitator and using the knowledge and confidence gained from the group.[4]

Two facilitators for each site received a two day shared training and were supervised weekly by a senior occupational therapist at site. All were paid at Grade 4 (UK NHS Agenda for Change) rates.

Intervention theory is located in promotion of self-efficacy.[10] It also takes account of a model, which proposes that occupational performance is determined by a transactional relationship between the person, their environment and the activities they undertake.[11] The emphasis of the intervention and how it is delivered is located in participants' identifying their own goals, sharing strengths and skills with others and provision of support required to overcome psychological barriers and enable practice of new or neglected activities in the community. Didactic sessions relevant to the needs of the specific group are woven into the programme to enhance knowledge of how to overcome the barriers to active engagement. It was hypothesised that this combination of approaches, including the positioning of the older person as the expert would facilitate both attitudinal and behavioural change.

How the different aspects contained within the intervention map on to the elements described within the underpinning theories are shown in Table 1. The various components contained within the manualized intervention are shown in the vertical axis and the elements within each theory on the horizontal axis.

Qualitative evidence can illuminate how individuals experience and perceive interventions.[12] It can also help to explain quantitative findings.[13] The primary RCT outcome was the mental health component of the SF-36,[14] which was not significantly different between the control and intervention groups at either 6 or 24 months.[15]

Overall impact of the intervention assessed by interviews at 24 months post randomization with the same trial participants and those who were also randomized to the control arm has been reported.[16] Despite this, it was considered that a shorter term analysis of the experience of the intervention would be beneficial in order to elicit participants' immediate reflections of their involvement in Lifestyle Matters. In addition, intervention facilitators' views of the intervention were obtained following intervention cessation to consider how delivery might be improved.

## Aim

The aim of these interviews was to understand the acceptability, experiences of and short term (6 months) impact of the Lifestyle Matters intervention upon participants and intervention facilitators, and consider the findings firstly within the context of our theoretical framework and secondly within the main trial results.

## Methods

The reporting of this study conforms to the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines.[17] A deductive framework approach was employed for analysis.[18] The experiences of participants are described within the context of the hypothesised theoretical underpinning as shown in Table 1. We applied methodological rigour, viewing the quantitative and qualitative data sets as being complementary, undertaking purposive sampling, interviewing at two time points and detailing our analyses.[19]

**Table 1** Intervention Theories and How They are Embedded Within the Intervention

| Theory Elements | Bandura | | | | Law | | |
|---|---|---|---|---|---|---|---|
| | Mastery | Vicarious Experience | Verbal Persuasion | Positive Emotional States | Person | Environment | Activity |
| **Intervention elements** | | | | | | | |
| Group membership | | X | X | X | X | X | |
| Community location and focus | | X | | X | | X | X |
| Group sessions | X | X | X | X | X | X | X |
| 1:1 sessions | X | | X | X | X | X | X |
| Decision making and leadership | X | X | X | X | | | |
| Sharing experiences skills and solutions | X | X | X | X | X | | |
| Enacting new and neglected activities with support from others | X | X | X | X | X | X | X |
| Didactic sessions | | X | X | | | X | |
| Identifying/making lifestyle changes | X | X | X | X | X | X | X |
| Sustaining lifestyle changes | X | X | X | X | X | X | X |
| Positive coping with illness and age related disability | X | X | X | X | X | X | X |

**Note:** X = intervention component maps on to theory.

## Participant Sampling and Recruitment

Trial participants allocated to receive the Lifestyle Matters intervention were purposively sampled upon cessation of their involvement in the intervention. Twenty potential participants were identified to represent differing rates of adherence to the intervention across the two sites (thereby ensuring comparability with the overall study sample; 19) and all were approached via mailed letter, which included study information. Other variables used to select participants for interview included living situation, education, occupation, and career type.

Thirteen consented to take part and seven decided not to, with reasons being unavailable (n=1), other commitments (n=1) and not being willing to take part (n=5).

All four intervention facilitators were approached via email following intervention cessation and all consented to participate in an individual interview at a venue of their choice. Written informed consent was obtained from all participants.

## Interview Process

Individual interviews took place in the home of each consented participant with duration ranging between 14 and 71 mins. The interviews of shorter duration were with those participants who were less invested in the intervention. This data was used so that the voice of these individuals could be represented as well as those who had been more committed. Facilitator interviews lasted between 55 and 95 mins.

Two interview topic guides for participants and facilitators, respectively, were derived from best evidence and researcher knowledge, particularly from the feasibility study.[6] Feedback on draft guides was sought from the study PPI representative.

Interviews were conducted by a senior experienced postdoctoral female co-applicant (SC), and a second female with a Masters degree employed on the study (co-author KS). Neither had met any of the interviewees prior to the interview. The topic guide was adhered to but prompting also occurred. Data saturation was discussed at regular intervals and interviews ceased once saturation was reached (more participants would have been recruited if this had not been identified). Transcripts were returned to both participants and facilitators for comments and corrections.

## Transcript Coding and Analysis

A small number of transcripts were coded to refine the initial analytic framework, which was then applied to the same two transcripts by the researchers who also conducted the interviews to ensure comparable coding. All transcripts were subsequently coded and analysed using NVIVO 10 software. Matrix charts created out of the analysis were examined for cross cutting themes and patterns to inform the final interpretation. Quotes were selected from the analysis to illustrate the breadth of opinion and differences in emphasis, particularly between

participants and facilitators. The study PPI representative provided feedback on the presentation of findings.

## Characteristics of Those Interviewed

As Table 2 shows, the ages of interviewed participants ranged from 65 to 90 years, thereby including different generations of older people. There were more females than males and those living alone predominated. Adherence to the intervention varied across the group. As can also be seen from Table 2, one person had only attended one group session but the majority had attended 10 or more. It can also be seen that adherence to the 1:1 sessions was poor; no one interviewed had received all four 1:1 sessions as required by the manualized intervention.

Following open advertisement, two female facilitators were recruited, trained, and supervised throughout intervention delivery at each site. For the North of England site, one was a social worker and the second a qualified occupational therapist. For the North Wales site, one was a community worker (also Welsh speaking) and the second a qualified occupational therapist. The ages of three were between 25 and 35, with the fourth, the community worker being in her 40s. To preserve anonymity we do not identify these individuals further in our report of study findings.

# Results

The views expressed by both participants and facilitators are described below. All participants gave examples of the factors that had mediated and moderated their engagement in the group element of the intervention.

## Intervention Characteristics

The facilitators noted the differences between Lifestyle Matters compared to other, more didactic groups. They described seeking to give control to participants, encouraging peer support and education and tailoring the intervention to the needs of the specific group.

> It's kind of like being more open, not stringent about the session plan, but being far more flexible and actually taking your lead from who are these people? Who is this group? Picking up from them and adapting the material you know. (Lynne; facilitator)

## Views of the Group Intervention

Facilitators reported that the most popular group topics were activity and health, physical and mental wellbeing, roles and routines, being stereotyped, safety in the community, food and nutrition and relaxation. Groups seldom focussed on friendships, spirituality and slips, trips, and falls.

Some groups identified additional topics from those in the manual including living on a pension, volunteering, local history and your community and how it has changed. Some topics stimulated more in-depth discussions, eg, health conditions such as dementia.

Diversity of group preferences was observed, eg, a poetry activity exploring stereotyping of older people worked well with one group.

> They were really thrilled with what they'd produced and the end result and it set off people bringing in poetry and it was a really creative thing. (Chris; facilitator)

**Table 2** Characteristics of Interviewees

| Psueudonym | Age | Gender | Age Completed Education | Occupation | Living Situation | No Groups Attended | No 1:1 Attended | Total Sessions |
|---|---|---|---|---|---|---|---|---|
| May | 68 | Female | 15 | Skilled (non-manual) | Alone | 10 | 1 | 11 |
| Denise | 70 | Female | 15 | Unskilled | With another | 9 | 0 | 9 |
| Susan | 69 | Female | 15 | Unknown | Alone | 14 | 2 | 16 |
| John | 92 | Male | 14 | Skilled (manual) | Alone | 9 | 2 | 11 |
| Liz | 79 | Female | 20 | Professional | With another | 1 | 0 | 1 |
| Fred | 72 | Male | 15 | Partly skilled | With another | 15 | 1 | 16 |
| Peter | 72 | Male | 22 | Managerial/Technical | Alone | 12 | 1 | 13 |
| Julie | 69 | Female | 15 | Skilled (non-manual) | Alone | 14 | 3 | 17 |
| Marion | 73 | Female | 26 | Professional | Alone | 14 | 3 | 17 |
| Trevor | 65 | Male | 18 | Managerial/Technical | Alone | 15 | 3 | 18 |
| Alan | 77 | Male | 15 | Partly skilled | Alone | 15 | 1 | 16 |
| Betty | 88 | Female | 14 | Unknown | Alone | 12 | 1 | 13 |
| Mavis | 77 | Female | 15 | Skilled (manual) | With another | 13 | 1 | 14 |

Whilst with another group the poetry;

> . . . .went down like a lump of lead. (Sarah; facilitator)

Facilitators spoke about needing to be aware of the potential sensitivity of some topics, eg, mental health and memory problems. They had to be able to adapt sessions to individuals and to the group and its dynamics.

## The Importance of Group Facilitation

Participants observed that group sessions were open, friendly and welcoming and that time had been made for everyone.

> We, it certainly been encouraged within the group for everybody to have their say, to sort of lead the conversation . . . even some of, some of the quieter er ladies came out of their shell after a few weeks, because given the encouragement and stimulation this is what happens, yeah. (Fred)

How the facilitators enabled groups to choose which topics to explore was appreciated.

> Facilitators ran it extremely well and they did open it up very much so that it became the group's decisions rather than their decisions, er, which was very good. (Peter)

It was noted that the facilitators appeared genuinely interested in older people.

> They really were, you could see, they really were interested and they put their heart and soul into it and you could talk to them about anything you know. (Denise)

Group dynamics were inevitably influenced by factors such as participant personalities, group size and peoples' different experiences and stories.

> . . . .you know you can't underestimate just how complex that is because you're treading a very fine line between making people feel safe and able to talk about things and maybe being a bit more challenging making sure that everybody in the room is getting a chance to speak, and making sure that things are going all OK and that people feel alright and keeping an eye on the kind of emotion in the room and the pace of activities, is it suiting everybody? (Chris; facilitator)

The behaviour of some group members could be challenging at times as illustrated by this example;

> Initially the group seemed to be treading on egg-shells a bit but then realised that this is who she is and just they, not accepted her so much but accepted her ways and I think a lot of people felt a bit sorry for her rather than scared of her so they had that sort of attitude change. (Debbie; facilitator)

One participant identified herself as being a challenging individual who did not wish to make relationships within anyone in the group.

> Sharing experience was irrelevant because they did not share; they had totally different lives; none of them were university people. (Marion)

## Transport and Venue

Participants are required to arrange their own transport; an on-going challenge in North Wales.

> . . . you are very limited as to what you can actually do, so it makes it difficult to get out and meet people and so on. (Peter)

Several participants described using community transport, or accompanying each other on public transport. This reportedly helped people to regain confidence when travelling.

The group venue was observed by facilitators as being integral to health and activity. Locally based amenities could be very accommodating, wanting to actively promote what they could offer.

> They made time for us they gave us a speaker they let us go round their gallery they opened up the place to us, they are busy and they did that you know I think you know we've been very lucky with people in the community and community groups have been very helpful. (Lynne; facilitator)

## Perceived Intervention Benefits

Activities participants had engaged with were wide ranging; eg, diet and nutrition, computer sessions, painting, visits to local archives, museums, libraries, local monuments, and steam railways. Participants had arranged speakers, eg, the police, a credit union representative, pharmacists, and auction house valuators.

> I mean one of the fellas in the group he was in his 70's but he's a volunteer on the welsh highland railway . . . He organised a block booking for us on the train, we had 12 seats reserved on the train . . . And that was a really good day I really enjoyed that . . . (Trevor)

It was evident that all participants understood that activity was an important part of the intervention, whether through providing opportunities to try new things, re-engaging in

neglected activities or assisting those who were disconnected and isolated to get involved. Participants also described the activity they experienced through the groups as doing something differently to what they did before.

> OK, Thursday, we've enjoyed it so much, why don't we go out and make Thursday an activity day'. We've nothing else to worry about, we've no dependents as such, we can go, go out any day, but Thursday 'cause we've got into a routine, 'yeah, let's go and try so-and-so. (Fred)

With the support, it was possible to find the impetus to pursue one or more activities or interests.

> It's opened more doors from a leisure aspect. (Mavis)

Several described how the intervention enabled them to understand that they could still take part in activities that they had set aside due to age or physical health. Even those who were active described how the intervention helped them to persevere, when previously they may not have bothered.

> I might go along to the sports hall and see if anyone does Tai chi there … I thought it was a bit stupid at the time, but afterwards I'd go home and … 'ah, bloody muscles' [laughs], you know, and I have said once all this is over and the summer holidays are over I'll call in because I used to go to the gym and go on the bike and that, you know, so I might try the Tai chi after it was brought up there, you know. (Alan)

Participants highlighted how activities were made interesting and fun by facilitators.

> Yes then there was the one on diets … it was well it was interesting well a bit of fun as well. (John)

However, several also talked about not enjoying some activities, either due to lack of interest or pre-existing knowledge.

Enjoyment could be more motivating than awareness of the benefits of activity but the importance of both was appreciated.

> Er I did see that it would promote health and recovery in people who'd perhaps been ill and people who don't do much in the way of activities, it would get them up and exercising, which is good. (Fred)

Facilitators described how some people who were initially reluctant could become enthusiastic.

> Another lady I've done a 1-1 with in that group … I can see changes in her as well … she was very very cautious and very quiet and very reticent and she has blossomed and is definitely wanting to engage in activities with other people. (Lynne; facilitator)

Awareness of the need to change unhelpful and sometimes unhealthy routines was fostered.

> I have been a creature of habit with a programme like a robot to a realisation to whatever I'm doing can be done at any time of day it doesn't have to be part of a set programme so er there's certain amount of freedom yeah. (Mavis)

Participants' resourcefulness was noted by the facilitators.

> At the beginning the members were just so enthusiastic and they came up with the idea of bringing books they'd read in to put on a table for the tea and coffee break and to swap them, and that was from the word go, they were thinking of what, what can we do to share stuff you know. (Lynne; facilitator)

However, some individuals remained unable to recognise their own contribution.

> We really did have a laugh, we had a good laugh but I don't know that I contributed anything … Oh I gave them some information. I took some leaflets about things, you know, but well you don't think that, do you? That you're contributing, you just do it, you just take things. (Denise)

Facilitators observed how participants began to challenge stereotypes and prevailing expectations. Through the support of the group, one person with an overly caring family had successfully arranged her own holiday away. The intervention also enabled the "internalised stereotyping" to be challenged such as that expressed by the following participant.

> I was significantly different socially and intellectually and motivationally and so on from the other people who were there. (Marion)

## Interpretations of the Individual Sessions

Facilitators all described the potential value of the individual sessions.

> … getting to know people better and people used (the individual sessions) in lots of different ways really just for, it could be anything from feeding back about the group and picking up something that had happened in the group, was useful for me for kind of relationship building and just looking at support systems and just reinforcing that kind of group experience. (Chris; facilitator)

However, they also struggled to both explain and get engagement with individual sessions. This was rationalised in part

by the focus upon group organisation during study recruitment but also because individual sessions could be potentially problematic.

> I don't know whether it veered on the, kind of, the patronising and intrusive, you know, like, well this is what, they'd agreed to come to a group, in their head, this is what they thought it was. (Lynne; facilitator)

It was described how those who saw themselves as outgoing, busy people with active lives said that they did not need individual sessions as they had no personal issues or goals that they wished to discuss.

This lack of clarity was reflected by participants with two of the 14 interviewed having no memory being offered individual sessions.

## Meeting New People, Belonging and Making Friends

Recruiting a group of strangers resulted in participants meeting new and different people.

> It's been, it's been a pleasure to go and meet that group of people, a cross-section of people I didn't know. (Fred)

This could bring opportunities for new learning:

> Seeing different people getting to know what they do and you know it's you know it you like alone but you don't want your own company all the time do you and I like to learn things so get to know different things … (Julie)

Both participants and facilitators commented on how the intervention could provide a feeling of belonging to an inclusive and cohesive group.

> I think there's sort of I dunno whether you call it camaraderie or sort of friendships you could see that sort of developing sort of bonding … (Trevor)

There were several descriptions of people forming friendships and how this brought people together and reduced isolation.

> One of them was giving the other one lifts in her car to the group and she said to me, I've made a really good new friend there you know, and to think that she only lives round the corner from me and we didn't even know each other, and now we've become friends. (Lynne)

Facilitators commented that friendships were particularly important for participants who had become socially isolated.

> They were going to these community things together and they seemed to form quite solid you know foundations for friendships … she was on her own in the flat you know she'd often not see anybody for a long time it'd make her feel down. (Sarah; facilitator)

However, long-term friendships demand a level of compatibility, as observed by this participant who withdrew from the intervention.

> I mean when you make friends you usually make friends with somebody who you are compatible with. Don't you? (Liz)

Positive experiences were at variance with other comments about how individual personalities could hinder a group gelling.

> We were very very lucky that there were very few personality clashes so, I have made a couple of friends and I know Ann has made several friends from it. (Fred)

Facilitators considered that several individuals needed more time than 16 weeks to get to know others before allowing new people into their space and into their life and some groups took a longer to settle and develop trust between people.

## Sharing Experiences, Expertise, and Solutions

Sharing suggestions on how to overcome barriers to taking part inspired people to adapt their behaviour or situation and "have a go" which could lead to an increased sense of self-worth.

> Well it felt nice because, I told them different things … I felt good being able to share my knowledge with other people and it would help them, you know. It's not, 'oh that's nice', it's, 'ooh I'll try that', you know … (May)

Both facilitators and participants commented on how sharing stories brought them together.

> There was some very good discussions went on in there, elderly discussions which other people wouldn't have joined in, about our youth and things like that, you know. (Alan)

Participants shared experiences and learning about a variety of subjects. They also talked about sharing personal experiences; eg, of bereavement, mental health, and learning difficulties. However, they also said that they could lose interest if the topic focus was protracted or repeated.

> We had quite a lot of sessions reminiscing, about old [the local area]as we remembered it from 50, 60, 70 years ago, which was quite interesting, but you know, once that had been gone through, then the only thing that's left for you to talk about is your illnesses.(Peter)

Several participants considered that attending the group had given them confidence to share opinions and knowledge on a whole range of issues that were of interest to others.

> Yes, I think it was, everybody contributed quite a lot, especially in our group, I cannot obviously comment on other groups, but everyone got involved, everyone was free to, to talk on any subject, free to suggest any activity. I think ours was a brilliant group, we had the right mix and people wanted to be involved and wanted to take part, so yeah that was good …. once we started confiding in each other to a degree, then ideas were passed backward and forwards on how to solve everyday problems in life which was brilliant, yeah. (Fred)

## Practicing Decision Making and Taking the Lead

The facilitators all thought that a unique feature of the intervention was how it fostered independent active choices.

> I think with Lifestyle Matters it's really core to what the programme's about isn't it not creating dependency not leading but trying to encourage people to do things for themselves. (Chris; facilitator)

They all commented on how members got involved in running the group in contrast to other psychosocial interventions, which are prescriptive and encourage passivity.

> It's not being done to the group, it's being done with the group. (Debbie; facilitator)

Nevertheless, participants could be challenged by the notion of taking decisions.

> That idea of having choice and kind of power and decision making can take some people a lot longer to kind of get their head around. (Chris; facilitator)

Participants described a democratic approach to decision-making. Facilitator support was important.

> Facilitators ran it extremely well and they did open it up very much so that it became the group's decisions rather than their decisions, which was very good. (Peter)

Constantly handing decision-making over was perceived by facilitators to be a necessary skill for participants and central to their role, but also challenging. They thought that resistance from participants was because it was not what they were used to.

> I think traditionally people when they come the groups expect to be in the role of the you know you're going to tell me … for some people it's quite a frustrating process. (Sarah; facilitator)

One facilitator said that participants seemed to think that they were incompetent students when they would not make decisions for the group. Another facilitator said it was important that participants did not view them as being health professionals who traditionally make decisions. They identified the importance of being clear about their role and not being risk adverse and over-protective.

## Individual Decision-Making About Lifestyle Choices

Several participants described being able to re-evaluate their lifestyles and make decisions about what and how to change, requiring significant attitudinal change.

> What I have realised through that is that its attitude that counts, not age. It's made me have a real look, sometimes I think I won't try that because I'm nearly 73 and old people don't do that, and that's helped push that idea to the back of my mind again, it's sort of revitalised me and I'm thinking, 'well, there are people there 10 years older than me doing the same activities so perhaps I should open my mind and, and increase my boundaries sort of thing, you know. Look to the horizon a little bit more and try more things because you do, as you get older, age becomes a barrier, but you've put the barrier in place. It's not, it's not what you can't do it's what you want to do and that's how it should be. (Fred)

## Choosing to Make Changes and Being Assertive

Helping participants to gain the necessary confidence to make changes was a theme that ran through all the facilitator interviews; eg, for someone recently bereaved.

> They were needing to find things to do by themselves or finding new groups and things to do and they might perhaps have been feeling a little bit down or lacking in confidence to go and do that by themselves before and this has helped with their confidence and things and given them extra connections I suppose which has helped with their well-being, their mental health. (Debbie; facilitator)

Another example was someone developing confidence in computing during individual sessions.

> One of the group members he'd never done anything computer before and you know just kind of moving the mouse or just doing very basic things. (Chris; facilitator)

## Sustaining Lifestyle Changes

Nearly all the participants talked about opportunities for groups to continue and action had already been taken to make this happen, eg, swapping telephone numbers, arranging a date to meet or contacting each other with invitations. Many talked about carrying on with activities and exploring new activities. Facilitators said that many but not all of the groups made plans to carry on meeting up as a whole or part of the group.

> Group 1 swapped numbers and I think there were pockets of people there that might stay in touch … Group 2 again there were a band that were going to the cinema but it was very different personalities … The group did swap numbers and say they would stay in touch … Group 3 arranged to meet at somebody's house and I know that happened!

> Group 4 had decided to meet in a month's time at a local pub and maybe do it monthly and see how that went … Group 5 had a meeting arranged to meet for a kind of coffee morning and see how that went and see how many people … group 6 I think again some people will stay in touch but not necessarily as a group … but they have made friendships. (Chris; facilitator)

Missing the intervention was a key driver for continuing to meet. Barriers to continuing included travel problems in rural areas, difficulties identifying when individuals could meet regularly due to other commitments, and a lack of leadership or volunteer organiser. Uncertainty and ambivalence were both expressed.

> You know I'm hoping there, very often these things start off enthusiastically and they might sort of taper off a bit. I'm interested to see how long it goes on and hopefully it will go on you know. (John)

> Well we've all got the phone numbers, but I haven't heard anything, so I don't know whether that's going to carry on, you know, but I would meet up and have coffee if, you know, I'm sure it will do, but this time of year you've either got your grandchildren or people's on holiday and things like that, you know, so I'm sure somewhere along the line we will, you know, sort something out. (Susan)

One group reportedly discussed widening their membership to invite friends who had not attended their group.

One of the facilitators raised ideas for a more gradual process of ending which they thought might be more productive.

> We were wondering would it be better if you handed a couple of sessions over where you weren't there and then went back and just were that bit of support for like, well alright you know, perhaps at week 20, you know, did you meet up and did it work? (Sarah; facilitator)

## Continuing New Friendships

Friendships appeared to motivate people to continue meeting. Certain activities require a companion or are more enjoyable if undertaken with others.

> Well I would like to go walking. Yes, I think that would be nice, or perhaps meet and go out for a meal sometimes, you know, maybe things that you'd, you can't, can't do on your own or you wouldn't do on your own. But if you've got company you would, you would go. (Betty)

Several participants described striking up and continuing close friendships with one or two individuals with whom they shared common interests.

"I mean I still go to Keep Fit with one of the ladies that was there … so we keep in touch that way … " (Denise) quote not formatted like the others

Another recounted.

> I've seen one of the ladies who went to the group, she's eighty-three and she's terrific, and she said have you ever been to bingo? So I said oh yes, I says I'm a bit partial to a game of bingo so she said, would you go with me? So I said sure … And we went last Saturday … I didn't win anything but it were good fun and we nattered and I go and pick her up she likes that. Yes she's a delightful lady and I'm grateful for the Lifestyle [Matters] just to meet. (May)

Participants invited other group members to go to their favoured activities outside the group; eg, one person invited others to go on a coach trip with her and someone else took a member to their bridge club.

However, not everyone wanted to stay in touch. Group dynamics had a significant effect on the potential for continuation for some, eg, poor group bonding due to lack of common ground.

> There was nobody in the group that I, if we'd met outside the group, that I would have said oh … we'll be friends for life. (Peter)

A second reason was the gender imbalance with some groups having more female members. The intervention failed to bridge this gap with some male participants expressing that they had less opportunity to bond with similar individuals and therefore had not built up friendships to take beyond the 16 weeks.

## Challenges to Participation

How disability can create barriers to involvement in this intervention and in life in general was a universal issue. Nearly all participants described experiencing limitations due to a health condition or age-related disability. However, there was also a strong expressed desire to remain independent.

> Well, I declined because I would've needed to use my wheelchair (during the out of venue activity) and my wheelchair has to be pushed, you know, it's not self-motivated. So [facilitator] said, 'no problem, one of … ', you know, 'one of us can help', and I went, 'that is the point, I don't want to go there and spoil somebody else's day, them pushing me round', you know. So I said, 'no I won't if you don't mind'. That's my independence. (May)

All the facilitators observed how graded engagement in activities led to changes in participants' attitudes towards their ability to be able to participate. An example was provided by a participant who had recently had a double-hip replacement.

> She absolutely turned out to be the person who was most gung-ho about trying everything you know from even if she was just sitting down to do things … she'd actually started going to Tai Chi outside of the group and she'd been getting two buses to get there. (Chris; facilitator)

Participants raised two very different attitudes towards age and ageing. Firstly that age in itself is not a barrier to change. Alternatively deteriorating health, disability and/or tiredness meant some participants felt unable to carry out activities they used to do particularly if previous standards had to be compromised as described by this participant who did not continue with the intervention.

> … and knitting, sewing, embroidery, you usually dabbled and done things then and usually by the time you're older oh my eye sights not as good as it was and my concentration isn't as good as it was and my bodily function you know I just can't do the things I used to do. (Liz)

Dislike was expressed of discussions that became dominated by ill health, particularly if it was not channelled into potential solutions. Attitude to illness could therefore affect group dynamics.

> I suppose it's inevitable, you are dealing with old people, but in the end it was, who, who was the, who was the more ill … you know like, I have got so and so, "ooh, have you?" "I've got that" … oh my god, which was a bit of a downer … It's, [pauses] there was more I think half full people than half empty. (Peter)

## Hearing Loss

For a small but significant number of participants, hearing loss posed significant problems and the carefully selected group venues could still fail to meet their needs.

> I didn't contribute a lot to it because of my hearing problem and then thinking, no I'll not saying anything because I can't, I can't really hear what other people were saying back to me sort of thing, you know it does hold you back a little, a little bit. (Betty)

The same individual described difficulties following conversations and how this led to frustration and thoughts of withdrawing.

Due to hearing problems some participants were limited to getting to know only the people they sat next to regularly.

> So you bond obviously with the person next to you and sort of because I'm deaf … I do have a hearing problem and I must be honest a lot of the things that the group said I didn't catch particularly those sitting on the other side of the room. (Julie)

> If there's more than one sound everything gets jumbled up. (Susan)

One participant suggested the use of an induction loop. Another wanted a quiet space with no noise from adjacent rooms. Another suggested more controlled chairing of discussions to avoid multiple voices at the same time.

> … so somebody's talking here, somebody's there, and you need a chairman with a gavel just one at a time please. (John)

Facilitators learnt from the experiences of deaf participants.

> We had one lady who's got a hearing aid in each ear, both ears, she goes to lip-reading classes and she educated us all about these hearing loop systems which I had knew nothing about … we all learnt a lot that day from that lady. (Lynne; facilitator)

Learning about an individual's hearing condition meant that the rest of the group could respond to this and be more inclusive.

> And there was a lady who'd become acutely deaf and she'd been to, on her own back, lip reading lessons, and it, when we realised if you'd gone up to talk, we had to face her because she'd pick up what you were saying … (Alan)

## Finance

The majority of participants considered themselves to be financially comfortable and able to pay for travel and group outings.

> There was no one who couldn't have afforded to throw a fiver up every now and again or something … (Alan)

Nevertheless, the costs associated with improving lifestyle, increasing activity levels, and engaging in the local community were acknowledged. One person raised the potential for embarrassment for those living on a small pension.

> When they were saying about going to the pictures and going for a meal yeah that's fine, nice but what you have got to remember is there's some people who live just off their pensions and that could've been embarrassing because if you go for a meal well it's gonna, how much is it gonna be? At least ten pound … and the transport, pay to go to the pictures, alright you go certain times you get it cheaper but it's an added expense … (May)

The facilitators had a different perception in that they perceived Lifestyle Matters to be a low-cost intervention and considered that they had suggested activities that all members could afford. Tips on money saving strategies between participants were encouraged, as was the exploration of free community resources.

## Language and Culture

National identity and language were very important to the Welsh participants. At least half the members of each Welsh group were Welsh first language speakers. Group discussions were held in English with the Welsh-speaking facilitator translating, making it possible for everyone to contribute.

> Oh yeah it was quite good because [facilitator name] she's bilingual so I mean one or two of the older ones you know they prefer some of the stuff in Welsh like which is okay cos I understand it anyway … so I mean you had that mix as well like which is quite good. (Trevor)

> When we've had people that are struggling to think of what they want to say in English, say it in Welsh and then we'll figure out what it is you're trying to say. (Debbie; facilitator)

One perceived advantage of the bi-lingual group sessions from the facilitator perspective was that they fostered community relationships.

> You get these localities where you get just English groups doing something or just Welsh groups doing something and what was really really nice actually was to see members of the same community coming together with different first languages and actually really getting on. (Lynne; facilitator)

Bi-lingual groups encouraged English speakers to practice speaking Welsh. It also offered the chance for new perspectives as reported about one participant.

> She said she felt restricted in her community some of the things were run by chapel that she just felt were very gossipy and she didn't want to be a part of but coming to this group had been like a breath of fresh air. (Lynne; facilitator)

The opposing argument was based on a facilitator saying that several Welsh-speaking members expressed a strong preference for the intervention being in Welsh. The importance of wider culture and not just language was emphasised by one of the facilitators.

> Personally, even though people did generally get on together very well, I think it is important in such strong Welsh speaking communities to have groups available that are run solely through the medium of Welsh, in terms of language, culture identity, and community, especially in those areas and they should be identified. (Lynne; facilitator)

## Overall Impact of the Intervention

Visits to local community facilities such as art centres and museums encouraged people to continue these activities after intervention cessation. There were several reports from facilitators of people carrying on new activities, eg, Tai Chi, or computer classes, having tried them out.

> We have had people saying well we wouldn't have done it if we weren't coming to this group. (Sarah; facilitator)

Plans to continue new activities varied amongst participants with the majority stating they would continue. Some thought they had experienced everything already or had little interest, or as one participant illustrated, had not been able to sustain their initial enjoyment.

> Well I did try it and I, I got a little office set up, I got bored. (Denise)

When asked directly, the majority of participants felt attending had not had any significant impact on their

daily life, but evidence of the intervention as an instigator of behavioural change could be identified when they talked positively about their lifestyle choices, attitude to life, self-awareness and also confidence to try new things which for some was on-going.

> No it hasn't ended. Yes the meetings might have ended but the programme within ourselves is still going on . . . (May)

## Discussion

Qualitative studies of lifestyle post-retirement illustrate the complex range and interplay of factors, which can influence the nature and course of later life (eg, 20; 21; 22, 23). The aims of this qualitative study were to understand the acceptability, experiences of and short-term impact of an intervention created to enable individuals to positively reframe lifestyle in later life, particularly by understanding the importance of activity for health and well-being.

In the short term, it appears that participation in Lifestyle Matters could assist participants to moderate and in some instances overcome the consequences of age-related illness, disability, and social isolation and make lifestyle changes.

How the benefits described by participants during these interviews mapped onto intervention theory is illustrated in Table 3.

This shows that certain aspects of the intervention; namely practising decision-making and taking the lead, sharing and enacting activities, and positively managing age-related illness and disability mapped on to all aspects of intervention theory. Succeeding with undertaking new or neglected activities due to verbal support, vicarious observations of others and behavioural modelling based upon those observations was a theme running throughout, which then resulted in more satisfying lifestyle experiences. This is in accord with the conclusions of Bandura,[10] which are that improved levels of self-efficacy encourage more individual effort and persistence leading to improvements in quality of life. Benefits relating to meeting new people, creating new friendships and sustaining lifestyle change following intervention cessation were only partially fulfilled and engagement in 1:1 sessions, specifically designed to pursue individual goals, was limited. While the overall intervention promotes the re-designing of lifestyle through the identification and enactment of life goals, neither participants nor facilitators described this explicitly. However, there were many implicit examples goal setting and working on goals within the interview data; eg, enacting and sustaining lifestyle changes. Nevertheless, the full extent of sustained behavioural change that the intervention might encourage was unlikely to be achieved due to incomplete delivery of the overall program. Other difficulties, which reportedly eroded ability to be able to gain verbal support from others and model behaviour included hearing loss and language and cultural requirements. In accord with the findings from the interviews at 24 months post intervention, the small numbers of participants who reported deriving significant benefit were those who also had experienced

**Table 3** Mapping Described Benefits to Intervention Theory

| | Bandura Mastery | Bandura: Vicarious Experience | Bandura Verbal Persuasion | Bandura Positive States | Law Person | Law Environment | Law Activities |
|---|---|---|---|---|---|---|---|
| **Benefits described** | | | | | | | |
| Involving and using locally based facilities | X | X | X | X | X | X | X |
| Taking the lead | X | X | X | X | X | X | X |
| Taking decisions | X | X | X | X | | | |
| Trying new activities/new learning | X | X | X | X | X | X | X |
| Sharing activities | X | X | X | X | X | X | X |
| Enacting lifestyle changes | X | X | X | X | X | X | X |
| Use of humour | | | | X | | | |
| Challenging routines and stereotypes | | X | X | X | X | X | X |
| Meeting different people | | X | X | X | | | |
| Attitudinal change | | X | X | X | | | |
| Sustaining change | | | | | X | X | X |
| New friendships | | | | X | | | |
| Keeping in touch | | | | X | X | X | X |
| Positively managing age related disability | X | X | X | X | X | X | X |

life-changing events and could as a consequence recognize the need to make changes.[16] Sustainability also has to be considered; the value of multimodal holistic interventions to promote lifestyle change has been noted in other evaluations, but also the need for relapse prevention.[24]

Despite the Lifestyle Redesign intervention demonstrating efficacy in the US[2,3] the trial of the UK adapted intervention found that the intervention had a neutral impact upon quality of life, although there was significant improvement to perceived loneliness.[15] One potential reason for neutral trial results may be that, although the intervention did have a positive effect on participants, this effect was not great enough to elicit a significant improvement to the trial primary outcome (SF-36 score). Participants recruited to the Lifestyle Matters trial were not necessarily in contact with health or social care services and had a relatively high SF-36 score at baseline.[15] In contrast, both US studies were conducted with specific populations; the first with people living in low-cost sheltered housing and the second with those already engaged with different forms of day service and who were therefore highly likely to have identified needs. Additionally, as the results of these interviews demonstrate, participants may have required more assistance than was available to them to benefit fully from the intervention and sustain any gains that they may have obtained.

Another issue, which may have compromised trial results is located in the utility of outcome measures for clinical trials.[25] For example, it has been proposed that generic health outcome questionnaires as such as the SF-36 are open to interpretation and do not identify some important issues when used with older people.[26] The Better Ageing Project[27] assessed the effect of a physical-activity programme upon the mental and physical well-being of older adults. Qualitative findings demonstrated some positive improvements, but this was not mirrored by the quantitative trial results. As with Lifestyle Matters, it was deduced that the quantitative measures may have not been sensitive enough to detect change in participants' well-being and it was also noted that participants were mentally and physically well compared to the intended trial population. In contrast, delivery of a multi-component multi component preventive physical health intervention to frail older people aged 80 and over did report short-term positive outcomes in the shorter term, underscoring the importance of intervention targeting.[28]

The Lifestyle Matters trial[15] highlighted the difficulties of recruiting those most in need of such an intervention; namely people who had become lonely, isolated, and inactive. The previously undertaken feasibility study of the same intervention[6] recruited those who met these criteria, demonstrating the limits of using recruitment data from feasibility studies to predict recruitment in larger randomized trials where a rapid recruitment drive is usually required,[29] and in particular recruitment to trials of interventions with a group element such as Lifestyle Matters.

This form of multicomponent intervention is still recommended for practice in the UK[30] and work continues across the globe to consider how such programmes, designed to allay the effects of age-related decline can be implemented to best effect.[21,31,32] This UK-based study was compromised by the study population; the majority were not experiencing decline. The UK challenge is the timely identification of individuals beginning to experience difficulties. Until this is possible, the true benefits of this intervention will not be realised.[33]

## Conclusions

The qualitative evidence presented here demonstrates the positive effect that this intervention could have upon the lives of older people but only if the entire intervention is delivered as intended and it is targeted towards a population who are on the cusp of age-related decline. It also underscores the challenges associated with undertaking large-scale pragmatic trials of complex behavioural interventions.

## Ethical Approval

Ethical approval for the main trial and this qualitative sub study was granted by the South Yorkshire Research Ethics Committee (reference number 12/YH/0101). All participants consented to participate in this qualitative study.

## Data Sharing Statement

All relevant data are published within this manuscript.

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## Disclosure

The authors report no conflicts of interest in this work.

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Publication 4 (Qualitative study): The long-term (24-month) effect on health and well-being of the Lifestyle Matters community-based intervention in people aged 65 years and over: a qualitative study

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# The long-term (24-month) effect on health and well-being of the Lifestyle Matters community-based intervention in people aged 65 years and over: a qualitative study

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## ABSTRACT

**Objectives** To assess the long-term effect on health and well-being of the Lifestyle Matters programme.

**Design** Qualitative study of a subset of intervention arm participants who participated in the Lifestyle Matters randomised controlled trial (RCT).

**Setting** The intervention took place at community venues within two sites in the UK.

**Participants** A purposeful sample of 13 participants aged between 66 and 88 years from the intervention arm of the RCT were interviewed at 24 months post randomisation. Interviews aimed to understand how participants had used their time in the preceding 2 years and whether the intervention had any impact on their lifestyle choices, participation in meaningful activities and well-being.

**Intervention** Lifestyle Matters is a 4-month occupational therapy intervention, consisting of group and individual sessions, designed to enable community living older people to make positive lifestyle choices and participate in new or neglected activities through increasing self-efficacy.

**Results** Interviews revealed that the majority of interviewed participants were reportedly active at 24 months, with daily routines and lifestyles not changing significantly over time. All participants raised some form of benefit from attending Lifestyle Matters, including an improved perspective on life, trying new hobbies and meeting new friends. A number of intervention participants spoke of adapting to their changing circumstances, but there were significant and lasting benefits for 2 of 13 intervention participants interviewed.

**Conclusion** The majority of those who experienced the Lifestyle Matters intervention reported minor benefits and increases in self-efficacy, but they did not perceive that it significantly improved their health and well-being. The two participants who had experienced major benefits also reported having had life-changing events, suggesting that this intervention is most effective at the time when lifestyle has to be reconsidered if mental well-being is to be sustained.

**Trial registration** ISRCTN, ISRCTN67209155, post results.

## Strengths and limitations of this study

- We present data obtained from a purposeful sample of 13 participants who received the Lifestyle Matters intervention within a randomised controlled trial.
- We analysed the interview data thoroughly using framework analysis.
- Recall may be an issue as participants were asked to recall events that occurred up to 2 years ago.

## BACKGROUND

Older adults can experience many life changing events in later life, such as retirement, disability and illness, which may have deleterious effects on mental and physical health and well-being.[1] In turn, decline and loss can result in social isolation and loneliness, which further erodes quality of life. Participation in meaningful activities can prevent this decline.[2 3] Occupational therapy aims to help individuals participate in both necessary and meaningful activities; it has an important role to play in health promotion and disease prevention by supporting engagement in activity and maintenance of occupational balance.[4]

The findings from recent systematic reviews support the use of psychosocial interventions for ageing well. Interventions identified through these reviews include engagement in meaningful social activities,[5] those designed to support occupational engagement[6] and multicomponent group-based health promotion interventions.[7] Guidance published by the UK National Institute for Health and Care Excellence (NICE) supports the use of group and individual sessions based on occupational therapy principles, where participants rather than facilitators are positioned as experts and peer support is fostered.[8]

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Two studies undertaken in the USA (and recommended in NICE guidance) have investigated the clinical and cost-effectiveness of the Lifestyle Redesign intervention.[9 10] This is an occupational therapy intervention designed to support older adults at risk of decline in the participation in meaningful activities, thereby increasing their health and well-being.[9 10] Quantitatively, Lifestyle Redesign was found to improve the health and well-being of older adults living in a form of sheltered accommodation in a first study,[9 11] and in independently living older adults attending some form of community provision in a second study.[10] No qualitative work has been published to describe participants' experiences of the US intervention. Lifestyle Matters was inspired by the US Lifestyle Redesign and has been adapted to the UK context.

Based on an occupational approach to healthy ageing, the manualised Lifestyle Matters intervention is designed to assist participants to improve their well-being and avoid the decline associated with social isolation and poor mental health.[12] It involves participants meeting in a weekly group of up to 12 people over 4 months at a local community venue. Participants are also asked to engage in monthly individual sessions with one of the two facilitators at mutually agreed locations. Session topics can either be chosen from the manualised programme or new topics identified.[12] The facilitators work with the participants to explore the selected topic through discussion, activities and enactment in the community. The emphasis throughout is on the identification of participants' own goals, empowerment through sharing strengths and skills and providing support to enable them to practice new or neglected activities independently, particularly in the community. The intervention was postulated to change behaviour through Bandura's theory of self-efficacy, which theorises that self-efficacy is developed through four main sources—performance accomplishments (where success undertaking an activity builds self-belief in efficacy), vicarious experiences (seeing people similar to oneself undertake a task successfully), verbal persuasion that one has the ability to succeed in a given activity and inferences from emotional stimuli indicative of personal strengths and vulnerabilities.[13]

We undertook the Lifestyle Matters randomised controlled trial (RCT) to examine the clinical and cost-effectiveness of Lifestyle Matters, the protocol for which is reported elsewhere.[14] Between August 2012 and April 2013, 288 individuals living in an urban area in the North of England and 12 rural area in North Wales were recruited to the Lifestyle Matters study via general practitioner (GP) mail outs, community engagement and healthcare professional referrals. Individuals recruited to the study were randomised to either the intervention or usual care, in couples (if both individuals consented to participate in the study) or individually. Participants randomised to the intervention received the manualised 4-month Lifestyle Matters intervention, facilitated by NHS band four staff who were provided with preliminary training and supervised by qualified occupational therapists throughout delivery. Both sets of participants were provided with questionnaires at baseline, 6 and 24 months. The primary outcome was the mental health component of the 36-Item Short Form Health Survey (SF-36) questionnaire, which was not significantly different between the control and intervention groups at either 6 or 24 months.[15 16] Participants were also interviewed qualitatively at 6 and 24 months to understand their experience of the intervention and any lasting effects.

Multi-methods research, where qualitative research is undertaken alongside quantitative methods, can be used in RCTs to explore the reasons for the quantitative findings and to explain variations in the effectiveness of an intervention.[17] Medical Research Council Framework recommends using qualitative research alongside trials 'to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes'.[18] We therefore undertook a qualitative study 24 months post-randomisation to understand the long-term effects of the Lifestyle Matters intervention in order to ascertain if changes in well-being which were not identified quantitatively could be identified qualitatively.

## METHODS

The reporting of this study conforms to the Consolidated criteria for reporting qualitative research (COREQ) guidelines.[19]

### Recruitment and data collection

Interviews were undertaken at 24 months postrandomisation (approximately 18 months after intervention delivery had completed) by JR (Female Research Assistant with PhD) and RC (Male Trial Manager), both having experience of undertaking interviews with older adults. Participants were recruited to the study through purposeful sampling from the intervention arm of the study. All intervention participants who had been interviewed at 6 months and had provided 24-month quantitative follow-up data were approached to participate once more (n=13). Potential participants were first approached by JR or RC via a telephone call to ascertain initial interest in the study; no other previous contact was had between the researchers and participants prior to this. If interested, a participant information sheet and copy of the consent form was sent by post, and the participant was telephoned again to confirm that the information had been read, and he/she was happy to participate. Of those approached, nine participated in the substudy. Participants did not participate due to either not being contactable (n=2), not being interested in participating (n=1) or had already withdrawn consent from the main trial (n=1). Six additional intervention group participants were then approached to reflect a range of health-related experiences and abilities (based on their SF-36 scores at 24 months follow-up, age, location (North Wales/Northern England) number of intervention sessions attended and professional background (skilled, non-skilled) and



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Table 1 Demographics of interviewed participants

| Participant ID | Site | Age range | Gender | SF-36 MH score (6 months) | SF-36 MH score (24 months) | Number of group sessions attended | Number of one-to-one sessions received/ number offered |
|---|---|---|---|---|---|---|---|
| P14 | Northern England | 65–74 | Female | 60 | 70 | 13 | 1/4 |
| P15 | Northern England | 65–74 | Male | 85 | 65 | 12 | 1/4 |
| P16 | Northern England | 65–74 | Female | 65 | 80 | 14 | 2/4 |
| P17 | Northern England | 65–74 | Female | 90 | 80 | 9 | 0/4 |
| P18 | Northern England | 85–94 | Female | 90 | 70 | 12 | 1/4 |
| P25 | North Wales | 85–94 | Male | 95 | 95 | 13 | 2/3 |
| P20 | North Wales | 75–84 | Male | 70 | 90 | 15 | 1/4 |
| P21 | North Wales | 65–74 | Male | 70 | 90 | 15 | 1/4 |
| P22 | North Wales | 65–74 | Male | 90 | 90 | 11 | 1/4 |
| P23 | North Wales | 65–74 | Female | 90 | 95 | 14 | 3/4 |
| P24 | North Wales | 75–84 | Female | 85 | 100 | 1 | 0/0 |
| P19 | Northern England | 65–74 | Male | 90 | 70 | 15 | 1/4 |
| P26 | North Wales | 65–74 | Female | 85 | 80 | 15 | 1/4 |

SF-36, 36-Item Short Form Health Survey, scored on a 0 (poor) to 100 (good) health scale.

gender). Four of these consented, with participants not participating due to not being contactable (n=1) and not being interested in participating (n=1). In total, 13 participants were interviewed at 24 months. Participant demographics are summarised in table 1. The average age of participants was 73.0 years and ranged from 65 to 88 years. Six males were interviewed and six participants lived alone. The average SF-36 score of the sample was 82.7. One participant was in a couple with another study participant (who was not interviewed in this qualitative study).

Lifestyle Matters group attendance ranged from 1 to 15 sessions. Interviewed participants represented eight Lifestyle Matters groups, four in each site. The number of individual sessions offered to participants ranged between zero and four, the number actually received ranged between zero and three. Although they were not asked directly about it, no participants mentioned attending any one-to-one sessions in their interviews.

The semi-structured interview schedule aimed to explore, over the previous 18-month period (ie, from the end of the intervention phase): a) any changes in use of time and social participation; b) any impact that Lifestyle Matters on their lives and if so how and why.

The interview scheduled was piloted with a patient representative; the data from which was not used in the final analysis. Table 2 presents the questions which participants were asked, including example prompts.

All interviews were conducted in the homes of participants; no one else was present and repeat interviews were not undertaken. The participants would have been aware of the researcher's interest in the Lifestyle Matters intervention. Consent to audio record the interview was obtained from all participants and recordings were

Table 2 Semi-structured interview questions and example prompts

| Question | Example prompt |
|---|---|
| How has life been for you over the last 18 months? | How has life changed for you over the last 18 months? Have things improved or got worse? |
| What does the term 'quality of life' mean to you? | What would improve the quality of your life? |
| How has life changed for you over the last 18 months? | Are you doing more or less activities (social or otherwise) |
| What do you think prevents you from engaging in social/leisure activities, or activities that you used to enjoy doing? | Has anything made it more difficult to do such activities? |
| Has the Lifestyle Matters group changed your life in any way? | Has the Lifestyle Matters group affected how easy or hard it is for you to engage in social activities? |



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transcribed verbatim. Data collection was ended when the diversity identified in the sampling frame had been reflected in the interviews. Interviews lasted between 20 and 50 min and field notes were made after the interviews. Transcripts were not returned to participants for comments or corrections. Although sample size was prespecified, data saturation was discussed and confirmed following completion of all interviews; transcripts were read and themes identified to ensure that no new themes were arising in the final few interviews.

### Data analysis

A deductive framework approach was used for data analysis,[20] the starting point for which was the theory by which the intervention was postulated to function (as described above). Framework Analysis is a five-stage process of: familiarisation, forming a thematic framework, indexing, charting and mapping and interpretation. Familiarisation was achieved through reading and rereading a selection of interview transcripts. A thematic framework, consisting of major themes and one level of minor themes, was developed by two researchers (JR and RC). A small number of transcripts were coded using the framework, after which the researchers met to discuss the framework and finalise any changes that needed to be made. The same two transcripts were coded by three researchers (JR, RC and OO) to ensure comparable coding; any differences were discussed. All other transcripts were coded by one researcher using NVIVO V.10 software. Matrices were then developed, with one theme per matrix. Themes were derived from the data. Matrices were split into activities, attitudes and personal resources, health, mobility, quality of life (overview), social, family, community and other experiences and effects of Lifestyle Matters. These matrix charts were then examined for cross cutting themes and patterns in the data were mapped to inform the final level of interpretation. In order to report the results in a coherent manner, health, mobility and quality of life matrices were combined to form 'mental and physical health'. Attitudes and personal resources and community were combined to form 'personal and community resources'. New matrices were coded using elements of other charts to form the following new major themes: new skills and knowledge, change in routine, new leisure activities, meeting new people, family commitments and bereavement. We attempted to identify if the intervention increased self-efficacy through any of Bandura's four sources of self-efficacy (verbal persuasion, performance accomplishment, emotional arousal and vicarious experience), using the participant's own words. Participants did not feedback on the findings.

### Ethical considerations

All participants gave written informed consent for participation in the study. Participants were telephoned to ascertain their interest in participating, and were sent a consent form and information sheet that explained the purpose of the study. The consent form was then signed in the presence of a researcher (RC or JR) by the participant on the day of the interview, when consent to record the interview was also obtained. Ethical approval for the main trial and this qualitative substudy was granted by the South Yorkshire Research Ethics Committee (reference number 12/YH/0101). Transcripts were anonymised prior to data analysis in order to preserve confidentiality.

## RESULTS

Table 3 summarises the impact of the intervention on interviewed intervention group participants and the associated theoretical underpinning.

### Mental and physical health

Eleven participants reported having either a short-term or long-term health condition that had not changed significantly over the time period. Three participants discussed how their health had declined due to major illness; two had been receiving treatment for cancer and one participant's health had declined due to chronic obstructive pulmonary disease. The intervention did not reportedly have any impact on the physical health of participants in the intervention group.

The intervention reportedly had a positive effect on mental well-being. Four participants stated that attending the intervention helped them to 'gain perspective' on their lives and what they have. For two of these, the change in perspective helped to broaden their outlook.

> …it's … helped me with … knowing what you could do… if there's a group of us, probably someone comes up with a suggestion or something you know and … it's probably broadened my outlook a little bit more. (P18, Female, Northern England)

> It has made me look at things in a different way. As I said, there are answers to be had, you don't have to give up, there is a way forward and there are people willing to help you too. (P22, Male, North Wales)

The other two participants related the apparent social isolation of fellow participants in the group to their own situation, helping them to appreciate what they have.

> (Lifestyle Matters has) given me an idea how the other half live, in a way, and I suppose in a way I was very pleased with my … position in life. (P25, Male, North Wales)

> …it makes me appreciate … my friends and my husband still being with me and the life that I have and my family that I have got… (P24, Female, North Wales)

It should be noted that this latter participant (P24) only attended one intervention session, so it is unlikely that the intervention had an effect on self-efficacy.

Other participants discussed how being involved had improved their mental well-being. Two described how attending the group aspect of the intervention provided



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Table 3 Impact of the Lifestyle Matters intervention and associated theoretical underpinning

| Participant ID | Benefit(s) | Self-efficacy source |
|---|---|---|
| P14 | Started computer lessons and now uses it regularly | Performance accomplishment |
| P15 | Took up Bridge following support from group | Verbal persuasion |
| P16 | Confidence and support after death of husband | Performance accomplishment |
| P17 | Made new friends<br>Joined a keep fit class following support from group | Performance accomplishment |
| P18 | Broadened outlook | Emotional arousal |
| P25 | Gave perspective seeing how 'less fortunate' people live | Emotional arousal |
| P20 | Improved confidence to socialise with new people; now socialises more | Performance accomplishment/vicarious experience |
| P21 | Helped 'pull out of misery' following illness | Emotional arousal |
| P22 | Gained perspective<br>Helped him 'find answers' (now using credit union) | Emotional arousal |
| P23 | Improved confidence in group situations | Performance accomplishment/vicarious experience |
| P24 | Gained perspective | Emotional arousal |
| P19 | Increased confidence to undertake new activities<br>Mental lift<br>Positive impact on spousal relationship | Performance accomplishment<br>Emotional arousal |
| P26 | Undertaking rock climbing with group has provided her with increased confidence to do other things<br>Provided healthy eating information | Performance accomplishment |

them with a 'mental lift', which lasted a short period of time after each session.

> …it give us a buzz which gave us a mental lift which lasted for 2 or 3 days after…it's when you talk about it that you think yes perhaps I should be joining some activities and I would get that again perhaps. (P19, Male, Northern England)

This had positive effect on the participant's relationship with his wife.

> because of what people said at the group made me appreciate how good she is and made me feel quite content, I have a lot to be happy, a lot to be happy and contented about but I probably didn't realise. (P19, Male, Northern England)

Another participant spoke of how the intervention helped to pull him out of misery following illness.

> Yes I was still having to go for outpatients appointments… but when you are sort of with a group and … it's a specific day you are motivated and I think … talking with the group and laughing and joking sort of spurs you on…you know pulls you out of your misery like. (P21, Male, North Wales).

The improvement of these participant's mental state, and the 'gaining of perspective' of other participants may have impacted on their somatic and emotional status, allowing participants to interpret stress reactions more positively and therefore possibly increasing their self-efficacy.

### New skills and knowledge

Around half of those interviewed who had received the intervention stated that they had gained new skills and knowledge from attending Lifestyle Matters. This included information about financial matters, healthy eating and services that can help older people. The majority of participants described gaining knowledge about financial matters and local adult education classes, including computers and keep fit.

> we talked quite a lot at …about eating and just sort of how we lived generally and I think it did just sort of widen our scopes a little bit… (P26, Female, North Wales)

### Adaptation to leisure activities

Even though, for the majority of participants, their health did not decline over the time period, physical health affected the activities participants were able to undertake. Participants had to stop or reduce certain activities due to their health. One participant used to walk regularly, but due to physical health/mobility limitations has instead started a new hobby (cooking), although this was not instigated by the Lifestyle Matters intervention.

> I use to enjoy going to the country and going for a walk, I've had to cut down on the (walking) that would help me…. [I've cut down because of] my knee, my back, my physical health. One of my main



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hobbies is cooking and that gives me pleasure. (P22, Male, North Wales)

Another stopped knitting due to dexterity and eyesight problems.

I used to do a lot of knitting I used to knit for the family and I used to sew my own clothes, but I don't do that anymore because I haven't got the same dexterity as I used to have and my eyesight is not as good as it was. (P24, Female, North Wales)

Learning about new activities as part of Lifestyle Matters meant that some participants developed new leisure pursuits, including computing, keep fit and attending opera with a group.

Three participants had discovered a new hobby through participation in the intervention and were still continuing the hobby at the time of their interview. One of these participants met new friends through the intervention and joined a keep fit class. Making a new friend appeared to provide a performance accomplishment for this participant.

You meet one person and then through that person you meet their friends… then you… join up with them and make friends then you start doing things with them. (P17, Female, Northern England)

Eight participants did not describe getting involved in new activities. They said that they already led busy lives and therefore did not have the time or impetus to continue with new activities.

Two participants had pursued and enjoyed new activities during group sessions, but did not continue these after the intervention ended. One of which tried and enjoyed crazy golf but did not continue with it; trying the new activity provided him with confidence to try other new activities in the future.

Some of the activities that we took part in be it crazy golf, visiting museums I did intend to go back and have a go at some of these activities but I have slipped back into my old… my own comfortable lifestyle. (P19, Male, Northern England)

Attending the group was good in [the] respect that I know there is things out there and if I want to go and have a try I can go and do it. (P19, Male, Northern England)

The second mentioned enjoying climbing during the intervention. She had not continued with this after the intervention had finished, but doing so had increased her confidence; as a result, she had the confidence to undertake an activity that she never thought were possible.

It's certainly given me the inclination to do the zip wire. Because we did the … wall climbing. I felt that doing that was, wow, it was just something that I never thought that I would be able to do. And the fact that I practically reached the top of the wall, I was only one grip away….and to be able to get up there and get down again, I thought was just amazing… I never thought that I would do that and I did it, means that I can do the zip wire if I feel so inclined. (P26, Female, North Wales)

The intervention provided both participants with a 'performance accomplishment', allowing them to succeed in a new hobby or activity in a safe environment. This positive experience built up their belief in their self-efficacy, making it much more likely that they would try the new activity (or other new activities) again. This was also true for other participants who tried computing and attending opera with the group.

One participant described how participation in the intervention had a major impact on his life. He had been a keen golfer but his health had deteriorated and he had had to give up golf a year before the study commenced. He had continued to attend the social events at the golf club for a period of time but then this had also stopped because he no longer had as much in common with the other members. He reported how he had started to become lonely, and Lifestyle Matters helped him to discover a new interest.

Bridge seemed like a good idea, but I'd never got off my backside and done anything about it, and the two girls that took the course were very good at kicking me up the backside and making sure I did do something about it, for which I've been very grateful as that's made a huge difference to my life. (P15, Male, Northern England)

The intervention facilitators provided this participant with verbal persuasion in order to help him increase his confidence to initiate a new activity.

### Meeting new people

All participants met new people as part of the Lifestyle Matters groups, but only a minority made 'meaningful' relationships that lasted past the end of the group. Around half of the interviewed intervention participants stated that they had not continued meeting with the group as they had not met people with similar interests.

…although the people were all right they were nice people there was nobody really that I would have wanted to have kept on with you know (P14, Female, Northern England)

Six participants had plans to meet up with their fellow group members after the intervention had finished, but this only lasted for a short period of time, as the person who volunteered to do the organising had not been in touch.

One of the members had promised to contact each one of us, he had all our telephone numbers, but he didn't do anything. (P17, Male, North Wales)



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Further group meetings also stopped after a few weeks or months because people started to drop out.

> We met up for, I think we were going to meet up one time and then everybody started going on holiday so it weren't possible but and I think it has just filtered off as I haven't seen them. (P16, Female, Northern England)

One participant was still meeting on a one-to-one basis with a fellow member of the Lifestyle Matters group, either talking by telephone or undertaking activities together, and subsequently making more friends.

> just by going to that health thing that we went to up there through this, that [Lifestyle Matters] group, I made some friends there that we still go out with, a couple of ladies and then a walking group we joined. (P17, Female, Northern England)

Meeting new people in a group situation provided two participants with self-efficacy via either performance accomplishment and/or vicarious experience; confidence was gained to interact with people in such situations.

> Participant: "I've got more confidence now in myself then I used to have years ago yeah".
>
> Interviewer: "…do you think that's anything to do with the groups…"
>
> Participant: "It just makes me talk a bit more perhaps". (P23, Female, North Wales)
>
> It might have been [the Lifestyle Matters group] … might have given me more confidence to walk into a room full of women… (P20, Male, North Wales)

### Family commitments

Family commitments influenced participant's use of time, with three interviewees reporting that family was a major part of their routine. One of those participants reported an increased commitment to taking care of family because he had recently started taking care of his grandchildren full time, which had resulted in a change in use of time:

> Apart from looking after the little girls full time, that's changed my life in the past eighteen months or so. This has restricted my personal activities a lot. So I sometimes feel that I don't get enough time to do what I want to do. (P17, Male, North Wales)

A frequently described situation was that of having to undertake routines to fit in with the work-life routines of family, specifically in order to take care of grandchildren. One participant commented that she did not feel the balance was currently in favour of her personal interests:

> because family when they are working and that you seem to get set days and that can you know so you end up doing that (….) whether you want to or not yeah you know they rely on you so you feel obliged to do it….At the moment no because I have had some of my grandchildren poorly so that has gone a bit haywire at the moment. (P16, Female, Northern England)

None of those interviewed described any impact on how they negotiated family commitments that could be attributed to the intervention.

### Personal and community resources

Availability of community resources reportedly affected the ability of some participants to undertake activities outside the home; four participants stated that they had been unable to continue to attend classes or the gym because of various reasons such as gym closure, a class having too few members to be viable any longer and death of the person who ran a class.

> I have not been able to do as much Thai Chi because I used to be able to do it 3 times a week and then because [instructor] didn't get many people going on a Wednesday he stopped doing it. (P14, Female, Northern England).

The participants who mentioned these challenges were already either attending several other classes, or were able to find a new gym, highlighting their desire to remain proactive. Lifestyle Matters aided them to locate new activities, with the participant who had to stop Thai Chi taking up computer classes instead; the facilitators assisted her to experience performance accomplishment, which resulted in her attending the class again

> [The facilitator] took us down [to the computer class] and introduced us…we have been ever since and we go every week. (P14, Female, Northern England).

### Bereavement

Bereavement was mentioned by a number of participants. Death of a spouse, family member or friend had a marked effect on lifestyle.

All participants who had lost a partner spoke of having to adapt and develop in some way, including developing new skills or re invigorating neglected ones and engaging in new social activities.

> …when you make new friends when you lose the friends that you have got if their still with their husbands it is, I don't know it makes you feel a bit, its hard to put into words sometimes [pauses] [cries] it is an emptiness and you have got to try and fill this emptiness yes [pause] the only way to do it is to, this is me, is to make myself do things and go out and speak to people. (P16, Female, Northern England)

Engagement in the intervention reportedly had a major impact on this participant's life. This woman's husband had died prior to her involvement in Lifestyle Matters. Participation reportedly helped her to deal with the recent bereavement which had left her low in confidence and with fewer social opportunities.



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> when you end up on your own you don't go out of these four walls I would think you can lose that confidence and very quickly. (P16, Female, Northern England)

Attending Lifestyle Matters helped her to regain her confidence and re-engage in social activities.

> I think it gives you something some kind of confidence when you when you know you do end up on your own and err and I just think it gives you confidence because to meet people and to be in a group. (P16, Female, Northern England)

It is clear that the intervention provided this participant with a 'performance accomplishment'—she was nervous about going alone to a new group of strangers, but having succeeded to make friends, she has more confidence to undertake such an activity again.

## DISCUSSION

This qualitative study found that those who had participated in Lifestyle Matters reportedly enjoyed the intervention and all spoke of receiving some form of benefit but only 2 out of the 13 we interviewed were able to describe any major long-term impact. Many participants described a process of adapting the type of activity they undertook following changes in their circumstance—two participants swapped active hobbies for sedentary ones (e.g., walking for cooking) following mental or physical decline; other participants, following a change in community resources, had to find new activities. A few participants had to adapt their activities following bereavement of their partner. Participants displayed self-efficacy to adapt to their new circumstances, although only two of the interviewed intervention participants were able to attribute this adaptability to the intervention. It is significant therefore that these two individuals had recently experienced a challenge in their lives immediately prior to their engagement in the intervention; one had been recently bereaved and the other had recently had to adjust to a reduction in mobility. This finding indicates that the Lifestyle Matters intervention was most meaningful for those at a 'trigger point' in their life which demanded transition and change. The intervention assisted those in the intervention arm who were at this trigger point to adapt to their new circumstances. Lifestyle Matters provided sign-posting to new activities for those individuals whose current activities were no longer available. Self-efficacy was boosted by providing participants with performance accomplishment (where participants succeeded at new activities) and modelling influences (where participants witness their peers undertake activities successfully).[13] Emotional arousal was provided by improving mental health and participant's outlook on life. It is clear that for two participants, the intervention assisted an increase in self-efficacy, which resulted in change in behaviour and increases in quality of life. For other intervention participants, there are examples described above of their self-efficacy increasing, but this did not result in a major change in their day-to-day activities and resulting quality of life. It is evident that barriers were present which prevented participants from adapting—barriers included family commitments, physical and mental health, community resources and bereavement.

This study has a number of strengths. Interviews were undertaken and analysed by two researchers, ensuring that objectivity was maximised. It should be noted that these interviews were undertaken during the winter at a time of prolonged snow and icy conditions; such weather conditions have previously been shown to reduce physical activity levels in older adults with self-reported limitations in activities of daily living.[21] Participants were asked to discuss life events covering a 2-year period. Recall may have also been an issue, especially when discussing the impact of an intervention they received 2 years previously. Participants experience of the intervention and resulting increases in self-efficacy were linked to Bandura's four sources of self-efficacy through analysing participant's experience of the intervention and associated benefits. It was difficult to determine if possible increases in self-efficacy (e.g., increased confidence) were due to vicarious experience or mastery experiences, as participants did not discuss explicitly which aspect of the intervention led to such changes.

This qualitative study highlights that in the Lifestyle Matters study, only a small number of participants were at a 'trigger point'. This is in contrast to the US Lifestyle Redesign studies, and the UK feasibility study which was undertaken prior to the RCT, which suggest that all participants gained from the intervention in a meaningful way when assessed in the USA[10 22] and in the UK.[1] However, this difference may be explained by the lack of long-term qualitative follow-up in these preceding studies; qualitative work was not undertaken in the US studies, and the UK feasibility study qualitatively followed up participants directly after the cessation of the facilitated group sessions and therefore did not assess the long-term impact of the intervention.

The quantitative and qualitative findings from this work did not demonstrate that the intervention had any impact on quality of life at population level. The majority of those recruited to participate reported being busy, active and resourceful, engaged in a diverse range of activities and with established social networks and it can therefore be argued that they had little to gain from the intervention. Inability to identify those at risk of mental decline appears to be a prime reason for the findings obtained through both quantitative and qualitative enquiry. Another issue that may have contributed includes the duration of the intervention (4 months), which was far shorter than for the US Lifestyle Redesign studies (6 months duration) and for the Lifestyle Matters feasibility study (8 months duration).[10 22] A longer delivery duration can give those with potentially 'hidden' challenges the time to become sufficiently confident to work with others to explore



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solutions. In addition, it can be argued that implicit issues such as social desirability and unacceptable disease bias,[23 24] which have been identified in other qualitative studies,[25] may mean that the benefit of the intervention was under-reported. One of the aims of the group sessions was to aid participants in moving forward together with all parties taking an active role in organising outings and meet ups. Unfortunately, the majority of participants did not continue in their groups after the cessation of the intervention, often because the person who volunteered to continue to organise the groups did not make contact with the other group members.

Clinicians and policy makers should consider who is best to facilitate an intervention such as Lifestyle Matters. In the current study, the facilitators were NHS band four therapists, who did not have in-depth training in how to manage such groups (although they did receive study-specific training). More highly trained facilitators, such as occupational therapists, may have improved the delivery of the intervention. In addition, the Lifestyle Matters intervention could be further developed in order to improve the benefit to participants. Although they were not asked specifically, none of the interviewed participants mentioned the one-to-one sessions in their interview or stated they had gained any benefit from them; the intervention could therefore be further developed by increasing the understanding of the purpose of the one-to-one sessions with both the intervention participants and facilitators.

Future research needs to be undertaken in order to identify how isolated older adults can be identified and recruited to preventative health interventions such as Lifestyle Matters. The fact that only 2 out of 13 intervention participants gained 'major' benefit from the intervention could be due to the recruitment methods used in this study, where participants were recruited, in the majority, via GP mail outs, resulting in a physically and mentally well population. The majority of participants who were interviewed in this study were not at a 'trigger point' in their life when they were in need of a health and well-being intervention such as Lifestyle Matters. Despite the emphasis current guidance places on recruiting isolated older adults to preventative lifestyle interventions, other studies have also discussed issues with identifying such individuals.[8 26 27] Future evaluations should be undertaken to assess the viability of other recruitment techniques, such as respondent-driven sampling, which has been used previously to recruit isolated adults with HIV.[28]

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**Competing interests** None declared.

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Pilot and Feasibility Studies

RESEARCH Open Access

# Journeying through Dementia, a community-based self-management intervention for people aged 65 years and over: a feasibility study to inform a future trial

Kirsty Sprange[1*], Gail A. Mountain[2], Katy Shortland[3], Claire Craig[4], Daniel Blackburn[5], Peter Bowie[6], Kirsty Harkness[7] and Maggie Spencer[2]

## Abstract

**Background:** A study to determine the feasibility of conducting a future population-based trial into a self-management intervention for community-living adults with early stage dementia included evaluation of intervention content and modes of delivery, staffing requirements, recruitment methods and the utility and usability of patient reported outcomes.

**Methods:** Participants identified through memory clinics in one city took part in an intervention called 'Journeying through Dementia'. The 12-week programme incorporating four individual sessions with one of the facilitators encourages participants to engage in discussion and activities related to health and well-being positioning them as the expert enabling long-term behavioural change. Participants ($n = 10$) and their nominated carers ($n = 7$) were all asked to complete selected outcomes at baseline, 8 weeks (participants only) and post intervention and invited to comment on their usability. All participants and carers were qualitatively interviewed before intervention delivery about their expectations and participants; nominated carers and facilitators were all interviewed after cessation about their experiences.

**Results:** The manualised intervention and modes of delivery proved acceptable to participants and carers. Reported benefits included increased confidence and self-efficacy, engagement in new or lapsed activities and re-engagement in fun and friendships. People with dementia and carers were able to self-complete all outcome measures, but time required to complete the measures is a key factor. Strategies for recruitment need to include direct contact within 24–48 h post invitation to the study. Analysis of data on the primary outcome did not reveal any trends. Facilitators found the training and support to be appropriate and helpful.

**Conclusions:** The tailored intervention reportedly met the needs of all participants. The study confirmed the need for careful identification and application of patient-reported outcome measures. Outcomes to measure some dimensions of reported benefit are not available.

**Trial registration:** Current Controlled Trials ISRCTN67209155.

**Keywords:** Dementia, Self-management, Quality of life, Community, Manualised intervention

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## Background

Dementia is a global and UK policy priority [1–3]. However, despite the policy focus and drive for early identification, the extent of unmet need amongst those who receive an early diagnosis is significant [4]. The impact of diagnosis and the symptomatology associated with dementia can lead to a sense of helplessness and apathy, increasing risks of depression in both people with the condition and their carers [5]. This together with decreased opportunities for participation can in turn result in reluctance to participate in life and associated rapid deskilling on the part of the person with dementia.

Evidence suggests that psychosocial interventions can play a significant role in supporting people post diagnosis [6] and in particular interventions that involve the person with the diagnosis and their caregiver with the aim of improving the quality of life of both [7]. However, questions remain about the extent to which speed of deterioration (which is highly specific to each person) might be ameliorated through psychosocial interventions.

Self-management is one form of psychosocial intervention, whereby those with a long term condition are encouraged to manage their physical and mental health by identifying solutions that meet their own needs, usually in partnership with professionals. Self-management programmes are well established for people with long-term conditions, but their use with people with early stage dementia is a relatively recent concept [2, 8, 9].

A preliminary study, in partnership with people with dementia and their carers, identified the potential value of a self-management intervention which would incorporate a tailored, health promoting approach to people post diagnosis. The consultation resulted in the draft 'Journeying through Dementia' intervention [10] which is designed to be delivered by occupational therapists.

Journeying through Dementia is based on the Lifestyle Matters programme [11] which was developed for the UK setting from a US intervention, Lifestyle Redesign. This intervention was found to promote physical and mental health and well-being, occupational functioning and life satisfaction in older adults [12, 13] as well as retaining approximately 90 % therapeutic gain up to 6 months post intervention [14].

In common with Lifestyle Redesign and Lifestyle Matters [13, 15], the intervention encourages continued participation by people following a dementia diagnosis [15] and is underpinned by social cognitive theory thereby aiming to increase participant self-efficacy [16]. Self-efficacy has been identified previously as a possible protective factor improving motivation and emotional well-being. Self-efficacy can lead to effective problem solving, followed by an increase of positive emotions and life satisfaction [17]. A holistic approach towards self-management can therefore promote self-efficacy which in turn can prevent decline [16].

The study described in this paper sought to examine the feasibility of a future population-based larger trial of this intervention. This included determining staff training and supervision requirements for delivery. The appropriateness of recruitment methods and usability of a range of potential outcome measures were also examined for application in a future trial.

## Methods

A single-site feasibility study was undertaken following the methodological framework stipulated in the Medical Research Council guidelines for development and evaluation of complex interventions [18]. According to the MRC guidelines, the feasibility stage of a trial provides essential preparatory work to test procedures for acceptability, compliance, recruitment, intervention delivery and retention. The aims and objectives of this study were designed to explore these factors in order to inform the design of a larger randomised controlled trial. In line with the guidance, a mixed method approach was also adopted to identify facilitators and barriers to participation.

### Aims and objectives

The primary aim was to explore the requirements for a future randomised controlled trial. The objectives to meet the aim were to

(1) Determine the appropriateness of potential outcome measures for a future study
(2) Identify the knowledge and skill set required to effectively facilitate the programme
(3) Finalise the content and delivery methods for the facilitator training programme
(4) Explore viability of proposed recruitment methods to a future study
(5) Explore the characteristics of those who might benefit from the programme
(6) Determine the optimum length of programme delivery and mode(s) of delivery
(7) Further refine intervention content

A CONSORT-style flow diagram is provided in Fig. 1 [19] to illustrate the study design.

The study was approved by Yorkshire & the Humber; Leeds West Research Ethics Committee, Sheffield Health & Social Care NHS Foundation Trust and Sheffield Teaching Hospitals NHS Foundation Trust. It is registered with Current Controlled Trials, reference ISRCTN67209155 as part of a programme of work.

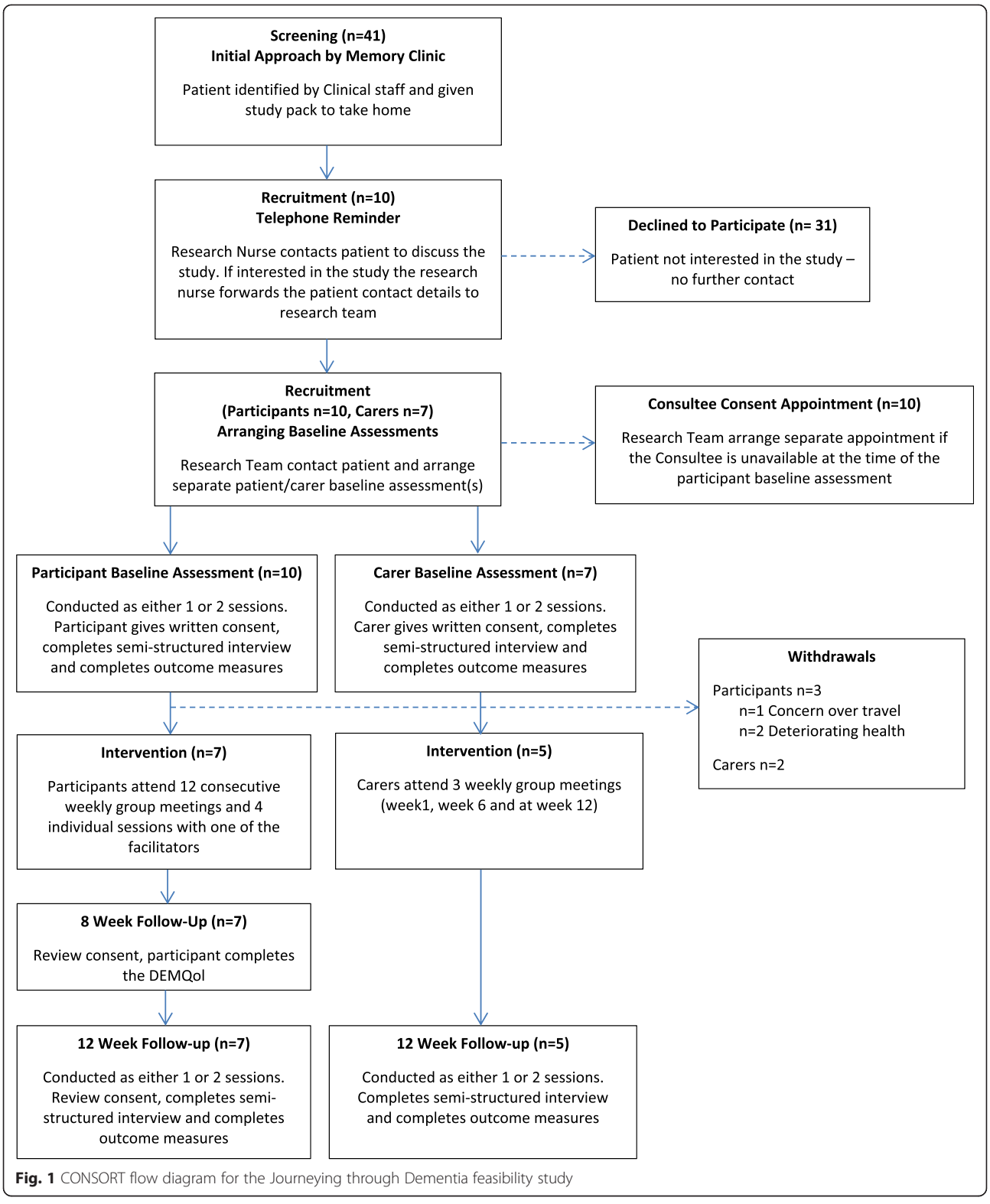


**Fig. 1** CONSORT flow diagram for the Journeying through Dementia feasibility study

## Participant recruitment

Participants with early stage dementia were recruited post diagnosis through memory services in one city. Information about the study was given to those who met the eligibility criteria and expressed interest (see Fig. 2). Suitability for participation was assessed by the Mini-Mental State Examination (MMSE) [20] as this instrument is deemed to be appropriate for measuring

***Inclusion criteria:***

1. Group 1 – Aged 65 years and over
2. Group 2 – Aged 64 years and under
3. Able to give informed consent
4. Recent diagnosis of dementia with a score of 20 or more on the Mini-Mental State Exam (MMSE) conducted by NHS service as part of diagnosis
5. Able to communicate verbally
6. Able to understand and communicate in English

***Exclusion criteria:***

1. Later stage diagnosis of dementia as determined by clinical partners
2. Individuals with Mild Cognitive Impairment (MCI) as determined by clinical partners
3. Not able to understand and communicate in English
4. Individuals who may express aggressive or disruptive behaviour (signs and symptoms of some forms of dementia)

Participation in the pilot study was not limited by scores derived from cognitive testing. NHS partners also used clinical judgement and discretion when identifying potential participants.

**Fig. 2** Eligibility criteria for the Journeying through Dementia feasibility study

cognitive capacity in larger studies as part of eligibility criteria [21, 22]. In addition, clinicians used their professional judgement when suggesting involvement. A carer information sheet was also provided.

Those who agreed to participate were then invited to involve a nominated family carer if they wished to do so, but this was not a condition of participation. Nominated carers had to be prepared to take part and also agree to complete a small number of selected outcome measures to determine their appropriateness including their usability. They were also invited to take part in pre and post intervention semistructured interviews.

### Ethics and mental capacity

Participants were also asked to nominate a consultee who would act on their behalf, should their ability to give informed consent change during the course of the study. All participants, carers and consultees provided written consent for their involvement [23, 24].

In accordance with the Mental Capacity Act 2005, assessment of capacity was reviewed throughout the study [23]. The knowledge and experiences of people with dementia and their carers were recognised and respected throughout, and participants were able to withdraw at any time.

### Intervention content and delivery

The intervention is a 12-week manualised participant-directed self-management programme. Content includes (but is not limited to) the following topics:

- Beginnings: Introductions, principles of self-management, exploring differences
- Ways of thinking about dementia: What is dementia, effects on everyday life, challenging stereotypes, sharing coping strategies
- Keeping physically well: Relationship between physical and mental well-being, embedding healthy activity in everyday life and diet
- Memory: Strategies to aid memory, impact on everyday life, learn and practise new techniques
- Keeping mentally well: Relationship between anxiety and memory and dementia and stress
- Endings: celebration of achievements and how to move forward

Delivery entails up to 12 participants (people with dementia) meeting weekly for approximately 2 hrs at a local community venue (which is assessed for suitability). Participants are facilitated to select topics of most relevance to them from the menu. Subsequent topic exploration involves a mix of didactic teaching, peer sharing and active experimentation with support from each other and from the facilitators. For example, an overall group goal could be using public transport in which case a community visit is organised together involving travel. Examples of associated activities that members identify as being valuable to pursue might include route finding and discussion of strategies for managing cognitive challenges in the community.

Participants also receive four individual sessions with one of the facilitators to pursue personal goals. The first of these individual sessions takes place before the group starts to introduce the participant to the programme and begin relationship building. The remaining three sessions take place at regular intervals over the 12 weeks.

Enhanced techniques are used where necessary for communication and to scaffold memory to promote engagement [25, 26]. These include the use of cue cards, written materials providing summaries of meetings and diaries for appointments or meeting dates.

Preparatory work confirmed the importance of involving family carers. Nominated carers are therefore invited to join the group on three occasions: the first, the middle and final group meetings and engage with individual goal setting sessions if participant goals involve them.

### Facilitators and facilitation

Two occupational therapists were trained to deliver the intervention, and two student occupational therapists were recruited and trained to provide cover for absence, thereby guaranteeing delivery.

Facilitators received weekly supervision during intervention delivery, provided by experts. This was delivered in face-to-face meetings and via the telephone when necessary.

Training content was determined through the previous modelling work [10]. Facilitators and participants who took part in the preliminary study were able to provide guidance on what should be included in a training package and the mode of delivery based on their experiences. It involves a 1-day experiential format with a mix of didactic teaching and experimental group work and reflective feedback, thereby replicating the intervention [27]. The intervention is designed to be delivered by occupational therapists, but an important question for future delivery is whether other healthcare professionals can be trained and supported to deliver it. Therefore, facilitators were asked to keep reflective diaries and maintain records of their involvement in addition to participating in post intervention focus groups.

### Outcome measures

Identified measures for the person with dementia to complete were

- Dementia Quality of Life Questionnaire (DEMQoL): UK developed scale to measure quality of life for people with dementia with both self-complete and proxy completion versions [28]. A higher score (min 28–max 112) represents better health-related quality of life.
- European Quality of Life 5 Dimensions (EQ-5D-5L): widely used measure of health outcomes with utility for cost analysis [29].
- Patient Health Questionnaire-9 (PHQ-9): a widely used measure of mood [30].
- General Anxiety Disorder-7 (GAD-7): a widely used measure of anxiety [31].
- Generalized Self-efficacy measure (GSE): to assess self-belief and coping mechanisms [32].
- Physical Self-Maintenance Scale Self-rated Version (PSMS): measure of ability to perform everyday functions independently [33].
- Instrumental Activities of Daily Living (IADL): assesses independent living skills and daily functioning [33].
- A bespoke Health and Social Care Resource Use questionnaire.

Selected measures for consented carers to complete were

- EQ-5D-5L [29].
- Zarit Burden Interview [34].
- Sense of Competence Questionnaire (SSCQ) [35, 36].
- PHQ-9 [30].
- A bespoke Health and Social Care Resource Use Questionnaire.

### Study data collection methods

Consent for participation in the study was followed by a request to complete the battery of measures at baseline. This could be split across two appointments if an individual became fatigued and could take place at their home or another venue, depending upon their choice. A carer could be present at the request of the person with dementia.

If a carer was also interested in participating, the researcher arranged a separate appointment for consent and measure completion.

At each measurement time point, all participants and carers were encouraged to provide feedback to the researcher on the assessment who made written notes and also observed ability to self-complete. Of particular interests were usability, ability to understand the questions being asked and make a response, and completion tolerance to individual measures and the entire battery.

People with dementia and carers were also interviewed qualitatively at baseline about their expectations of the programme before joining and again within 2 weeks of cessation of the programme about their experiences. Schedules were developed to guide interviews and enable people to express themselves in their own terms. Topics included

- Understanding and expectations of the programme.
- Acceptability and usability of the outcome measures.
- Experience of the programme and facilitator delivery.
- Barriers and facilitators to taking part in the programme.

- Effectiveness of the programme (group and individual sessions).

### Analyses

Results from the outcome measures were examined for usability together with researcher observations. The analyses undertaken were mainly descriptive to ascertain participants and carers ability to complete the measures and the time taken to do so. Validity of scores was considered to determine their use in a future trial. The findings were analysed using the statistical package 'R' version i386 3.0.3.

Both baseline and post intervention interviews were audio recorded (following permission). A sample of transcripts (30 %) were read for familiarisation and annotated for themes by two researchers. Agreed themes were then used to produce an overall index for in-depth integrated analysis within and across all transcripts using Framework Analysis in NVivo [37, 38].

Facilitator experiences (including those of recruited students) were explored through a facilitated focus group held immediately post intervention. All attendees were provided with a list of topics for discussion prior to the session to stimulate and maximise feedback. Topics included skills and knowledge required to deliver the programme, quality of training and supervision, experience using the manual and barriers and facilitators to participation.

## Results

### Patient reported outcome measures

Ten participants and their carers agreed to be interviewed at baseline. Table 1 provides details of those who took part.

The seven participants who subsequently took part in the group then completed the DemQoL at 8 weeks and the entire battery of measures post intervention.

All participant and carer scores for all outcome measures are reported in Table 2. Due to the small sample size in this feasibility study, results of the quantitative analysis were inconclusive.

Figure 3 illustrates the distribution of scores for the primary outcome, the DEMQoL, at baseline, 8-week follow-up and post intervention. Although small, the mean score was found to increase from baseline to 8-week follow-up and this was maintained post intervention. The greatest change appears to be for those participants who scored lower on the DemQol at baseline.

### Facilitator training and programme facilitation

Training and supervision reportedly equipped these experienced facilitators with the skills to deliver the

**Table 1** Demographic data for Journeying through Dementia participants and carers

| | | Participants | | Carers | |
|---|---|---|---|---|---|
| | | Baseline ($n = 10$) | Follow-up ($n = 7$)[a] | Baseline ($n = 7$) | Follow-up ($n = 5$)[b] |
| Sex | Female | 5 | 4 | 6 | 4 |
| | Male | 5 | 3 | 1 | 1 |
| Age | 40s | 0 | 0 | 1 | 1 |
| | 50s | 0 | 0 | 2 | 2 |
| | 60s | 1 | 1 | 1 | 0 |
| | 70s | 4 | 2 | 1 | 1 |
| | 80s | 5 | 4 | 2 | 1 |
| Ethnic group | White British | 9 | 6 | 6 | 4 |
| | Caribbean | 1 | 1 | 1 | 1 |
| Living arrangements | Spouse/partner | 5 | 3 | 6 | 4 |
| | Alone | 5 | 4 | 1 | 1 |
| Housing tenancy | Own outright | 8 | 7 | 5 | 4 |
| | Tenancy | 2 | 0 | 2 | 1 |
| Occupation | Employed/self-employed | 0 | 0 | 3 | 2 |
| | Retired | 10 | 7 | 2 | 1 |
| | Looking after home | 0 | 0 | 1 | 1 |
| | Other | 0 | 0 | 1 | 1 |
| Transport | Owns car | 5 | 4 | 5 | 4 |
| | Public transport | 5 | 3 | 2 | 1 |

[a]Three participants withdrew prior to the group commencement
[b]Two carers withdrew prior to group commencement

**Table 2** Participant and carer outcome measure scores by time point

| Outcome measure | Stage | Completed | Mean | SD | Min | Max |
|---|---|---|---|---|---|---|
| Participants | | | | | | |
| DemQol | Baseline | 10 | 89 | 11 | 72 | 105 |
| | 8 weeks[a] | 7 | 94 | 7 | 87 | 101 |
| | Post intervention | 7 | 94 | 12 | 69 | 106 |
| EQ-5D-5L | Baseline | 10 | 0.79 | 0.04 | 0.72 | 0.85 |
| | Post intervention | 7 | 0.77 | 0.09 | 0.65 | 0.88 |
| PHQ-9 | Baseline | 10 | 6 | 6 | 0 | 19 |
| | Post intervention | 7 | 3 | 3 | 0 | 9 |
| GAD-7 | Baseline | 10 | 4 | 5 | 0 | 18 |
| | Post intervention | 7 | 1 | 1 | 0 | 4 |
| GSE | Baseline | 10 | 27 | 5 | 20 | 36 |
| | Post intervention | 7 | 25 | 9 | 10 | 34 |
| PSMS | Baseline | 10 | 23 | 0 | 23 | 23 |
| | Post intervention | 7 | 23 | 0 | 23 | 24 |
| IADL | Baseline | 10 | 6 | 2 | 2 | 8 |
| | Post intervention | 7 | 6 | 2 | 3 | 8 |
| Carer | | | | | | |
| EQ-5D-5L | Baseline | 7 | 0.81 | 0.30 | 0.16 | 1.00 |
| | Post intervention | 5 | 0.75 | 0.38 | 0.09 | 1.00 |
| PHQ-9 | Baseline | 7 | 5 | 6 | 0 | 15 |
| | Post intervention | 5 | 7 | 10 | 0 | 23 |
| Zarit Burden | Baseline | 7 | 16 | 13 | 2 | 40 |
| | Post intervention | 5 | 24 | 18 | 4 | 52 |
| SCQ | Baseline | 7 | 31 | 6 | 19 | 35 |
| | Post intervention | 5 | 26 | 8 | 17 | 34 |

[a]The primary outcome, the DemQol, was also repeated at 8-week follow-up

programme, although less qualified staff may require specific training on dementia. Weekly supervision was considered important for guiding facilitators on tailoring the programme and planning sessions, and the level of support required was dependent on the experience of the facilitator. A higher level of supervision was preferred at the start of delivery when more guidance was needed. Supervision was considered most effective when undertaken directly after group delivery when issues were current.

Style of facilitation was very important to the participants, who described the facilitators as personally engaging,

> They were fun and they were, you felt confident in them. They were imaginative. they made things fun and I think that was a big part of it (Participant).

Good quality facilitation was also important for encouraging attendance,

> I thought it was run exceeding well, in fact if it hadn't done I might have made an excuse and not go. But no I was always ready to go (Participant).

Post-intervention delivery, facilitators advocated a 'client centred' (Facilitator 1) approach in congruence with the underlying ethos of the programme.

### Recruitment methods

Two groups were originally planned for the feasibility study, one for those aged 65 years and over and a second for participants aged 64 years and under. A total of 20–24 participants were therefore sought, 10–12 per group. Recruitment of those 64 years and under proved unsuccessful due to a limited number of participants being identified and recruited within the necessary time frame.

Initial low recruitment rates overall identified the need for direct phone contact within 24–48 h following receipt of information to ensure that the potential

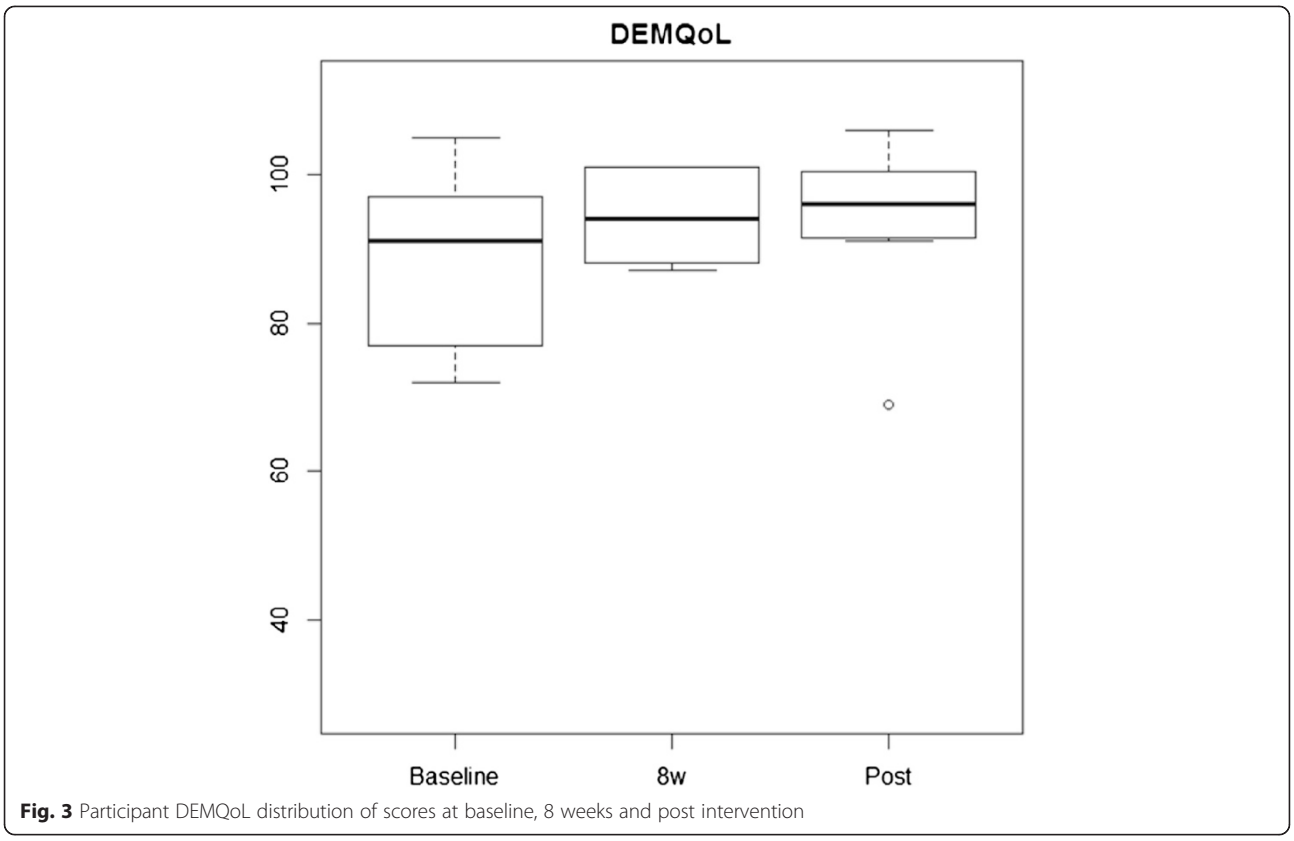


**Fig. 3** Participant DEMQoL distribution of scores at baseline, 8 weeks and post intervention

participant had read and understood what their involvement would entail.

Ten participants aged 65 years or over were successfully recruited and completed baseline assessment. Three then withdrew from the intervention prior to the group starting.

Branded study materials appeared to be an effective memory aid for participant recall during assessments. Information was deemed adequate to make an informed decision to take part and the time and opportunity to discuss the study with a researcher on a one-to-one basis was appreciated,

> You being here asking the questions has made it slightly easier for me to make me mind up (Participant).

Time and further explanation were required for the legal and ethics sections of the information sheet.

#### Who might benefit from the programme?

One group was delivered to seven people with dementia with five also having a family carer involved. The participation of carers was not related to any particular participant characteristics, for example, those with worse symptomology.

Attendance rates across the 12-week programme were 87 %. Reasons for non-attendance were either illness or attending hospital appointments. The minimum number of weekly meetings attended was nine and the maximum was 12. Six of the seven people with dementia took part in all four individual sessions. The seventh attended three and missed the fourth due to a fall. Nearly all participants were transported to and from the group by a relative or used public transport. Several participants were car owners and able to drive.

Group member diversity was described positively by participants,

> They were a lovely group of people to meet with as well. Totally different from each other (Participant).

Having people from different backgrounds and lifestyles with a range of dementia severity was even thought to improve group interaction by carers,

> They were different people from different groups, from different lifestyles. I think that everybody was able to give something… (Carer).

The group was considered to be a safe place to meet with similar people without prejudice, for exploring new ideas and experimenting with activities,

> a level playing field with this thing (Participant).

Although the group generally worked well together, participants did describe how the impact of dementia affected the contribution some participants were able to make to the group. This was noticed during involvement in activities as well as contributing verbally to discussions. However, this does not appear to have been detrimental to group bonding,

> We've said in fact again today, in fact nearly every week we have said we have been lucky because there's only [name] who hasn't been able to mix with us. You know, she's sat and listened, she's ever so sweet bless her but she just doesn't…didn't talk at all. If you spoke to her she'd answer you but you couldn't get her to talk er but the others we've all chatted together (Participant).

#### Optimum programme format and delivery

Facilitators considered the length of the intervention, 12 weeks, to be adequate to equip participants with the tools required to maintain learned skills without developing dependency,

> If it goes on for too long people get too needy of you and that expectation, the longer it goes on the harder it is for them to that see you not being there (Facilitator).

Although the participants talked about continuing to meet up following the end of the programme, the majority expressed some disappointment that the programme could not be permanent or at least continue in a different format,

> It would be nice to have a session…not frequently but probably every what 3 2 or 3 weeks? (Participant).

The size of the group supported inclusive engagement through sharing and listening,

> I think it was just right. I think had there been a lot… it wouldn't have been as intimate and had it been less we might have felt a bit less able to talk so I think as it was everybody got a chance to speak if they wanted to… (Participant).

A valued aspect of the intervention was the warm welcoming environment and selection of a suitable venue supported this ambience,

> It had a feeling about it where this type of meeting belonged…The environment was most important (Carer).

> I think it was ideal. With a great big table in the middle and a cup of coffee if we wanted it all there beside us. No I think as a venue it was brilliant (Participant).

Inappropriate venues, in particular busy, noisy places, could have a significant impact on the delivery of the intervention,

> We didn't like it when we got moved somewhere else…Especially to the University café because there's so much going on and coming and going and bits happening (Participant).

The chosen venue was centrally located with access to parking and public transport links which alleviated concerns about getting to the group. Facilitators also agreed using a local venue could support long-term transition of the group to self-management after programme cessation.

Participants described how the inclusion of outings, rather than just venue-based activities, provided opportunities to explore the wider community, put experiences into practice and build confidence. This particular group visited their local art gallery and city library,

> … we all realised that we were still capable of…going out and about er which is something I must admit I had stopped doing… (Participant).

Prior to involvement, all ten people with dementia described being keen to remain independent and saw the programme as an opportunity to support this goal. This aim was supported by the carers. Poor memory was cited by both participants and carers as being the main cause of loss of confidence and increased anxiety. Pre-programme pre-conceptions of memory capacity were therefore felt to be an indicator of ability to engage in the programme and a consideration for how beneficial it would be,

> Yeah I think it would depend on…how much he would take on board and retain…how useful it would be for him (Carer).

Post intervention participants were surprised at their ability to engage in and implement the programme content either by themselves or with the support from their family,

> They made us realise, you know, it wasn't the end of the world, that there was still life to live and I think some of us, probably myself included, had just thought, that's it. End of life, nice life doing things. I think it did give people a real feeling that, oh there was hope for the future. There were things that we could still do, there were places we could still go to and you could meet together (Participant).

The planned involvement of carers was described as enabling facilitators to establish clear boundaries for carer involvement, allay any anxieties and provide carers with the information they required to support the person they care for in taking forward learning out of the programme.

#### Intervention content

Compared to other groups, participants did not feel patronised by the intervention. The flexibility of the intervention through the manualised programme was enjoyed by the participants. In particular, how one topic could lead to different, unplanned topics and that the format of the programme allowed this diversity,

> We did some and we'd go off a bit and come back to it sort of thing which is…it's not like being at work or being at school where that's got to be done… (Participant).

Individual sessions were valued by facilitators as an opportunity to observe family dynamics, identify individual needs and discuss expectations of the programme. Goal setting during these sessions was found by the facilitators to be a difficult concept for participants to understand; however, using examples and discussing 'achievements' rather than goals meant, participants were able to explore and articulate their ideas. Goals identified by participants included cooking, reading and memory techniques such as using a daily diary and using a bookmark on which to write a brief synopsis of storylines and characters as a memory aid.

Carers' sessions were well attended, and participants considered that these were important for engaging carers,

> …because it keeps them more in touch with us… (Participant).

However, several carers wanted more detailed information on implementation of activities,

> …so if the papers that they sent or came home with were a little bit more explicit instead of just saying we talked about [topic] to actually say what they were actually doing about it (Carer).

Tools and techniques, for example daily diaries, memory cards and re-usable activity cards, explored as part of the programme appeared to increase self-efficacy,

> Every week I think you learnt something new and so it made it worthwhile going (Participant).

Participants explicitly described how the programme influenced a change in attitude from dwelling over the past to looking to the future,

> …I do feel that I'm looking forward to things more, no matter what they are, I'm looking forward to them er so I suppose it's, going there has helped me to erm get a better grip of myself'…I'm not walking about with a dull expression on my face or a dull thinking. I'm thinking more positive (Participant).

Having fun and laughter as part of the group were also important to participants as a way to engage with the programme and with other group members thereby destigmatising dementia,

> We would all laugh together or sympathise together and I think that was a very valuable part of the group because if someone hasn't experienced even anyone in the family having Dementia they've got no idea. Inside you're the same person" and "I mean listening to us talking you wouldn't have known that there was anything different about any of us (Participant).

Continuation of the group after programme cessation was cited as very important due to a perceived lack of available similar groups,

> … it'd be nice to meet up because there's nobody…there's no group round here like it…I think they'll probably find a vacuum now that it's finished and it'd be nice to have…somewhere to, once every so often, to go and meet up with them (Participant).

However, establishing deeper bonds was considered essential for continuation and could not be reliant on a shared diagnosis of dementia alone,

> It will be very interesting to see how long this group just meeting on their, you know, on their own with only that motivation that you, all, you share together your problems with memory loss, erm how long it will go on… (Participant).

It was clear that many of the carers felt that for the group to continue a 'leader' would be required,

I think that's good [group continuation] as long as they've got somebody there that can take the lead (Carer).

## Discussion

### Participant reported outcome measures

Findings from both the quantitative and qualitative analysis for participants and carers demonstrated feasibility of use and ability to complete a range of outcome measures about general health and well-being. The overall battery was not found to be burdensome, and all people with dementia were able to self-complete all selected measures. However, dementia severity did affect time required to complete the assessments. Completion of factual questions e.g. such as medications they are taking for the Health and Social Care Resource Use questionnaire was problematic if a family carer was not present. Carer presence also appeared to reduce anxiety but could also potentially lead to bias, influencing the openness of responses. Several dyads disagreed over questionnaire responses. Overall tolerance to a variety of outcome measures designed for use with people with dementia was good and supports their future use in an RCT.

The primary outcome, the DemQol, demonstrated an improvement in the mean score at 8 weeks and showed a very small decline post intervention. The findings were reflected in the qualitative data in which participants and carers described enjoying the intervention, followed by disappointment and sadness when it ended.

Currently, there is a lack of standardised specific instruments for measuring positive concepts in dementia [39] and reliable measures for capturing change in social support and social networks. However, consideration should be given to inclusion of such measures in a larger RCT. A potential measure which has demonstrated good validity would be the Lubben Social Network Scale (LSNS-6) which has been used with community dwelling older adults [40] and people with early stage dementia [41].

The type of respondent, including good orientation, attention and language skills, has been cited as more important than cognitive ability in self-complete dementia quality of life instruments [22, 42]. Reproducibility has been shown in studies with larger participant numbers [43]. What is important is the inclusion of participants in outcome completion, rather than relying on proxy completion, due to the subjective nature of these measures [44].

A recent diagnosis of dementia means at this stage people are coming to terms with the diagnosis. Researchers with experience of working with people with dementia must have the knowledge and skills required to ensure outcome measures are recorded as consistently as possible. This should include assessment of the reliability of participant responses [22]. Alternatively, good quality training is essential to develop these skills if inexperienced assessors are involved.

### Facilitator training and programme facilitation

The 1-day training programme and weekly supervision were found to be effective for occupational therapists with prior experience working with people with dementia, enabling them to feel sufficiently supported to deliver the intervention. Further training on dementia as a condition and provision of good quality supervision may be required for less qualified staff. In particular, supervision is likely to be required to manage the challenges of allowing participants with dementia to take control of the programme and make personal decisions about risk taking [10]. Interestingly, more important than professional qualifications were the personal characteristics of the facilitators and their delivery style which were found to be a motivator in participant attendance. Getting the right facilitators in place is therefore a key to successful delivery. Implications for a future study would be to identify staff with the necessary professional skills as well as personal skills to deliver the programme.

### Recruitment methods

Recruitment to this study raised a number of key issues. Firstly, although there was interest from people aged 64 years and under, the overall numbers in this category were too small to be feasible for a group intervention specifically for this age group. A group for people aged 65 and over was viable and accords with the greater prevalence in people aged 70 years and over as reported by Alzheimer's Research UK [45]. Age limits did not appear to be necessary and therefore any future trial would not set a defined age range for inclusion. Secondly, identification of potential participants was conducted solely through memory services, with no other strategies employed such as through mental health charities which could be considered for future research. However, alternative methods of recruitment would need consideration in order to capture individuals with early stage dementia. Thirdly, the information pack provided by clinicians to participants was found to be fit for purpose. However, in order to enhance recruitment, direct follow-up in the form of a telephone contact is required to help remind potential participants to read the information pack. Without this contact during recruitment, a number of participants may not have taken part. Fourthly, a balance is required to ensure carers do not feel excluded, but not allowing carers to become a focus of the intervention [10].

### Who might benefit from the programme?

Adults with early stage dementia were demonstrated to successfully engage in a person-centred self-management

group intervention. Journeying through Dementia appeared to meet the heterogeneity of needs of people with dementia by being tailored to their individual requirements as well as those of the overall group. This was evident during group meetings where content was selected by the group and discussions guided by what was identified as being important. Diversity amongst group members including age, lifestyle, background and understanding of dementia was considered a benefit and contributed to the enjoyment and learning experience of the programme. Capacity to participate in the intervention was considered to be influenced by memory. The benefits of taking part in the Journeying through Dementia intervention may therefore be affected by how well participants were able to engage with the recruitment and intervention materials.

Participant ability to engage in the intervention and contribution to the group did appear to be influenced by their dementia. What became clear was that the support from a third party, in this intervention the carer, was required to support participant continued engagement in learned activities outside of the group and potentially for continuation of the group. Therefore no amendments will be made to intervention design for a future study, but will continue to explore the level of engagement from carers and facilitators.

#### Optimum programme delivery

The manualised programme was implemented by the facilitators, and participants were able to select and explore topics of interest to the group. Individual sessions identified a range of valued activities with participants and pursued outcomes to enable re-engagement. Activities maintaining independence and hobbies were identified by this particular group including cooking, remembering appointments and reading. A number of participants also shared their ideas and successes from the individual sessions with the wider group in order to benefit everyone.

Although the length of the intervention was considered appropriate to impart skills to participants, it is essential that a dependency on the facilitators to lead the intervention does not develop. Group size should be no more than 12 to ensure facilitators have enough time and resources to support the group and deliver individual sessions during the intervention. However, too few and the sharing and learning experience of the intervention could suffer.

The original UK Lifestyle Matters intervention was 16 weeks in duration. Based on current NHS provision of group programmes for dementia patients, the intervention was reduced in-line with current service provision. The purpose was also to test whether the intervention could be successfully delivered in 12 weeks to people with early stage dementia, with an interim test at 8 weeks to explore whether the duration could be reduced even further.

It is anticipated that people with a recent diagnosis may need more support at the start of their treatment and therefore may go on to develop dependency on the facilitators and the intervention. The concept of 'excess disability' in dementia suggests that the level of perceived incapacity experienced by an individual, or dysfunctional treatment of that individual by others, can lead to greater actual impairment in his or her abilities [46]. Once a diagnosis has been confirmed, the relationship between the person with dementia and a caregiver can alter, leading to both character and attitude change [47]. As a self-management programme, the theory suggests that as participants develop greater confidence and self-efficacy, this will actually reduce dependency on the facilitators and the group and instead the group becomes another support mechanism along with family, the community and care providers [9]. As demonstrated in the results section, participants expressed enjoyment of the intervention and a wish for it to continue, which they facilitated themselves post intervention. This suggests that the intervention could be successfully delivered in 12 weeks with this particular group and that they harnessed their own and the group's resources to continue without dependency on facilitator support.

The qualitative evidence indicated that a number of benefits experienced by participants included increased self-confidence and self-efficacy post diagnosis [16]. Opportunities to go on outings, have thoughtful discussion, share ideas or concerns and develop new friendships were also identified by participants as positive outcomes of the programme. Supporting this assumption was group continuation after intervention cessation. The group met on at least two occasions post intervention at a local café. These meetings were facilitated by one member of the group. Although other programmes are available to participants via memory clinics and charitable organisations, the Journeying through Dementia intervention was thought to provide a novel option not currently available in the community. Participants felt the intervention was more about the person than about the condition and how they were still a functioning member of society and could retain life skills regardless of their dementia.

Participants and carers agreed that the carer attended sessions were informative and prevented feelings of exclusion. Engagement was also required if carers are to support the participant in further developing and sustaining skills after the programme ends. Facilitators indicated that although a person-centred programme, it was important to get carer buy-in which was provided by the carer sessions [10]. Participant and carer's trust in the

facilitators was found to be an essential factor in programme attendance and engagement.

### Content

Facilitators engaged with the manual and felt able to adapt suggested topics with the group to meet their needs. During this study, no new topics were identified by participants for the manualised programme. Further topics may be identified as part of a larger study with more participant input.

Facilitator, participant and carer's understanding of the purpose of the intervention is a key to its delivery. Terminology may need some revision, for example, an alternative to use of the term 'goal setting', to better engage participants. This could be managed on a group by group or individual basis.

Participants described the intervention as a fun and safe environment in which people with early stage dementia could meet, share and learn. The foundation of which supported learned activities post intervention and continuation of the group, who had already met and had further sessions arranged after intervention cessation.

## Conclusions

The purpose of this study was to ascertain the feasibility of conducting a larger RCT in the UK setting, and this was achieved. In addition, to further exploring the benefits of the intervention on a larger sample size, a future trial should also conduct a health economic evaluation to establish the cost-effectiveness of such an intervention and also include a measure to capture change in social support and networks.

#### Competing interests

Claire Craig and Gail Mountain are the original authors of the Journeying through Dementia programme.

#### Authors' contributions

The intervention was developed and the study conceived by GM and CC. Study design and protocol development were carried out by GM, KES, KJS, CC and MS with input from all other authors PB, DB and KH. KES managed the study and led the data collection and analysis along with KJS. Facilitator training was provided by CC. All authors reviewed and approved the final version of the manuscript.

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Publication 6 (Trial results): The Journeying through Dementia psychosocial intervention versus usual care study: a single-blind, parallel group, phase 3 trial

# The Journeying through Dementia psychosocial intervention versus usual care study: a single-blind, parallel group, phase 3 trial

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## Summary

**Background** There is an urgent clinical need for evidence-based psychosocial interventions for people with mild dementia. We aimed to determine the clinical benefits and cost-effectiveness of Journeying through Dementia (JtD), an intervention designed to promote wellbeing and independence in people with mild dementia.

**Methods** We did a single-blind, parallel group, individually randomised, phase 3 trial at 13 National Health Service sites across England. People with mild dementia (Mini-Mental State Examination score of ≥18) who lived in the community were eligible for inclusion. Patients were centrally randomly assigned (1:1) to receive the JtD intervention plus standard care (JtD group) or standard care only (standard care group). Randomisation was stratified by study site. The JtD intervention included 12 group and four one-to-one sessions, delivered in the community at each site. The primary endpoint was Dementia Related Quality of Life (DEMQOL) 8 months after randomisation, assessed according to the intention-to-treat principle. Only outcome assessors were masked to group assignment. A cost-effectiveness analysis reported cost per quality-adjusted life-year (QALY) from a UK NHS and social care perspective. The study is registered with ISRCTN, ISRCTN17993825.

**Findings** Between Nov 30, 2016, and Aug 31, 2018, 1183 patients were screened for inclusion, of whom 480 (41%) participants were randomly assigned: 241 (50%) to the JtD group and 239 (50%) to the standard care group. Intervention adherence was very good: 165 (68%) of 241 participants in the JtD group attended at least ten of the 16 sessions. Mean DEMQOL scores at 8 months were 93·3 (SD 13·0) for the JtD group and 91·9 (SD 14·6) for the control group. Difference in means was 0·9 (95% CI −1·2 to 3·0; p=0·38) after adjustment for covariates, lower than that identified as clinically meaningful. Incremental cost per QALY ranged from £88 000 to −£205 000, suggesting that JtD was not cost-effective. Unrelated serious adverse events were reported by 40 (17%) patients in the JtD group and 35 (15%) patients in the standard care group.

**Interpretation** In common with other studies, the JtD intervention was not proven effective. However, this complex trial successfully recruited and retained people with dementia without necessarily involving carers. Additionally, people with dementia were actively involved as participants and study advisers throughout. More research into methods of measuring small, meaningful changes in this population is needed. Questions remain regarding how services can match the complex, diverse, and individual needs of people with mild dementia, and how interventions to meet such needs can be delivered at scale.

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## Introduction

The Global Action Plan on Dementia[1] acknowledges the value of providing non-pharmacological (or psychosocial) interventions to people following diagnosis. These interventions are physical, cognitive, or social activities that maintain or improve functioning, interpersonal relationships, and wellbeing in people with dementia.[2] Therefore, non-pharmacological interventions encompass a range of interventions as identified and described in a comprehensive evidence review.[3] The importance of psychosocial interventions for those with mild dementia, including those recently diagnosed, is driven by the knowledge that a cure is unlikely in the near future and for people with dementia to be supported in order to live as well as possible with the condition.[3,4]

The 2015 national audit of UK memory services found that access to post-diagnostic services had increased but that the assistance people received was patchy and inconsistent.[5] At the time of the audit there were very few evidence-based psychosocial interventions for those with mild dementia and people were beginning to articulate their needs.

## Research in context

### Evidence before this study

People with dementia are being identified and diagnosed earlier and there are consequent demands from this patient group for meaningful, individualised, and non-pharmacological or psychosocial interventions from the point of diagnosis. This need is underscored by national and international policies. A scoping review of evidence of psychosocial interventions for people with mild-to-moderate dementia was done alongside this study. A systematic search strategy was done of national health service evidence (MEDLINE, PsycINFO, CINAHL, Web of Science, and Scopus) for relevant papers from Jan 1, 2000, to 2018 due to poor rates of diagnosis before 2000. The search terms used were (dement* OR Alzheimer*) AND (mild* OR early OR newly OR initial OR "home-based" OR "home based" OR "home-dwelling" OR "home dwelling") AND ("therap*" OR "counselling" OR "training" OR "intervention* "OR "education*" OR "rehabilitation" OR "reminiscence" OR "psycho*2) NOT ("severe "OR "long term" OR "long-term" OR institution* OR "nursing home*" OR "nursing-home*" OR "care home*" OR "care-home*" OR "hospital*") NOT ("drug*" OR "medic*" OR "pharmacologic*"). Additional search terms such as therapies (eg, "art therapy", "cognitive behavioural therapy", and "psychotherapy") and names of specific interventions were not used within this review due to resource limitations. Database searches were complemented by following up results from existing reviews and reference lists of key papers and relevant book chapters. Findings confirmed the need for stage-specific interventions, the value of a classification system for psychosocial interventions, and the need for pragmatic trials to test these interventions. However, when we commenced this study there were very few evidence-based psychosocial interventions for people following diagnosis—in particular for people without carer support. Involvement of patients with dementia in intervention design was scarce.

### Added value of this study

The Journeying through Dementia (JtD) randomised trial is one of the largest UK trials of a psychosocial intervention for people with mild dementia. The intervention was co-designed with people with mild dementia and informal carers and can be tailored to meet individual needs. Unlike most psychosocial interventions, people with dementia can take part without accompanying carers. We have shown it is possible to recruit and retain people with dementia as trial participants and to sustain their active involvement as study advisers; we had very good adherence. However, trial results found that the intervention did not improve quality of life at 8 months after randomisation and was unlikely to be cost-effective. One of the secondary outcomes, Diener's Flourishing Scale, did have a significant effect in favour of the intervention.

### Implications of all the available evidence

Other large-scale studies of psychosocial interventions for people with mild dementia have reported few clinical benefits and low cost-effectiveness. This study identified the need for reappraisal of methods. Our findings suggest that future randomised trials should use dementia-specific outcome measures of wellbeing and methods that can capture and record small, meaningful changes. We need to consider how to recruit people with dementia from diverse populations. Additionally, we require unobtrusive methods of assessing intervention fidelity. Finally, we must consider the service capacity required to deliver the psychosocial interventions and support that people with mild dementia say that they need.

Service gaps led to the co-creation of the Journeying through Dementia (JtD) intervention, which involved people with dementia informing us of what they considered would be helpful following diagnosis, including potential intervention topics and methods of intervention delivery.[6]

Social cognitive theory[7] underpinned the design of the JtD intervention, thereby including mechanisms to increase self-efficacy and effective problem-solving. It was postulated that these mechanisms would foster positive emotions, relationships, ability to self-manage, retention of functional skills, and wellbeing. The resulting intervention included a mix of facilitated group and one-to-one sessions over 12 weeks (maximum duration considered viable in a national health service [NHS] context). This was found to be acceptable to people with dementia and their carers.[6]

Over time services have become more aware of the needs of people after diagnosis, but the ability to respond to the complexity of needs that individuals can present with is restricted, in particular, how people can be enabled to adapt their lifestyles to living with dementia. The primary aim of the trial was to determine the clinical benefits and cost-effectiveness of the JtD intervention for people with mild dementia.

## Methods

### Study design and participants

We did a pragmatic single-blind, parallel group, individually randomised, phase 3 trial in 13 NHS Trust sites in England, recruited through the national Clinical Research Network.[8] There were two embedded studies: (1) a qualitative study explored the factors that mediated or moderated the effectiveness of the intervention from the perspectives of a sample of people who took part in or delivered the intervention,[9] and (2) an assessment of fidelity to the manualised training programme and to delivery of the intervention.[10] Facilitators were asked to complete itemised checklists of both group and individual sessions immediately following delivery to record the aspects of the intervention they considered to have been delivered. Attendance registers were also

maintained. Facilitator training sessions and group intervention sessions done in the meeting venue were recorded for fidelity assessment, but for methodological and ethical reasons it was not possible to record delivery of one-to-one sessions or groups held outside the meeting venue.

Eligible patients were in the mild stages of any type of dementia, with a Mini-Mental State Examination (MMSE) score of 18 or above, [11] lived in the community or sheltered accommodation, and were willing to engage in the 12-week intervention. Patients were not eligible if they had moderate or severe dementia (MMSE score <18), did not have dementia, did not have the capacity to consent according to assessment, lived in residential or nursing care, were not able to communicate in English, and were taking part in other pharmacological or psychosocial intervention studies. Informal carers (family or friends) could take part, but only if the person they cared for was recruited and agreed to their participation. Carers had to be older than 18 years, able to communicate in English, and able to give informed consent.

A variety of methods were used to maximise participant recruitment, including identification of potential participants via secondary care (appointments and letters), primary care (mailouts), the UK National Institute for Health Research Joint Dementia Research Database (advertising and searching), service user groups (dementia cafés or other groups), and general promotion (posters and leaflets). After agreeing to take part, individuals were asked to take part in screening to ensure that they met study eligibility criteria. Research staff visited each potential participant at home to complete the MMSE, determine capacity to consent, and ask other questions to determine eligibility. A formal assessment of capacity was not done during the initial home visit, but the researcher needed to be satisfied that the person was able to understand the nature and purpose of the study and the implications of taking part, including random assignment, the need for written consent and their right to withdraw at any point. All researchers were trained in how to make such judgements before the start of recruitment. All people with dementia and informal carers were required to provide written informed consent to take part.

A Data Monitoring and Ethics Committee, Trial Steering Committee, and Trial management group were all established at the outset and met regularly. The Trial Steering Committee included a person with dementia throughout. A patient and public advisory group of people with dementia and informal carers was consulted throughout. The study protocol is available online and was approved by UK Leeds East Research Ethics Committee, on July 1, 2016 (reference number 16/YH/0238). The study was reported according to the extended Consolidated Standards of Reporting Trials Statement.

### Randomisation and masking

Participants were randomly assigned (1:1) using a secure, centralised, internet-based interface to receive either the JtD intervention and standard of care (JtD group) or standard care only (standard care group). One of the trial statisticians (EL) generated the assignment sequence using computer-generated random numbers with a block size of four. Assignment was stratified according to site.

Rigorous methods were applied to limit contamination between groups. The risk of sites predicting allocation was minimal because randomisation was done by unmasked, centrally located members of the trial team who directly informed site-based facilitators and participants of allocation.

Outcome assessors—all of whom were researchers who received the same training in how to work optimally with people with dementia—were masked to intervention allocation. All instances of unmasking were recorded and, when practical, a new masked assessor did the subsequent assessments. However, this was not possible in all cases. The study statisticians (EL and SJW) and the health economist (TY) were masked throughout the trial. Contamination between groups was unlikely because similar interventions are rarely provided in the UK as part of usual care for people with mild dementia. Patients were unmasked to group assignment.

### Procedures

All recruited participants were assessed face to face in their homes at baseline before random assignment (intended to occur less than two months before intervention delivery) and again at 8 months and 12 months after randomisation.

The JtD group intervention is summarised using the template for intervention description and replication checklist in the appendix (pp 52–53). Consultations with five people with dementia and five carers, recruited through the voluntary sector, underpinned initial development of the JtD intervention.[12] The content of the draft intervention was subsequently explored with approximately 15 people with dementia and ten carers in a service context. The intervention was then refined with an additional ten people with dementia and seven carers during the feasibility study.[6]

See **Online** for appendix

The intervention was designed to promote independence and self-management in people with dementia. It supports individuals to recognise, build upon, and use existing skills, and develop new interests. The content was not designed for carers; the role of carers in the JtD intervention was to support the person with dementia with their involvement. However, carers were engaged alongside people with dementia as study advisers (K Sprange, University of Nottingham, personal communication). The JtD intervention comprised a menu of topics (appendix pp 52–53). However, groups can also identify their own topics to work on. Facilitators were trained to judge the extent of assistance groups

For the **study protocol** see https://bmjopen.bmj.com/content/9/9/e029207

required to identify topics to work on. Intervention delivery was composed of a mix of facilitated group and individual sessions, with individual sessions feeding into group sessions, and group sessions supporting individual sessions.

It was recommended that each intervention group should involve a maximum of 12 people with mild dementia who meet together on a weekly basis for 12 consecutive weeks. All participants commenced their involvement at week one. Each participant received four one-to-one sessions with one of the facilitators approximately every three weeks with the first one to one session being before commencement of the group sessions. As far as possible, the same facilitator should conduct all four one-to-one sessions with a participant. Group sessions were held in an accessible community venue and at least three sessions were held outside the meeting venue to promote putting learning into practice and mastery with support from others. Each group session was designed to have the same structure: first, welcome and sharing of aims; second, information giving (to set the context); third, group discussion of topics to build shared understanding, drawing upon participant strengths; fourth, a practical activity to provide an opportunity for active experimentation, particularly through out-of-venue activities; and finally, a summary of key messages and an opportunity to plan for the next session. Group discussion of each topic selected by the group was followed by facilitated exploration through in-venue practical sessions and didactic information if appropriate. Participants were encouraged to take what they had learnt into community settings and to work on their own challenges with both peer and facilitator support.

The nature and content of the one-to-one sessions were guided by the participant's expressed needs, interests, and aspirations. These sessions involved some discussion and enactment of activities in the home and the community, depending upon the participant's goals. Examples of goals taken forward during the feasibility study[6] included introducing methods to read recipes, maintain a diary, attend a community group, engage in physical activities, and prepare resources to take to a forthcoming group session.

Usual care was recorded at each site and could include pharmacological treatments, such as cholinesterase inhibitors and memantine and medication for other conditions (eg, depression); needs assessment; provision of educational material; and, in some instances, referral to various individual and group sessions and other health and social care services, such as community mental health teams. Usual care could also involve referral to third sector organisations, such as the Alzheimer's Society. Recorded usual care by site is provided in the appendix (p 14).

The per-protocol therapeutic threshold was defined as each participant randomly assigned to receive the intervention attending at least ten of the 16 sessions. Involvement of more sites and additional facilitators to meet the recruitment target necessitated different formats for delivery of facilitator training in the later stages of the trial, but content always followed the manualised format. Further details of support required for implementation of the intervention have been published previously.[13]

### Outcomes

The primary outcome was Dementia Related Quality of Life measure (DEMQOL),[14] at 8 months after randomisation. DEMQOL was assessed at baseline, 8 months, and 12 months after randomisation. DEMQOL was designed for self-completion by people with dementia and is a scale from 28 to 112, with higher scores representing higher health-related quality of life. The health economics evaluation was a cost–utility analysis that compared the intervention plus usual care with usual care over a year from the perspective of UK NHS and social care services.

Eight secondary outcome measures were used. We selected instruments to assess the benefits that we aimed to achieve through the JtD intervention. None were dementia-specific because of the absence of instruments to measure capacities, such as independence, resilience, and self-management. Several instruments used in this study had been applied in other studies of psychosocial interventions for people with dementia. The eight secondary outcomes were: (1) health and social care resource use assessed at 8 months to support the cost-effectiveness evaluation; (2) Generalised Self-Efficacy scale,[15] to measure the ability to feel self-efficient and manage day-to-day challenges, assessed at baseline and 8 months; (3) Diener's Flourishing Scale,[16] in which higher scores indicate greater self-efficacy and more psychological resources and strengths, assessed at baseline and 8 months; (4) Self-Management Assessment scale, a measure of perceived ability to self-manage, assessed at baseline and 8 months (appendix p 14); (5) Instrumental activities of daily living, which measures the ability to undertake complex activities of daily living, assessed at baseline, 8 months, and 12 months (appendix p 14); (6) EQ-5D-5L[17] a measure of self-reported health related quality of life based on 5 dimensions, which included a visual analogue scale rating overall health, applied at baseline, 8 months, and 12 months; (7) Patient Health Questionnaire (PHQ-9),[18] which measured severity of depressive symptoms at baseline and 8 months; (8) Generalised Anxiety Disorder-7,[19] which measured severity of symptoms of anxiety at baseline and 8 months.

Recruited informal carers completed the EQ-5D-5L, PHQ-9, and the Sense of Competence Questionnaire (SCQ)[20] for carers of people with dementia, at baseline and 8 months.

For the health economic analysis cost-effectiveness, results were expressed as costs per quality-adjusted

life-years (QALYs) over a 1-year timeframe. No discounting was applied. Intervention costs and costs for individual participants' use of routine health and social care services were estimated. Resource use cost sources are summarised in the appendix (pp 9–13). Costs are presented in the 2018–19 value of British sterling.

Utilities were estimated by applying van Hout and colleagues'[21] mapping algorithm to map EQ-5D-5L utility values to EQ-5D-3L values.[21] A total of 5000 bootstrap replicates were done to allow for uncertainty and bias-corrected bootstrap 95% confidence intervals were estimated. Sensitivity analysis was applied to alternative utility values and to allow for missing data (appendix p 13).

Serious adverse events (eg, resulting in death, threat to life, or requiring hospitalisation), were collected for participants with dementia throughout the study and communicated to the trial manager within 24 h of discovery. Local site investigators assessed whether serious adverse events appeared to be related to the intervention. The trial oversight committees reviewed serious adverse events at regular intervals. The trial sponsor (Sheffield Health and Social Care NHS Foundation Trust) and the NHS Research Ethics Committee were informed of any unexpected and related serious adverse events.

## Statistical analysis

The statistical analysis plan was created while the statistician was masked to treatment allocation. There were no major changes after trial commencement.

The sample size was calculated based on a 90% power of detecting a four-point difference (deemed to be clinically meaningful) in the DEMQOL 8 months after randomisation, with a two-sided α of 5%. The trial was individually randomised, but we inflated the sample size to allow for clustering by intervention group. This calculation assumes that the SD of the DEMQOL 8 months after randomisation was 11 and the intra-cluster correlation was 0·03 to account for the effects of group facilitation at site and an average cluster size of eight participants (equivalent to a design effect of 1·21), and that there would be 20% loss to follow-up. This led to a target sample size of 486 participants.

For analysis of the primary outcome, the DEMQOL total score at 8 months after randomisation was compared between the JtD and standard care groups using a mixed-effects linear regression model adjusted for baseline DEMQOL total score and stratification site (fixed effect), allowing for clustering of the outcome by intervention group (random effect). A partly clustered mixed-effects

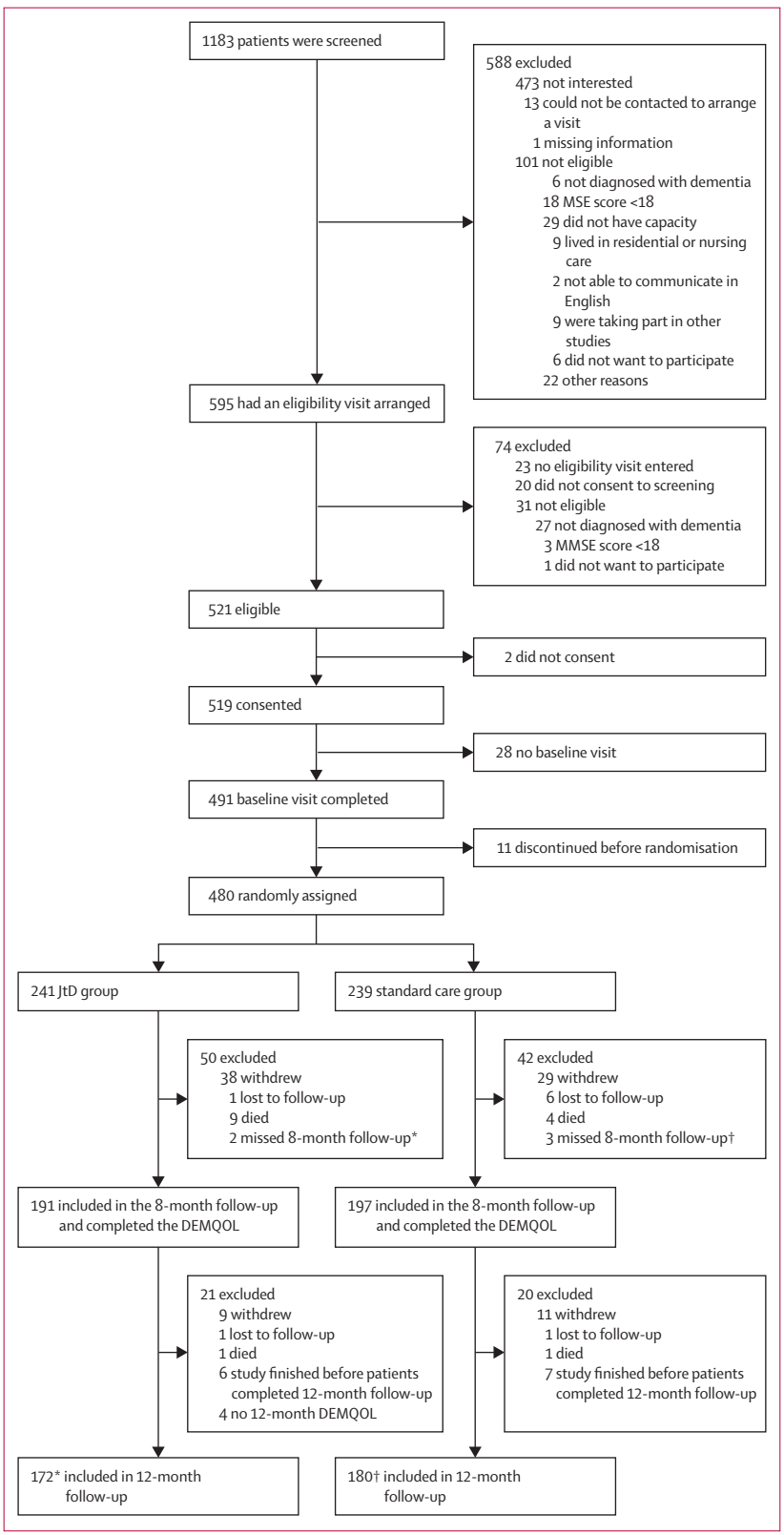


***Figure 1:*** **Flowchart of the Journeying through Dementia Trial.**
DEMQOL=Dementia Related Quality of Life. JtD=Journeying through Dementia. MMSE=Mini-Mental State Examination. *Two participants missed the 8-month follow-up, but completed 12-month DEMQOL follow-up. †Three participants missed the 8-month follow-up, but completed 12-month DEMQOL follow-up.

| | JtD group (n=241) | Standard care group (n=239) |
|---|---|---|
| Sex | | |
| Male | 136 (56%) | 143 (60%) |
| Female | 105 (44%) | 96 (40%) |
| Mean age (years) | 77 (7·0) | 77 (7·7) |
| Ethnicity | | |
| White | 238 (99%) | 232 (97%) |
| Non-White | 2 (1%) | 7 (3%) |
| Prefer not to say | 1 (<1%) | 0 |
| Lives with others | | |
| No | 62 (26%) | 63 (26%) |
| Yes | 178 (74%) | 176 (74%) |
| Lives with | | |
| Spouse or partner | 156 (65%) | 157 (66%) |
| Child or children | 15 (6%) | 6 (3%) |
| Both partner and children | 5 (2%) | 10 (4%) |
| Other | 2 (1%) | 3 (1%) |
| Accommodation type | | |
| Sheltered or retirement housing | 27 (11%) | 16 (7%) |
| Own home | 207 (86%) | 218 (91%) |
| Friend or relative's home | 7 (3%) | 3 (1%) |
| Other | 0 | 2 (1%) |
| Type of dementia diagnosed | | |
| Alzheimer's disease | 142 (59%) | 148 (62%) |
| Vascular dementia | 31 (13%) | 19 (8%) |
| Mixed Alzheimer's and vascular dementia | 51 (21%) | 58 (24%) |
| Dementia in Parkinsons disease | 3 (1%) | 3 (1%) |
| Frontotemporal dementia | 5 (2%) | 2 (1%) |
| Lewy body dementia | 1 (<1%) | 3 (1%) |
| Unspecified dementia | 7 (3%) | 5 (2%) |
| Other | 1 (<1%) | 1 (<1%) |
| Years since dementia diagnosis | 1·3 (1·5) | 1·3 (1·7) |
| MMSE (total score) | 24·5 (3·1) | 24·6 (3·2) |
| DEMQOL (total score) | 90·8 (13·0) | 90·3 (13·2) |
| PHQ-9 (total score) | 4·2 (4·4) | 4·0 (4·4) |
| GAD-7 (total score) | 2·8 (3·6) | 2·8 (3·5) |
| EQ-5D-5L (crosswalk value index) | 0·77 (0·21) | 0·78 (0·19) |
| EQ-5D VAS | 75·6 (16·7) | 73·8 (17·8) |
| GSE (total score) | 30·4 (5·5) | 30·9 (5·4) |
| Diener's Flourishing Scale | 45·3 (6·7) | 45·6 (7·2) |
| SMAS | 124·6 (20·7) | 125·6 (19·5) |
| IADL (total score) | 5·7 (1·8) | 5·8 (1·9) |

Data are n (%) or mean (SD). DEMQOL=Dementia Related Quality of Life. EQ-5D-5L= European Quality of Life – 5 Dimensions version. EQ-5D VAS=European Quality of Life – 5 visual analogue scale. GAD-7=Generalised Anxiety Disorder Scale. GSE=Generalised Self-Efficacy Scale. IADL= Instrumental Activities of Daily Living. JtD=Journeying through Dementia. MMSE=Mini-Mental State Examination. PHQ-9=9-question Patient Health Questionnaire. SMAS=Self-Management Assessment Scale.

***Table 1:*** **Characteristics of the participants at baseline including baseline measures**

linear regression model with homoscedastic errors was used to model clustering in the JtD group. Degrees of freedom were computed using the Satterthwaite approximation.[22]

Preplanned sensitivity analyses were done on the primary outcome and included imputation of missing data and Complier Average Causal Effect (CACE) modelling, and are displayed alongside the primary analysis results. CACE analysis used treatment allocation (instrumental) and covariates to predict treatment receipt (endogenous), before using this prediction in place of treatment in the primary analysis model.[23] We excluded participants with data collected more than 2 weeks before and more than 10 weeks after eight 8-month follow-up and those who attended less than ten of the 16 possible sessions. The CACE sensitivity analysis aimed to yield estimates of the effects of the JtD intervention for individuals who complied with treatment. Additional details regarding the statistical analysis are provided in the protocol.[8] The statistical analysis plan[24] is provided in the appendix (pp 15–51).

Secondary outcomes were analysed using a mixed-effects regression model, as done for the primary outcome. We did not correct for multiple comparisons in the evaluation of secondary or other outcomes. Thus, such results are exploratory and are reported as point estimates with 95% CIs. Analyses of outcome measures were done on an intention-to-treat (ITT) basis, defined as all participants who underwent randomisation and had valid outcomes. Two preplanned subgroup analyses based on type of dementia (Alzheimer's disease *vs* any vascular dementia *vs* other disease and presence of participating supporter) were undertaken. All statistical analyses were done with Stata (version 15) statistical software. The study is registered with ISRCTN, ISRCTN17993825

### Role of the funding source

The study funder reviewed and approved research protocols, but the funder took no part in the collection, analysis, or interpretation of the data; the writing of the report; or the decision to submit this paper for publication.

## Results

Between Nov 30, 2016, and Aug 31, 2018, 1183 patients were screened for inclusion, of whom 480 (41%) participants were randomly assigned: 241 (50%) to the JtD group and 239 (50%) to the standard care group (figure 1). At randomisation no site was imbalanced by more than two participants. Baseline characteristics are reported in table 1. 69 facilitators were recruited at the 13 study sites and were trained. 28 interventions were delivered during the study. Intervention adherence was good; 165 (68%) of 241 participants in the JtD group attended at least ten of the 16 available sessions (group and one-to-one), meeting the per-protocol therapeutic threshold.[8]

| | JtD group | | Standard care group | | Adjusted* | |
|---|---|---|---|---|---|---|
| | Patients (n=191) | Mean (SD) | Patients (n=197) | Mean (SD) | Mean difference (95% CI) | p value |
| **8 months** | | | | | | |
| DEMQOL score | 191 (100%) | 93·3 (13·0) | 197 (100%) | 91·9 (14·6) | 0·9 (–1·2 to 3·0) | 0·38 |
| PHQ-9 (total score) | 186 (97%) | 3·4 (4·2) | 193 (98%) | 3·6 (4·8) | –0·3 (–1·1 to 0·5) | 0·41 |
| GAD-7 (total score) | 185 (97%) | 2·4 (3·5) | 192 (97%) | 2·4 (3·8) | 0·1 (–0·5 to 0·7) | 0·76 |
| EQ-5D-5L (crosswalk value index) | 190 (99%) | 0·78 (0·21) | 195 (99%) | 0·78 (0·22) | 0·01 (–0·03 to 0·05) | 0·67 |
| EQ-5D VAS | 188 (98%) | 74·6 (18·3) | 193 (98%) | 72·1 (18·0) | 2·1 (–1·7 to 5·9) | 0·28 |
| GSE (total score) | 178 (93%) | 30·1 (5·5) | 185 (94%) | 29·5 (5·8) | 0·9 (–0·1 to 1·9) | 0·066 |
| Diener's Flourishing scale | 169 (88%) | 46·0 (6·3) | 177 (90%) | 45·1 (7·1) | 1·2 (0·1 to 2·3) | 0·028 |
| SMAS | 171 (90%) | 124·8 (20·2) | 176 (89%) | 123·7 (18·1) | 1·5 (–2·3 to 5·3) | 0·45 |
| IADL (total score) | 181 (95%) | 5·2 (1·8) | 190 (96%) | 5·2 (1·9) | 0·1 (–0·3 to 0·4) | 0·75 |
| **12 months** | | | | | | |
| DEMQOL (total score) | 172 (90%) | 92·3 (14·3) | 180 (91%) | 91·7 (13·9) | 0·4 (–1·6 to 2·5) | 0·69 |
| EQ-5D-5L (crosswalk value index) | 170 (89%) | 0·79 (0·22) | 178 (90%) | 0·78 (0·22) | 0·02 (–0·02 to 0·06) | 0·31 |
| EQ-5D VAS | 173 (91%) | 70·8 (19·1) | 177 (90%) | 70·9 (19·1) | –0·4 (–4·3 to 3·6) | 0·86 |

Mini-Mental State Examination was measured on a scale from 0 to 30; higher scores indicate better cognitive function; we used the cutoff scores of 21 to 26 for mild dementia to identify the trial population. DEMQOL is measured on a scale from 28 to 112; higher scores represent higher health-related quality of life. PHQ-9 is measured on a scale from 0 to 27; higher scores indicate more severe depressive symptoms. GAD-7 is measured on a scale from 0 to 21; higher scores represent increasing severity of anxiety. EQ-5D-5L score is measured on a scale from –0·224 to 1·00 (full health). EQ-5D VAS is measured on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state). GSE is measured on a scale from 10 to 40; higher scores indicate more self-efficacy. Diener's Flourishing scale is measured from 0 to 56; higher scores represent more psychological resources and strengths. SMAS is measured on a scale from 30 to 175; higher score indicates greater self-management ability. IADL is measured on a scale from 0 to 8; higher scores represent lower level of dependence. DEMQOL=Dementia Related Quality of Life. EQ-5D-5l=European Quality of Life – 5 Dimensions version. EQ-5D VAS=EuroQol-5 Dimension visual analogue scale. GAD-7=Generalised Anxiety Disorder Assessment. GSE=Generalised Self-Efficacy measure. IADL=Instrumental Activities of Daily Living. JtD=Journeying through Dementia. PHQ-9=9-question Patient Health Questionnaire. SMAS=Self-Management Assessment Scale. *Adjusted for baseline DEMQOL score, stratification site and JtD intervention group (random effect – partially clustered model)

***Table 2:*** **Primary and secondary outcomes**

Follow-up was between Oct 1, 2017, and May 31, 2019. Valid primary outcome data were obtained from 388 people with dementia (191 [79%] patients in the JtD group and 197 [82%] patients in the standard care group). ITT analysis found that the mean DEMQOL score at 8 months was 93·3 (SD 13·0) in the JtD group and 91·9 (SD 14·6) in the standard care group, with a difference in means of 0·9 (95% CI –1·2 to 3·0; p=0·38; table 2) after adjustment for covariates. The estimated mean difference was small and the 95% CI did not include the 4-point difference defined as being clinically meaningful. Figure 2 shows the results of sensitivity analyses on the 8-month DEMQOL score, which gave similar results to the primary analysis. At 12 months the mean DEMQOL score was 92·3 (SD 14·3) in the JtD group and 91·7 (SD 13·9) in the standard care group, with a difference in means of 0·4 (–1·6 to 2·5; p=0·69; table 2) after adjustment.

A modest difference was found in psychological wellbeing (Diener's Flourishing scale) in favour of the JtD intervention (1·2 [95% CI 0·1 to 2·3]; p=0·028; table 2). However, due to the large number of outcomes assessed, caution must be taken not to over-interpret one significant finding. Analysis of the other seven outcomes showed no evidence of differences between the groups. Analysis of outcome data also found some evidence of a difference in quality of life of carers who took part in the JtD group compared with the control group (mean difference in EQ-5D-5L crosswalk value index –0·06 [95% CI –0·09 to –0·02], p=0·0020; SCQ –1·4 [–4·3 to 1·5], p=0·34; PHQ-9 0·4 [–0·4 to 1·2], p=0·35) suggesting that the quality of life of carers in the intervention group was slightly lower than that of the control group carers at 8 months. Investigation of prespecified subgroups (participating carer [yes or no]; type of dementia [Alzheimer's disease, vascular dementia, or other]) found no reliable differences between subgroups in the primary outcome (appendix pp 5–6).

Health economics analyses showed that the observed difference in QALYs between the JtD group and the standard care group was small, non-significant, and favoured the standard care group (–0·003 [95% CI –0·044 to 0·038]; table 3). Resource use costs are summarised in the appendix (pp 9–13). The JtD intervention cost an average of £609 more per participant (95% CI 105 to 1179) compared to standard care (table 3). Overall, owing to the small effect size, JtD was more expensive and less effective than standard care, with an incremental cost per QALY of –£202 857 (95 CI –£534 733 to £483 739) suggesting that JtD might not be cost-effective. Sensitivity analyses are reported in the appendix (p 13) and showed that QALY differences remained small and in favour of the control group.

Unrelated serious adverse events were reported by 40 (17%) patients in the JtD group and 35 (15%) patients in the standard care group (appendix pp 6–7).

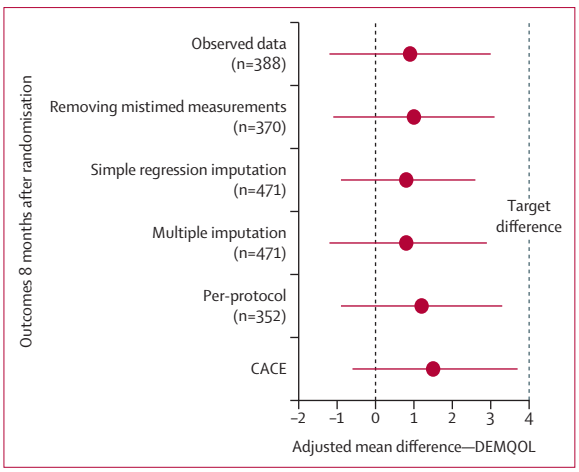


***Figure 2:*** **Forest plot of the mean difference in DEMQOL at 8 months after randomisation for the sensitivity analysis samples with the target difference of 4 points**

Error bars are 95% CI. DEMQOL is measured on a scale from 28 to 112; higher scores represent higher health-related quality of life. A positive mean difference implies the JtD group had the better health-related quality of life. Observed data were adjusted for baseline DEMQOL score, stratification by site and JtD intervention group. Removing of mistimed measurements removed outcome measures taken outside the window of 2 weeks before to 8 weeks after 8-month follow-up was due. Simple regression imputation used sex, age, presence of supporter, type of dementia, and baseline DEMQOL, PHQ-9 and GAD-7 scores as covariates. Multiple imputation used chained equations (regression) based on 100 imputed data sets, with age, sex, stratification by site, presence of supporter, type of dementia, duration of dementia, and baseline DEMQOL, GAD-7, and PHQ-9 score as covariates. The per-protocol population attended at least ten of the 16 possible sessions. CACE used two stage least squares regression with age, sex, presence of supporter, stratification by site, and baseline DEMQOL as covariates and standard errors that allow for intragroup correlation by JtD intervention groups. All other analyses used a mixed-effects regression model, with clustering in the standard care group only. CACE=Complier Average Causal Effect. DEMQOL=Dementia Related Quality of Life. GAD-7=Generalised Anxiety Disorder Scale. JtD=Journeying through Dementia. PHQ-9=9-Question Patient Health Questionnaire.

| | JtD group* (95% CI) | Standard care group (95% CI)† | Incremental costs and quality-adjusted life-years (95% CI) | Incremental cost-effectiveness ratio (95% CI) |
|---|---|---|---|---|
| Quality-Adjusted Life Years | 0·774 (0·744 to 0·802) | 0·777 (0·748 to 0·803) | −0·003 (−0·044 to 0·038) | .. |
| Overall costs (over 12 months) | £1676 (1367 to 2227) | £1067 (792 to 1484) | £609 (105 to 1179) | −£202 857 (−534 733 to 483 739) |

Incremental cost-effectiveness ratio is calculated as incremental costs divided by incremental quality-adjusted life years; a negative difference in incremental quality-adjusted life-years means that the standard care group had, on average, more quality-adjusted life-years; a positive difference in the incremental costs means that, on average, the intervention group incur more resources. 95% CIs are bias-corrected bootstrap intervals. JtD=Journeying through Dementia. *n=166. †n=173.

***Table 3:*** **Mean costs and quality-adjusted life years for main analysis and sensitivity analysis**

## Discussion

This study assessed the clinical benefits and cost-effectiveness of the JtD intervention, designed to promote wellbeing and independence in people with mild dementia, and co-designed with members of this population. The main study finding was that the intervention did not show a statistically significant or clinically important improvement in self-reported quality of life compared with standard care. There were indications of improved psychological wellbeing in those who received the intervention, but other secondary outcomes did not show any differences. This finding is echoed in other trials of psychosocial interventions for people with mild dementia published since 2018.[25–27]

Enabling people diagnosed with dementia to live as well as possible with the condition is a global policy imperative, particularly given the absence of a cure.[1,3] However, delivery of interventions to meet the complex needs of patients in the early stages of dementia is new territory for most services. Our fidelity assessment found good fidelity to delivery of the in-venue group aspect of the intervention,[10] but a limitation of the study was that it was not possible to record other essential elements of the intervention for fidelity assessment, namely, delivery of group sessions held in the community or one-to-one sessions. Therefore, questions remain regarding the capacity of services to deliver the range of psychosocial services and support that people with mild dementia identified as being important.

The paucity of existing measures to assess positive changes informed our use of DEMQOL as the primary outcome for this study. Although high, the mean baseline DEMQOL scores we obtained were similar to those obtained in similar studies,[25] and in the original study that developed the instrument.[28] Therefore, we deduce that DEMQOL might not be sufficiently sensitive to detect changes that might be attributed to interventions of this kind and that new approaches are required for measurement of psychosocial outcomes for those with mild dementia.[29] Additionally, most of the secondary outcome measures had not been validated in dementia populations due to an absence of available instruments to measure positive outcomes in people with dementia and might have been insensitive to differences or changes in outcomes over time or in health status. This might explain some of the small differences observed between the treatment groups. Use of the existing instruments, although unavoidable, was a limitation of the trial.

This study has underscored the need for a new focus on what people with dementia are still able to do—rather than deficits—and the need to identify ways of minimising requirement for recall when using measures. The embedded qualitative study[10] identified how participant outcomes were influenced by the dynamic relationships between a participant, their environment, and their resulting activity. It is important to consider how best to capture what people with dementia said was of importance to them during these interviews, such as community connectedness and continued engagement in meaningful activities. The qualitative study also highlighted the importance of subtle outcomes and effects, such as improved confidence through knowledge acquisition, feeling valued and empowered as a still functional member of society, and the benefits gained

from social contacts and friendships. The finding that the intervention was not cost-effective is set against a backdrop of uncertain cost-effectiveness for most, if not all, psychosocial interventions delivered through existing services.[26,30]

Our study has significant strengths. We recruited a seldom heard group in sufficient numbers to reach our target sample size, successfully retained study participants, and delivered a complex intervention across multiple sites. We also meaningfully involved people diagnosed with dementia and carers as research advisers throughout (K Sprange, University of Nottingham, personal communication). However, there were also several limitations. The speed of recruitment required for a trial of this nature can mitigate against targeting those most likely to benefit from the intervention (people with mild dementia with low levels of independence and wellbeing, but also with sufficient cognitive reserve to be able to take forward positive life changes). Facilitators also reported that some participants had a higher level of cognitive impairment than screening suggested.[10] Other factors which might have contributed to the trial outcomes were the limitations of the methods of the fidelity assessment and the absence of dementia-specific outcomes to record individual strengths, such as resilience, self-management, and independence.

The inherent challenges of responding to the complex and diverse range of needs that patients with mild dementia can present with are illustrated by our findings. Steps must now be taken to consider why the findings from this and other large-scale studies of psychosocial interventions for people with mild dementia are reporting similar results[26,27] and how the challenges might be addressed.

Future studies should consider using approaches that promote the inclusion of people with dementia in intervention design and delivery and that reflect the diversity that exists within this heterogenous group. Such approaches include forming productive relationships with people with dementia and their advocates and enhanced training for researchers. Policy changes are also required by funders to acknowledge the additional effort required to successfully do a trial with an underserved group, such as patients with dementia.

#### Contributors

GAM is the grant holder and wrote the initial version of the paper with assistance from CLC and JW. EL and SJW did the statistical analysis and verified the data. TY did the health economics analysis. CC, KB, KS, EM-C, TD, AL, ET, JB-D, BDT, BJT, and ELY reviewed the manuscript and assisted with data interpretation. All authors contributed to the design and conduct of the trial and to data acquisition. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

#### Declaration of interests

We declare no competing interests.

#### Data sharing

Requests for anonymised data can be submitted to the corresponding author. Relevant data might be released following consideration by Sheffield Clinical Trials Research Unit in conjunction with study investigators. Criteria for approval include that the researcher must have a valid research protocol and relevant ethics approval. Other documents including the study protocol and statistical analysis plan are available. Data requestors will be asked to sign a contract.

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# Assessing fidelity of a community based psychosocial intervention for people with mild dementia within a large randomised controlled trial

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## Abstract

**Background:** Understanding intervention delivery as intended, particularly in complex interventions, should be underpinned by good quality fidelity assessment. We present the findings from a fidelity assessment embedded as part of a trial of a complex community-based psychosocial intervention, Journeying through Dementia (JtD). The intervention was designed to equip individuals with the knowledge and skills to successfully self-manage, maintain independence, and live well with dementia and involves both group and individual sessions. The methodological challenges of developing a conceptual framework for fidelity assessment and creating and applying purposely designed measures derived from this framework are discussed to inform future studies.

**Methods:** A conceptual fidelity framework was created out of core components of the intervention (including the intervention manual and training for delivery), associated trial protocols and pre-defined fidelity standards and criteria against which intervention delivery and receipt could be measured. Fidelity data collection tools were designed and piloted for reliability and usability. Data collection in four selected sites (fidelity sites) was via non-participatory observations of the group aspect of the intervention, attendance registers and interventionist (facilitator and supervisor) self-report.

**Results:** Interventionists from all four fidelity sites attended intervention training. The majority of group participants at the four sites (71%) received the therapeutic dose of 10 out of 16 sessions. Weekly group meeting attendance (including at 'out of venue' sessions) was excellent at 80%. Additionally, all but one individual session was attended by the participants who completed the intervention. It proved feasible to create tools derived from the fidelity framework to assess in-venue group aspects of this complex intervention. Results of fidelity assessment of the observed groups were good with substantial inter-rater reliability between researchers KAPPA 0.68 95% CI (0.58–0.78). Self-report by interventionists concurred with researcher assessments.

(Continued on next page)

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**Conclusions:** There was good fidelity to training and delivery of the group aspect of the intervention at four sites. However, the methodological challenges of assessing all aspects of this complex intervention could not be overcome due to practicalities, assessment methods and ethical considerations. Questions remain regarding how we can assess fidelity in community-based complex interventions without impacting upon intervention or trial delivery.

**Trial registration:** ISRCTN17993825.

**Keywords:** Complex intervention, Self-management, Dementia, Fidelity assessment

## Background

Despite growing recognition of the value of psychosocial interventions to assist people to adapt and live well with dementia [1, 2] there is still a paucity of high quality research evidence for intervention effectiveness [3]. These psychosocial interventions are by their nature complex and therefore present evaluation challenges including the extent to which the intervention is delivered as intended. Factors to take into account include the impact of context upon intervention delivery [4] and whether the desired behaviour change is achieved [5]. Interest in intervention fidelity originated in response to treatment integrity concerns and demands for accountability in research. This was followed by a wider focus upon compliance (the extent to which those taking part in a trial follow the protocol) and increase in use of strategies such as intervention manualisation and training for systematic implementation and maintenance of fidelity [6, 7]. Reporting fidelity is now considered essential to determine the credibility, validity, and replicability of findings [8, 9]. As part of well-designed randomised controlled trials, fidelity studies can also help to establish intervention effectiveness and thereby support implementation into practice [10]. Embedded fidelity studies are therefore a feature of recent psychosocial dementia trials [11, 12]. Mixed-method trial designs are recommended to capture intervention effectiveness as well as fidelity of delivery [13, 14].

Intervention manualisation as well as intervention specific training and supervision can improve compliance and outcomes [15], thereby enhancing fidelity [6, 16]. Researchers are also encouraged to adopt outcome measures that offer validity [7, 17] and that can be measured consistently through rigorous processes such as randomised controlled trials to evidence effectiveness. However, the nature of complex tailored interventions could be considered in opposition to the idea of measuring consistent delivery [18]. For example, complex interventions often rely upon the judgements of those delivering the intervention to make any necessary adaptations. Therefore, fidelity assessment seeks to understand to what extent adaptations can be made without the intervention becoming different from what was intended [19]. Creation and application of appropriate measures to assess adaptation can improve our understanding of how different intervention components impact upon delivery and receipt of the intervention in context [20]. However, the uniqueness of complex interventions usually demands the creation of purposely designed measures for fidelity assessment, which lack demonstrable psychometric properties. Consequently bespoke fidelity measures and evaluation criteria (behaviours and activities observed) need to be formulated and located in the theoretical underpinnings, as well as in the aims and core content of the specific intervention [4].

This paper reports the results of an embedded fidelity assessment within a large randomised controlled trial to explore delivery of a psychosocial intervention, Journeying through Dementia [21]. The primary aim of the fidelity assessment was to evaluate how well the Journeying through Dementia intervention was delivered according to the trial protocol and intervention manual applying pre-defined fidelity standards. To achieve this, it was necessary to create appropriate fidelity documents and materials. This multicomponent community-based intervention was co-designed by people living with dementia [22]. It includes mechanisms to increase independence, self-efficacy and effective problem solving in people living with early-stage dementia, thereby enabling individuals to live as well as possible with the condition. This paper provides a working example of how fidelity assessment using a range of methods can be successfully implemented using purposely designed measures within the context of a trial of a complex psychosocial intervention, Journeying through Dementia, to inform future studies.

## Methods

### Trial design

We conducted a pragmatic, two-arm parallel group, randomised controlled trial of the Journeying through Dementia intervention alongside usual care or usual care alone which included an embedded fidelity assessment and qualitative sub-study [21]. Patients were randomised using a secure, centralized, internet-based interface. The assignment sequence was computer-generated with block size of 4 in a 1:1 ratio and stratification according to trial site. The primary outcome for the effectiveness study was quality of life, measured by the Dementia

Related Quality of Life (DEMQOL) at 8 months post-randomisation. A range of secondary outcomes measured other key components of the intervention. These were health and social care resource use; self-efficacy; well-being; self-management; activities of daily living and quality of life. A total of 480 participants with mild dementia (score of > 18 on MMSE) were recruited and randomised of which 241 were randomised to receive the intervention. The Trial was registered ISRC TN17993825, Date registered 11 Oct 2016.

## Sample

A convenience sample of four out of the 13 recruiting sites participating in the trial were approached and consented to take part in the fidelity assessment. Site selection for fidelity sites was pragmatic with criteria being that sites were actively recruiting and delivering the intervention. Geographical location and population size were also considered to ensure that selected sites were representative of those that took part in the trial. Unless otherwise stated data reported was collected during a 12-week programme at each of the four participating sites.

## Intervention

The Journeying through Dementia intervention, underpinned by social cognitive theory [23], is a manualised self-management multi-component intervention designed in consultation with people with dementia [22, 24]. It consists of 12 consecutive facilitated weekly group meetings held in a regular venue (in-venue) and four individual sessions with a facilitator to focus on personal goals. A minimum of three of the 12 group meetings are activities held in the community outside the regular venue (out of venue) to consolidate learning and practice neglected skills with support from others. Participation is designed to promote independence and self-management and support meaningful occupation including social interaction. Although manualised, the intervention enables tailoring of activities according to the needs of individuals and the group. This is achieved through a layered approach to learning and behaviour change within each of the different components (in-venue group meetings, individual sessions and out of venue activities). The intervention aims to elicit behaviour change through supporting greater self-efficacy, increased self-management and effective problem solving [25].

Mitchie's theory of behaviour change informed the intervention design and delivery [26]. Within this theoretical framework, the anticipated change was improved self-management and engagement in meaningful activity. The theory emphasizes the importance of capability addressed by imparting knowledge and training. Motivation is addressed by increasing understanding through experiential learning which leads to behaviour change being associated with positive feelings. Opportunity for change is addressed by enabling participants to experience change within the groups as well as in the community.

Prior to the trial starting it was agreed a therapeutic dose would constitute 10 sessions attended out of the potential 16 (group and individual sessions). This was a pragmatic decision taken by the trial team with clinical advice which took account of experience of delivering similar interventions.

### *Training*

An important aspect of fidelity is to reduce variability between interventionists. Inadequate or limited training can be factors in poor fidelity [7, 8]. Therefore, to maximize intervention delivery as intended a two-day training package was prepared for the purposes of the trial. It was delivered by the manual author, a highly experienced trainer with support from a second tutor with experience working with people with dementia. A standardised approach to training promoted consistent future delivery by interventionists. Following recommendations and learning from other studies [24, 27], training included experiential work to practice and model the intervention. The two-day training was intended to be delivered as close as possible to the beginning of intervention delivery for those who attended.

### *Supervision*

Once intervention delivery commenced, all facilitators received weekly supervision from an experienced clinical professional from within their organisation but whom did not have experience of the intervention. This was not ideal as 'real world' delivery supervisors would have direct experience of delivering the intervention. To account for this, members of the trial team, experienced in delivering and supervising psychosocial interventions within trials provided supervision to site based supervisors via monthly face-to-face or phone meetings [28]. Those in the site supervisor role were encouraged to attend day one of the two-day training alongside facilitators from their site. This was to ensure that all interventionists received the same information about the intervention, and to build relationships and support shared learning. In addition, all supervisors attended a separate half-day training session led by the trial team to discuss their role and raise any concerns. A supervision protocol (see supplementary document 1) was provided to all sites for the purposes of the study and to support intervention fidelity.

## Aims and objectives of the fidelity assessment

The aim of the fidelity assessment was to evaluate how well the Journeying through Dementia intervention was delivered according to the trial protocol and intervention manual, applying pre-defined fidelity standards and

criteria against which to measure these standards. The conceptual framework for this assessment is presented in Table 1. This framework was purposely designed using quality assurance parameters for provider training, delivery, receipt, and enactment based on criteria identified by the Behaviour Change Consortium [8] and NICE guidance on behaviour change [29].

### Data collection methods

The design of the fidelity framework (see Table 1) and the accompanying data collection instruments were adapted from the experiences of a previous trial of a complex psychosocial intervention conducted by the authors [27]. Throughout, the value of obtaining self-report and multiple perspectives, including the views of those both delivering and receiving the intervention training was prioritised. Consequently, in addition to the researcher observations, we obtained the perspectives of interventionists. Data collection completed by the interventionists also acted as a training tool to reinforce intervention delivery as intended and reduce facilitator drift [8]. However, to encourage completion rates as well as reduce the burden upon interventionists, acceptability and usability were prioritised when designing these data collection tools [17].

Study participants were not asked for their views as part of the fidelity assessment. This was because it was considered too burdensome to ask individuals to engage in activities beyond those already being requested of them, which included completing a number of questionnaires at multiple time points for all and additional qualitative interviews for some.

**Table 1** Fidelity conceptual assessment strategy for Journeying through Dementia

| Parameter | Standard | Fidelity criteria | Measure of criteria/assessment tool |
|---|---|---|---|
| **Facilitator training** | Standardised training | All facilitators and supervisors receive the same training delivered in a similar way. | • Two-day training delivered by the same trainer(s)<br>• Attendance registers for Two-day training<br>• Researcher Two-day training checklist<br>• Trainee Two-day training checklist |
| | Facilitator skill acquisition | All facilitators understand and engage with the intervention training in a similar way. | • Completion of training exercises by facilitators<br>• Researcher training checklist<br>• Trainee training checklist |
| **Intervention delivery** | Standardised delivery | All facilitators using the same intervention content:<br>• The manual<br>• Individual sessions<br>• Goal setting<br>• Out of venue activities | • Use of manualised intervention (Observations)<br>• Facilitator – Group meeting checklist<br>• Facilitator – Individual session checklist<br>• Researcher - Group meeting checklist |
| | Minimise drift in skills/ delivery | Compliance to training content and delivery within and across sites over time. | • Researcher - Group meeting checklist<br>• Record of provision of supervision<br>• Supervision checklist (Supervisors and Facilitators)<br>• Research supervision record |
| **Receipt of intervention** | Participant attendance and engagement | Numbers of participants attending the intervention.<br>All participants taking part in the group meetings and activities. | • Attendance at group in-venue sessions (Register)<br>• Attendance at Individual sessions (Register)<br>• Use of manualised intervention (Observations) |
| | Comparable treatment | All participants receive the same intervention tailored to the needs of the group/ setting. | • Attendance at group in-venue sessions (Register)<br>• Attendance at Individual sessions (Register)<br>• Facilitator – Group meeting checklist<br>• Facilitator – Individual session checklist<br>• Researcher - Group meeting checklist |

Adapted from Bellg et al. (2004) [8]

A range of assessment methods were used to reflect both researcher and interventionists' perspectives of intervention delivery [8]. Data were collected at multiple time points [30, 31] to enable findings to be compared for similarity or differences over time. Methods used included researcher completion of itemised checklists of non-participatory (unobtrusive) observations [32] of training and of a purposive sample of in-venue group meetings.

Observation is an established research method, enabling understanding of complex relationships and lived reality through observable phenomena and behaviour in context [33]. For this fidelity assessment observations were conducted to enable the researcher to have the same experience as participants whilst remaining detached from the group. Maintaining detachment during an observation can be challenging when present in the same space as participants. A level of engagement is sometimes inevitable for example when making introductions and explaining observer presence or putting participants at ease. In-person observations were selected over video recorded observations in response to learning from previous studies where the technology was found to be challenging for those involved [12].

Researchers also kept comprehensive observation field notes to support and evidence scoring decisions. Attendance registers for both group and individual sessions were analysed as an objective measure of engagement with the intervention [7] and interventionists self-report itemised checklists for the two-day training, in-venue group meetings, individual sessions and supervision were completed by interventionists at the fidelity sites to cross-validate with researcher observations.

All methods were performed in accordance with the relevant guidelines and regulations [34, 35].

### Data collection tools

Assessment tools were developed by the fidelity lead and members of the Trial Management Group (TMG) including the authors of the manualised intervention. Materials used during facilitator training, the manualised intervention and associated resources, and trial protocols all informed the content of these tools. They were all designed to interrogate:

- evidence of learning and skills acquisition
- receipt and enactment of core skills
- anticipated observed behaviours e.g. role-play (for training fidelity) and contributions to the group (for group intervention fidelity).

Since these were purposely designed tools to measure fidelity of the Journeying through Dementia intervention, they were deemed to be sufficiently sensitive to the complexity of the components and contextual variables specific to this intervention [4]. Two researchers, one who managed the feasibility study, scored pre-defined criteria using itemised checklists to rate the core components of the training or intervention [19]. The draft assessment tools were piloted and refined using observations of the first training session and the first group in-venue session at two of the fidelity sites. This process was conducted to identify items that could not be reliably scored by the researchers, improve consistency of scoring and make revisions before further application [36].

Details of the tools are listed below and copies of the final checklists and registers are provided as supplementary document 2.

**Training observation checklists** To evaluate interventionist training, observation checklists were completed concurrently by two researchers during delivery. A simplified version of the checklist was also completed by the interventionists immediately following training to record what they understood that they had received during the two successive days. Out of a total of six two-day training sessions offered to the interventionists from the four sites, the first three were observed and scored using an itemised checklist by the fidelity lead (KS) and a second researcher (SM or JBD).

**Supervision registers and checklists** Data reported for fidelity to the supervision protocol here are those completed for two intervention programs at three of the four fidelity sites and three at the fourth. Completion was dependent on how many groups each site delivered. All supervisors were asked to complete a register to record facilitator attendance and the format of every session they conducted (expected to be weekly throughout the entire intervention delivery period). Both facilitators and supervisors completed an itemised fidelity checklist derived from the supervision protocol to detail their views of delivery/receipt of supervision. This was requested at the end of the first, fifth and twelfth weeks of supervision for all interventions delivered.

**Attendance registers – group meetings and individual sessions** Attendance registers maintained by the facilitators during delivery of all group (including out of venue sessions) and individual sessions recorded compliance with attendance including the offer and acceptance or alternatively decline of sessions by participants.

**In-venue group meeting observation checklists** To assess fidelity of the in-venue group meetings, the observation checklists were completed by the researchers during

delivery of two sessions at each site. Comprehensive notes were also taken to evidence researcher scoring decisions. A simplified version of the checklist was also completed by the facilitators immediately after the group finished. Observations of eight in-venue meetings (one group per site, two meetings per group at approximately week three and week eight of delivery) were conducted in total. Observing two meetings per group also enabled us to examine any learning effects and identify potential facilitator drift as intervention delivery progressed [37].

**Individual session checklist** Direct observations or recording of individual sessions were considered too intrusive, particularly as these sessions were required to be in the participant's home or local community [12]. Facilitators were asked to complete a summary fidelity checklist evaluating their experience of delivering these sessions as intended. It was requested that these be completed immediately after each session.

**Out of venue activities** Out of venue activities were not observed or recorded as there were significant ethical and practical considerations; for example, when interacting in the community with people who were not part of the group or the trial.

## Methods of data analysis

### Time between training and delivery

Time lapse between the dates training was received and when intervention delivery commenced were recorded by the research team. Dates were then extracted from the trial database.

### Completion rates

Checklist and register completion rates were analysed to identify adherence to intervention as intended.

### Descriptive analysis of observational data

Frequency scores from the observation checklists for training and in-venue group sessions were compared to identify researcher rates of agreement for criteria achievement. Where there was disagreement, free text notes taken during observations were referred to reach agreement on the criterion score. The categories for scoring were '0' never observed, '1' sometimes observed and '2' observed most of the time. Several criteria within the checklists were rated on a binary 'Yes' or 'No' scale for presence or absence in this instance for the purpose of analysis if a criterion was rated 'Yes' this was converted to '2' and 'No' converted to '0'. All interventionist completed checklists were rated binary 'Yes' or 'No' for ease of completion. Fidelity scores were calculated based on percentage agreement on the final score (after moderation) obtained by each researcher as follows:

- 0–60% Unsatisfactory
- 61–70% Satisfactory
- 71–80% Good
- 81–90% Very good
- 91–100% Excellent

The percentage fidelity score obtained by the researchers on the observation checklists was then compared to that of the interventionists on the associated self-report checklist to look for convergence or divergence.

### Inter-rater reliability

Inter-rater reliability assessed the extent to which the two researchers attributed the same score to the same checklist item during session observations only. A weighted kappa using a predefined table of weights was applied to provide estimates of the degree of agreement between the two researchers. As per Cohens Kappa [38] values for inter-rater agreement are as follows:

- ≤ 0 indicating no agreement
- 0.01–0.20 none to slight
- 0.21–0.40 fair
- 0.41–0.60 moderate
- 0.61–0.80 as substantial
- 0.81–1.00 almost perfect agreement

## Results

### Training fidelity

#### *Interventionist training*

The first three out of six two-day training sessions were observed. These sessions were attended by a range of sites taking part in the trial in addition to the four fidelity sites as shown in Table 2.

Overall fidelity to the training was excellent in all observed three training sessions as scored by the researchers averaging 95% achievement (range 91–97), see Table 3. Facilitator and supervisor (trainee) scores averaged 94% achievement (range 88–97).

As Table 3 illustrates, the lowest fidelity score was obtained for the second of the three observed two-day training (23rd–24th Jan 2017). This could be explained by the necessary delivery modifications to accommodate the numbers attending, which had exceeded what was planned (see Table 2). These modifications included reducing the time spent on a topic/activity or excluding it altogether as well as limiting opportunities for practical activities/exploration. There was agreement between the researchers and trainees on the top three items that were not delivered during this modified session which were:

**Table 2** Two day training delivery and attendance

| Training session | Date of training | Fidelity site(s) attended | Date of first group meeting | Trainers | Overall numbers of attendees by role | | | Research observers |
|---|---|---|---|---|---|---|---|---|
| | | | | | Facilitators | Supervisors | Total per day | |
| 1 | 17 Jan 17 | Site 4 | 06 Apr 17 | CC/SB | 10 | 1 | 11 | KS/SM |
| | 19 Jan 17 | | | CC/SB | 10 | 1 | 11 | KS/SM |
| 2 | 23 Jan 17 | Site 1 | 24 May 17 | CC/SB | 21 | 6 | 27 | KS/SM |
| | 24 Jan 17[a] | Site 2<br>Site 3 | 24 Apr 17<br>06 Jun 17 | CC/SB | 21 | 1 | 22 | KS/SM |
| 3 | 22 Aug 17 | None | | CC/GM[b] | 7 | 1 | 8 | KS/JBD[c] |
| | 23 Aug 17 | | | CC | 7 | 1 | 8 | KS/JBD |

[a] Day 2 focusses on planning and delivering a session, due to large numbers of attendees and available time, the supervisors and research assistants were asked not to attend Day 2 on this session
[b] Due to the timing of this session and availability of the trainers a third trainer was recruited
[c] Due to staff changes a third researcher undertook scoring

- Item 7 'Did the trainer discuss the supporter attended sessions and relationship dynamics' (8 out of 18 trainees)
- Item 11 'Were you able to reflect on and share your own facilitation style and skills' (8 out of 18 trainees).
- Item 17 'Did you discuss the value and principles of supervision' (12 out of 18 trainees). This rating related predominantly to the second training session and was one of the topics affected by the modifications made to day-two of the training.

#### *Implementation of training*

Analysis of trial records found that on average, the time from training to delivery of a first intervention group at the four sites was 106 days (range 79–134).

### Supervision fidelity

At the fidelity sites, there were no changes to facilitators and supervisors during the assessment period. Supervision registers were completed and returned by 11 facilitators and five supervisors (one site had two supervisors who shared supervision responsibilities). Out of the 111 opportunities for supervision identified and recorded by the four sites 105 were recorded as having been completed. Five supervision sessions were not achieved due to annual or sick leave and one was cancelled by the supervisor. On three occasions, once at each of three sites, supervisors held an additional supervision session prior to commencement of a new intervention programme. Supervision with more than one facilitator, referred to as joint supervision in the supervision protocol, was held on 59 occasions and individual supervision on 42. Four sessions were recorded as being delivered as a combination a joint and individual session within the allocated time. Delivery format included 97 face-to-face sessions and eight using remote methods (telephone or Skype). The average time was 61 min (range 30–125 min) for joint supervision and 51 min (range 25–70 min) for individual supervision. Only one out of the four fidelity sites met the requirements for provision of a minimum of four individual supervision sessions as identified in the protocol. A further two sites did achieve stated requirements during delivery of their second intervention programme after receiving feedback and encouragement from the clinical experts on the trial team.

Supervisors rated their fidelity to the supervision protocol as being very good on all three observation checklists; averaging 82% achievement (range 77–86) (see Table 4). Supervisors recorded that they had delivered most components of supervision during each session. The component that was most frequently not fulfilled was 'Did you use a reflective diary as part of the supervision session?' which was optional for facilitators to complete.

**Table 3** Coder training overall fidelity score agreement

| Training session | Coder 1 | Coder 2 | Agreed score |
|---|---|---|---|
| 17-19th January 2017 | 75/78 | 76/78 | 75/78 (96) |
| 23-24th January 2017 | 70/78 | 71/78 | 71/78 (91) |
| 22-23rd August 2017 | 76/78 | 76/78 | 76/78 (97) |

**Table 4** Supervisor completed fidelity scores for individual sessions

| Week | Item completion rate/max score (%) | Agreement on completed scores (%) |
|---|---|---|
| **1** | 81/90 (90) | 70/81 (86) |
| **6** | 80/90 (89) | 67/80 (84) |
| **12** | 73/80 (91) | 56/73 (77) |

### Intervention fidelity

#### *Attendance registers*

Participant attendance was good with 25 out of 35 (71%) participants receiving the therapeutic dose of 10 out of 16 sessions (12 weekly meetings and four individual sessions). Five (14%) attended all 16 sessions.

Group session attendance was good. Of the total 331 available sessions to participants 264 (80%) were attended.

All 35 participants took part in the first individual session. Of those 35, eight participants then withdrew from the intervention between the first and second individual session and one before the third individual session. Of the remaining 26 participants, 25 took part in all four sessions.

#### *Group meeting checklist fidelity*

Observed fidelity to the group aspect of intervention was very good with researchers reaching between 88 and 95% agreement on observed items delivered (see Table 5). For all eight observed sessions Cohens kappa score of 0.68 demonstrated substantial inter-rater reliability 95% CI (0.58–0.78) between the two researchers.

The in-venue group meeting checklists for facilitators were all completed as requested (100%). The recorded ratings reflected those of the observing researchers with fidelity across all eight groups averaging 93% (84–100).

#### *Individual session checklist fidelity*

Individual session checklists for a total of 20 participants (out of a possible 35) were completed by the facilitators as part of intervention delivery. Seven of the 20 participants had incomplete records that could not be accounted for by intervention withdrawal. An average of 77% achievement (range 22–100) was found for items delivered during each session. The two lowest scored items for delivery were item 5 with 40% achievement 'Did you help the participant set any goals' and item 8 with only 22% achievement 'Did you enable the participant to rehearse skills learned in their everyday life'.

## Discussion

The aim of this embedded fidelity assessment was to determine how well the Journeying through Dementia intervention was delivered according to the trial protocol and intervention manual. A second aim was to further examine what methodologies can be practically, ethically and reliably employed for assessment of fidelity during pragmatic trials of complex interventions.

The assessment tools (checklists and registers) derived from the fidelity framework were found to be fit for purpose suggested by good completion rates and inter-rater reliability, and we were able to demonstrate compliance with the intervention and fidelity to delivery of the in-venue group component of the intervention. The caveat here was that we were not able to observe all core components of the intervention due to the inability to be able to capture the delivery of out of venue and individual sessions. Interwoven with this were ethical considerations such as participant rights to confidentiality and the intrusive and impractical nature of observation of these sessions [12]. Indeed, the findings from the qualitative sub study [39] indicated that the components that we were not able to assess were the more challenging aspects for facilitators to deliver and where participant behaviour change was critical for success. Examples included enabling participants to practice learning in the community with the support of others and being assisted to identify and work towards individual goals. The most appropriate methods for monitoring fidelity in psychosocial community-based complex interventions are therefore yet to be identified.

### Methodological challenges

Understanding social constructs and interpreting observed behaviours are influenced by the subjective interpretations of researchers [40]. The inherent challenges of measuring the subjective nature of observed outcomes of complex interventions such as those being promoted through Journeying through Dementia as well as the observation method itself means by design, any bespoke instruments will lack psychometric properties. Researchers have little choice but to use bespoke assessment tools to evaluate behavioural complex interventions and such tools need to be designed underpinned by intervention theory and content [4].

Certain behaviours and criteria detailed on the observation measure were more concrete to understand and therefore observe and score. One example was concerned with the practicalities of delivery, and whether

**Table 5** Fidelity and Kappa scores by sites

| | Researcher 1 score[a] | Researcher 2 score[a] | Agreed Researcher score | % | Kappa score | *P* value | CI |
|---|---|---|---|---|---|---|---|
| Site 1 | 127 | 124 | 127/144 | 88 | 0.77 | p = < 0.05 | 0.43–0.84 |
| Site 2 | 137 | 136 | 137/144 | 95 | 0.64 | p = < 0.05 | 0.39–0.78 |
| Site 3 | 123 | 122 | 123/144 | 85 | 0.66 | p = < 0.05 | 0.45–0.86 |
| Site 4 | 128 | 132 | 130/144 | 90 | 0.59 | p = < 0.05 | 0.57–0.96 |

[a]The score is a combined total per researcher for the two in-venue group meetings observed by site

two facilitators were present as required by the protocol. In comparison, other criteria were more subjective such as relying on the researcher observing and recognising specific behaviours, for example evidence of facilitators enabling participants. This required the researchers who were scoring to fully understand how behaviours manifest, and use their judgement when interpreting what they observed [41]. A significant amount of prior work was therefore needed by those who were going to undertake the observations to agree how to identify and rate the criteria on the observation checklist [42]. Piloting was essential and it quickly established that several criteria were unlikely to be observed during the in-venue group aspect of the intervention over a limited number of sessions, for example practicing learning in the community. It is essential that those who are to observe and score intervention fidelity are involved in identifying how criteria might manifest and how to score criteria. Therefore the recommendation is for observers to take comprehensive notes in addition to scoring the checklist to use as evidence to explain scoring decisions.

Evaluation of this intervention required a comprehensive and detailed understanding of the manualised programme and training package. The primary trainer was the author of the manual and some members of the research team including the Chief Investigator and Fidelity Lead had gained extensive experience of the manual during its use in the prior feasibility study [24]. This knowledge and experience aided the development of the conceptual framework for fidelity assessment and creation of assessment instruments. One of the observing researchers had detailed knowledge of the intervention from working on the feasibility study. Whether someone who is not fully immersed, or supported by an experienced person, in this intervention can understand and therefore score the nuances is debatable and we therefore posit that inclusion of researchers with experience of the intervention for fidelity assessment of complex interventions is preferable.

The tools and measures used for this fidelity assessment were based in the underpinning methodology and ethos of the intervention, yet the question of robustness remains [43, 44]. To increase credibility we incorporated data from multiple sources including from the researchers and from the perspective of interventionists via self-report [30, 31]. However, the influence of observer presence and interactions as well as the inclusion of the interventionists' self-report may have resulted in the Hawthorne effect and therefore reporting bias, with individuals potentially trying harder to achieve optimum scores on the fidelity checklists. As observers only attended two meetings at each site the fidelity researchers' presence was evident to both the facilitators and participants and had to be explained. However, our findings suggest that the similarity in scores obtained from the researchers and interventionists indicated that potential for bias was limited. In addition conducting observations over time [33] and use of multiple perspectives helped reduce these potential bias [10]. We are however unable to comment on how comparable the remaining eight sites were in their intervention delivery to the four fidelity sites.

The research developed and piloted bespoke itemised checklists for observations including agreement of scoring guidelines. Facilitators however, although given simplified versions of the checklist with binary scoring (Yes/No) for usability, were not asked to score observations but to indicate whether they recalled a specified item being completed or achieved. Therefore, inconsistencies may have occurred based on memory recall for the facilitators. However, as our findings found similarity in scores obtained from the observing researchers and from facilitator' self-report, this potential bias was limited. Encouraging and implementing simple and effective protocols for timely completion of self-report checklists could assist with completion rates as well as quality of data.

Timing of training in trials of group interventions is a well-known challenge [45]. The time lag between training and delivery of the intervention could have impacted upon fidelity but we mitigated against this by site supervisors being place and supervision of the site supervisors by the research team.

Lastly the assessment process was not applied to the individual sessions or out of venue activities due to several ethical considerations. These included the need to maintain participant confidentiality during individual sessions. It is essential this component of the intervention is seen as a safe space for the person to speak freely if they are to maximise participation in the intervention. And secondly confidentiality and consent issues when interacting with people who were not part of the trial during community based out of venue activities. We therefore relied on facilitator self-reports for these components of the intervention. We did consider asking participants themselves to provide self-report on these components but felt that due to other trial requirements this was deemed too burdensome. Obtaining participants contemporary views of the intervention would however provide nuanced data to better understand the intervention in action. If we are to evidence fidelity to delivery as intended as well as in relation to intervention effectiveness then all components of complex interventions need to be included in assessments.

## Conclusion

We have conducted a fidelity evaluation of a complex psychosocial intervention, demonstrating its fitness for assessing several core components specific to the

intervention. In addition, we have demonstrated that non-participatory observations in the community are possible when carried out in a regular venue. This approach can be used as a model for development of fidelity assessment for community based complex interventions. However, we were not able to observe all core components of the intervention due to the inability to be able to either observe or record all aspects. Therefore, questions remain about how to best observe and assess fidelity in community based complex psychosocial interventions where methodological and ethical issues prevent use of established assessment methods.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12877-021-02070-8.

**Additional file 1.**

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### Authors' contributions

Fidelity assessment lead – KS. Author of the manualised programme – CCr. Intervention trainers – CCr, GM, CM. Research supervisor to recruiting sites – KB. Design of the protocol, framework and measures – KS, JBD, GM, CCr, KB, JW, CCo. Data collection – KS, JBD, GM, CM, KB, JW, SM, BT. Data analysis – KS, JBD, GM, CCo. Development of manuscript – KS, GM. All authors reviewed and approved the final manuscript.

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### Availability of data and materials

The datasets generated and analysed for this study will be available upon request from the corresponding author.

### Ethics approval and consent to participate

Ethical approval was obtained in July 2016 (ref no. 16/YH/0238) from the United Kingdom National Health Service Research Ethics. United Kingdom Health Research Authority approval was given (IRAS reference 199383) in August 2016. Participating sites gained permission from the local NHS Trust Research and Development Department prior to commencing research activities as a study site.

### Consent for publication

We obtained written informed consent for the participants who took part in the interviews via the Trial Consent Form. This information is held as part of the archived record of the trial. Only anonymised nonidentifiable data are used in this report as per written consent.

### Competing interests

Clare Craig is the author of the Journeying through Dementia manual. All other authors declare no competing interests.

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ORIGINAL RESEARCH

# Journeying through Dementia Randomised Controlled Trial of a Psychosocial Intervention for People Living with Early Dementia: Embedded Qualitative Study with Participants, Carers and Interventionists

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**Objective:** To identify the barriers and facilitators to the implementation of a complex psychosocial intervention though a study exploring the experiences of participants, carers and interventionists during a trial.

**Methods:** Individual semi-structured interviews were conducted with participants, their carers, and interventionists from a sample of recruiting sites that took part in the Journeying through Dementia randomized controlled trial (RCT). Interview data were transcribed and analysed using framework analysis. Co-researcher data analysis workshops were also conducted to explore researcher interpretations of the data through the lens of those with lived experience of dementia. Triangulation enabled comparison of findings from the interviews with findings from the co-researcher workshops.

**Results:** Three main themes emerged from the interview data: being prepared; intervention engagement; and participation and outcomes from engagement. From these themes, a number of factors that can moderate delivery and receipt of the intervention as intended were identified. These were context and environment; readiness, training, skills and competencies of the workforce; identifying meaningful participation and relationships.

**Conclusion:** This study highlighted that the observed benefit of the intervention was nuanced for each individual. Mechanisms of change were influenced by a range of individual, social and contextual factors. Future research should therefore consider how best to identify and measure the multifaceted interplay of mechanisms of change in complex interventions.

**Trial Registration:** ISRCTN17993825.

**Keywords:** psychosocial, self-management, dementia, wellbeing, occupational therapy, qualitative

## Background

Approximately 537,000 people are living with a diagnosis of dementia in the UK[1] of which around 55% are in the mild stages of the condition.[2] Both global and UK policy recommendations emphasise the importance of post-diagnostic treatment and support to help people live well with a diagnosis of dementia.[3,4] Guidance in the UK now stipulates that activities to promote wellbeing should include psychosocial

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and occupational therapy interventions.[5] Proposed benefits include the promotion of self-efficacy to support independent living and meaningful activity.[6]

Self-management interventions are an established approach for those living with long-term conditions and are supported by the UK and international policy.[7] Participants are enabled to identify strategies to take back control and responsibility for their health and well-being. There is growing evidence for use of self-management techniques with people living with dementia; however, there is still a lack of high-quality research to examine the effectiveness of such interventions.

In complex interventions, understanding the[7,8] mechanisms of action and how they interact is challenging. The multi-component nature of such interventions means that any one part or the combination of parts may be a factor for change. It is important therefore that each individual component is described and evaluated.[9,10] MRC guidance recommends integration of qualitative methods to explore the interaction between mechanisms of change, context and outcomes.[11]

Journeying through dementia is a manualised occupational therapy-based self-management complex intervention for those with mild dementia and was co-created with people with lived experience of the condition.[12,13] The intervention is underpinned by social cognitive theory,[14] with a focus on behaviour change through increased self-efficacy[15] and effective problem solving thereby promoting increased self-management, independence, improved wellbeing and life satisfaction. It acknowledges the dynamic transactional relationship between the person, the environment in which they live and their occupations and roles.[16]

The intervention was evaluated through a pragmatic, two-arm, parallel group, individually randomised controlled trial.[17] A total of 480 participants were randomised of which 241 received the intervention. The intervention consisted of 12 consecutive facilitated weekly group meetings attended by up to 12 people held in the community. Participants also received four one-to-one sessions with a facilitator to focus on personal goals. During group sessions, participants were encouraged to explore topics from the manual using discussion and activities including community engagement. Consolidation of learning and experience was aimed for through a minimum of three out of venue activities (otherwise referred to as outings). Intervention facilitators received 2-days' training before commencing intervention delivery and had regular supervision from a senior clinician at their employing site throughout the period of the intervention delivery.

To better understand how a novel intervention such as Journeying through Dementia might be applied in a real-world context it is essential to ask a wide range of stakeholders involved in delivery and receipt for their experience, opinions and ideas.[18] Involving people with lived experience of a condition as co-researchers in meaningful co-creation of data through interpretation of findings by working alongside academics is becoming more accepted and respected.[19] Co-research adds validity by bringing insight to the data from a unique perspective of those with the condition.[20] This enables the identification of commonalities and divergences between researcher interpretations of the data is commensurate with those of people with lived experience of dementia. It has been demonstrated that it is possible and can be productive to involve people with lived experience of dementia as co-researchers in qualitative analysis.[21]

This paper reports a qualitative sub-study, embedded within a trial, which explored the perspectives from those involved in delivering and receiving Journeying through Dementia. Thereby evaluating how the intervention produces change and to inform future development of the intervention.

Reporting meets the requirements of COREQ guidance.[22]

## Aims and Objectives

The main aims were to understand the mechanisms of a complex psychosocial intervention and to identify the barriers and facilitators to implementation, through an exploration of the experiences and insights of interventionists (those facilitating the intervention and those supervising the facilitators), as well as those in receipt of Journeying through Dementia. This included

- The range and nature of issues that influence the experience of the intervention.
- Factors that may mediate or moderate the effectiveness of the intervention.
- Perceived skills and competencies required to facilitate the intervention.
- Effect of the intervention on participation and living with the diagnosis.

## Materials and Methods

We conducted interviews with people living with dementia who had attended the intervention and their participating carers (if they had been recruited to the study) as well as

with interventionists (all were NHS staff). We also interviewed participants who had withdrawn from the intervention to obtain different perspectives. The analysis was also informed by co-researcher data interpretation workshops which were convened with people with lived experience of dementia.

## Sample

The Research and Development (R&D) teams and Principle Investigators, at a purposive sample of four (out of 13) NHS delivery sites participating in the Journeying through Dementia trial, were approached to take part in the qualitative sub-study and all agreed. Site selection was pragmatic with criteria including approvals being in place, that sites were open and running the intervention, sites had or planned to conduct at least two successive intervention programmes for the trial and that interventionists had the capacity to participate in interviews. Consideration was also given to geographical location and population size so that selected sites represented the range of those that participated in the trial.

Intervention facilitators were sought from any relevant UK NHS professional background working at band 4 on the UK NHS Agenda for Change (AfC) pay scale.[23] In reality, we recruited facilitators working across bands 2–8 on the AfC pay scale. Supervisors were experienced clinicians from a range of clinical backgrounds employed at AfC bands 6–8.

A sampling frame (see Table 1) was used to purposively identify participants at each selected site who had received the intervention during a second wave of intervention delivery including participants who had withdrawn from the intervention. We also sought to interview the carers of participants who were being interviewed (see Table 2). Interviewed participants were selected to be representative of the overall trial population. Of those interviewed only age was not representative of the overall trial population but was representative of those who took part in the groups included in the qualitative sub-study. A total of 19 participants and 14 carers were invited to take part in the interviews, with 15 participants and 10 carers subsequently accepting. The spread of participants and carers approached and agreed to take part in interviews across the four sites is presented in Table 3.

Of the interventionists, all facilitators (n=10) and four of the five supervisors from the four selected sites were interviewed. All staff were employed in the participating NHS organisations.

**Table 1** Participant Characteristics

| Characteristics | Participant (n=15) |
|---|---|
| **Diagnosis** | Alzheimer's, n=6<br>Frontotemporal, n=2<br>Vascular, n=3<br>Mixed, n=3<br>Other – mild dementia, n=1 |
| **Age** | Range, 67 –90<br>Average, 77 |
| **Ethnicity** | White British, n=14<br>African/Asian, n=1 |
| **Gender** | Female, n=7<br>Male, n=8 |
| **MMSE score** | Range, 20–29<br>Average, 26 |
| **Living arrangements** | Living alone, n=2<br>Living with others, n=13 |

## Materials and Tools

Interview information sheets, consent forms and appointment letters were created by the research team; one version for participants and their carers and one for the interventionists. The trial Advisory Group of people living with dementia reviewed and advised on acceptability, content, language and presentation of the participant and carer versions of the documentation. They also suggested including a photograph of the researcher in the appointment letter to support participant recognition and reassurance on the day of the interview.

Interview topic guides (see supplementary documents) were initially developed by the qualitative lead for the trial using tacit knowledge and best evidence; with other

**Table 2** Participating Carer Characteristics

| Characteristic | Participating Carer (n=10) |
|---|---|
| **Age** | Range, 50–89<br>Average, 71 |
| **Gender** | Female, n=7<br>Male, n=3 |
| **Relationship** | Spouse, n=9<br>Child, n=1 |

**Table 3** Spread of Participant Interviews by Participating Site and How They Were Conducted

| | Total Number Approached | | Declines | | Number of Individual Interviews | | Number of Joint† Interviews |
|---|---|---|---|---|---|---|---|
| **Site** | **Participants** | **Carers** | **Participants** | **Carers** | **Participants** | **Carers** | |
| 1 | 6 | 5 | 1 | 1 | 3 | 2 | 2 |
| 2 | 5 | 5 | 2 | 2 | 3 | 3 | 0 |
| 3 | 3 | 1 | 0 | 0 | 3 | 1 | 0 |
| 4 | 5 | 3 | 1 | 1 | 2 | 0 | 2 |
| **Total** | **19** | **14** | **4** | **4** | **11** | **6** | **4** |

**Note:** †Where the participant and carer were interviewed together.

members of the research team then contributing towards refinement of the tools. For the participant and carer interviews, enhanced methods of communication were employed to support engagement and try and ensure meaningful findings.[24,25] The trial Advisory Group reviewed the topic guides and intended interview process with study participants and carers for usability and acceptability. Following their advice, we amended the language in topic guides, reduced the length of the proposed interview and implemented suggestions to aid recall such as having the intervention manual at the interview for participants to refer to.

## Semi-Structured Interviews

Individual semi-structured interviews were conducted with participants and carers as well as interventionists from the four participating sites. The number of interviews achieved met those aimed for in the trial protocol.[17] Interviews were conducted post completion of a second intervention group at each site. This was to allow interventionists time to become familiar with Journeying through Dementia so that when interviewed they could refer to delivery as intended rather than the learning period that would have occurred when implementing a new intervention.[26] All those who agreed to take part were free to withdraw at any time.

Interviews were conducted by three experienced members of the research team including the lead for the qualitative study (KS) and two researchers (JBD and BT).

Interviewers re-confirmed consent prior to commencement of the interview. Permission was sought to audio record each interview and all interviewees consented to recording. All recordings were transcribed and copies of individual transcripts shared with the interviewee for respondent checking to ensure what they had said had been intended. This was also considered a step to support participant engagement through scaffolding memory for consent for quotation to be used.[27] Transcripts were sent by post to all those interviewed accompanied by a letter providing details of what to do and how to contact the study team should they have any further comment. Two of those interviewed (both facilitators) provided additional comment on their transcripts using annotation and one of these also altered some of the grammar (interviews were transcribed verbatim).

### Participant and Carer Interviews

Consent was obtained to contact participants and carers to take part in interviews. The intervention facilitators provided a verbal reminder to participants about the potential interviews during the last few group sessions. The interview sampling frame was then created to select interviewees from those who had consented and approaches to those subsequently identified were made by telephone as soon as possible after the end of intervention delivery. Due to delays obtaining relevant approvals, confirming interviewee availability and changes to research staff, there was a time lag between finishing the intervention and the interview for some interviewees which may have contributed to poor recall. During the telephone call to finalise consent and make necessary arrangements, the researcher explained the purpose of the interview and what would happen. They emphasised the points that the participant or carer could decline to take part, they should take time to consider participation, and they could agree to participate verbally. If they declined, no further contact was made regarding the interviews. If more time was requested to consider their participation, they were sent a copy of the information sheet and a time was agreed and arranged for a follow-up contact. If they agreed to be interviewed an appointment was made and they were sent a copy of the information sheet and a personalised letter confirming the interview appointment details. A copy of participant

interview arrangements was also sent to their carer if the participant requested this.

A further telephone call was made to the participant (or their carer if requested by the participant) prior to the interview as a reminder. Interviews occurred between 6 March and 19 July 2018 taking an average of 38 minutes (range 13–75 mins) and all were conducted face-to-face in participants' own homes.

Individual participant interviews were encouraged to provide a confidential space for each voice to be heard and of the 15 interviews with people with dementia, 11 were achieved individually. However, it was the participants' decision to have a carer present or not. Nine individual interviews occurred in another room, but due to space limitations, two took place with the carer present in the same space. Where dyad interviews (n=4) were conducted this was at the request of the participant. Reasons for requesting a joint interview included participant reassurance or couples expressing they were a "partnership".

### Interventionist Interviews

An invitation was sent to individual facilitators and supervisors via email including an information sheet and consent form. Those who agreed to take part then contacted the research team and an appointment was arranged. Consent was obtained via email as all interviews were conducted by telephone. Interviews occurred between 30 Nov 2017 and 5 April 2018 and were an average duration of 49 minutes (range 30–70 mins).

## Co-Researcher Workshops

Two co-researcher data analysis workshops were held with people living with dementia and their carers acting as co-researchers. Co-research is a method of research enabling participants to act as joint contributors alongside academics.[28] Benefits include bringing insight to the data from a unique perspective of those with the condition. This enables identification of commonalities and divergences between researcher interpretations of the data and those of people with lived experience of dementia. Two workshops were organised to allow coverage of a reasonable amount of data and limit the length of each session so that those participating did not fatigue.

Our co-researchers were recruited from the Journeying through Dementia trial Advisory Group and from the Bradford Experts by Experience cohort https://www.bradford.ac.uk/dementia/experts-by-experience/. The first workshop was attended by seven co-researchers (two married couples in which one person had dementia and the other was their spouse and carer, one current carer, one past carer and one independent person living with dementia) and the second was attended by 12 co-researchers (five couples in which one person had dementia and the other was their spouse and carer, one independent person living with dementia and one independent carer). Three people (two people with dementia and one carer) attended both sessions. The workshops were hosted in community venues and remuneration for co-researchers followed INVOLVE best practice guidelines.[29]

Each workshop was led by two members of the research team, supported by other team members who took written notes of the discourse and any other salient observations. Written consent to audio record each session was obtained from each participant at the outset to supplement note taking and observations. Both workshops took place in the early stages of the data analysis process to check researcher understanding and interpretation of the data before the final classification framework was produced. Involvement of two researchers and the co-researchers aimed to reduce bias to any one point of view.[30] A comprehensive account of the process and outputs from the co-researcher workshops will be provided in a separate publication.

## Data Analysis

### Theoretical Perspective

The theoretical lens of critical realism assumes that not all knowledge is equal when trying to understand the real world but that there are multiple 'truths' that need to be acknowledged in order to explain social constructs.[31] By exploring a range of stakeholder perspectives (participants, carers and interventionists) we aimed to obtain the range of "truths" as perceived by different stakeholders and individuals and therefore provide a detailed and nuanced understanding of the implementation and receipt of the Journeying through Dementia intervention.

### Methods of Analysis

Analysis of the data was conducted by the qualitative lead and two researchers. The interview topic guides were used to provide an initial framework for the analysis, but coding was also inductive to holistically understand the data. This iterative process allowed for collapsing or expanding of initial themes and sub-categories. Coding was initially undertaken separately for participants and carers from the facilitators and supervisors before merging to produce a final classification framework. This approach enabled the

coders to manage the quantity of data as well as allow varying perspectives to emerge from the data.

Framework analysis[32] was used to explore the range of perspectives (multiple truths) in the interview data provided by participants, carers, facilitators and supervisors as required for critical realism.[31] Resulting themes identified from the data were evidenced by quotation from the interview transcripts. This method provides a clear step-by-step approach to analyse large data sets as described below, can link topics within the analysis, enables a holistic overview from multiple sources, takes into account the perspectives of more than one researcher and addressed the research questions. Data were managed using NVivo 12 computer-assisted qualitative data analysis software (CAQDAS).

### Step 1 – Familiarisation and Independent Open Coding

All transcripts were read for data familiarisation by two researchers who then independently open coded a purposive sample of half of the transcripts. The transcripts were selected to represent all four fidelity sites, the different interviewers and a cross section of interviewee viewpoints reflecting both positive and negative experiences of taking part.

### Step 2 – Development of Initial Frameworks

The two researchers then reviewed the open coding together to create an initial framework for analysis of the participant and carer interview data. The same process was followed for the second framework for analysis of the facilitator and supervisor data to ensure that different perspectives were maintained.

### Step 3 – Co-Researcher Review of Participant and Carer Interview Data

A selection of quotes illustrative of the range of themes and sub-categories identified from the initial framework (Step 1) created out of the participant and carer interviews were then presented at our co-researcher analysis workshops. A total of 20 quotations (9 in workshop one, and 11 in workshop two) were reviewed by the group. Each quotation was presented to the group one at a time typed in large font in black text on yellow paper[25] ensuring text was easier to read for those with compromised vision and/or sensory impairments. The co-researchers were then given time to read the quotation as well as hearing the workshop lead read it out loud. They were asked to review and respond to the quotation with particular focus upon language (what was being said and the words used), for example, was the content positive, negative or ambiguous? We also asked them to consider tone, for example, strength of the voice; was it passionate or dispassionate and finally we requested consideration of the overall meaning of the quote; that is their interpretation of what was being said. For each quote, the group was made aware of the voice being used ie participant or carer and were given a brief context, ie talking about an individual session or a group meeting. Interpretation of each quotation discussed by the co-researchers was tabulated with that of the researchers' understanding and compared for convergence, divergence or novel interpretation. Where interpretations diverged or were novel these were subsequently reviewed by the two researchers. Interpretations were used to develop the initial participant and carer framework produced in Step 2.

### Step 4 – Application of Frameworks to All Transcripts and Development of Modified Frameworks

The two researchers applied the initial frameworks to code all the transcripts and then reviewed the coding together to identify any new emerging themes. This resulted in two modified frameworks, one for participant and carer data and a second for facilitator and supervisor data.

### Step 5 – Comparison and Merging of Modified Frameworks

The two modified frameworks were then merged to compare and contrast perspectives and to chart the data into a matrix producing a final classification framework identifying key themes across all the data combined.

### Triangulation of Qualitative Findings

Triangulation can increase the validity of research findings by combining and evaluating multiple data sources and data collection methods.[33] A data triangulation protocol (see Table 4) was created and applied to enable comparison of the multiple data sources (range of interviews from different sources and interpretations from the workshops) and reduce the risk of bias.[34]

## Findings

Three main themes were identified from the analysis, see Table 5. Unique identifiers are used for reporting direct quotes and confidentiality maintained by removing identifiable information. Quotations have been selected to illustrate the identified themes.

**Table 4** Triangulation Protocol for Qualitative Analysis

| Step | Activity | Source |
|---|---|---|
| 1. Sorting | Sort the findings from each data source under the final classification framework to determine where there maybe overlap or divergence, presence, frequency and meaning. | Interview transcripts with participants, carers, facilitators and supervisors |
| 2. Convergence coding | Identify key themes from each data source using coded examples to determine prominence and compare findings. Then compare a sample of coded examples with co-researcher interpretations from the perspective of people living with dementia. | Interview transcripts with participants, carers, facilitators and supervisors. Co-researcher workshop selected quotation. |
| 3. Convergence agreement | Identify where there is agreement, divergent or ambivalent themes and interpretations between the two coding researchers and the researchers and co-researchers (people living with dementia). | Initial and modified analysis frameworks. Co-researcher workshop selected quotation. |
| 4. Convergence assessment | Identify global assessment for level of agreement between multiple researchers (including the co-researchers) as well as acknowledging different perspectives. | Final classification framework. |
| 5. Completeness | How results of the global assessment enhance the completeness of the overall findings and answer the research question. | Final classification framework. |

**Table 5** Themes Identified from Interview Data

| 1. Being Prepared | 2. Intervention Engagement and Participation | 3. Outcomes from Engagement |
|---|---|---|
| • Intervention training<br>• Resources and time commitment | • Eligibility<br>• Group dynamics<br>• Out of venue activities (outings)<br>• One-to-one sessions<br>• Intervention facilitation | • Confidence through knowledge and gaining perspective<br>• Enjoyment, feeling valued or empowered<br>• Social contact and friendships |

# Theme 1 – Being Prepared

## Intervention Training for Interventionists

The opportunity to practice components and share learning during the training was highlighted by all interviewed interventionists as being particularly helpful. However, several facilitators, including those who stated appreciation of the practical exercises during training, also described how the training had not met all their needs.

> I don't know whether it was just because there was quite a lot of information over the two days … we came away just a little bit confused. (Facilitator H)

## Resources and Time Commitment

Most interventionists indicated that, over time, experience of delivering the intervention led to greater proficiency. Some facilitators found the manual a helpful "toolbox" to dip in to whilst others thought it was overly comprehensive. One facilitator who said that the manual was too comprehensive also considered that the contents were therefore not always appropriate for people with more advanced impairments.

> We had a couple [of participants] who were quite further on in their [dementia] journey and so I guess lots of the materials and lots of the discussion points and activities were really extremely difficult for them to do and engage in. (Facilitator G)

The size of a group, the needs of the individual participants and the type of activities that the group engaged in were all cited by facilitators as factors that could influence resource requirements as illustrated by the following quote;

> Three [staff] as a minimum, but equally sometimes three was difficult particularly when we were going on outings. When we went on outings I felt that we needed probably at least four depending on the outing really. (Facilitator F)

All facilitators considered that the estimated time to undertake all aspects of the intervention (1 day per week) was inadequate but that the required time did diminish over time. However, it had still remained in excess of 1 day.

> … we had a bit of insight into what had worked for that first group and what had not … So yes it took less time

second time around definitely. However, it still took a lot of time … (Facilitator B)

## Theme 2 – Intervention Engagement and Participation

### Eligibility

All interviewed interventionists considered that the wide-ranging physical and cognitive impairments experienced by people with dementia had not matched their expectations and had challenged their ability to plan, organise and deliver the intervention as well as enable meaningful involvement of participants.

… I thought we were going to end up with people who were newly diagnosed and quite cognitively intact in those with mild dementia. That's not how it was. (Facilitator B)

Examples of how attempting to meet the needs of the whole group could lessen the experience of individual participants were provided;

There was still a couple of participants who were restless because they wanted to do more but we were almost having to tailor it for the slowest person. (Facilitator F)

Conversely, reports of participants continuing activities after the intervention had ceased suggested that at least some of those who had taken part were able to apply their experiences in their lives going forwards.

### Group Dynamics

Participants, carers and interventionists spoke about the impact of group dynamics and diversity factors that could influence their experiences of delivering or receiving the intervention.

A smaller group for me it's important, if you have a larger group, people may not share so much … " (Participant L, Individual)

It was useful because in fact although there were one or two men there similar to myself … you do meet people that are not within your same sphere. (Participant D, Individual)

Participants expressed varying perceptions and requirements of the intervention. Consensus obtained from one of the co-researcher workshops was that this quotation discussing the importance of the intervention setting was about respecting the needs and feelings of those taking part. Privacy, including in some instances from their carers was important for participants when discussing personal issues.

You also need a setting that is private because of the sensitive nature of the subject … it has to be in a place where we all knew it was safer, rather than public. (Participant L, Individual and quotation explored in the co-researcher workshop)

Having common ground was important but many of those interviewed (interventionists and participants) acknowledged that meeting people with different experiences was important for sharing and learning.

It did a terrific amount of good to you, to find that there was other people, you were not the only one …. (Participant E, Individual)

I think there was a few people within the group [who] reflected on peoples' different ways of approaching things. And if there hadn't been the group they would have never seen life in that different perspective. (Supervisor A)

### Out of Venue Activities (Outings)

Accompanying people with dementia into the community caused concern for some interventionists who expressed worries about the risks involved and the organisational accountability for this. There appeared to be tensions between duty of care to patients versus the "self-management" ethos of the intervention.

We are professionals; we are entering into this with service users. We have a responsibility and a duty of care. We need to do things properly. We do need to risk assess because we're in paid employment and we work for an organisation that would expect that of us … (Supervisor B)

Interestingly, despite concerns from some interventionists regarding the complexity of the intervention and in particular how participant ability could be challenged, some facilitators and most participants talked positively about the most challenging component of the intervention, the outings.

To be able to have the freedom to go out and about into the community with people, again that is something that we don't ordinarily get to do within our service. (Facilitator D)

One facilitator described how they had investigated activities for potential risk prior to suggesting them and also using the first outing as a test of abilities of the group. This person considered that selection of, and expectations of the outings had to be carefully managed due to the physical, as well as cognitive, abilities of group members.

> Because of the level of physical problems . . . it limited the range of the outings . . . until we got people out of there (in-venue) we didn't realise how impaired they were both cognitively and physically. (Facilitator B)

### One-to-One Sessions

Although the majority of facilitators recognised the importance of the one-to-one sessions, particularly for individual goal setting, all interventionists (facilitators and supervisors) described this activity as challenging, citing lack of participant understanding of the purpose of such sessions and lack of participant engagement.

> I didn't get a goal from anyone, I mean most of them said I just want to see what it's [intervention] all about, which isn't a goal . . . (Facilitator F)

> Sometimes it felt like I was trying to force a goal on them. (Facilitator A)

However, other facilitators described how goals could be identified and explored if participants were given time and support.

> Quite a few participants have struggled to know what goals they would like to achieve . . . I have just reassured them . . . and on subsequent sessions, we've been able to nurture those ideas into tangible goals. (Facilitator D)

Participants who recalled taking part in one-to-one sessions described them as being an opportunity for personal time and identifying support to meet their needs.

> I valued those one-to-one sessions quite a lot because that was 'me' time with [facilitator] . . . because I knew that was just me and her talking about the things that I felt uneasy about or something that I felt strongly about, so to me they were quite valuable sessions. (Participant L, Individual)

### Intervention Facilitation

Positive relationships between interventionists (co-facilitators and supervisors and facilitators) and between participants and facilitators were all described as being vital for successful intervention delivery and promoting the engagement of all taking part.

> We've [co-facilitators] got a good working relationship . . . we recognise each other's skill set and what's worked well in previous groups. So we will bring those skills together. (Facilitator D)

> [Facilitators] were brilliant, they let you talk, they shut you up when they had to . . . they didn't tell you what to do, they guided you, signposted you, they were brilliant. Yes I didn't feel as if they were patronising me in any way. (Participant K, Dyad)

Compared to existing service provision, Journeying through Dementia was described by several interventionists as being more proactive and interactive, offering early professional input, a community focus and supporting enactment through the outings.

> I'm working in a situation we haven't got OTs [Occupational Therapists] in at that earlier stage of someone's journey and I really see the significance and the value. So for me it's really reminded me of what difference some of this work can make on peoples' journey in life and to be able to take some control over their own situation and what benefit that is. (Supervisor A)

Several facilitators were of the view that without carer involvement some participants, and in particular those with more severe cognitive or physical impairments, could struggle to take part in the intervention.

> Where they [participant] are by themselves with no carer it's a very different picture both on the one-to-ones and . . . attendance to the sessions. (Facilitator B)

> I think it's the ones where the carers are keen in this group, they might keep in touch but if the carers aren't then they might not. (Facilitator A)

Conversely, some interventionists also expressed that greater carer engagement with the intervention could change the balance of power, thereby disadvantaging people with dementia.

> . . . I think they [participants] need that independence when they come to the group sessions. Sometimes having the carers there can stop them from saying things because they probably don't want to upset them. It would be difficult for them to be more open about their experiences. (Facilitator E)

## Theme 3 – Outcomes from Engagement

Despite the impact of impairment upon ability to take part many of the interviewed participants, although not all, reported a range of good outcomes and described positive behaviour change as a result of attending the intervention.

### Confidence Through Knowledge and Gaining Perspective

Most participants talked about gaining in confidence due to their involvement. Our co-researchers felt the following quote was a positive statement which revealed how this participant had gained confidence by focussing on what they could still do.

> It [the group] wasn't all about how bad my situation is, I'm going to lose my memory, I'm just going to lose it – No it was just a good thing, it was kind of building confidence not destroying people, but building them up. That there is life after this. (Participant L, Individual and quotation explored in the co-researcher workshop)

Group dynamics through sharing and peer support also played a significant role in supporting engagement in meaningful activity and enabling behaviour change. Our co-researchers were in agreement with the overall meaning of the quote but also focussed on the nuances of choice. On diagnosis people with dementia usually experience loss of self-management and decision-making, here the co-researchers considered that the individual had taken back control supported by the group.

> I've learned how to swim again. I didn't have the confidence to swim …. Well it feels like you've achieved something again, something worthwhile. I thought these groups was going to be all sort of bingo and nostalgia … but when I went to the group and I met these people and they weren't just talking … they were doing these things. (Participant K, Individual and quotation explored in the co-researcher workshop)

The majority of participants described valuing the opportunity to share their experiences and learn from others in the same situation. This was reiterated by our co-researchers who commented those newly diagnosed typically do not get a lot of information from health professionals. They agreed that confidence came with knowledge.

> I think I got more information about the difference between Alzheimer's and Dementia … and it was interesting listening to the other people as well, how they felt about their diagnoses and how people reacted to it. (Participant L, Individual and quotation explored in the co-researcher workshop)

### Enjoyment, Feeling Valued or Empowered

The majority of interviewed participants described enjoying the intervention, and particularly the new experiences it introduced to them. Only two expressed disappointment but had continued to attend intervention sessions.

> I thought it was quite a flippant intervention and I expected it to be a bit more digging deep and it didn't do that (Participant M, Individual)

Several participants talked about how attending the intervention had enabled them to contribute toward their community. For example, one participant started volunteering at the local Alzheimer's Society. Another expressed how they had become more independent.

> It's making me a bit more doing it myself not just sitting in and letting everybody else do it. (Participant I, Individual)

This was also observed by several carers.

> … having done that group he then decided he would go to respite care for a day … it made him decide that he would go somewhere, that was the really positive thing that came out of it. (Carer A, Individual)

### Social Contact and Friendships

Nearly all the participants talked about how the intervention had promoted social contact and friendships both during and post intervention delivery. However, participants also described the immediate sense of loss of social contact or friendships once their involvement ceased. This was despite being advised and supported by the facilitators regarding how they might keep in touch with others. Fear of rejection, memory, logistics or need for someone to take responsibility for facilitating communication was cited by various participants as reasons for not meeting with others after intervention cessation.

> I thought well I'm sitting here saying nobody's [contacted] me, but I haven't done it to anybody else either … it's a different environment though isn't it, I think you feel safe if you're in a group, rather than [contacting] somebody and perhaps get a negative [response]. (Participant O, Dyad)

## Discussion

The goal of the intervention is to enable the knowledge and skills to promote self-management and support independence. Achievement of this leads to improved well-being for the individual. The significant factor we identified that appeared to mediate behaviour change was the dynamic transactional relationship between the person, the environment in which they live and their occupations

and roles. This meant that reported benefits were nuanced in relation to impact and outcomes. A number of factors also emerged as being moderators of delivery and receipt of the intervention as intended. These included context and environment; readiness, training, skills and competencies of the workforce; and identifying meaningful participation and relationships.

## Context and Environment

The community based, participant-led self-management ethos of the Journeying through Dementia intervention did not always fit well within the organisational (NHS) or professional approach to risk management and patient safety. Current interventions tend to be limited to short-term programmes conducted within NHS premises or involve referral to the voluntary sector. The comfort and familiarity of a setting or workplace may be preferred by those delivering novel interventions and being able to fall back on organisational processes provides a safety net. Working in different ways to deliver Journeying through Dementia did present a challenge to some interventionists. Delivery within a health setting automatically distances an intervention from everyday life for those taking part and is particularly problematic when the intervention is community focussed.

## Readiness, Training, Skills and Competencies of the Workforce

In comparison to interventions currently available within NHS services, Journeying through Dementia was described by interventionists as being time consuming and resource hungry due to its length and multi-layered complexity. Whether organisations like the NHS should allocate limited resources to the intervention would need to be considered against the population-based impact of the intervention. This raises several questions. Is there a desire at the organisational level within UK health services to offer person-centred community-based complex interventions like Journeying through Dementia as part of everyday care provision? And secondly, whether the NHS has the resources to deliver such interventions safely to the volume of people needing support. How best to support people to live well with dementia in the community remains unresolved without further investment not only in research but also in in-service provision.

## Identifying Meaningful Participation

Readiness to engage in interventions and meaningful occupation not only refers to service provision but also a need and desire to engage from participants and their carers.[35] The impact of impairment on participation in occupational activity is complex and observations of capacity and capability may be influenced by other factors such as the individuals resilience,[36] self-confidence or self-determination[37] all of which are reliant on an intact and integrated sense of self.[38] Immediately post diagnosis is when many people will experience uncertainty and doubt about their future.[39] This intervention therefore is not just about adaptation of the activities to meet the needs of each individual it is also about challenging these uncertainties to provide a way forward for people living with dementia to live well with their diagnosis.[39] Despite participants having only mild dementia according to assessment criteria, it was still considered by the interventionists that for those with greater functional memory deficits the impact of the intervention would be limited. Impairment was overcome for some participants through the combination of intervention content, group dynamics, individual resilience and facilitation which was found to bolster participant confidence and support learning of methods of compensating for impairment. Therefore, who might benefit from this intervention cannot be determined by cognition alone.

## Relationships

The complexity of relationship dynamics and particularly the social networks of individuals was difficult to capture and understand in the trial setting.[40] However, the diversity and opportunity for social contact within groups was perceived as a strength. In addition, a sense of reassurance through commonality and acceptance was located in the group aspect of the intervention which supported participants to maintain this contact and group cohesion during delivery. However, participants and their carers clearly indicated the need for continued contact and social engagement. Since an ongoing intervention would not be possible within a health-care setting due to limited resources,[41] support is focussed on organisations in the UK such as the Dementia Engagement and Empowerment Project (DEEP)[25] who support people living with dementia in the community. However, the question remains whether they could also help provide a longer-term solution for interventions like Journeying through Dementia.

The qualitative results will provide deeper insight into the findings of the RCT which only provide a view from a whole trial population level. The qualitative results allow us to identify which aspects of the intervention were

acceptable and where there were challenges to delivery in the NHS. These issues would not have been evident from the trial analysis alone.

## Conclusion

This study highlighted that any observed benefit of the Journeying through Dementia intervention was nuanced to each individual. A one size fits all approach to intervention design cannot accommodate the complexity of dementia and people's experiences of living with dementia. Post-diagnostic care should be holistic, incorporating social care, physical and mental health.[42] As people are living longer and the number of people living with dementia as well as other co-morbidities increases, complex community-based interventions to support their health and wellbeing seem inevitable. Health services will need to be skilled, equipped and resourced to respond to this need.

## Data Sharing Statement

The datasets generated and analysed for this study will be available upon request from the corresponding author.

## Ethics Approval and Consent to Participate

Ethical approval was obtained in July 2016 (ref no. 16/YH/0238) from the United Kingdom National Health Service Research Ethics. United Kingdom Health Research Authority approval was given (IRAS reference 199383) in August 2016. Participating sites gained permission from the local NHS Trust Research and Development Department prior to commencing research activities at a study site. The study was conducted in accordance with the Declaration of Helsinki.

## Definitions

| | |
|---|---|
| Co-researchers | People either diagnosed and living with dementia or their carers |
| Facilitators/co-facilitators | NHS staff delivering the intervention |
| Interventionists | Group term for the facilitators/co-facilitators and supervisors who took part in the interviews |
| Supervisors | NHS staff supervising those delivering the intervention |

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## Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors report no conflicts of interest in this work.

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# Embedding patient and public involvement in dementia research: Reflections from experiences during the 'Journeying through Dementia' randomised controlled trial

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## Abstract

**Background:** The involvement of people with a diagnosis of dementia in patient and public involvement and engagement (PPIE) in research is an emerging field in the delivery of studies.

[†] J Beresford-Dent died on Jan 19, 2022

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Researchers need to understand and use the learning derived from various projects so that this growing body of knowledge can be applied in future research.
**Objective:** To embed PPIE throughout a randomised controlled trial of a psychosocial intervention called Journeying through Dementia. We identify and discuss the approaches to involvement that worked well and those where improvements were indicated.
**Design:** The Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF) is used to describe and critically appraise the approaches taken and the impact of PPIE involvement upon study processes, the study team and those people with dementia and their supporters who acted as advisors.
**Findings:** The involvement of people with a diagnosis of dementia and supporters as study advisors improved the accessibility and relevance of the research for people living with dementia. It also highlighted issues that researchers may have otherwise overlooked. Successful engagement of people with dementia and their supporters in the study was associated with staff skills and particularly use of techniques to scaffold meaningful involvement, as well as participants' memory and cognitive capacity. However, embedding robust and meaningful involvement processes required significant time and resources.
**Discussion:** We propose that certain research processes need to be adapted to be accessible and appropriate for people living with dementia. Recruitment of PPIE advisors needs to reflect population diversity. There also needs to be greater parity of voice between people with lived experience of dementia and researchers. These steps will increase the impact of PPIE in research and improve the experience for those who volunteer to be PPIE advisors.

**Keywords**
patient and public involvement and engagement, dementia, research

## Background

Funders, such as the UK National Institute for Health Research (NIHR) emphasise the value of patient and public involvement and engagement (PPIE) in the development, delivery and dissemination of research and demand that all studies evidence this (National Institute for Health and Care Excellence, 2021). Moreover, it is increasingly necessary to fully describe PPIE in published research outputs using reporting tools such as the GRIPP2 (Staniszewska et al., 2017). Integrity, quality, impact and relevance are just some of the benefits identified through involving those with lived experience (Miah et al., 2019; Poland et al., 2019). PPIE is therefore considered integral to good research design (Stevenson & Taylor, 2019). Guidance now exists on best practice to facilitate PPIE in the design and conduct of research including for people living with dementia (DEEP; National Institute for Health and Care Excellence, 2021).

However, it has been noted that undertaking meaningful PPIE can be challenging for both researchers and those who volunteer as PPIE advisors (Jackson et al., 2020), for example, those with lived experience may question researcher preferences or decisions (Rose & Kalathil, 2019). The power imbalance that can exist within healthcare and research contexts can result in service users being rendered unable to influence research design, implementation and outcome (Novek & Wilkinson, 2019). Therefore approaches to public involvement need to be relevant, accessible and support meaningful engagement (Burton et al., 2019). When working with people living with dementia this may involve managing individual expectations of cognitive capacity, including those

of the researcher (Waite et al., 2019), whilst also empowering and valuing the voice of lived experience (Birt & Poland, 2021). Alzheimer Europe's position on PPIE is one of inclusivity, and encouraging engagement such as identifying research priorities, interpretation of research findings and dissemination (Gove et al., 2018). Identifying and applying methods of PPIE that are acceptable and understandable to people living with dementia, both those living with a diagnosis of dementia and their family supporters, is therefore vital to improve the depth, delivery and utility of dementia research (Burton et al., 2019).

Journeying through Dementia is a psychosocial intervention designed for those diagnosed with mild dementia. It aims to equip individuals with the knowledge, skills and understanding to be able to self-manage and maintain independence and meaningful participation, thereby improving mastery, wellbeing and life satisfaction (Wright et al., 2019). PPIE was embedded throughout the entire Journeying through Dementia research programme from inception and design of the intervention (Mountain & Craig, 2012), through to feasibility testing (Sprange K et al., 2015) and the definitive randomised controlled trial involving 480 people with a diagnosis of dementia and 350 supporters (Wright et al., 2019) The terminology of 'carer' or 'supporter' was debated by the study team including PPI members who concluded that for people living with mild dementia the term 'carer' was inappropriate. We therefore refer to supporters throughout the trial to describe informal carers such as partners, relatives or neighbours. This paper describes our experience of PPIE in the Journeying through Dementia randomised controlled trial. Through reporting our experiences, we aim to highlight when and how PPIE strengthened our research, and also the challenges we encountered whilst endeavouring to deliver meaningful approaches towards PPIE.

## Methods

The GRIPP2 short form format for reporting involvement of patients and the public is used to report and critically reflect upon the PPIE processes and outcomes (Staniszewska et al., 2017).

### *Establishing and facilitating patient and public involvement and engagement in the trial*

Our approach to PPIE, was informed by NIHR INVOLVE guidelines (National Institute for Health and Care Excellence, 2021), the Dementia Engagement and Empowerment (DEEP) project (DEEP), the work of the Scottish Dementia Working Group (Alzheimer Scotland Action on Dementia, 2020), and the experiences of study team members. Our aims were to:

- Create opportunities for meaningful involvement of people living with dementia and family supporters in the design and delivery of the study and in the dissemination of results.
- Increase the relevance and accessibility of the research to people living with dementia and other members of the public.
- Create relevant, accessible and useful outputs from the study for people affected by dementia.

To support the aims of PPIE engagement in the trial the research team agreed and upheld a number of 'guiding principles' to inform the planning and execution of involvement activities, see Box 1.

**Box 1.** Guiding principles for PPIE involvement in the Journeying through Dementia trial

- All PPIE advisors compensated for their time in line with UK NIHR INVOLVE guidance (NIHR INVOLVE).
- A 'you said, we did' approach regarding how advice was used and taken forward.
- Use of best practice accessibility guidance (DEEP), for example, avoidance of jargon, acronyms and academic language.
- Meeting venues selected in consultation with PPIE advisors to ensure accessibility, for example, layout, transport, low noise levels. Provision of wayfinding advice to venues, for example, maps and instructions. Taxis provided if required while at the same time being mindful of offering support rather than becoming paternalistic (Roberts et al., 2019).
- Venue preparation to ensure a dementia friendly layout, provide additional signage and 'meet and greet' to help direct people.
- Inclusion of regular breaks during meetings as well as time and space to engage and respond to materials or discussion topics.
- Use of aide-memoires in all encounters with PPIE advisors, for example, flipcharts posted up in meeting rooms to remind members of the aims of the study and of the specific meeting, providing verbal or written updates on study progress.
- For all PPIE meetings content limited to one item per meeting, for example, input to documentation, dissemination activity.
- For Trial Steering Committee meetings, papers sent in hard copy well ahead of the meeting with highlighted sections and extensive annotations to explain reports and figures for specific consideration.

For any study it is essential that appropriate funding is allocated to PPIE activity for reimbursement or payment of time as well as for associated costs such as travel or equipment (NIHR INVOLVE). At the outset a budget was identified for PPIE for the Journeying through Dementia trial although this needed to be increased over time by moving finance from other budget lines within the overall grant allocation to meet the costs of additional activities. We provided regular updates to the funders about PPIE activities and their impact.

Applying an appropriate level of expertise towards PPIE engagement is recognised as being essential. A researcher with previous experience of facilitating engagement of people living with dementia in research (the PPI Lead), was responsible for identifying PPIE activities and co-ordinating involvement. They were also responsible for monitoring changes in capacity of our members living with dementia throughout the trial and supporting their individual needs. Membership did change in the advisory group during the trial due to changes in capacity as some individuals condition deteriorated. A research assistant was also identified to support PPIE activity.

All PPIE activities, records of discussions, the advice given to researchers and how it was subsequently used was recorded on a PPIE activity log (Mathie et al., 2020). This approach allowed us to continually review the impact of advice from our PPIE advisors upon the overall trial and provide transparency and accountability.

## Findings

### Patient and public involvement and engagement in trial oversight and operationalisation

The involvement of people living with dementia was rooted strategically and operationally in Journeying through Dementia trial governance and processes. It was embedded in trial oversight through PPIE membership of our Study Advisory Group and of the independent Trial Steering Committee as well as being included as a standing agenda item for the Trial Management Group. The role of each group/committee was as follows:

- The PPIE Study Advisory Group provided advice and guidance to the academic study team (as described below) using their experiences to inform study design and decision making.
- The Trial Management Group provided operational management of the study. The PPIE lead attended meetings on behalf of the PPIE Study Advisory Group although members could also attend if they wished.
- The Trial Steering Committee, including a PPIE member (who was not a member of the Study Advisory Group, provided independent study supervision, monitored conduct and progress and ensured that the safety and well-being of study participants was upheld (National Institute for Health and Care Excellence, 2019).

As it is important to provide a bridge between PPIE and researchers (Mathie et al., 2020), a cycle of identifying activities, discussion, reporting and taking action was established between PPIE advisors and the management and oversight committees; see Figure 1.

Strategies to support PPIE engagement in the trial tended to be researcher led in the first instance, for example using knowledge of best practice and observation of coping mechanisms of our PPIE members. This was then followed by PPIE member feedback which was used to inform better working practises to support engagement. For example, the research team initially identified dementia friendly venues to hold the PPIE meetings in the community. Difficulties in accessing a venue led to the group discussing other options, as well as improvements to the directions to the venue. Strategies to support engagement were therefore an iterative process throughout the trial as the PPIE group evolved (see Figure 1.).

### Patient and public involvement and engagement Recruitment

Recruitment of PPIE volunteers for membership of the Trial Steering Committee proved challenging. One person living with dementia, who was already active in research and known to the Trial Steering Committee members through existing research networks, was approached to join the Committee ahead of the inaugural meeting and remained a member throughout the four-year trial, attending every meeting. Although the initial intention had been to involve two PPIE members, we found it difficult to recruit a second member to provide cover, support and spread the workload. This may have been due to the four year time commitment, or perceptions of the necessary confidence and skills for this more formal role.

We established a PPIE advisory group to provide advice and guidance to the Trial Management Group throughout, thereby ensuring that our approach remained relevant and accessible to people living with dementia from recruitment to dissemination. Recruitment to the PPIE study advisory group was through the existing University of Bradford ‘Experts by Experience’ cohort of people with a diagnosis of dementia and supporters who volunteer to be involved in research and education

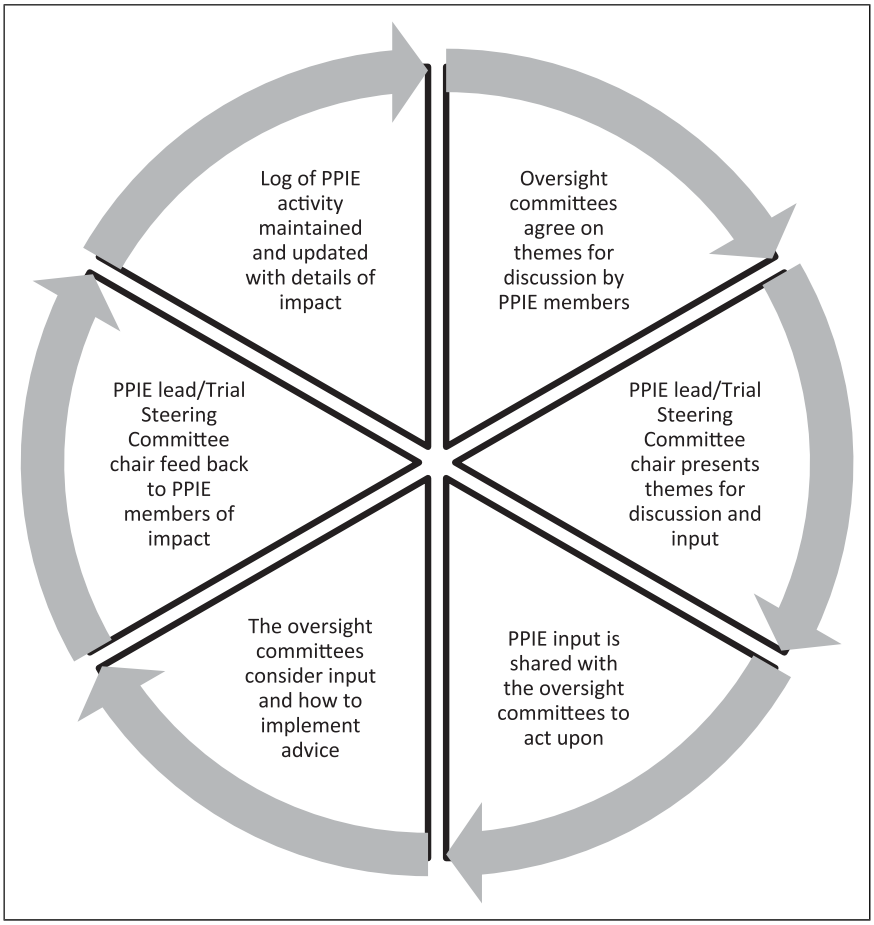


**Figure 1.** Patient and public involvement and engagement cycle of discussion, implementation and feedback.

(University of Bradford). We recruited individuals who were new to the cohort as well as long-standing members who may have had previous involvement in research. Consequently, some PPIE members had a deeper understanding of research than others. Initially the PPIE lead, and a second member of the research team conducted individual consultations with potential volunteers to explain the trial and what their involvement in the advisory group would entail. They emphasised to each potential volunteer that they could engage in as much or as little as they chose and that involvement in just one event would be valuable. Although interest in joining the group was high, with 10 applicants for the first meeting in July 2017, meeting attendance was initially poor (three people) due to a clash with another meeting held by a local dementia support group. However, the advisory group continued to meet between July 2017 and October 2019 and numbers steadily increased to 12. Several people with dementia attended with a spouse or another family member but others attended alone. Some changes in membership took place over time due to a change in commitments, through illness, and progression of dementia. The group were predominantly white and therefore did not reflect diversity and the experience of dementia by other ethnicities or social groups (Burton et al., 2019). Another limitation was the lack of representativeness of PPIE advisors across the different

geographical areas represented in recruitment to the trial. However, the limited geography enabled face-to-face meetings rather than making use of virtual meetings which was not exploited at the time.

## Supporting patient and public involvement and engagement involvement

*Trial steering committee.* The Trial Steering Committee for the Journeying through Dementia trial met twice yearly and involved members from clinical, academic and PPIE backgrounds.

To ensure that our Trial Steering Committee PPIE member was fully informed time was taken by the Chair and/or Trial Manager prior to each meeting to annotate any associated paperwork or preparatory materials. During meetings, the PPIE member sat adjacent to the Chair to facilitate communications. The responsibilities of the Chair were to ensure that the PPIE member understood all discussions throughout, including limiting the use of acronyms and overly technical language by all members and providing time for the PPIE member to consider and respond to an agenda item or question. With these adjustments in place the PPIE member was able to provide unique insights from the perspective of someone living with dementia and made significant contributions in key areas and documented her experiences of being involved in the trial as an adviser in her blog. The following quotes, obtained with verbal consent, from their publicly available blog, 'Which me am I today'(Mitchell W, 2014) illustrates their contribution and participation in the Trial Steering Committee.

> *'Many of the [meeting] papers were way beyond me but [name] had put a friendly post-it on each one telling me what each paper was about – wonderful idea. Definitely worth a brownie point'.* Trial Steering Committee PPIE member

> *'I raised the question of the reality of relying on our [participants with dementia] answers in follow-ups. And that raised a whole issue of current practices. I said that even if it shows how the current practices need to be revisited, that's a good outcome. I said revisits 8 months after an event and asking us to recollect is a tad adventurous. We don't like to feel embarrassed at not remembering so may make things up so we don't look stupid……or we simply give an answer that comes to mind today'.* Trial Steering Committee PPIE member

*Advisory group.* The operational management of the trial was overseen by the Trial Management Group who agreed that embedding high quality PPIE into protocol development and trial processes throughout was a priority. The PPIE lead for the trial (CM) and coordinator of the PPIE advisory group was a member of the Trial Management Group and PPIE was a standing-item on every meeting agenda.

To ensure that the PPIE advisory group felt supported and integrated into the study team we employed several methods. Firstly, we used our guiding principles to support the establishment and engagement of the group, see Box 1. One to one discussion was offered and taken up by some individuals instead of participation in a group or to aid their decision to join the group. When an advisory group had been assembled, we asked members about their preferences for involvement including how they would like to be communicated with throughout the study, the length and duration of meetings and meeting venues. All members did subsequently take part in the group but some people with dementia needed support from their accompanying supporter to achieve this. In addition, brief verbal and written reminders were provided at every advisory group meeting to reiterate the purpose of the study and what taking part entailed. A welcoming and informal structure was maintained to encourage active participation. At the start and end of each meeting time was

scheduled for refreshments, creating opportunities for PPIE advisors to enjoy a group atmosphere, and share more personal experiences and coping strategies whilst at the same time advising the study.

To promote inclusivity, support group dynamics and maintain active interest in the study, all members were invited to be involved in every activity. On most occasions all members attended, reflecting the overall interest the study generated and the possible benefits people were deriving from taking part. For larger groups however, it was challenging to ensure that the voices of all members were heard. PPIE advisors with a diagnosis of dementia could need additional time to process discussions and respond accordingly. This could lead to another person (often their supporter), speaking before them or on their behalf. We therefore used techniques such as turn-taking and signalling using purpose made cards or simply a 'hands-up' gesture to try and avoid this.

Dementia friendly, accessible venues in familiar city centre locations were identified by the group in preference to university campus settings which were deemed too busy and confusing. Use of community venues proved positive and some advisory group members reported that they had engaged in an activity in or near such venues following meetings such as shopping or going for lunch. Whether this was simply opportunistic or attending the advisory group resulted in greater confidence to do more activity is unclear.

Activities where the Trial Management Group requested specific input from PPIE advisors and how their contribution impacted the study included:

1. the design of participant newsletters which were originally designed in newspaper column format but were changed to a cross page format which our advisory group reported as being easier for people living with dementia to read.
2. the content of a study proforma completed by facilitators and sent to study participants, summarising the group or individual sessions as part of the intervention. With consultation identified that the content needed to be personalised by adding the participants name and that the overall language used should be simplified using less research terminology.
3. the content, deliverability and impact of burden for our qualitative interview schedule. Advisor feedback proposed that the language and wording should be more concrete for study participants to engage with and that to scaffold recall during the interview researchers should use prompts about what had taken place during intervention sessions. Consequently, the researchers asked shorter more direct questions for clarity and understanding; and referred to activities the participant took part in to prompt recall.

*Trial delivery and data collection.* Our PPIE group advisors' and Trial Steering Committee PPIE member's views and ideas on participant retention during the lifetime of the study were invaluable. For the trial we were collecting outcome data for up to 12 months after recruitment from all participants whether they had attended the intervention or been randomised to treatment as usual. Recommendations that were actioned included:

- Emphasising the value of contributions from all participants whether they received the intervention or not in the participant newsletter.
- Booking follow-up researcher visits in advance as part of their first visit with a participant. This would mean that all follow-up visits would be in the diary and a confirmation would just be needed nearer the time of the follow-up.

- Sending a reminder card (rather than letter or sheet) before attending follow-up appointments. PPIE members proposed that a card would be brighter and more visually appealing to participants thereby reducing the anxiety that a formal letter may provoke.
- Including a photo of, and a personal message from, the researcher doing the follow-up.
- Communicating with supporters about the importance of the person with dementia's participation in the study.

*Data analysis.* Advisory group members used their personal experiences of living with dementia to assist the researchers to understand and interpret our qualitative data.

Advisory group members were approached to participate in two half day validation workshops to discuss and reflect upon researcher interpretations of anonymised data from qualitative interviews conducted with participants and their supporters. Their contributions informed the final analysis of interview data (Sprange et al., 2021). We had to obtain consent from each participant at the outset and identified appropriate researcher resource to do this in a relaxed manner. However, this was could not be achieved with those who arrived late to the workshop where consent was taken at the earliest convenience, typically a break time, so as not to disrupt the flow of the group.

Quotations selected through researcher consensus to be representative of the themes identified in the framework were presented as raw data, i.e. without coding or categorisation (Sprange et al., 2021). These were presented for discussion one at a time alongside some descriptive and contextual detail to aid understanding. For example, who was speaking i.e. participant or supporter and what the person was talking about, such as an element of the intervention or about its facilitation. Consideration was given to how to present each quote to the group in a dementia friendly format to aid understanding (DEEP). This included use of large font size, colour of paper, amount of text per quotation and printing one copy per person. By using ongoing validation observation techniques such as listening and reflecting to gauge understanding and interest in the activity during the workshops the researchers were able to support participation.

The difficulties posed by dementia as experienced by participants were varied which made pitching the task correctly and maintaining the engagement of everyone a challenge for researchers. During our first workshop the level of direction provided by researchers was therefore relatively high. As this was a novel approach to PPIE in dementia research there was some concern expressed by the researchers of not wanting to overwhelm the group. Therefore, different approaches were needed to engage and support those with more severe memory deficits e.g. giving adequate time for the group to read and re-read quotation as well as presenting quotation in both written and verbal formats (facilitator read aloud the quotation). The facilitator also started with an open-ended question such as "what do you think this person is saying/feeling?", but this may have been followed up with a more structured question to aid contribution for example focussing on an interesting word or phrase in the quotation to initiate discussion. For those with less severe symptoms of dementia, and the supporters who took part, there was enthusiasm and great interest in the research and being part of the interpretation of findings. Those less cognitively able appeared to enjoy the social occasion but it was less clear whether they had been able to engage with all the materials.

Whether to provide participant training for this activity was debated amongst the research team. Some considered that training would be helpful to guide and support engagement in the activity (Roberts et al., 2019), whereas others felt that memory and retention of training prior to the activity may be challenging and therefore could cause frustration or distress. We ultimately decided not to undertake a separate training session prior to the workshops but instead we took time at the start of each session (after consent was taken) to summarise the study and the activity. We included a practice example which we worked through together where the researcher could prompt the group

on items we were looking for feedback such as languge used or emotions expressed in the quotation. In addition we also provided visual aids in the form of flip charts bullet stating key facts about the trial to scaffold memory (DEEP).

To support engagement we provided props such as 'I want to speak please' cards (DEEP) as a communication aid to indicate when a person wanted to speak. However, we found in our experience that these cards were seldom used. Potential reasons were that firstly, the group were not used to using these props and therefore there was no habit to do so, and secondly this was a well-established group where supporters as well as the more cognitively able members already felt comfortable speaking with each other and enabling each other to participate. However, we also noted that those who were more challenged by symptoms of dementia were more likely to use the cards.

*Dissemination activity.* Advisory group members were consulted on the format and content of both hard copy and online versions of a lay summary of study results. These documents were intended for a wide readership including people living with dementia who had taken part in the trial, members of the public and health and social care professionals. PPIE feedback led to the inclusion of information about organisations that can support people living with dementia and information about how the results might be used to inform healthcare and future research. The group also helped us design and produce a satisfaction questionnaire to obtain feedback regarding the presentation and comprehensibility of the summary findings. This was considered important to review whether our findings were accessible and relevant to people living with dementia and those who care for them as well as for the lay public, clinicians and academics.

Our final trial dissemination event open to all was held in a central public venue with invitees including researchers who had been associated with the study, people living with dementia, members of the public and health and social care professionals. Advisory group members suggested the need for a speaker protocol to encourage presenters to make their session accessible for people living with dementia including means by which those attending might interact with speakers. Consequently, all speakers were provided with a protocol and large cards were made available at the venue that stated, 'I don't understand', 'I want to ask a question' and 'Please speak more slowly' which delegates did use.

PPIE advisors also recommended that study team members wore brightly coloured sashes that identified them as 'helpers' and suggested they should be situated at the main public transport hubs where people attending the event might arrive and at the venue entrance. A member of the advisory group, a former supporter, also volunteered to co-host the event reception desk with a member of the study team. At a previous meeting, advisory group members had been invited to speak about their experiences of being involved in research, but none accepted. Several advisory group members did however volunteer to be involved in making a video to demonstrate the intervention as part of a study dissemination film (https://www.sheffield.ac.uk/scharr/research/centres/ctru/jtd) which was viewed at the event.

## Discussion

We achieved involvement in all stages of this large randomised controlled trial at a time when this level of engagement of people with a dementia diagnosis was not established practice. Importantly the voice of people living with dementia and their supporters was heard first-hand and acted upon, which is acknowledged as being essential (Poland et al., 2019). However, we also found that meaningful involvement could be challenging at times and our aspirations could not always be met,

particularly given that PPIE described here was for a trial with necessary study processes such as rigid methods of consenting people into a trial.

During PPIE involvement in data analysis activities we found that the informed consent process could easily disempower people, including those with the capacity to consent. The process was time consuming and burdensome for some people with a diagnosis of dementia who found it confusing to have to agree to numerous statements. It is important that people living with dementia feel empowered to make decisions for themselves when consenting (Thorogood et al., 2018). We therefore suggest that using a simplified consent form, co-produced with people living with dementia, would minimise unnecessary participant burden whilst complying with research governance requirements. At the outset of this trial, researchers aspired to create and test methods of video consent for potential trials participants, but it was quickly realised that this could not be achieved within the resource constraints of the study.

Having reliable methods in place to encourage and capture the impact of involvement activities was greatly facilitated by having a designated PPIE lead, a role now compulsory with some funders such as the UK NIHR. In addition, researchers within the study team who were both knowledgeable and supportive of PPIE was essential. Our experiences underscore the need for researchers to have expertise in working with people living with dementia or that the requisite training and support is provided so that they always take a sensitive and considered approach, enabling involvement in an informed and nuanced manner (Gove et al., 2018). The more we undertake research involving people living with dementia as PPIE advisors or co-researchers the more we learn to pave the way for models of successful participation in research (Roberts et al., 2019).

Patient and public involvement and engagement advisory group members were recruited from existing PPIE cohorts and networks. Whilst this approach perhaps led to a more relaxed exchange of ideas between researchers and PPIE advisors, it created limitations in terms of diversity. Almost all our PPIE advisors were White. Also, some members were living with more advanced stages of dementia which did not reflect the population of study participants. As the membership of the PPIE advisory group evolved, people living in earlier stages of dementia, including some who lived alone joined the group. How to ensure the involvement of the range of people who represent any one group remains a challenge (Witham et al., 2020) and in common with overall recruitment to dementia studies, achieving diversity is difficult (Field et al., 2019). We recommend that to reflect the study population, early liaison, during the design phase of research, with representatives from relevant community organisations might gain support, both for participant recruitment and for recruitment of PPIE representatives. This may in turn increase interest in research from underrepresented groups.

It may require time for people living with dementia to feel participation in research is meaningful (Stevenson & Taylor, 2019). Feeling useful and being able to help others is important to people living with dementia (Perkins R et al., 2013) but it is important to consider what might be other motivations and needs of people acting as PPIE advisors to research. We found that members who had recently received their diagnosis sought personal support and specific advice from the group and from researchers regarding their recent diagnosis and what this meant for their future. Those supporting PPIE therefore need to understand the boundaries between research, clinical advice and personal support and be prepared to respond by signposting individuals to appropriate services. Family members can feel the need to protect people living with dementia, which can lead to a form of gatekeeping, taking decisions on behalf of the person with dementia (Waite et al., 2019). During this study we found that some supporters spoke on behalf of their spouse on occasion. Researchers were aware of the need to listen to the voice of the person with dementia (Gove et al., 2018) and study team members explored ways of achieving this for example ‘turn taking’ and using smaller discussion groups. It has also been observed that offering guidance to supporters on how to enable the

people they support to be involved in PPIE activities may be beneficial and make the supporter feel valued (Gove et al., 2018).

Involvement in the Trial Steering Committee for this study did not meet agreed best practice (National Institute for Health and Care Excellence, 2019) in that only one person with a diagnosis of dementia was recruited to the committee. The arrangement was considered to work well due to the skills and previous experience of the PPIE representative but having two members to take account of absence and meet needs for peer support is recommended. Being a Trial Steering Committee PPIE member had different demands compared to the PPIE advisory group member, for example, due to the time lag between meetings and the necessary independence of the Trial Steering Committee which aids objectivity but also creates distance from the study. This can affect ability of all PPIE members to retain knowledge and understanding of the trial, but particularly if the person is living with memory issues. Therefore, approaches to scaffold memory and recall are helpful and should be provided as we identified during this study.

In accord with best practice (Ashcroft et al., 2016; Litherland et al., 2018; Wilson et al., 2015), providing opportunities to share experiences and coping strategies whilst at the same time advising on the study proved important. Additionally, we found that hosting advisory group meetings in a community setting could provide social opportunities that might not have occurred otherwise. Most of our PPIE advisors were, or had recently been, involved in other research studies which perhaps created an understanding of research, and familiarity with other PPIE advisors, that was helpful to enable them to participate.

Our experiences have confirmed that PPIE approaches, and processes need to be established early on to have greatest effect upon the design and implementation of a study. The time taken to establish the advisory group meant that some decisions which would have benefited from PPIE input were initially taken in the absence of consultation, for example, the format and presentation of newsletters sent to study participants which was subsequently changed following recommendations from the advisory group.

Questions remain about how to achieve maximum involvement in research outputs such as presentations and publications. The window within which meaningful engagement can occur is influenced by a complex interaction of factors including the impact of diminishing cognitive abilities, other impairments as a consequence of dementia and the resilience of the individual. However, when working with people with a diagnosis of dementia (as some of our PPIE advisors were) the convention of writing most outputs at the end of a study can limit the participation of PPIE advisors as it relies on recall. Indeed, in the preparation of this paper for publication we left writing up towards the end of the trial and the PPIE advisor approached to contribute felt they could not recall their involvement sufficiently to directly contribute, thus creating disparity between the voice of the researchers and the voice of people living with dementia. We therefore propose assisting PPIE advisors to record their experiences in real time which might result in authentic publication. This would also build up evidence for dissemination or create opportunities for on-project dissemination activities reinforcing the value of the PPIE role and contribution.

Involving people living with dementia in the analysis of data can improve the quality of research, and if done well can be a satisfying experience for PPIE advisors and researchers (Stevenson & Taylor, 2019). The importance of providing PPIE members with appropriate training and support for this and for other aspects of the role is indisputable but questions remain about how this can be achieved to best effect when involving people living with dementia (Roberts et al., 2019). More specifically; for people with a diagnosis of dementia when does PPIE involvement become too much of a challenge (Waite et al., 2019) and who decides; and secondly how can needs for training and support be most effectively met (Wilson et al., 2018).

## Conclusion

We posit that we could improve engagement of people living with dementia in research through increasing diversity and adjusting research processes to be more accessible. This in turn would create parity of voice between people with lived experience and researchers and increase the impact of meaningful PPIE in research whilst improving the experience for PPIE advisors. Many aspects of our approach to involving people living with dementia in supporting study processes were effective in that members of the advisory group reported their involvement as enjoyable, sociable and satisfying. Regular review of the purpose and approach to PPIE on any study is necessary and can improve the experience for PPIE members. There is also a need to be realistic in time people with dementia might be willing to give and any opportunity for shorter commitment with 'succession planning' in place.

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### Author contributions

CM led PPIE recruitment and co-ordination supported by GM, JW, CC and JBD. LB provided advice and guidance on PPIE involvement in qualitative analysis. WM was the TSC PPIE Member. KS and JBD lead the qualitative analysis workshops supported by CM, GM and JW. GM, KS and JBD developed the manuscript. All authors reviewed and approved the final manuscript.

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The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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### Ethical approval and consent to participate

Ethical approval was obtained in July 2016 (ref no. 16/YH/0238) from the United Kingdom National Health Service Research Ethics. United Kingdom Health Research Authority approval was given (IRAS reference 199383) in August 2016.

### Informed consent

We obtained written informed consent for the participants who took part in the qualitative analysis workshops via a Consent Form. This information is held as part of the archived record of the trial. Only anonymised

nonidentifiable data are used in this report as per written consent. Members of the advisory group and trial steering committee gave their permission for their quotes to be used.

## Availability of data and material

The datasets generated and analysed for this study will be available upon request from the corresponding author.

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COMMENTARY

# The implementation of Journeying through Dementia: Strategies to run a successful pragmatic multicenter trial of a complex intervention

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## Abstract

**Objective:** A key challenge in delivering pragmatic trials of complex interventions is effective implementation within the study period and beyond. We describe a trial of an intervention to improve quality of life in mild dementia (Journeying through Dementia), describe some of the challenges raised in terms of implementation, and illustrate the methods used to ensure effective implementation.

**Method:** The intervention was delivered by staff within local services and supervised by more experienced clinicians within those services in order to test the intervention in real-world settings and establish the potential for future embedding into practice. Researchers delivered training sessions for all facilitators and supervisors, met at regular intervals with intervention supervisors, and provided feedback on summaries of intervention sessions created by facilitators. We conducted a thematic analysis of the content of meetings and written correspondence between the researchers and intervention supervisors regarding implementation issues.

**Results:** Key themes relating to difficulties with implementation were: staff absences and staff leaving posts; participant lack of engagement with intervention; difficulties with delivery of supervision; difficult group dynamics; lack of time to deliver the intervention; and lack of adherence to the intervention and its ethos.

**Conclusion:** We provide guidance for researchers involved in the trialing of other complex interventions in how these challenges might be overcome. These include: recruiting additional staff to deliver the intervention; having clear protocols in place for managing staff absences; using supervision to problem solve participant attendance at intervention sessions and difficult group dynamics; monitoring staff engagement in supervision and addressing problems with engagement with staff and managers when this occurs; giving staff ring-fenced time to deliver the intervention and engage in supervision; and regular monitoring and feedback in relation to the content of the

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intervention to ensure that it is consistent with ethos and content of the intervention manual.

KEYWORDS
complex intervention, dementia, implementation, pragmatic trial

## 1 | INTRODUCTION

A complex intervention is a programme of interconnected components, which may be implemented in a variety of ways to address problems in health and social care settings (Craig et al., 2008). New complex interventions should be evaluated through randomized controlled trials (RCTs) (Craig et al., 2008). RCTs are either explanatory or pragmatic. Explanatory trials measure the benefit of an intervention using a homogenous, well-defined sample of participants with highly trained interventionists. Pragmatic trials measure effectiveness—the benefit of the intervention for routine practice (Tosh et al., 2011).

One key problem in the delivery of pragmatic trials of complex interventions is poor implementation of intervention models (Ditcher et al., 2017; Sturkenboom et al., 2016). Implementation refers to reach (the proportion of participants receiving the intervention); fidelity (whether the intervention is delivered as planned); and dose delivered and received (the amount of intervention delivered and the extent to which participants responded to it) (Linnan & Steckler, 2002). Complex interventions have scope for variation in delivery so are vulnerable to components not being implemented as intended (Carroll et al., 2007). This is problematic as the level of implementation is a key moderator of outcomes (Carroll et al., 2007). Researchers often attempt to optimize implementation through obtaining "buy in" from key stakeholders, the use of manuals, training and supervision and monitoring and feedback (Gearing et al., 2011; Powell et al., 2013).

In this paper, we describe our experiences as researchers in overseeing the delivery of a complex intervention within a pragmatic RCT. In describing our experiences, we aim to highlight to other researchers the challenges that can present in implementing and evaluating complex interventions within the context of pragmatic RCTs. We also aim to use our collective experiences of successful and less successful intervention implementation both within this trial and other trials to describe how some of these challenges might be overcome.

## 2 | METHOD

### 2.1 | Summary of trial and intervention

The Journeying through Dementia intervention was designed to promote independence, self-efficacy, and continued participation in life by people with mild dementia. It involved 12 weekly, 2-h facilitated groups with 8–12 participants with dementia delivered in a community venue, as well as four one-to-one sessions ideally with the same facilitator for individual goal setting. The intervention was designed for delivery by two Band 4 staff NHS Agenda for Change members (either healthcare support workers or assistant psychologists who were not registered health or social care professionals) and supervised by a minimum Band 7 staff member NHS Agenda for Change (either a senior nurse or other allied healthcare professional).

The mannualized intervention contained a menu of topics, which were identified through consultation with people with dementia (Mountain & Craig, 2012) and explored within a feasibility study (Sprange et al, 2015). Topics included understanding dementia, relationships, physical and mental well-being, daily living, skill development, and planning for the future. Each group session involved the same structure, which included information giving, discussion, and practical activity with an essential component being enactment of activities in the community with support from each other and the facilitators. The content of the one-to-one sessions was guided by the participant's choice but also involved enactment of activities in the home and/or community. The first one-to-one session with each participant took place before the commencement of the groups. This provided an opportunity for the facilitator to meet the participant and discuss the practicalities of attending groups and any concerns.

Facilitators were asked to document all intervention sessions on a proforma provided by the trial team and post these to the participants before the next session, thereby providing a record and reminder of what had taken place. One-to-one session records were intended to be written in collaboration with participants. Facilitators were told that all documents should be written in accordance with DEEP (Dementia Empowerment and Engagement Project) guidance for best practice in providing documentation for people with dementia (e.g., first person, accessible language, etc.) (DEEP, 2013).

A large, multicenter RCT was conducted to understand how effective Journeying through Dementia was in improving well-being, self-management abilities, and independence of people with mild dementia and how much the intervention cost compared to treatment as usual (Wright et al., 2019). The trial involved 13 sites and 480 participants diagnosed with dementia. There were 28 groups across the sites involving 69 facilitators and 21 supervisors. The trial included a fidelity substudy to determine if the intervention was delivered as planned and help understand the study outcomes, as opposed to using findings to inform and improve delivery during the trial (Sprange et al., 2021a). The trial also included a qualitative study to help contextual findings (Sprange et al., 2021b).

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## 2.2 | Procedures to support successful implementation of the intervention

Facilitators received training prior to delivering the intervention. Once intervention delivery commenced, facilitators all received weekly supervision for at least an hour from a more senior professional from their place of work who had also received training in the intervention model and the role of supervision in the trial. Facilitators and those supervising them all maintained records of the nature and duration of each supervision session using trial proformas. A supervision protocol was provided to guide supervision and included the importance of a mix of individual and group supervision with facilitators (see Sprange et al., 2021 supplementary material).

In order to circumvent the challenges associated with delivering a new intervention, which neither supervisors nor facilitators had prior experience of, members of the research team delivered a mixture of individual and group supervision to the supervisors via monthly face-to-face or phone meetings. These members of the research team were experienced clinical psychologists who undertook the same training as facilitators, but also had extensive previous experience of both delivering and supervising psychological therapies as part of RCTs. As a further measure to ensure that the intervention was being delivered as intended, facilitators were asked to photocopy records and other documents relating to the intervention and send them to the research team for review. Sites were initially requested to send the records at the end of the 12-week intervention period. However, to improve intervention fidelity on an on-going basis, half way through the study, site interventionists were asked to return records every three weeks. Generic cross-site feedback on deviations and consequent further guidance was provided by email communication to all sites actively delivering the intervention. Personalized feedback was not given to sites as it was felt that this process was not in keeping with the ethos of a pragmatic "real-world" trial.

## 2.3 | Analysis of implementation challenges

In order to provide a systematic means of summarizing key challenges to implementation and focus our discussion on ways to mitigate potential difficulties in running a pragmatic trial, we carried out a thematic analysis of data from supervision records. Supervision records were word files that documented the content of meetings between members of the research team responsible for overseeing implementation and the site supervisors, as well as email correspondence between the research team and supervisors. These records and email correspondence were maintained by the research team. We carried out the thematic analysis of anonymized versions of this data in line with the steps outlined by Clarke and Braun (2013). The first step involved the first author (KB) reading anonymized versions of the logs and email correspondence several times to facilitate familiarization and highlight relevant issues. Next, a more detailed analysis was carried out to identify initial codes using an inductive, data-driven approach. Related codes were grouped into "code families." Data for each code and the relationships between codes was explored by KB and in conjunction with an undergraduate researcher. This enabled codes to be grouped together to form overarching themes, which were verified and refined as the analysis proceeded. Reflexivity is the process of acknowledging and reflecting upon the researcher's role and reflective experience (Clarke & Braun, 2013). KB is a clinical psychologist with experience in the delivery and supervision of a number of different trials of psychosocial interventions. The other authors who commented on the analysis are all experienced trialists of psychosocial interventions.

# 3 | RESULTS AND DISCUSSION

There were six main themes in the data, which relate to implementation challenges. We use these themes to structure our discussion of how to successfully overcome challenges and run a pragmatic trial of a complex intervention. In doing so, we draw on both our past experience of running trials (foreseen problems) and lessons learnt in the current study (unforeseen problems).

## 3.1 | Staff absences and leaving posts

One of the most significant challenges to implementation that arose during supervision sessions with the research team was staff absences and turnover. Difficulties in identifying and retaining people to deliver interventions is a secondary recruitment target, which is a usually overlooked but common problem for trials of complex interventions (Biggs et al., 2020) and can reflect the frequent high levels of staff sickness and turnover within health services (Willard-Grace et al, 2019). The issue affected both facilitators and supervisors but did not disrupt the delivery of the intervention due to a number of measures we put in place. First, we encouraged sites to train more than the two required facilitators to deliver the intervention before they commenced delivery. In this regard, we also recommended that additional facilitators were introduced to group participations at the outset in the event that they needed to step in. There is a risk that these facilitators may forget aspects of the training if they are not delivering the intervention on a weekly basis, but this was less of a concern given that the group was co-facilitated. Second, we delivered bespoke training to new facilitators or supervisors, which was supported by online resources. We used this system when people left a post or to train extra staff at sites where intervention or supervision delivery were proving difficult. Third, following queries from sites about what to do in the case of staff absences, we had a clear protocol for sites to follow in the event of a planned or unplanned absence, which involved liaising closely with the research team to ensure that sessions went ahead unless totally unavoidable and that the most suitable cover was provided. If no trained facilitators were available, substitute facilitators included supervisors or other clinically experienced staff supported by the research team through phone calls.

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### 3.2 | Participant lack of engagement with intervention

Another implementation issue that was discussed within supervision with the research team was that of participants not attending group intervention sessions. We sought to recruit 12–13 people per group, anticipating an average weekly attendance of 6–8 participants. Despite low numbers at some sessions (defined as less than four participants), we made a post hoc decision to go head and run groups with less than four people. We considered that it was more ethical to run the session for those who attended than to cancel it. When group sessions regularly had low numbers, supervisors noted that this impacted upon the morale of facilitators and we encouraged supervisors to reflect on these reactions as part of supervision. Reasons for participant nonattendance identified by supervisors included holidays, engagement in other social activities, hospital appointments, illness, and problems with travel. The former two reasons probably reflected the fact that participants in our trial were relatively high functioning despite their diagnosis (Wright et al., 2019). Conflicts with hospital appointments were due in part to our population being older and therefore more likely to be experiencing comorbid health problems. The challenges with travel were somewhat foreseen and resulted from the fact that some people were no longer able to drive, lacked confidence in using public transport (which could also be unreliable with limited coverage in some locations) and carer reluctance to let participants travel independently. In a number of instances, facilitators were encouraged through supervision to work with people to overcome travel challenges (e.g., practicing the route, sharing lifts, etc.). However, such problem solving needed to be discussed before the individual attended the first group meeting and we advised facilitators that the first one-to-one session should be used for this purpose. Notifying people in advance of the dates and times of each session also helped to reduce clashes of different commitments. The fact that the intervention was delivered over 16 sessions (12 group and 4 individual) helped to ensure that even if people could not attend every session they would still be able to receive a significant therapeutic dose (defined as attending 10 of the available 16 sessions including the one-to-one sessions).

### 3.3 | Supervision delivery

Problems in the delivery of supervision due to lack of perceived need by facilitators or the busy schedules of supervisors were raised as issues by supervisors in monthly meetings with the research team. We anticipated attendance at supervision may have been an issue, which was a primary reason for recording and monitoring supervision using logs, which were submitted to the research team. Staff level of engagement in supervision often reflects the organization's culture and whether or not it is supportive of supervision (Snowdon et al., 2020). Where these problems occurred, we discussed possible solutions with the supervisors themselves or site principal investigators. Factors that facilitated the delivery of supervision sessions, which were ideas generated with supervisors during the trial, included delivering some supervision sessions via online platforms when supervisors and facilitators were based at different sites, scheduling all supervision sessions in the diary in advance of intervention delivery commencing and training a second supervisor if one supervisor was feeling overburdened. The commitment of service managers to deliver interventions and the supervision structure to support it is also key and involving these individuals during the design or set up phase helped to ensure this commitment as highlighted in previous studies (Raphael et al., 2021).

### 3.4 | Group dynamics

The dynamics between participants during group sessions and how this could affect delivery of the intervention were issues that were often raised and addressed within supervision and also raised with the research team by supervisors. The impact of group dynamics on delivery of group-based interventions has been previously documented in trials of group-based interventions (Biggs et al., 2020), but also in routine clinical settings (Montgomery, 2002). Although there were no easy solutions to the problems posed, we recognized that it was important for facilitators to have an opportunity to reflect upon the difficulties they were facing during supervision and collectively think of ways to manage the situation, particularly as supervisors reported that these difficulties during the trial could negatively impact upon the enthusiasm of facilitators. A commonly reported challenge that our supervisors identified was that of group members being passive, making it hard for facilitators to engage them in collaborative decisions about how the group should be run and which topic areas to cover. Some supervisors reported to the research team that this was a particular problem for less experienced facilitators who were inclined to make decisions on behalf of the group. However, according to supervisors, some groups and facilitators did grow in confidence over time, resulting in more collaborative decision making by participants. This increase in confidence was attributed to greater experience in running the groups and suggests that more opportunities to role-play difficult group dynamics within training or opportunities to initially co-facilitate with more experienced staff may have been beneficial. Consistent with previous research, some supervisors highlighted a mismatch between the group of people who would be picked as ideal candidates for each group versus those consecutive people meeting study inclusion criteria who had been randomized to the intervention arm of the trial (Biggs et al., 2020). Supervision was used to discuss differences between delivering interventions as part of a research trial and delivering a group intervention in clinical practice.

### 3.5 | Time to deliver the intervention

Facilitator workload and time pressures was a frequent theme raised during supervision. This barrier was anticipated and not surprising given how overstretched health services often are (Willard-Grace et al., 2019). In order to minimize the impact of these constraints, we tried to

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ensure that the facilitators had ring-fenced time to deliver the intervention through clear agreements with their employing organizations and by asking the supervisors to regularly check that people were being released from other duties for the agreed periods of time. These regular checks ensured that the research team could be alerted to problems early on and highlight any problems with site principal investigators who had accepted overall responsibility to ensure the delivery of the intervention. Supervisors also frequently worked with facilitators to help them manage their time and assert themselves if asked to carry out competing demands during time that had been allocated to the study. A number of sites did, however, reflect that preparing for sessions took longer than anticipated, especially during the early stages of the study when they were less familiar with the intervention. This highlights the importance of ensuring staff build in sufficient preparation time early on. Although we had previously piloted the intervention delivery (Sprange et al., 2015), this had involved more highly trained facilitators who may have been able to able deliver the intervention more efficiently. Delivering an intervention with less experienced staff may reduce the costs of the intervention and may increase the availability of potential supervisors, but the fact that less experienced staff may require more time and support to get the intervention up and running must be factored into planning.

### 3.6 | Ethos of intervention and way it is delivered

The ethos of the intervention focused on working in partnership with people with dementia, enabling them to make their own decisions within the sessions and their own lives. The pre-intervention training placed a strong emphasis upon the importance of challenging paternalistic attitudes and risk aversion, which are common within the health service (Shapiro, 2010). Nonetheless, conflict between the ethos of the intervention and risk averse culture of the host organizations frequently emerged throughout intervention delivery. This issue was particularly apparent in relation to the out-of-venue activities, which were a key aspect of the intervention. Out-of-venue sessions were to help people maintain independence and practice new or neglected life skills in community settings. Supervisors reported that facilitators often raised concerns about risks associated with these activities during supervision. In some instances, such concerns had resulted in facilitators wanting to avoid community-based activities altogether. It was therefore important to address this issue by regularly checking with supervisors regarding the scheduling of out-of-venue activities and encouraging them to manage facilitator anxieties as part of supervision. For example, supervisors were encouraged to help facilitators to articulate specific concerns about what might go wrong during community-based activities and think through contingency plans in event of their fears be realized. Part of this process also involved reminding supervisors of conveying the benefits of positive risk taking and the need to respect participants' choices if they had capacity to make the decisions in question.

Two further issues arose during the trial, which were related to the delivery of the intervention. First, facilitators were required to write summaries at the end of each session, which could then be used as an aide memoir by participants. The research team regularly checked these summaries for two reasons, first to review the content of the intervention being delivered and second to determine the accessibility of such records for participants. This process was also very important in alerting us to the use of clinical language by some facilitators. Supervisors were subsequently asked to review end-of-session summaries as part of supervision and provide facilitators with guidance on how to use lay language and dementia friendly presentation, with some improvements noted over time.

Second, supervisors reflected that those facilitators that were less experienced often lacked confidence in delivering the one-to-one sessions possibly due to the lack of specific detail about what to cover within the intervention manual and training. When we reviewed the facilitators' records of the sessions, we also noted that one-to-one sessions were sometimes just a recap of the previous group sessions with the individual. In response to these issues, we asked supervisors to encourage facilitators to think in more detail about how to tailor one-to-one sessions to the needs and wants of each person. We proactively encouraged supervisors to feedback both strengths and possible areas for improvement to facilitators, with the knowledge that supervisors can sometimes be less able to provide feedback in relation to the latter (Lefroy et al., 2015).

## 4 | CONCLUSIONS AND SUMMARY OF RECOMMENDATIONS

This paper summarizes challenges that arose in implementing and evaluating a psychosocial intervention for people with mild dementia as part of a complex RCT. It also outlines how we used our collective experience from both previous studies and within this current study to circumvent and deal with these challenges. It is important to identify and surmount such challenges in order to uphold the validity of the trial findings and provide value for money (Tosh et al., 2011). Key challenges such as staff attrition, varying levels of participant and staff participation in aspects of the intervention and lack of adherence to the ethos or content of the intervention are likely to be faced by other researchers who seek to implement and evaluate complex interventions in real world settings. We hope that some of the strategies we used to circumvent these challenges may be useful for others. Other challenges and potential solutions are more specific to the nature of our intervention and our target participants. We believe that this paper is particularly timely given the recent proliferation of psychosocial interventions for people with a diagnosis of dementia, as well as for other groups of people living with complex long-term conditions.

One of the most significant challenges to implementation that we successfully circumvented by training additional facilitators and supervisors was staff absences and turnover. We therefore recommend that implementers should build in sufficient resource to train additional staff and offer this training in a range of formats on a regular basis. There should also be protocols in place for introducing potential new staff to participants and clear protocols regarding the skills and

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qualities of those who might be substituted. In terms of maximizing participant attendance at group sessions in particular, we would recommend slightly over recruiting to groups to ensure the number of participants per group session does not drop to unacceptably low levels for either facilitators or the participants themselves. Where attendance is low, we also recommend that facilitators work closely with individual participants to identify and solve problems as far as is possible. This solution-focused thinking should be built into the early stages of the intervention, including the possibility of scheduling all intervention sessions in advance. We would also recommend using supervision to help facilitators reflect upon issues that low attendance may raise for them in terms of morale. To maximize staff attendance at supervision (which is an essential mechanism for ensuring effective delivery of interventions), we recommend a means of regularly monitoring levels of supervision and addressing local barriers, which could be both attitudinal and pragmatic, in a timely manner.

Within the context of a trial of an intervention involving delivery of group sessions, there may be little that can be done to circumvent the inherent challenges with group composition, unless recruitment rates are high and groups are running simultaneously and in close locations. However, it is possible to reduce the impact of resulting difficulties in group dynamics by using supervision to raise, validate and, where possible, address problems. Recruiting facilitators experienced in group work and/or have good skills engaging others may also help address staff lack of confidence, although this may not always be possible due to the aforementioned difficulty in recruiting intervention deliverers.

In line with other trials and research exploring barriers to implementing interventions in routine practice (Raphael et al., 2021), we found that it is essential that staff are given ring-fenced time to deliver the interventions and that this is supported by senior and immediate level management. We also recommend that the time needed for novice facilitators to deliver the intervention and the consequent need for adequate backfill should not be underestimated to avoid building resentment from either intervention deliverers or their managers if the work is more time-consuming than expected.

Reasons for lack of adherence to the ethos of the intervention or its content were specific to the intervention, which we were implementing and evaluating. For example, our findings highlighted the some staff within community services for people with dementia may not have been fully socialized or equipped to work in "dementia friendly" ways. Nonetheless, issues of facilitator adherence are pertinent across all trials and are likely to be more significant in implementing complex interventions in the context of pragmatic trials or routine clinical practice (Tosh et al., 2011). Our findings highlight the importance of providing adequate training on all aspects of the intervention, clear and detailed manuals, and monitoring of adherence within the context of supervision with oversight from experienced clinicians within the research team. Within pragmatic trials, there is, however, a careful balancing act between implementing the intervention as intended without enhancing the intervention beyond what would ever be possible to deliver in real world settings. One way to manage this balancing act is for researchers to co-create interventions with key stakeholders such as potential participants, their carers, intervention deliverers, and their managers (Richard et al., 2017).

## AUTHOR CONTRIBUTIONS

Conceptualization: KB, GM, KS, and CC. Formal analysis: KB. Funding acquisition: GM and CC. Writing—review and editing: all authors. Writing—original draft: KB.

## CONFLICT OF INTEREST

None to declare.

## TRANSPARENCY STATEMENT

The manuscript is an honest, accurate, and transparent account of the study being reported.

## ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This paper is a commentary so did not receive ethical approval per se but the trial we refer to had full ethical approval and participant written informed consent. The trial protocol was approved by UK Leeds East Research Ethics Committee, on 01/07/16, reference number 16/YH/0238.

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## CONSENT FOR PUBLICATION

We gained consent to publish this paper from all supervisors within the trial.

## PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1002/brb3.2436

## DATA AVAILABILITY STATEMENT

Anonymized data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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# Chapter 5 - Main findings

This thesis has presented ten publications, four for the Lifestyle Matters trial and six for the Journeying through Dementia trial. Eight of these are methodological publications covering qualitative evaluation and fidelity assessment, as well as implementation and PPI engagement. The remaining two publications report the main trial results. Findings from this body of work raise a number of important considerations in relation to the design and conduct of fidelity assessment in clinical trials, policy, practice and future research of self-management interventions for adults experiencing age-related decline including those living with early-stage dementia. These are:

1. Acceptability of the self-management model by older adults at risk of age-related decline including those experiencing age-related decline, their carers; as well as services delivering such interventions.
2. Limitations of current fidelity assessment methods to evaluate community-based self-management interventions.
3. The utility of existing outcomes measures for older adults experiencing age-related decline including those living with early-stage dementia.
4. Requirements for intervention design to support engagement and improve effectiveness in these populations.
5. Challenges recruiting those who would most benefit from self-management interventions designed to prevent decline and promote healthy ageing.

The following chapter will now explore each of these considerations in greater detail which will be followed by a summary of the strengths and weakness of the included works.

## 5.1 Acceptability of the self-management model

### 5.1.1 Risk averse health and social care culture

What both trials revealed was an embedded risk averse culture in health and social care settings. This appeared to be exacerbated when introducing self-management interventions for what were deemed vulnerable adults. Self-management interventions are still relatively new in services and differ to existing service provision. For example, Journeying through Dementia was described as more proactive and interactive than current services, offering early professional input, a community focus and supporting enactment through the out-of-venue activities *[Publication 8]*. This was therefore a challenge for facilitators on both Lifestyle Matters and Journeying through Dementia interventions in which their approach to delivery was impacted by their sense of duty of care and ethical practice rather than empowering participants as per the self-management approach. For example, in Journeying through Dementia, one facilitator, from a healthcare background, expressed concerns about accompanying participants into the community. They specifically questioned organisational accountability and performed a formal

risk assessment prior to an activity *[Publication 8]*. This suggests a key dilemma facing health care providers, that of balancing organisational liability with the self-management approach.

The UK healthcare system may not be set-up or prepared for self-management interventions that place the participant in control, and that time and training is required to embed new practice so that it becomes the norm and for staff to feel confident [107]. This was our reflection from the Journeying through Dementia trial which highlighted the need for adequate staffing and ring-fenced time for training to deliver the intervention and engage in supervision *[Publication 10]*. One solution could be to employ non-health professional facilitators like the approach used in social prescribing which connects people to services in their community to meet the practical, social and emotional needs that affect their health and wellbeing [108]. Such individuals would be closer to their communities creating a potentially stronger support network for self-management to flourish during and beyond the intervention. There is also an argument that a social care or community underpinned approach could also be more cost effective than employing health professionals for delivery within a health setting [109].

### 5.1.2 Participant understanding and engagement

Acceptability of an intervention is influenced by our understanding of its purpose and benefits[59]. A clear example of this in both trials was that of understanding the purpose of the individual session component of the interventions. Adherence to this component was very poor in Lifestyle Matters, which was rationalised by the facilitators; a) citing participant lack of understanding of goal setting or even the need for such sessions, b) over emphasising the importance of the group component of the intervention *[Publication 2]*, and c) their perception of participant dis-engagement through non-attendance *[Publication 3]*. Through improved training of facilitators in the Journeying through Dementia trial, individual session adherence was much improved. However, facilitators still cited participant understanding as the main reason for lack of engagement in this component *[Publication 8]*. Insufficiently skilled facilitators could result in participant dis-engagement. Ultimately adequate skilling of facilitators is essential for the delivery of an intervention. Training may require customisation to meet the needs of the wide range of health, social care and community staff who could facilitate such interventions *[Publication 2]*. What was not considered at the time of designing these trials, but should be considered, is the need for greater participant awareness and understanding of the self-management model if we are to maximise engagement and therefore any benefit. For example, improved participant information describing expectations for participation and outcomes.

Another example from Lifestyle Matters, reported by the facilitators, was participant resistance to take control of the intervention. For example, a reluctance to select topics for discussion at

group meetings, identifying goals during individual sessions and responsibility for organising out-of-venue sessions *[Publication 3]*. One facilitator felt their role needed to be clearer for participants, especially if they were from a health professional background, a role traditionally seen to make health care and/or treatment decisions *[Publication 3]*.

Another challenge experienced in the Journeying through Dementia trial, was managing expectations. This specifically related to the Patient and Public Involvement (PPI) advisory groups we enlisted to conduct the trial. It became clear that a distinction between what is clinical and what was research was necessary to prevent disappointment and disengagement *[Publication 9]*. For example, for those early in their dementia diagnosis journey and their carers, saw participation in the advisory group as a way to seek clinical support and guidance. This was also reflected in the intervention, in which facilitators who had a clinical background struggled to separate duty of care as a clinician with the role of intervention facilitator in a clinical trial *[Publication 8]*. This suggests the self-management concept of taking shared responsibility was difficult for participants and facilitators, and challenged the expectations and 'norms' both of the health professional role and of the structure of a facilitated group.

### 5.1.3 Value of quality patient and public involvement

To improve acceptability, we need to improve PPI. The value and benefits of PPI engagement in the design of trials including intervention design and outcome selection is now recognised and encouraged by leading UK funders such as the NIHR[110]. The Journeying through Dementia trial is an exemplar of how this can be achieved working with what are considered a vulnerable population *[Publication 9]*. A finding from the Journeying through Dementia trial was that research processes, although there to protect individuals, also create limitations for engagement in research particularly for those with co-morbidities or living with dementia. A significant example in this trial was the consent process for our dementia advisory group. When participating in data analysis workshops, the consent process was found to be burdensome, time consuming and ultimately disempowering for those participating due to the complexity of the forms requiring multiple initials, signatures and copies. If we are to encourage and engage these populations in the design, development and delivery of self-management interventions co-production of the fundamental processes to participation is key. Co-production is a collaborative approach where professionals and service users (such as patients, carers, or community members) work together as equal partners to design accessible and relevant trial designs and interventions. It is based on the principle that people who use services have valuable expertise through lived experience that can improve the relevance, quality, and effectiveness of research.

What Journeying through Dementia demonstrated is the need for good quality, meaningful and innovative engagement with people with lived experience which uses approaches to support and scaffold participation. Our PPI work showed that significant time, funding and resources are required to successfully engage people living with dementia and their carers *[Publication 9]*. For example, the need for a dedicated trained PPI lead with expertise working with people with dementia. The best methods and tools to support engagement requires further exploration and needs to consider the challenges in changes in capacity when working with people living with dementia [111] or co-morbidities, and how to train and support those with lived experience[112].

## 5.2 Inadequate fidelity assessment methods

### 5.2.1 Bespoke assessment checklists

Existing frameworks identify core aspects of fidelity that are relevant and essential to evaluate self-management interventions. However, how best to assess these aspects typically rely on being able to observe and rate set criteria, which implies some kind of standardisation across observations. Self-management interventions, like that of Lifestyle Matters and Journeying through Dementia, include a number of interlinked adaptations for personalisation for each participant. Whether it is possible to measure a range of adaptions using a standardised checklist requires further consideration *[Publication 2]*. For both trials we developed bespoke assessment tools purportedly capable of capturing this tailored approach (see Appendix 4). These tools were underpinned by the intervention criteria, facilitator training package, manualised programme and a multidisciplinary team including those who developed the interventions. Yet, despite this and a rigorous process of checklist development including a review of existing literature, PPI review and piloting, there were significant challenges in both Lifestyle Matters and Journeying through Dementia *[Publications 2 and 7]*. Much of what we needed to observe related to behavioural change which by its nature is subjective, for example evidence of facilitators enabling participants or participants enacting learned skills. This required the researchers who were scoring assessments to fully understand how such behaviours manifest and use their judgement when interpreting what they observed. A significant amount of prior work was therefore needed by those who were going to undertake the observations to agree how to identify and rate the criteria on the observation checklist *[Publication 7]*. This suggests those undertaking such a role in designing and scoring assessment checklists would benefit from a comprehensive knowledge and understanding of the intervention and facilitator training. Without prior knowledge of the intervention and its underlying ethos such observation and agreement would have been challenging and may have increased potential for errors in data collection and interpretation.

### 5.2.2 Observation methods

Despite using recognised MRC recommended guidance for evaluating complex interventions, both fidelity assessments were limited by our inability to observe all intervention components *[Publications 2, 7]*. More specifically the individual sessions and out of venue components which were restricted by the need to maintain participant confidentiality as well as the integrity of the intervention alongside issues around consent in the community setting. For example, in Lifestyle Matters, we had originally expected to observe some evidence from individual goal-setting activities during the group sessions, but this was not the case *[Publication 2]*. Therefore, our only understanding of delivery of this component, and the out-of-venue component was from the facilitator and participant interviews which are self-report and reliant on memory *[Publications 3, 4]*. The issues of confidentiality could be argued to increase for those living with Dementia in which stigmatisation may be amplified *[Publication 8]*. An attempt was made to improve our understanding of delivery of the individual sessions and out of venue components in Journeying through Dementia. As observations were still deemed inappropriate for the individual session and out-of-venue components for the same reasons, we collected data via the semi-structured interview study as well as using facilitator self-report checklists to better understand adherence to intervention delivery *[Publication 7]*. However, this remained subjective as it was reliant on self-report and limited to the facilitator perspective. We did not seek participant input other than qualitatively in interviews due to concerns over participant burden and intrusion on the intervention *[Publication 7]*.

### 5.2.3 Timing of assessment

Due to funding and resource limitations of the RCT methodology both fidelity assessments, for Lifestyle Matters and Journeying through Dementia, only involved the observation of a small number of intervention sessions. It may therefore be inevitable that some facilitator and participant behaviours may not have been observed that could have affected intervention delivery *[Publications 2 and 7]*. As these were both large multi-site trials being able to conduct fidelity assessment in all sites would be the ideal but was not pragmatic or resource efficient. How many observations, at what time point in intervention delivery and what components to observe will most likely remain dependent on the complexity of the trial and availability of resources. For example, observing consecutive sessions may be prudent to capture more information regarding participant receipt and enactment, whereas those further apart will more likely catch facilitator drift and intervention acceptability *[Publication 2]*.

## 5.3 Utility of outcome measures

### 5.3.1 Sensitivity of existing outcome measures

An issue that may have compromised results in both Lifestyle Matters and Journeying through Dementia was the utility of outcome measures for clinical trials[113]. For example, in Lifestyle

Matters we used the SF-36 mental health dimension which found had no difference between randomised groups. One explanation could be that the effect of the intervention was not great enough to elicit a significant improvement in the SF-36 mental health dimension *[Publication 3]*. It may also be possible that the SF-36 was not sensitive enough to see an improvement. There is evidence to suggest the SF-36 may not identify some important issues specific to older adults[114]. A similar problem can be found in outcome measures in dementia research which typically focus on cognition and functional ability, rather than meaningful outcomes including living well with dementia[77]. Despite selecting a quality-of-life primary outcome measure in Journeying through Dementia, the DEMQol, this may still not have been sufficiently sensitive to detect changes in psychosocial outcomes that might be attributed to self-management interventions of this kind *[Publication 6]*.

### 5.3.2 Are we measuring what is meaningful?

Additionally, many of the secondary outcomes used in the Journeying through Dementia trial at the time had yet to be validated in dementia populations and may explain some of the small differences we observed between the treatment groups *[Publication 6]*. The use of these existing measures, although unavoidable, was deemed a limitation of the trial. Our qualitative work highlighted what could be described as subtle outcomes such as improved confidence through knowledge acquisition, feeling valued and empowered as a functional member of society as well as benefits gained from social contacts and friendships *[Publication 8]*. This leads us to question whether current outcome measures capture key, yet nuanced aspects including quality of life, wellbeing, social or community connectedness and continued engagement.

## 5.4 Intervention design and delivery

### 5.4.1 Skilled facilitation – complex interventions

A core element of delivery for both Lifestyle Matters and Journeying through Dementia interventions was that facilitators were trained to encourage and educate participants in how to become more self-efficacious. What training didn't cover, and was raised in the Lifestyle Matters qualitative study by facilitators, was a need for training on how to avoid dependency relationships *[Publication 2]*. This was supported by interview evidence that suggested for some participants a growing dependence on the facilitators to enable participation rather than fostering independence *[Publication 3]*. We also found in both interventions that a significant mechanism of action was the facilitator/participant partnership and once the intervention ended so did this relationship and therefore potentially any effectiveness beyond the intervention *[Publications 4, 8]*. This raises a quandary for researchers designing self-management interventions for older adults and those living with early-stage dementia. Although some structure is required[73] for example through trained facilitation to support

engagement with self-management, too much structure fosters dependence, whilst too little may result in failure to engage.

Our experience from these trials also indicates that self-management interventions for older adults experiencing age-related decline are still relatively new. There was a demonstrable lack of awareness and understanding of the self-management model by those delivering both the interventions and from those supervising *[Publication 2]*. Indeed, we proceeded to include further support for supervisors via the research team in the Journeying through Dementia study. Our experience suggested a number of things to potentially improve fidelity assessment. Firstly, that observation of supervision sessions to evaluate competence should be implemented in future fidelity assessments *[Publication 10]*. Secondly that checklists or a variant thereof could be adapted and used as a reflective tool by facilitators to help regulate performance and delivery of a novel intervention *[Publications 2 and 10]*.

For research purposes we tend to be testing whether training has been adequate to upskill staff to deliver the intervention. Deterioration of facilitation skills is common post training and especially if there is a time lag between training and first delivery. This is well known but could be exacerbated by the novelty of self-management interventions. How to translate intervention training and more specifically booster training into practice needs further consideration *[Publication 2]*.

### 5.4.2 Factoring in group dynamics

As might be expected, both Lifestyle Matters and Journeying through Dementia were found to empower some people but disempower others. This reflects the complexities of multiple-component self-management group-based interventions that can be influenced by individual differences and group dynamics[115]. We found personality and approach to life (self-motivation, self-awareness) played a significant role in the successful participation, engagement and benefit in both Lifestyle Matters *[Publication 3]* and Journeying through Dementia *[publication 8]*. This maybe more acute in groups designed for people living with progressive conditions that are already stigmatised such as dementia, in which building trust may take more time. Indeed, we found participants in Journeying through Dementia expressed a need for privacy including from carers when discussing personal issues with the facilitators *[Publication 8]*.

Having common ground was recognised as reassuring, but sharing different experiences and perspectives was also seen as important for learning *[Publication 8]*. Where group members may not gel due to personality differences there may be less opportunity for shared learning and validation resulting in lower engagement. This is where group interventions may fall foul of the randomised controlled trial methodology. Due to time and financial pressures to recruit,

randomisation usually occurs once the desired number of participants has been met to start a group and does not factor in personality types. This results in potentially mismatched groups that may affect intervention effectiveness[116].

### 5.4.3 Support networks

Interestingly, both Lifestyle Matters and Journeying through Dementia were designed to be participant focussed, although Journeying through Dementia did enable carers (one family member) to attend 3 group sessions as observers. This appears to contrast with the approach set out by NHS England[33], in that self-management is personalised care in 'partnership' with professionals, family and the wider community. The need for greater carer engagement and support was reported by the Journeying through Dementia facilitators who suggested that without carer involvement some participants with more severe cognitive and physical impairments would struggle to participate *[Publication 8].* The latest report from Dementia Carers Count (2025) suggests, however, that a reliance on family carers for care provision is unrealistic and potentially harmful to both the person living with dementia and their carer[117]. More significantly they found over a third of carers reported that their physical (33%) or emotional health (34%) would impact their ability to care in the future.

Lifestyle Matters and Journeying through Dementia were novel in their design focussing on the individual with less emphasis on carers. This was not considered detrimental to the effectiveness of the intervention since similar interventions, reporting moderate fidelity, that have included greater carer engagement have also been found to be ineffective[38]. So, the question remains how best to engage carers in self-management interventions for ageing populations when their own health may also be deteriorating. It is also essential that self-management intervention designs do not inadvertently change the balance of power and dependence between the participant and carer *[Publication 8]*. The main aim being not to disenfranchise the individual (participant), but to support engagement during and beyond the intervention. We need to appreciate and better understand what independence means to older people and their carers in the context of self, personhood, family and the community if we are to design self-management interventions that are effective.

### 5.4.4 Intervention duration

Both Lifestyle Matters and Journeying through Dementia were time limited interventions (12-16 week programmes respectively) which posed a significant barrier for these populations. This was despite participants in the Lifestyle Matters intervention being described as 'well-elderly' (high physical, psychological, and social functioning). Of those participants interviewed, they still expressed a preference for ongoing professional/formal facilitation beyond the intervention *[Publication 3]*. In Journeying through Dementia participants even went as far as to state

professional or formal facilitation was a necessity to support ongoing participation *[Publication 8]*. It may simply not be reasonable to expect some individuals, particularly those experiencing significant age-related decline, to be able, or want, to take responsibility for organising groups. One solution could be a longer delivery duration which would give those with potentially 'hidden' challenges the time to become sufficiently confident to work with others to explore solutions *[Publication 4]*. This could result in more sustainable outcomes, but what this looks like in terms of frequency, facilitation, content and cost would need exploring. Under resourced health and social care service provision remains a significant barrier to accommodate longer term interventions.

## 5.5 Recruitment challenges

### 5.5.1 Age and disability

Not unexpectedly, due to the age range in the Lifestyle Matters trial, nearly all participants described themselves as having a disability and that this was a significant challenge to their participation during and post intervention delivery *[Publication 3]*. This could explain why there was no reported impact on physical health. However, there was a positive impact on mental wellbeing, for example gaining perspective of other participants which may have allowed participants to interpret and cope more positively with change thereby increasing their self-efficacy and independence *[Publication 4]*. These findings suggest that age may not necessarily be a barrier to participation and resulting behavioural change, but experience of deteriorating health, and/or physical disability could be a compromising factor.

### 5.5.2 How to identify people at risk of decline

In the Lifestyle Matters trial we found that those experiencing the biggest life changes such as a bereavement was when the intervention had the biggest impact in terms of re-building confidence and social opportunities *[Publication 5]*. Yet despite best efforts to recruit through health and social care services to identify and refer at risk eligible participants, the trial came to rely on GP practice mail outs which resulted in a biased self-selected sample *[Publication 1]*. On comparing Lifestyle Matters with the original US Lifestyle Re-design® trial[92] there were a few differences which may explain our recruitment challenge. Participants in the US study were independently residing in retirement communities and private homes; those in private homes visited senior community centres. In our trial, older adults were also independently living but were recruited from the community and did not necessarily have any involvement in community centres or assisted living facilities. It can be deduced that participants recruited to Lifestyle Matters were not at a stage of their life when they would benefit most from such an intervention, nor were they actively seeking support when recruited *[Publication 1]*. Proactive recognition and signposting strategies are required; the benefits of which were strongly indicated in previous feasibility work for the Lifestyle Matters intervention[93].

The trial samples were not representative of the broader clinical populations, particularly due to limited ethnic diversity *[Publications 1 and 6]*. This under-representation was therefore reproduced within the fidelity subsamples, thereby constraining the methodological robustness of the fidelity assessment. Because fidelity relies on capturing variation in delivery, receipt, and enactment across the full spectrum of those who may receive the intervention in practice, a restricted sample limits the ability to assess whether the intervention operates equivalently across cultural, linguistic, and socio-demographic groups. Consequently, the conclusions drawn did not fully reflect the heterogeneity of the clinical population *[Publications 2 and 7].*

### 5.5.3 Encouraging recruitment through services

The Journeying through Dementia feasibility study highlighted the value of using local communities to identify those who might benefit and the need to recruit through healthcare services *[Publication 5]*. The Journeying through Dementia trial fared better than Lifestyle Matters, with more participants referred through services, which may be due to a clearer understanding of the purpose of the intervention and a more defined clinical population (people diagnosed with early-stage dementia) *[Publication 6]*. The speed of recruitment required within the RCT methodology, was also deemed to significantly impact our ability to recruit via services and therefore those most likely to benefit from the intervention *[Publication 6]*. The complexities of recruiting an at-risk population living with conditions that are progressive or changeable, such as dementia, was also highlighted through qualitative report that some participants had a higher level of cognitive impairment when they joined the intervention than prior eligibility screening suggested *[Publication 8]*.

## 5.6 Strengths and limitations of the underpinning studies

Co-design is a strength of these studies in that they involved national multi-disciplinary teams including people with lived experience who were actively involved at all stages of the research process. All the studies included in this thesis were funded by the NIHR and/or MRC and therefore underwent rigorous peer review as part of the competitive process. The trial findings have been published as open access peer reviewed publications. In addition, they have been reviewed and approved by ethics committees and adhere to the UK research governance framework thereby providing a level of confidence that this is a robust body of work conducted to the highest standards of research.

The same research team worked across both Lifestyle Matters and Journeying through Dementia trials meaning we were able to apply learning between the two trials. This knowledge enabled us to revise and improve several aspects of the Journeying through Dementia trial design and intervention delivery. Firstly, we were able to target our recruitment strategy and

applied tighter eligibility criteria to better identify people entering decline. Secondly, we adapted and increased facilitator training to improve adherence to the individual session component, improving fidelity to delivery of the intervention and therefore ability to see any intervention effect. Lastly, we revised the fidelity assessment framework to include methods of data collection on intervention components previously excluded; the individual sessions and out-of-venue activities. Thereby we were better able to understand implementation of the intervention. However, despite these improvements' barriers remained in our attempts to observe all components of the intervention due to the same ethical considerations identified when delivering the Lifestyle Matters trial. Indeed they may have been amplified by the stigmatisation associated with a diagnosis of dementia.

For the Journeying through Dementia trial, we included two qualitative data analysis and interpretation workshops as part of PPI engagement to ensure findings were meaningful to people living with dementia and their carers. This is particularly important in dementia research where co-production with people with lived experience is increasingly deemed not just important, but essential to successful research design and delivery[118]. How best to include people with cognitive capacity issues is ongoing for aspects of delivery, data collection, analysis and dissemination[119]. Our own reflections of our experience of the Journeying through Dementia trial were shared in Publication 9 to help improve future practice.

Although both trials achieved excellent recruitment and follow-up rates, demonstrating large RCT's can be successfully delivered in older adult populations; identification of people entering age related decline or who were already experiencing age-related decline was challenging. This was despite including a wide-ranging recruitment strategy which included targeted recruitment through service providers and the community. For example, the majority of participants in the Lifestyle Matters trial were self-referrals from GP mail-outs which led to a self-selecting sample of what were deemed 'well-elderly' participants. This was despite sustained efforts to recruit through services. We were able to make improvements in the Journeying through Dementia trial in which services were more engaged and active in recruitment. Our experience suggests delivery of interventions to meet the complex needs of patients entering decline or living with the early stages of dementia is relatively new territory for most services. There is also the caveat that time pressures to deliver research, in terms of the speed of recruitment for large public funded RCTs, may significantly impact on reaching those most likely to benefit. Any benefits of the interventions would therefore have been much smaller than predicted.

The lack of ethnic diversity in the sample populations for both Lifestyle Matters and Journeying through Dementia trials is a significant limitation, and all the observations made in this thesis can only largely be applied to a homogenous population. Although the Lifestyle Matters trial,

being conducted in North Wales, was offered to participants in Welsh, including group and individual facilitation and completion of outcomes, take up was minimal. Other ethnic populations may have been discriminated against due to language barriers and eligibility criteria in which participants were required to understand English. This approach is not unusual in clinical trials although the landscape is changing with funders, such as the NIHR, now actively encouraging engagement of under-served populations[120]. Indeed, an estimated 25,000 people from ethnic minority backgrounds are living with dementia in the UK[121]. It is therefore essential we introduce religious and culturally sensitive training for researchers working to develop such interventions [122]. Until we become more culturally aware, barriers will remain for intervention development and engagement. This is also in line with personhood and respecting how cultural and religious beliefs are part of our identity.

Reflecting on these strengths and limitations provides important context for interpreting the trial findings and understanding their applicability across fidelity assessment research. Importantly, they also illuminate the methodological and practical gaps that this work helps to address. The next section discusses the study's contribution to knowledge and its implications for research, practice, and policy.

# Chapter 6 - Contribution to knowledge and impact

This thesis presents ten peer reviewed publications evaluating two self-management interventions designed to support independence, self-efficacy and resilience in community living older people experiencing age-related decline, including those living with early-stage dementia. Through open access publication the findings and detailed fidelity assessment and process evaluation methodologies have been shared to further inform the development and evaluation of self-management interventions, as well the design and delivery of future research into their efficacy.

The Lifestyle Matters self-management intervention was inspired by the occupational therapy Lifestyle Re-Design® programme which had been found to be effective with older people living in the community in the United States. We were unable to replicate this effectiveness in the UK setting where our findings were neutral. However, NICE guidance continues to support the use of self-management interventions to support ageing well[7,72]. The Lifestyle Matters programme[100] remains in publication and is currently being implemented in several UK NHS services across England, Wales and Scotland.

The Journeying through Dementia feasibility study, conducted as part of the Lifestyle Matters programme grant, enabled us to secure NIHR HTA funding of £2,017,925 (Ref 14/140/80) to deliver the definitive trial. The Journeying through Dementia programme is currently implemented in a number of UK NHS health services nationally (East Sussex NHS Trust, Sheffield, West Wales) and is part of the West Wales dementia wellbeing pathway[123]. The intervention is also advocated by the Allied Health Professional (AHP) Scottish policy, 'Connecting People, Connecting Support' guide[124]. It has been successfully implemented by certain health boards and health services including Fife and Aberdeenshire. Health and Social Care Alliance Scotland self-management funding was secured for roll out across a further 7 Boards in Scotland, in 2021. Self-management interventions remain within scope for a model of healthy ageing advocated by the UK NHS Long term plan[33].

Lifestyle Matters and Journeying through Dementia, along with several comparable large-scale trials, have demonstrated the potential of complex self-management interventions to support people at risk of age-related decline, including those in the early stages of dementia[37,38,125]. However, these findings are drawn from a predominantly homogenous population, limiting their generalisability to more diverse groups. These trials have also underscored the methodological difficulty of assessing fidelity in large, multi-component interventions. For instance, consistent with the patterns observed in Lifestyle Matters and Journeying through Dementia, the COTiD-UK trial, a multi-site UK trial evaluating a structured, occupational therapy-based intervention aimed at supporting daily functioning and independence for people

living with dementia and their caregivers, reported wide variability in fidelity despite a well-specified intervention protocol[38,126]. Such variability is perhaps expected within pragmatic trial designs and reinforces the value of fidelity assessment as a lens for understanding heterogeneity in outcomes, where some individuals benefit substantially, others moderately, and some minimally.

The remainder of this chapter outlines the contribution of the work presented in this thesis in relation to three key areas. First, it discusses the implications for the future design and conduct of fidelity assessments in trials of complex interventions for older adults experiencing age-related decline, including early dementia. Second, it examines the impact of this research on intervention design and evaluation processes in practice. Finally, it explores how policy developments have shaped the increasing prominence of preventative self-management interventions and the capacity of services to respond to these policy imperatives. The interconnections among these areas are acknowledged throughout the chapter.

## 6.1 Methodological learning and implications for future fidelity design

### 6.1.1 RCT design, complex interventions, and fidelity assessment

The recent growth in personalised medicine has brought into question the validity of the RCT paradigm as the gold standard research design to evaluate complex multi-component interventions in clinical trials [127]. Even when trials are designed pragmatically, the need for control, standardisation, and internal validity can constrain the flexibility and responsiveness that underpin effective behavioural and psychosocial interventions. As a result, RCTs often struggle to answer the crucial questions of for whom and under what circumstances such interventions work. This tension was evident in both Lifestyle Matters and Journeying through Dementia in which facilitators were encouraged to embrace the flexibility of the intervention which supported engagement but made strict protocol adherence challenging[128,129]. These adaptations were essential for maintaining person-centred and/or dementia-sensitive practice yet risked being coded as fidelity deviations within a conventional RCT trial design.

Where traditional RCTs fail to capture the influence of social systems and contextual dependencies on causal relationships, alternative methodologies may provide greater explanatory value[130]. Realist evaluation, for instance, examines how intervention components function individually and collectively, testing mechanisms across contexts to inform programme theory and policy[131]. Whilst cluster RCTs offer another approach, minimising contamination between intervention and control groups and facilitating delivery at the group or community level. However, cluster designs typically require larger sample sizes to maintain statistical power[132], which can be challenging in older adult populations or where recruitment of at-risk individuals is difficult as found in Lifestyle Matters and Journeying through Dementia. Selecting

an appropriate design is therefore critical to maximise the likelihood of demonstrating meaningful effectiveness while maintaining fidelity.

Both Lifestyle Matters and Journeying through Dementia, like other similar high-quality trials[37,38,107], showed qualitative benefits at the individual level but limited population-level effectiveness. Feasibility and pilot studies often demonstrate a signal of effect[93,103], likely reflecting their smaller scale, greater flexibility, and the intensive investment by research teams. However, translating these benefits into large, multi-centre trials is challenging due to resource constraints, stricter timelines, and the need to maintain methodological rigour, highlighting the importance of careful planning to balance fidelity and feasibility.

Both Lifestyle Matters and Journeying through Dementia illustrate that although multi-dimensional fidelity frameworks can be operationalised within an RCT design, doing so is not without significant challenges. While the MRC Framework offered a valuable overarching structure[13], it did not fully account for the contextual variability, participant heterogeneity, and site-specific factors that shaped intervention delivery. As a result, achieving consistent implementation and meaningful participant engagement proved difficult. The dispersed and flexible nature of the interventions compounded these challenges, making it difficult to observe all components systematically while preserving the integrity of delivery. Although insights from Lifestyle Matters informed the fidelity strategy for Journeying through Dementia, including the introduction of additional measures, both trials were constrained by the lack of clear methodological guidance for observing and assessing complex psychosocial interventions in real-world settings. This inevitably limited the depth and completeness of fidelity assessment.

Embedding behavioural theory more systematically in future trials is therefore essential and would enable fidelity assessment to capture both procedural adherence and whether intended behavioural processes are being activated in practice. This approach would provide a more nuanced understanding of implementation, support the identification of where adaptation may be necessary, and help preserve the core components essential for achieving meaningful outcomes in complex psychosocial interventions. Behavioural frameworks such as the Theoretical Domains Framework (TDF)[16] and the Behaviour Change Wheel (BCW) and COM-B model[133] have strengthened fidelity assessment by clarifying mechanisms of change in complex interventions. Applied retrospectively to Lifestyle Matters and Journeying through Dementia, these frameworks could have helped identify where fidelity processes faltered for example, due to limited facilitator training (capability), organisational or contextual barriers (opportunity), or participant disengagement (motivation). Like Lifestyle Matters and Journeying through Dementia both COTiD-UK[126], and a second complex intervention dementia trial NIDUS-Family[134], used logic models to articulate theoretical mechanisms. Whereas a third study,

PRIDE[22] applied the BCW to develop strategies for improving implementation. Notably, only NIDUS-Family demonstrated clear evidence of effectiveness, underscoring the need for further research into how models such as BCW, COM-B, and TDF can actively strengthen fidelity and clarify mechanisms of change.

### 6.1.2 Inequalities and cultural limitations – implications for fidelity assessment

Structural inequalities such as differences in ethnicity, language, education, digital literacy, transport access, and socioeconomic status shape who is able to access, engage with, and benefit from health interventions [135,136]. These factors have important implications for fidelity assessment, as they can lead to differential implementation fidelity whereby some groups experience reduced access, lower-quality delivery, or greater difficulty enacting intervention components in everyday life. For example, individuals from marginalised communities, such as older adults experiencing age-related decline, may encounter barriers related to transport, technology, or culturally insensitive content[137]. Incorporating equity-sensitive strategies, such as monitoring demographic patterns in participation, exploring cultural appropriateness, and qualitatively assessing contextual barriers, can help ensure that fidelity assessment reflects not only adherence to protocol but also fairness in delivery and access.

Both Lifestyle Matters and Journeying through Dementia highlighted these equity related challenges. Despite efforts to recruit across geographically diverse areas, both trials struggled to include participants from minority ethnic backgrounds. Similar patterns are evident in other dementia trials, including PRIDE[37], COTiD-UK[38] and NIDUS-Family[125] all of which involved well-characterised mild dementia populations but remained unrepresentative of the UK's cultural diversity. This raises several key points of discussion. Firstly, under-representation limits generalisability of trial findings[138], and therefore constrains fidelity assessment as it becomes unclear whether interventions function similarly across cultural groups. In the case of Lifestyle Matters and Journeying through Dementia, fidelity findings largely reflected majority-ethnic experiences, providing limited insight into how delivery, receipt, or enactment might differ for culturally diverse older adults. This underscores the need for deeper cultural adaptation that goes beyond language translation to account for differing values, beliefs, literacy levels, and stigma related to ageing or dementia[139]. Fidelity frameworks and data collection tools must similarly be adapted to detect variation in engagement, understanding, and enactment so as not to perpetuate systematic misrepresentation of delivery or receipt.

Cultural adaptation frameworks emphasise modifying content, delivery, and context while protecting mechanisms of change[140,141]. Yet there is limited consensus on what can be adapted without compromising fidelity. Lifestyle Matters illustrates this challenge. Although the programme was translated into Welsh uptake remained low, suggesting that surface

adaptations alone are insufficient. More meaningful cultural adaptation may be required to address local beliefs, literacy levels or stigma surrounding ageing and dementia[139]. Addressing structural inequalities and cultural relevance within fidelity assessment is therefore also essential to avoid interventions unintentionally favouring majority populations or overlooking inequities in uptake and outcomes.

Balancing adaptation with fidelity therefore requires clear programme theory, articulated mechanisms of action, and additional post-adaptation fidelity checks[142]. Behavioural frameworks such as the BCW and TDF offer structured ways to integrate diversity into fidelity assessment. Applied to Lifestyle Matters and Journeying through Dementia, these models could have strengthened fidelity assessment by capturing adaptations made for cognitive, social, or cultural needs and by linking these adaptations to mechanisms of self-management. Embedding such frameworks in future trials may enhance the interpretability and generalisability of findings across more diverse older adult populations.

### 6.1.3 Patient and public involvement in interpretation of fidelity

Embedding lived experience into the interpretation of trial findings challenges traditional evidence hierarchies by positioning participants as active contributors to the understanding and framing of results. This approach enhances transparency and rigour by revealing how interventions are experienced, not merely how they are delivered or measured. It brings to light relational, contextual, and emotional dimensions of fidelity, such as perceived relevance, acceptability, or burden that are often invisible in standard fidelity metrics[119,143].

Meaningful involvement of people with lived experience of dementia in the design and delivery of research remains relatively limited[119,144]. However, there is increasing recognition of its value and growing guidance on how best to support inclusive, accessible participation[143,145]. Journeying through Dementia contributed to this evidence base by involving people living with dementia at all stages from intervention and trial design through to the interpretation of the trial findings[119,146]. Their input helped frame the outcomes within a person-centred, participatory perspective, grounding the results in the lived realities of those who would ultimately receive the intervention[128].

This involvement also provided important explanatory insights for fidelity assessment. While quantitative outcomes were modest in the Journeying through Dementia trial, lived experience contributors identified meaningful qualitative benefits, such as increased confidence, social participation, reassurance, and a renewed sense of agency that were not fully captured by existing standard measures such as the DEMQoL[146,147]. These insights support more nuanced interpretation of fidelity by highlighting outcomes and mechanisms that participants valued,

informing whether the intervention was delivered as intended from their perspective, and identifying areas where content or delivery could be strengthened. However, Journeying through Dementia also revealed practical and ethical challenges in involving people with dementia in research interpretation[119]. Ensuring that engagement was meaningful required tailored communication, flexible facilitation, and a supportive environment[148]. Methods such as guided discussion, visual prompts, and iterative feedback were used to enhance accessibility, yet involvement of participants with more advanced cognitive impairment remained challenging[146]. These limitations must be acknowledged when integrating lived experience into co-production ways of working including fidelity analysis.

Despite these challenges, the Journeying through Dementia trial demonstrates that lived experience involvement makes dementia research more responsive to the priorities and values of the people it seeks to support. Embedding PPI into fidelity design and interpretation helps ensure that interventions are not only theoretically sound and protocol-adherent but also meaningful and acceptable[143,145]. This enhances the usefulness of trial evidence for policy and service implementation.

### 6.1.4 Researcher positioning and positionality in fidelity assessment

Researcher positioning acknowledges how a researcher's background, experiences, and assumptions influence all stages of the research process, while positionality refers to the reflective practice of examining these influences and their implications for rigour and credibility[149]. In the Lifestyle Matters and Journeying through Dementia trials, positioning was particularly salient in qualitative and fidelity assessments, where researchers were often closely involved in intervention development and evaluation. Some team members occupied an 'insider' role and were familiar with intervention theory, delivery context, and, in some cases, facilitators[128,129]. This insider knowledge enhanced contextual sensitivity and rapport but also introduced potential bias in interpreting observed behaviours or participant narratives[150]. In Journeying through Dementia, for example, researchers' prior involvement in intervention co-design and feasibility work may have shaped assumptions about facilitator competence and participant engagement, potentially influencing how fidelity data were coded and interpreted.

Explicit attention to positionality in both Lifestyle Matters and Journeying through Dementia is evident through co-production of the fidelity frameworks, peer debriefing following coding of observations and triangulation of fidelity findings. This approach may have strengthened trustworthiness in the data, but it is likely impossible to eliminate all bias. In both Lifestyle Matters and Journeying through Dementia trials, this reflexivity did allow the fidelity team to distinguish variability, for example when reflecting on what may have been deemed contextual adaptation from deviations from the intervention model. Engaging with positionality thus

supported a more nuanced interpretation of fidelity, situating researcher subjectivity as an integral part of understanding complex, person-centred interventions for older adults and people living with dementia[19,23].

### 6.1.5 Sampling limitations in fidelity assessment

Underrepresentation of diverse populations including older adults remains common in clinical trials despite continued efforts to strive for representativeness[151]. Therefore samples used in fidelity assessments are also under representative. In both Lifestyle Matters and Journeying through Dementia, fidelity assessments relied on purposive or convenience sampling of sites, sessions, and participants, reflecting pragmatic constraints such as time, cost, and staff availability[128,129]. Both trials observed only a small number of sessions for a sub-set of groups. This strategy, while practical, constrained the breadth of fidelity data and introduced potential biases. Selective sampling[19] for example, may have disproportionately captured sites, facilitators, or participants that were more engaged or better resourced, potentially leading to an overestimation of adherence, competence, and enactment.

Comparable challenges have been reported in other dementia complex intervention trials. NIDUS-Family[125]used purposive sampling of dyads and facilitators across multiple sites to capture variation in engagement and tailoring, while COTiD-UK[38] employed stratified sampling to reflect heterogeneity in delivery contexts. Across all these trials, resource limitations prevented comprehensive observation of every session, meaning that sampling strategies could only approximate the variability needed to support meaningful fidelity assessment. Despite these constraints, strategic sampling across facilitators, sessions, and time points can still generate valuable insights into patterns of adherence, competence, and enactment, and reveal how contextual factors such as organisational resources, facilitator experience, and participant characteristics can shape implementation. Lessons from Lifestyle Matters, Journeying through Dementia and other trials highlight the importance of transparent and equity-sensitive sampling approaches to support robust interpretation of fidelity in practice. Nonetheless, these methods offer only a partial, and sometimes overly optimistic view of intervention delivery. Acknowledging these limitations is essential for interpreting trial findings.

### 6.1.6 Intervention training and fidelity

We know that interventionist training is a fundamental component of fidelity assessment, shaping the quality, and integrity of intervention delivery[26,104]. To prevent inconsistent training, which can lead to drift, compromised outcomes and interpretability challenges[141], both Lifestyle Matters and Journeying through Dementia employed bespoke training strategies. All interventionists received standardised training delivered by the intervention authors to minimise variability across facilitators and sites and to support appropriate adaptation in

community settings while preserving core components. Although fidelity to training was high in both trials, this did not consistently translate into high-fidelity implementation[128,129]. Similar patterns are observed in other dementia complex interventions, for example in the COTiD-UK Trial fidelity of delivery reported wide site and therapist variation[126], while in the PRIDE Feasibility study mean researcher-rated fidelity dropped between interventions sessions[22].

One explanation for implementation challenges in both Lifestyle Matters and Journeying through Dementia is that facilitators may not have received sufficient training to deliver the interventions with high fidelity, ultimately affecting the measurement of effectiveness. In both trials, facilitators frequently reported "learning on the job," reflecting not only the novelty of the interventions but also the extent to which their delivery diverged from traditional duty-of-care models[146,152]. Although guidance on fidelity assessment emphasises that competence includes interpersonal, relational, and process-level skills[12] the training provided, while replicating key intervention components such as group activities, manualised content, and goal setting, was largely classroom-based. As a result, facilitators could demonstrate conceptual understanding during training but often struggled to translate this learning into practice when confronted with the complexity, diversity, and competing demands of real-world delivery. Future research should consider expanding training programmes to incorporate structured opportunities for supervised practice in real-world environments, accompanied by iterative feedback from experienced practitioners, before facilitators assume full responsibility for intervention delivery.

Both Lifestyle Matters and Journeying through Dementia also demonstrated that participants' understanding of the intervention ethos is just as critical as facilitator competence. Although patient-facing materials including information sheets were underpinned by strong PPI co-production[119] and multidisciplinary input, concerns emerged about tone and clarity. This was evident in how some participants perceived the individual sessions as patronising or stigmatising, which contributed to reduced adherence, an issue particularly pertinent for older adults and those with a recent dementia diagnosis, for whom stigma surrounding support needs may be heightened. These insights prompted revisions in Journeying through Dementia, where improvements in the patient information sheet and enhanced facilitator training on how to explain the purpose of individual sessions led to greater uptake. This demonstrates that clear, accessible, and respectful communication is essential for supporting engagement and adherence. Overall, the findings highlight the need to balance theoretical precision and regulatory or ethical requirements with participant-friendly explanations so that older adults can meaningfully engage with complex self-management interventions ultimately strengthening fidelity.

### 6.1.7 Methods of fidelity assessment

#### *Observational methods*

Both Lifestyle Matters and Journeying through Dementia highlighted ongoing inadequacies of existing fidelity assessment methods when employed in community settings. Specifically failing to assess all intervention components, despite using a mixed methods approach including the 'gold standard' for assessment; that of direct observations using prespecified criteria[153]. Firstly, observations were deemed inappropriate for the out-of-venue activities due to breaking participant confidentiality in a public setting. Secondly, the individual sessions due to maintaining integrity of the intervention which in part relies on a bond of trust between facilitator and participant. The main concern was that observations of these two components would be seen as potentially intrusive resulting in participants disengaging with the intervention. However, poor adherence to any single component of a complex intervention has the potential to erode receipt of any benefit.

It is understood that an individual's behaviour is interwoven with their environment and within context[154], hence the need to observe interventions happening in situ. Unobtrusive observation methods, typically used in ethnographic research, could help us understand how people socially interact in public spaces and have been suggested as an untapped method for health research[155]. This typically involves researchers immersing themselves in the communities they observe. How this could be incorporated in community-based self-management interventions would need investigation alongside implications for additional time and resources. As an example for Lifestyle Matters and Journeying through Dementia, an observer could have been explained as a 'helper' during out-of-venue activities. However, the ethical implications of such observation methods needs exploration including issues of transparency, consent and deception [156]. In addition, maintaining participant confidentiality, particularly for those experiencing stigmatising conditions such as dementia, will require additional consideration. Further work is needed with patients and members of the public to explore acceptability of this method, understand how unobtrusive observations as part of fidelity assessment may impact intervention delivery, and to explore alternative ways to conduct fidelity of such components.

How to analyse observational fidelity data is the next challenge. Self-management interventions, including Lifestyle Matters and Journeying through Dementia, are about behaviour change in response to a range of intrinsic and extrinsic factors, both for the participant and potentially those facilitating the intervention. The bespoke design of observation checklists for what are heterogenous interventions requires a significant amount of time and piloting to refine. Fidelity assessment methods across similar trials like COTiD-UK[126], PRIDE[22] and NIDUS Family[134] reflect the growing sophistication of implementation-measurement in psychosocial interventions for dementia and ageing. However, they also

demonstrate the continued reliance on bespoke tools which may underpin variability in fidelity seen across sites, facilitators, and intervention components rather than fidelity to the intervention. This underscores the need for robust fidelity assessment tools to interpret outcomes effectively.

Through publication of fidelity assessment frameworks and tools, including those of Lifestyle Matters and Journeying through Dementia, future research can learn in order to inform the design of more robust and potentially consistent assessment tools for complex self-management interventions[126,128,129,157]. Recommendations from Lifestyle Matters and Journeying through Dementia included the addition of fidelity assessment of those providing professional supervision alongside to those facilitating an intervention. This was deemed particularly important in novel complex interventions in which poor delivery can be exacerbated by poor supervision. Another recommendation was the provision of an intervention delivery checklist for those facilitating and supervising the intervention as part of the training package to enable self-regulation thereby reducing potential drift. Although this approach provided greater depth to the fidelity assessment it required more time and resources as well as additional burden for site staff and facilitators conducting the intervention. Overall further work is needed to systematically review published observation checklists for self-management community-based complex interventions for older adults to identify consistencies and differences to produce recommendations for future research.

### *Multi-purpose interviews*

A multi-purpose interview approach was undertaken in both Lifestyle Matters and Journeying through Dementia trials to explore participant experiences, acceptability, and engagement whilst simultaneously collecting fidelity-related data. This approach offered several advantages including reducing participant burden by addressing multiple research aims in a single interaction, and providing a more holistic understanding of intervention delivery by linking adherence and enactment to participants lived experiences. Multi-purpose interviews also enabled flexibility, allowing structured fidelity components to be explored alongside informal adaptations. This was aligned with the person-centred ethos of both interventions capturing which elements participants found meaningful or feasible. However, this approach also presented limitations in Lifestyle Matters and more particularly Journeying through Dementia. Addressing multiple objectives within a single interview may have compromised both the depth and clarity of the data, particularly for participants experiencing fatigue or recall difficulties, who may have perceived the interview as having competing priorities, leading to confusion or diluted responses. Although the interview schedules for both trials were co-designed with PPI contributors who advised on wording, structure, and length and were subsequently piloted for acceptability[119], the interview process still proved challenging for some participants. In addition

social desirability bias, or the tendency to present oneself in a favourable light, may have been heightened amongst participants given that interviewers were affiliated with the interventions[158] and is a phenomenon found to increase with age[159]. Despite these challenges in Lifestyle Matters and Journeying through Dementia, this approach enriched the contextual understanding of fidelity, highlighting the importance of careful interview design, skilled interviewers, and rigorous PPI engagement to ensure reliable and meaningful data.

### 6.1.8 Outcome measures

Findings from the Lifestyle Matters and Journeying through Dementia trials found that many traditional outcome measures designed for adults experiencing age-related decline may not be adequate; and even more so for people living with early-stage dementia. This presents researchers with a significant challenge how to demonstrate the effectiveness of such interventions. The problem appears to be two-fold. Firstly, existing outcomes validated or otherwise may not be measuring what is meaningful to these populations. Killen and Macaskill (2020) categorised positive life events in community-dwelling older adults to examine their alignment with psychological well-being models[160]. They found that existing models of well-being are inadequate to describe older people's experiences and even identified 'personal well-being' as a factor that required additional consideration for older populations. Secondly, where outcomes do exist are they sensitive enough to measure small but meaningful changes in populations with complex and fluctuating needs including age-related decline and multi-morbidity[107,161]. A scoping review conducted in 2020 of instruments measuring well-being in people with dementia found none of the measures reviewed demonstrated sensitivity to change[161]. Nor had they been evaluated for responsiveness or their ability to detect clinical and personally meaningful change over time. Since research which yields positive findings is more likely to see greater uptake in practice, it is even more important we use the right outcomes to ascertain whether self-management interventions are effective. There are new outcomes in development such as the Well-being of Older People (WOOP), comprising a set of well-being domains relevant to older people, as identified by older people[162] which may start to bridge the gap once validated in relevant populations.

Both Lifestyle Matters and Journeying through Dementia were designed for the participant, not for carers, therefore outcome measures were self-report only. It is worth noting that self-report can be challenging, particularly in populations impacted by episodic memory and recall in which people with dementia may prefer contemporary report[161]. Individuals may require more assistance completing measures, but this can then lead to increased risk of bias depending on the person assisting. Part of the solution could be improved training in conducting such outcome measures including the assessment of the reliability of participant and/or carer responses to improve completion[163]. Accuracy and consistency are important if we are to

ascertain whether self-management interventions are effective for older adults and people living with early-stage dementia. Only through application of relevant and sensitive outcome measures can we conduct robust research of self-management interventions designed for people experiencing age-related decline including those living with dementia.

When compared with other trials such as COTiD-UK[38] and NIDUS-Family[125], it becomes evident that Lifestyle Matters and Journeying through Dementia are more closely aligned with self-management outcomes in comparison to more functional or carer-oriented measures found in these other trials. The PRIDE[37] feasibility study however did include the new Positive Psychology Outcome Measure (PPOM) designed to assess hope and resilience in people living with dementia, offering a strengths-based alternative to deficit-focused tools[79]. It captures positive psychological wellbeing aligned with person-centred and self-management approaches and has shown good reliability and acceptability in mild-to-moderate dementia.

This distinction points to a wider challenge in fidelity and implementation. Flexible, individualised interventions like Lifestyle Matters and Journeying through Dementia can be difficult to evaluate using standardised functional scales, which often fail to capture subtle changes in self-management, personal enactment, and progress toward individual goals. The relationship between fidelity assessment and outcome measurement is therefore critical. Future trials of self-management interventions for older adults, including those with early-stage dementia, should therefore prioritise outcome measures that reflect the intervention's underlying theory of change and participant priorities such as goal attainment, social participation, and maintenance of identity, and that are sensitive to subtle but meaningful improvements rather than large shifts in cognition or daily functioning.

### 6.1.9 Participant recruitment challenges

To enable us to state with any certainty whether an intervention is effective or not requires us to identify, target and recruit the population who will most benefit from that intervention. Identifying older people at risk of age-related decline and taking action at that point has already been identified as a priority by UK health, social care and other agencies[7]. However, findings from Lifestyle Matters and Journeying through Dementia suggest that health and social care services may still be reluctant to offer research opportunities to individuals identified as being at risk of age-related decline. This, combined with the rapid recruitment timelines required in RCTs and the resource constraints faced by both trials, meant that teams often prioritised participants who were easier to recruit rather than those who were harder to reach but more representative of the target population[164]. This approach likely contributed to self-selection bias. Consequently, older adults continue to be excluded from clinical research[165] despite the NIHR Research Inclusion Strategy emphasising the importance of equitable access to research[166]

and the introduction of new guidance aimed at supporting researchers to achieve this[167]. In fact, age should not be a factor affecting access to trial participation. Instead more important factors need to be addressed including physical disability, the patient/professional relationship, cultural sensitivity and need for adaptation to meet the needs of older people[168].

A significant challenge to identification of older adults entering age-related decline is that they can become invisible to health and social care services and even within the community. Responsibility therefore falls to primary care and more specifically GP's. A GP gatekeeper model is already well established in the UK NHS in an attempt to standardise access to healthcare and older adults experiencing age-related decline are more likely to have a historical and trusted relationship with their GP[169]. Such referral relationships could be an effective and ethical way to recruit into clinical trials particularly for under-served groups including older people at risk of age-related decline. The key being to engage clinicians in research, uphold fair participant selection, reduce misunderstanding or miscommunication about research and respect patients' privacy and confidentiality [170]. Working with GPs has previously been championed as an efficient recruitment pathway for older adults at risk of age-related decline[165]. Indeed, GP mailouts were essential to recruitment into Lifestyle Matters, yet we still did not obtain those entering or in decline. This suggests that GP mail outs are most likely a blunt tool for such populations. Although efficient for the GP in terms of resources, mail outs do not allow for personal conversations with patients who may need greater support, for example via direct contact in follow-up to a mail out. The challenge is whether GPs have the time and resources to do this. A solution could be that of Community Research Link Workers (CRLWs) associated with primary care including GP practices. Such roles could be an invaluable link to older adults experience age-related decline[171]. However, CRLWs are a very new role, therefore, how to harness this potential needs further consideration.

Consensus is required on the responsibility of clinicians, especially community services and primary care, for identifying those on the cusp of decline/at risk populations to participate in research, and the exact methods by which they can be identified. Until that time further exploration is needed on how to encourage health and social care recruiters who are sufficiently knowledgeable and willing to identify and engage community-dwelling older adults at risk of age-related decline. Understanding the current barriers and facilitators, to their engagement and provision of specialist training would support more robust recruitment into trials and therefore improve evaluations of the effectiveness of self-management interventions.

## 6.2 Policy and service delivery

### 6.2.1 Influencing practice

There is growing recognition that a healthier later life is not only influenced by biological ageing, but also by social and environmental factors, as well as early intervention. Indeed the 2023 UK Chief Medical Officers annual report recognised the need for health policy to catch-up with the changing needs of an ageing population[172]. More specifically how to enhance independence and quality of life whilst reducing the duration of illness between reaching older age and the end of life. This highlights a growing need for both person-centred and prevention approaches as part of standard health and social care services. Policy frameworks including the NHS Long Term Plan[33], the Healthy Ageing: Applying All Our Health guidance[9], the Healthy Ageing Consensus Statement[173], and NICE guidelines[7] collectively advocate for community-based, personalised self-management interventions that promote social participation, wellbeing, and resilience. Both Lifestyle Matters and Journeying through were strongly aligned with these ambitions, offering structured opportunities for older adults experiencing age-related decline to develop skills, maintain independence, and strengthen social connection. However, what they also demonstrated, as reflected in previous research[28], is a need for organisational and cultural change within health services to enable delivery of successful self-management interventions for older adults experiencing age-related decline. This suggests a disconnect between government priorities and the capacity and capability to deliver within health services. Addressing this gap requires organisational and cultural change within health and social care, alongside investment in community capacity, cross-sector collaboration, and implementation strategies that realistically reflect service pressures. For researchers, it also demands designing interventions that are future-proofed for the policy trajectory towards prevention, while acknowledging increasing expectations that people take greater responsibility for their health and wellbeing.

### 6.2.2 Social Return On Investment

With that in mind it's not possible to reflect on policy and service provision without considering cost implications. Self-management interventions are often promoted as relatively low-cost approaches, with an anticipated outcome of reduced dependency on health and social care services. From a commissioning perspective, even small improvements in health or wellbeing may therefore be considered cost-effective[109]. However, neither Lifestyle Matters nor Journeying through Dementia demonstrated cost-effectiveness, a finding replicated for other similar complex interventions including COTiD-UK [38,174]. There is however growing evidence that conventional cost-effectiveness analyses may not fully capture the broader value of self-management programmes. For example the Promoting Activity, Independence and Stability in Early Dementia (PrAISED) study highlighted the importance of assessing outcomes beyond direct financial savings and instead proposing a focus on 'social return on investment' (SROI)[175].

SROI quantifies the social, environmental, and economic value generated by an intervention and translates these outcomes into monetary terms. This approach offers a more comprehensive understanding of the impact of self-management interventions within their wider societal context particularly in terms of wellbeing, empowerment, and social participation, outcomes that are often underrepresented in traditional cost-utility analyses.

Further work is therefore needed to explore the SROI[176] for interventions like Lifestyle Matters and Journeying through Dementia. Importantly, incorporating an SROI perspective also aligns with the current discourse around fidelity assessment and cultural diversity in which there is growing recognition that the benefits of self-management programmes, economic or otherwise, may not be evenly distributed across different social or ethnic groups. Without attending to issues of cultural relevance, accessibility, and implementation fidelity in diverse populations, there is a risk that interventions may inadvertently perpetuate inequities rather than reduce them. By quantifying this social and environmental value, SROI can aid informed decisions about where to invest resources in self-management interventions and also demonstrate impact.

### 6.2.3 'Normalising' self-management interventions in practice

The findings from both Lifestyle Matters and Journeying through Dementia fidelity assessments suggests organisational and professional acceptability of the self-management model, requires further embedding in health care provision or 'normalising'[107]. For example, highlighting the need for appropriate training resources, recognising the need for longer term solutions and addressing a risk averse culture in which age-related stigmatisation persists. Alongside this, a change in public perception of self-management interventions is also required. Self-management is about taking responsibility for one's own health. We need to understand how best to support those living with age-related decline in terms of how participation can be affected by health literacy, mental health difficulties and socio-economic factors[177]. Ways to improve acceptance could include better education, service confidence and provision, alongside proven outcomes from robust clinical trials. Without all parties on board with the self-management model, which is fundamental to its success, it is difficult to see how we can achieve and evaluate effective interventions.

### 6.2.4 Building community links

Both Lifestyle Matters and Journeying through Dementia identified that wider support networks, although present, are not always effective in building relationships to support older adults 'aging in place' i.e. in their homes and in the community. This could be explained in two ways, firstly as a reflection of the postcode lottery that affects all health and social care, and

community services in the UK[178]. Secondly, a lack of education in health and social care services on how best to support those at risk of age-related decline and their families to age well in their community. Therefore, inherent to intervention and fidelity assessment design should not only be people with lived experience and their supporters, but also a much wider community engagement working in partnership to develop the clinical and social networks required for self-management interventions to flourish[57,58]. Social prescribing could help address this issue in that it connects people to services in their community to meet practical, social and emotional needs that affect their health and wellbeing[108]. The NHS has recently introduced the role of Social Prescribing Link Workers (SPLW) in primary care in order to improve population health[179]. SPLWs take a holistic approach to help individuals access community-based support tailored to their needs. For example, statutory services, financial guidance, and welfare advice all of which can impact health and wellbeing. However, such roles are relatively new and need time to establish, but they could be an ideal resource to support a self-management model in practice as well as support research conduct.

# Chapter 7 - Recommendations for future research

The methodological insights emerging from Lifestyle Matters and Journeying through Dementia underscore the need for a more nuanced approach to designing and trialling complex psychosocial interventions for older adults. While RCTs remain valuable for establishing effectiveness, they often oversimplify interventions that depend on adaptation, and relational delivery. Both trials reveal the importance of considering alternative or complementary designs, strengthening feasibility testing, and assessing not only whether an intervention was delivered as intended but how it was received and enacted across diverse populations. Equally important is the integration of equity, cultural relevance, and meaningful PPI throughout the research process. Structural inequalities, cultural diversity, and varying levels of cognitive impairment shape who can access and benefit from interventions, and these influences must be embedded within recruitment strategies, adaptation processes, and fidelity assessment. Collectively, the learning from Lifestyle Matters and Journeying through Dementia highlights the need for integrated, context-sensitive, theory-informed methodologies that support the development of effective, scalable, and equitable psychosocial interventions. These considerations form the foundation for the recommendations that follow.

## 7.1 A qualitative study to develop community-based recruitment strategies

A qualitative study to understand how to recruit those at risk of age-related decline to clinical trials. Individuals just entering age-related decline can be invisible to services at that stage and can be hidden in the community. A different approach is therefore needed through community and primary care to identify potential participants and then obtain their involvement. The aim would be to identify ways in which people at risk of age-related decline could be identified directly. The study would seek views and ideas from those working in primary care, for example GPs, CRLWs and those working with older adults in the community setting to provide guidance on recruitment strategies for future trials.

## 7.2 Scoping review to synthesise fidelity assessment observation checklists

A scoping review and evidence synthesis to identify and synthesise fidelity assessment observation checklists used in research to evaluate multi-component self-management interventions designed for populations at risk of age-related decline. There is a growing evidence base of published bespoke fidelity assessment frameworks and tools which are invaluable to the future design and delivery of fidelity assessments in multi-component self-management interventions. However, this work has not been synthesised to my knowledge. The aim of this review would therefore be to collate existing evidence to identify consistencies and differences in checklist items used to assess fidelity of multi-component self-management interventions. Findings would inform the design of future fidelity assessment checklists and could potentially provide reference standards to allow for validation across studies.

## 7.3 Qualitative study to identify factors affecting implementation of observational methods in fidelity assessments

A qualitative focus group study would enable us to better understand how observation methods impact on those participating in trials of complex multi-component self-management interventions. The aim would be to identify factors that may influence participation including for example potential intrusion, disengagement, practical issues and ethical considerations. The study would include both those who are participating in and those facilitating an intervention to understand barriers and enablers from different perspectives. The outcome would be recommendations for future research mapping the advantages and disadvantages of observations methods for evaluation of fidelity for interventions designed for people at risk of age-related decline.

## 7.4 Realist review to understand the mechanism of behaviour change in self-management interventions for people at risk of age-related decline

Lastly a realist review to determine if, how, when, why and for whom self-management interventions like Lifestyle Matters and Journeying through Dementia work to improve independence and self-efficacy.

Critical realism is one potential theory that could benefit the development and understanding of self-management interventions for older adults and people living with early-stage dementia. Although relatively new in health research, good practice guidance is available such as RAMESES[180]. Realist evaluation specifically looks to establish what works, for whom and in what circumstances, on the assumption that the same intervention will not work for everyone everywhere. At the heart of realist evaluation are context-mechanism-outcome (C-M-O) configurations from which hypotheses are developed about potential intervention mechanisms that may be observed in context and how these causal mechanisms impact on outcomes. Fletcher et al (2016) described how realist evaluation principles could be applied within all phases of the MRC framework for evaluating complex interventions including self-management[181]. This includes intervention development, feasibility testing, evaluation and implementation of complex interventions to address the problem of under-theorised and under-researched interventions in context. We need to look for ways to build theory to link interventions to outcomes and impact. This is particularly important in complex interventions where there are typically multiple dynamic and interdependent components as well as contextual factors in play. When we understand what works, for whom and under what circumstances, interventions can be translated and adapted to varying populations and contexts[182].

The aim of this study would be to explore what it is about self-management interventions (context), that motivate individuals at risk of age-related decline to act (mechanism) to change their behaviour to improve independence and self-efficacy (outcome) drawing on behaviour change theories[133]. The objective would be to understand how self-management interventions work in different contexts to change behaviour (e.g. people/places). The outcome would be the co-production of a programme theory how self-management interventions may work for this population and a guidance document for researchers to inform better design of self-management interventions for individuals at risk of age-related decline.

# Chapter 8 - Conclusion

Collectively, Lifestyle Matters and Journeying through Dementia demonstrate that it is possible to design and deliver large-scale randomised controlled trials with older adults, including those living with early-stage dementia. These trials show that older people can meaningfully engage with self-management interventions; however, they also reveal a persistent gap between intervention development and evaluation in research settings and their implementation in routine practice. The ten publications that comprise this body of work contribute substantively to the evidence base on designing, delivering, and assessing fidelity in complex interventions, emphasising the need for pragmatic and context-sensitive approaches that can inform future research, policy, and service delivery.

Together, these studies highlight the significant methodological, contextual, and practical challenges inherent in translating complex psychosocial interventions from theory into real-world practice. Maintaining fidelity in multi-site, community-based research requires balancing structured delivery with the person-centred flexibility needed to accommodate the heterogeneity of ageing populations. Variability in facilitator training, organisational support, and participant engagement introduces differences in implementation quality and outcomes, underscoring the importance of fidelity frameworks that assess not only adherence, but also adaptation, receipt, and enactment. Structural inequalities and cultural factors further shape who participates and how interventions are received, reinforcing the need for equity-sensitive and culturally responsive fidelity assessment.

These insights underline that designing and evaluating complex interventions for older adults, particularly those experiencing early cognitive decline, requires methodological pluralism, sustained reflexivity, and the integration of theory-driven fidelity models to ensure interventions are both effective and equitable in the contexts in which they are delivered. Crucially, fidelity assessment must recognise that adaptation does not inherently compromise effectiveness, provided core mechanisms of change are preserved, though evidencing this relationship remains an ongoing methodological challenge.

Looking forward, intervention development must move beyond the constraints of controlled research environments to embrace the complexity of community-based delivery. Central to this is co-production with older adults, carers, and practitioners, ensuring programmes are relevant, accessible, and culturally appropriate. Clear fidelity frameworks and robust process evaluations will support this balance by illuminating how context shapes implementation. Alongside this outcome measurement also requires reorientation. Metrics must reflect the lived experience of ageing such as autonomy, identity, social participation, and confidence. Integrating fidelity

assessment with outcome measurement is essential for understanding whether observed changes align with the intended delivery and activation of mechanisms of change.

Finally, at organisational and policy levels, sustained and effective implementation depends on investment in workforce capacity and supportive infrastructures. Structured training, ongoing supervision, and organisational commitment are crucial for maintaining delivery quality. Fidelity assessment offers valuable feedback loops for organisations, highlighting areas where facilitators require support and how contextual pressures influence implementation. Sustainable delivery also relies on strong partnerships between academic, health, and community sectors to ensure continuity beyond the lifespan of research projects. Embedding fidelity principles within commissioning and service-design frameworks can help ensure that interventions retain their core mechanisms as they are scaled into practice.

# Appendix 1 – Trial Protocol references

**Lifestyle Matters Trial protocol**

***Sprange K,*** Mountain GA, Brazier J, Cook SP, Craig C, Hind D, Walters SJ, Windle G, Woods R, Keetharuth AD, Chater T, Horner K. Lifestyle Matters for maintenance of health and wellbeing in people aged 65 years and over: study protocol for a randomised controlled trial. Trials. 2013, 14:302.

**Journeying through Dementia Trial protocol**

Wright J, Foster A, Cooper C, ***Sprange K***, Walters S, Berry K, et al. Study protocol for a randomised controlled trial assessing the clinical and cost-effectiveness of the Journeying through Dementia (JtD) intervention compared to usual care. BMJ Open 2019;9:e029207.

## Appendix 2 - Statement of authorship

Professor Gail Mountain was the Chief Investigator and fund holder of the Lifestyle Matters Trial, Journeying through Dementia Feasibility study and the Journeying through Dementia Trial. Kirsty Sprange's contributions to the included publications is as follows:

**Publications 1 – 4 Lifestyle Matters Trial**

KS contributed to the design and development of the protocol and supporting documents and managed the project. KS developed and delivered the fidelity assessment framework and embedded qualitative study including developing and piloting data collection tools, conducting interviews with facilitators and participants and observations of staff training and intervention delivery. KS analysed and interpreted the fidelity data and contributed to the interpretation of the qualitative data and overall trial findings. KS drafted and was first author on the protocol and fidelity publications and contributed to and was co-author on the qualitative and results publications. KS also presented findings at the MRC Lifelong Health and Wellbeing Showcase Conference.

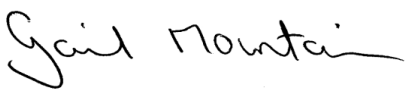
**Publication 5 – Journeying through Dementia Feasibility Study**

KS contributed to the design and development of the protocol and supporting documents and managed the project. KS led data collection and analysis and drafted the manuscript. She is the first author on the publication.

**Publications 6-10 – Journeying through Dementia Trial**

KS contributed to the design and development of the protocol and supporting documents. KS led the fidelity assessment and embedded qualitative study including developing and piloting data collection tools, conducting interviews with facilitators and participants and observations of staff training and intervention delivery. KS analysed and interpreted the fidelity and qualitative data and contributed to interpretation of the overall trial findings. KS drafted and was first author on the fidelity and qualitative publications and drafted and was co-author on the protocol, Results, PPI and implementation publications. KS also presented findings at the Alzheimer's Society Conference 2019.

I accept this statement as a true reflection of Kirsty Sprange's contribution to these publications.



Professor Gail A Mountain Date: 13th April 2025

Honorary Professor of Health Services Research (assisted living research)

# Appendix 3 – Authors contributions (alphabetical by surname)

The numbers represent the associated publication.

| Authors name | Concept | Study design | Study co-ordination (inc set-up, training, oversight, management) | Data collection | Data analysis | Results interpretation | Wrote first draft | Edited manuscript versions |
|---|---|---|---|---|---|---|---|---|
| Kirsty Sprange | 2, 3, 5, 6, 8, 9 | 1, 2, 3, 5, 6, 7, 8, 9, 10 | 1, 2, 3, 5, 6, 7, 8 | 1, 2, 3, 5, 6, 7, 8 | 1, 2, 3, 5, 6, 7, 8 | 1, 2, 3, 4, 5, 6, 7, 8 | 2, 5, 7, 8, 9 | 1, 3, 4, 6, 10 |
| Katherine Berry | 10 | 6, 7, 10 | 6, 7 | 6, 10 | 6, 10 | 6, 10 | 10 | 6, 7 |
| Jules Beresford-Dent | 7, 8, 9 | 6, 7, 8, 9 | 6, 7, 8 | 6, 7, 8 | 6, 7, 8 | 6, 7, 8 | 9 | 6, 7, 8 |
| Linda Birt | | 9 | | | | | | 9 |
| Daniel Blackburn | | 5 | | | | 5 | | 5 |
| Peter Bowie | | 5 | | | | 5 | | 5 |
| Tim Chater | | | 1 | | | 1 | | 1 |
| Robin Chatters | 4 | 4 | 4 | 4 | 3, 4 | 3, 4 | 4 | 1, 3 |
| Sarah Cook | | 1 | 1 | | 1, 4 | 1, 4 | | 1 |
| Cindy Cooper | | 6,7, 8, 10 | 6, 7, 8, 10 | | 6 | 6, 7, 8, 10 | | 6, 7, 8, 10 |
| Rebecca Courtney-Walker | | 10 | 10 | | | 10 | | 10 |
| Claire Craig | 1, 2, 5, 6, 7, 8 | 1, 2, 3, 5, 6, 7, 8 | 1, 2, 5, 6, 7 | | | 1, 5, 6, 7 | | 1, 2, 4, 5, 6, 7, 9 |
| Tom Denning | | 6 | 6 | | | 6 | | 6 |
| Kirsty Harkness | | 5 | | | | | | 5 |
| Daniel Hind | | 1 | 1 | | | 1 | | 1 |
| Anju Keertharuth | | 1 | 1 | | 1 | 1 | | 1 |
| Ellen Lee | | 6 | 6 | | 1, 6 | 1, 6 | | 1, 6 |
| Amanda Loban | | 6 | 6 | | | 6 | | 6 |
| Shazmin Majid | | | | 7 | | | | 7 |
| Clare Mason | | 7, 8, 9 | 7, 8 | 7 | | 7, 8 | | 7, 8, 9 |
| Esme Moniz-Cooke | | 6 | 6 | | | 6 | | 6 |
| Gail Mountain | 1-10 | 1-10 | 1-10 | | 3, 4, 5 | 1-10 | 1, 3, 6 | 2, 4, 5, 7, 8, 9, 10 |
| Louise Newbould | | | 1 | 1 | | | | 1 |
| Lauren Powell | | | 1 | 1 | | | | 1 |
| Jennifer Roberts | | 1, 4 | | 4 | 4 | 1, 4 | 4 | 1 |
| Katy Shortland | | 5 | | 1, 5 | 5 | | | 1, 5 |
| Maggie Spencer | | 5 | | | | 5 | | 5 |
| Benjamin Thomas | | | | 6, 7, 8 | | 6, 7, 8 | | 6, 7, 8 |
| Benjamin Thompson | | | | 6 | | 6 | | 6 |
| Emily Turton | | | | 6 | | 6 | | 6 |
| Stephen Walters | | 1, 6 | 1, 6 | | 1, 6 | 1, 6 | | 1, 6 |
| Gill Windle | | 1 | 1 | | | 1 | | 1 |
| Robert Woods | | 1 | | | | 1 | | 1 |
| Jessica Wright | 7, 8, 9 | 6, 7, 8, 9, 10 | 6, 7, 8, 9, 10 | 6, 7 | 6 | 6, 7, 8, 9, 10 | | 6, 7, 8, 9, 10 |
| Emily Young | | | | 6 | | 6 | | 6 |
| Tracey Young | | 6 | 6 | | 6 | 6 | | 6 |

- Publication 1: A preventative lifestyle intervention for older adults (lifestyle matters): a randomised controlled trial.
- Publication 2: Evaluation of intervention fidelity of a complex psychosocial intervention Lifestyle Matters: a randomised controlled trial.
- Publication 3: Lifestyle Matters Randomized Controlled Trial of a Preventive Health Intervention for Older People: Qualitative Sub Study with Participants and Intervention Facilitators.
- Publication 4: The long-term (24-month) effect on health and well-being of the Lifestyle Matters community-based intervention in people aged 65 years and over: a qualitative study.
- Publication 5: Journeying through Dementia, a community based self-management intervention for people aged 65 years and over: a feasibility study to inform a future trial.
- Publication 6: The Journeying through Dementia psychosocial intervention versus usual care study: a single-blind, parallel group, phase 3 trial.
- Publication 7: Assessing fidelity of a community based psychosocial intervention for people with mild dementia within a large randomised controlled trial.
- Publication 8: Journeying through Dementia Randomised Controlled Trial of a Psychosocial Intervention for People Living with Early Dementia: Embedded Qualitative Study with Participants, Carers and Interventionists.
- Publication 9: Embedding patient and public involvement in dementia research: Reflections from experiences during the 'Journeying through Dementia' randomised controlled trial.
- Publication 10: The implementation of Journeying through Dementia: Strategies to run a successful pragmatic multicentre trial of a complex intervention

# Appendix 4 – Fidelity Checklist

## Lifestyle Matters: Training Delivery observation checklist – Research coders

| Scale: 0=**None** of the time; 1= **Minority** of the time; 2=**Most** of the time; 3= **All** of the time | | | | |
|---|---|---|---|---|
| **TRAINER** | | | | |
| Domain | Criteria | Scale | Score | Comment/Evidence |
| Trainer | 1. The trainer is the same for all training | ✓or X | | |
| | 2. The trainer is an author of the programme | ✓or X | | |
| | 3. Demonstrates a range of group work skills (didactic teaching, peer sharing, interactive activities, active experimentation etc) | ✓or X | | |
| Materials | 4. PowerPoint presentations and materials directly relate to the goals of the training | ✓or X | | |
| | 5. Provides a CD of training content and materials to all trainees | ✓or X | | |
| Tailoring | 6. Training is tailored to recipients' skill level, experience or work background | ✓or X | | |
| | 7. Training is tailored in response to the observed needs of the trainees, and feedback from the trainees during the sessions | ✓or X | | |
| Content | 8. The goals of the training are covered | ✓or X | | |
| | 9. Examples of the core themes and examples of subsidiary themes are covered | ✓or X | | |
| | 10. Mandatory themes are covered:<br>• A celebration of achievements<br>• Activity and health<br>• Endings | ✓or X | | |

| Scale: 0= **None** of the trainees; 1= **Minority** of the trainees; 2=**Most** of the trainees; 3= **All** of the trainees | | | | |
|---|---|---|---|---|
| **TRAINEES** | Performance in discussion, role play, problem solving, expressive exercises, reflective exercises shared, written tests | | | |
| Domain | Criteria | Scale | Score | Comment/Evidence |
| Understanding | 11. Critically discuss demographic changes and the concept of active ageing | 0 - 3 | | |
| | 12. Discuss the evidence for Lifestyle matters | 0 - 3 | | |
| | 13. Identify the ideas that are key to Lifestyle Matters, including<br>• enabling group members to do things for themselves<br>• transferring skills from the safety of the group to their wider lives | 0 - 3 | | |
| | 14. Discuss the content of the Lifestyle Matters manual and how to apply it | 0 - 3 | | |
| Self -awareness | 15. Share their prior expertise, hopes and expectations of the training | 0 - 3 | | |
| | 16. Share their own perceptions of ageing and how this may impact on the programme | 0 - 3 | | |
| | 17. Reflect on and share their own facilitation style and skills | 0 - 3 | | |
| Skill acquisition | 18. Use the LifeStyle Matters manual to practice planning sessions within themes | 0 - 3 | | |
| | 19. Identify how to locate and access community resources | 0 - 3 | | |
| | 20. Respond to potential scenarios, using creative problem solving and considering individual needs (including risk taking) | 0 - 3 | | |
| Group work | 21. Understand and demonstrate a range of group work skills (didactic teaching, peer sharing, interactive activities, active experimentation etc) | 0 - 3 | | |
| | 22. Understand and demonstrate how to manage group dynamics | 0 - 3 | | |
| | 23. Understand and demonstrate an enabling style of group facilitation | 0 - 3 | | |
| | 24. Demonstrate how to tailor the intervention to the needs and choices of group members | | | |
| Individual sessions | 25. Explore the value of 1:1 sessions and potential activities to use in these | 0 - 3 | | |
| Group outings | 26. Explore the value or outings and how to help group members to plan them | 0 - 3 | | |
| Reflection & evaluation | 27. Explore reflective practice and discuss its value | 0 - 3 | | |
| | 28. Practice evaluating and planning actions | 0 - 3 | | |
| Supervision | 29. Discuss the value and principles of supervision | 0 - 3 | | |

## Lifestyle Matters: Programme Delivery video observation checklist – Research coders

| Scale: 0=**None** of the time; 1= **Minority** of the time; 2=**Most** of the time; 3= **All** of the time | | | | |
|---|---|---|---|---|
| **FACILITATOR** | | | | |
| Domain | Criteria | Scale | Score | Comment/Evidence |
| Resources | 1. Two facilitators deliver | ✓or X | | |
| Personal qualities | 2. Shows warmth and empathy | 0 - 3 | | |
| | 3. Listens actively and respectfully | 0 - 3 | | |
| Enabling | 4. builds on the assets, skills and abilities that each person brings | 0 - 3 | | |
| | 5. Encourages the group to make choices | 0 - 3 | | |
| Group work skills | 6. Facilitates communication and interaction (to ground rules?) | 0 - 3 | | |
| | 7. Draws in quiet members of the group | 0 - 3 | | |
| | 8. Facilitates peer exchange and guidance, and peer modelling | 0 - 3 | | |
| | 9. Manages space, time and opportunity effectively | 0 - 3 | | |
| | 10. Facilitates the members to explore differences between them, or conflict and resolution | 0 - 3 | | |
| | 11. Builds mutual support and group cohesion | 0 - 3 | | |
| Goals and needs | 12. Balances meeting individual needs and goals and group needs | 0 - 3 | | |
| | 13. Balances sufficient challenge in activities with ensuring they are achievable | 0 - 3 | | |
| | 14. Tailors activities to the needs of members | 0 - 3 | | |
| Content | 15. Focuses on the themes in the programme, or new themes chosen by group members | 0 - 3 | | |
| | 16. Uses group activities, not just discussion (activities from the manual or from elsewhere) | 0 - 3 | | |
| | 17. With members, selects and plans group outings that explore and extend the themes in the programme | ✓or X | | |

| Scale: 0= **None** of the members; 1= **Minority** of the members; 2=**Most** of the members; 3= **All** of the members |
|---|

| **GROUP MEMBERS** | | | | |
|---|---|---|---|---|
| Domain | Criteria | Scale | Score | Comment/evidence |
| Understanding | 18. The relationship between activity, health and aging, or one of the other themes from the programme | ✓or X | | |
| Occupational self analysis | 19. Analyse their own daily occupations (their significance, impact on health, components) and make choices | ✓or X | | |
| | 20. Sharing and reflecting on experiences of participating in activities (Occupational storytelling) | ✓or X | | |
| Goal setting | 21. Own goals identified within the group and within activities | ✓or X | | |
| Grading and layering | 22. Grading and layering of activities to constantly revisit and extend skills and build confidence | ✓or X | | |
| Mutual support | 23. Show mutual appreciation and support | 0 – 3 | | |
| Creativity | 24. Practice any of: self expression, innovation, problem solving and adaptation within the safety of the group | 0 – 3 | | |
| | 25. Engage in enjoyable and stimulating activities | 0 – 3 | | |
| Older people as experts | 26. Acknowledge and appreciate their own skills and how they can contribute to the group | 0 – 3 | | |
| | 27. Bring in and share their own skills and knowledge | 0 – 3 | | |
| | 28. Group members in turn take leadership or contribute ideas | 0 – 3 | | |
| Transfer to everyday life | 29. build skills, solutions or confidence within the group | 0 – 3 | | |
| | 30. Report the transferring of skills, solutions or confidence from the group to wider life | 0 – 3 | | |
| Change over time | 31. Plans for individuals are taken forward, whilst respecting each person's need to balance opportunities and risk | 0 - 3 | | |
| Confidence and hope | 32. Achievements are celebrated | ✓or X | | |
| | 33. Adventures and dreams are welcomed | ✓or X | | |

## Journeying through Dementia: Training Delivery observation checklist – Research coders

| Scale: 0=**None** of the time; 1= **Some** of the time; 2=**Most** of the time; 3= **All** of the time OR ✓equals a score of 3, a X equals a score of 0 | | | | | |
|---|---|---|---|---|---|
| **TRAINER Domain** | **Criteria** | **Scale** | **Independent Score** | **Agreed Score** | **Comment/Evidence** |
| **Trainer** | 1. The trainer is the same for all training | ✓or X | | | |
| | 2. The trainer is an author or skilled in the JtD intervention | ✓or X | | | |
| | 3. Did the trainer model a range of group work skills: | | | | |
| | • teaching | ✓or X | | | |
| | • peer sharing | ✓or X | | | |
| | • interactive activities | ✓or X | | | |
| | • active experimentation (Testing things out) | ✓or X | | | |
| **Materials** | 4. PowerPoint presentations and training materials directly relate to the goals of the training | 0 - 3 | | | |
| | 5. Provides handouts and materials to all trainees | ✓or X | | | |
| **Tailoring** | 6. Does the trainer elicit information about skills levels/previous experience | 0 - 3 | | | |
| | 7. Training is tailored in response to the observed needs of the trainees, and feedback from the trainees during the sessions | 0 - 3 | | | |
| **Content** | 8. Discuss dementia and its impact | ✓or X | | | |
| | 9. Discuss the evidence for JtD | ✓or X | | | |
| | 10. The goals of the training are covered | ✓or X | | | |
| | 11. Examples of topics are covered from the manual | ✓or X | | | |
| | 12. Mandatory themes are covered: | | | | |
| | • A celebration of achievements | ✓or X | | | |
| | • Activity and health | ✓or X | | | |
| | • Endings | ✓or X | | | |
| | 13. Individual sessions | | | | |
| | • Purpose | ✓or X | | | |
| | • Goal setting | ✓or X | | | |
| | • Participant relationship with supporter | ✓or X | | | |
| | • How the participant & supporter work together on the programme | ✓or X | | | |
| | 14. Discuss supporter attended sessions and relationship dynamics | ✓or X | | | |

| Scale: 0= **None** of the trainees; 1= **Some** of the trainees; 2=**Most** of the trainees; 3= **All** of the trainees | | | | | |
|---|---|---|---|---|---|
| **TRAINEES**<br>**Domain** | **Criteria** | **Scale** | **Independent Score** | **Agreed Score** | **Comment/Evidence** |
| **Understanding** | 15. Identify and understand the ideas that are key to JtD inc:<br>• Enabling group members to do things for themselves<br>• Transferring skills from the safety of the group to their wider lives | 0 - 3<br>0 - 3 | | | |
| | 16. Discuss the content of the manual and how to apply it | 0 - 3 | | | |
| **Self - awareness** | 17. Share their prior expertise, hopes and expectations of the training | 0 - 3 | | | |
| | 18. Share their own perceptions of dementia and how this may impact on delivering the intervention | 0 - 3 | | | |
| | 19. Reflect on and share their own facilitation style and skills | 0 - 3 | | | |
| **Skill acquisition** | 20. Use the JtD manual to practice planning sessions | 0 - 3 | | | |
| | 21. Identify how to locate and access community resources | 0 - 3 | | | |
| | 22. Discuss strategies for peer support | 0 - 3 | | | |
| | 23. Take part in and contribute to potential scenarios | 0 - 3 | | | |
| **Group work** | 24. Understand and demonstrate a range of group work skills (didactic teaching, peer sharing, interactive activities, active experimentation etc) | 0 - 3 | | | |
| | 25. Understand and demonstrate how to manage group dynamics | 0 - 3 | | | |
| | 26. Demonstrate how to tailor the intervention to the needs and choices of group members | 0 - 3 | | | |
| **Individual sessions** | 27. Explore the value of 1:1 sessions and potential activities to use in these | 0 - 3 | | | |
| **Group outings** | 28. Explore the value of outings and how to help group members to plan them | 0 - 3 | | | |
| **Reflection & evaluation** | 29. Explore reflective practice through feedback within the training and the group | 0 - 3 | | | |
| **Supervision** | 30. Discuss the value and principles of supervision | 0 - 3 | | | |

## Journeying through Dementia: Training Delivery observation checklist – Facilitator trainees

**Dates of training**

**Your role** (e.g. Facilitator/Supervisor)

We would like to ask you to take part in the fidelity assessment for the trial. This will help us to find out whether the results of the trial are due to the intervention or due to other influences outside the intervention. One aspect that could affect the intervention is the quality of the training provided. We would therefore like to ask you to take a few minutes at the end of your 2 day training to complete the questions below about the trainer(s) and the training you received. Thank you.

| **Questions** | | |
|---|---|---|
| 1. | Did the trainer use a range of group work skills, for example teaching, peer sharing, interactive activities? | Yes ☐ No ☐ |
| 2. | Were presentations and training materials related to the objectives of the training? | Yes ☐ No ☐ |
| 3. | Did you feel the training was tailored to your understanding and/or experience? | Yes ☐ No ☐ |
| 4. | Did the trainer(s) respond to feedback from the trainees during the sessions? | Yes ☐ No ☐ |
| 5. | Were examples of topics covered from the manual? | Yes ☐ No ☐ |
| 6. | Did the trainer discuss the individual sessions including their purpose, goal setting and relationships (between participant and carer)? | Yes ☐ No ☐ |
| 7. | Did the trainer discuss the supporter attended sessions and relationship dynamics? | Yes ☐ No ☐ |
| 8. | Were you able to discuss the content of the manual and how to apply it? | Yes ☐ No ☐ |
| 9. | Were you able to share your expertise with the group and your expectations of the training? | Yes ☐ No ☐ |
| 10. | Were you able to share your own perceptions of dementia and how this may impact on delivering the intervention? | Yes ☐ No ☐ |
| 11. | Were you able to reflect on and share their own facilitation style and skills? | Yes ☐ No ☐ |
| 12. | Did you use the JtD manual to practice planning sessions? | Yes ☐ No ☐ |
| 13. | Did you discuss strategies for peer support? | Yes ☐ No ☐ |
| 14. | Did you discuss how to manage group dynamics? | Yes ☐ No ☐ |
| 15. | Did you discuss how to tailor the intervention to the needs and choices of group members? | Yes ☐ No ☐ |
| 16. | Did you explore the value of 1:1 sessions and potential activities to use in these? | Yes ☐ No ☐ |
| 17. | Did you discuss the value and principles of supervision? | Yes ☐ No ☐ |

## JtD Programme Delivery Video observation checklist – Research coders

Scale: 0=**None** of the time; 1= **Some** of the time; 2=**Most** of the time ✓equals a score of 3, a **X** equals a score of 0

| **FACILITATOR Domain** | **Criteria** | **Scale** | **Coder 1 Score** | **Coder 2 Score** | **Agreed Score** | **Comment/ Evidence** |
|---|---|---|---|---|---|---|
| Resources | 1. Two facilitators deliver the group | ✓or X | | | | |
| | 2. Uses range of teaching techniques and/or materials e.g. flipcharts as aide memoirs | ✓or X | | | | |
| | 3. Utilises the manual (menu of topics) and/or associated activities | ✓or X | | | | |
| | 4. Discusses use of resources e.g. community, technology, the group itself | ✓or X | | | | |
| Personal qualities | 5. Shows warmth and empathy | ✓or X | | | | |
| | 6. Listens actively and respectfully the group | ✓or X | | | | |
| Enabling | 7. Builds on the assets, skills and abilities that each person brings | 0 - 2 | | | | |
| | 8. Encourages the group to make choices and supports these | 0 - 2 | | | | |
| | 9. Grading and layering of activities to extend skills and build confidence | 0 - 2 | | | | |
| Group work skills | 10. Facilitates communication and interaction | 0 - 2 | | | | |
| | 11. Ensuring participants are not overwhelmed e.g. with too much information | 0 - 2 | | | | |
| | 12. Draws in quiet members of the group | 0 - 2 | | | | |
| | 13. Supports the group managing use of space and time effectively | 0 - 2 | | | | |
| | 14. Supports the group managing noise levels and tempo of the sessions to ensure discussions are not rushed allowing people to contribute | 0 - 2 | | | | |
| | 15. Facilitates the group exploring group dynamics, or conflict/resolution | 0 - 2 | | | | |
| | 16. Builds mutual support and group cohesion | 0 - 2 | | | | |
| Goals and needs | 17. Balances meeting individual needs and goals and group needs | 0 - 2 | | | | |
| | 18. Balances challenge in activities with ensuring they are achievable – tailoring the intervention | 0 - 2 | | | | |
| Content | 19. Focuses on manual topics, or new topics chosen by group members | 0 - 2 | | | | |
| | 20. Uses activities (manual or from elsewhere), not just discussion | 0 - 2 | | | | |
| | 21. With members, selects and plans group activities and/or outings that explore and extend the themes in the programme | 0 - 2 | | | | |
| | 22. Explores techniques to compensate for ways in which dementia impacts on everyday life | 0 - 2 | | | | |

| Scale: 0=**None** of the time; 1= **Some** of the time; 2=**Most** of the time ✓equals a score of 3, a **X** equals a score of 0 | | | | | | |
|---|---|---|---|---|---|---|
| **GROUP MEMBERS** | | | | | | |
| **Domain** | **Criteria** | **Scale** | **Coder 1 Score** | **Coder 2 Score** | **Agreed Score** | **Comment/ Evidence** |
| Understanding | 23. Explore importance of the relationship between activity, health and wellbeing | ✓or X | | | | |
| | 24. Opportunity to share and discuss feelings about the impact of dementia in context of the topic | 0 - 2 | | | | |
| Occupational self-analysis | 25. Discuss daily occupations (their significance, impact on health, components) and make choices | 0 - 2 | | | | |
| | 26. Sharing and reflecting on experiences of participating in activities (Occupational storytelling) | 0 - 2 | | | | |
| Goal setting | 27. Goals identified within the group and/or within activities | 0 - 2 | | | | |
| Mutual support | 28. Show mutual appreciation and support | 0 - 2 | | | | |
| | 29. Achievements are celebrated | 0 - 2 | | | | |
| Creativity | 30. Practice of self-expression or innovation within the safety of the group | 0 - 2 | | | | |
| | 31. Practice of problem solving or adaptation within the safety of the group | 0 -2 | | | | |
| | 32. Appear to be engaging in enjoyable and stimulating activities | 0 - 2 | | | | |
| Participants as experts | 33. Acknowledge and appreciate their own skills and how they can contribute to the group | 0 - 2 | | | | |
| | 34. Bring in and share their own skills and knowledge | 0 - 2 | | | | |
| | 35. Group members in turn take leadership or contribute ideas | 0 - 2 | | | | |
| | 36. Build skills and/or learn solutions within the group | 0 - 2 | | | | |

## Journeying through Dementia: Programme Delivery checklist - Facilitators

Whilst thinking about the group meeting you have just finished, can you please answer the following questions. It doesn't matter if you have not done something on the checklist during a particular meeting, we do not expect you to cover everything at every session.

| **Questions** | | |
|---|---|---|
| 1. | Did you use a topic from the manual or cover a new topic during the meeting? | Yes ☐ No ☐ |
| 2. | Did you explore the importance of the relationship between activity, health and wellbeing in the topic covered during the meeting? | Yes ☐ No ☐ |
| 3. | Did you discuss how participants could access resources to support the topic e.g. local community, technology, skills within the group? | Yes ☐ No ☐ |
| 4. | Did you encourage the group to make choices on topics and supports these choices? | Yes ☐ No ☐ |
| 5. | Were you able to help people communicate effectively in the group? | Yes ☐ No ☐ |
| 6. | Were you able to facilitate peer exchange and sharing of ideas and experiences within the group? | Yes ☐ No ☐ |
| 7. | Did you feel you encouraged mutual support in the group and group cohesion e.g. people working together/getting along? | Yes ☐ No ☐ |
| 8. | Were you able to balance ensuring activities were challenging with ensuring they were achievable for all participants (i.e. tailoring the intervention)? | Yes ☐ No ☐ |
| 9. | Did you use group activities, for example a quiz, a taster session, and not just discussion to explore the topic? | Yes ☐ No ☐ |
| 10. | Did you discuss or reflect on any new or existing goals identified by the group? | Yes ☐ No ☐ |
| 11. | Do you think the participants engaged in enjoyable and stimulating activities? | Yes ☐ No ☐ |
| 12. | Do you think participants acknowledged and appreciated their own skills and how they contributed to the group? | Yes ☐ No ☐ |
| 13. | Do you think participants were able to build skills and/or learn solutions within the group? | Yes ☐ No ☐ |

## Journeying through Dementia: Individual Session checklist - Facilitators

Whilst thinking about the session you have just finished, can you please answer the following questions. It doesn't matter if you have not done something on the checklist during a particular session, we do not expect you to cover everything at every session.

| **Questions** | | |
|---|---|---|
| 1. Did you explain the importance and purpose of the individual session? | Yes ☐ | No ☐ |
| 2. Did you feel that you have established or built on the participant/facilitator relationship? E.g. mutual regard and trust | Yes ☐ | No ☐ |
| 3. Did the participant have an opportunity to voice any worries, fears or concerns? | Yes ☐ | No ☐ |
| 4. Did you explore any issues or goals of importance to the participant? | Yes ☐ | No ☐ |
| 5. Did you help the participant set any goals? | Yes ☐ | No ☐ |
| 6. Did you talk to the participant about managing change in a positive way? | Yes ☐ | No ☐ |
| 7. Did you enable the participant the opportunity to explore ideas and topics | Yes ☐ | No ☐ |
| 8. Did you enable the participant to rehearse skills learned in their everyday life? | Yes ☐ | No ☐ |
| 9. Did you explore the participant's relationships with family and friends? | Yes ☐ | No ☐ |
| 10. Did you reflect on the group meetings and the participants understanding of what had been covered? | Yes ☐ | No ☐ |

# Appendix 5 – Thesis references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