Adaptation and evaluation of an intervention to reduce loneliness amongst adults with depression

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Abstract

Loneliness is highly prevalent amongst adults with mental disorders and tackling loneliness is a policy priority in the United Kingdom. This thesis builds the evidence base for an intervention to reduce loneliness amongst adults accessing NHS secondary care services for depression. Loneliness was targeted using a psychosocial intervention to increase social connectedness. The aims of this thesis were to adapt an existing intervention called Groups4Health for adults (18-65) with depression, and to evaluate the feasibility of delivering this adapted intervention in a future clinical trial.

The thesis was conducted in line with the Medical Research Council (MRC) framework for designing and evaluating complex interventions and a mixed methods multiphase design was used. Four sequential studies were conducted.

First, a systematic review of measures of social connectedness was conducted to identify measures for use in the feasibility study evaluation and to develop a conceptual framework of social connectedness. The systematic review found 27 studies and 21 different measures. The Interpersonal Needs Questionnaire-Thwarted Belonging measure was identified as having the strongest psychometric properties. The measures were thematically analysed to develop a conceptual framework of social connectedness. This framework comprised five dimensions: Closeness, Identity and common bond, Valued relationships, Involvement, and Cared for and accepted (giving the acronym, CIVIC). The CIVIC framework provided a theory base to guide the adaptation of Groups4Health by identifying key targets for intervention and indicating potential mechanisms of change.

Second, experiences of social connectedness were explored in a qualitative interview study involving 13 adults with mental disorders and nine mental health

professionals. The aim was to explore the validity of the dimensions within the CIVIC framework, and to highlight any areas of difference between the conceptual framework and the themes generated from the data. Inductive and deductive thematic analysis was used. Both the inductive and deductive analyses provided validation of the conceptual framework, with all five themes from CIVIC of Closeness, Identity, Valued relationships, Involvement, and Cared for and accepted identified. In addition, themes of Shared mental health experiences, Stigma, and Connectedness beyond social relationships were identified in the inductive analysis. Shared mental health experiences and Stigma were added to the five original dimensions of the CIVIC framework, which led to the seven dimension CIVIC-Mental Health framework. Connectedness beyond social relationships was not included as the focus in this thesis was upon human relationships.

Third, three sub-studies were conducted to adapt the Groups4Health intervention manual for use with people experiencing depression, and to generate a logic model of the intervention to guide evaluation. These studies comprised: (a) a pilot intervention study of Groups4Health with stakeholders (n=4); (b) one-to-one interviews with adults with mental disorders and staff (n=22); and (c) an international expert consultation survey (n=12). Ten recommended adaptations to Groups4Health were adopted, such as having one-to-one meetings with intervention recipients before the first group session. Eight recommendations were not adopted, such as providing a support worker to accompany participants to social activities and extending the length of the intervention. The findings were used to develop a logic model, facilitator manual, and participant workbook for the modified intervention, named Groups4Health-Depression.

Fourth, Groups4Health-Depression was delivered and evaluated in a feasibility study involving adults accessing secondary care services for depression (n=29). This intervention involves a one-to-one meeting followed by five group sessions

delivered over a six week period. All participants completed pre-post standardised measures of loneliness, social connectedness, depression and social anxiety, and 13 participants took part in process evaluation interviews. Five participants per month were recruited into the study on average, which is an acceptable recruitment rate given limited study resources. There was a 31% dropout rate, which is comparable to related interventions. The largest effect size among the candidate outcome measures was found for the Patient Health Questionnaire-9 depression measure (d=-0.79, p<0.001), followed by the University of California Loneliness-8 measure (d=-0.28, p=0.046). The process evaluation interviews identified candidate refinements to the intervention to more effectively target loneliness.

The feasibility evidence is supportive of a future clinical trial of Groups4Health-Depression. The Patient Health Questionanaire-9 would be the appropriate primary outcome measure, with the University of California Loneliness Scale-8 used as a secondary outcome measure. Sample size calculations indicated that 54 participants per arm (108 in total) would be required to power a future trial. This thesis describes the initial stages of adapting a complex intervention to reduce loneliness amongst adults with depression. Groups4Health-Depression has potential as a new approach to decrease the loneliness experienced by many people living with depression.

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List of abbreviations

CBT	Cognitive behavioural therapy
CFI	Comparative fit index
CI	Confidence interval
CIVIC	Closeness, Identity, Valued relations, Involvement, Cared for and accepted
CIVIC-MH	CIVIC-Mental Health
COSMIN	COnsensus-based Standards for the selection of health status Measurement INstruments
DF	Degrees of freedom
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, Fifth edition
EADME-BDA	Ecological Assessment of Drug Misuse Experiences-Belonging-Drugs/Alcohol subscale
EADME-BR	Ecological Assessment of Drug Misuse Experiences-Belonging-Recovery subscale
FISI	Four Item measure of Social Identity
G4H	Groups4Health
G4H-D	Groups4Health-Depression
GI-AG	Group identification with any group measure
GI-SU	Group identification with mental health service users measure
GP	General practitioner
ICC	Intra-class correlation coefficient
ICD-10	International Classification of Diseases-Version 10
INQ-TB	Interpersonal Needs Questionnaire-Thwarted Belonging subscale
IPT	Interpersonal psychotherapy
ISEL-B	Interpersonal Support Evaluation List-Belonging subscale
LSAS	Leibowitz Social Anxiety Scale
LSAS-A	Leibowitz Social Anxiety Scale-Avoidance subscale
LSAS-FA	Leibowitz Social Anxiety Scale-Fear Anxiety subscale
MEIM-B	Multigroup Ethnic Identity Measure-Belonging subscale
MGM	Multiple Group Memberships Scale
MHSIP-SC	Mental Health Statistics Improvement Program-Perception of Social Connectedness subscale
NHFT	Nottinghamshire Healthcare NHS Foundation Trust
OR	Odds ratio

PCA	Principal component analysis
PHQ-9	Patient Health Questionnaire-9
PPI	Patient and public involvement
PROSPERO	International prospective register of systematic reviews
RCT	Randomised controlled trial
RMSEA	Root mean square error of approximation
SCS-R	Social Connectedness Scale-Revised
SD	Standard deviation
SI-C	Social identification with community group measure
SI-D	Social identification with people with depression measure
SI-MI	Social identification with people with mental illness measure
SI-NI	Social Inclusion Scale-Neighbourhood Integration subscale
SI-SU	Social identification with substance using peers measure
SI-T	Social identification with therapy group measure
SI-TC	Social identification with therapeutic community measure
SIGN	Social Identity and Group Network
SIM	Social Identity Mapping tool
SIM-2	Social Identity Map-2 measure
SMART	Specific, Measurable, Attainable, Realistic, Time-bound
SMD	Standardised mean difference
SOBI-P	Sense of Belonging Instrument-Psychological subscale
SRMR	Standardized root mean square residual
SRQR	Standards for Reporting Qualitative Research guidelines
TLI	Tucker Lewis Index
TMG	Trial management group
TSC	Trial steering committee
UCLA-3	University of California Loneliness Scale-3
UCLA-8	University of California Loneliness Scale-8
UK	United Kingdom
USA	United States of America
VIF	Variance inflation factor
WHO	World Health Organization

List of publications arising from the thesis

Hare-Duke, L. (2017). The importance of social ties in mental health. *Mental Health and Social Inclusion*, 21(5), 264-270.

Hare-Duke, L., Dening, T., de Oliveira, D., Milner, K., & Slade, M. (2019). Conceptual framework for social connectedness in mental disorders: Systematic review and narrative synthesis. *Journal of Affective Disorders*, 245, 188-199.

Chapter 1. Introduction

Chapter overview

The aims of this thesis are to adapt an existing intervention to reduce loneliness amongst adults with depression and to evaluate the feasibility of delivering this intervention to secondary care service users. This chapter provides a brief overview of what will be covered in this thesis. Section 1.1 describes the background context to the thesis. Section 1.2 gives an outline of the structure of the thesis. Section 1.3 provides a summary of each subsequent chapter.

1.1. Context

1.1.1. Loneliness

This thesis focusses on reducing loneliness amongst adults accessing secondary care services for depression. Loneliness has historically been associated with older adults and characterised as a social care problem (Townsend, 1955; Tunstall, 1963) and some authors still largely frame loneliness in this manner (Victor et al., 2009). However, in recent years loneliness has been increasingly discussed in more widespread public health terms (Holt-Lunstad et al., 2017) and as a priority target for clinical interventions in mental health services (Johnson, 2017).

The shift in discourse from social care to public health came following an accumulation of evidence that loneliness increases the risk for adverse physical health conditions to a similar degree as more established risk factors such as smoking and obesity (Holt-Lunstad et al., 2010). Large scale public health campaigns have since emerged in the United Kingdom (UK), such as the Campaign to End Loneliness launched in 2011 by a coalition of third sector and local authority organisations. This campaign aims to make public services more

effective at reducing loneliness by lobbying commissioners to prioritise loneliness as well as public campaigning to raise awareness more widely.

Recently, loneliness has become a particular concern for MH services, and therefore a potential target for new interventions. Loneliness has been found to be highly prevalent amongst UK adults with mental disorders, with over half reporting this to be a problem (Stickley & Koyanagi, 2016). Moreover, loneliness is a predictor of poorer prognosis, particularly for major depressive disorder (Holvast et al., 2015; Jeuring et al., 2018; van Beljouw et al., 2010). In the light of such evidence, there have been calls to develop new clinical interventions to reduce loneliness amongst mental health service users (Johnson, 2017; Mann et al., 2017; Wang et al., 2017).

1.1.2. Social connectedness and psychosocial mental health interventions

A psychosocial approach to reducing loneliness will be taken in this thesis by increasing people's social connectedness, i.e. the quantity and/or quality of people's social relationships. Social connectedness is therefore assumed to be one potential antidote to loneliness. However, the definition of social connectedness is unclear. The conceptualisation and empirical association between loneliness and social connectedness is therefore explored in detail in Section 2.1.3.

Psychosocial interventions in mental health are at a relatively early stage of development compared to pharmacological and psychological interventions (Johnson, 2017). Psychosocial interventions can be defined as any intervention with a specific social component which addresses both psychological and social needs rather than biological or solely psychological needs (Webber & Fendt-Newlin, 2017). Some examples of psychosocial interventions include Individual Placement and Support to improve employment outcomes amongst adults with mental disorders (Kinoshita et al., 2013) and Housing First initiatives to support independent living (Stergiopoulos et al., 2015).

In the domain of social relationships the most frequently evaluated mental health interventions have focussed on social skills training (Kopelowicz et al., 2006; Kurtz & Mueser, 2008). These types of interventions have been found to improve symptomatology across different disorders and improve performance-based measures of daily living skills (Barth et al., 2016; Kurtz & Mueser, 2008). However, these interventions have rarely been evaluated with regards to social relationship outcomes such as loneliness. Similarly to mental disorder, loneliness has been associated with social skill deficits (Segrin, 1999), yet social skills training does not appear to reduce loneliness in general population samples (Masi et al., 2011). Thus, it is not clear that psychoeducational interventions lead to improved social relationship outcomes.

More recently, interventions to increase the size of mental health service users' social networks have been developed and evaluated. There is now preliminary evidence that these interventions can be effective (Anderson et al., 2015). However, as will be discussed in Section 2.1.1, loneliness and social isolation are distinct experiences. Interventions which aim to increase the number of participants' social contacts have been found to be successful at reducing social isolation but not loneliness (Masi et al., 2011). New interventions specifically targeting loneliness amongst adults with mental disorders have therefore been called for (Mann et al., 2017).

1.1.3. Mental disorders and depression

Mental disorders

This thesis begins by considering the experiences of loneliness and social connectedness amongst adults with any mental disorder but later narrows down onto adults with depression for reasons that will be discussed in Chapter 5.

Many terms are used to refer to mental health problems, such as mental illness and madness. In line with UK legislation (Department of Health, 2007) the term mental disorder will be used in this thesis for the sake of brevity as well as to avoid making assumptions about the source or nature of distress (e.g. mental illness) or focusing on a sub-set of experiences (e.g. madness).

Depression

Depression is understood here to be a heterogeneous experience which varies in terms of its symptomatology, intensity and duration (Fried, 2017). The term depression will be used in this thesis to correspond to the diagnosis of Major Depressive Disorder. Two commonly used diagnostic manuals for depression are the International Classification of Diseases-Version 10 (ICD-10; World Health Organization, 1993) and the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5; American Psychiatric Association, 2013). These two manuals define depression in terms of the following symptoms: persistent low mood (for at least two weeks); loss of pleasure and enjoyment in usual activities (two weeks); increased or decreased appetite; fatigue or lack of energy (ICD-10 only); difficulties with sleeping; slowing down or agitation of movements; feelings of worthlessness, guilt or self-blame; poor concentration and/or indecisiveness; low self-confidence (ICD-10 only); and frequent thoughts of death, suicidal ideation or self-harm.

In the DSM-5 the number of presenting symptoms, combined with the level of functioning impairment, is taken to indicate the severity of depression (American Psychiatric Association, 2013). Mild depression is defined as experiencing five to six symptoms which result in minor functional impairment. Moderate depression is classed as having more than five symptoms along with a considerable impact upon functioning. Severe depression occurs when one experiences the majority of

symptoms listed above and has a high level of functional impairment which interferes with daily functioning.

A psychiatric model of depression will be adopted within this thesis. However, it has been argued that depression exists on a continuum and that setting diagnostic thresholds to determine when the experience becomes a clinical concern is arbitrary (Haslam et al., 2012). Alternative models to psychiatric diagnosis have been proposed, such as case formulation (Eells, 2011) and the Power Threat Meaning Framework (Johnstone & Boyle, 2018). Nonetheless, psychiatric models of depression and other mental disorders have been defended on pragmatic grounds that they help to facilitate treatment in clinical contexts (Goldberg, 2000; Maj, 2016). A psychiatric model of depression will be adopted in this thesis in order to define the population of interest. However, this is a pragmatic decision and it is not intended to assume anything about the nature, assessment or treatment of depression, which are issues beyond the scope of this thesis.

The most recent nationally representative survey estimated that there is a 3.3% one-week prevalence rate of clinical depression amongst UK adults aged 16 and over (McManus et al., 2016). Using the 2011 census figures this would correspond to roughly 1.5 million adults. It has been estimated that by 2026 the annual cost of depression in terms of the impact on UK public services and lost employment will be £15.2 billion (McCrone et al., 2008). Globally, the total number of people with depression was estimated to exceed 300 million in 2015 (World Health Organization, 2017). The World Health Organization currently ranks depression as the single largest contributor to global disability.

Mental health services in the UK

This thesis focuses on adapting an intervention to be delivered in secondary care mental health services for adults with depression. Mental health services in the

UK are split between primary and secondary care. Primary care is provided in the community by general practitioners (GPs) and the Improving Access to Psychological Therapies programme for people with mild to moderate mental disorders. Secondary care is provided in both community and hospital settings by specialist teams for people with more severe and complex mental disorders.

1.1.4. Summary

Loneliness is highly prevalent amongst adults with mental disorders and is associated with adverse physical and mental health outcomes. This thesis will first consider the social experiences of adults with a variety of mental disorders and later focus on adults with clinical depression. A psychosocial approach to reducing loneliness will be taken in this thesis. This approach will involve examining how an intervention to increase social connectedness might be used to reduce loneliness amongst mental health service users.

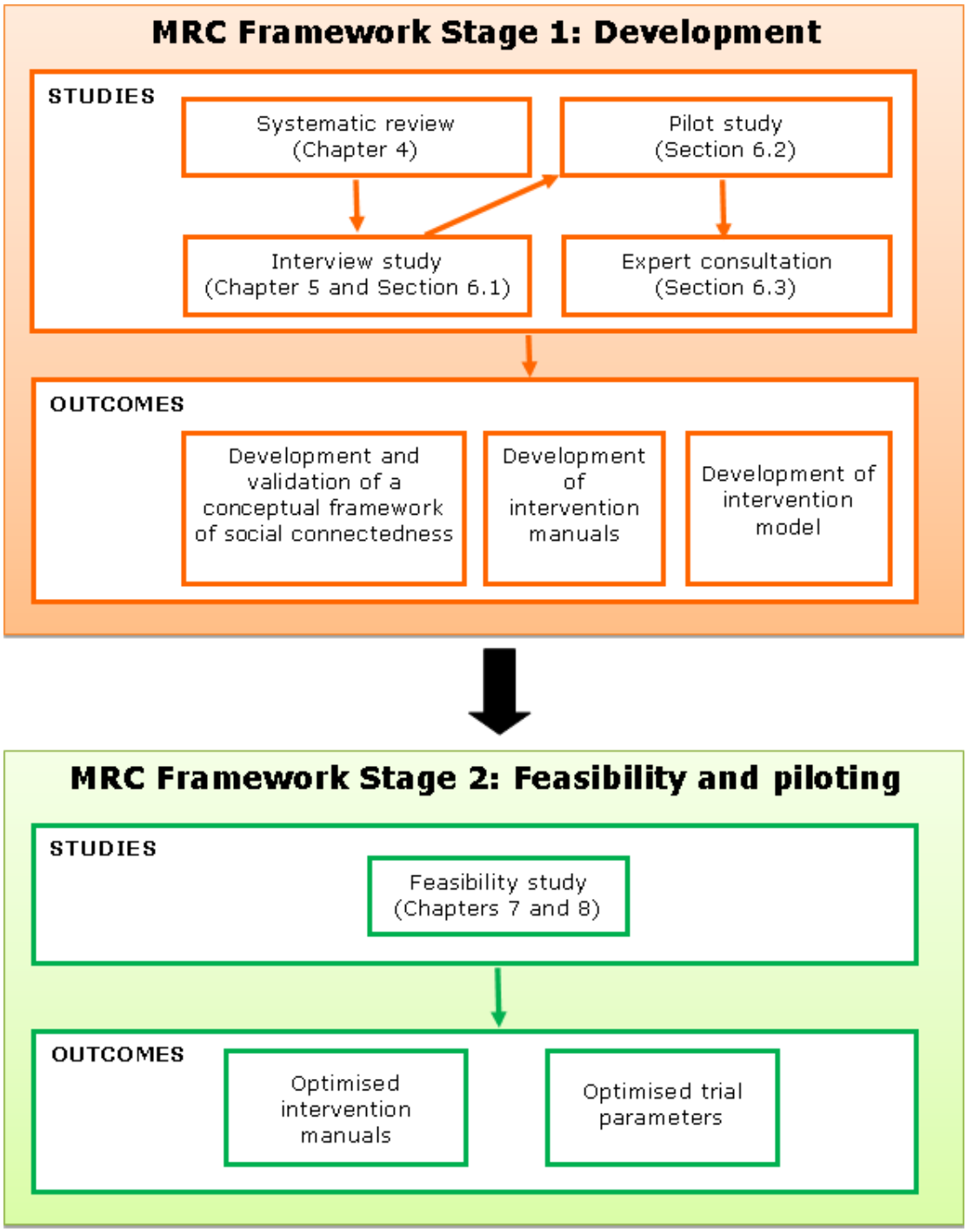
1.2. Structure of the thesis

The structure of this thesis follows the Medical Research Council (MRC) framework for the development and evaluation of complex interventions (Craig et al., 2008; Moore et al., 2015). This framework has four iterative stages which are summarised here and described in more detail in Chapter 3.

Stage 1 ('Development') involves the identification of existing evidence in order to develop the intervention to a point where it can be expected to have a beneficial effect. This is followed by developing the theory base for the intervention and outlining the likely processes of change. Stage 2 ('Feasibility and piloting') involves assessing the feasibility of the intervention and the methods used to evaluate it. Stage 3 ('Evaluation') involves the evaluation of the intervention to determine effectiveness. Stage 4 ('Implementation') involves the routine implementation of the new intervention in practice settings.

This thesis spans Stages 1 and 2 of the MRC framework, involving the development of a theory-based intervention and a feasibility evaluation. Figure 1.1 shows the design of the thesis mapped onto the MRC framework.

Figure 1.1 Design and methods of the thesis



1.3. Summary of chapters

This thesis is comprised of nine chapters. These are summarised as follows.

Chapter 1 introduces the thesis and situates the work within the existing policy and research context.

Chapter 2 presents a literature review of loneliness, social connectedness and mental health. The first part explores the conceptual and empirical associations between loneliness and social connectedness. The importance of tackling loneliness is then outlined in terms of the impact upon physical health, mental health, and recovery. Existing interventions are reviewed and the need for new interventions is outlined. Finally, the Groups4Health intervention is introduced. This intervention model provides the basis for an adapted intervention for adults with depression. The aims and objectives of the thesis are then listed in light of the literature review.

Chapter 3 outlines the methodology and research methods used to meet the objectives of the thesis. The critical realist philosophical assumptions of the thesis are described and linked to the decisions made in terms of the methodology and research design. The MRC framework is detailed. How patients and members of the public were involved in the thesis is described. A rationale is given for the research design of each individual study. Finally, some of the main ethical considerations of the thesis are discussed.

Chapter 4 describes the systematic review of measures of social connectedness. The two aims of this review were to identify the range of social connectedness measures which have been used amongst adults with mental disorders and to develop a conceptual framework of social connectedness. The results of the review are discussed in relation to how the conceptual framework informs the

adaptation of the Groups4Health intervention and in terms of the most appropriate measure to use in the feasibility study.

Chapter 5 presents the findings of a qualitative study to explore the experiences of social connectedness amongst adults with mental disorders and mental health professionals. The validity of the conceptual framework of social connectedness is evaluated against these data. It is discussed how the conceptual framework relates to similar conceptual work and how the study findings may further inform the adaptation of the intervention, the development of a logic model for the intervention and the design of the feasibility study.

Chapter 6 describes the development of the adapted intervention manual and logic model. These were informed by data from three sub-studies: interviews, a pilot study, and an expert consultation. This chapter describes the methods and results from these three sub-studies as well as the process of developing the manual and model and how the final versions were completed.

Chapter 7 describes the methods used in the intervention feasibility study. It details the design, setting, sampling, measures, topic guides, procedures and data analysis approach.

Chapter 8 presents the results of the feasibility study. It describes the recruitment, retention, candidate outcome measures, missing data and sample size calculation in terms of the parameters for a future trial. It also describes the results of the process evaluation in terms of the participant's perceived outcomes and mechanisms of the intervention.

Chapter 9 gives a broad discussion of the results of the thesis as a whole and how these sit within the wider literature. The main findings are discussed in relation to each of the thesis objectives. The implications of the feasibility study findings are described in terms of the further refinement of the intervention and a

potential future trial. The overall strengths and limitations of the thesis are discussed and some concluding reflections on the process of conducting the thesis are offered.

1.4. Chapter conclusion

This chapter introduced the topic of the thesis, namely the development of loneliness interventions for use in mental health services, and briefly outlined the methodology, studies and structure of the remainder of the thesis. The next chapter provides a more in-depth review of some of the key concepts and evidence relating to this thesis. This includes a conceptual review of loneliness and social connectedness as well as the empirical evidence relating to loneliness and loneliness interventions.

Chapter 2. Loneliness, social connectedness and mental health

Chapter overview

This chapter provides an overview of the literature concerning loneliness, social connectedness and mental health. The arguments and rationale for choosing the aims and objectives of this thesis are also described throughout this chapter. An abridged version of this overview was published in the *Mental Health and Social Inclusion* journal (Hare-Duke, 2017).

The conceptual and empirical literature on loneliness and social connectedness in the general population is described in Section 2.1. The prevalence of loneliness in the general population and amongst adults with mental disorders is detailed in Section 2.2. Demographic and individual-level factors associated with loneliness are discussed in Section 2.3. The relationship between loneliness and mental disorder is discussed in Section 2.4. The importance of reducing loneliness is argued for in Section 2.5 and the rationale for developing new interventions is given in Section 2.6. An existing intervention called Groups4Health, which is adapted as part of this thesis, is introduced in Section 2.7. A summary of the literature discussed in this chapter is given in Section 2.8 as well as the rationale for how this literature informed the thesis objectives. Finally, the thesis objectives are provided in Section 2.9.

2.1. Loneliness and social connectedness

2.1.1. Definition of loneliness and social connectedness

Loneliness

Many definitions have been suggested for both loneliness and social connectedness. A brief review of these definitions will be provided here. Table 2.1 provides a selection of definitions of loneliness.

Table 2.1 Example definitions of loneliness

Reference	Definition
De Jong Gierveld (1998, pp. 73-74)	Loneliness is a situation experienced by the individual as one where there is an unpleasant or inadmissible lack of (quality of) certain relationships. This includes situations in which the number of existing relationships is smaller than is considered desirable or admissible, as well as situations where the intimacy one wishes for has not been realized
Lopata (1969, p. 250)	A wish for a form or level of interaction different from the one presently experienced
Moustakas (1961, p. 24)	Existential loneliness is an intrinsic and organic reality of human life in which there is both pain and triumphant creation emerging out of long periods of desolation. In existential loneliness man is fully aware of himself as an isolated and solitary individual while in loneliness anxiety man is separated from himself as a feeling and knowing person
Sullivan (1953, p. 290)	Loneliness, which is the exceedingly unpleasant experience connected with inadequate discharge of the need for human intimacy
Weiss (1973, p. 17)	Loneliness is caused not by being alone but by being without some definite needed relationship or set of relations… In many instances it is a response to the absence of provision of a close, indeed intimate, attachment. It also may be a response to the absence of the provision of a meaningful friendship, collegial relationship, or other linkage to a coherent community
Young (1979, pp. 171-172)	The absence or perceived absence of satisfying social relationships, accompanied by symptoms of psychological distress that are related to the actual or perceived absence

As shown in Table 2.1, different definitions of loneliness have been offered by different theorists. Broadly, loneliness has been framed as a situation, a wish, a form of anxiety, a response or an absence. Peplau and Perlman (1982) identified three common elements to the majority of definitions in their seminal review of the literature. They found that theorists commonly suggest that loneliness (a)

results from perceived deficiencies in one's social life; (b) is a subjective rather than objective condition; and (c) is a painful, distressing experience. Peplau and Perlman therefore offered the following definition of loneliness: 'the unpleasant experience that occurs when a person's network of social relationships is deficient in some important way, either quantitatively or qualitatively' (Peplau & Perlman, 1982, p. 8). That is, loneliness is understood to comprise both a cognitive component (the perception of social deficits) and an affective component (aversive emotions arising in response to this perception). This integrated definition has now been widely adopted by many researchers from across different disciplines and is the standard definition used in current research (Cacioppo & Patrick, 2008; de Jong Gierveld et al., 2016; Victor et al., 2009). This definition has also been adopted within UK policy (Department for Digital, Culture, Media and Sport, 2018) and is used by the UK Office for National Statistics (Office for National Statistics, 2018). This definition will therefore be adopted in this thesis and is shown in Box 2.1.

Box 2.1 Definition of loneliness used in this thesis

The unpleasant experience that occurs when a person's network of social relationships is deficient in some important way, either quantitatively or qualitatively

Four features of this definition need to be highlighted. First, loneliness is conceived of as a social experience. The focus in this thesis will be upon people's relationships with other human beings rather than other kinds of relationships. It is acknowledged, however, that people can have important non-social relationships. People report having personal relationships with God or a deity, for instance, an experience which is negatively associated with loneliness (Kirkpatrick et al., 1999). Similarly, people's relationships with animals may have an influence

on loneliness (Gilbey & Tani, 2015). Nonetheless, this thesis will focus on human relationships given that stronger and more consistent associations are observed for loneliness in terms of human relationships than for other types of relationship (Gilbey & Tani, 2015; Kirkpatrick et al., 1999; Thomas, 2016).

A second feature of this definition is that loneliness is conceived of as a subjective experience, as distinct from the objective experience of social isolation. In this sense loneliness is a subjective experience arising from a perceived lack of social contact, whilst social isolation is an objective circumstance of dropping below a certain (arbitrary) enumeration of social interactions. This now common distinction between feeling lonely and being alone or isolated has come from the observation that loneliness can occur even without the absence of relationships (Smith & Victor, 2019). This phenomenon is sometimes referred to as feeling 'lonely in a crowd', e.g. being lonely in a marriage (Peplau & Perlman, 1982). Likewise, the solitude of being alone is often sought out by people, may offer many personal benefits, and does not necessarily engender feelings of loneliness (Koch, 1994). This thesis will therefore focus on loneliness, not on social isolation or solitude.

A third consideration is that this definition of loneliness refers to both quantitative and qualitative features of one's social relationships. In other words, in addition to perceptions regarding the objective features of one's relationships (e.g. number of social contacts), appraisals of relationship quality have also been highlighted as important to people's experiences of loneliness (Hyland et al., 2019; Pinquart & Sörensen, 2003). As opposed to social isolation, loneliness is primarily construed as a social psychological phenomenon, relating to the perceived adequacy of both objective and subjective dimensions of one's relationships. The perceived adequacy of objective dimensions of social relationships will be assumed in this thesis to be a function of individual personality traits (Hensley et al., 2012) and

contextual social norms (Van Tilburg et al., 2004). Perceived adequacy of social contact will therefore be highly individual. Interventions to alleviate loneliness will need to accommodate individual preferences in this regard by allowing participants to set their own social goals for social network size and frequency of contact.

By contrast, it will be assumed in this thesis that there may be common subjective dimensions of social relationships which are desired by most people. This assumption draws upon theories of evolutionary psychology which argue that there are universal motivations to achieve certain kinds of social relationships (Baumeister & Leary, 1995; Bowlby, 1969; Erikson, 1963). If there were such common subjective dimensions then any intervention would need to be developed with a view towards helping participants form relationships characterised by these dimensions. Thus, whether there are indeed common subjective dimensions of social relationships which people are motivated to experience will be one focus within this thesis.

Fourth, the definition of loneliness characterises the experience as being exclusively negative. It must be acknowledged, however, that not all perspectives on loneliness have viewed the phenomenon as being wholly negative. In particular, the existential approach to loneliness views the experience as being a universal feature of the human condition and does not necessarily take it to be a problem (e.g. Moustakas, 1961, 1972). A distinction can be made between an inevitable 'existential loneliness' which offers people the potential for self-examination and growth, with the aversive experience of 'loneliness anxiety' which concerns 'a basic alienation between man and man' (Moustakas, 1961, p. 24). It is loneliness anxiety which is of concern in this thesis.

Beyond the four considerations identified from the loneliness definition, the time scale of the experience of loneliness also needs to be considered. That is,

loneliness can sometimes be a temporary state in response to contingent circumstances and at other times it is a more chronic experience. Occasional experiences of loneliness will be assumed to be a normal part of daily life which serve an adaptive function of prompting people to reconnect to others (Cacioppo & Patrick, 2008). Meanwhile, chronic loneliness appears to have the biggest impact on health and wellbeing (Martín-María et al., 2019; Qualter et al., 2010; Shiovitz-Ezra & Ayalon, 2010). Therefore, in line with the vast majority of other studies in this area (Cacioppo & Patrick, 2008), experiences of persistent or chronic loneliness will be the focus of the present research.

Social connectedness

The term social connectedness has previously been used to refer to either objective or subjective features of social relationships, or both. For instance, some authors have used the term to refer to objective social network size or to community involvement (e.g. Cornwell et al., 2008). However, in keeping with the definition of loneliness used in this thesis, social connectedness will be understood in a subjective sense, in terms of one's perceptions of their relationships. A selection of definitions of subjective social connectedness is given in Table 2.2.

Table 2.2 Example definitions of social connectedness

Reference	Definition
Hagerty et al. (1993, p. 293)	When a person is actively involved with another person, object, group, or environment, and that involvement promotes a sense of comfort, wellbeing, and anxiety-reduction
Hutcherson et al. (2008, p. 720)	To be trusted and loved, and to trust and love in return
Kearney (1998, p. 508)	A sense of having a safe place within a community and a meaningful role to play

Table 2.2 continued

Reference	Definition
Lee and Robins (2000, p. 484)	An enduring and ubiquitous experience of the self in relation with the world, as compared with social support, adult attachment, and peer affiliations, which represent more discrete, current relationships
Mauss et al. (2011, p. 739)	Engagement in close, mutually satisfying relationships and the formation of long-term cooperative bonds
Newcomb (1990, p. 479)	[Connectedness involves] bonding, attachment, friendship, intimacy, and companionship
Santini et al. (2015, p. 54)	The degree to which a person experiences belongingness, attachment, relatedness, togetherness, or entrenchment in one's social relationships
Timpone (1998, p. 59)	The level of an individual's integration into his or her social milieu and the fullness of the resulting associative networks

Two themes emerge from the range of definitions of social connectedness given in Table 2.2. First, social connectedness can be understood at two different levels. Some authors refer to social connectedness in terms of specific relationships and particular people (e.g. Hagerty et al., 1993; Mauss et al., 2011) whilst others refer to non-specific experiences in relation to the wider social context (e.g. Kearney, 1998; Lee & Robbins, 2000).

Second, there is not a clear consensus on the dimensions of social connectedness or the appropriate terminology to use in defining them. A previous conceptual review of social connectedness stated that the concept was multi-dimensional but did not specify what these dimensions might be (Townsend & McWhirter, 2005). The definitions in Table 2.2 list around 20 qualities that may to be relevant to the underlying dimensions of social connectedness. It seems likely that several closely related terms are being used across different definitions and that the actual number of major dimensions of social connectedness is considerably fewer than suggested by the example definitions. Nonetheless, the question of how many dimensions social connectedness consists of and what these dimensions are remains unclear. Answering this question will therefore form one of the objectives of this thesis.

Preliminary working definition of social connectedness

A preliminary working definition of social connectedness will be used for the remainder of this chapter and will be later refined in Chapter 4. This definition is shown in Box 2.2.

Box 2.2 Working definition of social connectedness

A subjective psychological bond that people feel in relation to individuals and groups of others

This definition was drawn from the work of researchers currently studying social connectedness (Haslam et al., 2017) and was chosen for two reasons. First, it sets out three parameters by characterising social connectedness as a feature of one's social relationships, and as both a subjective and an individual-level phenomenon. As one of the aims of this thesis is to inform interventions to tackle loneliness, these three parameters are appropriate given the common definition of loneliness. Second, this definition is sufficiently broad that it avoids making too many a priori assumptions about the nature and dimensions of social connectedness. Given the contested understanding of social connectedness, this broad definition allows for a more comprehensive review of this concept and the related empirical literature.

2.1.2. Other related concepts

There is a large array of concepts related to loneliness and social connectedness. These will be discussed here to characterise the overlap and boundaries between them. Table 2.3 summarises some of the key related concepts.

Table 2.3 Definitions and measures of concepts related to social connectedness

Concept	Definition	Objective or subjective	Level	Example measure
Social isolation and social disconnected-ness[a]	The absence of social contact and social networks (Rook, 1984)	Objective	Individual	Social Network Index: Network size subscale (Cohen et al., 1997)
Social support	(1) Actual availability of support from others (2) Perceived availability of support (Thoits, 2011a)	(1) Objective (2) Subjective	Individual	Interpersonal Support Evaluation List (Cohen et al., 1985)
Social inclusion	Participating in opportunities and choices afforded to other people (e.g. employment, education, housing and community participation) (Coombs et al., 2013)	Objective	Individual	Social and Community Opportunities Profile (Huxley et al., 2012)
Belonging and relatedness[b]	Frequent, nonaversive interactions within an ongoing relational bond (Baumeister & Leary, 1995)	Objective and subjective	Individual	General Belongingness Scale (Malone et al., 2012)
Social integration	The diversity of types of relationships (e.g. spouse, religious groups) one has (Cohen et al., 2004)	Objective	Individual	Social Network Index: Social integration subscale (Cohen et al., 1997)
Social capital	(1) Networks and norms: Social networks and the norms of reciprocity and trustworthiness that arise from them (Putnam, 2000) (2) Resources: Resources accruing to a person/group from their access to a social network (Bourdieu, 1986)	(1) Objective and subjective (2) Objective	(1) Community (2) Individual	(1) UK Social Capital Measurement Framework (Harper & Kelly, 2003) (2) Resource Generator (Van Der Gaag & Snijders, 2005)

[a]Social isolation and social disconnectedness are terms frequently used synonymously in the literature (e.g. Cornwell et al., 2008; Zavaleta et al., 2014);

[b]belonging and relatedness are terms used synonymously (e.g. Hagerty et al., 1993; Ryan & Deci, 2000)

Table 2.3 describes eight concepts, with social support and social capital each having two definitions. Of these eight concepts, six can be immediately distinguished from social connectedness understood as a subjective, individual-level phenomenon. First, five of these are defined in reference to objective characteristics of social relationships. These comprise social isolation/disconnectedness, social inclusion, actual social support, social integration and social capital defined as resources. In addition, social capital defined as social networks and norms refers to properties of collectives rather than individuals. Social capital as networks and norms also sometimes refers to how people relate to others at the community-level rather than the individual-level. In either case, this concept is at the community-level.

However, two of the concepts shown in Table 2.3 describe subjective characteristics of relationships at the individual level in line with the working definition of social connectedness of this thesis. These are perceived social support and belonging/relatedness. It is unclear to what extent social connectedness overlaps with these two concepts.

2.1.3. Conceptual and empirical links between loneliness and social connectedness

In this thesis a psychosocial approach to reducing loneliness is taken, namely by increasing social connectedness. The conceptual and empirical links between these concepts are now considered.

Conceptual links

The terms loneliness and social connectedness are often used interchangeably and are sometimes even defined in relation to the absence of the other, including by leading researchers in the field (e.g. Cacioppo & Patrick, 2008; Kok & Singer, 2017). This provides some initial suggestion of an intimate link between

loneliness and social connectedness. Additional examination of the conceptual work done into these topics further exemplifies this link. This section will focus on loneliness as the majority of literature concerns loneliness rather than social connectedness.

Two broad theoretical approaches to loneliness can be identified in the literature: the 'social needs' or 'deficit perspective' and the 'cognitive approach' (Dykstra & Fokkema, 2007; Marangoni & Ickes, 1989; Peplau & Perlman, 1982; Sønderby & Wagoner, 2013). The social needs approach is most commonly associated with the work of the sociologist Robert Weiss, whose seminal book, *Loneliness: The experience of emotional and social isolation* (1973) has had a great influence on much subsequent research into the problem over the last 45 years (Cacioppo & Patrick, 2008; Marangoni & Ickes, 1989; Sønderby & Wagoner, 2013; Victor et al., 2009). Weiss suggested that two different social deficits were implicated in cases of loneliness, and correspondingly that two distinct experiences of loneliness itself can be identified. First, he suggests that a person can experience 'emotional loneliness' in response to the lack of an intimate relationship. Second, Weiss argues that one can also experience another type of loneliness which he termed 'social loneliness', a state characterised by feelings of marginality, boredom and aimlessness. This state of loneliness arises where there is a deficit in an individual's wider social networks.

In contrast, the cognitive approach states that loneliness arises from a lack of the kinds of social relationships which an individual personally desires, without specifying what those relationships might be (Hawkley & Cacioppo, 2010; Perlman & Peplau, 1981; Russell et al., 1980). Individuals are thought to possess personal preferences or standards for social contact. Therefore, the key determinant of loneliness is not the absence of contact per se but the discrepancy between the form and/or degree of contact desired and that which is achieved.

Differences in people's experiences of loneliness are thought to be characterised by only the intensity of the feeling, not by qualitative differences in the phenomenological experience of loneliness as is suggested by Weiss (Marangoni & Ickes, 1989).

Nonetheless, as with the social needs theorists, the cognitive perspective rests upon an assumption regarding *some* form of social needs. Cognitive theorists often suggest that loneliness stems solely from cognitive processes or can be defined in purely intrapersonal terms (see e.g. Cacioppo & Patrick, 2008; Peplau & Perlman, 1982). But to say that some kind of social contact is desired and deemed to be lacking leaves open the question of what forms of contact are actually desired.

A key question, then, is what the social deficiency of loneliness consists of. In other words, how one's social life is deemed to be inadequate as indicated in the definition of loneliness. Different answers have been given to this question. Prominent theorists have suggested that loneliness stems from the unmet need for intimacy (Fromm-Reichmann, 1959; Sullivan, 1953), affiliation (Weiss, 1973), social support (Andersson, 1998), belonging (McWhirter, 1990), integrated involvement (Shaver & Buhrmester, 1983) or the lack of people to share emotional experiences with (Rook, 1984). It is therefore not clear what the social deficit of loneliness might be. More importantly, however, all of the possible answers that have been given by theorists involve concepts drawn from the social connectedness literature as seen in Table 2.2. This provides a stronger theoretical reason to suggest that loneliness is indeed a lack of social connectedness as many authors have used these terms (e.g. Hawkley & Cacioppo, 2010; Lim & Gleeson, 2014).

Empirical associations between loneliness and social connectedness

Empirical research further suggests that there might be a strong link between loneliness and social connectedness. This section describes studies using measures of social connectedness which meet the preliminary working definition of social connectedness used in this thesis: 'a subjective psychological bond that people feel in relation to individuals and groups of others'.

To the author's knowledge, no studies have been conducted to compare the factor structure of measures of loneliness and social connectedness. However, studies suggest that there is a moderate to large association between the two concepts. In one US study of adults with major depressive disorder (n=31), there was a very strong inverse association (r=-0.76) between social connectedness and feelings of loneliness (Hagerty & Patusky, 1995). Other studies of non-clinical samples (n ranging from 100 to 875) across different age groups and nationalities have found moderate to large inverse correlations (r=-0.66 to -0.80) between different measures of loneliness and social connectedness (Chen & Chung, 2007; Hagerty et al., 1996; Lee et al., 2001; Malone et al., 2012).

These empirical findings can be assessed according to the psychometric property of convergent validity: the degree to which two measures of constructs that theoretically should be related, are in fact related. Conventional criteria suggest that convergent validity between two measures is established with a correlation coefficient of 0.50 or above (Terwee et al., 2007; Terwee et al., 2012). Considering this criterion, the observed associations between measures of loneliness and social connectedness suggest that they are measuring either the same or very similar constructs. Indeed, the results suggest that measures of loneliness and social connectedness also meet the more stringent criteria required for criterion validity (correlation ≥0.70) which is defined as the ability of the measure to predict a variable that is designated as a criterion (often an

externally-defined 'gold standard') (Terwee et al., 2007). The psychometric evidence therefore suggests that loneliness and social connectedness are closely related.

There is also preliminary evidence that loneliness and social connectedness covary over time. One Australian intervention study with 56 young adults experiencing psychological distress found that reductions in feelings of loneliness were predicted by increases in social connectedness (Haslam et al., 2016).

Whilst there remains a level of complexity and uncertainty regarding the link between the concepts of loneliness and social connectedness, there is a substantial degree of conceptual and empirical overlap between them. Therefore, three key assumptions will be made in this thesis, as shown in Box 2.3.

Box 2.3 Assumptions regarding loneliness and social connectedness

(1) Loneliness and social connectedness are strongly associated phenomena

(2) These experiences have a relationship which is either bipolar (polar opposites of a single dimension) or oblique (two distinct dimensions which are highly correlated)

(3) Effective interventions which target either loneliness or social connectedness will have a strong, if not direct impact, upon both phenomena

Given the assumptions stated in Box 2.3, the terms loneliness and social connectedness will be used as synonyms for the purposes of this thesis. Interventions designed to increase social connectedness will be assumed to decrease loneliness correspondingly.

2.2. Prevalence of loneliness in general and clinical populations

2.2.1. UK general population

Loneliness has been measured in the UK element of the European Social Survey (third round) which included a single item for loneliness. This item asked participants, 'please tell me how much of the time during the past week you felt lonely,' with the options 'none or almost none of the time,' 'some of the time,' 'most of the time,' and 'all or almost all of the time'. Victor and Yang (2012) examined the UK data for 2,393 participants aged 15–97. They found that 6% of participants reported feeling lonely almost all of the time or most of the time, 21% were lonely some of the time, and 73% reported that they were never lonely.

Single item measures can sometimes have poor reliability as there is an increased risk of measurement error (Hoeppner et al., 2011). In the case of loneliness there are additional concerns regarding social desirability bias from using questions asking directly about loneliness given that it can be a stigmatised experience (Office for National Statistics, 2018). There are also ongoing conceptual debates over the complex nature of loneliness and whether a single item, or even a unidimensional scale, is a valid measure of the phenomenon (de Jong Gierveld & Van Tilburg, 2010; Penning et al., 2014; Rook, 1988).

However, previous studies have shown that single loneliness items are strongly related to the overall score obtained from different multi-item loneliness scales (de Jong Gierveld & Van Tilburg, 1999; DiTommaso & Spinner, 1993; Russell et al., 1978). Therefore, the estimates given by Victor and Yang (2012) can be taken as indicative of the prevalence of loneliness in the UK.

2.2.2. Adults with mental disorders

The experiences of loneliness amongst UK adults with mental disorders have been measured within the Adult Psychiatric Morbidity Survey (McManus et al., 2009). Stickley and Koyanagi (2016) analysed data from the 2007 wave which included a single item measuring loneliness. This item asked participants to what extent they had felt 'lonely and isolated from other people in the past two weeks' with the response options: 'very much', 'sometimes', 'not often' and 'not at all'. Six categories of common mental disorder were measured using the Clinical Interview Schedule Revised: depressive episode; mixed anxiety and depression; generalised anxiety disorder; panic disorder; phobia; and obsessive compulsive disorder. No data were reported for individual disorders. The prevalence of loneliness amongst adults with and without any common mental disorder is shown in Table 2.4.

Table 2.4 Prevalence of loneliness amongst adults with and without a common mental disorder (n=7,360)

Common mental disorder	**n**	**Loneliness (n, %)**			
		Not at all	***Not often***	***Sometimes***	***Very much***
Yes	1,266	318 (25.1)	216 (17.0)	548 (43.2)	184 (14.5)
No	6,094	4,205 (69.0)	977 (16.3)	837 (13.7)	75 (1.2)

Data extracted from Stickley and Koyanagi (2016)

As seen in Table 2.4, whilst only a minority of adults without a common mental disorder reported experiencing loneliness either sometimes or very much (15.0%), a majority of adults with at least one of the specified mental disorders reported this degree of loneliness (57.8%).

Meltzer and colleagues (2013) used the same dataset to analyse the association between loneliness (combining the categories of 'sometimes' and 'very much' to indicate loneliness) and each of the six common mental disorders as well as psychosis. Psychosis was assessed using the Schedules for Clinical Assessment in Neuropsychiatry (World Health Organization, 1999). After adjusting for age, sex,

ethnicity, marital status, employment, tenure and debt it was found that loneliness was positively associated with the presence of all measured disorders. Compared to no disorder, the strongest associations were found for depression (Odds ratio [OR]=10.85, 95%Confidence Interval [CI] 7.41–15.94, p<0.001), phobia (OR=11.66, 95%CI 7.01–19.39, P<0.001) and obsessive-compulsive disorder (OR=9.78, 95%CI 5.68–16.86, P<0.001).

These findings correspond to other studies using different datasets. For example, adults with depression reported a high prevalence of loneliness (≥35.7%) across all age groups in a representative sample of 2,393 UK adults (Victor & Yang, 2012). Similarly, in a representative sample of 12,286 adults living in Switzerland, 25.3% of adults with major depressive disorder, as indicated by the Composite International Diagnostic Interview (Kessler et al., 1998), reported feeling lonely very often compared to 2.5% of those without depression. Polish adults with psychosis (n=207) were found to have a significantly higher degree of loneliness than a general population sample (n=20,000) (Chrostek et al., 2016). In a nationally representative sample of 15,010 German adults, loneliness was associated with depression (OR=1.91, 95%CI 1.74–2.09, p<0.001) and generalised anxiety disorder (OR=1.21 95%CI 1.09-1.34, p<0.001) after controlling for age, gender, relationship status and socioeconomic status (Beutel et al., 2017). It is not clear why the reported strength of associations between loneliness and mental disorder differed so markedly between the German (Beutel et al., 2017) and UK samples (Meltzer et al., 2013). Differences in the measurement of mental disorder, loneliness and the covariates used in each study may help to explain this.

In summary, there is strong evidence that adults with mental disorders experience feelings of loneliness more frequently than the general population in the UK and other countries.

2.3. Factors associated with loneliness

Very few studies have examined factors associated with loneliness amongst clinical populations specifically. However, there is a substantial literature examining a variety of different factors related to loneliness in the general population. Loneliness is a multi-factorial phenomenon arising from a complex interrelationship between demographic, structural, physiological and psychological factors (de Jong Gierveld et al., 2016). The main demographic and psychological risk factors are presented here, to give an overview of the population groups most vulnerable to loneliness in order to inform which groups will be focussed on in this thesis.

2.3.1. Age

In the UK and other European countries there is a U-shaped distribution of loneliness across the lifespan with people aged 15-24 and those over 75 reporting the highest levels (Lasgaard et al., 2016; Victor & Yang, 2012; Yang & Victor, 2011). This indicates that working age adults experience lower levels of loneliness relative to other age groups. However, this thesis will focus on working age adults for four reasons.

First, amongst adults with depression loneliness remains consistently high across the lifespan rather than showing an age gradient (Meltzer et al., 2013; Victor & Yang, 2012). Second, most studies to date have focussed on adolescents and older adults (Gardiner et al., 2018). Therefore, research into loneliness amongst working age adults with a mental disorder is currently under-researched. Third, accumulating theory and evidence suggests that social motivations change across the lifespan and these motivations may therefore be distinct across different age groups (Carstensen, 1987; Charles & Carstensen, 2010; Fingerman, 2011). Fourth, there may be unique additional factors contributing to poor social relationships in children, adolescents and older adults, including physical health

status, parental styles and bereavement, which would also need to be considered within an intervention (de Minzi, 2006; Pinquart & Sörensen, 2003). Thus, specific intervention components may be required to target different social needs across age groups and interventions may be most effective when targeted at one age group in particular (Dickens et al., 2011). Therefore, this thesis will focus on working age adults with mental health disorders.

2.3.2. Gender

In the UK, 7.6% of women reported feeling lonely compared to 4.6% of men assessed using a single item direct measure of loneliness (Victor et al., 2005). Results from a meta-analysis of 102 studies involving 73,213 participants found that women report significantly higher levels of loneliness than men (mean difference g=0.15, 95%CI 0.14-0.17) (Pinquart & Sörensen, 2001). This relatively small difference was more pronounced in studies in which loneliness was measured with single-item direct indicators. This difference might be related to social desirability bias in terms of men's greater reluctance to report feelings of loneliness in response to direct questions (de Jong Gierveld et al., 2006).

Given that the gender difference in loneliness is small and may be partly explained by social desirability bias, this thesis will not be restricted to a particular gender.

2.3.3. Ethnicity and migration

Very few studies have examined the prevalence of loneliness amongst different ethnic groups. In a survey of 300 adults aged over 65 in the UK, high levels of loneliness were found amongst minority elders of Chinese, African, Caribbean, Pakistani and Bangladeshi origin (Victor et al., 2012). The prevalence of older adults from these minority groups stating that they 'often' or 'always' felt lonely

ranged from 24% to 50%. This compared to 8% of Indian participants and 9% in a comparable White British sample.

A few studies have also examined the impact of immigrant status upon reported loneliness, typically amongst older adults. These studies generally show an increase in loneliness amongst migrant groups, except for migrants with a similar language and culture to that of the host country (Fokkema & Naderi, 2013; Gierveld et al., 2015; Uysal-Bozkir et al., 2017).

However, nationally representative data regarding ethnicity and migration are not currently available for the UK. As current evidence is relatively limited this thesis will not focus on any particular ethnic group.

2.3.4. Relationship factors

Different types of relationship have been examined in terms of their association with loneliness, including marriage/partnership, family relationships and non-kin relationships. In the UK, adults who are married or in a relationship report the lowest levels of loneliness (3.4%) compared to those who are single (6.6%), divorced/separated (13.1%) or widowed (19.3%) (Victor & Yang, 2012).

Family relationships, including parent-child and sibling relationships, are also known to be important. Some evidence suggests that family relationships can be compensatory by reducing loneliness for people lacking other types of relationship (Dykstra, 1993; Milevsky, 2005; Pinquart, 2003; Ponzetti & James, 1997).

Non-kin relationships with close or best friends also reduce loneliness, notably in adolescence (Vanhalst et al., 2014) and in adults who never partnered or did not have children (Dykstra, 1993; Pinquart, 2003). Characteristics of social networks also help to explain levels of loneliness. In particular, having relationships characterised by closeness has been found to reduce loneliness amongst younger

and older adults (Green et al., 2001). One study found that the four relationships in a person's network which are rated as the closest provided the greatest buffer against loneliness with additional close relationships not having a strong influence (Van Tilburg, 1990). However, maintaining a diverse range of relationship types within one's social network also appears to be protective. For instance, adults with networks consisting primarily of family ties report greater loneliness than adults with a range of relationships (Silverstein et al., 1996). Social networks can be characterised by both strong and weak ties, referring respectively to relationships with high and low levels of contact, emotional intensity and intimacy (Granovetter, 1973). Studies have found that both strong and weak ties are protective against loneliness (Sandstrom & Dunn, 2014; Van Tilburg, 1990). In summary, loneliness does not concern the lack of one particular type of social relationship. The quantity and quality of many different types of relationship have been associated with loneliness (Bruce et al., 2019).

Personal expectations for relationships can also influence loneliness. The value an individual attaches to different types of relationship partly determines their emotional reaction to the absence of a given relationship. For example, widowers who attach less importance to having a partner report less feelings of loneliness than widowers who highly value this type of relationship (Dykstra & De Jong Gierveld, 1994).

Previous experiences of social relationships also influence loneliness. Early experience of social relationship adversities have been found to influence loneliness throughout the lifespan (Ejlskov et al., 2019).

As different types of relationship have been found to be associated with loneliness, this thesis will not focus on any particular relationship type.

2.3.5. Socioeconomic factors

Most research into socioeconomic factors related to loneliness has focussed on levels of income. Studies suggest there is a low to moderate association between income and loneliness (Bosma et al., 2015; Mullins et al., 1991; Özdemir & Tuncay, 2008). However, income is typically measured as household income, and it is unclear whether the income-loneliness association can be explained by confounding variables such as partner status (Bosma et al., 2015; Hawkley et al., 2008).

Relatively little empirical research has been conducted on the impact of socioeconomic factors such as social class or income inequality though these have been hypothesised to be associated with loneliness (de Jong Gierveld & Tesch-Römer, 2012). As there is not currently enough evidence regarding socioeconomic factors and loneliness, no particular socioeconomic group will be targeted within this thesis.

2.3.6. Personality

A number of different personality traits have been associated with loneliness, including shyness (Jackson et al., 2002), low self-esteem (Brewer & Kerslake, 2015; Skues et al., 2012), low extraversion, and high neuroticism (Hensley et al., 2012; Vanhalst et al., 2012). Attachment style, understood as a cognitive working model of how an individual perceives and interacts with his or her social world (Bowlby, 1951), also affects loneliness. Adults with a secure attachment style, characterised by both a positive self-view and a positive view of others, have lower levels of loneliness than adults with other attachment styles (DiTommaso et al., 2003).

Loneliness is sometimes construed as a stable personality trait (e.g. Cacioppo & Patrick, 2008; Perlman & Peplau, 1981). This assumption will not be made in this thesis as loneliness may instead be caused primarily by social or environmental

factors such as objective isolation, bullying or discrimination (Ireland & Qualter, 2008; Shankar et al., 2011; Świtaj et al., 2015). It will instead be assumed that loneliness is caused by a multitude of social and psychological factors and that multiple factors may need to be addressed within a single intervention.

2.3.7. Geographical factors

Mixed results have been found in studies examining differences in loneliness between urban and rural environments. Some studies have found higher rates of loneliness in rural areas (Drennan et al., 2008) whilst other find no difference (Matthews et al., 2019; Menec et al., 2019). Given the mixed evidence, this thesis will not focus on urban-rural differences in loneliness.

2.3.8. Cultural factors

Cultural norms can influence individual-level experiences of loneliness. Individualism-collectivism is a cultural dimension wherein individualist cultures emphasise autonomy and self-orientation, whilst collectivist cultures place greater value on communal ties and are more bound by them (Triandis, 2001). One hypothesis is that loneliness will be higher in collectivist-oriented communities where sensitivity to exclusion is stronger than in more individualist communities (Johnson & Mullins, 1987). There is some evidence for this hypothesis, with higher levels of loneliness found in countries indexed as collectivist compared to individualist countries (Lykes & Kemmelmeier, 2014; Swader, 2018). However, it can be inappropriate to infer conclusions at the individual level from data derived at the group level, an issue sometimes known as the ecological fallacy (Robinson, 1950). Cross-cultural studies have found that collectivism measured at the individual level, i.e. personally endorsed collectivism, is negatively associated with loneliness whilst individualism is positively associated (Heu et al., 2018).

One possible explanation for the mixed findings is that there is an interaction between personally endorsed norms, societal norms, and social relationship factors. For example, it has been hypothesised that loneliness may be highest for individuals living alone in countries where adults without a partner are expected to live with their families (Imamoglu et al., 1993; Jylhä & Jokela, 1990). Evidence for such interactions were found in a recent study of 21 European countries (n=36,760) in which the highest levels of loneliness were found for individuals who were personally collectivist and living alone in a collectivist country (Swader, 2018).

Other cultural factors also appear to be important to the experience of loneliness. There is emerging evidence that the stigmatisation of different population groups is associated with loneliness. Adults reporting experiences of discrimination with regards to various different personal characteristics have higher levels of loneliness. This includes discrimination based on mental health (Świtaj et al., 2015), ethnicity (Priest et al., 2017), age, weight, physical disability, and appearance (Sutin et al., 2015).

In this thesis it will be assumed that the majority of adults accessing secondary mental healthcare services in the UK will come from similar national backgrounds. That is, the majority will be British and will have broadly similar cultural understandings of loneliness. It is possible, however, that adults living with a mental disorder experience cultural factors such as stigma which affect their social experiences. Therefore, the main focus of this thesis with regards to culture will be whether adults with mental disorders have unique experiences of loneliness and social connectedness.

2.3.9. Summary

In reviewing the factors associated with loneliness a number of decisions were made regarding which populations groups to focus on in this thesis. In summary, this thesis will focus on adults aged 18-65 with mental disorders from all demographic backgrounds in the UK.

2.4. The relationship between loneliness and mental disorder

The relationship between loneliness and mental disorder is unclear yet the precise relationship has important implications for this thesis. There are four possible relationships: loneliness as a symptom of mental disorder; loneliness as a risk factor for mental disorder; loneliness as a consequence of mental disorder; and a bidirectional relationship between loneliness and mental disorder.

There are theoretical, empirical and practical implications stemming from these possible relationships. For example, there is already strong evidence supporting the effectiveness of existing clinical interventions for various mental disorders. Thus, the rationale for the development of new interventions would be very different, and possibly much less convincing, if loneliness were understood to be a symptom of mental disorder rather than distinct from disorder. Meanwhile, if loneliness was primarily a risk factor for mental disorder then this may suggest that preventative efforts should be made at a public health level. On the other hand, if loneliness is primarily a consequence of mental disorder then interventions may be most useful within clinical settings.

2.4.1. Is loneliness a symptom of mental disorder?

The first question is whether loneliness is a symptom of mental disorder. The high prevalence of loneliness amongst adults with mental disorders might suggest that loneliness is indeed a symptom. This argument has often been made in the case

of depression, with feelings of loneliness often described as part of the clinical presentation of this disorder (Beck, 1967). Indeed, some screening instruments to measure depression in the general population include items referring to feelings of loneliness (Radloff, 1977). Similarly, items to assess loneliness have been used in measures of schizotypy (Chapman et al., 1976) and questions about the overlap between loneliness and social anxiety have recently been made (Fung et al., 2017).

It may be noted that if psychiatric diagnosis is taken to be invalid, such as might be assumed under a psychosocial (Johnstone & Boyle, 2018) or network model of mental health (Borsboom & Cramer, 2013), then the question of whether loneliness is a symptom of mental disorder does not arise. However, a psychiatric model of depression is being assumed in this thesis to identify the target population for the intervention (see Section 1.1, p.5) and thus this question should at least be considered.

Symptoms can be defined as physical or mental features which are regarded as indicating a condition of disease. Following the standard disease model, mental health symptomatology arises from a common cause in the body (Hyland, 2011). Other more recent approaches to psychopathology suggest that symptoms are boundaried either in terms of property clusters which share multiple different mechanisms (Kendler et al., 2011) or as nodes within a network which directly causally reinforce one another (Borsboom, 2008). Of most relevance to this thesis is that all approaches to psychopathology suggest that there is a clustering of symptoms which can be empirically observed.

Psychometric modelling approaches can be used to analyse the correlations between symptoms to determine the structure of this clustering (Reise & Waller, 2009). This section will describe studies which have used factor analysis whereby the correlations of observed variables are analysed in terms of a lower number of

unobserved variables known as factors. A factor which is identified from psychiatric measures is taken to represent an underlying unified disorder and therefore observed variables which load onto this factor can be understood to represent the symptomatic boundaries of a particular disorder (Reise & Waller, 2009). If measures of loneliness load onto the same factor as that of psychiatric measures then loneliness can be understood to be a symptom of disorder. If loneliness measures load onto separate factors then loneliness can be understood to be distinct from mental disorder.

Empirically, studies using factor analysis have examined the relationship between loneliness and depression, schizotypy, and anxiety. All of these studies have found that loneliness is a distinct construct. These studies have used established measures of each of the respective constructs and found separate factors emerge for loneliness and the respective mental disorders. To the authors' knowledge, there have been six such studies for depression (Anderson & Harvey, 1988; Cacioppo et al., 2006; Fung et al., 2017; Russell et al., 1980; Weeks et al., 1980), one study for schizotypy (Badcock et al., 2016), and two studies for social anxiety (Anderson & Harvey, 1988; Fung et al., 2017). The studies using measures of depression have found that the items load onto a single factor whilst the items for loneliness measures load onto one or more separate factors. The exception to these general findings is for a study which used the Center for Epidemiologic Studies Depression Scale, which has an item referring to feelings of loneliness. In this study the loneliness item from the depression measure loaded onto the loneliness factor (Cacioppo et al., 2006).

Whilst some uncertainty remains regarding the role of loneliness in the presentation of mental disorders the empirical evidence indicates that loneliness is not a symptom of disorder. This will therefore be the assumption made in this

thesis. This subsequently raises the question of whether loneliness is a cause or a consequence of mental disorder.

2.4.2. Is loneliness a cause or a consequence of mental disorder?

Most longitudinal observational studies examining the prospective association between loneliness and mental health have focussed on depression. In a review of such studies Hawkley and Cacioppo (2010) concluded that there is likely to be a reciprocal relationship between the two experiences. That is, loneliness appears to be both a cause and a consequence of depression. Preliminary evidence from non-clinical samples also shows that loneliness is prospectively associated with symptoms of anxiety (Cacioppo et al., 2006), delusions (Myin-Germeys et al., 2001) and paranoia (Lamster et al., 2017) after controlling for the baseline severity of these symptoms. Therefore, it will be assumed in this thesis that loneliness is not simply a consequence of mental disorder but may also play a role its aetiology.

2.4.3. Summary

The arguments and empirical evidence presented in this section have been used to justify two assumptions regarding the relationship between loneliness and mental disorder. These assumptions are highlighted in Box 2.4.

Box 2.4 Assumptions regarding loneliness and mental disorder

(1) Loneliness is not a symptom of mental disorder

(2) Loneliness may be a cause as well as a consequence of mental disorder

2.5. Importance of reducing loneliness amongst adults with mental disorders

The importance of reducing loneliness amongst adults with mental disorders can be described in terms of the impact upon physical health outcomes, mental health outcomes and for personal recovery and wellbeing.

2.5.1. Physical health outcomes

The high rates of loneliness amongst adults with mental disorder may be one factor which contributes to the poor physical health outcomes of this population. Adults with mental disorders are at an increased risk of morbidity and mortality. This increased risk is partly explained by lifestyle factors (Saxena & Maj, 2017; Walker et al., 2015). Loneliness has been associated with increased incidence of adverse physical health outcomes across the lifespan. For instance, loneliness exhibits a dose-response relationship with cardiovascular health risk in young adulthood (Caspi et al., 2006) and has been associated with increased systolic blood pressure in middle-aged adults (Hawkley et al., 2006). It has also been associated with the development of coronary heart disease and stroke (Valtorta, Kanaan, Gilbody, Ronzi, et al., 2016). Meta-analyses suggest that those who feel lonely have 22% to 26% increased likelihood of all-cause mortality (Holt-Lunstad et al., 2010; Rico-Uribe et al., 2018). Interventions to reduce loneliness amongst adults with mental disorders may therefore help to improve their physical health.

2.5.2. Mental health outcomes

Most of the clinical research on the impact of loneliness on mental health symptomatology has focussed on major depressive disorder. As well as being a risk factor for worsening depressive symptomatology amongst general population samples (Cacioppo et al., 2015), loneliness is also associated with a poorer

prognosis for adults with an existing diagnosis of depression (Holvast et al., 2015; Jeuring et al., 2018; van Beljouw et al., 2010; van den Brink et al., 2018).

Less consistent findings have been found for adults with psychosis. Lim and colleagues (2018) found only three studies, all cross-sectional, which examined the relationship between loneliness and psychotic symptoms in their systematic review of the literature. Two found no significant relationship (Chrostek et al., 2016; Świtaj et al., 2014) whilst one found a positive correlation for both positive and negative symptoms (Sündermann et al., 2014). However, their review also identified a consistent association between loneliness and depression in this population.

In summary, the current evidence for the negative impact of loneliness on clinical mental health outcomes is strongest in the case of depression. Interventions to increase social connectedness amongst adults with depression in particular may therefore lead to improved clinical outcomes.

2.5.3. Personal recovery and wellbeing

Personal recovery can be defined as 'a deeply personal, unique process of changing one's attitudes, values, feelings, goals, skills, and/or roles. It is a way of living a satisfying, hopeful, and contributing life even with limitations caused by illness' (Anthony, 1993). A recovery orientation now forms part of UK mental health policy (Department of Health, 2011) and is recommended internationally (World Health Organization, 2013).

Loneliness is negatively associated with personal recovery in mental health (Roe et al., 2011) and increasing the social connectedness of adults with mental disorders may also support their personal recovery. A systematic review of all studies, either quantitative or qualitative, which synthesised empirical data about the processes involved in recovery identified 'connectedness' as one of the five

key recovery processes (Leamy et al., 2011). International perspectives on recovery also tend to make reference to the importance of interpersonal relationships (Roberts & Boardman, 2013). Hence, the importance of social connectedness for adults with mental disorders is indicated by its potential role in the process of recovery.

In addition, increasing social connectedness may also enhance the wellbeing of adults with mental disorders. Wellbeing has recently been linked to personal recovery, with some authors suggesting an overlap between the two constructs and that recovery might be orientated towards achieving wellbeing (Resnick & Rosenheck, 2006; Schrank et al., 2014; Slade, 2010). Wellbeing itself is a complex, multidimensional construct with some conceptions suggesting that positive relationships with others are a core feature of the construct itself (Keyes, 2005; Ryff & Keyes, 1995). Empirical evidence suggests that the quality of one's social relationships are a very strong predictor of wellbeing no matter how these constructs are operationalised (Geerling & Diener, 2018; Government Office for Science, 2008). For instance, a study of 222 students in the United States of America (USA) looked at the association between 'happiness', assessed using a number of different procedures, with measures of interpersonal relationships, personality and psychopathology. It was found that having high quality relationships was the only consistent factor amongst participants rated as 'very happy' (Diener & Seligman, 2002).

Hence, as well as the potential benefits for physical health, mental health, and personal recovery, increasing social connectedness and reducing loneliness amongst adults with mental disorders may also enhance their wellbeing.

2.6. The need for new interventions

2.6.1. Effectiveness of existing interventions

The evidence base for loneliness interventions targeted at mental health populations is currently quite limited as most existing studies have focussed on older adults specifically (Mann et al., 2017). This section will describe the intervention studies targeting loneliness or subjective social connectedness amongst people with any mental disorder. Intervention studies targeting purely objective outcomes such as social network size were not included. The studies were identified from four previous reviews: (1) A systematic review of all systematic reviews of loneliness interventions for all population groups conducted between 2008 and 2018 (Victor et al., 2018); (2) A state of the art review of loneliness interventions in mental health (Mann et al., 2017); (3) A systematic review of social participation interventions for people with mental disorders (Webber & Fendt-Newlin, 2017); and (4) A meta-analysis of loneliness interventions amongst all population groups which was excluded from the Victor et al. review (Masi et al., 2011). As there are currently so few interventions in this area, studies here will include those recruiting participants of any age and with or without a formal diagnosis of mental disorder. A total of nine studies were identified, which are described in Table 2.5.

Table 2.5 Loneliness/social connectedness intervention studies amongst adults with mental disorders (n=9)

Author	Country	n	Sample	Design	Intervention	Control	Measure	Summary of outcomes
Conoley and Garber (1985)	USA	38	Female university students; (1) Moderate depression (Beck Depression Inventory) and; (2) High loneliness (University of California Loneliness [UCLA] Scale)	RCT	Loneliness-focussed counselling	Waiting list	20 item UCLA Loneliness Scale	2-week follow-up: No significant intervention effect (Standardised mean difference [SMD]: -0.32, 95% Confidence Interval [CI]: -0.96, 0.32)
Haslam et al. (2016)	Australia	56	University students; (1) Socially isolated (Friendship Scale) and; (2) Mild symptoms of depression and/or anxiety (Kessler Psychological Distress Scale)	Pre-post	Social connectedness group programme (Groups4Health): 5 weekly 90 minute sessions focussing building group-based social identifications	None	8 item UCLA Loneliness Scale	Immediate follow-up: Significantly reduced loneliness (SMD: -0.86, 95%CI n/a, p<0.001)
Heckman and Barcikowski (2006)	USA	90	Older adults (≥50) with HIV/Aids; (1) Diagnosis of major depressive disorder, partial remission of major depression, dysthymia, or minor depressive disorder and; (2) A score of ≥75 on the Modified Mini-Mental State Examination	RCT	12 weekly 90-min telephone conference calls emphasizing coping	Waiting list	10 item UCLA Loneliness Scale	3-month follow-up: No significant intervention effect (SMD: 0, 95%CI: -0.41, 0.41)

Table 2.5 continued.

Author	Country	n	Sample	Design	Intervention	Control	Measure	Summary of outcomes
Morrow-Howell et al. (1998)	USA	61	Older adult service users of a suicide crisis hotline or referred from family members, friends, or professionals due to depression and social isolation	RCT	Weekly telephone calls with a social worker to administer multidimensional psychosocial evaluation, assistance with social services, and supportive therapy	Waiting list	OARS Social Resource Rating Scale	4-month follow-up: No significant intervention effect (SMD: -0.09, 95%CI: -0.59, 0.41)
Petryshen et al. (2001)	Canada	36	Adults (18-65); Affective disorder (67%); Schizophrenia (22%); Non-psychotic disorder (11%)	Pre-post	Social recreation programme (information sessions, workshops, self-help groups, weekly community walks)	None	4 item UCLA Loneliness Scale	1-year follow-up: Significantly reduced loneliness (SMD: -0.59, 95%CI: -0.88, -0.30)
Saulsberry et al. (2013)	USA	58	Adolescents (14–21); Sub-threshold depressive symptoms (Patient Health Questionnaire-Adolescent)	Pre-post	Online self-help course based on cognitive behavioural therapy (CBT), behavioural activation and IPT PLUS either GP-provided motivational interviewing or brief advice	None	1 item: 'I felt lonely' [time period not stated]	1-year follow-up: Significantly reduced loneliness for both interventions (SMD: -0.49, 95%CI: -0.18, -0.79)

IPT=Interpersonal psychotherapy

Table 2.5 continued.

Author	Country	n	Sample	Design	Intervention	Control	Measure	Summary of outcomes
Sheridan et al. (2015)	Ireland	70	Adults meeting the International Classification of Diseases 10 (ICD-10) criteria for schizophrenia, schizophrenia spectrum and delusional disorders; mood (affective) disorders; neurotic, stress-related and somatoform disorders; and mental and behavioural disorders due to psychoactive substance use – drug-induced psychosis	RCT	Supported socialisation: matched with a volunteer partner to do social activities for approx. 2 hours weekly over 9 months, and received a €20 monthly stipend	Received €20 monthly stipend only	Social and Emotional Loneliness Scale for Adults – Short Form	Immediate follow-up: No significant intervention effect on any loneliness subscale (Social loneliness: group effect f=0·78, p=0.38) (Family loneliness: f=0·03, p=0.86) (Romantic loneliness: group effect f=1.65, p=0.21)
Sorenson (2003)	USA	9	Postpartum mothers aged>19 reporting significant 'psychological disruption' following childbirth	Pre-post	Group CBT (5 monthly sessions of 4 hours each)	None	20 item UCLA Loneliness Scale	Immediate follow-up: Significantly reduced loneliness (SMD: -4.81, 95%CI: -7.09, -2.53)
Williams et al. (2004)	USA	200	Navy recruits 'at risk' for depression (≥18 Beck Depression Inventory or ≥30 Perceived Stress Scale)	RCT	Group CBT (45 minute sessions for 9 weeks)	No treatment	20 item UCLA Loneliness Scale	Immediate follow-up: Significantly reduced loneliness (SMD: –0.36, 95%CI –0.64, –0.08)

RCT=randomised controlled trial

Since conducting this review there have been three further studies which have evaluated loneliness interventions amongst adults with mental disorders. First, a feasibility study of a six-week group positive psychotherapy intervention for adults with a diagnosis of a psychotic disorder (n=16) found a significant pre/post reduction in loneliness (d=1.51, p<0.001) (Lim, Penn, et al., 2019). However, this was not sustained at three-month follow-up (d=0.07, p=0.81). Second, a feasibility study of a six-week positive psychology smartphone intervention for young adults (16-25) with diagnosis of a psychotic disorder (n=12) found a reduction in loneliness (Lim et al., 2019). Inferential statistics were not calculated in this study but descriptive analysis found that loneliness scores dropped from pre-intervention (M=50.0, SD=8.5) to post-intervention (M=48.1, SD=10.4) and three months post-intervention (M=42.9, SD=7.0). Third, a trial of a two-month social connectedness group programme (Groups4Health) for adults with psychological distress found a significant reduction in loneliness for participants receiving the intervention (Haslam et al., 2019). Groups4Health is described in more detail in Section 2.7 along with previous evaluations of the intervention.

Overall, these 12 studies provide a mixed set of results for loneliness and social connectedness interventions amongst adults with mental disorders. All of the studies measured loneliness as an outcome measure rather than social connectedness specifically. Only two of the six RCTs found significant reductions in feelings of loneliness amongst those receiving the intervention. Whilst all six of the pre/post studies found significant decreases in loneliness post-intervention, the lack of control groups raises concerns over the internal validity of these findings. Moreover, in the single pre/post study in which loneliness was evaluated at three-month follow-up, the reduction in loneliness was not sustained. In addition, only eight of the 12 studies used samples of adults with a formal clinical diagnosis or who were screened for probable 'caseness'. The remaining four studies used samples of 'distressed' or 'at risk' adults who may not have met the

criteria for a formal diagnosis. Hence, it is not clear whether these four interventions would be suitable for a clinical population. In summary, there is a very limited evidence base for current interventions.

The interventions showing a significant reduction in loneliness scores were heterogeneous in design. They comprised group CBT, online CBT, group social recreation activities, group positive psychology, a positive psychology smartphone app, and a group social connectedness intervention. Meanwhile the interventions failing to show an effect included one-to-one counselling, one-to-one supported socialisation and telephone-based social support. Hence, group-based activities might appear to be most effective but it is impossible to determine that this is the mechanism of action for the interventions on the basis of the included studies. One possibility is that the studies failing to demonstrate an effect were underpowered. Active control groups may also be required. Alongside no treatment, active control arms providing non-specific social contact may be needed to assess whether treatment-specific effects occur.

In summary, no particular type of intervention has a robust evidence base in reducing loneliness amongst adults with mental disorders. This conclusion is similar to the conclusions of review authors examining interventions amongst better studied populations, such as older adults (Dickens et al., 2011; Gardiner et al., 2018; Victor et al., 2018).

However, the authors of the aforementioned reviews on the effectiveness of loneliness interventions across population groups have identified a number of common observations which are of relevance to this thesis. First, there is substantial heterogeneity in the interventions delivered and few interventions turn out to be effective. Second, interventions are more likely to be effective if they have been (a) developed on the basis of a theoretical framework, and (b) involve targeted groups (Dickens et al., 2011; Gardiner et al., 2018; Victor et al., 2018).

Therefore, this thesis will address the need for new interventions which are theoretically-grounded and targeted at specific groups.

2.6.2. Different intervention approaches

Different approaches to reducing loneliness have been proposed. Broadly, these can be categorised as psychosocial or biological approaches. Psychosocial interventions are defined here as interventions with a specific social component which address psychological and social needs rather than biological ones (Webber & Fendt-Newlin, 2017). Biological interventions, by contrast, will be defined as those involving pharmacological components which target physiological mechanisms.

Biological interventions have recently been promoted to reduce the incidence of loneliness amongst different populations (Cacioppo et al., 2015). Suggested interventions include the administration of selective serotonin reuptake inhibitors, neurosteroids or oxytocin.

However, all current evidence for biological approaches comes from animal studies, which may not translate to humans (Pound et al., 2004). Therefore, this thesis will take a psychosocial approach to reducing loneliness, that is, by enhancing social connectedness.

2.7. The Groups4Health intervention

2.7.1. Background to Groups4Health

Groups4Health (G4H) is a group-based social connectedness intervention which aims to increase participants' membership of, and identification with, social groups (Haslam et al., 2016). G4H was developed by a team of clinical and social psychologists in Australia, as a transdiagnostic intervention for adults experiencing psychological distress as a result of loneliness.

The theoretical foundation of G4H is based on the social identity approach to health (Haslam et al., 2018; Haslam et al., 2009; Jetten et al., 2012). This approach draws upon social identity theory (Tajfel & Turner, 1979) and self-categorisation theory (Turner et al., 1987). These theories suggest that one's membership of social groups is internalised to become part of an individual's identity. These social identities can form an influential part of one's self-concept and thus help to explain individuals' behaviour (Turner et al., 1987).

G4H is a manualised group programme comprising five 90-minute sessions delivered by two facilitators to groups of 5-8 people over eight weeks. The first four sessions are delivered weekly with a one month gap between sessions 4 and 5 for participants to try out new social activities they have identified in previous sessions before coming back for the final session. Each session focusses on a different topic, such as reconnecting with old friends and joining new groups, and includes exercises which participants complete in a workbook during the session.

Applying social identity theory to the health domain, the developers of G4H focussed on four areas to enhance general health and wellbeing: (a) multiple group memberships, (b) group compatibility; (c) group maintenance or continuity; and (d) new group acquisition (Haslam et al., 2016). G4H involves exercises designed to assess participant's existing group relationships, their valued social identities, new social activities they would like to try and the social and psychological barriers they might face in acquiring or maintaining social group memberships.

G4H has been evaluated in two studies. First, participants reported a significant reduction in loneliness between baseline and follow-up assessments in a non-controlled feasibility study of Australian students screened for loneliness and mild symptoms of depression and/or anxiety (n=56). The results of this study, reported by Haslam et al. (2016), were shown in Table 2.5. Second, G4H

significantly decreased loneliness in an Australia trial amongst adults receiving the intervention (β=-0.74, p<0.001, between-groups effect size not calculated) (Haslam et al., 2019). The design and results of this trial are described in more detail in Section 9.1.6.

2.7.2. Rationale for using Groups4Health in this thesis

In this thesis the G4H intervention will be delivered to a clinical sample and evaluated for its feasibility. There are three reasons why G4H was chosen for use in this thesis. First, G4H is one of only seven identified interventions which have shown preliminary evidence of effectiveness in reducing loneliness amongst adults with mental disorders.

Second, of the seven identified interventions with preliminary evidence of effectiveness, G4H is one of the few which has a clearly identified theory base for reducing loneliness (two other interventions being based on positive psychology). Loneliness interventions developed in accordance with relevant theory have been highlighted as being more likely to be effective by review authors (Dickens et al., 2011; Victor et al., 2018; Windle et al., 2011) and topic experts (de Jong Gierveld et al., 2016).

Third, G4H is already manualised, which offers three advantages relevant to this thesis. First, an intervention manual can facilitate the implementation and use of an intervention within clinical practice (Carroll et al., 2007). Second, manuals can help standardise the treatment provided by different clinicians and teams, which is an important consideration for most RCTs, particularly trials aiming to explore the impact of different elements of the intervention (Carroll & Nuro, 2002). Manuals can also help discriminate between the intervention and the comparison/control conditions within trials as well as between the intervention and other approaches for the disorder. Third, manualising the intervention also enables future replication and generalisation across settings. Thus, using a

manualised intervention in this thesis such as G4H will allow the findings to be more easily replicated in other settings and could be used in future definitive trials.

2.8. Summary and rationale for this thesis

Loneliness and social connectedness appear to have substantial conceptual and empirical overlaps. However, there is a lack of clarity regarding how social connectedness should be conceptualised and operationalised. Therefore, one objective in this thesis will be to develop a conceptual framework of social connectedness for adults with mental disorders. A further objective will be to evaluate the validity and relevance of this framework amongst the target population. In order to evaluate this phenomenon amongst adults with mental disorders an additional objective will be to identify measures of social connectedness used with this population.

Research into loneliness and social connectedness has found that these experiences play an important role in physical and mental health as well as personal recovery for many adults with mental disorders. However, interventions to reduce loneliness in people with mental disorders are currently limited with no robust evidence base for any particular intervention. Social connectedness is explored in this thesis as one potential means of reducing loneliness in mental health populations (see Box 2.3). One intervention which shows some promise is the G4H intervention, which will be adapted within this thesis.

Given that many different types of interpersonal relationship have been found to be associated with loneliness, this thesis will not focus on supporting people to develop any particular type of relationship. Whilst there is ostensibly a focus on group-level relationships within G4H, the expectation is that participants will also form one-to-one relationships as part of this process. As there is no, or weak,

evidence that loneliness is strongly associated with demographic, socioeconomic or rural/urban settings, this thesis will not focus on any particular subgroup. However, whilst most existing research focuses on older adults or adolescents, loneliness appears to be a concern for adults with mental disorders of all ages. Therefore, this thesis will focus on working age adults to address this knowledge gap.

Previous reviews have identified the need for new interventions which are developed for particular population groups. Therefore, an additional objective of this thesis is to adapt G4H for adults accessing secondary care mental health services. Reviews have also identified the need for interventions to be based upon a clear theoretical framework. A further objective is to adapt G4H in accordance with a logic model for the intervention as well as the conceptual framework of social connectedness in order to enhance the theory base of the intervention.

2.9. Aims and objectives of this thesis

The thesis will initially take a transdiagnostic approach given that loneliness is common across a range of mental disorders. The focus of the thesis will then narrow onto adults with depression. The rationale for narrowing down by diagnostic group is given in Section 5.4.3.

The aims of this thesis are to adapt G4H for adults with depression and to evaluate its feasibility for delivery to this population. The six objectives are:

1. To identify measures of social connectedness for use in mental health research
2. To develop a conceptual framework of social connectedness in mental health
3. To evaluate the validity of the conceptual framework of social connectedness

4. To identify adaptations to the G4H intervention for adults with depression
5. To develop a logic model and intervention manual of adapted G4H for adults with depression
6. To evaluate the feasibility of adapted G4H for adults with depression

2.10. Chapter conclusion

This chapter provided an overview of the key concepts used in this thesis as well as the empirical evidence relating to these concepts. The G4H intervention was introduced and the aims and objectives for adapting this intervention for adults with depression were outlined. The next chapter describes the philosophy, methodology and research methods used to address these aims and objectives.

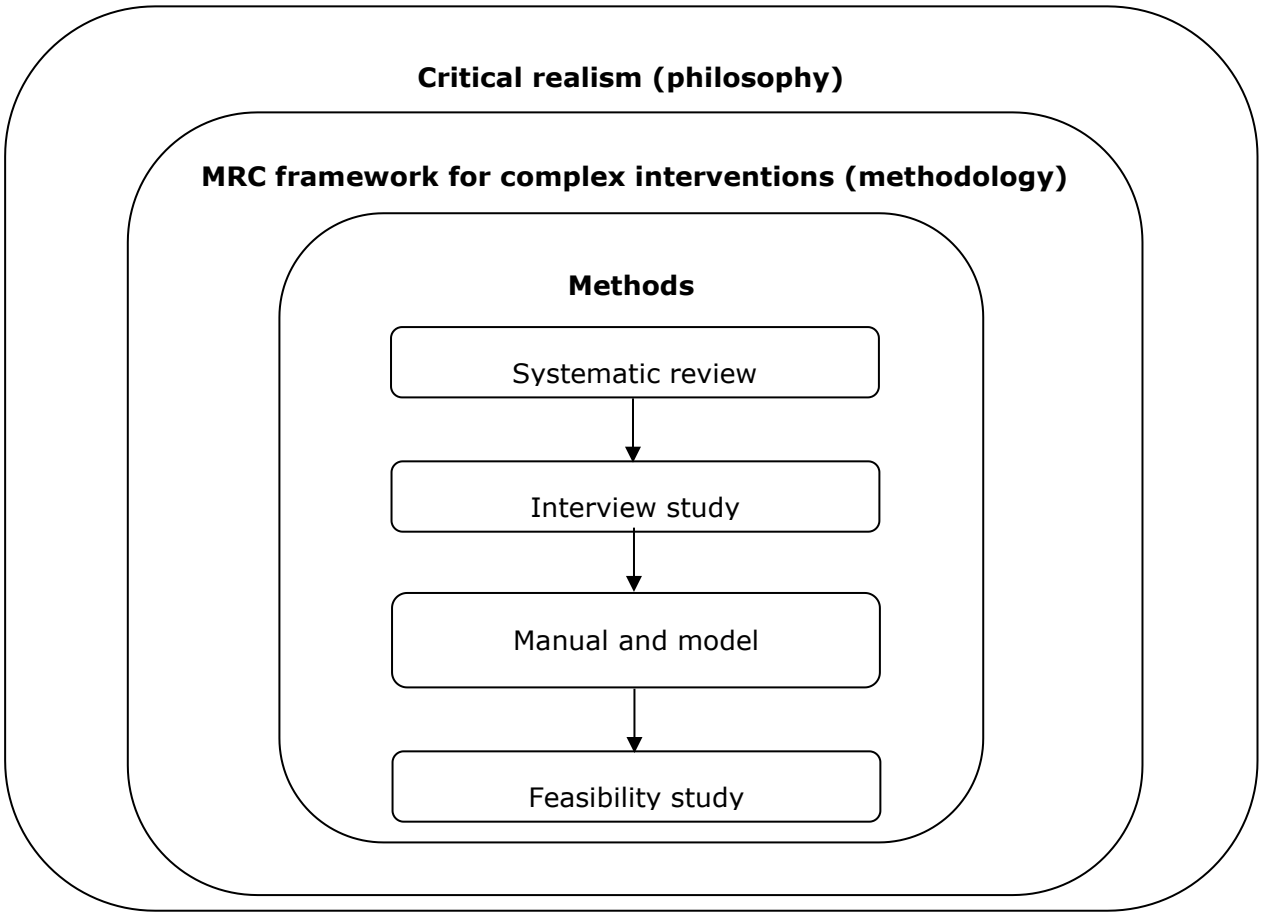
Chapter 3. Methodology and methods

Chapter overview

Chapter 2 reported on a literature review to provide the background and rationale for the aims and objectives of this thesis. Chapter 3 describes the philosophy, methodology and research methods chosen to achieve these aims and objectives. The focus in this chapter is upon providing the underpinning rationale for the research approach and methods adopted. Subsequent chapters will give details on the processes and procedures used for each method.

An overview of the research approach is depicted in Figure 3.1 and each component is described in the following sections of this chapter.

Figure 3.1 Philosophy, methodology and methods of the thesis



This chapter begins in Section 3.1 with a discussion of critical realism, the philosophical paradigm underpinning this thesis. The methodological approach of the thesis is then described in Section 3.2. How patients and the public were involved in the design and conduct of the thesis is described in Section 3.3. An overview of the methods used in the thesis is given in Section 3.4. As shown in Figure 3.1, four main methods were used in this thesis: a systematic review, an interview study, sub-studies for manualising and modelling G4H, and a feasibility study. The rationale for using these four methods is described in Sections 3.5 to 3.8 respectively. The chapter concludes with a discussion of some of the ethical considerations pertinent to the thesis in Section 3.9.

3.1. Philosophy: Critical realism

The philosophical assumptions made by researchers guide the questions they choose to investigate and the general approach they adopt in attempting to answer them (Rosenberg, 2012). The philosophical approach of this thesis is that of critical realism (Bhaskar, 1975). This approach will be outlined in this section as it informed the choice of research objectives and particular methods used in the thesis.

Critical realism combines two key philosophical assumptions. The first is an ontological assumption that the objects of social science have an independent reality. In line with so-called 'objectivist' or 'realist' researchers, this is the belief that the objects of social scientific investigations represent objective facts about the world. These phenomena are understood to be part of a mind-independent reality. This is contrary to the assumptions of 'constructivist' researchers who believe in a relativist ontology and assert that multiple realities exist which are constructed inter-subjectively through the social and experiential generation of meaning (Bryman, 2012).

One implication of the realist ontology being assumed in this thesis is that a form of social connectedness must exist beyond, or at another level from, the subjective experiences of human actors. This may be viewed as being in line with both ancient philosophical accounts of humans as being constitutively social animals (Rackham, 1990), and with more recent evolutionary accounts of social relationships which suggest that there is a biological basis for human sociality (Baumeister & Leary, 1995; Bowlby, 1969). Thus, social connectedness is assumed to have a material basis at some level rather than being entirely socially constructed.

The second philosophical assumption of critical realism is an epistemological stance that we can only ever possess fallible knowledge of the objects of our investigations because our accounts and theories of them are personally and socially constructed (Bryman, 2012). This position is often associated with 'interpretivist' researchers and sometimes understood as the proposition that reality itself is socially constructed and thus positioned as antithetical to realism. However, critical realists have taken an intermediate stance which states that it is not reality per se which is constructed, only our theories of reality (Greenwood, 1994; Rogers & Pilgrim, 2014). The epistemological assertion of this thesis is therefore that our ability to understand the world is fallible and that our accounts of it can only ever be partial. This fallibility arises as we have evolved sense-making capacities to understand what we observe in the world but that these capacities are necessarily limited and constrained by our own past experiences. This epistemological constructivism leads to the position that there are multiple scientifically valid ways of describing a single objective reality.

Some researchers (e.g. positivists) adopt an alternative epistemological position that there is only one valid (true) way of describing reality. This approach may be more appropriate for research into directly measurable phenomenon (such as

blood pressure) and a more controllable intervention (such as psychopharmacology). Whilst it is assumed here that social connectedness does exist in some form beyond our perceptions (realism), it is equally asserted that this phenomenon manifests itself and can be apprehended only through experiential and social-cultural processes. Meaningful descriptions of these processes are always contestable and accounts of them are necessarily limited due to our fallible sense-making capacities. Therefore, a constructivist epistemology was adopted in this thesis as it is not feasible to directly observe social connectedness nor is it appropriate to try and give a single, true account of the phenomenon.

Adopting a critical realist approach has implications that guide the design of this thesis, including the choice of methodology and particular methods. How critical realist philosophy informed these choices is described in the following sections.

3.2. Methodology: MRC framework

3.2.1. Summary of the MRC framework

Research methodologies, understood as the study of how best to design, conduct, analyse, and evaluate research, inform the adoption of particular methods within a given research project. The Medical Research Council (MRC) framework for the development of complex interventions (Craig et al., 2008; Moore et al., 2015) was the methodological approach taken in this thesis.

Complex interventions in healthcare are defined as interventions with multiple components and in which individual, collective and organisational elements act both independently and interdependently (Moore et al., 2015). The manner in which complex interventions affect outcomes is not always clear as there are often multiple interactions between intervention components and contextual factors.

Within the MRC framework, randomised controlled trials (RCTs) are the preferred method to determine whether or not there is a causal relationship between an intervention and an intended outcome. Yet it is also acknowledged that many interventions do not influence outcomes as expected and RCTs frequently do not assess whether this was due to ineffectiveness or because of other issues such as an implementation failure or an inadequate feature of the intervention (Campbell et al., 2007; Moore et al., 2015). These issues make it difficult to determine both whether an intervention works as intended, and at what point to conduct an RCT to test the effectiveness of an intervention.

To address some of these issues, the MRC framework focuses on the development of a theory base for interventions to establish how an intervention is intended to work, as well as process evaluations and feasibility or pilot studies prior to conducting RCTs (Moore et al., 2015).

The MRC framework was initially developed in 2000 (Campbell et al., 2000) and revised in 2008 (Craig et al., 2008). Additional guidance specifically on process evaluations was published in 2015 (Moore et al., 2015). A new iteration of the framework is due to be published in 2019-2020 but is not yet available (Skivington et al., 2018). This thesis therefore follows the 2008 version of the MRC framework with the process evaluation guidance informing one sub-study. The 2008 framework has four stages as follows:

Stage one (Development) involves three steps: identifying the evidence base, developing theory and modelling process and outcomes. First, the existing evidence base is examined in order to determine how an intervention can be developed such that it is likely to have the intended effect. It is recommended that a systematic review is conducted if no recent and relevant review has been done. Second, a theory base for the intervention needs to be developed to determine the likely mechanisms of impact for an intervention, regardless of

whether the intervention has already been evaluated elsewhere. Third, this theoretical foundation provides the basis for a model which specifies the intervention components, processes of change and intended outcomes. This is often depicted as a logic model describing inputs that the intervention involves, the processes that these initiate, and the mechanisms via which these are intended to realise positive outcomes.

Stage two (Feasibility and piloting) focusses on the feasibility of evaluating the intervention. This includes assessing its acceptability, recruitment, retention, compliance and delivery for a future trial. Feasibility studies help to assess the unknown parameters which are likely to impact upon the outcomes of full scale trials. Further refinements may be made to the intervention theory at this stage to optimise the intervention design, logic model and the proposed evaluation design prior to definitive trial testing.

Stage three (Evaluation) involves the evaluation of the intervention in terms of its efficacy or effectiveness. It is recommended, wherever possible and appropriate, that RCTs are used at this stage as these designs have the highest internal validity for determining causality (Shadish et al., 2002). The results from feasibility and pilot studies can help inform the selection of outcome measures at this stage. Process evaluations are also recommended to examine the various issues which may influence the outcome of the intervention including the fidelity and implementation of the intervention, processes of change and contextual factors.

Stage four (Implementation) focusses on how the intervention may be introduced into routine practice. The findings from a study need to be provided in accessible formats and actively disseminated. Recommendations include involving stakeholders at each stage of the intervention development and translating study findings into specific recommendations. The implementation stage can also

involve long-term follow-up studies of the intervention once it has been disseminated more widely. These studies can examine whether short-term changes persist, whether effect sizes change across different contexts and if there are any (rare) adverse effects of the intervention which the original RCTs were not powered to detect.

These four stages are viewed as cyclical, with each stage potentially informing work at all other stages. This approach to intervention development is intended to support the development of theoretically-based and empirically-supported interventions which provide greater confidence that the outcomes of RCTs will have greater external validity and may be incorporated more successfully into healthcare practice.

3.2.2. Rationale for using the MRC framework

One key reason for using the MRC framework in this thesis was its focus on the theoretical development of interventions prior to evaluation testing. This focus is in line with the critical realist underpinnings of the thesis. In particular, one key aim for critical realists is the elucidation of causal mechanisms which drive observable phenomena and the contexts in which these function (Bhaskar, 1975).

Furthermore, there is a need to further develop the theory base of the intervention to support evaluation processes. G4H is located within the social identity approach and informed by the Social Identity Model for Identity Change, which theorises that joining new groups leads to changes in personal and social identities and subsequently reduces loneliness (Jetten & Panchana, 2012). However, the social identity approach and model have been developed as an account of social psychology in the general population (Reicher et al., 2010) rather than as a clinical theory. It is likely that there are additional needs and challenges faced by adults with mental disorders beyond their social identities which bear upon their experiences of loneliness. MRC methodologists have argued

that it is necessary to examine whether a particular theoretical model for an intervention will transfer across different contexts and that it is inadvisable to draw upon a single theory from a particular discipline in the development of an intervention (Moore et al., 2015). In addition, it is likely that a complex group intervention such as G4H will involve more processes than identified by the social identity model (Moore et al., 2015; Yalom & Leszcz, 2005).

The G4H intervention does not currently have a well-developed theory base for adults with depression, nor is it known what processes of change may be involved. Therefore, one important objective for this thesis is to try and explore the mechanisms involved in the G4H intervention and the contextual factors which impinge upon them. Thus, it was decided to adopt the MRC framework as a theory-driven approach to adapting and evaluating the G4H programme.

Other major frameworks for the development or adaptation of interventions exist. One is the Multiphase Optimisation Strategy framework (Collins et al., 2005). This was not used in this thesis as the focus in this particular framework is upon optimising behaviour interventions and determining the role of different intervention components whilst the present study aims to develop a theory-base for a new intervention. A second major approach is realist evaluation (Pawson & Tilley, 1997). This approach draws upon critical realist philosophy and focuses on the development of programme theories for the evaluation of interventions (Bonell et al., 2012). It therefore aligns with the philosophical underpinnings and theory-driven approach of this thesis. However, realist evaluation focuses on building, testing and refining theories and does not in itself provide a methodology for the development of interventions (Fletcher et al., 2016). This approach was therefore not adopted as the focus of this thesis is upon intervention development and evaluation.

3.2.3. Applying the MRC framework in this thesis

The research presented in this thesis spans Stage one (Development) and Stage two (Feasibility and piloting) of the MRC framework. As recent reviews of the evidence were already available (see Section 2.6.1, p.42), Stage one focusses on the generation of a theory base for G4H and adapting the intervention for adults accessing secondary care mental health services. Within Stage one, the methods chosen to develop the theory base and model of the intervention were: (1) a systematic review (see Section 3.5 in this chapter and Chapter 4); (2) an interview study (Section 3.6 and Chapter 5); and (3) interviews, piloting and expert consultation on G4H (Section 3.7 and Chapter 6). The rationale for using these methods is described in later sections in this chapter.

Following the MRC framework, Stage two of this thesis involved a feasibility study (Section 3.8 and Chapter 7). The first aim of this study was to further refine the design and development of G4H. The second aim was to inform the design of a future definitive RCT, where 'definitive' in this context refers to an appropriately powered study focusing on effectiveness or efficacy.

Applying the MRC framework in this thesis using these four studies corresponds to a multiphase mixed methods design. These designs involve sequential studies, with each study informing the next, to address a central programme objective. Such designs are typically used for the development and evaluation of interventions (Creswell & Clark, 2011).

3.3. Patient and public involvement

The methods used in this thesis were informed by a patient and public involvement (PPI) group. This section describes why this PPI group was formed and how it played a key role in the development of the thesis.

Involving healthcare service users, carers and the public in research is increasingly common across health and social care. PPI has been described as research 'being carried out "with" or "by" members of the public rather than "to", "about" or "for" them' (INVOLVE, 2012). It concerns the active contribution of patients, carers and the public towards the design, delivery and dissemination of research.

PPI formed a part of this thesis in order to improve the quality and relevance of the research. A systematic review of the impact of PPI found that it offers multiple benefits, including ensuring user-focused research objectives, user-friendly study information, appropriate recruitment strategies and improved implementation and dissemination of results (Brett et al., 2014). In addition, the MRC framework also recommends that potential stakeholders are involved in the process of developing complex interventions as a means of both improving the theory base and to enhance the impact and dissemination of the study findings (Craig et al., 2008). For these reasons, PPI was incorporated into this thesis to guide the design of the studies.

Members of the PPI group included individuals with lived experience of mental health problems identified from community groups and a service user advisory group based at the University of Nottingham. The PhD researcher gave talks on the proposed research and four individuals came forward to contribute to the study. A PPI group was established and seven meetings facilitated by the PhD researcher were arranged. PPI members had their travel expenses reimbursed.

The PPI group was established towards the end of the first year of the thesis, by which time the systematic review was underway. Informal discussions with PPI members were had on the emerging thesis findings and formal meetings were set up thereafter. Members provided four types of input into the thesis, including advice on: (1) the overall objectives of the thesis; (2) the design of all

subsequent studies; (3) direct stakeholder involvement in the adaptation of G4H (described in Section 3.7 and Chapter 6); and (4) one PPI member was involved in a collaborative data analysis for the qualitative study (described in Chapter 5) and was reimbursed for her time. The group meetings are summarised in Table 3.1.

Table 3.1 List of PPI meetings

Session No.	Date	Agenda	Input/Actions
1	September 2017	Discuss and agree upon the research design and study materials	Adding a measure of social anxiety to the feasibility study (see Chapter 7); revisions to Participant Information Sheets, interview topic guides, and Lay Summary of the study
2	May 2018	Give updates on study progress; examine and practice G4H materials for session 1	PPI suggestions for adapting G4H were incorporated into the manualisation and modelling of the adapted intervention (see Chapter 6)
3	June 2018	Give updates on study progress; examine and practice G4H materials for session 2	
4	June 2018	Examine and practice G4H materials for session 3	
5	July 2018	Give updates on study progress; examine and practice G4H materials for session 4	
6	July 2018	Examine and practice G4H materials for session 5	
7	August 2019	End of study; dissemination	PPI members recommended and facilitated sharing the findings with local healthcare, social care and voluntary sector organisations

3.4. Methods: Overview

Different methods were used to meet the objectives of the thesis. The use of multiple methods is supported on both philosophical and methodological grounds. First, critical realism provides a rationale for data triangulation insofar as this helps to address the limitations of particular methods and perspectives to provide

a more complete account of particular phenomena (Olsen, 2004). Multiple methods were therefore used to develop a more comprehensive account of social connectedness and the theory base for the adapted G4H intervention. Similarly, multiple methods were used in the feasibility study (questionnaires and interviews) in order to provide different forms of data with which to address the objectives of this study.

Methodologically, the MRC framework also supports the use of multiple methods for the development of complex interventions. In broad outline, it is recommended that literature reviews, qualitative and quantitative methods are all used in the beginning two stages for the development and feasibility evaluation of new interventions. For the latter stages there is a focus on quantitative methods to evaluate intervention effectiveness (Craig et al., 2008).

The methods used in this thesis include a systematic review of the literature, interviews, piloting, expert consultation, and a feasibility study. The rationale for choosing these particular methods is discussed in the following sections, whilst details on the procedures and results of the studies are described in subsequent chapters.

3.5. Systematic review

A systematic review was carried out to meet Objectives 1 and 2 of this thesis: (1) to identify measures of social connectedness for use in mental health research; and (2) to develop a conceptual framework of social connectedness in mental health. The methods and results of the review described in Chapter 4.

The MRC framework recommends performing a literature review as the first step in developing a complex intervention. Amongst the many different types of literature review (see Grant & Booth, 2009) a systematic review was chosen for

the purposes of this thesis. This choice of design was guided by both the philosophical assumptions and methodological approach of this thesis. First, critical realists assert that there are multiple valid ways of describing reality and thus the generation of a strong theory base for the intervention will need to take into account potentially quite varied perspectives of what constitutes social connectedness. Specifically, this implies that the review ought to span different academic disciplines across which different views on social connectedness may exist. The review should also span different journals and time periods to avoid privileging certain perspectives.

Second, one of the objectives of this thesis was to identify existing measures of social connectedness for use in the feasibility study evaluation. As research into social connectedness and mental health crosses disciplinary boundaries, including nursing (e.g. Hagerty et al., 1992), psychology (e.g. Lee & Robbins, 1995), geography (e.g. Fields, 2011) and psychiatry (e.g. Fisher et al., 2015) a comprehensive review of the literature is required to identify all of the available measures which have been used to date.

Finally, from a methodological point of view, systematic reviews of the literature are specifically recommended within the MRC framework. For these three reasons, a systematic review design was chosen to help develop the theory base of G4H.

3.5.1. Transdiagnostic scope of the review

The initial approach of the thesis was to explore social connectedness as a transdiagnostic phenomenon rather than focussing on a particular diagnostic group. The systematic review therefore used transdiagnostic inclusion criteria for the selection of studies. There were three reasons for taking this approach. First, G4H itself was developed as a transdiagnostic intervention (Haslam et al., 2016). Second, social connectedness is typically theorised to be a common or universal phenomena which does not differ in nature between individuals, groups or

cultures (Baumeister & Leary, 1995; Cacioppo & Patrick, 2008). Third, the factors which might impinge upon service users' experiences of social connectedness, such as prolonged isolation, heightened social anxiety and discrimination, cross diagnostic boundaries (Perese & Wolf, 2005; Thornicroft et al., 2016). The thesis later narrows down to focus on depression due to the findings of the interview study (see Section 5.4.3).

3.6. Interview study

Following the systematic review, an interview study was conducted to meet Objectives 3-5 of the thesis. These were: (1) to evaluate the validity of the conceptual framework of social connectedness; (2) to identify adaptations to the G4H intervention for adults with depression; and (3) to develop a logic model of adapted G4H and intervention manual for adults with depression. The specific methods and results of the interview study are described in Chapters 5 and 6.

The interview study was used to triangulate the data derived from the systematic review by cross-referencing the conceptual framework of social connectedness with the intended recipients of the G4H intervention. Data triangulation can help address the limitations of particular methods and perspectives to provide a more comprehensive account of particular phenomena (Olsen, 2004).

The second reason for conducting the interview study stemmed from the critical realist underpinnings of the thesis. Critical realists assume that the social world consists of an open interaction between social structures, causal mechanisms and human agency (Archer, 1995). If the theoretical base of the intervention does not cohere with the accounts of social connectedness held by the intended recipients then this may potentially affect the processes of change and perceived acceptability of the intervention. The interview study was therefore conducted to

evaluate whether the conceptual framework fits with participant's understandings of social connectedness.

The third reason for conducting an interview study was methodological, with the MRC framework suggesting that interviews with relevant stakeholders (potential users and facilitators of the intervention) are an appropriate means of developing the theory base of the intervention (Craig et al., 2008).

Two key decisions were made during the course of the interview study which also require further explanation. First, the interviews were conducted in a community setting. Second, as well as adults with mental disorders, mental health professionals were interviewed regarding their own perceptions of social connectedness in mental health. The rationales for these two decisions are described as follows.

3.6.1. Community setting

Potential participants for the interviews were recruited from mental health support groups in the community rather than a clinical setting. This recruitment strategy was used because members of such groups have experience of seeking and improving their social connectedness (in the form of the group) whilst facing the challenge of on-going mental health difficulties. These individuals were therefore considered to have key insights into the potential barriers to enhancing social connectedness faced by adults with mental health problems, as well as possible solutions to these.

At the same time, because the interview study was intended to inform an intervention to be implemented within mental health services, an effort was made to recruit both current mental health service users and non-service users. This was considered potentially important as one characteristic associated with treatment-seeking is social network composition and perceived social support

(Thoits, 2011b). Adults with mental disorders not accessing treatment may therefore have different conceptions of social connectedness and different psychosocial needs in this regard to those known to services.

3.6.2. Staff participants

Staff participants were recruited into the interview study primarily to address objectives 3 and 4 of the thesis which concern adapting G4H. However, they were also asked to comment on the conceptual framework and their experiences of social connectedness amongst mental health service users. The reason for doing so was to provide an external, observer perspective on social connectedness for adults with mental disorders. There are three reasons why such a perspective may be valuable: reduced bias, triangulation and transferability of the conceptual framework to different populations.

First, including staff participants may help to address the risk of socially desirable responding. As loneliness is a stigmatised experience (Rokach, 2013) there is a risk that participants may seek to present themselves more positively to the interviewer and ascribe more favourable attributes to their social relationships than they have in fact experienced. Staff participants were asked to report on others' experiences and therefore the risk of socially desirable responding is reduced. The term bias is not commonly used in the context of qualitative research (Williams et al., 2019). However, relevant concepts, such as social desirability bias, will be used for the sake of brevity in this thesis to refer to potential sources of influence on the data rather than to inaccuracies.

Second, including the perspectives of staff participants provides alternative, observer reports to the self-report of the participants with mental disorders which may help to triangulate the findings. It will be assumed that the external observation of overt behaviours and actions can provide some insight into subjective phenomena. This same assumption underpins the practice of clinical

diagnosis. Methodologically this approach is also in line with established practices in qualitative research such as the use of ethnographic observation to construct theories of personal subjectivity and agency (Biehl et al., 2007) as well as the use of observer reports for psychological constructs such as personality (Oh et al., 2011). Importantly, observer-report and self-report of psychological and behavioural phenomenon can vary substantially (Kagan, 2007), including reports on mental health experiences such as depression (Uher et al., 2012). For the purposes of validating the conceptual framework of social connectedness it may therefore be valuable to triangulate data collected via self-report and observer-report.

The third reason to include staff participants is that it provides one means of assessing the degree to which the conceptual framework is transferrable to other populations. The conceptual framework focuses specifically on social connectedness for adults with mental disorders. However, social connectedness is also argued by many theorists to be a universal human experience (Baumeister & Leary, 1995; Cacioppo & Patrick, 2008; Maslow, 1943). It is therefore valuable to assess whether the conceptual framework is specific to people with mental disorders or if it may have wider validity. This may inform the theory base for the adaptation of G4H by suggesting whether the intervention needs to be based upon clinical foundations and target psychopathological deficits or if more general social theories applicable to all groups would be more appropriate.

Staff members from mental health teams or organisations which provide specific services or support for social engagement were also targeted for recruitment. These staff members were thought to have key insights into social connectedness and practical experience in supporting individuals to enhance it. Staff from across health, social care and voluntary services were recruited as different approaches

and practice cultures to improving social connectedness may occur across these different sectors.

3.7. Manual and model development

The findings from the interview study were used to inform the process of adapting and modelling the G4H intervention (objectives 4 and 5 of the thesis). Two further methods were also used for this purpose, piloting G4H and an expert consultation. This section first describes how and why it was decided to develop a manual and logic model for the adapted intervention and then outlines why the above methods were chosen to inform this process. The specific processes used to develop the adapted manual and logic model are described in Chapter 6.

3.7.1. Development of the intervention manual

The G4H intervention manual, comprising a facilitator manual and participant workbook, is copyrighted and therefore written authorisation was retrieved to adapt the manual. The G4H manual was adapted for adults with depression according to the methodology set out by Fraser and colleagues (Fraser & Galinsky, 2010; Fraser et al., 2009), which is described in detail in Section 6.4.2. This methodology was chosen as it focuses on the development and adaptation of psychosocial interventions with specific guidance on the development of manuals. The MRC framework itself does not offer guidance on manual development.

3.7.2. Development of the intervention logic model

All interventions rest upon a theory for how a programme leads to certain outcomes, and to improve the effectiveness of interventions it needs to be examined whether this theory is valid (Pawson & Tilley, 1997). Intervention models are recommended within the MRC framework in order to help clarify causal assumptions and identify intermediate outcomes of an intervention which can subsequently be used to evaluate whether an intervention is working as

intended (Moore et al., 2015). Models detailing the mechanisms of change for complex mental health interventions have been found to support evaluation by identifying appropriate indicators to evaluate all stages of the causal pathway through which an intervention achieves impact (De Silva et al., 2014). A model of the adapted G4H intervention was therefore developed in this thesis.

Different approaches to modelling can be taken. Models used to support evaluations of intervention implementation, or 'how' they work, often depict the exact activities and sequence of events necessary for undertaking the intervention. Meanwhile models used to identify mechanisms of change and 'why' interventions work instead focus on explicit statements concerning the assumptions, underlying theory and contextual factors thought to explain how the intervention achieves the intended outcomes. In this thesis the intended purpose of the intervention model is to inform the feasibility study of G4H which aims to examine both the implementation and potential mechanisms of the intervention. The modelling approach used in this thesis therefore used both approaches, focussing on both 'how' and 'why' G4H is hypothesised to work.

Logic models are a graphical inventory of a specified programme which details its components from start to finish (Kellogg Foundation, 2004). Although other types of models have been used in healthcare research (e.g. De Silva et al., 2014), logic models are specifically recommended by the MRC (Moore et al., 2015). They are also flexible and can be used for both implementation-focussed models and process evaluation models as is required for this thesis.

The development of the logic model followed the guidance set out by the Kellogg Foundation (2004). This includes depicting the inputs, activities, outputs, outcomes, assumptions and external/contextual factors of the intervention. *Input* (or 'Resources') refers to the human, financial, organisational and/or community resources required to implement the programme. *Activities* are the processes,

tools, events, technology, and actions that are an intentional part of the programme implementation. These interventions are used to bring about the intended programme changes or results. *Outputs* are the direct products of programme activities. They are usually described in terms of size and scope of the services or products delivered or produced by the programme. They indicate whether or not a programme was delivered to the intended audiences at the intended 'dose'. *Outcomes* are the specific changes in programme participants' behaviour, knowledge, skills, status and level of functioning. By convention, 'short-term outcomes' are those which should be attainable within 1-3 years, 'medium-term outcomes' within 4-6 years and 'long-term outcomes' within about 7-10 years (Kellogg Foundation, 2004). As the adapted G4H intervention targets short-term outcomes, only these will be referenced in this study.

Some models also include details on the intended 'Impact' of the programme. This refers to change occurring in organisations, communities or systems as a result of programme activities within 7 to 10 years. Impact will not be described in this study as the focus is upon outcomes achieved at the participant-level rather than an organisational or systems level. The *Assumptions* of the model refer to the reasons for how and why identified change strategies should work in the target population and context. Finally, the *External/contextual factors* concern how the programme functions in relation to other personal, economic, social, and political factors outside of the programme remit but which may be influential.

In order to develop the logic model, as well as to identify any necessary adaptions to the G4H manual three methods were used: qualitative interviews, piloting G4H and an expert consultation. An overarching rationale for using multiple methods was to triangulate across data sources whilst the reasons for using each method in particular are described as follows.

3.7.3. Interviews

Some of the reasons for using interviews with relevant stakeholders have already been described in Section 3.6, including the methodological fit with critical realism and the MRC framework. Additionally, it was decided to use one-to-one interviews because this format allowed for more in-depth discussion on the possible mechanisms of change involved in the intervention as well as to describe the complex intervention processes in detail and answer any queries from participants.

3.7.4. Pilot study of G4H

Information on how to adapt and model G4H was also gathered through a pilot of the intervention with PPI members and a mental health clinician (described in Chapter 7). The pilot study was conducted in addition to the interview study for two main reasons. First, it was intended that the PPI contribution to the thesis would include a meaningful level of involvement in developing the intervention. This is in line with the ethos of co-production (Pinfold et al., 2015) and user-controlled research (Beresford & Croft, 2012). To this end PPI members were invited to participate in a pilot of G4H and to offer their views on how to adapt the intervention.

Second, the pilot provided the opportunity to collect a different form of data from the qualitative interviews. Data was collected through oral and written feedback as well as participant observation of the group as they undertook the G4H exercises. Participant observation provided a means of gathering information such as participants' nonverbal expression of feelings, determine who interacts with whom, grasp how participants communicate with each other, and check for how much time is spent on various activities (Marshall & Rossman, 2014). Participant observation also avoids certain types of bias which can be found in interviews or formal feedback such as social desirability bias. For instance, participant

observation can capture behaviours such as dislike or aversion to G4H activities that participants may not have explicitly disclosed for fear of being impolite. In contrast to semi-structured interviews, which are guided by a topic guide, participant observation and unstructured feedback also allows for new, unexpected findings to emerge (DeWalt & DeWalt, 2002). Finally, participants in the pilot had direct in vivo experience of G4H compared to the interview participants for whom the intervention was only described. The experiences of the pilot participants may therefore help to triangulate the interview findings.

3.7.5. Expert consultation

Recommendations on how to adapt G4H were also sought from independent experts in mental disorders, complex interventions and recovery. An online survey was conducted for this purpose with two aims: to provide a third source of data for adapting G4H (alongside the interviews and study pilot), and to assess the credibility of the findings from the interview and pilot sub-studies. The latter aim is sometimes referred to as 'peer debriefing' (Marshall & Rossman, 2014), in which independent experts who are familiar with the phenomena of interest examine and interrogate the research results. Through questioning the assumptions and interpretations being made by the research team and by ensuring the results are sensible and comprehensible to a disinterested observer, external reviewers can support the rigour of the analysis and research process. Expert consultation was therefore used in this thesis in order to enhance the credibility of the research.

3.8. Feasibility study

Once the necessary adaptions and modelling of G4H had taken place, the intervention was evaluated in a feasibility study with adults accessing secondary care mental health services for depression. The feasibility study was designed to

address Objective 6 of the thesis: evaluate the feasibility of the adapted G4H intervention for adults with depression.

This section describes the reasons why a feasibility study was conducted as well as the rationale for embedding a process evaluation within it. The methods and results of the feasibility study are described in Chapters 7 and 8 respectively.

3.8.1. Rationale for the feasibility study

In evaluating complex interventions, precursor studies are recommended as a first step to identify potential challenges and enhance the rigour of later trials (Feeley et al., 2009). Precursor studies are referred to, sometimes interchangeably, as feasibility and/or pilot studies (Lancaster, 2015). Arain and colleagues conducted a review of previous precursor studies to bring more clarity to these study designs (Arain et al., 2010). According to these review authors 'feasibility studies' are those conducted before a main study and aim to estimate important parameters that are needed to design the main study. Meanwhile 'pilot studies' are a smaller version of the main intended trial that aims to test whether the components of the main study can all work together.

A feasibility study design was chosen in this thesis because the aim was to optimise the G4H intervention and to assess the most appropriate means of evaluating it in a future trial. The proposed design for a future RCT is still under development and could therefore not be examined in a pre-planned pilot study.

3.8.2. Process evaluation

Process evaluations can be defined as the evaluation of individual or collective perceptions and actions in implementing an intervention and their influence on the overall result of the intervention (Abildgaard et al., 2016). These evaluations are recommended within the MRC framework to investigate how the intervention works, including its active ingredients and how they effect change (Moore et al.,

2015). Evaluations of the processes by which an intervention worked or did not work can be used to inform future practice (Grant et al., 2013).

Process evaluations run alongside intervention studies and aim to explore the underlying mechanisms of the intervention. These evaluations can help to answer questions of how an intervention works, the processes involved in an intervention, potential mediators and moderators, implementation issues, the utility of the theoretical model underpinning the intervention, and generate hypotheses for future research (Moore et al., 2015). Thus, a process evaluation was used to support the development of the theory base and modelling of the adapted G4H intervention.

Both qualitative and quantitative research designs can be used for this process (Oakley et al., 2006). A qualitative process was used in this thesis as this may best capture the complex processes involved in social connectedness. The systematic review of measures of social connectedness identified that social connectedness consists of multiple dimensions but none of the available measures assessed all dimensions (see Chapter 4). Therefore, a quantitative approach was not thought to be viable to account for the potentially complex and varied processes involved in the adapted G4H intervention.

3.9. Ethical considerations

Some of the ethical considerations of this thesis are applicable to all types of human research and some considerations are specific to the thesis. The Declaration of Helsinki is a set of ethical principles developed by the World Medical Association for all medical research involving human subjects (World Medical Association, 2013). This includes the principle that the wellbeing of individual research participants should take precedence over the interests of science and society. The Declaration also specifies that a research protocol should

be developed and submitted for consideration by regulatory bodies. In this thesis all studies proposals were submitted to the relevant ethical review committees and the protocol for the feasibility study was registered on clinicaltrials.gov (NCT03446963).

The Declaration further states that all participants must be volunteers and be informed about the nature of the research. Informed consent includes being informed of the aims, methods, sources of funding, institutional affiliations of the researcher, and the anticipated benefits and potential risks of the study. In this thesis this information was provided within information sheets given to potential participants before consent was taken. Finally, participants must also be made aware of any potential conflicts of interest with regards to the research. The PhD researcher reported no financial or non-financial conflicts of interest in relation to the thesis.

To be able to give consent to take part in a research study, individuals must have capacity to make this decision. The Mental Capacity Act 2005 states that a person lacks capacity if they are unable to make a specific decision, at a specific time, because of an impairment of, or disturbance, in the functioning of mind or brain (Department of Health, 2005). The capacity to consent should only be questioned in cases where a person is unable to understand the information given to them or the decision being made, retain this information, use the information in making the decision, or communicate that decision. In line with current UK legislation, all potential participants for studies in this thesis were assumed to have the capacity to provide informed consent.

In addition to the ethical considerations relevant to all research involving human subjects, there were three further considerations for this thesis in particular. First, within the interviews and intervention, discussing social relationships may bring some participants to dwell on unmet needs, loss, or traumatic experiences in

relationships. Time and space were therefore provided by the interviewer or group facilitators for participants to discuss their experiences if they so wished and to ensure a supportive atmosphere was provided. To ensure the discussion did not become too upsetting for any individual, the interviewer and intervention facilitators prepared questions to change the topic under discussion if needed.

Second, some theorists have suggested that factors related to social connectedness play a role in suicidal behaviour (Ribeiro & Joiner, 2009). All efforts were made in this study for participants to be made to feel accepted by the research team and to facilitate a supportive atmosphere within the G4H groups conducted with the PPI group and in the feasibility study. In line with Good Clinical Practice a safeguarding procedure was agreed by the PhD researcher and the supervisory team in cases of suicide risk or harm.

Third, maintaining confidentiality is a crucial part of the research process. In group contexts this requires all participants to agree to maintain confidentiality. The ground rules for G4H were set by the group members themselves rather than the facilitators. This meant that maintaining confidentiality may not have been agreed as a rule for the G4H groups established as part of this thesis. In anticipating this possible situation, the intervention manual was revised to include guidance for facilitators to suggest confidentiality as a possible ground rule if this is not already raised by group members.

3.10. Chapter conclusion

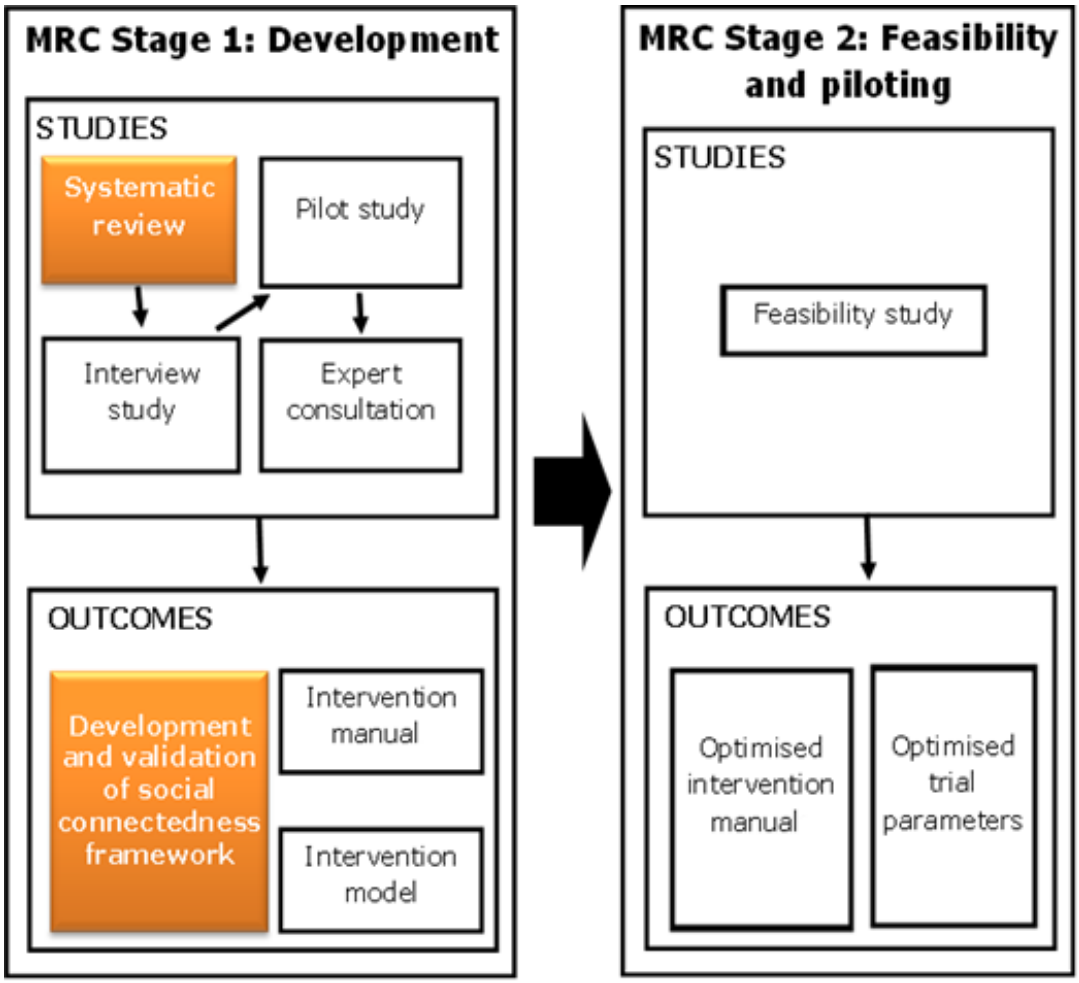
This chapter described the philosophy, methodology and methods which were used to address the aims and objectives of the thesis and provided a rationale for these choices. The next chapter reports on the methods and results of the systematic review of measures of social connectedness, which was the first study conducted as part of the thesis.

Chapter 4. Systematic review of measures of social connectedness in adults with mental disorders

Chapter overview

Chapter 3 described the methodology of the thesis. Chapter 4 now presents the systematic review of measures of social connectedness. The systematic review was conducted as part of Stage 1 of the MRC framework process for adapting G4H. Figure 4.1 shows how the systematic review sits within the overall thesis.

Figure 4.1 Locating the systematic review in the thesis



In this chapter the background to the study and the aims of the review are described in Section 4.1. The methods used in the systematic review are detailed in Section 4.2. The results are presented in Section 4.3 and discussed in Section 4.4.

The protocol for the systematic review was pre-registered on the International prospective register of systematic reviews (PROSPERO) database (reference CRD42017078116). The review was published in the *Journal of Affective Disorders* (Hare-Duke et al., 2019).

4.1. Background

Currently there is not a generally agreed definition or conceptualisation of social connectedness. The term social connectedness is used interchangeably with many others, including social identity (Cruwys, Haslam, Dingle, Haslam, et al., 2014), companionship (Thoits, 2011a), relatedness (Ryan & Deci, 2000), belonging (Lee & Robbins, 1995) and affiliation (McClelland, 1987). The conceptual ambiguity around social connectedness raises two issues which are pertinent to this thesis. First, the ambiguity makes it difficult to develop appropriate interventions which target this outcome. Whilst social connectedness remains poorly defined, it is impossible to determine whether G4H is sufficiently developed. Second, it is unclear how to select valid and reliable measures for use in evaluating this intervention.

To date, there has been limited conceptual work to inform the development of new interventions targeting social connectedness. Recent reviews have instead taken a broader approach to develop frameworks which integrate the terminology and conceptualisations of diverse social-relational concepts across both objective and subjective domains (e.g. Valtorta, Kanaan, Gilbody, & Hanratty, 2016; Wang et al., 2017). Whilst such broad frameworks can support the synthesis of existing

empirical studies they do not focus on identifying each of the subjective dimensions of social-relational concepts.

Conceptual frameworks have been defined as 'a network, or a plane, of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena' (Jabareen, 2009, p. 51). It is likely that various measures of social connectedness have been developed according to different theoretical frameworks and operationalise distinct constructs. Synthesising empirical operationalisations of social connectedness across different disciplines therefore provides one way of developing such a comprehensive framework.

The aims of this review were:

1. To identify the range of measures used to measure social connectedness amongst adults with mental health problems (objective 1 of the thesis)
2. To develop a conceptual framework for social connectedness as operationalised by the included measures (objective 2 of the thesis)

4.2. Methods

4.2.1. Eligibility criteria

Types of measures

Measures included in this review met the following criteria:

1. Quantitative measure of social connectedness or a closely related construct (i.e. a subjective perception of one's social relationships, in accordance with the working definition of social connectedness used in this thesis: a 'subjective psychological bond that people feel in relation to individuals and groups of others')
2. Multi-item unidimensional measures, single item measures, or multidimensional measures where social connectedness is a factor or subscale

3. Reported data from samples: (i) aged 18-65; (ii) presenting with any disorder recognised in existing versions of the ICD or DSM. Mental disorder was identified by: (1) clinical diagnosis; (2) screening measures; or (3) currently using mental health services

During a pilot test of the review it was found that a number of studies used samples where only a minority of participants met criterion 3. Therefore, the original protocol was altered to specify that at least 50% of the study sample needed to meet this criterion.

Setting

There were no restrictions by type of setting. Data were reported from participants in inpatient, outpatient or community mental health services. Community samples were also included where mental disorder had been identified.

Study types

Studies of any design using quantitative measures of social connectedness were included.

Language

Only studies published in English were included.

4.2.2. Search strategy

A three step search strategy was used. First, a scoping search to refine the search strategy was undertaken. This involved a search of MEDLINE and PsycINFO using the terms 'social connectedness' and 'mental health', followed by analysis of the titles and abstracts, and of the index terms used to describe these articles. Second, a systematic search using all the identified keywords and index terms was undertaken, tailored for each database. The full search strategy used for

MEDLINE is given as an example in Appendix 1. For reasons of feasibility and in order to focus the review on measures of subjective, individual-level perceptions of relationships, terms related to social relationships were not used if they referred to concepts which are objective (e.g. social networks, social integration, social inclusion), feature multiple non-social domains (e.g. social inclusion/exclusion), ecological-level (e.g. some versions of social capital) or refer to resources provided within relationships (e.g. social capital, social support). Terms were used if they are used interchangeably with social connectedness and describe a subjective dimension of social relationships. Seven particular diagnoses were specified in the search strategy in addition to generic terms for mental illness in order to maximise the sensitivity of the review. These were generalised anxiety disorder, depression, obsessive–compulsive disorder, phobia, panic disorder, mixed anxiety and depressive disorder and psychosis. These disorders were selected as they have each been found to have significant associations with feelings of loneliness (Badcock et al., 2015; Chrostek et al., 2016; Hatcher & Stubbersfield, 2013; Meltzer et al., 2013). Third, the reference lists of included studies were screened for additional studies.

Information Sources

Six databases were searched. These focus on different disciplinary areas and may index different records across the multidisciplinary empirical research into social connectedness. These databases were searched from inception to September 2017: MEDLINE (Ovid interface, 1946 onwards), CINAHL (EBSCO interface, 1980 onwards), PsycInfo (Ovid interface, 1806 onwards) and Sociological abstracts (ProQuest interface, 1953 onwards). The search for unpublished studies included the two following databases: EThOS (Electronic Thesis Online Service) and ProQuest Dissertations and Theses.

Study selection

Following the search, all identified citations were collated and uploaded into Endnote and duplicates were removed. Two independent reviewers screened the titles and abstracts for assessment against the inclusion criteria for the review. The reviewers were both PhD students: Laurie Hare Duke (LHD) and Katja Milner (KM). Due to limited resources for the review, the second reviewer (KM) screened a random sub-sample of 100 articles. Studies meeting the inclusion criteria were retrieved in full. The full text was assessed in detail against the inclusion criteria by both reviewers. Full-text studies that did not meet the inclusion criteria were excluded and reasons for exclusion noted. Any disagreements between the two reviewers were resolved through discussion. The review authors were not blind to the journal titles, study authors or institutions. The included studies were quality appraised by the first reviewer (LHD) and a random sub-sample (10% of the total) was independently assessed by the second reviewer (KM).

4.2.3. Data extraction

One reviewer (LHD) extracted data from papers included in the review using a tailored data extraction tool. All data were entered onto Microsoft Excel and the items of the measures entered onto NVivo for analysis. The following data were extracted:

- Identification of the study: author, title, citation, publication type, country
- Characteristics of the study: purpose/objectives of the study, design, sample size
- Measurement properties: internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity and responsiveness
- Individual question items of social connectedness measures

Authors of papers were contacted to request missing or additional data where required.

4.2.4. Quality appraisal

The methodological quality of the selected studies was evaluated using the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist (Terwee et al., 2012). In accordance with COSMIN, nine measurement properties were assessed. These were (1) Internal consistency: defined as the degree of inter-relatedness of items within a measure. (2) Reliability: comprising test-retest reliability (consistency over time) and inter-rater reliability (consistency between different individuals on the same occasion). (3) Measurement error: the systematic and random error of an individual's score that is not attributed to true changes in the construct to be measured. (4) Content validity: whether the content is an adequate reflection of the construct to be measured. (5) Structural validity: the degree to which measurement scores adequately reflect the dimensionality of the construct to be measured. (6) Hypotheses testing: the degree to which the scores of a measure are consistent with hypotheses. (7) Cross-cultural validity: the degree to which the performance of the items on a translated or culturally adapted measure are an adequate reflection of the performance of the items of the original version. (8) Criterion validity: degree to which the scores of a measure are an adequate reflection of a 'gold standard'. (9) Responsiveness: the ability of a measure to detect change over time (Mokkink et al., 2010). For a given measure, each property is assessed using between five and 18 checklist items. The psychometric results were judged against the criteria developed by Terwee and colleagues (2012), rating each checklist item on a four-point scale: excellent, good, fair or poor. An overall quality score for each measurement property reported in a study is defined as the lowest rating of any item within that section.

4.2.5. Data synthesis

Review aim 1: Measures

The range of measures available to measure social connectedness amongst adults with mental health problems was tabulated and summarised descriptively. As there is currently no empirical method to statistically synthesise psychometric results, a best evidence synthesis approach was undertaken as proposed by the Cochrane Back Review Group (Furlan et al., 2009). Best evidence synthesis here refers to the possible overall rating for a measurement property ('positive', 'indeterminate', or 'negative'), accompanied by a level of evidence (strong, moderate, limited, conflicting, unknown). The criteria for synthesizing evidence are adapted from (Terwee et al., 2007) and summarised in Table 4.1.

Table 4.1 Levels of evidence for the rating of the measurement property (Terwee et al., 2007)

Level	Rating	Definition
Strong	+++ or ---	Consistent findings in studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in studies of fair methodological quality OR in one study of good methodological quality
Limited	+or -	One study of fair methodological quality
Conflicting	±	Conflicting findings
Unknown	?	Studies of poor methodological quality

Review aim 2: Conceptual framework

The conceptual dimensions operationalised by existing measures of social connectedness were integrated using a modified narrative synthesis approach (Popay et al., 2006). This approach involved three stages described as follows.

Stage 1: Preliminary synthesis

A preliminary synthesis was conducted through a thematic synthesis of the items from all included measures (Thomas & Harden, 2008; Thomas et al., 2012).

Thematic synthesis involves, first, line-by-line inductive coding of the scale items; second, similarities and differences between the codes are identified to group them into a coding framework of descriptive dimensions; and finally, analytical dimensions are inferred from the descriptive dimensions with reference to the review question (Thomas & Harden, 2008). In this review the individual items from all measures were pooled. Items were excluded if they referenced social connectedness directly (e.g. 'I feel connected to those around me') as such items are not amenable to thematic analysis. Common themes across the remaining items were identified using inductive thematic analysis by two independent researchers (KM and LHD). Potential themes and sub-themes were discussed and iteratively refined to produce a coding framework. This framework served as the basis for a preliminary conceptual framework identifying dimensions of social connectedness.

Stage 2: Explore relationships in the data

The preliminary synthesis was explored in two ways. First, by vote counting each identified dimension to identify the frequency with which these appeared across measures. Second, evidence relating to the empirically established dimensions of included measures was examined and compared against the preliminary synthesis. Empirical evaluation of dimensionality typically uses factor analysis. In this review studies using principal component analysis (PCA) were also included. PCA seeks to determine the optimum number of index variables (components) and weightings which can account for the maximum amount of variance in the observed variables. This procedure does not assume or model latent variables and so cannot be used to determine the dimensions of constructs such as social connectedness. Nonetheless, if communalities (variance of observed variables accounted for by a common factor) are large, then the results of PCA and factor analytic techniques can be similar and therefore PCA results were included in this review for consideration.

Stage 3: Assess the robustness of the synthesis

The robustness of the synthesis was assessed through the independent thematic synthesis conducted by two reviewers (KM and LHD), as well as a sub-group analysis of studies rated as having good content validity. Measures were judged to have high content validity if four conditions were met: study authors had made an assessment that items were (a) relevant; (b) comprehensive for the latent construct; (c) relevant to the target population; and (d) rated 'fair' or above on all other questions from the content validity section of the COSMIN checklist.

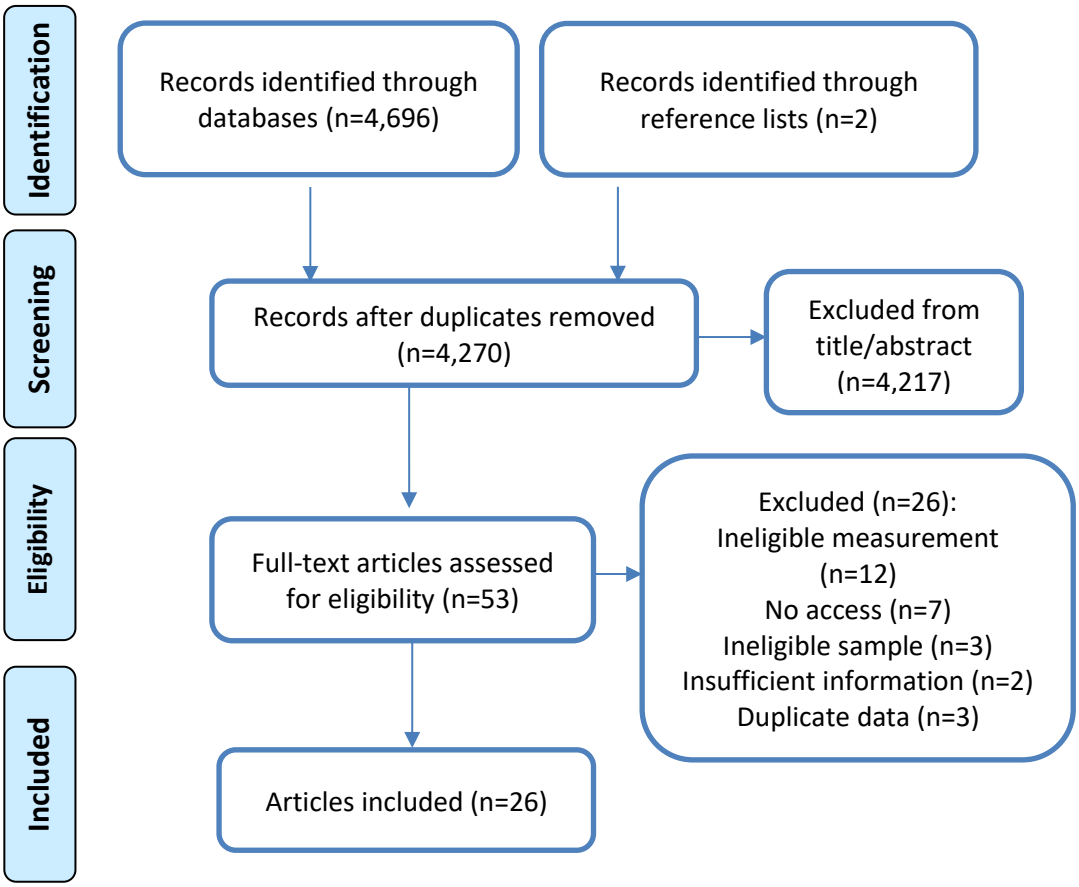
Analytical procedures not used in this review

This review adopted the following standard procedures of narrative synthesis: 'translating data' (thematic synthesis) for developing the conceptual framework, as well as 'vote counting', 'tabulation' and 'groupings/clusters' to assess the relationships between studies and sub-groups of studies (Popay et al., 2006). Three additional suggestions from the Popay framework for narrative synthesis were not used in this review. First, for narrative reviews of intervention studies it is recommended to develop a theoretical model of how an intervention works, why and for whom. Such a model was not used in this review as the focus was on measurement and operationalisation, not on interventions. Second, 'textual description' of studies is recommended to produce a descriptive paragraph on each included study. This procedure was not used in the present review as textual description is typically used when there are a small number of identified studies in order to provide contextual information to assess the reported data. In this study it was expected that there would be a large number of identified studies and the focus of the synthesis was on the measures used, not the reported data. Third, 'translating data into a common rubric' was not used as this applies principally to reviews of numerical data which take different statistical forms.

4.3. Results

The flow diagram is shown in Figure 4.2.

Figure 4.2 PRISMA flow diagram of included articles



A total of 4,698 records were identified: 4,696 in the database searches and two additional papers retrieved after contacting study authors of papers found in the database search. There were 428 duplicate records. After reading the title and abstract, a further 4,217 records were excluded. The full texts of 53 articles were retrieved and 26 of these met the inclusion criteria. One article featured two studies, resulting in a total of 27 studies and 21 different measures. Table 4.2 describes the 27 included studies.

Table 4.2 Data extracted from studies included in this review (n=27)

No.	Included paper	Social connectedness measure/subscale (original paper reference)	Country	Design	Mental disorder(s)	Setting	n
1	Choenarom et al. (2005)	Sense of Belonging Instrument-Psychological subscale (SOBI-P; Hagerty & Patusky, 1995)	USA	Single group pre/post	Depression	Outpatient	51
2	Cotton and Butselaar (2013)	Social Connectedness Scale-Revised (SCS-R; Lee et al., 2001)	Australia	Single group pre/post	Service users, unknown diagnoses	Community	108
3	Cruwys et al. (2014)	Social identification with community group (SI-C; adapted from Doosje et al., 1995)	Australia	Single group pre/post	51.9% unspecified, formal diagnosis ('mostly depression or psychotic disorder'). 48% participants non-diagnosed	Community	52
4		Social identification with therapy group (SI-T; adapted from Hinkle et al., 1989; Leach et al., 2008; Luhtanen & Crocker, 1992)	Australia	Single group pre/post	Depression; anxiety	Outpatient	92
5	Cruwys and Gunaseelan (2016)	Social identification with people with depression (SI-D; Cruwys & Gunaseelan, 2016)	Australia India USA	Cross-sectional	Depression	Community	250
6	Cruwys et al. (2016)	Social Identity Mapping tool (SIM; Cruwys et al., 2016)	Australia	Cross-sectional	Depression; anxiety	Community	69
7	Dingle et al. (2015)	Social identification with therapeutic community (SI-TC; adapted from Doosje et al., 1995) Social identification with substance using peers (SI-SUP; adapted from Doosje et al., 1995)	Australia	Single group pre/post	Substance misuse	Community	132

Table 4.2 continued

No.	Included paper	Social connectedness measure/subscale (original paper reference)	Country	Design	Mental disorder(s)	Setting	n
8	Forrest et al. (2016)	Interpersonal Needs Questionnaire/ Thwarted belongingness subscale (INQ-TB; Van Orden et al., 2008)	USA	Cross-sectional	Anorexia; binge eating disorder; other specified feeding or eating disorder; unspecified feeding or eating disorder	Inpatient	98
9	Hagerty and Patusky (1995)	SOBI-P	USA	Cross-sectional	Depression	Inpatient and outpatient	31
10	Hames et al. (2015)	INQ-TB	USA	Cross-sectional	Depressive disorders; alcohol use disorders; generalised anxiety disorder; cannabis dependence; social phobia; borderline personality disorder	Outpatient	415
11	Haslam et al. (2016)	Four Item measure of Social Identity (FISI; Postmes et al., 2013) Multiple Group Memberships Scale (MGM; Haslam et al., 2008)	Australia	Single group pre/post	Depression; anxiety	Community	56
12	Lemieux et al. (2015)	Mental Health Statistics Improvement Program/Perception of social connectedness subscale (MHSIP-SC; Center for Mental Health Services, 1996)	USA	Cross-sectional	Major depression; thought disorder; bipolar disorder; schizophrenia; schizoaffective disorder; other (ADHD, psychosis); mood disorder, not otherwise specified)	Outpatient	125

Table 4.2 continued

No.	Included paper	Social connectedness measure/subscale (original paper reference)	Country	Design	Mental disorder(s)	Setting	n
13	Lloyd et al. (2008)	Social Inclusion Scale/ Neighbourhood integration subscale (SI-NI; Lloyd et al., 2008)	Australia	Cross-sectional	Bipolar disorder; schizophrenia; schizoaffective disorder; major depression with psychosis; delusional disorder; dissociative identity; major depression; generalised anxiety disorder with panic	Community	26
14	Norman et al. (2013)	Interpersonal Support Evaluation List/Belonging subscale (ISEL-B; Cohen & Hoberman, 1983)	Canada	Cross-sectional	Schizophrenia; schizoaffective disorder; schizophreniform, substance induced; psychosis not specified; delusional disorder; affective psychosis	Outpatient	84
15	Matto et al. (2006)	Ecological Assessment of Drug Misuse Experiences/Belonging-Recovery subscale (EADME-BR) /Belonging-Drugs and Alcohol subscale (EADME-BDA; Matto et al., 2006)	USA	Cross-sectional	Substance misuse	Outpatient	103
16	Mawson et al. (2015)	Social Identity Map-2 items (SIM-2; Best et al., 2014) Group identification with any group (GI-AG; adapted from Haslam et al., 2008)	Australia	Cross-sectional	Drug or alcohol misuse disorder	Inpatient	20
17	van Orden et al. (2012)	INQ-TB	USA	Cross-sectional	DSM Axis I mental disorders, not specified	Outpatient	397
18	Rüsch (2006)	Social identification with people with mental illness (SI-MI; adapted from Jetten et al., 1996)	Germany Switzerland	Cross-sectional	Social phobia; borderline personality disorder	Outpatient	90

Table 4.2 continued

No.	Included paper	Social connectedness measure/subscale (original paper reference)	Country	Design	Mental disorder(s)	Setting	n
19	Rüsch et al. (2009)	SI-MI	USA	Cross-sectional	Schizophrenia; schizoaffective disorder; bipolar I and II, recurrent unipolar major depressive disorder	Outpatient	85
20	Sargent et al. (2002)	SOBI-P	USA	Cross-sectional	Depression	Community	200
21	Silva et al. (2015)	INQ-TB	USA	Cross-sectional	Multiple diagnoses (not specified)	Outpatient	997
22	Sohn et al. (2014)	MHSIP-SC	USA	Cross-sectional	Service users, unknown diagnoses	Outpatient	7029
23	Watson et al. (2007)	Group identification with mental health service users (GI-SU; adapted from Jetten et al., 1996)	USA	Cross-sectional	Multiple diagnoses (not specified): 'serious mental illness (e.g. bipolar, schizophrenia or MDD)'	Outpatient	71
24	Wieland et al. (2007)	SOBI-P	USA	Cross-sectional	Schizophrenia; schizoaffective disorder	Outpatient	58
25	Williams et al. (2002)	SOBI-P	USA	Single group pre/post	Depression	Community	200
26	Williams et al. (2004)	SOBI-P	USA	RCT	Depression (66% of sample: 'at risk' of depression [Beck Depression Inventory II > 18] AND Perceived Stress Scale > 30). Healthy participants (34% of sample 'not at risk' of depression).	Community	244
27	Wong and Longshore (2008)	Multigroup Ethnic Identity Measure/Belonging subscale (MEIM-B; Phinney, 1992)	USA	Single group pre/post	Substance abuse	Community	114

Most studies were conducted in high-income countries, primarily in the USA (n = 16) or Australia (n = 8). There was a spread of outpatient (n=14) and community (n=11) samples with two inpatient studies and one study conducted with a combined inpatient/outpatient sample.

Samples included people with a wide range of common and severe mental disorders. Single-disorder samples were found for depression (studies 1, 5, 9, 20, 25, and 26) and substance misuse (studies 7 and 27). All other studies used samples featuring multiple different diagnostic groups.

4.3.1. Measures of social connectedness

Of the 21 measures, 13 were full scales and eight were subscales of larger measures. The names of the 21 measures spanned six related terms: social connectedness, social support, social identity, sense of belonging, group memberships and neighbourhood integration. The number of items in each measure ranged from two to 20. Five measures had a mix of both positively phrased items (social connectedness) as well as negatively phrased (social disconnectedness), whilst 16 measures had exclusively positive items.

Two of the measures (EADME-BR and EADME-BDA) were subscales identified from within the larger Ecological Assessment of Substance Abuse Experiences measure. Both subscales referred to social connectedness though items were not identical in each. Half of the items referred to the context of one's recovery from substance misuse (Belonging-Recovery [BR] subscale), and half referred to one's status as a substance misuser (Belonging-Drug/Alcohol [BDA] subscale). These were therefore included as two separate measures.

The COSMIN quality assessment of the measures is shown in Table 4.3.

Table 4.3 Best evidence synthesis of measurement properties for all measures (n=21)

Measure	Studies (n)	Content validity	Internal consistency	Reliability	Structural validity	Criterion validity	Hypothesis testing	Responsiveness
INQ-TB	4	+	+++		++	++		
SOBI-P	6	+	++		-		+	
MHSIP-SC	2	-						
ISEL-B	1	-						
SI-TC	1	-	?	+				
SI-SU	1	-						
SI-D	1	+	?					
MEIM-B	1	-	?					
SI-C	1	-	?					
SI-T	1	+	?					
FISI	1	-	?					
MGM	1	-	?					
SCS-R	1	+						
EADME-BR	1	-	?		-			
EADME-BDA	1	-	?		-			
SI-MI	1	-	?					
SI-NI	1	-	?	?				
GI-SU	1	-	?					
GI-AG	1	-						
SIM	1	+	?					?
SIM-2	1	-						

Most of the measures (n=18) had been used in only one study and had limited evidence for their measurement properties. None of the measures had data relating to all nine COSMIN measurement properties and none assessed the properties of measurement error or cross-cultural validity. In 14 of the 21 measures, information was available for only one or two properties. The most commonly assessed property (in 15 out of 21 measures) was internal consistency. This property was in most cases rated as unknown.

Across most measures (n = 15), content validity was rated as poor. Six measures were rated as having good content validity. The SOBI-P was developed as a 'mental health concept' (Hagerty 1996), partly from case studies of psychiatric nurses (Hagerty, 1992) and items were developed by clinicians. The SCS-R was developed from psychoanalytical theory (Kohut, 1984) and items developed by counsellors. The items from the SI-D and SI-T measures were developed by clinical academics and specifically adapted for use in mental health samples (depressed/therapy group). The INQ-TB was developed in accordance with the interpersonal theory of suicide (Joiner, 2005) and was validated in a clinical sample. Finally, the SIM was developed by clinicians and validated in a clinical sample. The authors of these six measures had also made some assessment of their relevance and comprehensiveness.

The measure with the strongest psychometric properties was the INQ-TB, rated as moderate or strong for internal consistency, structural validity and criterion validity and was assessed as being of good content validity. This measure has also been used by different research groups, including four different studies identified in this review.

4.3.2. Preliminary synthesis: Conceptual framework of social connectedness

Six items referred to social connectedness directly and were not used in the analysis. Synthesis of the remaining 144 items from all measures identified five dimensions describing the experience of social connectedness. These were labelled *Closeness*, *Identity and common bond*, *Valued relationships*, *Involvement* and *Cared for and accepted*, giving the acronym CIVIC. The five dimensions of the CIVIC conceptual framework are summarised in Table 4.4.

Table 4.4 Definitions and examples of the CIVIC conceptual framework

Dimensions	Definition	Example items
Closeness	The degree of mutual dependence between two people	*There are people I feel close to in this clubhouse or social group*[20] *These days, I am close to other people*[1]
Identity and common bond	Sharing key characteristics with other people and 'fitting in'	*I feel similar to the average person with depression*[3] *How representative are you of the group as a whole?*[23]
Valued relationships	Valuing an existing dyadic or group relationship and viewing this relationship positively	*I'm glad to be a member of the therapeutic community group*[10] *I am happy that I am a member of the group I belong to*[13]
Involvement	Feeling socially engaged with others and experiencing companionship	*I feel left out of things*[4] *I'm involved in the activities of lots of different groups*[11]
Cared for and accepted	Feeling that one is accepted, valued and cared for by others	*I generally feel that people accept me*[4] *I am a worthy member of this group*[9]

It was also found that all of the dimensions of the CIVIC conceptual framework could be rated in two ways, in relation either to specific or non-specific relationships. Items assessing social connectedness within specific relationships

referred to feelings of connection to specific individuals or groups. Other items asked non-specific, decontextualized questions about a person's perceptions about relationships or social experiences in general, without reference to particular interpersonal relationships. Examples of specific relationship types included particular individuals, defined groups (e.g. 'therapy group') or undefined networks (e.g. 'friendship network'). Non-specific relationship types included undefined geographical groups (e.g. 'neighbours' or 'community') as well as 'others' in general.

4.3.3. Relationships in the data

Vote counting

Table 4.5 shows the five dimensions of the CIVIC conceptual framework, specific and non-specific ratings and the frequency of each of these across the 21 included measures. Each row in the table shows the number of items (and item-total percentage) of each measure which relates to each of the five dimensions.

Table 4.5 Distribution of items per dimension and relationship types across all measures (n=21)

Scale or subscale	Items (n)	CIVIC dimension, n (%) of items					Specific vs. non-specific	
		Closeness	***Identity and Common Bond***	***Valued Relationships***	***Involvement***	***Cared for and Accepted***	***Specific items, n (%)***	***Non-specific items, n (%)***
EADME-BR	5		1 (20%)		1 (20%)	3 (60%)	4 (80%)	1 (20%)
EADME-BDA	4		1 (25%)		1 (25%)	2 (50%)	2 (50%)	2 (50%)
FISI	4		2 (50%)	2 (50%)			4 (100%)	
GI-SU	4	2 (50%)	2 (50%)				4 (100%)	
GI-AG	2		2 (100%)				2 (100%)	
INQ-TB	9	1 (11%)	3 (33%)		1 (11%)	4 (44%)		9 (100%)
ISEL-B	10	4 (40%)	1 (10%)		4 (40%)	1 (10%)	10 (100%)	
MEAM-B	7	1 (14%)	3 (43%)	3 (43%)			1 (14%)	6 (86%)
MGM	4	2 (50%)	1 (25%)		1 (25%)		4 (100%)	
MHSIP-SC	4	2 (50%)	1 (25%)			1 (25%)	3 (75%)	1 (25%)
SCS-R	20	2 (40%)	13 (30%)		2 (20%)	3 (10%)	9 (50%)	11 (55%)
SI-TC	4	1 (25%)	2 (50%)	1 (25%)			4 (100%)	
SI-SU	2		1 (50%)	1 (50%)			2 (100%)	
SI-D	11	2 (36%)	7 (64%)	2 (36%)				11 (100%)
SI-C	4	1 (25%)	2 (50%)	1 (25%)			4 (100%)	
SI-T	11	1 (9%)	1 (9%)	6 (55%)	1 (9%)	2 (18%)	11 100%)	
SI-MI	5	2 (40%)	3 (60%)				2 (40%)	3 (60%)
SIM	7		2 (29%)	3 (43%)	1 (14%)	1 (14%)	7 (100%)	
SIM-2	2		1 (50%)	1 (50%)			2 (100%)	
SI-NI	7	1 (14%)	1 (14%)		2 (29%)	3 (43%)	7 (100%)	
SOBI-P	18		10 (56%)		2 (11%)	6 (33%)	7 (39%)	11 (61%)
Total	**144**	**22 (15%)**	**60 (42%)**	**20 (14%)**	**16 (11%)**	**26 (18%)**	**89 (61%)**	**56 (39%)**

The number of CIVIC dimensions per measure was as follows: one dimension (n = 1), two dimensions (n = 6), three dimensions (n = 9), four dimensions (n = 4), five dimensions (n = 1). The majority of measures therefore demonstrated at least two of the five dimensions, and two-thirds (67%) demonstrated three or more dimensions. The single measure which operationalised only one dimension was the two-item GI-AG measure which assessed Identity and common bond. Across all measures the number of dimensions increased with the number of items. Those measures assessing two dimensions had between two and four items, three dimensions (4–18 items), four dimensions (7–16 items) and five dimensions (one measure: 11 items). The single measure incorporating all five dimensions of the CIVIC framework was the SI-T measure. Across all measures the most commonly assessed dimension was *Identity and common bond* (n = 21 measures), followed by *Closeness* (n = 12), *Involvement* and *Cared for and accepted* (both n = 10) and finally *Valued relationships* (n = 9). Of the 21 measures, seven (33%) contained items referring to both specific and non-specific relationships, two measures (10%) referred to non-specific items, and 12 (57%) measures referred only to specific-only items.

4.3.4. Comparing the conceptual framework with factor analysis results from included studies

Four of the 21 measures, all subscales of larger measures, had been empirically evaluated on their dimensionality (see Table 4.6). One measure, the INQ-TB, was evaluated using confirmatory factor analysis. The other three measures, the SOBI-P, EADME-BR and EADME-BDA were each analysed by the scale developers using PCA.

Table 4.6 Factor structure of measures (n=4)

Full measure (subscale included in review)	Method	Hypothesis	Results
EADME (Belonging-Recovery and Belonging-Drugs/Alcohol)	PCA	Not reported	Two components Component one (EADME-BR) Loadings: 0.543-0.898 Fit: Not reported Component two (EADME-BDA) Loadings: 0.474-0.819 Fit: Not reported
INQ (Thwarted-belongingness)	Confirmatory factor analysis	One factor: 'Belonging'	One factor Loadings: 0.514-0.877 Fit: RMSEA (0.075), SRMR (0.060), CFI (0.915), TLI (0.898)
SOBI (Psychological)	PCA	Two components: 'Valued involvement' and 'Identity (fit)'	One component Loadings: 0.48-0.85 Fit: Not reported

CFI=Comparative Fit Index; RMSEA=Root Mean Square Error of Approximation; SRMR=Standardized Root Mean Square Residual; TLI=Tucker Lewis Index

A single factor or component was identified for all four measures. Data for goodness-of-fit of the models was reported only for the INQ-TB for which absolute and incremental fit indices suggested that a single factor was at best only marginally adequate in reproducing the underlying structure of their data (Hu & Bentler, 1999). In a separate study reported in the included paper (Study 17: Van Orden et al., 2012), the scale developers conducted exploratory analysis of the full INQ scale in a non-clinical sample (data not included here). They reported a four-factor solution as showing the best fit (compared to 1-, 2- and 3-factor models) though they did not examine this model further given the low number of indicators per factor and because it was not theoretically predicted. Similarly, the developers of the SOBI-P examined 1, 2, 3 and 5 component solutions for the

SOBI measure on the basis of Scree test results (Hagerty and Patusky, 1995). A 2-factor solution ('Psychological' and 'Antecedents' subscales, the former being included in this review) was selected on the basis of 'component significance, eigenvalues and conceptual clarity'. The other solutions were not presented or discussed.

4.3.5. Sensitivity analysis

The robustness of the preliminary synthesis was assessed through a sensitivity analysis of those measures rated as having good content validity. Six of the 21 measures met all COSMIN criteria for good content validity: INQ-TB, SCS-R, SI-D, SI-T, SIM and SOBI-P. When reanalyzing the items of these six measures (n = 70) the same five dimensions described in the CIVIC framework were found. Likewise, the relative distribution of items per dimension was very similar in these measures as to that seen in the full set. This similarity in distribution may be expected given that the six high quality measures together totalled 70 items, comprising over half of the 144 items in the full set of measures. Compared to the full analysis the number of dimensions assessed per measure was higher in the six measures included in the sensitivity analysis (two dimensions, n = 1; three dimensions, n = 1; four, n = 3; five, n = 1). The relative frequency of each dimension changed slightly with *Cared for and accepted* becoming the second most common across measures and consisting of the second highest number of items. By contrast, this was one of the least frequent dimensions in the full analysis. In assessing the distribution of items rating either specific or non-specific social connectedness, more non-specific than specific items were found (specific=23; non-specific=47). Three of the six measures featured items referring to both types of connectedness, which is slightly more than in the full set, where eight of the 21 measures (38%) assessed both. Overall, there were no marked differences between the sensitivity analysis and the full analysis.

4.4. Discussion

4.4.1. Existing measures

A total of 21 measures were identified in the review. In most cases the evidence for the measurement properties of these measures was weak. It is unclear whether the majority of the measures reviewed in this paper are valid and reliable for use in different mental health populations. The measure with the strongest psychometric properties was the INQ-TB, which assessed four of the five CIVIC dimensions in non-specific relationships. As such, this can be recommended as a general purpose measure for assessing social connectedness amongst adults with mental disorders.

In this review it was possible to synthesise the measures of various constructs such as social support (ISEL-B), social inclusion (SI-NI), belonging (SOBI-P) and social identity (SIM). The divergent validity of these measures (and potentially other related measures not included in this review) is therefore unclear. It is possible that conceptual obfuscation has led to the unnecessary duplication of work and has limited researchers' ability to synthesise data from related measures (see e.g. Hatcher & Stubbersfield, 2013). Moreover it is not clear which of the multiple factors of social connectedness should be focused on to improve outcomes for adults with mental disorders (Cruwys, Haslam, Dingle, Haslam, et al., 2014; Mann et al., 2017). As an example, whilst reviews suggest that social interventions are effective in the treatment of depression, there are mixed findings as to whether increases in 'social support' mediate these effects (Nagy & Moore, 2017).

Future work following on from this review, which will not be undertaken within this thesis, may include psychometric validation studies. Several of the measures identified in this review could be assessed for their communal and unique variance. This would help explore and test the dimensionality of social

connectedness. Subject to the findings of such work, there may be scope to develop a new, multidimensional measure of social connectedness.

Finally, many of the measures included in this review combined items of both specific and non-specific social connectedness into a single measure. The measurement of social connectedness may require distinguishing between these two rating levels depending on the level of analysis required for a given research question. For instance, measures of specific social connectedness may be most relevant in assessing the subjective dimensions of particular social networks. Meanwhile, non-specific social connectedness may bear the strongest empirical association with other generalised experiences such as loneliness.

4.4.2. Conceptual framework of social connectedness

The CIVIC dimensions

Five dimensions of social connectedness were identified in this review. These were labelled *Closeness, Identity and common bond, Valued relationships, Involvement* and *Cared for and accepted*. It was also found that each of these five dimensions of social connectedness were assessed in relation to both specific relationships as well as non-specific relationships. That is, social connectedness can be experienced as a bond to a single person but also a non-specific sense of social connectedness to other people in general. The same five dimensions appeared in measures of both higher and lower content validity.

All existing measures assess social connectedness as a unidimensional construct and do not measure all five CIVIC dimensions explicitly. In the four measures analysed for structure a single dimension for social connectedness was found whilst this review identified at least three dimensions in these four measures. These results therefore offered limited validation of the conceptual framework. However, goodness-of-fit indices were either missing or suggested weak support

for the model being tested. One of the most appropriate strategies for assessing the unknown dimensionality of measures is exploratory factor analysis (Joliffe & Morgan, 1992) though none of the studies used this procedure in a clinical sample. One of the included papers did in fact report a sub-study with a non-clinical sample (data therefore not included in the review) which used exploratory factor analysis with the INQ-TB (Van Orden et al., 2012). A four factor solution showed the best fit. This finding was dismissed by the scale developers as it was not theoretically-predicted and given the low number of items per dimension.

The discrepancy between the preliminary synthesis of this review and the measurement models of these studies may also be partly due to other design factors, with these measures having fewer items per dimension than is typically recommended for exploratory analysis and most of the studies using small sample sizes (Costello & Osborne, 2005). In conclusion, the evidence for the latent structure of included measures is quite weak and does not provide suitable empirical data to compare against the conceptual framework of social connectedness suggested by the present analysis.

Existing literature

The CIVIC framework corresponds to some existing empirical studies which highlight the inter-relationship between the five dimensions of the framework. For example, small to moderate associations have been found between perceived acceptance and social support (Brock et al., 1998), social identity support with closeness (Weisz & Wood, 2005) and between closeness and social support (Chow & Buhrmester, 2011; Feng & MacGeorge, 2006; Reis & Franks, 1994; Reis & Shaver, 1988; Salazar, 2015). Such findings suggest that these are distinct, though related subjective dimensions of social relationships.

Importantly, there may be interactions between these different dimensions of social connectedness which have a bearing upon different health outcomes. For

instance, some studies suggest that received social support is associated with beneficial outcomes only when there is a shared social identity between participants for indices such as stress (Branscombe et al., 1999; Frisch et al., 2014; Haslam et al., 2005), cognitive health (Haslam et al., 2015) and general wellbeing (Crabtree et al., 2010).

The dual rating of social connectedness within specific and non-specific relationships also fits with theories of interpersonal relationships arguing that individual differences in interpersonal behaviours and perceptions can be analysed at both levels (Kenny, 1994; Reis et al., 2002; Zayas et al., 2002). For instance, 'attachment style' has been found to show significant variation at both general and relationship-specific levels (Fraley et al., 2011; Fraley et al., 2015; Overall et al., 2003), with general and specific attachment showing differential associations with various psychological and social outcomes (Cozzarelli et al., 2000; Klohnen et al., 2005).

Other social relationship constructs

Previous reviews have addressed the conceptualisation and measurement of specific social relationship concepts as they apply within the context of mental health. These more established concepts include social integration (Baumgartner & Susser, 2013; Ware et al., 2007), social inclusion (Baumgartner & Burns, 2013; Boardman, 2011; Schneider & Bramley, 2008), social capital (Almedom & Glandon, 2008; McKenzie et al., 2002) and social support (Brugha, 1995; Thoits, 2011a). To the author's knowledge this is the first systematic review of social connectedness specifically.

It may be asked whether the construct of social connectedness provides any added value in describing the situation and needs of adults with mental disorders beyond these more well-established constructs. As social connectedness has clear theoretical and empirical associations with loneliness (Haslam et al., 2016; Weiss,

1973), this may be one area where social connectedness has unique value given the high levels of loneliness reported by people with mental disorders (Meltzer et al., 2013).

Other recent reviews have attempted to synthesise the various concepts and measures of social relationships which have been used across health research (e.g. Valtorta, Kanaan, Gilbody, & Hanratty, 2016; Wang et al., 2017). These reviews took a broader focus than the one reported here, aiming to integrate all of the various social relationship terms used in the literature as well as covering both the objective and subjective domains. Whilst such overarching reviews can be successful in bringing more clarity to the wider literature they do not examine specific concepts such as social connectedness in detail. In particular, previous reviews have typically described the subjective dimensions of relationships using generic terms and definitions such as 'network quality', 'network support' or 'social support'. It may be argued that more comprehensive frameworks may be required in order to delineate the multiple subjective dimensions of social relationships. For instance, recent research suggests that other subjective dimensions such as social identity (Cruwys, Haslam, Dingle, Haslam, et al., 2014; Haslam et al., 2018) and social acceptance (DeWall & Bushman, 2011) may also play an important role in physical and mental health outcomes. The conceptual framework developed in this review attempts to map out each of these subjective dimensions.

4.4.3. Strengths and limitations of the study

Strengths

There are three main strengths of this study. First, this review is the first attempt to systematically conceptualise social connectedness. Second, in order to incorporate different perspectives on a complex phenomenon this review included measures developed in different academic disciplines. Third, despite the

complexity of the construct, the consistency of the identified dimensions of connectedness across measures and within the sensitivity analysis suggests that findings of this review are relatively robust.

Limitations

One limitation of this study is the deductive approach taken. Social science researchers often argue that theory generation needs to start from the raw data of people's experiences, devoid as far as possible from researchers' assumptions and preconceptions about the phenomena of interest (Glaser & Strauss, 1967). In this review, it is likely that existing conceptualisations of social connectedness will have influenced the development of the CIVIC framework. Many of the measures from which the CIVIC framework was derived were themselves operationalised according to existing theoretical frameworks. In addition, it is likely that the knowledge of the existing social-relational measurement literature informed the data analysis process for at least one of the analysts (LHD). Thus, both the data and the data synthesis may have biased the resulting framework towards fitting the existing theoretical perspectives found within empirical research rather than being grounded in the experiences of adults with mental disorders.

A second limitation concerns the scope of this review. The potential breadth and complexity of the construct of social connectedness necessitated restricting the scope of this review in several ways. A working definition was used to scaffold the review which pre-defined social connectedness as: (1) a characterisation of one's social relationships, (2) subjective and (3) an individual-level phenomenon. This is likely to have limited the resulting framework in several ways.

Regarding criterion (1), this review focussed on social connectedness conceived of as a social relationship construct yet some theorists have approached it as a personality trait (e.g. Lee & Robbins, 1995). In addition, there are related, more generalised constructs which may involve additional non-social dimensions. For

instance, 'connectedness' may involve spiritual dimensions (de Jager Meezenbroek et al., 2012) whilst 'belonging' is thought to consist of not only social relations but also space/place and historical dimensions (Miller, 2003). The social-relationship world was treated as a distinct domain in this review and how the social domain overlaps or intersects with other domains was not explored. It is possible that distinct domains cannot be analysed separately and a more comprehensive understanding of social connectedness may need to take other domains into account.

The working definition also restricted social connectedness to subjective dimensions. It is likely, however, that these dimensions are intimately linked to objective features of social relationships. In this case, a more complete framework of social connectedness may need to take this into account. For example, structural features of social networks such as their size or density may influence subjective dimensions of groups such as *Identity and Common Bond* (Molina-Morales et al., 2013). Observable social behaviours may also be important. For example, *Closeness* may depend on levels of self-disclosure or physical intimacy between individuals whilst *Involvement* may depend upon geographical proximity.

Finally, the working definition focussed on social connectedness as an individual-level phenomenon, i.e. an individual's perceptions of their personal involvement with others. Social connectedness at the group or community level (e.g. group/social cohesion) may demonstrate different dimensions to those described by the CIVIC framework. Focussing on the individual-level also ignores important contextual dimensions such as the social norms for relationships and social interaction which are likely to influence people's perceptions.

Further limitations include being restricted to English-language papers, that the majority of studies included in this review were from high-income countries, and

that none of the measures had been assessed for cross-cultural validity. The results of this review may therefore not generalise across different socio-economic or cultural contexts. A major assumption of this review was that a universal, context-independent framework of social connectedness may exist. However, it is likely that conceptions of social connectedness will vary considerably across social and cultural contexts. For example, cross-cultural studies have found that loneliness relates more strongly to family connections in some societies and more to friendship and having a confidant in others (Lykes & Kemmelmeier, 2014).

Likewise, cultural orientations may influence the salience of different social connectedness dimensions or generate different dimensions altogether. As an example, in collectivist societies where the self-concept is conceived of in interpersonal terms (Triandis, 2001), a strong emphasis may be placed on dimensions concerning self-other overlap such as *Identity and Common Bond* and *Closeness*. Within individualist societies the self is considered to be a personal phenomenon and thus greater importance may be afforded to dimensions concerning one's self in relation to others such as *Cared for and Accepted*.

It is not clear whether the framework identified in this review provides a universal or culture-specific account of social connectedness. Notably, it is not clear whether it applies to non-English speaking populations, older adults and children/adolescents or to people without mental disorders. Cross-cultural qualitative studies and those with healthy populations of different ages would be required to assess this. Such studies are beyond the scope of this thesis, which has focussed on working age adults with mental disorders living in the UK.

Finally, the CIVIC framework is based upon a systematic empirical synthesis, not a narrative conceptual review and thus there may be other search terms relevant to social connectedness which were not used in this review. The search strategy

also involved backward citation tracking but not forward citation tracking. These limitations may have led to relevant articles being missed from the review.

4.4.4. Implications for this thesis

Given the noted limitations of deriving a new conceptual framework from existing research measures, the next step will be to evaluate the validity of the CIVIC framework using an inductive approach. To determine whether the CIVIC framework adequately captures the meaning of social connectedness, qualitative research is required to explore people's experience of this phenomenon. This will be done through an interview study with adults with mental disorders and mental health professionals, which is reported in the next chapter. The CIVIC framework will inform these semi-structured interviews by indicating which areas need to be focussed on within the topic guide.

It was decided to use the INQ-TB to assess social connectedness in the subsequent feasibility study. This decision was made on four grounds: (1) the INQ-TB has the strongest overall psychometric properties of all measures included in this review; (2) shows good content validity; (3) assesses four of the five CIVIC dimensions; and (4) focusses on non-specific social connectedness. A non-specific measure is appropriate for evaluating the G4H intervention as this may be more closely associated with the generalised concept of loneliness than a specific measure.

The CIVIC framework developed in this review also indicates different areas which need to be accounted for within G4H. Potential interventions for social connectedness indicated by the CIVIC framework, identified from the wider mental health literature, as well as those already featured in the G4H intervention are shown in Table 4.7.

Table 4.7 Social connectedness interventions indicated by the CIVIC framework

CIVIC dimension	Potential intervention(s)	Intervention components used in G4H
Closeness	Attachment therapy (Heard et al., 2009); positive psychology interventions, e.g. gratitude visits and writing (Algoe, 2012)	Exercises on managing relationship conflict and the importance of reciprocity
Identity and common Bond	Social identity mapping tool (Cruwys et al., 2016); identifying valued social identities	Social identity mapping tool
Valued relationships	Social identity mapping tool	Social identity mapping tool
Involvement	Behavioural activation (Veale, 2018); increasing opportunities for social interaction (Webber & Fendt-Newlin, 2017); supported socialisation (Sheridan et al., 2015)	Increasing opportunity for social interaction
Cared for and accepted	Enhancing social support (Hogan et al., 2002); peer support groups (Crabtree et al., 2010)	Peer support within G4H group

4.5. Chapter conclusion

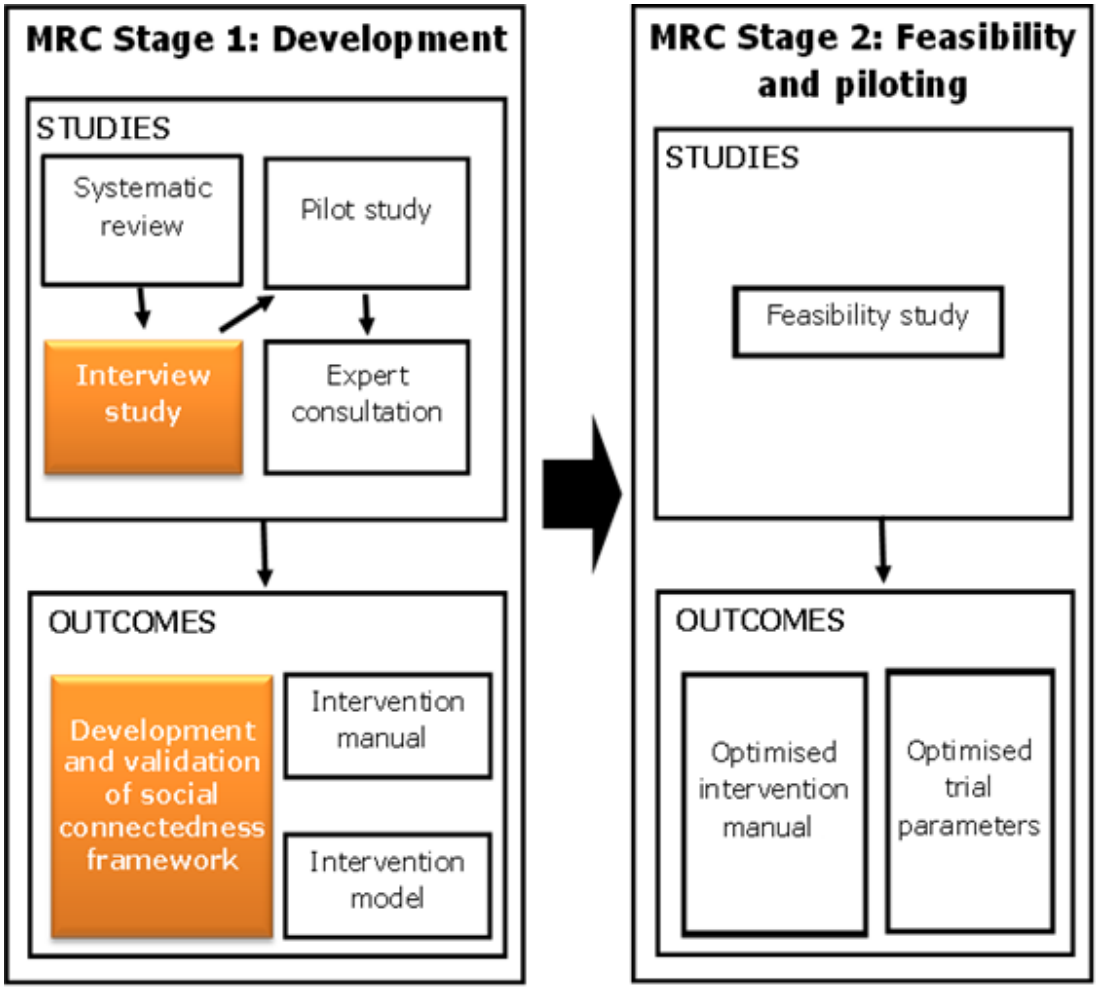
This chapter reported on the systematic review of measures of social connectedness. There were two key findings of relevance to this thesis. First, the INQ-TB was identified as an appropriate measure of social connectedness for use in the feasibility study. Second, the CIVIC framework was developed which will form part of the theory base for the adaptations of G4H. The next chapter reports on a qualitative interview study with relevant stakeholders which explores their experiences of social connectedness and the extent to which the CIVIC framework provides an adequate account of these experiences.

Chapter 5. Evaluating the validity of the CIVIC framework

Chapter overview

Chapter 4 reported on the systematic review of measures of social connectedness from which the CIVIC framework was developed. This chapter describes an interview study which focussed on whether the CIVIC framework is a valid representation of the experiences of social connectedness of adults with mental disorders. The interview study was conducted as part of Stage 1 of the MRC framework to further refine the theory base of the thesis. This is depicted in Figure 5.1.

Figure 5.1 Locating the interview study in the thesis



The background to this study is described in Section 5.1. The methods used to evaluate the validity of the CIVIC framework are then described in Section 5.2. The findings of the study are reported in Section 5.3 and discussed in Section 5.4.

5.1. Background to the study

The term 'validity' is typically used to refer to the degree to which the measure of a construct accurately represents that construct and thus this term is not often used in the context of qualitative research (Lub, 2015). Instead, the term validity will be used here to refer to the ecological validity and relevance of the CIVIC framework for adults with mental disorders.

Ecological validity refers to the degree to which the results obtained from a research setting translate to real-world settings (Brunswik, 1956). The CIVIC framework was derived from a review of measures which had been developed by academics for research purposes rather than from personal accounts of adults with mental disorders. Notably, none of the measures identified in the review were developed using qualitative studies with the target population, despite this being recommended practice (Streiner et al., 2015). Therefore, it is possible that the framework does not capture how social connectedness is actually experienced by adults living with a mental disorder. Qualitative research can be used to assess the validity of a phenomenon by addressing whether the subject is relevant and meaningful to the population of interest and can be applied to settings beyond that in which the research was conducted (Hammersley, 2007).

Whether the CIVIC framework is ecologically valid and meaningful to adults with mental disorders will determine its suitability in forming the theory base of the adapted G4H intervention. First, it will be important that G4H targets social outcomes which are valued by potential recipients. Second, the CIVIC framework will inform the rationale given to G4H recipients regarding the purpose of the

intervention. It has been argued that providing a clear rationale which is accepted by recipients is a central feature of effective psychosocial interventions (Wampold, 2015). This rationale needs to be credible to the population to whom the intervention is delivered and it must fit with their existing beliefs and understandings. The importance of 'population-fit' for a given rationale is suggested by a meta-analysis demonstrating increased effectiveness for culturally-adapted psychosocial interventions compared to non-adapted interventions (Benish et al., 2011). As 'social connectedness' remains a broad and nebulous term, it is possible that different understandings of the concept are used in different social contexts. Therefore, if the CIVIC framework is to provide the theory base for the adapted intervention it may be important to adapt the framework to fit the understanding of social connectedness held by the target population.

The objective of this study was to evaluate the validity of the CIVIC conceptual framework of social connectedness and identify candidate refinements to the framework (Objective 3 of the thesis).

5.2. Methods

5.2.1. Ethical approval

Approval for the study was granted by the Division of Psychiatry and Applied Psychology Ethics Sub-committee at the University of Nottingham (ref 249, 09.02.2018). In addition, organisation-level approvals were received from Nottinghamshire County Council and the charities Improving Lives and Middle Street Resource Centre.

5.2.2. Participants

Inclusion criteria for participants living with a mental disorder (hereafter identified as 'lived experience participants'):

- Aged 18-65
- Self-reported mental disorder
- Ability to speak/read English
- Ability to give informed consent

Inclusion criteria for staff participants:

- Mental health professional
- Currently supporting adults with mental health disorders
- One year or more of experience supporting adults with mental disorders

5.2.3. Setting

All participants were recruited in Nottinghamshire. Lived experience participants were recruited from mental health peer support groups. Staff participants were recruited from one mental health team and two voluntary sector charities.

5.2.4. Procedure

Recruitment

A convenience sampling recruitment strategy was used. Convenience sampling involves recruiting participants meeting the inclusion criteria from the first available source (Holloway & Galvin, 2017). For the lived experience participants, mental health support groups in Nottinghamshire were targeted. Efforts were made to recruit a diverse range of participants in terms of age, gender, ethnicity, socioeconomic background (neighbourhood of residence), mental disorder and service use.

Staff participants were recruited from a mental health team based within a local authority and two charities. Participants with different professional backgrounds were sought.

For lived experience participants, the interviewer (LHD) attended support groups three or more times to introduce himself and become more familiar with the setting and context. Potential participants were then initially approached by the group organisers who provided them with a participant information sheet for the study. Those interested in the study were provided with contact details for the research team. It was then arranged to meet potential participants individually to discuss the details of the study and answer any questions. Informed consent from participants was taken either immediately from people willing to take part or another meeting was arranged if potential participants wanted more time to consider their involvement.

For staff participants the interviewer attended team meetings to introduce himself and provide background information on the study. Potential participants were approached by team managers and provided with a participant information sheet. Those interested then contacted the interviewer who arranged to meet potential participants, explain the study and obtain informed consent.

Participants were contacted to arrange a suitable time and venue to conduct the interview. Individual semi-structured interviews were conducted. Interviews took place in a private room at voluntary or local authority premises.

Before starting the interviews participants were given details about the consent process and given the opportunity to withdraw from the study. Issues surrounding confidentiality were discussed, with the participants given adequate time to ask any questions. It was stressed that participants did not have to answer any

questions they were uncomfortable with, and that they were free to withdraw at any time.

Recruitment and interviews took place from February to April 2018. Recruitment continued until theoretical saturation was achieved whereby any additional data were captured within the existing themes, all of which had been fully explored (Holloway & Galvin, 2017).

Following the interviews, all participants were invited via email to take part in a process of respondent validation. Participants who were willing to take part were posted a copy of the coding framework developed in the analysis (see Section 5.2.5) along with a feedback form and a prepaid return envelope. On the feedback form participants were asked if there was anything they would change about the analysis as a whole, and for each theme specifically.

Data collection

A sociodemographic form was completed at the beginning of the interview. Two versions of the form were used, one for lived experience participants and one for staff. A single topic guide was used for all participants with slightly amended questions used with lived experience and staff participants (see Appendix 2 for topic guide). PPI members reviewed the topic guide and suggested refinements to the questions and prompts. The topic guide was split into three sections. The first section comprised questions about the participants' understanding and experiences of social connectedness. The second section asked for their views on the CIVIC framework. Responses to the first and second sections were used as data to examine the validity of the conceptual framework and are reported in this chapter. The third section of the topic guide introduced the G4H programme and asked for suggestions in adapting it for use with adults with depression. Analysis of these responses will be reported in Chapter 6.

In line with best practice, the initial topic guide was adapted iteratively in response to emerging issues (Schutt, 2012). Adaptation was conducted by analysing field journal notes and concurrent analysis of the transcripts which helped to identify emergent themes which could be fully explored in subsequent interviews. For instance, in relation to the concept of social connectedness, some participants were not sure whether to describe their experiences of ideal social connectedness or their current experiences, which may have been less than personally satisfactory. Hence, participants were asked about their desired or ideal experiences of social connectedness. Meanwhile, staff members were not sure whether to describe social connectedness in relation to service users or to themselves and subsequently were asked to describe this in relation to both whilst highlighting any areas where they believed differences occurred.

Interviews lasted between 20-80 minutes. All interviews were audio recorded, transcribed verbatim, and anonymised.

Data handling

Documentation containing identifiable information, such as the consent forms and contact details, were stored separately from the assessment forms. All paper-based data were stored in a locked cabinet in a locked room only accessible to LHD. An electronic file containing all study information was stored on a secure server at the University of Nottingham along with a password-protected database containing the participant identification numbers.

Data were recorded onto a digital recorder, downloaded onto a protected drive on a University of Nottingham computer, deleted from the recorder, and transcribed with pseudonymisation. Raw data files (i.e. the sound file) were deleted at the end of study.

5.2.5. Data analysis

The procedures of thematic analysis were used to analyse the data (Braun & Clarke, 2006). This involved six steps:

1. *Becoming familiar with the data*. Each transcript was read repeatedly and initial thoughts on the data were noted down.
2. *Generating initial codes*. A list of meaningful and interesting fragments of text was created across the entire data set.
3. *Searching for themes*. Broader overarching themes were searched from among the initial codes. This involved merging or splitting codes and themes and identifying levels and relationships between them.
4. *Reviewing themes*. The data were visited repeatedly to refine the themes by further splitting and collapsing them, and to identify a definition for each theme. A candidate thematic map (or coding framework) was produced with the goal to adequately capture the contours of the coded data. New themes that were missed before were also sought out at this step.
5. *Defining and naming themes*. Each theme was clearly described and delimited to produce a final refined coding framework. This was then applied to the entire dataset.
6. *Producing the report*. A report was written following analysis to document the results.

The analysis followed these six steps and also applied several additional techniques, each of which are recommended to enhance the rigour of analysis: iterative inductive coding, line-by-line coding, memo taking, constant comparison, negative case analysis and discussion and consensus among two or more analysts (Strauss & Corbin, 1998). Iterative coding refers to generating initial codes, reflection and discussion of these between researchers and then recoding. Line-

by-line coding refers to the application of codes to each line of the interview transcript. Memos are reflective notes about what the researcher is learning from the data. Constant comparison refers to repeatedly going back to the data, recoding, and checking the evolving coding framework against new and existing data. Negative case analysis involves identifying data from participants which does not fit initially formulated hypotheses and themes and beginning to revise the themes to account for this.

Within thematic analysis it is possible to use either inductive coding, theoretical coding or both (Braun & Clarke, 2006). Inductive coding identifies themes strongly linked to the data and are not directed by a particular theoretical perspective of the analyst. By contrast, theoretical coding is more strongly influenced by the analyst's theoretical perspective. In this study the objective was to evaluate the validity of a predefined conceptual framework but also to explore participant's personal understanding of social connectedness in order to identify key areas of difference and novel insights. For this reason both inductive and theoretical coding were used. First, inductive codes were generated directly from the data. Second, theoretical codes using categories from the CIVIC framework were used to assess their fit to the data.

Thematic analysis can also use either semantic level or latent level coding (Braun & Clarke, 2006). Semantic level coding refers to the explicit or literal meanings of what a person has said. Latent level coding refers to underlying assumptions or concepts which are theorised to influence the explicit statements a person has made. As the objective of this study was to assess the validity of the conceptual framework, latent coding may have been overly influenced by the analyst's knowledge of the existing framework and it was decided that semantic coding would be used to adhere more closely to the data.

A collaborative data analysis approach was taken in this study with analysis being conducted by Robbie Dewa (RD), a PPI co-researcher, alongside an academic researcher (LHD) (Jennings et al., 2018). Having two researchers analyse qualitative data is recommended to highlight the different ways in which data can be interpreted, to alert researchers to new interpretations, and to facilitate discussion and the reflective revision of codes (Glaser & Strauss, 1967). The philosophical framework of this thesis is that of critical realism, which calls for a critical account of one's own understanding of the world. Collaborative analysis between two or more researchers facilitates critical reflection and reduces the influence of one individual's perspective (Cornish et al., 2013).

The additional benefit of PPI collaborative analysis is in having a member of the analyst team who provides a perspective on the data informed by lived experience of mental health difficulties and current service use. This helped to incorporate a lived experience standpoint in the analysis to complement the academic standpoint of the other analyst. This was particularly important for this study as the research questions concern the personal experience of social connectedness which may have been partly shaped by mental health issues.

The procedure for collaborative data analysis was as follows. First, an inductive analysis was conducted. LHD met RD to discuss and explain the analysis process and procedures. They independently coded 10 of the 22 transcripts using inductive coding, meeting four times to discuss findings and iteratively develop new codes and preliminary coding frameworks. Once a coding framework was agreed upon LHD then used this framework to code the remaining transcripts. Where new data suggested amendments to the framework these were discussed with RD. The final framework was used by both researchers to code a new transcript and inter-rater reliability was calculated using the kappa statistic (Viera & Garrett, 2005).

Where data arising from the inductive coding process were seen to fit within the parameters of the CIVIC framework this is presented alongside other data relating to that CIVIC theme; for example, where inductive analysis suggests a shift in emphasis or amendment to a CIVIC theme. New data emerging from the inductive analysis which did not fit with the CIVIC framework, such as a new superordinate theme, are highlighted in the results section.

Second, a deductive analysis was conducted using a predefined coding framework comprising the CIVIC dimensions identified in the systematic review described in Chapter 4. This procedure was conducted as part of the negative case analysis to identify cases or parts of the data which did not fit with the CIVIC framework. LHD and RD used the coding framework to independently analyse 10 transcripts then met one further time to discuss their findings and identify deviant cases. This coding framework is shown in Table 5.1.

Table 5.1 Deductive coding framework derived from the CIVIC framework

Superordinate theme	**Subordinate theme**
Closeness	
Identity and common bond	
Valued relationships	
Involvement	Group or network involvement Companionship
Cared for and accepted	Social acceptance Social support

One pre-planned sub-group analysis was performed, analysing the data by participant type (lived experience participant vs. staff). Themes arising from each sub-group were compared to assess points of divergence. Quotes from lived experience participants and staff are identified separately to assist in this comparison.

Transcripts were coded and analysed using NVivo® version 10 (QSR, 2014), a computer software package used to manage qualitative data.

5.2.6. Study quality

In order to support the methodological quality and rigour of the study several approaches were considered including credibility, transferability, dependability and confirmability (Lincoln & Guba, 1985).

Credibility addresses the 'fit' or congruence between respondents' views and the researcher's representation of them. Credible qualitative research is that which provides an accurate account of the perspectives of others. The following strategies were employed to enhance the credibility of the inquiry:

Prolonged and varied field experience (Creswell & Miller, 2000). To gain an adequate understanding of the group/organisation context and to develop trust and rapport with participants, each support group or staff team was visited at least three times over a period of 9 months prior to the interviews.

Peer debriefing (Guba, 1981). Examination and discussion of the emerging findings were discussed with the thesis supervisory team who were not directly involved in the study to invite critical questions on the perspectives and assumptions taken by analysts.

Triangulation (Creswell & Miller, 2000). Data collected using multiple methods were compared to facilitate a deeper understanding of social connectedness. This comprised the interview data, systematic review results, self-report (lived experience participants) and observer-report (staff participants).

Reflexivity (Creswell & Miller, 2000). A field journal was maintained during the course of the data collection and analysis to note down observations of the context and interaction of the interviews. This was used to note thoughts and

reflections during the study in order to support a contextual understanding of the interviews and to increase the interviewer's awareness of his own role in the research process.

Member checking (respondent validation) (Lincoln & Guba, 1985). To check whether the analysis gave an accurate account of participant's views, respondent validation was used. Synthesised results were provided to participants to discuss whether the analysis gave a fair representation of their experiences.

Negative case analysis (disconfirming evidence) (Creswell & Miller, 2000). To examine whether or not the emerging findings were fully supported by the data, elements of the data which did not support the conceptual framework of social connectedness or contradicted it were sought out and discussed.

Collaboration (Creswell & Miller, 2000). A PPI co-researcher with lived experience of mental health difficulties was involved in the data analysis with the aim of generating accounts of participants' views that were informed by a shared understanding of their experiences.

Transferability refers to the degree to which the results of qualitative research can be transferred to other contexts with other respondents. Two strategies were used to inform how well the study results may translate to other populations. First, efforts were made to recruit a diverse sample from different settings, roles and personal characteristics (notably mental health experiences). This may support the transferability of the results to different contexts (Bitsch, 2005). Second, the Standards for Reporting Qualitative Research guidelines were followed (SRQR; O'Brien et al., 2014). The SRQR describes 21 items for full, transparent reporting of qualitative studies. With respect to transferability, following the SRQR may allow others to make a judgement about how well the

results from this study transfer to other settings (Lincoln & Guba, 1985). Table 5.2 reports on the SRQR checklist for this study.

Table 5.2 SRQR checklist for reporting the quality of qualitative studies

Item No.	Item	Section reference
S1	Title: Concise description of nature of topic	5.1
S2	Abstract: Summary of key elements of the study	Abstract
S3	Problem formulation: Description and significance of phenomenon studied	5.1
S4	Purpose or research question: Purpose/objectives of study	5.1
S5	Qualitative approach and research paradigm	3.1 and 5.2.5
S6	Researcher characteristics and reflexivity: Researchers' characteristics which may influence the study	5.2.5 and 5.4.1
S7	Context: Site setting	5.2.3
S8	Sampling strategy: How and why participants were selected	3.6 and 5.2.4
S9	Ethical issues: Research approval and documentation of consent	5.2.1 and 5.2.4
S10	Data collection methods: Type of data; procedures; dates; modification of procedures	5.2.4
S11	Data collection instruments: Description of instruments (e.g. interview guides) and devices (e.g. recorders)	5.2.4
S12	Units of study: Number and characteristics of participants	5.3
S13	Data processing: Methods for processing data prior to analysis	5.2.4
S14	Data analysis: Process by which themes were identified	5.2.5
S15	Techniques to enhance trustworthiness	5.2.6
S16	Synthesis and interpretation: Main findings	5.3
S17	Links to empirical data: Evidence of findings (e.g. quotes)	5.3
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	5.4.1
S19	Limitations: Trustworthiness and limitations of findings	5.4.2
S20	Conflicts of interest	3.9
S21	Funding	Acknowledgements

Dependability concerns the stability of results over time such that consistent results might be found in further studies. Dependability was supported in this study by detailing the study process, as shown in Table 5.2, so that others can assess the appropriateness of the approach and techniques used (Lincoln & Guba, 1985).

Confirmability is the extent to which the findings of a study are shaped by the respondents themselves and not the researcher's own perspective, motivation or interest. To support the confirmability of the findings three steps were taken. First, the study processes and decisions made during analysis were documented (Lincoln & Guba, 1985). Second, a reflexive field journal documented LHD's reflections to elucidate areas of potential influence on the analysis (Bitsch, 2005). Third, respondent validation was used to assess whether the synthesised findings fit with participants' experiences.

5.3. Findings

Participants

A total of 22 individuals participated in the interviews, comprising nine staff participants and 13 lived experience participants. Table 5.3 shows the sociodemographic and clinical characteristics of the participants.

Table 5.3 Sociodemographic and clinical characteristics of participants (n=22)

Characteristic	**Participant group**	
	Lived experience (n=13)	***Staff (n=9)***
Age in years (mean, SD)	49.3 (11.9)	47.3 (9.1)
Gender (n, %)		
Male	9 (69)	4 (44)
Female	4 (31)	5 (56)
Ethnicity (n, %)		
White British	13 (100)	8 (89)
White Other	0	1 (11)
Living arrangements (n, %)		
Live alone	9 (69)	
Live with others	4 (31)	
Partner status (n, %)		
Single	6 (46)	
In a relationship	3 (23)	
Divorced or separated	4 (31)	
Self-reported diagnosis (n, %)[a]		
Depression	7 (54)	
Anxiety	5 (38)	
Schizophrenia	3 (23)	
PTSD	3 (23)	
Psychosis	1 (8)	
Bipolar	1 (8)	
Schizoaffective disorder	1 (8)	
Social anxiety	1 (8)	
Prefer not to say	1 (8)	
NHS mental health service user (n, %)[b]	9 (75)	
Profession (n, %)		
Occupational therapist		1 (11%)
Clinical psychologist		1 (11%)
Social worker		5 (56%)
Support worker		2 (22%)
Years of work experience (mean, SD)		12.6 (9.9)

[a]Seven participants reported multiple diagnoses; [b]One participant preferred not to say

Themes

A single coding framework was developed as no meaningful differences were found between the themes emerging from lived experience participants compared to those with staff. Eight participants (six lived experience, two staff) participated in the respondent validation process, with no changes suggested for the analysis. Agreement between the analysts was substantial (Kappa=0.74). The coding

framework developed through inductive analysis is shown in Table 5.4, with new themes not present in the original CIVIC framework shown in bold.

Table 5.4 Coding framework developed in the inductive analysis

Superordinate theme	**Subordinate theme**
Closeness	**1.1 Feeling comfortable** **1.2 Trust and confiding**
Identity and common bond	
Valued relationships	
Involvement	4.1 Regular group involvement 4.2 Companionship
Cared for and accepted	5.1 Acceptance 5.2 Social support
Shared mental health experiences	**6.1 Source of commonality** **6.2 Feeling accepted** **6.3 Source of support**
Stigma	**7.1 Feeling fundamentally different** **7.2 Feeling judged and excluded**
Connectedness beyond social relationships	**8.1 Spiritual connectedness** **8.2 Connectedness to animals**

All the CIVIC dimensions were represented as superordinate themes in the data with three new superordinate themes also identified. Each theme will now be considered, with negative cases described in full for each theme.

1. Closeness

Most participants described feeling close to others as being an important part of social connectedness. Inductive analysis found that closeness was described in terms of two new subordinate themes which were labelled *Feeling comfortable* and *Trust and confiding*.

1.1 Feeling comfortable

Experiencing closeness with others was characterised in terms of feeling comfortable around them, which involved feeling relaxed around the other person

and having a sense of familiarity with them. Some participants stressed that closeness was not synonymous with 'intimacy', which was described in more physical and romantic terms relating to intimate relationships.

> *It's about relationship building and familiarity and feeling relaxed and trustful with someone.* (Staff #15)

Participants suggested that developing closeness in terms of comfort and familiarity was largely as a process of time. It was also possible to develop closeness when two or more people share characteristics or have a common interest.

> *…the only person who I feel close to if you like is <name> because he's got the same interest as myself* (Lived experience #16)

1.2 Trust and confiding

Closeness was characterised by a high level of trust between people. Self-disclosure and confiding between people was also seen as a central means of nurturing trust, but that this process could take time.

> *I've been in this job for ten months…and they are only now starting to open up when they meet for twice, two-hour every week at the groups.* (Staff #17)

Negative cases: Closeness not essential for everyone

Five participants (two lived experience, three staff) reported that closeness was not an important dimension of social connectedness. Four different reasons were given. First, two participants argued that, whilst closeness is important overall, it is not necessary within every relationship. This means that you can still experience connectedness within a relationship without closeness.

> *But I don't know if it's that important. I think that's maybe a long view, longer goal... Many people operate around just linking in with things to be socially connected, don't necessarily need that strong bond.* (Staff #14)

Second, one participant argued that he could feel connected to people in certain ways, but not in terms of closeness, as his mental health symptoms interfered with this.

> *I don't feel that sort of close to people… being paranoid it makes it difficult to sort of trust people and feel comfortable in your surroundings.* (Lived experience #3)

Third, one participant argued that closeness overlapped with intimacy, and the latter was not a part of social connectedness.

> *I don't feel it has to be necessarily relationship kind of closeness, you know what I mean, intimacy or anything like that.* (Lived experience #11)

Finally, one participant suggested that whilst closeness might be an ideal goal for people, individuals with past experiences of negative relationships may not feel comfortable with closeness in relationships.

> *I think perhaps some people can't tolerate too much intimacy or connectedness with other people…I think people strive for that [closeness], that's kind of what they want, but depending on people's backgrounds and upbringing, that can obviously be quite problematic for them... But as an ideal that is what I think people strive for.* (Staff #6)

2. Identity and common bond

Having something in common with others was seen as being important to social connectedness. This commonality could involve a wide range of different

characteristics including mutual interests, a common activity or purpose, or a shared background. Sharing important individual characteristics with others, particularly in a group context, was seen as part of the experience of 'fitting in'. The more shared commonality there was between people, the stronger their social connectedness was seen to be.

> *If you don't have a particular element that is running through everyone then there is no way to socialise with them.* (Lived experience #9)

3. Valued relationships

The majority of participants felt that valuing or positively appraising one's relationships were an important part of their social connectedness. Participants described valued relationships in terms of their perceived importance as well as their positive impact upon wellbeing. Valuing or viewing others positively was a key part of participants' motivation for socialising. Likewise, viewing a relationship negatively was seen as a barrier to social connectedness.

> *I think it's about feeling that you've got people around you who are of importance to you, also that you are of importance to.* (Staff #22)

Negative cases: Valued relationships not essential for everyone

Five participants (three lived experience, two staff) argued that valued relationships were not a necessary dimension of social connectedness. Four different explanations were given. First, one participant explained that you can be part of a group where you view one or two individuals in that group negatively yet nonetheless value the group as a whole.

> *Well you're never going to find a group of people, more than two, that you feel very, everybody is a positive element…some people will never be on your wavelength, but that's OK.* (Lived experience #9)

Second, one participant argued that valued relationships are important overall but that sometimes mental health symptoms can lead people to desire 'negative connections'.

> *I think for most people positive connection would be needed, I think there are some people who have become so cynical that maybe a negative connection is almost a positive for them. I think in the worst of my depression it might even have been me at one point. But for the most point, positive is very much a plus but for some people they are at the point where they can't even comprehend that it's possible for them so just some connection at least is what gets them by in the meantime, if that makes any sense.* (Lived experience #12)

Third, one participant argued that she could connect to negative people or 'drainers' because she could emphasise with their experience.

> *I can feel the shared experience you know…I know I've been a drainer in the past so you've got to have an element of compassion and empathy.* (Lived experience #11)

Finally, two participants said that how positively they viewed others fluctuated over time depending on their recent experiences with them. They suggested that social connectedness is based upon a positive judgement of others seen from a historical perspective. This allows temporary deteriorations in relationship appraisals without negating connectedness.

> *I think it is possible to feel connected to groups that you feel quite negatively towards, in my mind, and maybe not necessarily groups so much as individuals…I think friends or individuals that you know can let you down or you feel that your trust has been misplaced… but I recognise all the other good things that they'd done or said … the issue then*

> *becomes is whilst ever the good outweighs the bad it's OK, but if it continued that you were let down or people were negative towards you then I think that you would become less connected, you know.* (Staff #4)

4. Involvement

Maintaining a level of involvement or contact with others was seen by participants as a crucial part of developing and sustaining social connectedness. Involvement was characterised in terms meeting others and doing activities together. This was represented by two subordinate themes which were labelled *Regular group involvement* and *Companionship*.

4.1 Regular group involvement

Participants described how social connectedness necessitated being part of a group or network of people whom you saw regularly.

> *Without that regular contact it kind of just starts to evaporate a bit*. (Staff #14)

4.2 Companionship

Participants also suggested that one-to-one companionship was important. This can be understood in the sense of having at least one other person with whom you can engage in activities, rather than being in a group setting.

> *[Connectedness means] if you want to go out you have someone to go out with.* (Lived experience #7)

5. Cared for and accepted

The feeling of being cared for and accepted was described by participants as a key part of their experience of social connectedness. This theme had two

subordinate themes of *Acceptance* and *Social support*, which were already represented in the original CIVIC framework.

5.1 Acceptance

The perception of being socially accepted was described by participants with reference to both the attitudes and behaviours of others. First, acceptance was understood partly in terms of the attitudes others took towards them as a person. Acceptance in this sense referred to feeling understood, not being judged and being valued as a person. There was also a behavioural component to acceptance which involved being welcomed and included in social activities.

> *And if you do feel accepted and people are non-judgmental…to make you feel welcome.* (Lived experience #7)

5.2 Social support

Feeling cared for by others also involved being supported by them. This was especially important when facing a difficult or stressful situation. Participants described several types of support including emotional and practical support.

> *…whether it be someone who will take on-board your upset, your bereavement, your situation and discuss it with you.* (Lived experience #9)

6. Shared mental health experiences

Participants suggested that the shared experience of mental disorder was a salient contextual factor influencing how people connected with others. In particular, three subordinate themes emerged which describe how shared mental health experiences can be a source of commonality, acceptance and/or support.

6.1 Source of commonality

Shared mental health experiences provided a foundation for shared identities or a common bond between people. Participants reported that they 'fitted in' rather

than feeling like an outsider in social contexts where others were known to have similar mental health issues.

> *Most of the people here have some kind of similar mental health related issue and that helps them connect…It's a lot harder to feel like an outsider.* (Lived experience #12)

6.2 Feeling accepted

Sharing similar mental health experiences with others reassured people that they would be socially accepted rather than mistreated.

> *People come here and they feel probably safe because they know everybody's got a common [reason] why we're here.* (Lived experience #2)

6.3 Source of support

Experiencing the same challenges as others can also facilitate the processes of social support. This could occur through: (i) a better understanding of the nature of the challenges faced by the other person; (ii) sharing what has been helpful to them in the past; and (iii) instilling hope.

> *It can help sometimes knowing that there's other people have the same issues as yourself knowing that they can do it, can give you… the oomph to do what they're doing.* (Lived experience #20)

7. Stigma

Many participants described how mental health stigma was a barrier to social connectedness. Two subordinate themes emerged which concerned the two main ways in which stigma can reduce social connectedness.

7.1 Feeling fundamentally different

Mental health stigma can negatively influence social connectedness by interfering with perceptions of commonality with others. Stigma can lead to people feeling left out or fundamentally different from others.

> *You feel stigmatised and prejudiced by the way people talk to you and treat you. You just feel they know you're different…That's a big barrier.* (Lived experience #3)

7.2 Feeling judged and excluded

Mental health stigma also reduces perceptions of being accepted by others. Stigmatising attitudes, which ascribe negative stereotypes to groups of people, directly oppose the feeling of social acceptance.

> *Without making people feel that they're iso-, not isolated, that they are labelled, basically, yeah, because mental health still has barriers, so many barriers. It's so unacceptable in today's world. Any world. Always has been. Because they're dangerous, they're weird.* (Lived experience #9)

8. Connectedness beyond social relationships

Some participants referred to connectedness in a broader sense than is captured by the CIVIC framework. It emerged in the inductive analysis that there can be alternative meanings of connectedness beyond social relationships.

8.1 Spiritual connectedness

Connectedness beyond social relationships included a type of spiritual connectedness with some participants making reference to connectedness against a background of their spiritual or religious beliefs rather than due to social processes specifically.

> *Yes course we're all connected in some way! We're all God's children.* (Lived experience #18)

8.2 Connectedness to animals

Some participants also suggested that connectedness could involve non-human relationships and described a feeling of connectedness to animals.

> *We have supported people in the past that really get a good sense of connectedness and peace by having an animal for example, having a dog, and they actually prefer that over sort of mixing with other people.* (Staff #5)

Points of divergence between data analysts

During the deductive analysis there was some initial disagreement between the two analysts. There were differences in interpreting whether or not a person had agreed or disagreed with the CIVIC framework for a particular theme. For example, where a person said 'I don't have close friends' or 'I don't feel accepted by others', the analysts discussed whether this meant they were saying the CIVIC framework was inaccurate or not. The analysts agreed upon a distinction between how people described idealised/desired social connectedness as compared to their actual current experience. Thus, when participants described the absence of one of the CIVIC themes within their current social experiences, this was not taken to negate the framework.

In addition, when organising the data into overarching themes, two different suggestions were made by the analysts. First, LHD initially suggested having a separate theme about the overlap between the original CIVIC themes. It was decided not to use this theme as it did not come out strongly enough in the data for RD and did not make sense to her as a single theme. Second, another point of divergence concerned whether to use 'trust' as a superordinate theme or as a

subtheme of *Closeness*. RD initially suggested having a superordinate theme of 'trust' on the basis that you can trust someone without feeling close to them as well as feeling close without trusting someone. LHD suggested instead that the interviewees spoke about trust in relation to closeness and thus appeared, in his opinion, to fit better as a subordinate theme of *Closeness*. RD agreed with this reasoning.

5.4. Discussion

5.4.1. Validity of the CIVIC framework

The results from this study suggest that the CIVIC framework provides a meaningful account of the experiences of social connectedness amongst adults with mental disorders. The qualitative data affirmed the relevance of each of the five themes which had previously been identified in the systematic review.

There were also clear overlaps between themes in the data. For example, the subordinate theme of 'Companionship' was organised under the superordinate theme of *Involvement* but also demonstrated cross-over with the 'Social support' subordinate theme within *Cared for and accepted*. Such overlap suggests that the CIVIC themes are related social phenomena and that it is appropriate to locate them within a single framework. However, it also suggests that alternative frameworks and organisation of the themes could provide other plausible accounts of social connectedness. Therefore, it is important to emphasise that the CIVIC framework represents only one defensible way of conceptualising social connectedness amongst many others.

There were no meaningful differences between lived experience participants and staff in their accounts of social connectedness. This lends some support to those theories which describe there being a universal motivation to achieve social connectedness (Baumeister & Leary, 1995; Maslow, 1943). Further studies with

samples from different cultural backgrounds could be conducted to assess the trustworthiness of the CIVIC framework in relation to other groups.

Refinement of the CIVIC framework

The data in this study have identified refinements to the CIVIC framework. Three new superordinate themes which contextualised the experience of social connectedness for adults with mental disorders emerged during the analysis. First, shared mental health experiences emerged as a key facilitator of social connectedness. Shared experiences underpinned a source of support, perceived acceptance and commonality with others. The salience of shared mental health experiences is corroborated by research on peer support relationships (Gillard et al., 2015).

Second, mental health stigma emerged as a barrier to social connectedness. This fits with previous findings that perceived and experienced stigma from others can lead to feelings of social isolation (Dinos et al., 2004). Internalised self-stigma is also associated with social withdrawal (Kleim et al., 2008) and social isolation (Lysaker et al., 2007).

Third, it was found that participants could experience connectedness beyond social relationships. This finding suggested that one could connect with non-human agents such as pets or religious deities. Related research into mental health recovery has found that some adults with mental disorders experience their connections with animals as being meaningful and important to their recovery (Yeung et al., 2019). However, this thesis focuses on human relationships and therefore this finding will not be incorporated into the CIVIC framework.

The findings also identified refinements to the existing CIVIC dimensions. Two new subordinate themes, 'Feeling comfortable' and 'Trust and confiding', emerged

under the theme of *Closeness*. This provides more detail on the characteristics and processes of *Closeness* than was present in the original framework. The finding that confiding in others supports closeness is consistent empirical evidence suggesting a linear relationship between self-disclosure and relationship closeness (Greene et al., 2006). Similarly, the data provided more in-depth description of other subordinate themes, such as 'Regular group involvement', 'Social acceptance', and 'Social support', each of which lacked clarity in the original framework.

Reflexivity

When analysing the data, I identified at least three sources of potential influence on my interpretations. The first concerns how the study was being conducted as part of a larger programme to inform the development of an individual-level intervention. This may have led me to selectively attend to individual-level aspects of the data to the exclusion of community or macro-level issues. However, I would argue that this influence did not unduly affect the study as new themes beyond the individual-level emerged during the inductive analysis. Examples of such themes include *Stigma* and *Connectedness beyond relationships*.

The second source of potential influence was my academic background and knowledge of the literature. For instance, during the analysis I argued that trust should be organised as a subordinate theme under the superordinate theme of *Closeness*. This may have been guided by my knowledge of previous studies that, for instance, the majority of adults understand closeness in non-romantic relationships in terms of self-disclosure and trust (Parks & Floyd, 1996).

A third source of potential influence was my own understanding of social connectedness, which is a phenomenon everyone has some experience of. In the systematic review described in Chapter 4, I was one of the analysts who initially

developed the CIVIC framework. I may have partly drawn upon my own experiences of social connectedness to make sense of the data in developing the CIVIC framework. In the opposite direction, the process of engaging with and synthesising the data may likewise have influenced my conceptions of social connectedness in line with the CIVIC framework. Thus, in the present study, I may have been already persuaded of the validity of the CIVIC framework and been more sensitive to parts of the data which fit with the framework compared to data which did not. The potential for this source of influence on my analysis was part of the reason for conducting such an extensive process of negative case analysis and for involving an independent analyst (RD) who was not involved in the original development of the CIVIC framework.

5.4.2. Strengths and limitations of the study

Strengths

The main strength of this study was the inclusion of a co-researcher with lived experience as part of the analyst team. The research question focussed on whether the CIVIC framework was meaningful to adults experiencing mental health difficulties. The data analysis was therefore strengthened by incorporating the perspective of a person with relevant lived experience into the process, rather than being limited to an academic or clinical standpoint.

A second strength was the use of both inductive and deductive analyses. In qualitative work inductive analysis is necessary to explore participant's own experiences of the phenomena of interest. In this study the inductive analysis helped to explore new, unexpected themes of social connectedness which were not captured within the CIVIC framework as well as elaborating upon the existing CIVIC themes. The deductive approach was valuable for three reasons. First, it helped to address one of the challenges for this study which had been highlighted by the PPI group. This challenge concerned the ambiguity of the term 'social

connectedness' as it is both vague and also potentially serves as a referent for a number of distinct concepts (e.g. objective social network size, subjective feelings of belonging or social media activity). Therefore, participants may either struggle to describe their experiences or describe different phenomena. Second, terms used for social bonds (e.g. closeness and support) are often used interchangeably which raises difficulties in interpreting the meaning of qualitative data on this subject. Thus, describing and providing a definition for each of the CIVIC themes also helped to establish the meaning of different terms within the context of the interview. Third, the deductive analysis allowed for a 'mandated breakdown' of the framework (Agar, 1986). That is, it allowed for a systematic and in-depth negative case analysis, thereby increasing the rigour of the analysis.

Limitations

Presenting participants with the CIVIC framework may have raised the risk of 'social desirability bias', in which participants give a response they believe will be favourable to the researcher, or 'acquiescence bias', in which participant's agree to a statement when in doubt. In this study such biases may have led to the finding that the CIVIC framework was meaningful when in fact participants did not think so or they were unsure. However, the inductive analysis of responses to open questions about social connectedness suggested that the CIVIC framework did in fact fit with participants' experiences. Moreover, efforts were made to mitigate against the risk of these biases. First, participants were informed before the interview that the purpose of the study was to change or even to discard the framework if appropriate. Second, participants were encouraged during the interview to offer divergent views if applicable. Third, the respondent validation procedure gave participants another chance to disconfirm the analysis though none of the participants did so. This process was conducted remotely via emailed written responses. This arguably introduces less potential for social desirability bias than face-to-face data collection where participants might feel under more

pressure to agree with statements offered by the researcher. Given each of the above reasons, it is argued that social desirability and acquiescence bias are unlikely to have been major influences in this study.

Another limitation concerns whether saturation was reached in this study. Saturation was assumed when data from four new interviews did not lead to a change in the analysis. It is acknowledged, however, that the concept of saturation is controversial and that it is ultimately impossible to verify whether it was achieved in this study (O'Reilly & Parker, 2013). For example, given participants' wide variety of mental health diagnoses, it is possible that more subtle group differences in the experiences of social connectedness would have emerged amongst a larger sample. Nonetheless, it is argued here that any such differences are unlikely to be substantial enough to have a major influence on the development of social connectedness interventions. If large differences did exist, then these are likely to have been identified within this study.

A third limitation relates to the sampling strategy used which may have influenced the findings. Most of the participants were either a member of a mental health support group or helped to facilitate one. This may have led to the finding that shared mental experiences are a facilitator of social connectedness as participants could be expected to believe in the benefits of mental health groups. It is possible that other adults with mental disorders would prefer not to develop their social connectedness in this manner. Although attempts were made to recruit participants who were not accessing support groups this did not prove feasible.

A final limitation is the lack of ethnic diversity in the sample. Despite deliberate efforts to approach groups targeting adults from ethnic minorities, nearly every participant was White British. This limits the transferability of the results across different cultural groups. For example, other ethnic groups may report distinct conceptions of social connectedness stemming from their cultural values and

norms regarding social engagement and social relationships (Victor et al., 2012). Other factors which are not accounted for within the CIVIC framework, such as geographical place or 'place attachment' (Raymond et al., 2010), may also be more salient dimensions of social connectedness for adults who have migrated to the UK from their place of birth. It is beyond the scope of this thesis to investigate the full socio-cultural transferability of the conceptual framework and applicability of the G4H intervention. However, it should be considered a priority in future research to investigate how social connectedness is experienced by adults from different ethnic backgrounds.

5.4.3. Implications for this thesis

From CIVIC to CIVIC-Mental Health (CIVIC-MH)

The findings from this study suggest that the CIVIC framework is valid and therefore could be used to inform the process evaluation of the feasibility study. However, the findings also suggest that applying the CIVIC framework to particular population groups may require incorporating contextual factors pertinent to each group.

One third theme identified in this study, Connectedness beyond social relationships, was not added to the CIVIC framework as this thesis focuses upon human relationships (see Section 2.1.1, p.11). However, two relevant contextual themes of social connectedness were identified for adults with mental disorders: Shared mental health experiences and Stigma. These two themes can be added to the original five-dimension CIVIC framework. This new seven-dimension framework will be referred to as the CIVIC Mental Health (CIVIC-MH) framework which comprises: Closeness; Identity and common bond; Valued relationships; Involvement; Cared for and accepted; Shared mental health experiences; and Stigma.

The CIVIC framework may represent a general framework for social connectedness and population-specific refinements for adults with mental disorders are required. The CIVIC-MH framework will therefore be used in the remainder of this thesis to form the theory base underpinning the adapted G4H intervention.

For the purposes of the feasibility study process evaluation, the CIVIC-MH themes may represent key processes of change within the intervention. Hence, the framework will be to inform the field note form used for data collection during group sessions and the topic guide for process evaluation interviews with group participants.

Focusing on depression

The finding that shared mental health experiences can facilitate social connectedness may suggest that G4H will be most effective when targeted at people with similar experiences. Therefore, the inclusion criteria for the feasibility study will specify that participants must have a particular mental health diagnosis. The process evaluation will then examine whether this feature of the groups had any impact.

For this thesis the diagnosis of depression was chosen as the inclusion criterion given that adults with depression have some of the highest reported levels of loneliness (Meltzer et al., 2013) and loneliness is known to negatively impact on prognosis in this population (Holvast et al., 2015; Jeuring et al., 2018). However, the findings from this study do not provide a rationale to exclude people who also have other mental health experiences besides depression. Therefore, participants with either a primary or secondary diagnosis of depression will be recruited and no exclusion criteria will be used in the feasibility study.

Specifying the target of the intervention

The findings concerning the distinction between Closeness and intimacy have some implications for the positioning of this thesis. In Chapter 2, the work of the prominent loneliness theorist Robert Weiss was described. Weiss distinguished two types of loneliness: *emotional loneliness* which results from a lack of intimacy from a romantic partner and *social loneliness* resulting from a lack in one's social network. For the purposes of intervening in cases of loneliness, Weiss's typology implies that there are two different social needs which a loneliness intervention could target in view of the fact that 'different forms of loneliness are…responsive to different remedies' (Weiss, 1973, p. 18). There is on-going debate concerning the dimensionality of loneliness and the applicability of Weiss' two-category model (Penning et al., 2014). Assuming that Weiss' distinction is valid, the target for intervention in this thesis is social loneliness rather than emotional loneliness. Additional interventions which target emotional loneliness would therefore need to be designed but this is beyond the scope of this thesis.

Candidate adaptations to G4H

The findings of this study suggest that certain amendments should be made to the format and content of G4H. For example, the finding that regular contact is important may suggest that the one month gap between sessions 4 and 5 should be reduced. Meanwhile, the importance of self-disclosure to the development of *Closeness* may suggest that the guidance for group facilitators might include considering to self-disclosing themselves in order to promote this process amongst the group members. These candidate adaptations will be discussed further in Chapter 6.

5.5. Chapter conclusion

Chapter 4 reported on the development of the CIVIC framework of social connectedness. Chapter 5 reported on a qualitative study of participants experiences of social connectedness and evaluated the validity of the CIVIC framework. It was found that the CIVIC framework fits with participants' experiences but additional themes also emerged. These additional themes were incorporated into the original framework to form the CIVIC-MH framework. This new framework will inform the development of the manual and model of the adapted G4H intervention. Chapter 6 reports on the methods and results used to develop the intervention manual and model.

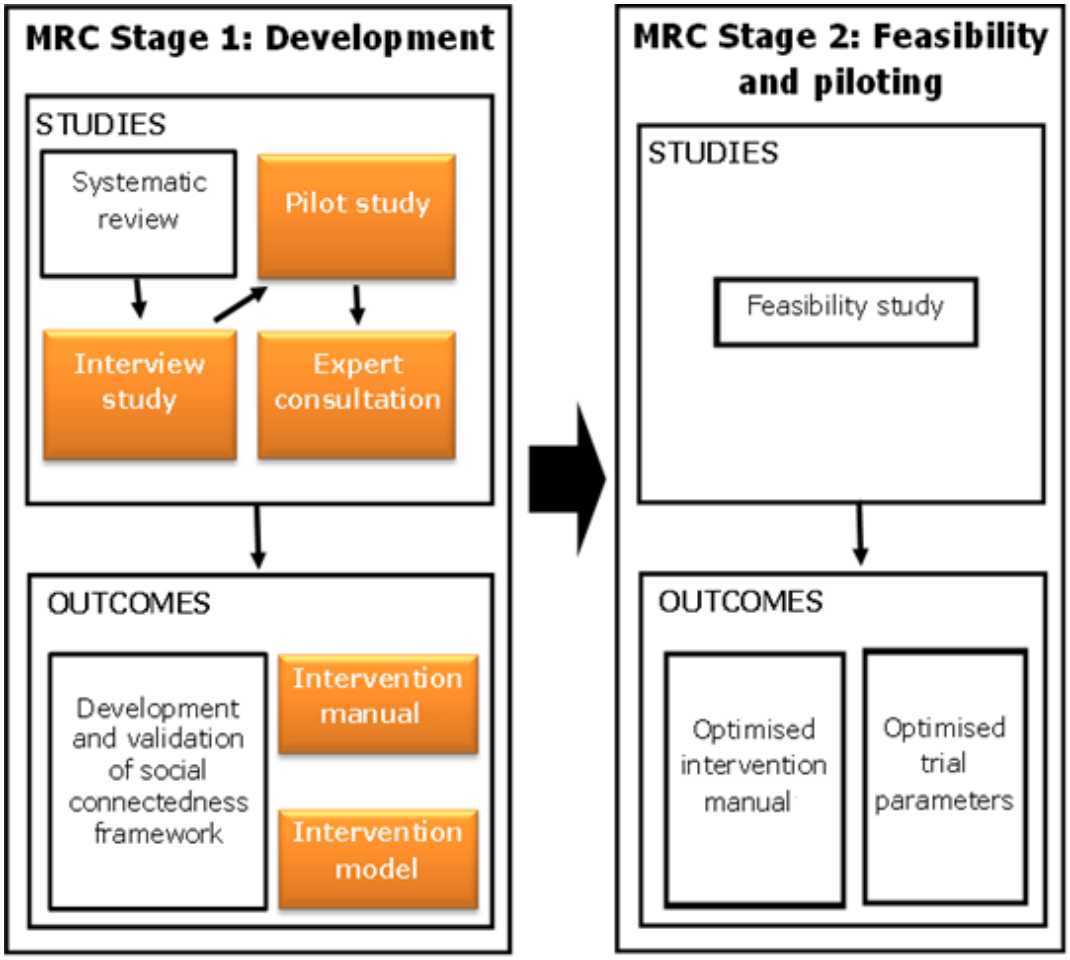
Chapter 6. Manualisation and modelling of the adapted intervention

Chapter overview

Chapter 5 described a qualitative study which led to the development of the CIVIC-MH framework. This framework forms part of the theory base to inform the adaptation of G4H for adults with depression (G4H-D). This chapter aims to further advance the theory base of G4H-D by developing a logic model as well as identifying candidate adaptations to G4H to develop the intervention manual for G4H-D.

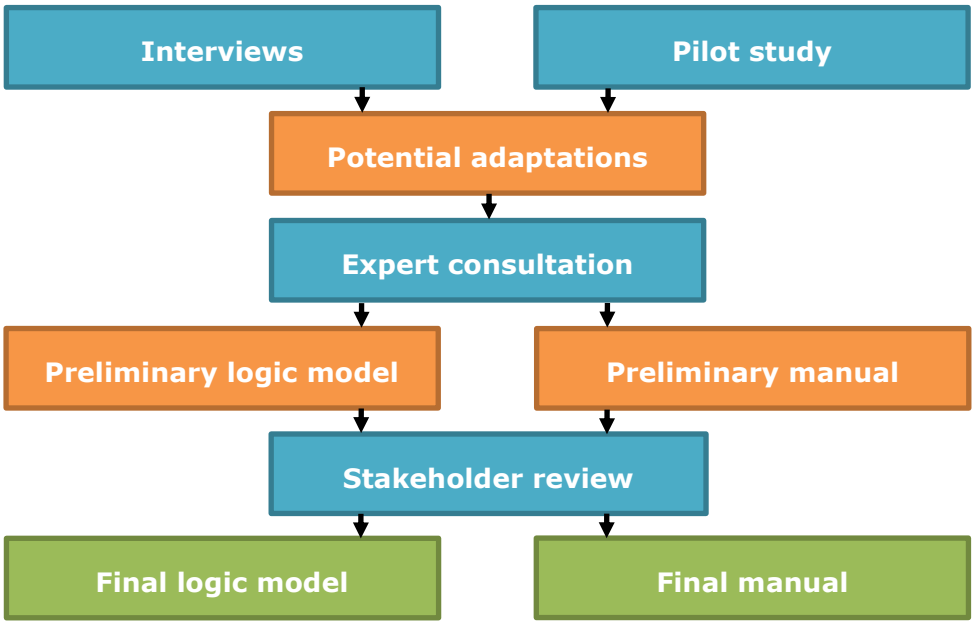
The manualisation and modelling of G4H-D represents the final step in Stage 1 (Development) of the MRC framework. This is shown in Figure 6.1.

Figure 6.1 Locating the manual and modelling procedure in the thesis



Preliminary drafts of the G4H-D intervention manual and logic model were developed iteratively using three sub-studies: (1) qualitative interviews; (2) G4H pilot; and (3) expert consultation. The manual and model were then finalised following a stakeholder review. Approval for the overall study was granted by the Division of Psychiatry and Applied Psychology Ethics Sub-committee at the University of Nottingham (ref 249, 09.02.2018). The overall design and sequencing of this study is shown in Figure 6.2.

Figure 6.2 Sub-studies (blue), findings (orange) and knowledge products (green) of the manualisation and modelling process



The objectives of the studies reported in this chapter are to identify adaptations to G4H for adults with depression (Objective 4 of the thesis) and to develop a logic model and manual for G4H-D (Objective 5 of the thesis). The methods and results of each of the three sub-studies are reported sequentially. The qualitative interviews are covered in Section 6.1. The G4H pilot is described in Section 6.2. The expert consultation is reported in Section 6.3. The development of preliminary drafts of the G4H-D logic model and intervention manual are described Section 6.4. The stakeholder review of these drafts is described in Section 6.5. The final versions of the logic model and manual are described in

Sections 6.6 and 6.7 respectively. Finally, a discussion of the overall results and the implications for the thesis is given in Section 6.8.

6.1. Interviews

6.1.1. Methods

Participants

Interview participants were the same as those participating in the interview study described in Chapter 5 (Section 5.2.2, p.117).

Procedures

Semi-structured interviews were conducted with adults with mental disorders and with mental health professionals. Details on the recruitment, setting and interview procedures can be found in Sections 5.2.3 (p.117) and 5.2.4 (p.117).

The interview topic guide topic guide was split into three sections. Data from the first two sections, concerning participants' experiences of social connectedness and their views on the CIVIC framework, were reported in Chapter 5. The third section of the topic guide focused on participants' views on G4H. Data stemming from the third section of the topic guide are reported in this chapter. In this section the G4H programme was summarised following guidance on reporting interventions (Hoffmann et al., 2014). The initial topic guide was adapted iteratively in response to emerging issues. In particular, it was reported in the previous chapter that shared mental health experiences were an important dimension of social connectedness (see Section 5.3, p.128). This finding led to a revision of the topic guide to focus on adapting G4H for depression specifically, as opposed to mental disorders more generally. Participants were asked for their overall views on G4H, followed by specific questions regarding structure and content. They were also asked for their views on candidate mechanisms within

G4H leading to improved levels of social connectedness, and for suggestions for adapting G4H for adults with depression. The topic guide is shown in Appendix 2.

Analysis

Thematic analysis was used to analyse the data. The general process of thematic analysis has been described in Chapter 5 (see Section 5.2.5, p.121). In this study two deductive analyses were used. The first analysis addressed objective 4 of the thesis (identifying adaptations to G4H for adults with depression). This analysis involved using a deductive coding framework with two predefined categories of Challenges and Proposed adaptations. The Challenges and Proposed adaptations were further grouped into generic issues (applicable to any psychosocial intervention or applicable across several G4H-D sessions) and session-specific issues. It was decided to use these predefined categories of generic and session-specific issues as a means of distinguishing between (a) general features known to be important across psychosocial models and diagnostic groups (Wampold, 2015) and (b) specific issues relevant to G4H-D.

The second analysis addressed objective 5 of the thesis (developing the G4H-D logic model) by examining the processes and mechanisms by which the intervention might operate. This analysis used a deductive coding framework comprising predefined categories related to each of the recommended components of a logic model (Kellogg Foundation, 2004): inputs; activities; outputs; outcomes; causal assumptions; and external/contextual factors of the intervention. For both analyses data were inductively organised into distinct thematic areas. The analysis was repeatedly discussed between the two independent analysts, LHD and RD (PPI co-researcher), and iteratively refined to produce two final coding frameworks.

6.1.2. Findings

A total of 22 individuals took part in the interviews, comprising 12 adults with mental disorders and 10 staff (see Table 5.3, p.129, for participant characteristics).

Candidate adaptations to G4H

Four generic themes emerged as challenges: *Structural issues*, *Negative/traumatic relationships*, *Psychological issues* and *Unclear group rationale*. Corresponding solutions for these challenges and ideas for adapting G4H were proposed. These challenges and suggested adaptations are summarised in Table 6.1.

Table 6.1 Generic challenges and suggested adaptations

Theme	Challenge	Suggested adaptation(s)
Structural issues	Meaningful social outcomes (e.g. reduced anxiety and increased confidence to form new social connections) might not be achieved within the two-month timeframe	• Extend the length of the programme and include more sessions • Acknowledge that two months may not be long enough for change • Check that people do not finish the programme feeling that they have failed
	The month-long gap between sessions four and five is too long. People may lose interest and motivation during this period or experience increased anxiety. Dropout rates would therefore be high	• Reduce the month-long gap between sessions four and five to a shorter period
	The group facilitators should not hold too much control or direction over the group and should avoid imposing too much structure on the sessions	• Provide plenty of time for open group discussion • Use a collaborative approach with input from individual members into the running of the group
Negative/ traumatic relationships	Discussion of social relationships would likely remind participants of negative or traumatic experiences of relationships	• Acknowledge and support people having difficult experiences • Debrief at the end of sessions to support people • Encourage mutual support within the group • Liaise with professionals to check that unsupported relapses had not occurred
	Participants may have experienced stigma and discrimination which makes them feel different to others and excluded	No suggested adaptations: stigma was viewed as a societal issue and not amenable to intervention within G4H-D
Psychological issues	Difficulties in getting to the group due to anxiety or low mood; social anxiety during the sessions	• Have a one-to-one session before the first group session • Normalise anxiety about new situations • Use icebreakers, activities and 'softeners' • Focus on social connectedness rather than mental health problems • Provide support for anxiety
	Low motivation to attend group sessions or complete the homework tasks	• Have a one-to-one session before the first group session • Involve people's own interests • Include fun activities (e.g. painting/music)
	Attention difficulties	• Reduce the length of the sessions from 1.5 hours to 45 minutes
Unclear rationale	Purpose and rationale of the intervention is not very clear	• Establish a common purpose and identity for the group • Highlight the link between social connectedness and wellbeing

Exercise-specific challenges and proposed solutions were also identified. These are outlined in Table 6.2.

Table 6.2 Exercise-specific challenges and suggested adaptations

Session	Exercise	Challenge	Suggested adaptation
1	Quiz ranking different factors with health outcomes	The quiz and related exercises on the health benefits of social connectedness are too abstract and not meaningful	• Provide practical examples of potential benefits • Show videos or testimonial from past participants on the benefits
2	Social identity mapping tool	Individuals may have few or no groups/relationships	• Reassure participants that being part of few or no groups is common and the purpose of the group is to build these up • Have participants who are struggling with this exercise refocus on thinking about the groups they might want to join in the future
3	Discussion of barriers to social connectedness	Sharing personal experiences of groups/relationships in a group may be anxiety-provoking	• Don't expect everyone to self-disclose • Allow gradual disclosure
4	Self-concept pie chart exercise	People may struggle to identify their own personal and social identities	• Identify people's interests early on to support them
	Goal setting exercise	Goal setting might be worrying or pressurising; people may struggle to execute their goals due to anxiety	• Encourage people to have an open mind about socialising • Frame goal tasks in such a way as to take the pressure off • Ask people to help each other to pursue their goals • Alter exercise to focus on setting one small goal • Facilitator should support people to enact goals
5	Provide supported socialisation	Participants may not feel ready to attend other groups or may not feel able to maintain the G4H-D group without facilitation	• Identify someone who might coordinate ongoing activities • Extend length of intervention • Suggest other peer-led or facilitated groups

Logic model components

Participants provided suggestions for three components of the logic model: Outcomes; Causal Mechanisms; and External/contextual factors. No suggestions were made for Inputs, Activities, or Outputs.

Outcomes

Six potential outcomes of G4H-D were suggested: (i) increased non-specific social connectedness; (ii) increased specific social connectedness; (iii) increased G4H-D specific social connectedness; (iv) reduced loneliness; (v) reduced depressive symptoms; and (vi) reduced social anxiety symptoms.

Participants suggested that the intervention may have three possible outcomes with regards to social connectedness. First, non-specific social connectedness might occur if participants felt generally more connected. Second, specific social connectedness could occur if participants became more socially active outside of the group. Third, G4H-specific connectedness might increase for participants who form bonds with other intervention recipients.

It was not clear from the interview data which of the six potential outcomes was expected to demonstrate the largest change. Participants likewise suggested that the outcomes may be interlinked, such that an increase (or decrease) in one outcome could influence a corresponding change in another.

Mechanisms of change

Five potential mechanisms for achieving the outcomes of G4H-D were identified. These five mechanisms were labelled as follows: (1) *feeling comfortable, trust and self-disclosure*; (2) *group identity and unity*; (3) *increased motivation*; (4) *regular contact*; and (5) *mutual support*.

(1) *Feeling comfortable, trust and self-disclosure*. G4H-D recipients may experience three inter-linked processes: feeling more comfortable in the group; increased trust of others within the group; and increased self-disclosure. Group members are likely to begin sharing their personal experiences. If these self-disclosures are responded to with respect and validation then levels of trust within the group may increase. This could then result in further, more intimate disclosures.

(2) *Group identity and unity*. The importance of forming a group identity and sense of unity was stressed by several participants. At least two potential sources of this identity or unity were suggested. First, fostering a collaborative context in which group members each have some input into the group decisions and discussion could generate a sense of shared ownership over the group. Second, group members' shared experiences of mental health challenges may also form the basis of a group identity.

(3) *Increased motivation*. One challenge for G4H-D participants' access and engagement with the intervention may be low motivation. This could be due to either anxiety about attending the group sessions or the general amotivation associated with depression. Increasing participants' enthusiasm for participating in the group was seen as a necessary precursor to their involvement and engagement.

(4) *Regular contact.* Meeting weekly during the group sessions would be important to build group members' familiarity and comfort with each other.

(5) *Mutual support*. Mutual support provided within the group may help participants to feel more connected with other members. Perceived support within the intervention group might help participants to feel more confident about joining other groups in the future.

External/contextual factors

Six external factors were proposed that may influence the activities, change mechanisms and outcomes of the intervention. There were: (i) physical health; (ii) mental health; (iii) finances; (iv) transport; (v) knowledge of local community resources and; (vi) existing social network resources.

Physical health, particularly in relation to mobility, could influence G4H-D participants' attendance of the group and their ability to engage in groups outside of the intervention. Mental health symptoms such as low mood, anxiety and paranoia may also be potential barriers to accessing the intervention. Participants' symptoms may fluctuate and this could affect their attendance and engagement across different sessions. Some participants may not have the financial means to travel to the site of the intervention or have any means of transport to attend. Participants' and facilitators' knowledge of local community resources, groups and activities may influence the extent to which group members can engage with the intervention exercises such as goal-setting. Finally, group members' existing social network resources are a potential facilitating factor. Those who can access support from their existing networks to attend new social activities may find the group exercises easier to complete.

6.1.3. Summary and implications

The findings from the interview study include a series of potential adaptations to G4H, listed in Tables 6.1 and 6.2, which may inform the development of the G4H-D manual. This provided a preliminary set of candidate adaptations for use in the expert consultation study. The interview findings also include data to inform three of the components of the G4H-D logic model: outcomes; mechanisms; and external/contextual factors. The potential components of the logic model were used to inform the development of a field note form which was used during the G4H pilot.

6.2. G4H pilot

6.2.1. Methods

Participants

There were no formal study participants for the G4H pilot. Instead, the people taking part were already involved in the overall thesis. They comprised PPI members, who all had lived experience of depression, and a senior mental health nurse (AG). The nurse was the clinical lead for the Specialist Depression Service at Nottinghamshire Healthcare NHS Foundation Trust and a co-facilitator of G4H-D in the subsequent feasibility study. Recruitment for the PPI group was described in Section 3.3 (p.62). For brevity, everyone who took part will be referred to as 'participants'.

Procedures

Participants were informed that the purpose of the pilot was to test the programme of G4H in order to explore whether the structure and content were suitable and acceptable for adults with depression. Participants were informed that they were under no obligation to take part and could withdraw at any time without giving a reason. Written consent was not obtained.

The full five session G4H programme was delivered over a period of three months (May-July 2018). This period was longer than the normal timeframe of two months to take account of participant availability. The sessions were facilitated by LHD. All sessions were held at the University of Nottingham. Participants' travel expenses were reimbursed.

Participants were asked to provide on-going verbal feedback on their experiences of each session and particular exercises. Following each session a written feedback sheet was also completed asking questions on the following areas:

overall experience of the session; anything liked about the session; anything disliked; views and suggested adaptations of the exercises, homework, facilitation, structure (e.g. length or frequency of sessions) and group setting; potential mechanisms; and potential outcomes of the group.

Field notes were also completed during and after each session using a field note form. Wherever possible, observations were recorded during the group sessions (for example, whilst participants were completing individual tasks) or otherwise immediately following each session. Both LHD and AG, the nurse participant, recorded their own field notes. These notes included any direct oral feedback from participants as well as observations on: potential logic model components identified during the interview study; the physical setting; participant's current circumstances; group logistics; participants' behaviour/engagement during the session; participants' engagement with the homework; acceptability and accessibility of individual exercises; and, for LHD, personal reflections on facilitating the group.

LHD and AG met after each session to discuss their observations, note any areas of discrepancy in their interpretations, log events that the other person had missed or ignored, and to agree on learning points. The rationale for using two people to record field notes was to address the issues of selective reporting and interpretation which can occur in the observations of a single researcher (DeWalt & DeWalt, 2002).

The field notes and written feedback were entered onto a spreadsheet to identify candidate suggestions for adapting the G4H manual and potential components of the G4H-D logic model.

Analysis

Thematic analysis was applied to the data generated from the field notes. The same analytic procedures as were described for the interview sub-study were used (see Section 6.1.1). The results were repeatedly discussed between LHD and the supervisory team.

6.2.2. Findings

Four participants took part in the pilot: one mental health nurse and three members of the PPI group. Participants were two men and two women, ranging in age from 43 to 64 years old. All three PPI members had a diagnosis of depression, and two additionally reported anxiety. All PPI members were currently accessing mental health services, two from secondary care and one from primary care.

Adaptations to G4H

Generic challenges and possible adaptations to G4H were identified as well as exercise-specific challenges and adaptations. The results are shown in Table 6.3.

Table 6.3 Challenges and suggested adaptations from G4H pilot group

Level	Challenge	Suggested adaptation
Generic	Speaking in pairs can be too intimate and anxiety-provoking	• Give people the option of talking in a group or pairing up • Go round in a circle rather than open discussion as this is the norm for mental health groups
	People will be very anxious at the beginning	• Facilitate so that quieter, more anxious members get a chance to speak • Facilitator to model self-disclosure where appropriate
	The facilitator sometimes disrupted the flow of conversation to keep group on task	• Better to let the group discussion run (if on a relevant topic) rather than sticking too closely to the schedule of task exercises. This facilitates sharing of experiences of relationships, more natural bonding and greater enjoyment
	Participants disliked the large gap between sessions and regular contact would have been preferable	• Keep to the normal weekly schedule • Shorten month-long gap between sessions 4 and 5
	People were worried about how the group might stay in touch and/or where they would get support after the group ended	• Identify someone who might coordinate ongoing activities • Signpost participants to other sources of support
Session 1	*Exercise (quiz on risk factors for poor health outcomes)*: Talking about health risks of loneliness/isolation is anxiety-provoking (people with anxiety might react badly to the health message) and off-putting (people would be 'destabilised', not motivated)	• Drop the exercise
Session 2	*Exercise (social identity mapping tool)*: One member found it very uncomfortable doing the exercise – made him reflect on negatives. He couldn't complete the exercise which made him feel isolated from the rest of the group and felt it exposed his social problems	• Facilitator should acknowledge how difficult the exercise is; both cognitively in terms of thinking through the complexity of the questions and emotionally if there are any gaps or negatives in the map
	Exercise (social identity mapping tool): It was very difficult to understand the question of 'how typical are you' of a group; it was difficult to follow the instructions in general; people were envious of each other's maps	• Rephrase unclear questions • Facilitator should encourage a group discussion about people's experience of doing the exercise • Use a large example map to highlight where each of the scores should go • Facilitator should acknowledge that people naturally make (negative) social comparisons during this exercise

Table 6.3 continued

Level	Challenge	Suggested adaptation
Session 3	*Exercise (planning a BBQ)*: One participant asked if they were restricted to inviting people who were still alive and this made her feel upset	• Facilitator needs to be careful to focus on people who are still alive
	Exercise (discussing barriers to getting more from groups): One member worried that his social skills are un-practiced and wanted to know if G4H 'taught' any social skills	• Facilitator needs to make it clear that participating in the group is a way of practicing key social skills (e.g. getting to know people, sharing experiences, opening up and self-disclosing) and some of the activities (e.g. discussing reciprocity) are to highlight positive social behaviours
Session 4	*Exercise (self-concept pie chart)*: People with low self-esteem will find it difficult to reflect on their personal attributes. One member could not complete the exercise. People tried to address all prompts (e.g. 'personality', 'values', 'aspirations' etc.)	• Alter exercise by dropping reference to 'aspirations' and 'personality'
	Exercise (SMART goal-setting): Two participants didn't like the exercise and did not complete it. For some it reminded them of similar exercises in stressful/pressured environments such as job centres. Some noted that the SMART acronym often varied in meaning which was discrediting. One member said it felt too constraining in comparison to the other exercises which were more open and exploratory	No specific recommendation was made
Session 5	*Exercise (social identity mapping tool)*: People again struggled to understand certain instructions e.g. 'how typical are you of a group?', and 'how compatible/easy is it to be part of multiple different groups?'	• Need to clarify instructions in easier language

Components of the logic model

Potential components of the G4H-D logic model which were identified during the pilot sessions comprised the Outcomes, Causal Assumptions and External/contextual factors of the model. The identified components are shown in Table 6.4.

Table 6.4 Potential components of the G4H-D logic model

Component	**Potential feature of G4H-D**
Outcomes	• Reduced anxiety within group
Causal assumptions	• Regular contact/Reduction in anxiety through exposure • Mutual support • Increased trust/sharing experiences/self-disclosure • Experiences validated and normalised
External/contextual factors	• Similarity to other interventions/services

Outcomes: Participants became less anxious and more comfortable within the group with each session. This was both observed by the facilitator and self-reported by participants. It was not clear, however, whether this reduction in anxiety was generalised to other contexts or if it was limited to the context of the group.

Causal assumptions: Four potential mechanisms of change were identified.

(1) Regular contact/reduction in anxiety through exposure: Participants became less anxious due to repeated contacts with each other. They also reported disliking the irregular, relatively infrequent timing of the pilot sessions.

(2) Mutual support: Group members offered each other emotional support and advice when expressing a personal vulnerability or difficulty in engaging in an exercise.

(3) Increased trust/sharing experiences/self-disclosure: Participants disclosed increasingly personal information over time and commented that they felt safe to do so within the group.

(4) Experiences validated and normalised: Participants and the facilitator repeatedly sought to validate other group members. This included commenting that their experiences were common rather than abnormal.

Mechanisms 1-3 were previously identified in the stakeholder interviews. Mechanism 4, however, was a new finding.

External/contextual factors: Some features of G4H were similar to other interventions that participants had taken part in. Depending on each participant's experiences of previous interventions, this similarity could be perceived either as a barrier or a facilitator of engagement. For example, during the goal setting exercise in Session 4 one participant commented that it reminded them of CBT and they were less motivated to do the exercise for that reason. In response another participant said that they too had experienced CBT but that it had been helpful for them. All participants, however, reported disliking the format of the goal-setting exercise as it used the SMART model (Specific, Measurable, Attainable, Realistic, Time-bound), which they all had a negative experience of in employment contexts.

6.2.3. Summary of recommended adaptations and logic model components

Many of the potential adaptations and logic model components found in the pilot study had previously been identified in the interview study, though there were also some new findings. Overall, there were 50 suggested adaptations to G4H across the interview and pilot sub-studies. It was decided that 39 of these would be adopted without further consideration because these either represented standard good practice for facilitation (n=29), or were already explicitly incorporated in G4H (n=11) (see full list and rationale in Appendix 3). The remaining ten candidate adaptations concerned changes to the structure or content of G4H. LHD and the supervisory team made a preliminary decision on whether to adopt these ten adaptations before submitting them to expert consultation (see Table 6.5).

Table 6.5 Summary of interview and pilot study recommended adaptations, preliminary decisions and rationale

#	Recommendation	Adopt?	Rationale for decision
1	Include one-to-one session before the first group session	Yes	(1) Improve engagement by identifying participants own motivations for involvement (2) Facilitators gain information to support individuals with particular exercises
2	Reduce the time interval between sessions 4 and 5 from one month to two weeks	Yes	(1) Participants need regular contact to form social connectedness within the group (2) Participants are more likely to drop out over a month-long interval
3	Session 1: Drop the quiz about risk factors for health. Focus on the benefits of social connectedness not the risks of loneliness	Yes	Focussing on the risks of loneliness may be anxiety-provoking and demotivating for participants
4	Session 4: Alter 'self-concept reflection exercise' by dropping reference to 'aspirations' and 'personality'	Yes	(1) Thinking about 'personal aspirations' may be challenging for those with mental health issues who feel hopeless and pessimistic (2) Thinking about one's 'personality' may be difficult for people with low self-esteem
5	Session 4: Alter goal-setting exercise to focus on setting one small goal	Yes	People may set multiple goals or goals which are quite challenging which will later feel overwhelming and unachievable within the time frame
6	Use a shared decision-making approach	Yes	Collaborative approaches may build a group identity and sense of ownership
7	Reduce session length to 45 minutes and deliver 2 sessions/week	No	Unfeasible. The time and resources for the research project and the NHS services hosting the study are too limited
8	Facilitator or other worker to accompany individuals to new groups and activities	No	(1) Unfeasible (as above) (2) Fidelity. Extended one-to-one support may introduce an additional befriending component to G4H-D
9	Include fun activities (e.g. painting and music) to increase motivation	No	(1) In the practice sessions in sub-study 1.2 it was already difficult to cover all the material within the timeframe (2) Participants in sub-study 1.2 already found the intervention enjoyable (3) Fidelity. Group activities such as music therapy are separate interventions which may affect wellbeing for reasons other than social connectedness
10	Add more sessions to the programme	No	(1) Unfeasible (as above) (2) Fidelity. Including new sessions and material may affect the fidelity of the model

The potential components of the logic model for G4H-D thus far are summarised in Table 6.6.

Table 6.6 Summary of potential logic model components identified from the interviews and pilot study

Component	Suggestion
Inputs	None
Activities	None
Outputs	None
Outcomes	(1) Increased specific social connectedness within G4H-D (2) Increased specific social connectedness outside of G4H-D (3) Increased non-specific social connectedness (4) Reduced social anxiety (5) Reduced depression (6) Reduced loneliness
Causal assumptions	(1) Increasing comfortableness, trust and self-disclosure (2) Group identity forms (3) Increasing levels of motivation (4) Regular contact/reduction in anxiety through exposure (5) Mutual support (6) Experiences validated/normalised
External/ contextual factors	(1) Physical health (2) Mental health (3) Finances (4) Transport (5) Knowledge of local community resources (6) Existing social network resources (7) Similarity to other interventions/services

The data from the interviews and pilot study produced a dataset of proposed adaptations and logic model components. This dataset was used in the next study to evaluate whether expert consultants concurred with these proposals. As seen in Table 6.6, there were no identified suggestions for the logic model Inputs, Activities or Outputs. Therefore, the original developers of G4H were also consulted on these components.

6.3. Expert consultation

6.3.1. Methods

Design

Two approaches were used as part of the expert consultation. First, an online survey was conducted to gather the views of international experts on G4H to identify candidate adaptations for adults with depression. Second, the developers of G4H were consulted to support the development of the logic model for G4H-D.

It was decided to focus the online survey on identifying candidate adaptations to G4H rather than gathering participants' views on the development of the logic model. As a complex social intervention it may have been difficult for participants who did not have first-hand experience of G4H to suggest how the intervention would work in practice. In contrast to the interview study, a researcher was also not available to answer in-depth questions about the intervention. Thus, it was considered that the online survey method might not produce good quality data with respect to the logic model.

Participants

Participants were international experts with expertise in at least one of the following four areas: (a) developing psychosocial interventions; (b) clinical experience with depression and other mental health disorders; (c) lived experience; and/or (d) recovery. These topic areas were chosen as they relate to expertise in four key areas for this thesis: designing psychosocial interventions within a clinical context; clinical experience with the target population for G4H-D; lived experience of developing social connectedness whilst struggling with depression; and targeting non-clinical outcomes in clinical populations, respectively.

The developers of G4H were members of the University of Queensland Social Identity and Group Network (SIGN) (Haslam et al., 2016).

Recruitment

Recruitment for the expert consultation was conducted by email. Academic and clinical experts were initially identified and approached by contacting those known to have published work in the development and evaluation of related psychosocial interventions and/or the treatment of mental health conditions. Recovery experts listed within the Recovery Research Network directory were contacted (researchintorecovery.com/rrn). Lived experience experts were recruited from a depression support group based in the East Midlands. LHD emailed a group member to introduce the study who then discussed it with other members. LHD was then invited to attend a group meeting to provide more information and to take email contact details of potential participants. This particular support group was selected because it was originally organised by service users who had attended a 12-week wellbeing group run within secondary care several years previously. They had continued as an informal social group. Therefore, members of this particular group were expected to have relevant experience of psychosocial interventions and the processes of social connectedness. All potential participants were emailed with a link to the online survey which contained information about the study and a consent form before taking part.

In addition, members of the SIGN group at the University of Queensland who were involved in the development and evaluation of G4H were contacted directly by email.

Data collection

Data were collected using an online survey. The online survey was set up using the onlinesurveys.ac.uk service. The survey used open-ended questions and was

split into two sections. Section 1 presented a summary of G4H and provided a link to a more detailed description of the intervention. Participants were asked for their views on the intervention and whether it needed to be adapted for adults with depression. In Section 2, participants were given information on candidate adaptations arising from the interviews and pilot study. They were also provided with the preliminary rationale developed by the research team to either adopt or not to adopt each adaptation (as listed in Table 6.5). Participants were asked to select a yes/no response indicating whether they agreed with the preliminary rationale for each candidate adaptation. Participants who disagreed with the preliminary rationale were asked to give their reasoning in an open-ended text item. An excerpt of the survey form is shown in Appendix 4.

Data from the SIGN members were collected via email. Participants were invited to suggest potential components of the G4H-D logic model.

Analysis

Two analyses were conducted. First, responses to the open-ended survey questions were analysed using thematic analysis. Data from the first part of the survey, concerning expert consultants' own views on the intervention, were inductively analysed to explore any new issues not previously indicated from the interviews or pilot study. Data were coded using the same categories used in the prior sub-studies: Challenges/Proposed solutions and Generic/Session-specific issues. Data were analysed to produce an initial coding framework which was refined through discussion with the supervisory team and as new data were collected.

The second part of the survey, concerning whether participants agreed with the previously identified proposals, was analysed using descriptive statistics. Expert consensus in mental health research usually necessitates multiple stages of data collection (Jorm, 2015). As only one round of data was collected in this study, it

was assumed that full consensus agreement on a complex psychosocial intervention such as G4H-D would be unlikely. Therefore, it was decided that agreement by at least two-thirds of participants would constitute a strong level of agreement for a particular proposed adaptation. All dissenting opinions were recorded and described narratively.

6.3.2. Findings

Online survey

A total of 16 individuals were approached, with 12 (75%) agreeing to participate. The background and experience of participants is shown in Table 6.7.

Table 6.7 Description of expert consultants (n=12)

Country	Expertise in target areas	Background
Australia	Complex interventions; Depression/Mental health	University professor; clinical psychologist; research into psychosocial interventions in clinical populations
Australia	Complex interventions; Depression/Mental health	Lecturer and senior research fellow; clinical psychologist; research into psychosocial interventions in clinical populations
Netherlands	Complex interventions; Depression/Mental health; Recovery	University professor; medical sociologist; research into recovery and psychosocial interventions in clinical populations and published guidance on implementation in clinical contexts
UK	Depression/Mental health	Associate professor; depression specialist
UK	Lived experience	Secondary care service user
UK	Lived experience	Secondary care service user
UK	Lived experience	Secondary care service user
UK	Lived experience	Secondary care service user
UK	Recovery	Director of a recovery non-governmental organisation
UK	Complex interventions Recovery	Director of a mental health non-governmental organisation; research into recovery and psychosocial interventions in clinical populations
UK	Complex interventions; Depression/Mental health	Senior lecturer in mental health; social worker; research into psychosocial interventions in clinical populations
UK	Complex interventions; Depression/Mental health; Recovery	University professor; social worker and clinical psychologist; research into recovery and psychosocial interventions in clinical populations

Three experts were from countries outside of the UK. Each of the four target areas of expertise was represented by at least four respondents. Participants came from a variety of backgrounds and often had more than one source of expertise (e.g. being a clinical academic), including academia (n=5), service users (n=4), non-governmental organisations (n=2) and clinical practice (n=5).

Expert consultant views on the G4H programme

Table 6.8 summarises the generic and exercise-specific suggestions, the final decision by LHD and the supervisory team whether to adopt each suggestion, and the rationale for these decisions.

Table 6.8 Suggestions by expert consultants, decision and rationale (n=12)

Level	Suggestion	Experts (n)	Adopt?	Rationale for decision
Generic	Hold more frequent sessions	1	No	(1) Unfeasible. The time and resources for the research project and the NHS services hosting the study are too limited (2) Fidelity. Including more sessions and new material may affect the fidelity of the intervention model
	Hold sessions less frequently	1	No	(1) Unfeasible (as above)
	Holding longer (3 hour) sessions	1	No	(1) Unfeasible (as above) (2) Fidelity (as above)
	Rearrange the order of the sessions: put session 4 content into session 1 or 2	1	No	Session 4 content involves joining new groups and goal setting whilst the focus in the first two sessions is partly about participants familiarising and integrating themselves into the G4H-D group
	Reduce the month-long gap between sessions 4 and 5	1	Yes	(1) Participants will need more regular contact to form social connectedness within the group (2) Participants are more likely to drop out over a month-long interval

Table 6.8 continued

Level	Suggestion	Experts (n)	Adopt?	Rationale for decision
Generic	Hold sessions in the late afternoon	1	Yes	Afternoon sessions may be most accessible as sleep can be disrupted during episodes of poor mental health
	Add icebreakers to every session	1	Yes	This may help reduce anxiety and support self-disclosure within the group
Session 2	Refer to past as well as current group relationships	1	Yes	Participants may have past relationships which they want to rebuild
Session 3	Include discussion of participants' strengths in relationships	1	Yes	(1) Character strengths may support social connectedness (2) Aligns with the ethos and design of other psychosocial interventions which focus on participants resources rather than remedying individual deficits (Priebe et al., 2014)

Expert consultant views on the proposed adaptations

Expert consultants' views on the adaptations proposed by the research team are shown in Table 6.9.

Table 6.9 Expert consultant (n=12) views on proposed adaptations to G4H

Adaptation	Adopt?	Expert agreement, n (%)	Experts disagreeing, n (%)	Reason for disagreement
1-to-1 sessions	Yes	10 (100)	0	
Reduce gap between sessions 4 and 5 from 4 to 2 weeks	Yes	11 (92)	1	Four weeks may be required for individuals to implement their goals
Session 1: Drop the quiz about risk factors for health	Yes	10 (83)	2	(1) The quiz could be reframed positively (2) Quizzes may provide a good means of explaining the idea of the importance of social connectedness for health
Session 4: Alter 'self-concept reflection exercise' by dropping reference to 'aspirations' and 'personality'	Yes	10 (83)	2	Talking about aspirations and personality could be a positive experience for individuals
Session 4: Alter goal-setting exercise to focus on setting one small goal	Yes	10 (83)	2	This exercise should be tailored to each individual
Use a shared decision-making approach	Yes	100	0	
Reduce session length to 45 minutes and deliver 2 sessions/week	No	100	0	
Facilitator or other worker to accompany individuals to new groups and activities	No	11 (92)	1	(1) It can be difficult to attend new activities on your own (2) Could identify others (such as family or friends) who might be able to support the individual in these activities
Include fun activities (e.g. painting and music) to increase motivation	No	100	0	
Extend the programme by adding more sessions	No	9 (75)	3	Individuals may not have benefited from the intervention within the timeframe and should be offered longer support

Logic model: consultation with the developers of G4H

The lead developer of G4H, a clinical academic, agreed to take part in the consultation. She identified a number of additional components of the logic model which had not previously been identified:

Inputs: Recruitment and training of facilitators.

Activities: Group session exercises.

Causal assumptions: Participants gain knowledge and social skills for managing their social environment. In particular, participants learn to maintain their group-based relationships and to develop new group memberships. New skills could be developed through two processes. First, some of the session content focuses on developing social skills, such as maintaining reciprocity and how to identify new groups. Second, the G4H group itself provides a social environment within which participants could practice their social skills.

External/contextual factors: Quality and quantity of local community groups.

6.3.3. Summary of expert consultation

Within the online survey, expert agreement ranged from 75% to 100% for the research team's preliminary decision on whether to adopt each proposed change to G4H identified in the previous sub-studies. Where individual experts disagreed, the concerns and rationales given were judged by the research team not to override their original rationale. The exception was for the adaptation concerning the quiz on health factors. One expert concern was that the quiz exercise could be revised to focus on the benefits of social connectedness rather than dropping the exercise altogether. The adaptation was therefore revised in line with this expert opinion. The research team decided to adopt all the other proposed changes (see Table 6.5) to G4H as well as four of the new proposals suggested by the experts

(shown in Table 6.8). In summary, ten of the proposed adaptations to G4H were adopted.

A number of additional potential components for the G4H-D logic model were also identified during the consultation. These were incorporated with the components previously identified during the interviews and pilot study.

The data from the interviews, pilot study and expert consultation provided a dataset with which to develop a preliminary logic model of G4H-D and the adapted intervention manual.

6.4. Developing the adapted intervention logic model and manual

6.4.1. Logic model

The development of the logic model followed the guidance set out by the Kellogg Foundation (2004), including the depiction of the inputs, activities, outputs, outcomes, causal assumptions and external/contextual factors of the intervention. Details of these components are described in Section 3.7.2 (p.71).

For G4H-D these model components were developed in three steps. First, as a model for standard G4H does not exist, a preliminary model for G4H was developed using data collected from the consultation with the original developer of G4H. Second, the preliminary model was revised using data from the qualitative interviews and G4H pilot study which were synthesised to describe candidate inputs, activities, outputs, outcomes, causal assumptions and external factors related to G4H-D. A deductive thematic analysis of the data was conducted. This involved using a pre-defined coding framework consisting of categories referring to the different components of logic models as described in Section 3.7.2.

Third, the data were further organised in line with the CIVIC-MH framework for the 'causal assumptions' component. Each identified assumption was mapped onto a CIVIC-MH dimension where possible. The first aim of this analysis was to improve the theoretical basis of the logic model by incorporating the CIVIC-MH framework into its development. The second aim was to assess whether there were areas of the CIVIC-MH framework which were not represented within the preliminary model. Where discrepancies were identified, the logic model was revised in line with CIVIC-MH by incorporating new components where appropriate. If revising the model in line with CIVIC-MH was inappropriate, for example because it did not fit with the G4H-D programme, the discrepancies were used to identify potential areas for the future development of G4H-D.

6.4.2. Intervention manual

The preliminary G4H-D manual was developed in line with guidance from Fraser and colleagues (Fraser & Galinsky, 2010; Fraser et al., 2009). This process has three steps. Step 1 involves developing a logic model to identify malleable mediators which can be targeted in the intervention. Step 2 involves developing a first draft of the manual within the research team. Step 3 involves a review of the manual by stakeholders, including those from the target population of the intervention and potential intervention facilitators.

Step 1 was described in Section 6.4.1. Step 2, developing a first draft of the G4H-D manual, is described in this section. Step 3, the stakeholder review, is described in the next section.

The intervention manual, comprising a facilitator manual and a participant workbook, already exists for G4H. The G4H-D manual was developed by modifying the G4H manual in three steps. First, new sections of the manual were written to incorporate the adaptations identified in the interviews, G4H pilot and expert consultation. Second, the manual was modified according to researcher-

rated cultural factors, such as language, assumptions, and references to services. Third, additional information was included in accordance with the components of psychosocial intervention manuals recommended by Fraser and colleagues (2009). These recommendations are listed in Table 6.10.

Table 6.10 Key components of an intervention manual (Fraser et al., 2009)

Introduction
Describe the problem being addressed
Review incidence or prevalence data
Rationale for the intervention
Specify a logic model and/or a theory of change
Describe the intervention format and recommend strategies for using programme materials
Optional: provide or refer to a literature review on which programme theory is based
Intervention sessions
Determine system level of change (community, organisation, family, group, individual)
Determine system level of implementation
Duration and frequency of intervention sessions
Intervention setting
Method of delivery (lecture, hands on activities, video)
Intervention agent (who delivers the intervention)
Mode of intervention (face-to-face, telephone, computer)
Goals, objectives and content for each session
Suggestions for adapting content on the basis of race/ethnicity, culture, language, religion, or other factors
Decision rules for alternative interventions, if applicable
Details of specific intervention activities
Guidelines for selection of participants
Description of outcomes
Standards for training and supervision of practitioners
Screening and recruitment materials (for facilitators)
Examples of scripted dialogue (for facilitators)

6.5. Stakeholder review of intervention logic model and manual

6.5.1. Methods

Participants

Participants were the same as those participating in the pilot study (see Section 6.2.1).

Procedure

Draft versions of the G4H-D manual and logic model were emailed to participants for feedback. For the manual, feedback was requested regarding the accessibility of the language used, the relevance of the exercises and examples to the local context, and how easily the exercises could be completed by potential group participants. Feedback requested for the logic model included whether it addressed all the necessary components of the intervention and the plausibility of the causal assumptions and intended outcomes.

6.5.2. Findings

Five participants took part in the review: four PPI members and a mental health clinician. These stakeholders suggested minor amendments to the facilitator manual and the participant workbook. Two themes were highlighted.

Theme 1: Balancing flexibility and structure

Participants emphasised that whilst some degree of structure was important to provide participants with a sense of both purpose and safety within the group, it was argued that the process of group formation and bonding would occur through the more organic social processes of open group discussion. Therefore, it was stressed that group facilitators should allow time for such discussion.

The G4H-D facilitator manual was revised to reflect this finding. Specifically, the guidance for facilitators was updated to advise that time should be allowed for group discussion. Discussion should not be curtailed by facilitators so long as it remains on the topic of social connectedness.

Theme 2: Long-term support

It was stressed that intervention participants would probably need support going beyond the planned six week period of G4H-D. Whilst stakeholders noted that time and resource considerations may limit the type of adaptations which could be made to the intervention, it was suggested that participants in the planned feasibility study of G4H-D could be signposted to other local organisations where they might be able to access similar types of support.

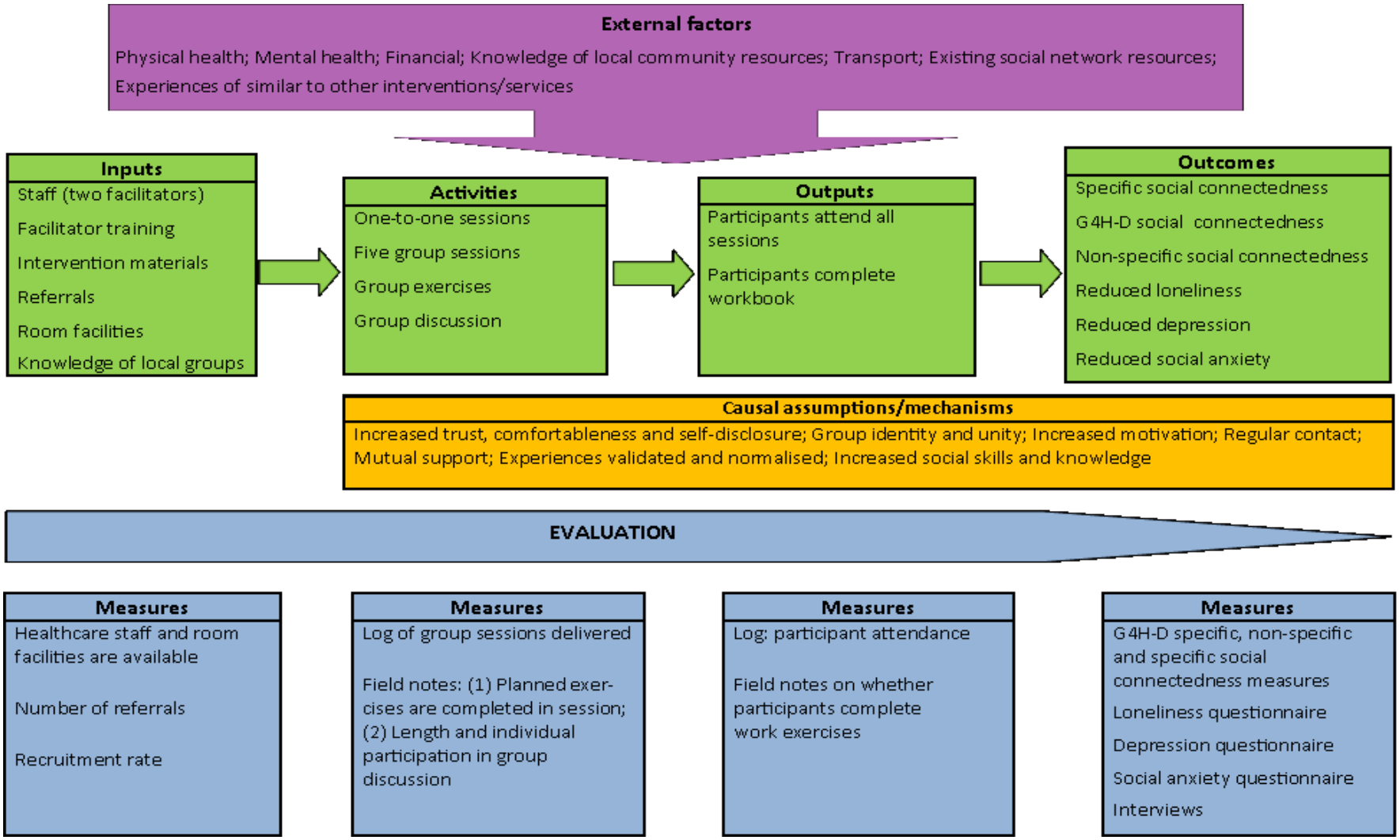
In light of this finding the G4H-D manual was revised to include a handout in the final session which featured a list of local resources which participants could access following the end of the intervention.

Following the revisions resulting from the stakeholder review the G4H-D manual and logic model were finalised.

6.6. Final logic model for G4H-D

The finalised logic model for G4H-D is depicted in Figure 6.3.

Figure 6.3 G4H-D logic model



External factors

The external factors which may influence the implementation or outcomes of G4H-D comprised physical or mental health problems as well as participants' personal finances, knowledge of local resources, access to transport, existing social relationships, and experience of similar interventions and services.

Inputs

The required inputs for G4H-D include staff time, intervention materials, referrals, room facilities, staff training, and knowledge of local community resources. One staff member is required to conduct the one-to-one sessions before the group. An additional staff member is required to help co-facilitate the group sessions. One of these two staff members is additionally required to organise recruitment. Intervention materials comprised copies of the facilitator manual, the participant workbook and stationery required for the exercises. In order to recruit suitable participants, referrals from clinical teams are required. Room facilities in a community-based site in which to conduct the one-to-one sessions as well as the group sessions are required. Finally, facilitators require knowledge of on-going groups provided across the health, social care and third sectors. Facilitators must be familiar with the G4H-D facilitator manual and preferably have group facilitation experience. Facilitators must also be knowledgeable of local community groups and resources.

Activities

The activities involved in G4H-D include one-to-one sessions and five group sessions involving session-by-session exercises and group discussions. The one-to-one sessions are conducted prior to the first group session by one of the group facilitators. These interviews focus on identifying the goals and motivations of participants for the group sessions as well as their broader social goals. These sessions are also intended to build up an initial rapport between the facilitator and

participants. Thereafter, five group sessions take place which involve both planned exercises and group discussion on relevant topics as detailed in the intervention manual.

Outputs

The intended outputs of G4H-D are the attendance of all participants in the one-to-one and all group sessions as well as full engagement in these activities. Engagement includes completing the participant workbook, contributing to group discussions and developing and initiating a social goal plan by the end of the intervention.

Outcomes

Six potential outcomes of G4H-D were identified. These were: (1) reduced loneliness; (2) reduced depression; (3) reduced social anxiety; (4) increased specific social connectedness outside the G4H-D group; (5) increased G4H-specific social connectedness; and (6) increased non-specific social connectedness. These outcomes can be measured using established questionnaires (further discussed in Chapter 7).

Causal assumptions/mechanisms

The mechanisms of the model relate to the behaviours and perceptions of the participants which correspond to the hypothesised underlying processes of change, linking the activities of the intervention to the intended outcomes. In total there are seven potential mechanisms involved in G4H-D. These mechanisms were used to inform the development of the finalised intervention manual. Table 6.11 lists these mechanisms, how they relate to the CIVIC-MH framework, and how they were used to inform the development of the finalised G4H-D manual.

Table 6.11 Description of logic model mechanisms, corresponding CIVIC-MH dimensions and incorporation into the finalised G4H-D manual

Potential mechanism	Related CIVIC-MH dimension	Incorporation into finalised manual
Increased trust, comfortableness and disclosure	Closeness	Facilitator guidance: Encourage participant disclosure
Shared group identity	Identity and common bond Shared mental health experiences	Facilitator guidance: Highlight shared characteristics and experiences of group members
Increased motivation	Valued relationships	Incorporate a one-to-one meeting before group sessions
Increased knowledge and social skills	None	Already incorporated into G4H
Regular contact	Involvement: Group involvement	(1) Reduce time interval between sessions 4 and 5 (2) Participants encouraged to meet as a group outside of the intervention
Mutual support	Cared for and accepted: Support	(1) Facilitator guidance: provide support during group discussions (2) Encourage mutual support
Experiences validated and normalised	Cared for and accepted: Acceptance	(1) Facilitator guidance: validate participant's experiences (2) Allow discussion of negative experiences

The G4H-D logic model mechanisms broadly mapped onto the seven CIVIC-MH dimensions. The exception was for the mechanism 'increased knowledge and social skills', which did not fit into the CIVIC-MH framework. In addition, the *Stigma* dimension of the CIVIC-MH framework was not represented within the logic model.

6.7. Final intervention manual for G4H-D

Structure of G4H-D

G4H-D comprises a participant-facilitator meeting followed by five group sessions over six weeks. Groups involve approximately eight participants.

A one-to-one session between one of the facilitators and each participant takes place before the first group session. There are two aims of this one-to-one session: to increase the participant's motivation and engagement with the intervention; and to develop rapport with the facilitator. The facilitator will use motivational interviewing techniques (Miller & Rollnick, 2012). These techniques use a guiding style as opposed to a directive style. This involves engaging clients, clarifying their strengths and aspirations, evoking their own motivations for change and promoting autonomy in decision making. The aim is to elicit the motivation to change from the client, rather than to try to instil this in them.

A total of five group sessions are delivered, each lasting 90 minutes with a 10 minute mid-session break. Sessions take place weekly with a two-week interval between sessions four and five. Each session begins with a welcome, recap and 'check-in' exercise in which each participant is given time to describe their experiences and learning since the previous session. The main session topic and exercises are introduced. The emphasis in each session is on flexibly working through the content of the manual. That is, the focus is on facilitating group discussion related to the topics of social connectedness highlighted in the manual rather than strictly adhering to the schedule of the manual. This is in order to increase participant engagement and allow the group to form a collective identity in a more organic process. A summary of the exercises completed in each session is provided in Appendix 5.

Manual

A draft manual for G4H-D was produced, comprising a facilitator manual and a participant workbook. The facilitator manual provides session-by-session guidance with example scripts and tips for the facilitators (see excerpt in Appendix 6). It also provides more general guidance for facilitator conduct. This includes advice for facilitators to participate in the group as equal members. This is intended to

support the collaborative approach of G4H-D. Specific advice for facilitators includes completing the exercises themselves, contributing to the group discussions and self-disclosing when appropriate (Barnett, 2011). One of the identified processes of change within G4H-D is for participants to share their personal experiences with the group though this may be difficult for some participants initially. If used appropriately, self-disclosure by facilitators may support other group members to share their own experiences (Henretty & Levitt, 2010).

Facilitators are tasked with guiding participants through the exercises outlined in the manual. They need to try and keep the group focused so that they achieve the objectives of the session, but flexibility as to timing is needed to allow natural group discussion. Although the focus of the intervention is on positive experiences of social connectedness, where participants share negative experiences these are to be validated by the facilitators.

The participant workbook is given to all intervention recipients for them to keep and personalise. An excerpt of the participant workbook is shown in Appendix 7. The workbook contains an outline of the programme and summary pages for all sessions. It describes and gives a rationale for each exercise as well as space to complete them. The participant workbook is written in accessible language as indicated by a score of 79.1 on the Flesch Reading Ease test and 4.3 on the Flesch-Kincaid Grade Level test. These tests were calculated on Microsoft Word with the scores indicating that the participant workbook is written in language appropriate for school children in Year 8 and above (Flesch, 1979).

Facilitation

G4H-D is delivered by two facilitators who follow the facilitator manual. G4H-D can be facilitated by a wide range of professionals, including psychologists, teachers, counsellors, nurses, social or youth workers. Familiarity with the

facilitator manual is essential. Previous training in counselling skills, group facilitation and suicide risk assessment is recommended.

6.8. Discussion

6.8.1. Summary of findings

Logic model

The G4H-D logic model featured causal assumptions/mechanisms which closely mapped onto the CIVIC-MH framework. This may raise a question over the status of the CIVIC-MH framework as to whether it describes the state of social connectedness or the preceding mechanisms which engender it. That is, whether social connectedness is a process or an outcome. It is argued here that this question may be understood via a distinction between behaviour and perception. The causal assumptions of the G4H-D logic model represent behaviours enacted within the group, such as the facilitators validating the experiences expressed by a participant. These behaviours correspond to the perceptions of social connectedness described by the CIVIC-MH framework, such as feelings of acceptance. In the social support and mental health literature, for example, the distinction between actual and perceived social behaviour is known to be important (Uchino et al., 2016). Whilst repeated experiences of *received* support are believed to form the basis of *perceived* support (Uchino, 2009), different outcomes are associated with each construct when measured at a single time point (Thoits, 2011a).

One of the dimensions of the CIVIC-MH framework and one sub-dimension were not represented within the logic model. First, the *Stigma* dimension did not have a corresponding causal mechanism within the logic model. Whilst stigma was highlighted as a potential barrier to social connectedness within the interviews, it was also suggested that stigma is a societal issue and a problem of others'

attitudes which would not be amenable to change within G4H. Thus, participants did not think G4H could be adapted to reduce stigma and that the intervention would not increase social connectedness via this mechanism. Second, the *Involvement-Companionship* sub-dimension was not represented within the logic model. This sub-dimension concerns the availability of one or more companions for social activities. This relates to one of the recommendations made by study participants to include a 'supported socialisation' component to help individuals to join other groups following the final G4H-D group session. This recommendation was not adopted and thus *Companionship* was not featured in the logic model.

Intervention manual

The study findings suggested that a number of adaptations to the G4H manual were needed in order to successfully deliver the programme to adults with depression. These included changes in the guidance to group facilitators as well as altering both the structure and some of the content of the G4H manual.

It should be acknowledged that whilst most of the participants in this study agreed to the underpinning rationale of G4H-D as exemplified in the logic model, the majority also thought that clinical populations would experience the intended process of change at a slower rate compared to the general population. Thus, by the end of the intervention recipients were not expected to have achieved the intended outcomes. Participants therefore recommended making one of two changes: either extend the programme by providing more sessions or augment the programme with a supported socialisation component. These suggested changes were discussed by the research team but it was decided that these were not viable adaptations. The decision not to adapt G4H-D in this manner may represent important limitations of the intervention which need to be further explored.

Findings from the interview study also suggested that certain mental health symptoms, notably paranoia, anxiety and depressed mood, may be significant barriers to social connectedness. Whilst participants in this study did not explicitly suggest targeting mental health symptoms themselves, this was nonetheless an option for adapting G4H. It was decided not to adapt the intervention to tackle these symptoms directly. This decision was taken primarily because G4H-D is intended to target social, not clinical outcomes. In addition, as highlighted in the logic model, reduced symptoms of anxiety and depression are already expected outcomes within the G4H-D model. There is some preliminary evidence that enhancing dimensions of social connectedness can indeed lead to a reduction in mental health symptoms. For instance, in a longitudinal study using a nationally representative dataset of New Zealand adults (n=21,227) social connectedness was found to predict reduced distress measured in terms of depressive and anxiety related symptomatology (Saeri et al., 2017). Interventions designed to increase participants' social identification with groups also appear to reduce depressive symptoms (Cruwys et al., 2014; Haslam et al., 2016). Similarly, a longitudinal study of young adults (n=206) found that social identification predicted reduced levels of paranoia over time but not vice versa (Sani et al., 2017) and an experimental study (n=15) also found that increased social identification reduced paranoia (Haslam, Reicher, et al., 2016). Nonetheless, it is possible that G4H-D may be most effective as an adjunct intervention alongside clinical interventions directly targeting mental health symptoms.

6.8.2. Strengths and limitations of the study

Strengths

A strength of this study was the use of four different sources of data in the development of the adapted manual and model for G4H-D: interviews; pilot study; expert consultation; and a stakeholder review. The development of complex interventions on the basis of a variety of sources of evidence is

recommended as different stakeholder groups have diverse perspectives and insights (De Silva et al., 2014).

A second strength of the study was the collaborative approach taken to identify adaptations to the intervention and in modelling G4H-D. The development of the logic model and intervention manual was heavily informed by the contributions made by the PPI group as well as a mental health clinician. This is in line with the principles of co-production (Pinfold et al., 2015) and service user involvement in research (Beresford & Croft, 2012).

Limitations

Limitations of this study include using small sample sizes, limited representativeness, possible social desirability bias and not incorporating wider theory. First, each sub-study used relatively small samples and the stakeholder review involved the same participants as the pilot sub-study. This may mean that important perspectives on how to adapt G4H were not captured. A related limitation is that the samples may not be sufficiently representative of the target populations for each respective sub-study. However, efforts were made to recruit a diverse sample, including participants both within and outside of mental health services as well as professionals from a broad variety of backgrounds. Future studies to investigate the adaptations to G4H for particular sub-groups such as ethnic minority groups may be warranted.

A further limitation concerns the potential for social desirability bias related to participant conformity in each of the sub-studies. In particular, when asking for respondent's views on necessary adaptations to G4H for clinical populations, participants may have felt pressured to offer an overly positive view of G4H. To reduce the risk of this bias, all participants were informed beforehand that adaptations were expected and that the researchers wanted to hear all views on the intervention. Given that participants suggested several major adaptations to

G4H, it does not appear that social desirability bias was a major influence in this study.

The approach used in this study prioritised lived experience and clinical expertise in the development of the G4H-D logic model and manual alongside the theory-base provided by the CIVIC-MH framework. However, this approach ignores wider theoretical considerations which may have been useful to incorporate. For example, behavioural change theories may have been incorporated in to the development of the logic model (Michie et al., 2013). This may be an area for further development of the intervention in future studies.

6.8.3. Implications for this thesis

The three main outputs of this study are the participant workbook, facilitator manual, and logic model for G4H-D. The participant workbook and facilitator manual will be used to implement the feasibility study of G4H-D (see Chapters 7 and 8). The logic model describes six outcomes of G4H-D. Measures of these six outcomes will be included as part of the feasibility study (see Section 7.5.1). The logic model will also inform the evaluation of the feasibility study with questions relating to the model assumptions included as part of the process evaluation (see Section 7.5.2).

In addition, mental health symptoms were identified as one potential challenge for the intervention. This may mean that G4H-D is most effective as an adjunct to particular types of clinical interventions to manage these mental health symptoms. Therefore, data were also collected during the feasibility study on the types of treatment currently accessed by participants to evaluate whether these moderated the retention or intervention outcomes.

6.9. Chapter conclusion

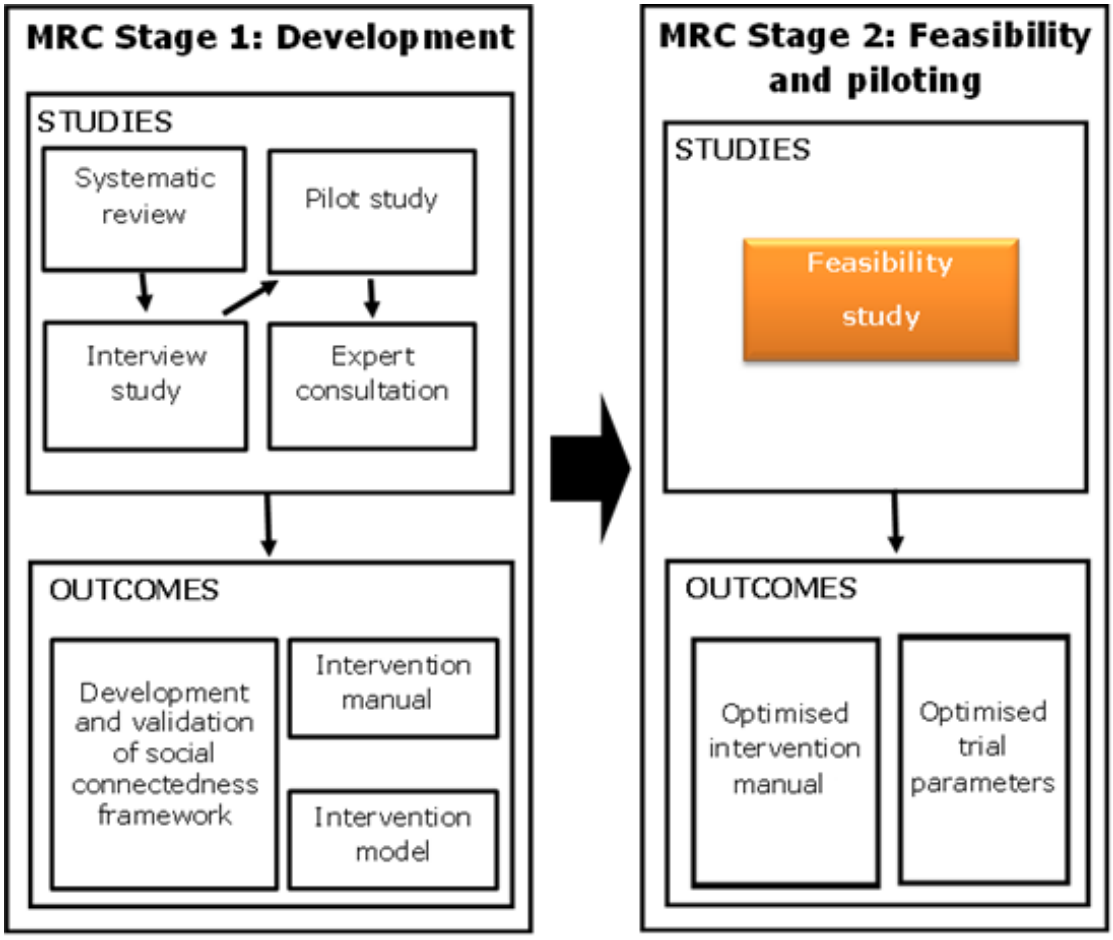
This chapter reported on the procedures used to develop the intervention manual and logic model for G4H-D. A series of potential adaptations to G4H were identified and a rationale was given for why some of these adaptations were adopted but not others. The manual and logic model will inform the design and conduct of the G4H-D feasibility study. Chapter 7 describes the methods used to evaluate the feasibility of G4H-D for delivery to adults accessing secondary care services for depression.

Chapter 7. Methods for the G4H-D feasibility study

Chapter overview

Chapter 6 detailed the process of developing the G4H-D manual and model as part of Stage 1 (Development) of the MRC framework. Chapter 7 describes the methods used to conduct a feasibility study of G4H-D. This study covers Stage 2 (Piloting and feasibility) of the MRC framework as represented in Figure 7.1. The results of the feasibility study (MRC Stage 2 'Outcomes') are reported in the following chapter.

Figure 7.1 Locating the feasibility study methods in the thesis



The aim of this study was to evaluate the feasibility of delivering G4H-D in a clinical trial for adults with depression (objective 6 of the thesis). The objectives were to:

1. Estimate recruitment rate
2. Estimate dropout/completion rates
3. Evaluate acceptability of the intervention
4. Evaluate candidate outcome measures
5. Evaluate contextual factors influencing participant outcomes
6. Estimate sample size requirements
7. Identify potential refinements to the intervention
8. Identify potential refinements to the logic model

The methods used to address these objectives are described as follows.

7.1. Study design and registration

This study consisted of an uncontrolled pre-post design with embedded process evaluation. The quantitative and qualitative components of the study address different objectives and were weighted equally. A sequential design was used with the quantitative component proceeding the qualitative. Where each component contributes data addressing the same objective (objectives 3 and 5), the data were integrated at the level of inference within the discussion of the results.

This study followed the MRC framework for process evaluations of complex interventions (Moore et al., 2015). This framework specifies four areas for investigation: implementation; acceptability; mechanisms of impact; and contextual factors. Acceptability is typically the focus of MRC Stage 2 evaluations such as this feasibility study. Implementation, mechanisms of impact and contextual factors are sometimes focussed on only in the later stages of the MRC framework (Stages 3 and 4). However, given the emphasis in this thesis on

intervention theory development and the exploratory nature of the study to determine where G4H-D might fit into mental health services, all four areas were included. Implementation was assessed using a field note log of each session whilst the acceptability, mechanisms and contextual factors of G4H-D were addressed in participant interviews.

Guidance on the conduct of feasibility studies was also followed (Lancaster et al., 2004; Leon et al., 2011). In particular, this included not using the study data to perform hypothesis testing as well as using different procedures to estimate the power calculation.

The protocol for the study was registered on clinicaltrials.gov (NCT03446963).

7.2. Trial steering committee and trial management group

MRC guidelines for Good Clinical Practice (2017) define a three-committee oversight structure for clinical intervention studies: the Trial Management Group (TMG), the Trial Steering Committee (TSC), and the Data Monitoring Committee. A TMG is responsible for the day-to-day delivery and conduct of the study. For the feasibility study the TMG comprised LHD and the supervisory team. A TSC is the executive decision-making group that can make recommendations to the funder and/or sponsor of a study as well as to the TMG. TSC models vary according to the context of the study (Harman et al., 2015). Some of the responsibilities of the TSC are to ensure patient safety, the progress of the trial, adherence to the protocol and to oversee complaints. A TSC was established to provide overall supervision of the feasibility study and review emerging data. The role of a Data Monitoring Committee is to review safety and efficacy data. The TSC decided not to form a Data Monitoring Committee as this would be disproportionate.

MRC guidance (2017) recommends a minimum TSC membership consisting of an independent Chair and at least two other independent members, including a PPI

contributor, and at least one non-independent member of the TMG. In this study the TSC comprised the four individuals detailed in Table 7.1. All TSC members were independent from the study with the exception of the TMG member.

Table 7.1 TSC membership

TSC role	Name	Job role/experience
Chair	Dr Donna Maria Coleston-Shields	Consultant Clinical Psychologist & Neuropsychologist. Programme Manager for a complex intervention trial
Clinician	Dr Tim Carter	Assistant Professor. Mental health nurse
PPI	Dave Waldram	Secondary care service user. PPI contribution to a number of clinical trials
TMG member	Laurie Hare Duke	PhD student. Responsible for the design and day-to-day conduct of the study

The TSC met three times between August 2018 and May 2019 to discuss the terms of reference for the committee and the design, delivery, and results of the study. LHD also provided monthly reports to the TSC which detailed issues regarding ongoing recruitment, conduct of the groups, adverse events and preliminary findings.

7.3. Setting

Participants were recruited from mental health teams across Nottinghamshire Healthcare NHS Foundation Trust (NHFT). This Trust employs over 9,000 staff and supports approximately 190,000 people across Nottinghamshire each year.

7.4. Sample

7.4.1. Eligibility criteria

The inclusion criteria for participants were:

- Aged 18-65
- Clinical diagnosis of depression (primary or secondary)
- Score six or above on the University of California Loneliness Scale-3 item version (UCLA-3) (Hughes et al., 2004). Scores of six and above on the UCLA-3 are more than one standard deviation higher than the UK population averages for all age groups (Matthews et al., 2016; Whisman, 2010) and a cut-off of six has been used in previous research to indicate 'high' levels of loneliness (Steptoe et al., 2013)
- Able to speak/read English
- Able to give informed consent

No exclusion criteria were applied. More specific diagnostic inclusion and exclusion criteria were considered, such as excluding those with comorbid substance misuse or personality disorders. However, a recent review of depression research suggests that using such criteria can exclude between 75-85% of potential participants (Halvorson & Humphreys, 2015). Therefore, it was decided that using broad inclusion criteria would better reflect the service user populations in clinical practice and therefore would maximise the relevance of the findings for informing a future RCT.

7.4.2. Sample size

The aim of this study was to assess feasibility rather than effectiveness, and thus sufficient power for inferential statistical analysis was not required. Whilst there are sample size recommendations for feasibility studies in which the primary purpose is to inform the power calculation for a later RCT (e.g. Julious, 2005; Sim

& Lewis, 2012), there are no clear guidelines for feasibility studies with multiple objectives.

A 2013 audit of the sample sizes across feasibility and pilot healthcare studies then underway in the UK found that studies using continuous outcomes had a median of 30 participants, ranging from 8 to 114 (Billingham et al., 2013). Sample size recommendations for feasibility studies have ranged from 12 (Julious, 2005) to 30 (Browne, 1995). Therefore, a target of between 20-40 participants was set for this study.

No sample size criteria were applied for the process evaluation and all participants taking part in the feasibility study were invited to take part in the process evaluation.

7.5. Measures and topic guides

7.5.1. Measures

It is not always clear which outcome measures should be selected for feasibility studies or clinical trials. This is especially true in the evaluation of new interventions where the underpinning theory, active ingredients and hypothesised mechanisms of action are still being explored. Choosing an inappropriate outcome measure can lead to trial results suggesting ineffectiveness when instead it may be that the chosen measure was insensitive to change or incongruent with the conceptual causal model of the intervention (Coster, 2013). Precursor feasibility studies can therefore help researchers identify the most appropriate outcome measures and interpret the results of definitive trials.

Six outcomes – loneliness, depression, social anxiety, non-specific social connectedness, specific social connectedness, and G4H-specific connectedness – were assessed in this study. These outcome domains were chosen on the basis of the G4H-D logic model described in Chapter 6. The measures selected to assess

these six outcomes were either free to use or written permission for their use was retrieved.

Loneliness

Loneliness was assessed with the 8-item version of the University of California Loneliness Scale (UCLA-8; Hays & DiMatteo, 1987). The UCLA-8 is a self-completed measure of loneliness, including six negatively phrased items such as 'There is no one I can turn to' and two positively phrased questions such as 'I can find companionship when I want it' which are reverse scored. Each item is rated from 1 (never) to 4 (always) with sum scores ranging from 8 to 32 and the total score being the sum of all ratings. UCLA-8 is a unidimensional measure with higher scores indicating greater levels of loneliness. The UCLA-8 measure was used in this study as it has been well validated in general population samples (Allen & Oshagan, 1995; Hays & DiMatteo, 1987; Russell, 1996; Russell et al., 1984). For instance, Russell, Peplau, and Cutrona (1980) report high internal consistency for the scale (α=.94), as well as support for concurrent and divergent validity. Although this measure has not been validated specifically for clinical populations, it is frequently used in samples of adults with mental health disorders, including major depressive disorder (Hagerty & Patusky, 1995; Hagerty & Williams, 1999; Trémeau et al., 2016).

An alternative measure for loneliness, which is commonly used in Europe, is the De Jong Gierveld Loneliness Scale (de Jong Gierveld & Kamphuls, 1985). This scale was not used in this study as it was primarily developed and validated using older adult samples, whilst this study focusses on working age adults.

Depression

Depression was measured using the Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001). The PHQ-9 is a 9-item self-completed measure of

depressive symptoms which assesses each of the nine DSM-5 criteria for depression (American Psychiatric Association, 2013). Ratings for each symptom are between 0 (not at all) and 3 (nearly every day). Scores on the PHQ-9 can range from 0 to 27, with higher scores indicating more severe symptoms. A score ≥10 on the PHQ-9 has been identified as the threshold for identifying clinically significant depression, and a score ≥20 indicates symptoms of severe depression. Using these cut points, the PHQ-9 was found to have a sensitivity for major depression of 88% (screened positive for probable major depression) and a specificity of 88% (12% will have a false positive finding). The PHQ-9 is a short scale, which may help keep respondent burden low. It has excellent internal reliability (α=0.89) and test-retest reliability (kappa=0.84 over 48 hrs). Evidence also supports the criterion validity, external validity, and factor structure of this measure (Kroenke et al., 2001).

Social anxiety

This domain was measured using the self-report version of the Liebowitz Social Anxiety Scale (LSAS; Baker et al., 2002). The LSAS is a 24-item self-completed scale that measures fear and avoidance of social situations over the past week. It consists of 11 items relating to social interaction and 13 items related to public performance. Each item is rated on two 4-point Likert-type scales. The first rating is a measure of fear/anxiety and ranges from 0 (none) to 3 (severe). The second rating is a measure of avoidance and ranges from 0 (never) to 3 (usually). A total score is calculated by summing all of the fear and avoidance rating with higher scores indicating greater anxiety. The LSAS has shown good test–retest reliability, internal consistency, convergent and discriminant validity and sensitivity to change in samples of adults with social anxiety (Baker et al., 2002; Fresco et al., 2001).

Non-specific social connectedness

Non-specific social connectedness was defined in Chapter 4 as decontextualized perceptions about relationships or social experiences in general without reference to particular interpersonal relationships. This domain was measured using the Thwarted Belongingness subscale of the Interpersonal Needs Questionnaire (INQ-TB; Van Orden et al., 2012). The INQ-TB is a 9-item self-completed measure, including six positively phrased items such as 'These days, other people care about me' and three negatively phrased items such as 'These days, I often feel like an outsider at social gatherings'. Each item is rated from 1 (not at all true for me) to 7 (very true for me). The total scores can range from 9 to 63 with higher scores indicating a lower sense of social connectedness. The INQ-TB demonstrated convergent, concurrent and predictive validity, acceptable factor structure and good internal consistency (α=0.83) in a US sample of mental health inpatients and outpatients (Hill et al., 2015; Van Orden et al., 2012).

The INQ-TB was identified as the measure of non-specific social connectedness with the strongest psychometric properties in the systematic review described in Chapter 4. It has also previously been used in samples of adults with depression (Kleiman et al., 2014).

Specific social connectedness

Specific social connectedness was defined in Chapter 4 as feelings of connectedness to specific individuals or groups. This domain was assessed using the Social Identity Mapping tool (SIM; Cruwys et al., 2016). The SIM involves participants constructing a visual map in three steps. First, participants identify all the individuals to whom they are connected or groups to which they belong. Second, each group is rated from 1-10 on four dimensions: representativeness (how much a person believes they 'fit in' to a group); supportiveness (how much support they receive from a group); positivity (how positively a group is

perceived); and engagement (number of days per month of a group is engaged with). Third, connections between groups are drawn to represent the compatibility of each group in relation to each other.

The SIM is not a unidimensional measure and does not produce a composite score. Cruwys et al. (2016) recommend that each SIM item is analysed separately and that the following variables can be calculated:

- *Number of groups*: Total number of social groups
- *Number of representative groups*: The number of groups with a 'representativeness' score of between eight and ten
- *Number of supportive groups*: The number of groups rated eight to ten for support
- *Number of positive groups*: The number of groups rated eight to ten for positivity
- *Number of engaged groups*: The number of groups with whom respondents saw or contacted at least weekly
- *Group compatibility*: Proportion of links between two groups rated as 'very easy' to be a member of both groups at the same time

The SIM was identified in the systematic review of measures as an acceptable measure of specific social connectedness (Chapter 4). The procedure was also already incorporated as an exercise within G4H-D itself, which helped reduce respondent burden.

G4H-D specific social connectedness

Social connectedness within the G4H-D group itself was evaluated using a modification of the SIM measure. Whilst completing the SIM participants were asked to include the G4H-D group as part of their maps and rate the group accordingly.

7.5.2. Interview topic guide

The interview topic guide for the process evaluation was developed in a four step process. First, four broad sections of the guide were identified in line with MRC framework guidance (Moore et al., 2015): acceptability of the intervention and the evaluation process; potential refinements; mechanisms of change; and contextual factors impinging on participation and impact. Second, questions were added to the mechanisms of impact section which addressed each of the hypothesised mechanisms detailed in the G4H-D logic model. Third, open-ended questions were added to each section of the guide. Fourth, PPI members reviewed and refined the questions and prompts. The topic guide is shown in Appendix 8.

7.5.3. Field note form

A field note form was used to log attendance as well as to evaluate the implementation of G4H-D. Implementation was assessed in terms of fidelity (whether the intervention was delivered as intended) and dose (the quantity of intervention implemented). The form included sections on the logistics of the session (timings, completion of activities), participants' recent circumstances, physical setting, applicability of the logic model, facilitator self-reflection, and any other issues that arose.

7.6. Procedure

7.6.1. Recruitment

A convenience sample was recruited between September 2018 and February 2019. Recruitment was conducted through two routes. First, eligible service users were referred by mental health clinicians. The study was introduced to clinicians in the participating teams. Clinicians were asked to identify potentially eligible service users from their caseload and to provide them with information about the study. Potential participants who gave assent to clinicians to share their contact

information were contacted by LHD and a meeting was scheduled to give further information on the study.

The second recruitment process involved posters and advertisements being placed in different NHFT sites as well as advertised in community venues, an online website and social media. Individuals who self-referred were provided with information about the study and asked to confirm that they were under the care of NHFT and met the relevant inclusion criteria, which was later confirmed by checking patient records. The usual care team of participants who self-referred were informed of their involvement in the study.

Meetings with potential participants took place at NHFT team bases. LHD explained the study in more detail, provided written information, and gave people an opportunity to ask questions. Individuals were also informed that, following written consent, a final screening measure would need to be administered to determine their eligibility for the study. Individuals were offered a second meeting if they wished to have time to further consider their participation. Once the participant had given informed consent, the UCLA-3 screening measure was administered and participants were informed whether or not they were eligible for the study.

7.6.2. Baseline assessment

Assessments were completed prior to the intervention at the time of consent. Eligible participants received a unique ID number and completed baseline assessments, comprising all participant-rated measures (INQ-TB, UCLA-8, PHQ-9, and LSAS) except for the SIM measure, which was completed during group sessions 2 and 5. The intervention facilitators provided support if needed. Support involved reading and filling in the forms if participants requested, or supporting the person to complete the forms by themselves. Demographic information (age,

sex, and ethnicity) and service use data (diagnoses and treatment history) were retrieved from patient records by one of the facilitators (AG).

7.6.3. Intervention

An overview of the format of the G4H-D intervention can be found in Section 6.8.1 (p.189) and a summary of the activities carried out in each session is provided in Appendix 5. In summary, a one-to-one session with a facilitator (LHD) was held before the first group session. Each group then met for five sessions at weekly intervals, with a two-week gap between sessions four and five. The intervention was delivered to three group cohorts.

The groups were co-facilitated by LHD and Anne Garland (AG). Anne is the clinical lead for the Specialist Depression Service at NHFT and is a national expert on CBT for chronic, recurrent depression (Garland & Scott, 2008; Kinsella & Garland, 2008; Moore & Garland, 2004; Morriss et al., 2016). LHD is not a mental health professional and has no clinical training or experience. LHD and AG discussed AG's experience and expertise in CBT and judged that this might influence her delivery of G4H-D. It was agreed that LHD would lead the group in order to ensure fidelity to the intervention model. AG's role was to support LHD in facilitating group discussions and help participants to complete the intervention exercises. LHD attended a one-day facilitation training workshop led by the developer of G4H and practised facilitating the intervention with the pilot study group (see Section 6.2, p.160).

Three group cohorts were run consecutively over a period of five months between November 2018 and March 2019, details for which are shown in Table 7.2.

Table 7.2 Dates, participants and location for each group cohort

Cohort	Start date	End date	Participants (n)	Location
1	14 November 2018	19 December 2018	9	Trust headquarters
2	9 January 2019	13 February 2019	8	Trust headquarters
3	6 February 2019	13 March 2019	12	Community resource centre

7.6.4. Post-intervention assessment

Participants completed post-intervention assessments immediately after the final session of the intervention, with the exception of the SIM, which was completed during the final session. If participants were unable to attend the final session, then post-intervention assessments were completed within the following two weeks. Post-intervention assessments were completed by the end of March 2019.

7.6.5. Process evaluation interviews

One-to-one semi-structured interviews took place 1 to 3 weeks following the end of the intervention for each group cohort. All participants were invited to take part, including both intervention completers and dropouts. A participant information sheet was given to participants and informed consent was obtained. It was emphasised that the interview was confidential, that participants did not have to answer any questions they did not feel comfortable with and that they could withdraw from the study at any point without needing to give a reason. It was further stressed that one of the objectives of the interview was to identify improvements which could be made to the intervention and reassured participants that criticism and feedback in this regard would be welcome.

Interviews took place at different sites within NHFT. Each participant was interviewed once. Interviews were structured around the topic guide and conducted in a conversational style, with the questions and prompts being used

flexibly to suit each participant. Interviews lasted between 20 and 60 minutes. Participants were given the opportunity to ask questions at the end of the session.

All interviews were conducted by LHD and recorded using a digital audio recorder and transcribed verbatim. Any potentially identifying data within the transcript were removed to ensure anonymity and the data was stored using participants' unique ID. Interview data collection was completed by March 2019.

In line with best practice in qualitative research (Mays & Pope, 2000), and with the critical realist perspective adopted in this thesis, the interviewer engaged in a self-reflexive activity following each interview to record his initial impressions. The interviewer was also a group facilitator and had his own understandings of how the intervention had gone. Therefore, one purpose of this reflective exercise was to identify any assumptions which might have influenced the conduct of the interview. A second purpose was to assist with the data analysis by noting participants' verbal and non-verbal communication where this might indicate a stronger theme (e.g. a point of emphasis) or weaker theme (e.g. uncertainty) which may not be represented in the written transcript. Finally, these reflections were used to identify any modifications to be made to the topic guide, for use in future interviews.

7.6.6. Data handling

LHD attended Good Clinical Practice training and followed NHS Research Governance arrangements. All data handling was compliant with the EU General Data Protection Regulation. Documentation containing identifiable information, such as the consent forms and contact details, were stored separately from the assessment forms. All paper-based data were stored in a locked cabinet in a locked room accessible only to LHD. A Trial Master File containing all study information was stored on a secure PC at the University of Nottingham along with a password-protected database containing the participant identification numbers.

Quantitative data were entered into a password protected Microsoft Excel spreadsheet. Validation rules were applied for each item in the assessments to ensure that only valid responses which matched those available on the corresponding measure could be entered. A random sample of 10% of the data were checked following data entry to ensure that what was entered into Excel matched the paper records. No errors were identified. A process of data cleaning was undertaken including checking for spelling inconsistencies and reviewing summary statistics to identify erroneous entries.

Qualitative data were recorded onto a digital recorder, downloaded onto a protected drive on a University of Nottingham computer, deleted from the recorder, and transcribed with pseudonymisation. Raw data files (i.e. the sound file) were deleted from the PC at the end of the study.

7.6.7. Reporting adverse events

All adverse events relating to the intervention were monitored and the TSC was informed where appropriate.

7.7. Analysis

7.7.1. Quantitative analysis

To assess the parameters for a future trial, six outcomes were evaluated:

1. Recruitment: Number of participants recruited per month
2. Dropout/completion: Proportion of participants dropping out and completing the intervention
3. Missing data: Percentage of missing data at baseline and post-intervention
4. Candidate outcome measures: Sensitivity to change; floor/ceiling effects; internal consistency
5. Sample size/Power analysis

6. Association between intervention outcomes and sociodemographic and clinical characteristics

Analysis of dropout

Dropout was assessed in terms of both *pre-intervention dropout* and *during-intervention dropout* (Fernandez et al., 2015). Pre-intervention dropout refers to the number of participants who agreed to take part in the intervention but discontinued prior to the initial one-to-one session. During-intervention dropout refers to the number of participants who attended fewer than three group sessions, i.e. less than half the group sessions (Haslam et al., 2019). Independent samples t-tests and χ^2 tests were used to analyse differences in demographic and clinical characteristics between completers and dropouts.

It has been found that pilot trials overestimate dropout rates by approximately 4.4% compared to definitive trials (Cooper et al., 2018). To account for such potential variability, the criterion for dropout feasibility was set as a range rather than a set-point. A dropout rate of between 32-40% was set as the upper threshold for the feasibility of a future trial. This rate represents the 95% confidence interval of dropout from group psychotherapy, which was viewed as an appropriate comparator (Fernandez et al., 2015; Swift & Greenberg, 2012).

Missing data analysis

Missing data could influence the analysis of the candidate outcome measures in this study by reducing statistical power and biasing parameter estimation. The treatment of missing data depends on the pattern of 'missingness' in the data. Data which are *missing completely at random* are those that are independent of their hypothetical values as well as the values of other variables. Data *missing at random* depend on other variables, but not on their hypothetical values. Data *not missing at random* depend on the values of the missing variables.

Missing data analysis involved four steps. First, the frequency of missing data across items and variables was examined. Second, it was explored whether the missing data related to the missing variable or other observed covariates. This was to judge the possible mechanisms behind the missing data, namely whether the data were missing completely at random, missing at random or missing not at random. For data that were missing completely at random or missing at random the third step of analysis involved two separate strategies: (a) imputing the values for the missing data using mean substitution to maintain the sample size and (b) casewise deletion (if missing data <5%; Schafer, 1997). Mean substitution was used rather than deleting the data in order to maintain the sample size.

Although model-based methods such as multiple imputation and maximum likelihood estimation would have had the advantage of maintaining data variability by introducing an error component into the analysis, these methods were introduced for large surveys (Rubin, 1987) and can produce variable estimates using small samples (Allison, 2001; Schafer & Olsen, 1998). Likewise, the Last-Observation-Carried-Forward method was not used for missing post-intervention data as the assumptions of this method were not appropriate for the feasibility study. This method is typically used when there have been repeated assessments over time and it can be assumed that any observed trend in the initial assessments has stabilised rather than continuing to increase or decrease. In the feasibility study there are only two assessment points, meaning that no trend can be observed, and it is not assumed that participant scores will remain the same between baseline and post-intervention assessment. The Last-Observation-Carried-Forward method is therefore not suitable for the sensitivity-to-change evaluation of the candidate outcome measures.

Since mean substitution reduces the variability in the data, casewise deletion was also used for separate analyses to examine whether there were substantive differences in the results. For data that were not missing at random, casewise analysis but not mean imputation was conducted.

Analysis of candidate outcome measures

The intra-class correlation coefficient (ICC) was calculated to determine the degree of clustering across intervention group cohorts. The ICC provides a ratio of the group-level variance in outcomes as a proportion of the total sample variance. It is measured by Rho (ρ), which ranges from 0 to 1. Scores closer to 1 indicate a higher degree of clustering. The ICC for each outcome was estimated using a random intercept multilevel model with group cohort as the level 2 unit. A design effect was calculated to determine the effect of independence violations on standard error estimates using the following formula (Kerry & Bland, 1998):

$$Design\ effect = 1 + (n_c - 1)ICC$$

Where n_c = average number of participants per group.

Type II errors are the non-rejection of a false null hypothesis, sometimes known as false negative findings. A design effect of 2 or more identifies an inflated risk of Type II errors and indicates that clustering needs to be accounted for within the analysis (Muthén & Satorra, 1995). All statistical models were adjusted using cluster-robust standard errors for outcomes demonstrating non-trivial clustering.

Sensitivity to change of each measure was assessed using dependent samples t-tests to examine whether the changes in post-intervention outcome scores differed significantly from baseline. Approximate normality of the differences between paired data was assessed by examining the skewness and kurtosis of each measure. Skewness and kurtosis were visually examined using histograms

and calculated using Pearson's moment coefficients. Skewness >2 or kurtosis >7 in absolute value were considered to indicate a non-normal distribution (West et al., 1995). Test statistics for skewness and kurtosis were conducted using the *sktest* function in Stata. The Shapiro-Wilk test was also used to assess normality.

Sensitivity to change was further analysed in terms of standardised change by dividing the mean change by the standard deviation of the changes whilst accounting for the dependency in the data. Standardised change (*d*) was calculated using the formula suggested by Cooper and colleagues (2009):

$$d = t\sqrt{\frac{2(1-r)}{n}}\ ,\ t = \frac{\mu 1 - \mu 2}{\sqrt{s^2/n}}$$

Where *r*=correlation between dependent data; *n*=sample size; *t*=paired t-test statistic; $\mu 1$ and $\mu 2$=mean of baseline and post-intervention; and s^2=sample variance of the differences.

Where the clinical outcome measures (PHQ-9 and LSAS) were found to be sensitive to change, these were further assessed on two indices of clinically significant change if empirically-based criteria were available. These indices comprised the minimum clinically important difference (PHQ-9) and remission (PHQ-9 and LSAS). First, the minimum clinically important difference has been defined as the smallest difference that patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management (Jaeschke et al., 1989). For the PHQ-9 the minimum clinically important difference has been conservatively estimated as a change score of 5 or greater for individuals receiving depression treatment (Löwe et al., 2004). Second, remission is defined as the absence or near absence of symptoms following illness, accompanied by a return to premorbid levels of functioning (Bandelow, 2006). For the PHQ-9 this has been identified as scores

≤9 (Kroenke et al., 2001; McMillan et al., 2010) and for the LSAS as scores ≤30 (Mennin et al., 2002; Rytwinski et al., 2009).

Floor and ceiling effects for each measure were assessed by calculating the percentage of participants who achieved the lowest possible score and the highest possible score. Data from both baseline and post-intervention assessments were evaluated and whichever time point had the most participants with the lowest or highest scores was used for the analysis. Floor or ceiling effects are considered to be present if more than 15% of participants achieved the lowest or highest possible score, respectively (McHorney & Tarlov, 1995). The presence of floor or ceiling effects can suggest that extreme items are missing in the lower or upper end of the scale, thereby narrowing the measurement of the construct and reducing content validity. Floor and ceiling effects can also mean that participants with the lowest or highest possible score cannot be distinguished from each other which reduces the reliability of the measure. Finally, the responsiveness of the measure is also limited because changes cannot be measured in these participants (Terwee et al., 2007).

Internal consistency, defined as the degree of the interrelatedness among the items of a measure (Mokkink et al., 2010), was also calculated for each of the outcome measures. The internal consistency of a measure can vary between different population groups (Onwuegbuzie & Daniel, 2002). With the exception of the PHQ-9, the measures used in this study have not been frequently used with the target population and their psychometric properties have not been evaluated. Therefore, internal consistency was assessed using Cronbach's alpha coefficient which is calculated as a function of the average inter-correlation among items and the number of test items. Analysis was conducted using the baseline outcome assessments as this represented a larger sample than the post-intervention

assessments due to loss to follow-up. The SIM measure does not reflect a unidimensional construct and so was not assessed for internal consistency.

Analysis of contextual factors

To evaluate whether contextual factors influenced participant outcomes, hierarchical regression on the outcomes found to be sensitive to change in univariate analyses was conducted to assess whether any social or clinical characteristics were significantly associated with outcomes. Hierarchical regression, which compares nested regression models, was used for two reasons. First, this procedure permits analysis of the additional outcome variance accounted for by different independent variables. Second, this approach mitigates against the possibility of multicollinearity, defined as a high degree of correlation between independent variables such that their contribution to the variation in the dependent variable cannot be determined. Dependent variables were calculated as the pre-post difference score (Time 2-Time 1). A four-step regression model was run for each dependent variable: Step 1 (Baseline outcome score), Step 2 (Age, Gender), Step 3 (Length of treatment history, Depression diagnosis, Therapy utilisation), and Step 4 (One-to-one session utilisation, Number of group sessions attended).

The linearity of the regression model was assessed using scatterplots with linear and quadratic lines of best fit. Analyses were run both with and without polynomial regression terms for variables indicating a non-linear relationship. The modelled residuals were checked for normality (histogram of residuals; Shapiro-Wilk test), homoscedasticity (residual-by-predicted scatterplot; Cameron and Trivedi's test), and outliers (residual-by-predicted scatterplot; standardised residuals). Multicollinearity was assessed using the Variance Inflation Factor (VIF), which estimates the degree to which multicollinearity has increased the

variance of coefficients. VIF values over 10 were taken to indicate substantial issues with multicollinearity (Mason et al., 2003).

Univariate outliers were defined as values that were smaller than the lower quartile minus 1.5 times the interquartile range or larger than the upper quartile plus 1.5 times the interquartile range (Tukey, 1977). Univariate outliers were assessed using box plots. Bivariate and multivariate outliers were assessed using scatterplots and defined as standardised model residuals greater than ±2 (i.e. those outside the range of 95% of residuals, assuming a normal distribution). All analyses were conducted both with and without outliers to assess their influence.

Sample size/Power analysis

Power calculations for a future trial were conducted by combining data available from this feasibility study (follow-up mean score, standard deviation, and dropout rate) with data taken from another study with a similar design and participant characteristics (control arm follow-up mean score and standard deviation) (Morriss et al., 2016). A comparison of the characteristics of the feasibility study and the Morriss et al. (2016) trial are shown in Appendix 9. Power, the ability to find a statistically significant difference when the null hypothesis is false, was set at 80%. In other words, the probability of a Type II error occurring (beta) was set at 0.2. Type I errors are the rejection of a true null hypothesis. The probability of a Type I error occurring (alpha) was set at 0.05.

Three different power calculations were performed. First, the effect size estimate observed from the feasibility data was used in the calculation. Second, sensitivity analyses were conducted corresponding to a small (d=0.2) and a medium (d=0.5) effect size in favour of the intervention arm. Third, effect size estimates corresponding to clinically meaningful differences were used for candidate outcome measures for which this information is available (Leon et al., 2011).

All statistical analyses were conducted in Stata® version 15 (StataCorp., 2017).

7.7.2. Qualitative analysis

Interview data were analysed using the thematic analysis approach as described in Section 5.2.5 (p.121). Two analysts assessed the interview data. LHD and a research assistant (AC), independently coded 25% of the data. They then met several times to discuss coding and to iteratively develop a coding framework. A preliminary framework was then discussed with two supervisors (MS, DO) with further refinements made. LHD and AC then used the framework to code an additional transcript from which inter-rater reliability was calculated. Substantial reliability was achieved (kappa=0.88) and LHD used the framework to code the remaining transcripts.

All qualitative analyses were conducted in NVivo® version 10 (QSR, 2014).

7.8. Study quality

The feasibility study comprises both a quantitative and a qualitative component. The meaning of quality in mixed methods studies is still contested and no definitive criteria have been established (Fàbregues & Molina-Azorín, 2017; O'Cathain et al., 2008). However, the quality of this study can be assessed against the reporting guidance developed by health service research methodologists (O'Cathain et al., 2008; O'Cathain, 2010). This guidance has been cited in best practice guidelines for mixed methods research by the US National Institutes for Health (NIH Office of Behavioral and Social Sciences, 2018). In particular, this guidance addresses how the findings are integrated, which is an issue highlighted within the MRC framework (Moore et al., 2015).

The six areas cited in mixed methods reporting guidance (O'Cathain et al., 2008) are reported as follows:

(1) *Describe the justification for using a mixed methods approach to the research question*. In this study the quantitative and qualitative components address different research objectives (Section 7.1).

(2) *Describe the design in terms of the purpose, priority, and sequence of methods*. The purpose, priority and sequencing of this study are described in Section 7.1.

(3) *Describe each method in terms of sampling, data collection and analysis*. See Sections 7.4 to 7.7.

(4) *Describe where integration has occurred, how it has occurred, and who has participated in it.* Integration took place at the level of inference when discussing the study findings, which will be presented and discussed in Section 8.2. Integration was conducted in two ways. First, where quantitative and qualitative data both related to a given research objective, the data were discussed in terms of their consistency with respect to this objective. This first process was conducted by LHD. Second, to address the overall aim of the study the data relating to all the objectives were integrated to evaluate whether G4H-D was feasible for a clinical trial. This second process was conducted via discussion between LHD and the supervisory team.

(5) *Describe any limitation of one method associated with the presence of the other method*. None applicable to this study.

(6) *Describe any insights gained from mixing or integrating methods*. For two of the research objectives using multiple methods allowed for data triangulation (see Sections 8.2.3 and 8.2.4. For one objective the mixed methods generated a more comprehensive dataset (Section 8.2.5). Integrating the methods also enabled the generation of hypotheses regarding the G4H-D mechanisms of action (Section 9.1.6).

7.9. Ethical considerations

Approval for the study was granted by the East Midlands – Nottingham 2 Research Ethics Committee (ref 18/EM/0054, 06.04.2018). Organisation-level approval was also received from NHFT.

The study design raises one ethical consideration in relation to the consent procedure. Consent was taken from participants before the UCLA-3 screening measure was administered to determine participant eligibility. The procedure was a requirement of the NHFT Research and Innovation department. The argument in favour of this procedure was that administering the screening measure constituted a study activity and, in line with Good Clinical Practice guidance, consent should take place before any study activities. The risk of this approach was that people's expectations may have been raised by completing the consent form only to be disappointed if they were later found to be ineligible. This concern was addressed in the study by describing this screening process to potential participants before they signed the consent form and highlighting the possibility that they might be ineligible.

7.10. Chapter conclusion

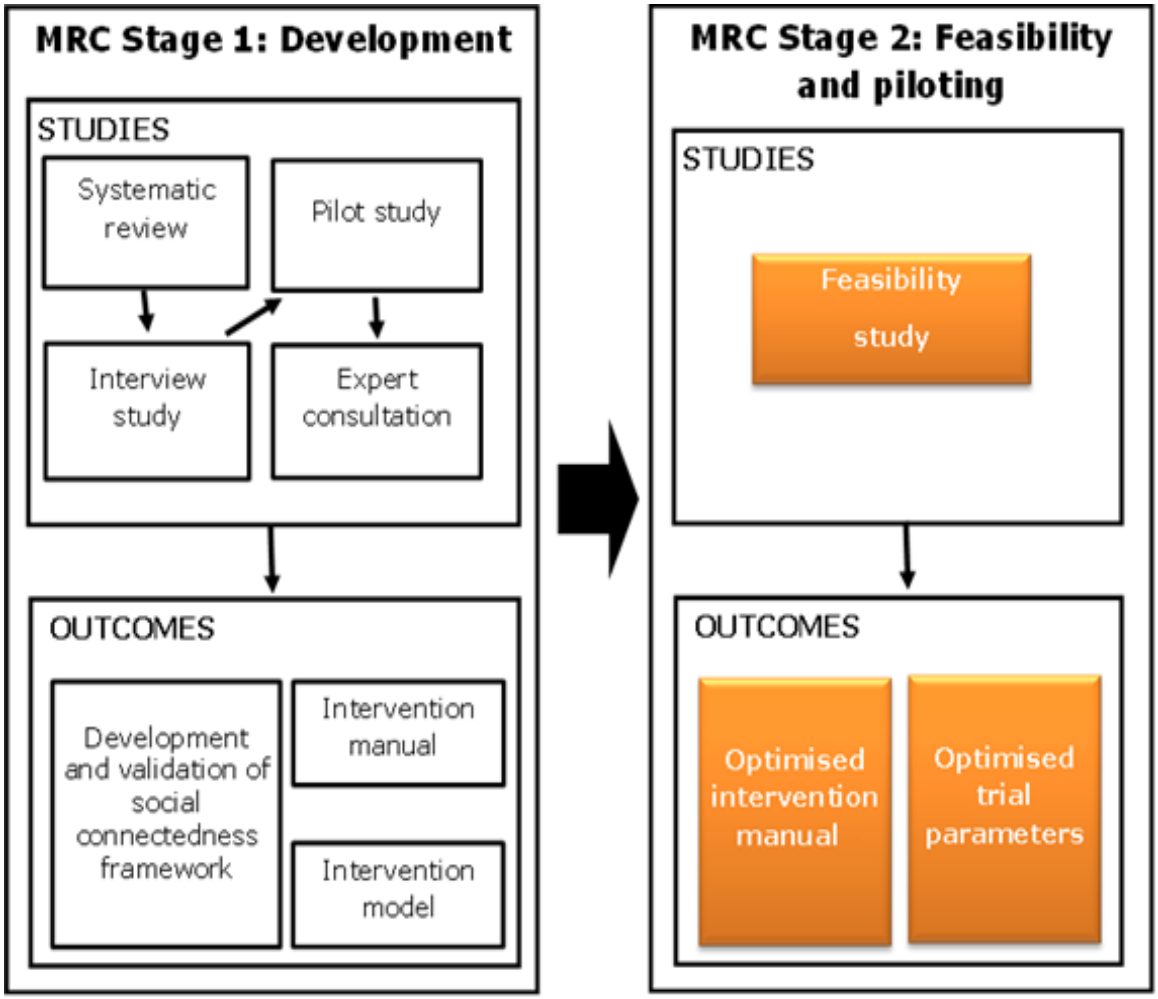
This chapter described the methods used to address the research objectives of the feasibility study. An uncontrolled pre-post design with an embedded process evaluation was described. The sample, measures, procedures and data analysis approach used in the study were detailed. The next chapter presents the results of the feasibility study and discusses these results in relation to whether a clinical trial may be warranted.

Chapter 8. Results and discussion of the G4H-D feasibility study

Chapter overview

Chapter 7 outlined the methods used in the G4H-D feasibility study. Chapter 8 describes the results of this study (Section 8.1) and discusses these results in terms of the feasibility evidence for a clinical trial of G4H-D (Section 8.2). This represents the final step in Stage 2 of the MRC framework ('Outcomes') as shown in Figure 8.1.

Figure 8.1 Locating the feasibility study results in the thesis



8.1. Results

8.1.1. Referrals and recruitment

A total of 60 referrals were made to the study, comprising 51 referrals from secondary care mental health clinicians and nine self-referrals. Referrals were received from 13 different clinicians based in nine different mental health teams. Mental health teams comprised six community mental health teams and three specialist services. The nine self-referrals were received from potential participants who had been made aware of the study via posters placed in secondary care clinics and community venues (n=7), social media (n=1) and an advertisement placed in NHFT's *Positive* magazine (n=1). All participants were in receipt of on-going treatment within NHFT during the period of the study.

Of the 60 total referrals, four (7%) were ineligible for the study. Of the eligible participants, 29 people (52%) consented to take part and 27 (48%) declined. Of the 27 people who declined to take part, six declined after being informed of the study by their care coordinator and 21 declined following further telephone or email contact with the research team. The reasons people gave for declining to take part are listed in Table 8.1.

Table 8.1 Reasons for non-participation (n=27)

Reason	**n**	**%**
Clashed with other commitments (e.g. work, education, childcare)	8	29.6
Not interested in a social connectedness intervention	7	25.9
Not ready to engage in this type of intervention	4	13.7
Poor physical health: Getting to the group would be impractical	1	3.7
Too mentally unwell	1	3.7
Not interested in peer support/therapy groups	1	3.7
Too big a time commitment	1	3.7
Financial: Couldn't afford transport to group	1	3.7
Not declared	3	11.1

Four people referred to the study were ineligible. Three people did not have a diagnosis of depression and one person was judged by the lead clinician for the study (AG) as being too high risk given their recent history of violent offences.

All of the potential participants who gave their consent to taking part in the study were eligible when screened on the UCLA-3.

Table 8.2 shows the monthly recruitment rate of participants who gave consent to participate in the study between September 2018 and February 2019. Five participants per month were recruited on average over this period.

Table 8.2 Recruitment rate per month

Month/year	**Target recruitment, n**	**Actual recruitment, n (% of target)**
September 2019	8	1 (12.5%)
October 2019	8	7 (87.5%)
November 2019	8	2 (25%)
December 2019	8	6 (75%)
January 2019	8	10 (125%)
February 2019	4	3 (75%)

Sample demographic data

The demographic profile of the participants is summarised in Table 8.3.

Table 8.3 Participant demographic characteristics (n=29)

Demographic variable	**Summary statistics**
Age, mean (SD)	48.3 (13.4)
Gender, n (%)	
Female	20 (68.9)
Male	9 (31.1)
Ethnicity, n (%)	
White British	27 (93.1)
Other	2 (6.9)
Primary diagnosis, n (%)	
Major depressive disorder	20 (69.0)
Psychosis	2 (6.9)
PTSD	2 (6.9)
Schizophrenia	2 (6.9)
Bipolar disorder	1 (3.5)
Personality disorder	1 (3.5)
Schizoaffective disorder	1 (3.5)
Secondary diagnosis, n (%)	
None	11 (37.93)
Major depressive disorder	8 (27.58)
Personality disorder	3 (10.34)
Asperger syndrome	2 (6.90)
Generalised anxiety disorder	2 (6.90)
Agoraphobia	1 (3.45)
Dyslexia	1 (3.45)
Eating disorder (not otherwise specified)	1 (3.45)
Movement disorder	1 (3.45)
Psychosis	1 (3.45)
Social anxiety disorder	1 (3.45)
Number of years treatment, mean (SD)	9.71 (8.19)*

*Clinical records were incomplete for most participants

All participants had a primary or secondary clinical diagnosis of depression, meeting the inclusion criteria, except for one participant who had a diagnosis of bipolar disorder rather than depression which meant that she was technically ineligible for the study. This protocol deviation occurred as the participant

concerned had arrived at a group session having seen the study information on a poster and being told about the group venue by word-of-mouth. She confirmed at that point that she was in treatment for depression (and met other inclusion criteria). The error was identified following the completion of the intervention when her clinical records were checked. It was decided to include this participant in the analysis as she had volunteered her time for the study and it was considered that her experiences of depression as part of her bipolar diagnosis were relevant to the study.

Table 8.4 lists the types of treatment that participants were receiving within NHFT secondary care.

Table 8.4 Types of treatment being received by participants (n=29)

Type of treatment	**Number receiving, n (%)**
Pharmacological	
Antidepressant	27 (93)
Antipsychotic	10 (35)
Mood stabiliser	6 (21)
Anxiolytic	4 (14)
Thyroid hormone preparations (T3, T4)	3 (10)
Sleep medication	2 (7)
None	1 (4)
Psychological	
Individual CBT	5 (17)
Brief family therapy	2 (7)
Compassionate mind therapy	2 (7)
CBT for psychosis	1 (4)
Mindfulness-based cognitive therapy	1 (4)
None	19 (66)
Modality of therapy	
Individual	7 (24)
Group	3 (10)

8.1.2. Dropout and attendance

Completers and dropouts

A total of 20 (69%) participants completed the intervention and nine (31%) participants dropped out. Five participants (17%) dropped out pre-intervention and four (13%) dropped out during the intervention.

The profile of dropout participants, including their attendance rates and reasons given for dropout, is given in Table 8.5.

Table 8.5 Profile of dropout participants (n=9)

Type of dropout	Sessions attended	Reason for dropout	n
Pre-intervention	None	Anxiety about being in a group	1
	None	Anxiety that the group size was larger than originally anticipated	2
	None	Deterioration of agoraphobia	1
	None	No reason given	1
During intervention	One-to-one session and one group session	Judgement by the lead clinician of the study that the participant was unable to continue	1
	One-to-one session and two group sessions	No reason given	2
	One-to-one session and two group sessions	Flu and deterioration in mood	1

One participant was asked to leave the study by the lead clinician for the study (AG). This followed an incident where they became distressed following the end of a group session. An incident report was provided to the TSC Chair, who decided that the incident was unrelated to G4H-D and that it had been handled appropriately. This participant was classified as a dropout.

Table 8.6 compares the social and clinical demographics of the dropout and completer participants. Participants who dropped out pre-intervention and during-intervention were pooled during analysis as there were insufficient data to do sub-group analysis. There were also insufficient data to analyse the association between dropout and attendance of the one-to-one intervention session.

Table 8.6 Comparison of demographic characteristics of dropout and completer participants (n=29)

Demographic variable	**Dropout group (n=9)**	**Completer group (n=20)**	**Comparison**
Age, mean (SD)	46.7 (12.8)	48.9 (13.4)	t_{27}=0.40, p=0.686
Sex, % female	66.7	70.0	χ^2=0.03, p=0.858
Primary diagnosis depression, (%)	66.7	70.0	χ^2=0.03, p=0.858
Baseline UCLA-8, mean (SD)[a]	22.6 (3.2)	23.3 (4.2)	t_{25}=0.40, p=0.686
Baseline PHQ-9, mean (SD)[a]	18.9 (6.3)	19.2 (4.5)	t_{25}=0.13, p=0.894
Baseline INQ-TB, mean (SD)[a]	34.1 (10.8)	34.0 (13.2)	t_{25}=0.40, p=0.686
Baseline LSAS, mean (SD)[ab]			
Fear and Anxiety	52.4 (5.1)	44.9 (14.1)	t_{23}=-1.20, p=0.245
Avoidance	47.1 (18.1)	33.1 (16.1)	t_{23}=-1.89, p=0.070
Total	99.6 (30.8)	78.0 (27.2)	t_{23}=-1.71, p=0.099
Treatment history, (years)	9.6 (6.8)	9.8 (8.9)	t_{26}=0.40, p=0.686

[a]Dropout group n=7; [b]completer group n=18

There were no differences between the dropout and completer participants using non-imputed data. However, when imputing missing values a significant difference was found on the Avoidance subscale of the LSAS (t_{25}=-2.11, p=0.044), with participants who dropped out being more likely to score highly on this subscale. No significant differences were found for any of the other demographic or clinical characteristics.

Attendance

A total of 18 participants (62%) attended the one-to-one session before the group. The total number of group sessions attended by participants was as follows: 0 sessions (n=5, 17%), 1 session (1, 3%), 2 sessions (3, 10%), 3 sessions (4, 14%), 4 sessions (6, 21%), and 5 sessions (10, 34%).

8.1.3. Missing data

Dropout participants provided either no data at all (n=2) or provided baseline data but not post-intervention data (n=7). One completer participant was also lost to follow-up. It was assumed that the post-intervention data were missing not at random given the difference in scores between completer and dropout participants on the imputed LSAS-Avoidance subscale. Imputation was therefore not conducted for dropout participants.

Where participants did complete the assessment batteries there were no missing data on three of the five measures: INQTB, PHQ-9, and UCLA-8. For the remaining two measures, LSAS and SIM, two different patterns of missing data were identified.

First, LSAS appeared to have data missing at random. For this measure, two participants had missing baseline data on one item each. The missing data per item was 3.7%. There was no demographic similarity between the two participants, who were from different gender and age groups. These two respondents had mean scores of 71 and 36 on the measure compared to a sample mean of 73 (omitting the missing items). Thus, no clear pattern of missingness was found either in relation to possible covariates or the missing outcome variable. However, given that not every possible covariate can be examined, it was assumed for the remaining analyses that the data were missing at random rather than completely at random.

A second pattern of missing data was observed on the SIM measure. Some participants did not complete the SIM measure at all. Amongst intervention completers (n=20), 10 participants (50%) did not complete the measure at baseline and six (30%) had missing follow-up data. In addition, some participants had data missing for individual items within the measure. Table 8.7 shows the missing data for each SIM item amongst the 13 participants who completed the measure.

Table 8.7 Missing data on SIM measure items (n=13)

SIM item	**Baseline missing, n (%)**	**Follow up missing, n (%)**
Number of groups	4 (31)	1 (8)
Group importance	4 (31)	1 (8)
Group positivity	6 (46)	1 (8)
Group representativeness	6 (46)	1 (8)
Group support	6 (46)	1 (8)
Days engaged with group per month	6 (46)	1 (8)
Group compatibility	8 (62)	11 (85)

Field notes collected as part of the process evaluation suggested that some of the participants found the SIM measure to be complex and difficult to complete. For this reason it cannot be assumed that the data are missing at random. Instead, it is possible that the missing data will vary according to participants' cognitive abilities. Missing data on the SIM was therefore not imputed for further analyses.

8.1.4. Candidate outcome measures

Floor and ceiling effects

The floor and ceiling effects for each of the measures are shown in Table 8.8.

Table 8.8 Number of highest and lowest possible scores for either baseline or follow-up assessments (n=27)

Measure	Lowest possible score, n (%)	Highest possible score, n (%)
UCLA-8 (8 to 32)	0	0
PHQ-9 (0 to 27)	0	0
INQ-TB (range: 9 to 63)	2 (7)	0
LSAS[a]		
Total (0 to 144)	0	0
Fear/anxiety (0 to 72)	0	0
Avoidance (0 to 72)	0	1 (5)
SIM		
Support (1 to 10)	3 (23)	6 (46)
Positivity (1 to 10)	2 (15)	9 (69)
Representativeness (1 to 10)	1 (8)	8 (62)
Engagement (1 to 10)	0	0

[a]n=25

As shown in Table 8.8, the SIM measure demonstrated floor effects on two subscales (Support and Positivity) and ceiling effects on three subscales (Support, Positivity, and Representativeness) according to the pre-specified criteria (n >15%).

Internal consistency

The internal consistency of the four scale measures were as follows: UCLA-8 (α=0.71); PHQ-9 (α=0.76); INQ-TB (α=0.85); and LSAS (Full scale α=0.96; Fear/Anxiety subscale α=0.93; Avoidance α=0.96).

Sensitivity to change

Table 8.9 displays the group-level clustering for change scores on the UCLA-8, PHQ-9, INQ-TB, and LSAS.

Table 8.9 Group-level clustering on the UCLA-8, PHQ-9, INQ-TB and LSAS (groups=3, n=17)

	UCLA-8	PHQ-9	INQ-TB	LSAS-FA	LSAS-A	LSAS-Total
ICC (ρ)	0.041	<0.001	<0.001	<0.001	0.147	0.073
Design effect	1.369	~1.000	~1.000	~1.000	2.323	1.657

LSAS-FA=LSAS-Fear Anxiety subscale; LSAS-A=LSAS-Avoidance subscale

Only the LSAS-Avoidance subscale demonstrated substantial group clustering (design effect >2). However, analyses using mean imputed data (calculated both for the whole sample and for individual group cohorts), did not identify clustering on this subscale. The remaining analyses were therefore conducted both with and without cluster-robust standard errors for this subscale to compare the results.

Visual inspection of histograms suggested that there may be a positive skew for two of the four outcome measures (PHQ-9, LSAS-total) and one subscale (LSAS-A). The coefficients of skew and kurtosis for these measures (PHQ-9 skew: 0.4, kurtosis: 2.1; LSAS-total skew: 0.3, kurtosis: 2.3; LSAS-A skew: 0.8, kurtosis: 2.8) and all other measures did not exceed the pre-specified criteria for a departure from normality of skew >2 or kurtosis >7. The skew/kurtosis test and the Shapiro-Wilk test did not reach statistical significance to reject the null hypothesis of normal distributions for each measure (all p values >0.05). The data were therefore assumed to be approximately normally distributed. One outlier was identified for the LSAS-FA subscale.

The results from the paired t-tests and standardised mean difference (*d*) calculations are shown in Table 8.10.

Table 8.10 Paired t-test and standardised mean difference of the UCLA-8, PHQ-9, INQ-TB, and LSAS

Measure	n	Baseline mean (SD)	Follow up mean (SD)	t (df)	Sig.	*d*
UCLA-8	19	23.2 (4.3)	21.9 (4.3)	-2.14 (18)	**0.046**	**-0.281**
PHQ-9	19	19.1 (4.6)	13.9 (7.1)	-4.37 (18)	**<0.001**	**-0.787**
INQ-TB	19	35.3 (2.8)	36.3 (2.9)	0.54 (18)	0.594	0.079
LSAS Total		78.5 (25.7)	80.8 (31.7)	0.39 (18)	0.700	0.078
Fear/anxiety	17	45.7 (12.9)	44.0 (17.0)	-0.51 (18)	0.613	-0.112
Avoidance		32.7 (16.2)	36.8 (15.4)	1.11 (18)	0.281	0.252

df=degrees of freedom; significant findings are shown in bold

As seen in Table 8.10, there was a significant difference between groups in PHQ-9 and UCLA-8 scores. Further evaluation of the change scores on the PHQ-9 is shown in Table 8.11.

Table 8.11 Change scores on the PHQ-9 (n=19)

Indicator	n	%
Absolute change from baseline to post-intervention		
Increase (i.e. worsening)	3	16%
No change	1	5%
Decrease (i.e. improvement)	15	79%
Minimum clinically important difference (≤5)	12	63%
Remission (sum score≤9)	7	37%

As shown in Table 8.11 the majority of participants (79%) showed an improvement in depressive symptoms with 63% showing a clinically significant improvement and 37% achieving remission.

Sensitivity analysis

Analysis of the imputed data (n=20) did not generate substantively different results compared to those shown in Table 8.10. The results of the LSAS-FA

subscale, which had one outlier, did not substantively change when tested without the outlier, either with or without imputation. One outlier was identified for the INQ-TB measure when using imputation analysis but results did not substantively differ between analyses with (n=20) and without (n=19) this outlier. Using cluster robust standard errors to test the difference on the LSAS-A subscale also did not change the results from those shown in Table 8.10.

Correlation between outcomes

Shapiro-Wilk and skew-kurtosis tests indicated that the changes scores on the UCLA-8, PHQ-9, INQ-TB, and LSAS (total) were all approximately normally distributed (all p values >0.05). Visual inspection of scatterplots indicated that the association between change scores was linear only between the PHQ-9 and UCLA-8 measures. These two variables also had one bivariate outlier.

Table 8.12 shows the correlation between the pre-post outcome change scores for the UCLA-8, PHQ-9, INQ-TB, and LSAS (total).

Table 8.12 Pair-wise correlation between pre-post outcome change scores (n=17)

	UCLA-8	**INQ-TB**	**PHQ-9**	**LSAS-Total**
UCLA-8	1.00			
INQ-TB	-0.27 (0.249)	1.00		
PHQ-9	0.44 (0.056)	0.01 (0.939)	1.00	
LSAS-Total	0.05 (0.823)	0.13 (0.610)	0.37 (0.132)	1.00

Significance levels are in brackets

As seen in Table 8.12, none of the correlations between the outcome change scores are significant. However, when the bivariate outlier for UCLA-8 and PHQ-9 was dropped this pair-wise correlation increased and became significant (r=0.514, p=0.029). A similar result was found when analysing the full data (including the outlier) using the Spearman rank correlation, which is less sensitive to outliers than Pearson correlation (r_s=0.54, p=0.024).

Data from the SIM measure were assumed to be missing not at random and the collected data represents a small sample (n=7 for most SIM items). Examination of the distribution of the differences suggested that the SIM data were not normally distributed and many items had one or two outliers. Therefore, descriptive statistics were conducted rather than inferential tests (see Table 8.13). The 'number of compatible groups' item is not shown because only one participant provided data at both assessment time points.

Table 8.13 Descriptive statistics for the SIM measure (baseline and follow up)

SIM item	n	Mean (SD)		Median (IQR)	
		Baseline	***Follow up***	***Baseline***	***Follow up***
Number of groups	9	3.2 (2.7)	3.8 (2.6)	3 (1, 5)	4 (1, 5)
Number of important groups	9	1.2 (1.1)	1.4 (1.4)	1 (0, 2)	1 (0, 2)
Number of positive groups	7	1.6 (2.1)	2.7 (2.1)	1 (0, 4)	3 (1, 4)
Number of representative groups	7	1.9 (2.0)	2.3 (1.7)	1 (0, 4)	2 (1, 4)
Number of supportive groups	7	1.57 (1.8)	2.7 (3.0)	1 (0, 4)	1 (0, 5)
Number of active/engaged groups	7	2.1 (2.5)	2.9 (2.5)	1 (0, 4)	3 (1, 5)
G4H-D group					
Importance		1.4 (0.5)	2.1 (0.7)	1 (1, 2)	2 (2, 3)
Positivity	7	6.0 (2.7)	6.3 (2.7)	7 (3, 8)	7 (3, 8)
Representativeness		5.6 (3.0)	7.1 (2.3)	5 (4, 8)	7 (5, 10)
Support		6.0 (2.9)	7.6 (2.3)	6 (3, 9)	8 (5, 10)

Table 8.13 shows that small absolute increases were observed across all SIM items, although this was not confirmed by inferential statistics. For the G4H-D group specifically there were larger increases in representativeness and support than in importance and positivity.

8.1.5. Sample size calculation

Sample size calculations were conducted using the PHQ-9 as the primary outcome measure, which showed a mean of 13.9 and standard deviation of 7.1. To power a future RCT of G4H-D with 80% power at two-tailed 5% significance would require 35 participants per arm (70 in total). A 30% attrition rate was observed in this study. Adjusting for this attrition rate would require 50 participants per arm (100 in total) at trial entry.

Calculations based on the clinically meaningful difference score for the PHQ-9 (≤5) indicated that a trial would require 38 participants per arm (76 in total). With a 30% attrition rate this increased to 54 participants per arm (108 in total) at trial entry.

Sensitivity analysis assuming a small effect size (d=0.2) in favour of the intervention and 30% attrition resulted in a required sample of 574 participants per arm (1,148 in total). Assuming a medium effect size (d=0.5) for the intervention and 30% attrition resulted in a required sample of 65 per arm (130 in total) and 93 per arm (186 in total) when accounting for attrition.

8.1.6. Predictors of loneliness and depression outcomes

Table 8.14 shows the correlations between the demographic variables and the change scores for the loneliness and depression measures. Ethnicity is not reported as there was not enough variability in the data as nearly all participants were White British.

Table 8.14 Association between UCLA-8 and PHQ-9 changes scores with demographic and clinical variables (n=19)

	UCLA-8 change	**PHQ-9 change**	**Age (r)**	**Gender (r_s)**	**Treatment history (r)**	**Depression: primary/ secondary (r_s)**	**Therapy: yes/no (r_s)**
UCLA-8 change	1.00						
PHQ-9 change	0.44 (0.056)	1.00					
Age (r)	-0.03 (0.896)	-0.10 (0.665)	1.00				
Gender (r_s)	-0.14 (0.550)	-0.32 (0.179)	-0.18 (0.444)[a]	1.00			
Treatment history (r)	-0.41 (0.075)	0.08 (0.715)	0.32 (0.089)	0.18 (0.439)[a]	1.00		
Depression: primary/ secondary (r_s)	-0.20 (0.408)	-0.12 (0.611)	-0.17 (0.374)[a]	0.355 (0.058)	0.15 (0.445)[a]	1.00	
Therapy: yes/no (r_s)	0.09 (0.712)	0.05 (0.839)	0.20 (0.388)	**-0.51 (0.021)**	-0.34 (0.150)[a]	**-0.51 (0.022)**	1.00

r=pearson correlation; r_s=spearman correlation; [a]spearman correlation reported between continuous and categorical demographic variables; p-values shown in parentheses; bold=p<0.05

Visual inspection of scatterplots indicated that the relationship between the UCLA-8 dependent variable and the seven independent variables was a fairly weak linear relationship for four variables (gender, primary/secondary diagnosis, accessing therapy, accessed one-to-one session). A moderately negative relationship was observed with treatment history, which also appeared slightly curvilinear. This indicates that having more years in treatment was associated with a smaller change in loneliness. A similar curvilinear relationship was found for age. However, these curvilinear relationships were strongly influenced by outliers. The number of sessions attended appeared to have a parabolic relationship with the UCLA-8 but this also appeared to be partly influenced by an outlier, without which the relationship was linear. Sensitivity analyses were conducted by running models with and without bivariate outliers and polynomial terms. Similar relationships were found for the PHQ-9, except that treatment history showed a slightly positive linear relationship.

The results of hierarchical regression analysis are shown in Table 8.15 for the UCLA-8 and Table 8.16 for the PHQ-9. Residual analysis indicated that the statistical assumptions were confirmed for both models. Sensitivity analyses found that the results did not substantively change when using different modelling assumptions and without bivariate outliers.

Table 8.15 Hierarchical regression on loneliness (UCLA-8) change score by baseline loneliness, sociodemographic and clinical characteristics, and G4H-D attendance (n=19)

Independent variables	Change in UCLA-8							
	Step 1		Step 2		Step 3		Step 4	
	β	Sig.	β	Sig.	β	Sig.	β	Sig.
Baseline loneliness severity	-0.118	0.340	-0.103	0.427	-0.249	0.137	-0.277	0.149
Age			-0.17	0.676	-0.052	0.262	-0.080	0.220
Male gender			0.929	0.426	0.954	0.489	1.034	0.495
Treatment history (years)					0.066	0.320	0.063	0.399
Baseline depression severity					0.198	0.249	0.191	0.356
Secondary depression diagnosis					2.731	0.112	2.698	0.213
Accessing therapy					1.771	0.289	2.513	0.267
Attended 1-1 G4H-D session							0.646	0.763
Number of G4H-D sessions							0.835	0.456
R^2 (Adjusted R^2)	0.057 (-0.00)		0.111 (-0.079)		0.451 (0.066)		0.495 (-0.073)	
R^2 change			0.054		0.340		0.044	
F change			0.425		1.548		0.349	
Sig. F change			0.661		0.242		0.713	

β=unstandardised beta coefficient

Table 8.16 Hierarchical regression on depression (PHQ-9) change score by baseline depression, sociodemographic and clinical characteristics, and G4H-D attendance (n=19)

Independent variables	Change in PHQ-9							
	Step 1		Step 2		Step 3		Step 4	
	β	Sig.	β	Sig.	β	Sig.	β	Sig.
Baseline depression severity	0.076	0.789	0.215	0.468	0.217	0.561	0.168	0.743
Age			0.048	0.624	0.035	0.777	-0.045	0.794
Male gender			4.347	0.140	4.177	0.292	4.393	0.300
Treatment history (years)					-0.110	0.546	-0.121	0.554
Secondary depression diagnosis					2.375	0.586	2.276	0.689
Accessing therapy					1.484	0.740	3.556	0.555
Attended 1-1 G4H-D session							2.070	0.723
Number of G4H-D sessions							2.228	0.454
R^2 (Adjusted R^2)	0.004 (-0.057)		0.163 (-0.015)		0.205 (-0.228)		0.263 (-0.391)	
R^2 change			0.159		0.042		0.058	
F change			1.332		0.192		0.355	
Sig. F change			0.292		0.900		0.709	

As seen in Tables 8.15 and 8.16, none of the independent variables showed a significant association with the UCLA-8 or PHQ-9 dependent variables. A relatively large proportion of the variance in the UCLA-8 dependent variable was predictable from the independent variables (Table 8.15, Model 4 R^2=0.495) but this appears to be due to the large number of independent variables in the model (Model 4 Adjusted R^2=-0.073).

8.1.7. Process evaluation

Implementation

Over half of the time in each session was taken up by group discussion which meant that some of the planned exercises were not completed in each group. This resulted in a number of exercises and discussion points being prioritised in each session as follows:

Session 1: Icebreaker; discussing the link between social connectedness and depression.

Session 2: SIM exercise.

Session 3: BBQ party; discussing barriers to connecting with existing social ties.

Session 4: Pie chart exercise; goal-setting exercise.

Session 5: SIM exercise; discussing challenges in achieving goals.

For the exercises undertaken in the group sessions, all participants were able to take part and complete these exercises in their workbooks with minimal support from the facilitators. However, the SIM procedure was reported to be complex and difficult to complete by many participants.

In the first group cohort most of the exercises planned for the first session were not completed as there were delays in starting this session. For this cohort, only the introduction to the group and the icebreaker exercise were completed.

One-to-one semi-structured interviews

A total of 13 participants took part in interviews, comprising 12 intervention completers and one dropout. The dropout participant had not taken part in any of the intervention activities.

A coding framework was developed (as described in Section 7.7.2, p.218) and applied to the interview data (see Table 8.17).

Table 8.17 Coding framework for the acceptability, perceived mechanisms, reported outcomes, and contextual factors of the intervention

Superordinate themes	Subordinate themes
1. Group member characteristics	1.1 Shared mental health experiences support social connectedness 1.2 Diversity of group members' backgrounds 1.3 Mental health symptoms can interfere with the intervention processes
2. Facilitator characteristics	
3. Intervention structure and workbook	3.1 One-to-one session 3.2 Number of sessions 3.3 Time of sessions 3.4 Room size 3.5 Participant workbook
4. Group processes	4.1 Feeling accepted and supported 4.2 Group discussion and mutual disclosure 4.3 Increasing trust and comfortableness 4.4 Valuing the group 4.5 Group unity

Table 8.17 continued

5. Group exercises	5.1 Participant self-reflection 5.2 Identifying and overcoming barriers to social connectedness 5.3 Goal-setting 5.4 Handouts
6. Reported outcomes	6.1 Greater motivation to re-engage socially 6.2 Behavioural changes 6.3 New approaches and perspectives on relationships 6.4 Re-learning and practicing social skills 6.5 Greater social confidence 6.6 No changes
7. Contextual factors	7.1 Location and accessibility of the group 7.2 Social support from others outside the intervention

These themes are now elaborated.

Group member characteristics

Shared mental health experiences support social connectedness

Knowing that other members of the group were struggling with similar mental health experiences helped participants to integrate into the group. Shared mental health experiences engendered increased feelings of acceptance, social support, group unity, increased confidence to self-disclose and share experiences, and reduced feelings of being different from others.

> *Yeah, I always find it reassuring to be with other people who are depressives. It's always reassuring to know that you're experiencing the same things…And again, there was that, "Oh good one, I'm not the only alien on the planet... Because you're talking about something that's a day to day experience for us. See I can say "us" because everybody seemed to feel the same."* (Participant #10)

Diversity of group members' backgrounds

Some participants positively commented on the diversity of the group. Participants valued the different perspectives which other members of the group brought to bear upon their shared experiences.

> *Even though we had the shared core of our depression and social anxiety, we all came with our challenges from slightly different ways and achieved them in slightly different ways.* (Participant #10)

One negative case regarding the diversity of sociodemographic characteristics came from a young participant in her early twenties in a group of others aged 50 to 60.

> *I was easily the youngest person there…it's a little bit ostracizing.* (Participant #14)

Mental health symptoms can interfere with the intervention processes

Mental health symptoms were a barrier to participation and engagement in the intervention. The dropout participant cited her mental health challenges as the main barrier to attending the group.

> *Agoraphobia [means] some weeks I can get out…some days I can't. And part of the mental health problem is that I don't want to be letting people down, so I don't want to say take somebody's place and then an hour before the group say, no I can't get out of the door today.* (Participant #24)

Participants who attended the group noted that fluctuations in their mental health affected whether they could attend particular sessions or engage with the exercises and group discussions.

> *At the time I was quite unwell and I couldn't really, as I say, I couldn't really cope with the amount of written work [in the group]… Well, I missed the last session because I was having a bit of a downer*. (Participant #30)

Facilitator characteristics

The intervention facilitators were perceived to be supportive and listened to the group members. Facilitators' non-judgemental attitudes were noted as being particularly helpful.

> *The, [name of co-facilitator] being there, you being there, not judgemental, allowing us to talk, very helpful towards me*. (Participant #30)

Self-disclosure by the facilitators also encouraged other group members to self-disclose themselves which was found to be beneficial.

> *I liked that you shared your experiences with us. Yeah I found that good because sometimes nobody wants to be the first one to speak up…then it felt easier to share our experiences.* (Participant #17)

Intervention structure and workbook

One-to-one session

Meeting one-to-one with a group facilitator to build rapport prior to the group sessions was seen as beneficial. Participants felt more confident and able to attend the group as they were more familiar with the group facilitator.

> *I think it did make it easier, I mean if the group had been led by someone I had never met before it would have been a lot more intimidating.* (Participant #19)

Although it was not a planned feature, the one-to-one sessions also provided an opportunity for participants to discuss any potential barriers they might face in attending the group or engaging with the exercises which was felt to be reassuring.

> *I thought you would probably understand my situation a bit better [after the one-to-one session]. And I know there was some things I couldn't talk to the rest of the group about, because they are personal to me and that.* (Participant #23)

At the time of the interview the dropout participant did not realise that a one-to-one session was a component of the intervention. When asked what might have helped her attend the group, she responded that meeting a facilitator beforehand to discuss her barriers to attending the group would have helped.

> *If I get to know the person [facilitator] first maybe I am…you know a visit to my home or something. Build up a bit of trust and get to know that person for a brief time, and then have a look at, at that point have a look at what are my barriers to even getting to that group.* (Participant #24)

Number of sessions

The length of the intervention was thought to be too short with only one participant suggesting that the six-week duration was sufficient. Participants suggested that a longer duration would have enabled them to make more sustained progress on their social goals, formed stronger bonds within the group, and provided more time to go through the workbook material.

> *Having more sessions would have worked better for me…now we have finished I have no one to be accountable for. So I feel like in the back of my mind I am slowly going to start slinking back again, and I don't want to.* (Participant #14)

Time of sessions

Three participants raised the issue of group timings. One participant noted that he had initially declined to attend the group when it was scheduled for the late afternoon as this clashed with his other commitments. Another participant in a separate group reported that she missed a session when she was feeling unwell which was partly because her group was scheduled in the late afternoon which made her feel anxious about getting home afterwards. A third participant noted that her mental health challenges give her sleeping problems and that she would have missed a lot of sessions had they been in the morning.

> *I'm suffering from anxiety and I was bit concerned about the lateness of the group because I didn't finish at half past four, well I've got a long way to go…so that's probably why I didn't come to the last one*. (Participant #30)

Room size

The size of the group relative to the size of the room in which the group met was highlighted. Two participants from one group reported that the first session was less comfortable because it was a large group in a small room and felt crowded. A third participant from another group suggested that the room in which her group met was too big for the number of people in her group which made other members feel more distant.

> *No, the room was too big. Yeah, it would have been nicer to have…something that reflected the group size…sometimes it seemed like one of those dinner tables that people sit either end, whereas I think if we'd been even just a chair apart, because that old lady, [participant], it became a bit cliquey her and [participant].* (Participant #10)

Participant workbook

Most participants reported that the participant workbook was both accessible and engaging. However, one participant suggested that the language was not accessible as well as suggesting that, due to her concentration difficulties, the workbook could be designed with a bigger font size and coloured text to highlight key messages. Two other participants also suggested that the dark colouring used in one section of the workbook made it harder to read the text and complete the exercises.

> *Some of the colours were a bit dark. I think it was [section] five had a whole block that was really dark, it was really hard to read. But other than that, no, it was good*. (Participant #10)

Group processes

Feeling accepted and supported

Participants described feeling both accepted and supported within the group. These perceptions were partly attributed to the actions of the facilitators and partly to participants' knowledge that other group members had similar mental health experiences. Participants reported feeling accepted quite early on in the intervention as they knew from the start that everyone had shared difficulties.

> *I think that [feeling accepted] was probably from the end of the first session. Because I mean everybody had had a word and everybody knew that we wouldn't be in that group if we didn't have some shared experiences or some shared damage.* (Participant #10)

The perceived supportiveness of the group stemmed from two sources. First, participants found it reassuring that their more troubling experiences were shared by others which reduced their sense of isolation. Second, group members

discussed different perspectives on, and strategies for, their common difficulties which others had not previously considered and found useful to know about.

> *I found it really, really supportive that there were people round the table saying the same thing that I felt, somebody who said, for example, I can sit in an armchair and it takes me two hours to summon up the energy to go and clean my teeth and I'm thinking yes, that's exactly how I feel and the value in somebody else saying that reduces the feelings of isolation greatly.* (Participant #7)

Group discussion and mutual disclosure

The opportunity to share and discuss their experiences, including some of their personal difficulties, was described by participants as one of the most beneficial features of their participation. Two benefits from this process emerged from the interviews. First, it allowed participants to express themselves and any difficulties which were quite central to their day-to-day lives. Second, mutual disclosure helped to support other group processes, such as increasing familiarity, trust and acceptance between participants.

> *Yeah, it was just nice to have the opportunity to speak. Because I don't share my experiences with people outside of my medical care team, you know with family.* (Participant #8)

The group discussion was explicitly described by a few participants as being a more useful component of the intervention than the specific exercises. Many participants described the flexibility of the group as being beneficial for this reason.

> *…but the written material wasn't that important and I think the group became more important than the actual written work really* (Participant #30)

Increasing trust and comfortableness

The first group session was experienced as difficult and anxiety-provoking but later sessions became easier. Engaging in the intervention helped one participant to realise that groups eventually become safe.

> *…it made me realise that, to stay well, we have to have interaction with other people and group situations become safe after a while.* (Participant #30)

Feeling safer and more connected within the groups was related to the regular contact of the group and mutual disclosure within discussions which increased participants' trust and comfortableness with each other.

> *Yeah, I think it was more of a getting to feel the rhythm of it and beginning to trust each other. Like I knew you and I knew [intervention co-facilitator] very well, but there's always that kind of experimental to see how the others react and sounding people out.* (Participant #10)

Valuing the group

Participants reported that they began to see the group as important during the course of the intervention. Increases in the perceived value of the group encouraged participants' attendance and engagement within sessions.

> *No [nothing else supported my involvement] … I don't think so other than being part of the group itself and, as I say, it became, even though it was a relatively short period of time, it did become important to me and I started to look forward to seeing everybody who was involved.* (Participant #7)

Group unity

Participants felt that a degree of group unity or identity had emerged towards the end of the intervention.

> *…eventually once we got to know each other a bit and get a bit more comfortable... it felt just like a circle of … not really friends at first, because we didn't know each other very well, but a team.* (Participant #19)

However, some participants stressed that the group unity was relatively unstable and that the group might have become self-sustaining only after a longer intervention.

> *…even though we all exchanged numbers and things I don't think I would call people. Whereas had you been going a little bit longer then it might have given you more of a group identity.* (Participant #8)

Group exercises

Participant self-reflection

The main benefit of the session exercises was how they prompted a process of self-reflection for participants. The exercises concerning participant's existing networks helped people to identify elements of their existing social networks which they had not previously acknowledged, both positive and negative, in ways they found to be useful.

> *I don't think we'd have had a go [at re-joining a group] if it hadn't been for having the sessions, because until I charted everything, that was Session Two when we did all the little squares, I hadn't realised how important some groups were to me, the groups that I still had in my life, and how many groups I'd lost, I'd turned away from.* (Participant #10)

However, several participants noted that the exercises concerning people's existing social networks problematically assumed that everyone had at least some social contacts. Those without a social network found these exercises off-putting and left them feeling excluded.

> *I found some of it challenging… there was almost a supposition that you did belong to some groups and that you did have some kind of social interactions myself. With no family to speak of, no children, not working, living on my own, being very isolated, a lot of it self-imposed, felt quite difficult doing the exercises…that really just fazed me and I was surprised how strong that was.* (Participant #2)

The pie chart exercise, which asked people to map out their personal and social identities, helped participants to reflect on some of the more positive aspects of their identity which they do not normally consider.

> *…it made me think that when you're depressed you think you're totally worthless, but later when you look back on it you have a very different idea and doing that pie chart brought it home to me.* (Participant #19)

However, some participants found this exercise difficult to complete because their self-concept was either unstable or solely negative.

> *When I think about myself it's just well, I'm angry, frustrated, I can't be bothered. You asked about that other stuff, hobbies and values but that's, that's not how I think about myself.* (Participant #4)

Identifying and overcoming barriers to social connectedness

Some of the exercises involved identifying personal barriers to social connectedness and potential strategies to overcome these barriers. Participants reported that it was relatively easy to identify their main obstacles in connecting with others. These barriers were predominantly psychological, including low self-

esteem, fears of rejection or of not fitting in, and certain behavioural habits.

> *Yes, my biggest barrier is me and my lack of belief that I am worth other people's time.* (Participant #14)

Some participants reported that they had managed to identify a potential strategy to overcome their personal barriers within the group whilst others suggested that the group had not helped them to do this.

> *It has yeah, because it makes you look at it, stuff like a different way. Because the problem with my friend and stuff it's … I realise now that I am going to write stuff, if I have got it in my head, I will write it down, instead of writing it to her. And then let her see it another day, so I am not going to fall out with her or whatever, that's one thing that's helped me to understand.* (Participant #17)

> *I mean barriers are barriers aren't they? You can't do very much about that.* (Participant #4)

Goal-setting

One exercise was for participants to set themselves one or more social goals to attempt and report back on their progress to the group. Some participants reported that they had been able to set themselves a goal and act upon it. However, some participants reported that they found the process of identifying an appropriate goal too difficult or felt currently unable to act on their goals.

> *But the goal setting I found very challenging, it was trying to find a goal that was both challenging and feasible is difficult. Because there are some things that I could think of that are definitely challenging, but there is no way I have been able to do them yet. And some that would have been feasible, but far too easy to be worth bothering with.* (Participant #19)

The importance of having ongoing support from the group was highlighted in case participants' goals had not gone to plan.

> *…if it had been disastrous, then not having therapy [G4H-D] to back me up, I would have needed to come to the group in that way and say, "Oh my God, this didn't work, what did I do wrong?"…I think if I'd set myself to go to a group that was a hostile environment, then Session Five would have been extremely important, because either I'd have had a great challenge and done really well or I'd have failed miserably and needed friends around me to give me the courage to try again.* (Participant #10)

Handouts

A handout which listed other potential social groups and opportunities in the local area was distributed at the final session. However, none of the participants reported using this handout and thus it did not appear to be useful.

Reported outcomes

Participants reported a range of beneficial outcomes as a result of the intervention. No adverse outcomes were reported.

Greater motivation to re-engage socially

Most participants described how G4H-D had given them the motivation to work on their social relationships, including joining other groups, contacting old friends and being more proactive in existing groups.

> *Because that's what I have been wanting to do lately: to do things I haven't done before. And I think this [G4H-D] has given me an incentive to do things… gets you out to do things, whereas otherwise you probably wouldn't do and that. And that's what I found good about it.* (Participant #23)

Behavioural changes

A few participants reported having taken steps to increase their social connectedness. Changes to participants' social networks or social behaviours included reconnecting with old friends and re-joining old groups.

> *I wish you'd been there that night when I actually went back to that group, because they didn't jump all over me and overwhelm me and it was so lovely. I had such a nice time and just got to catch up with people I hadn't seen for nearly two years…I feel that that door's open now, whereas before it was slammed shut.* (Participant #10)

One participant reported that he had dropped a number of his groups following G4H-D. He suggested that the intervention had given him a chance to reflect on both the benefits and the drawbacks of group memberships and that he had realised he would be more satisfied with a smaller social network.

> *It also made me realise which groups were the most important, i.e. which groups were positive and negative, so therefore which groups were good for me. I went away to think about this approach later and decided to get rid of some of my groups… just because you're in a group doesn't mean it's something you want to be in, it just happens to be where you are standing, it doesn't mean that you're actually involved in that group or want to be.* (Participant #4)

New approaches and perspectives on relationships

Some participants reported that attending the intervention had given them a different perspective or approach to their relationships. This included changes in people's perceptions of themselves and others as well as new strategies to use to develop and maintain relationships.

> *There's nothing wrong [with me]...I realise now, one of the barriers I've had to joining groups is they'll get to know me and they won't like me. Perfectly alright to join a group and just be the person you are in that group and not have all the rest of it and I'm quite excited by that idea now.* (Participant #2)

Re-learning and practicing social skills

Some participants reported that long periods of isolation or hospitalisation had meant that their social skills were left unpractised. The group had provided them with the opportunity to practice and relearn their social skills in safe space.

> *It helped me rediscover my social skills because I felt as if I'd lost them coming from hospital and was not able to talk and my memory was very poor…I think that they were non-judgemental…in a closed group like that it was easier to talk about things*. (Participant #30)

However, other participants stated that the group had not had any impact upon their social skills, which they felt were already well developed.

> *I don't think I was lacking in social skills before, but, and as I'm in my sixties I don't think my social skills are going to suddenly change by being part of one group, I think I've developed all of that before.* (Participant #9)

Greater social confidence

Some participants reported that they felt more confident to engage in social activities since attending the intervention. Participants suggested that being part of the G4H-D group gave them enough support and encouragement to attempt new social activities. Participants who had achieved the social goals they set themselves during the intervention suggested that this success had given them more confidence to attempt further social activities in the future.

> *It [G4H-D] challenged me to do something a bit different, to return to a social group that I'd been in before that I was missing, but not really going to do, so it gave me the courage to dare myself to go… it worked really well. As a matter of fact, it exceeded expectation so it makes me a little bit braver to try again… gives me courage to try again with some of the others that I've walked away from. Because it might work next time.* (Participant #10)

No changes

Two participants reported that they had not experienced any tangible changes since attending G4H-D and suggested that this was due to the short timescale of the intervention.

> *I don't think there is a generally short-term difference in things I do, I think it all adds up eventually. I think it has definitely helped me, I mean it's helped me to apply myself to some new ideas. But it's going to be some time before if there is any noticeable … it's not like I am just going to go for a group and then be a different person.* (Participant #19)

Contextual factors

Location and accessibility of the group

The accessibility of the group was important in terms of its proximity to where participants live as well as parking availability or other transport options. Location was reported to be both a barrier and facilitator of attendance. Participants who happened to be based quite close to where the intervention was held found this facilitated their attendance whilst those living further away found this to be a barrier. Participants living further away reported that distance was a barrier both in terms of travelling time but also how in how well they integrated into the group.

> *…it's a distance thing because I had to come so far to come to the group…It's also money because for me to form friendships in [city] and be driving to [city] is quite difficult, both on a financial and an anxiety level of driving places…I didn't really feel, as I say, I didn't really feel an allegiance with the people on the group and I think it was just my own pre-conception once I found out they all lived in [city].* (Participant #2)

Social support from others outside the intervention

Some participants suggested that individuals outside of the intervention, including both friends and clinicians, had encouraged and supported their involvement in G4H-D. For a few participants, clinicians had recommended that they participate in G4H-D which gave the intervention some credibility and some clinicians subsequently checked whether they were still attending the group.

> *It was just my friend [who supported my involvement], my friend [anon] yeah.* (Participant #17)

Reflexivity

In this study I led the G4H-D groups, conducted the interviews, and was one of the two data analysts. Performing each of these roles created at least two potential sources of influence on the process evaluation. First, by the time of the interviews I had already formed some impressions about whether G4H-D had been helpful and why. This may have sensitised me to parts of the data that confirmed my pre-existing beliefs. For this reason, an independent researcher was involved in the analysis. Second, some of the data concerned the characteristics of the facilitators. Participants may have felt obliged to report overly positive experiences of the group facilitation. However, I also felt that I had developed good relationships with the participants and that many would therefore feel comfortable offering me critical feedback. Such feedback was also explicitly invited before the start of the interview.

8.2. Discussion

The aim of this study was to evaluate the feasibility of delivering G4H-D in a future clinical trial. This section will discuss the results in relation to the eight study objectives as well as the strengths and limitations of the study. The next chapter will offer a more wide ranging discussion of the implications of the results, including the design of a future clinical trial. The results corresponding to the eight feasibility study objectives that were set out at the start of this chapter will now be discussed in turn.

8.2.1. Objective 1: Estimate recruitment rate

Five participants per month were recruited into this study on average. Given the likely sample size required for a definitive trial (see Section 8.1.5), this represents a relatively low recruitment rate. By comparison, a physical activity trial for adults with depression had a recruitment rate of 18 participants a month which was judged to be low and resulted in amendments to the trial protocol (Chalder et al., 2012). However, there was only one person conducting the recruitment activities in this study (LHD). A larger trial team is likely to attain a higher recruitment rate and may also involve several centres. For example, 100 participants could be recruited over five months by a team of four researchers at the estimated recruitment rate. In addition, new strategies such as having the trial adopted by the National Institute for Health Research Clinical Research Network may be useful.

8.2.2. Objective 2: Estimate dropout/completion rates

In this study 69% of participants completed the intervention and 31% of participants dropped out. Of those who dropped out, 17% did so before the intervention and 14% did so during the intervention. The dropout rate is comparable to that seen in group psychotherapy. Meta-analyses of group psychotherapy have found an average pre-intervention dropout rate of 15%

(Fernandez et al., 2015) and 20% during-intervention (Swift & Greenberg, 2012). This suggests that the estimated dropout rate in this study is reasonably accurate and within the expected range for mental health interventions.

8.2.3. Objective 3: Evaluate acceptability of the intervention

All process evaluation interview participants who completed the intervention indicated that G4H-D was acceptable in its current form. The interview participant who had dropped out, and was unaware that a one-to-one session was included as part of G4H-D, suggested that intervention was unacceptable primarily because she would have liked a one-to-one session before the group.

Dropout rate can also be used as a proxy indicator of acceptability (Okumura & Ichikura, 2014). The dropout rate in this study is comparable to that of group psychotherapy which is considered to be an acceptable clinical intervention and often implemented in practice (Morris, 2016).

The findings from this study fit with other studies which have found that related psychosocial interventions using facilitated peer support groups are acceptable to adults with clinical depression (e.g. Ali et al., 2010; Gater et al., 2010).

8.2.4. Objective 4: Evaluate candidate outcome measures

Evaluation of the candidate outcome measures for a future trial indicated four findings. First, the PHQ-9 showed the largest change and may therefore be the appropriate primary outcome measure for a trial. Second, UCLA-8 scores also showed a small reduction and changes in UCLA-8 and PHQ-9 scores were correlated. This suggests that the UCLA-8 is a candidate secondary outcome measure for a trial.

Third, the SIM data and the process evaluation findings suggested that some participants increased their social engagement following the intervention.

However, the data collected on the SIM was limited and it was noted in the field notes that participants found the SIM to be difficult and complex to complete. In addition, it may be noted that the SIM is incorporated into the intervention and was completed during group session two, rather than at baseline, which may have influenced the results. Therefore, another measure of specific social connectedness may be used. Other candidate measures of specific social connectedness identified in the systematic review reported in Chapter 4 focused on particular domains, such as connectedness to a therapy group or a community group. However, it would be more appropriate to use a generic measure that does not specify which types of relationships G4H-D participants might choose to pursue. Therefore, a validated measure such as the Social Network Schedule, which assesses the quantity and quality of mental health service users social networks (Dunn et al., 1990; Wang et al., 2017), could be used as a secondary outcome measure in a trial.

Fourth, the SIM data and the process evaluation findings also suggested that participants felt more connected within the G4H-D group. A measure of the dynamics of mental health intervention groups, such as the Group Questionnaire (Krogel et al., 2013), may therefore be used as part of a trial process evaluation.

There are at least four possible explanations for the large reduction in depressive symptoms observed in this study. First, the result may have been due to random variation in the measurement of depression. In this case there may have been participants with a mean score in the normal range but who had an extreme score at baseline by chance. For such participants their scores will, on average, tend to fall in subsequent assessments; a phenomenon known as regression to the mean. However, it was found that baseline severity of depression did not predict change in depression scores in this study. This may suggest that there was not a strong tendency towards regression to the mean. Second, depression has a fluctuating

course (Vergunst et al., 2013) and therefore the result may have been due to a time effect. Third, participants' on-going treatment in secondary care may have led to a reduction in their symptomatology. It was not possible to evaluate this hypothesis in this study as no control group was used. Fourth, there may have been an intervention effect as intended, namely an increase in social connectedness. Some theoretical perspectives on depression suggest that interpersonal functioning plays a central role in the condition (e.g. Hames et al., 2013; Joiner & Coyne, 1999). Thus, it is plausible that an increase in social connectedness could have reduced participants' depressive symptoms. In summary, uncertainty about the effect of the intervention on depressive symptomatology means it would be appropriate to evaluate G4H-D in a clinical trial.

8.2.5. Objective 5: Evaluate contextual factors influencing outcomes

The process evaluation findings indicated that the location and accessibility of the group was an important contextual factor determining intervention engagement. This suggests that the intervention should be held at a venue which is known and accessible to participants, such as community mental health team bases or other community venues. In addition, the size of the room in which the group is held was found to influence participants' perceptions of the intervention. Therefore, a room which is appropriate to the size of the intervention group would be most appropriate.

This study also examined context in terms of evaluating which population groups G4H-D might be most effective for and where the intervention might be situated within secondary care but the findings were unclear. The majority of participants in this study were female, White British, and aged 40-60. However, the observed changes in depression and loneliness did not vary by age or gender in this study, suggesting that G4H-D may be applicable for a range of demographic groups.

Moreover, the similarity in demographics between the sample in this study and the sample used in the Morriss et al. trial of the Specialist Depression Service (see Appendix 9) suggests that the demographic profile in this study was not driven by different treatment preferences or the acceptability of G4H-D to different groups. Rather, it seems to reflect more general differences in access to mental health services across population groups.

Similarly, clinical characteristics such as diagnosis, treatment history, and access to psychotherapy did not predict changes in depression or loneliness. However, it is unclear what role diagnosis played in the study. On the one hand, there were no differences in change in loneliness or depression between those with a primary and those with a secondary diagnosis of depression. In contrast, the process evaluation findings suggested that shared mental health experiences within the group, in particular shared depressive symptoms, improved the experience of some participants. Further research is required to determine whether G4H-D is effective in each of three scenarios: (1) targeted at a particular diagnostic group such as depression; (2) delivered to a variety of different diagnostic groups but with a homogenous diagnostic casemix in each group; and (3) delivered as a transdiagnostic intervention.

8.2.6. Objective 6: Estimate sample size requirements

It was estimated in Section 8.1.5 that 100 participants would be required to power a definitive trial of G4H-D using the PHQ-9 as the primary outcome measure. However, the feasibility study used a small sample and did not meet the quality criteria of well-funded trials. It is known that inflated effect sizes often result from studies using small samples (Zhang et al., 2013) or of low quality design (Cuijpers et al., 2010). This could lead to an underestimation of the sample size needed for a fully powered trial. Additional analyses were therefore conducted in line with best practice (Leon et al., 2011).

A second analysis used an estimate based upon the minimum clinically meaningful difference score for the PHQ-9 (Löwe et al., 2004). It was estimated that 54 participants per arm (108 in total) at study entry would be required to adequately power a trial. This estimate may be used to inform the design of a future trial given the small sample limitations of the study. It can be noted, however, that the two power calculations did not differ substantively. This is because the mean difference score observed in this study (5.16) was very similar to the minimum clinically meaningful difference score (≥5) on the PHQ-9.

8.2.7. Objective 7: Identify potential refinements to the intervention

There were three specific refinements to G4H-D which were indicated in this study: adapting the SIM procedure; adapting the one-to-one session; and adding more sessions to the intervention.

First, the SIM procedure may need to be refined for adults with depression. As well as being used as a measure of social connectedness in this study, the SIM procedure is also embedded into the G4H-D intervention itself as an activity which takes place in two of the sessions. It has already been discussed that some participants found the SIM to be complex and difficult to complete. At the same time, some participants reported that the SIM exercise helped to reflect on the positives of their existing social networks and motivated them to socially re-engage. Therefore, it may be recommended that a simpler version of the SIM, involving fewer elements and instructions, could be used in a future trial. For example, instructions for the SIM which were particularly confusing, such as asking 'How representative are you of this group?', and elements which were not viewed as being particularly helpful, such as ratings of compatibility between groups, could be omitted.

The second refinement of the intervention concerns the one-to-one session. The one-to-one sessions were originally designed to achieve two aims: (a) increase

participants' familiarity with one of the group facilitators, and (b) increase participants' motivation for attending the group sessions by discussing their hopes and goals. These sessions were seen as beneficial to participants and the findings suggested that these sessions improved attendance rates for the group sessions. However, it is also noteworthy that dropout participants showed higher rates of social avoidance than completers. A third aim of the one-to-one sessions could therefore be to more actively address the potential barriers to attending the group faced by participants with high levels of social avoidance. This fits with the recommended practice within group psychotherapy of using additional one-to-one sessions to identify and resolve issues that precludes the participant's work in the group (Yalom & Leszcz, 2005).

The third refinement indicated by this study is to extend the length of the intervention by increasing the number of group sessions. It can be noted that it is not uncommon for psychosocial intervention recipients to suggest that interventions are too short even where they appear to be effective. For example, a 10-week clinical trial compared a peer support group intervention with an antidepressant control arm. There was a greater reduction in depressive symptoms in the intervention arm yet participants reported that the group was too short to meet their needs (Gater et al., 2010). Nevertheless, it should also be acknowledged that extending the length of the intervention was one of the key recommendations made by stakeholders during the development of G4H-D described in Chapter 6. Therefore, this refinement needs to be explored further.

It was unclear from the evaluation precisely how many more sessions would be required. One benchmark comes from a meta-analysis of group psychotherapy which examined the correlation between group cohesion and improvement in symptomatology. The authors found that group interventions consisting of 12 or more sessions demonstrated the strongest correlation between cohesion and

improved outcomes (Burlingame et al., 2011). Assuming that approximately 12 sessions would be required to achieve optimal outcomes in G4H-D, this would indicate that seven more sessions would need to be added to the current intervention. This raises the question of what content should be added to these additional sessions, which will be explored further in the next chapter.

8.2.8. Objective 8: Identify potential refinements to the logic model

The findings from the process evaluation broadly supported the G4H-D logic model developed in Chapter 6, including the proposed mechanisms of change (see Figure 6.3, p.183). However, there was no evidence of change for two of the outcomes specified in the model, non-specific social connectedness and social anxiety, using the INQ-TB or LSAS measures respectively. These outcomes may therefore be omitted from the logic model. The final amended logic model is shown in Appendix 10.

G4H-D was not designed to target social anxiety specifically so the study findings may not be surprising for this outcome. Given that G4H-D is intended to be a social connectedness intervention, the finding for non-specific social connectedness is worth exploring further however. Research in the related area of social support may help understand why the INQ-TB showed no change in this study. Social support is typically categorised into actual support and perceived support. Perceived support is understood to relate to one's attributions and expectations of the global availability of support (House et al., 1988). Research suggests that perceived support is a relatively stable characteristic and is linked to one's self-concept (Blain et al., 1993; Sarason et al., 1991). It has been theorised that perceived social support is a trait which develops as a product of one's history of social interactions and experiences of actual support in different contexts (Sarason et al., 1990). Some theorists have suggested that non-specific social connectedness may operate as a similarly stable characteristic (Lee &

Robbins, 1995), and thus it may not be expected to change over the course of a relatively brief intervention.

8.2.9. Strengths and limitations of the study

Strengths

Exploratory studies can be vulnerable to research design choices made on the basis of researchers' prior beliefs and understandings of the phenomena of interest (Reiter, 2017). Although this was an exploratory study, several design features were chosen on the basis of prior research. For example, the process evaluation was informed by the G4H-D logic model (see Chapter 6) and two of the candidate outcome measures were selected on the basis of a systematic review (see Chapter 4).

Threshold criteria for the feasibility of a potential clinical trial were pre-defined where appropriate benchmarks were available. Specifically, a threshold for dropout rate was set to determine whether a trial would be feasible both in terms of dropout as well as the acceptability of the intervention. This is a recommended practice for feasibility studies but it is often not implemented (Arnold et al., 2009).

Limitations

A convenience sampling approach was used and, as with the previous studies in this thesis, the sample consisted almost entirely of White British participants. The sample therefore does not reflect the general service user population in the UK (NHS Digital, 2018) and the applicability of the results to other ethnic groups is not clear. Further research may need to focus on minority ethnic groups specifically.

None of the demographic or clinical characteristics assessed in this study were associated with changes in depression or loneliness. However, some of the independent variable categories had low frequencies, e.g. there were only seven participants with follow-up data who were attending therapy. Thus, the study is unlikely to have been powered to detect any relevant group differences. The regression estimates may have also been unstable due to the low sample size (Maxwell, 2000). Moreover, the data for the service use history variable was incomplete. Therefore, it may be recommended that these sociodemographic and clinical characteristics are re-examined in a future definitive trial when a larger sample is available for analysis.

This study lacked a control group and the assessment procedures were unblinded. It was therefore not possible to evaluate some of the trial parameters recommended for feasibility studies, such as participants' willingness to be randomised, feasibility of blinding, or the acceptability of control group procedures (Leon et al., 2011).

Data from this feasibility study was used to perform power calculations for a clinical trial. This approach is controversial due to the inherent imprecision in effect size estimates from studies with small samples (Kraemer et al., 2006). A large effect size was found for the PHQ-9 in this study. Sensitivity analyses using reduced effect size estimates were therefore used to in order to explore the risk that a future trial would be underpowered. It is also recommended that power calculations for future trials use effect size estimates are based upon clinically meaningful effects (Leon et al., 2011). In the case of the PHQ-9 this is estimated to be a 5-point difference (Löwe et al., 2004), which was approximately the mean difference observed in this study.

Finally, LHD developed G4H-D, facilitated the G4H-D groups, and conducted the data collection and analysis. This may have biased the results in favour of the

intervention. Future evaluation of G4H-D should use independent researchers and clinicians at each stage of the study and employ blinding procedures to address this potential bias (Day & Altman, 2000).

8.3. Chapter conclusion

This chapter reported on the results of the feasibility study of G4H-D. The results indicated that the G4H-D intervention is feasible to deliver to adults accessing secondary care services for depression. This provides evidence that a clinical trial of G4H-D would be warranted. Chapter 9 discusses candidate refinements to the intervention, the potential design of a future trial, and the wider implications of the thesis as a whole.

Chapter 9. Discussion and conclusion

Chapter overview

Chapter 8 reported on the results of the G4H-D feasibility study and discussed these in relation to the objectives of that study. Chapter 9 offers a broader discussion covering the thesis as a whole and situates the research within wider literature and debates. Section 9.1 summarises the findings of each of the previously reported studies with regards to the six overall objectives of the thesis. Section 9.2 compares the intervention approach used in this thesis with other approaches. This is used to highlight both the strengths and the limitations of G4H-D. Section 9.3 highlights the implications of the thesis findings for the future development and evaluation of G4H-D. Section 9.4 discusses the general strengths and limitations of this thesis as a whole. Section 9.5 discusses some of the ethical considerations of the thesis. Some personal reflections on the PhD journey are given in Section 9.6. The overall conclusions of the thesis are then given in Section 9.7.

9.1. Summary of the findings for each objective of the thesis

The aims of this thesis were to adapt G4H for adults with depression and to evaluate its feasibility for a future RCT study. The six objectives were:

1. To identify measures of social connectedness for use in mental health research
2. To develop a conceptual framework of social connectedness in mental health
3. To evaluate the validity of the conceptual framework of social connectedness
4. To identify adaptations to the G4H intervention for adults with depression

5. To develop a logic model and intervention manual of adapted G4H for adults with depression
6. To evaluate the feasibility of adapted G4H for adults with depression

These six objectives are shown in Table 9.1, alongside the sub-studies which were conducted to meet these objectives and the main findings.

Table 9.1 Thesis objectives, sub-studies and main findings

Objective		**Chapter**	**Sub-studies**	**Main finding(s)**
1	Measures of social connectedness	4	Systematic review	Review of 22 measures. INQ-TB measure had strongest properties
2	Conceptual framework of social connectedness	4	Systematic review	The CIVIC conceptual framework
3	Validity of the conceptual framework	5	Interview study	The CIVIC-MH conceptual framework
4	Adaptations of G4H for depression	6	1. Interview study 2. G4H pilot study 3. Expert consultation	Ten candidate adaptations to G4H were adopted
5	Model and manual for G4H-D	6	1. Interview study 2. G4H pilot study 3. Expert consultation	Development of the G4H-D logic model and intervention manual
6	Feasibility of G4H-D	7 and 8	Feasibility study	G4H-D was acceptable; PHQ-9 measure is an appropriate primary outcome measure; some intervention refinements were indicated

9.1.1. Objective 1: Measures of social connectedness

The first thesis objective was to identify the range of measures of social connectedness which have been used amongst adults with mental disorders. The measure with the strongest psychometric properties was the INQ-TB which was subsequently used in the G4H-D feasibility study. However, none of the reviewed measures assessed all five dimensions of the CIVIC framework of social connectedness. Therefore, there may be scope to develop a new multi-dimensional measure of social connectedness. Future research to develop a new measure could first involve qualitative studies with adults with mental disorders to determine appropriately worded items to assess each of the five hypothesised dimensions followed by psychometric studies to evaluate the properties of the measure.

A second finding was that the reviewed measures assess social connectedness at two different levels: specific and non-specific. Specific measures assessed social bonds with a single individual, defined groups (e.g. 'sports club') or interpersonal networks (e.g. 'friends' or 'family'). Non-specific measures assessed social bonds with undefined groups (e.g. 'community') or to others in general. Few psychosocial interventions in depression have been evaluated using measures of both specific and non-specific social connectedness (Nagy & Moore, 2017). It is possible that data assessed by specific and non-specific measures will have differential associations with other phenomena such as loneliness, depression and wellbeing. Future survey research may examine the associations between specific and non-specific measures of social connectedness as well as with mental health related outcome measures. The distinction between specific and non-specific measures of social connectedness may also be relevant for the evaluation of interventions (see Section 9.1.6).

9.1.2. Objective 2: Conceptual framework of social connectedness

The CIVIC conceptual framework was developed in order to meet the second objective of the thesis. This framework describes five dimensions of social connectedness: *Closeness*, *Identity and common bond*, *Valued relationships*, *Involvement*, and *Cared for and accepted*.

The main implication of the CIVIC framework for the development of psychosocial interventions is that such interventions may need to target multiple dimensions of social connectedness in order to be most effective. It can be hypothesised that interventions targeting single dimensions such as *Involvement* (e.g. Anderson et al., 2015) will be less effective than interventions such as G4H-D which target multiple dimensions. This hypothesis could be tested in a trial comparing different types of psychosocial interventions on social connectedness.

9.1.3. Objective 3: Validity of the conceptual framework

The validity of the CIVIC framework was assessed in a qualitative interview study. The findings from this study indicated that the CIVIC framework did indeed fit with participants' experiences. However, it should be emphasised that CIVIC framework is not intended to represent a universally applicable model of social connectedness. One risk in developing such frameworks is that they are applied to diverse population groups. For instance, the CIVIC framework has already been used by others to characterise the experiences of adults without mental disorders (Blake et al., 2019). It is assumed here that, even for common or universal experiences such as social connectedness, the greater the aggregation of findings, the less relevant those findings will be to particular individuals and sub-groups. Thus, it is very unlikely that the CIVIC framework can be applied to all adults with mental disorders in all contexts. Future work to develop psychosocial mental health interventions may therefore need to be based upon theoretical frameworks

which are tailored to particular groups in order to maximise their effectiveness (Benish et al., 2011).

In the interview study reported in Chapter 5 the CIVIC framework was found to be contextualised by participants' experiences of mental disorder in two ways. First, participants felt that shared mental health difficulties provided a sufficiently strong basis for social connectedness in its own right. Second, the stigma attached to mental disorders emerged as a key barrier to social connectedness for this group. These findings resulted in the revised CIVIC-MH framework. Hence, whilst the CIVIC framework appeared to describe the participants' experiences of social connectedness in abstract terms, there were particular ways in which these experiences were expressed or impeded for adults with mental disorders. This finding suggests that even if there are universal human motivations for social connectedness, these will become manifest in particular ways for different groups at different times.

The CIVIC-MH framework informed the decision to focus on adults with depression to emphasise the shared experiences of the intervention recipients. There may also be wider implications of these findings in terms of making the shared experiences of mental health service users more visible as a means of increasing social connectedness in clinical settings. One approach might involve supporting service users to develop and share their own stories of mental health. It has been suggested that this would help service users to form social bonds (Gold, 2007) and build collective identities (McWade et al., 2015). There is some preliminary evidence that sharing mental health narratives helps to build connectedness (Rennick-Egglestone et al., 2019) though this approach has not been formally evaluated as an intervention. One way to evaluate this approach may be to conduct a process and outcome evaluation of mental health services

which aim to support people in this manner, such as Recovery Colleges (Nurser et al., 2018).

The finding that adults with mental disorders often socially connect on the basis of their shared experiences of mental disorder is also worth exploring further. As already mentioned, this finding was used to support the decision to restrict participation in the feasibility study to people with a diagnosis of depression. The underlying assumption behind this decision was that participants would form stronger bonds within a group if everyone had experiences of depression specifically, rather than of mental distress more generally. This is an untested assumption and so it remains unproven as to whether G4H-D could be delivered to groups with mixed diagnoses or should be restricted to homogenous groups. It is possible that shared experiences of depressive symptoms can bring people together but it seems equally possible that experiences which are shared across diagnoses may be just as salient, such as functional impairment, discrimination, hopelessness, or isolation (McWade et al., 2015).

Similar ambiguities exist in related literatures. For example, in the case of peer support work it is unclear from empirical papers whether the relationships between peers workers and service users are built upon a shared experience of specific symptoms or of generalised 'mental health problems' (Gillard et al., 2015). In the group psychotherapy literature there is mixed evidence over whether interventions with homogenous diagnostic groups are more effective at reducing symptoms of different disorders than heterogeneous groups (Burlingame et al., 2003; Chamberlain & Norton, 2013). Diagnostic casemix may therefore be a fruitful area for future research into group-based psychosocial interventions and at present it is unclear whether G4H-D may be suitable for diagnostically mixed groups.

Adding to the complexity, it can be noted that some people identify with their diagnostic label itself (Cruwys & Gunaseelan, 2016). Thus, the label of depression itself may be a source of social connectedness for some people. For example, one Australian study of 108 depressed outpatients found that participants identified more strongly with therapy groups which had a stated focus on depression than on anxiety (Cruwys et al., 2019). This may suggest that attaching diagnostic labels to groups can help members to bond but, again, it is also possible that using a broader stated focus for intervention groups such as 'mental health problems' would have the same effect. Equally, some people may not want to identify with a diagnosis (Van Voorhees et al., 2005) and using such labels may interfere with the processes of social connectedness. One implication is that the degree to which participants identify with the diagnostic labels attached to group interventions may be a moderator of effectiveness which could be explored in future research.

9.1.4. Objective 4: Identify adaptations of G4H for depression

The fourth objective of the thesis was to adapt G4H for adults with depression. A number of adaptations were identified in a series of sub-studies with relevant stakeholders and experts. These included psychological challenges, such as low motivation and social anxiety, as well as a risk that the intervention may remind participants of upsetting relationship experiences in the past given the higher rate of traumatic experiences in this population (Mandelli et al., 2015). Related to such challenges was the suggestion that adults with depression would require a longer period of support to increase social connectedness compared to the general population.

What was not clear from the thesis findings was whether diagnosis-specific adaptations were required for adults with depression as opposed to generic adaptations for people with complex psychosocial needs. For instance, the

psychological challenges identified for people with depression are common across various diagnostic groups (Barch, 2004; Barkus & Badcock, 2019; Harvey et al., 2004). The higher likelihood of adverse childhood experiences is also common across multiple different diagnostic groups (Maniglio, 2009), and psychosocial interventions have been adapted to accommodate these experiences in other mental health populations, such as adults with psychosis (e.g. Riches et al., 2016). It may also be noted that most of the participants in the feasibility study had other diagnoses in addition to depression. This may indicate that G4H-D would be suitable for other mental health populations.

In summary, two key findings emerged in relation to Objective 4 of the thesis. First, adaptations to G4H were indeed required for adults with depression. Second, it is not clear that the required adaptations were depression-specific or were adaptations that may be indicted for adults with any mental disorder. Future evaluation of G4H-D with other diagnostic groups is therefore warranted.

9.1.5. Objective 5: Develop model and manual for G4H-D

The fifth thesis objective was to develop a logic model and intervention manual for G4H-D. With regards to the logic model, the hypothesised mechanisms of change (e.g. comfortableness and self-disclosure, experiences validated and normalised) have a considerable overlap with the non-specific mechanisms of change identified within group psychotherapy (Yalom & Leszcz, 2005) and peer support (Gillard et al., 2015). This raises the question of whether G4H-D operates via specific processes particular to the intervention, or generic processes inherent in many psychosocial interventions. This would need to be evaluated in an RCT comparing G4H-D with a neutral comparator which is designed to have non-specific effects, such as a facilitated group which meets regularly to discuss current affairs, but not specific effects related to G4H-D.

9.1.6. Objective 6: Feasibility of G4H-D

The final thesis objective was to evaluate the feasibility of delivering G4H-D to adults with depression. It was found that depressive symptoms would be the appropriate primary outcome domain for this trial given the large reductions in depressive symptoms observed in the feasibility study, with loneliness measured as a secondary outcome domain.

Although G4H-D was designed to increase social connectedness, one measure of social connectedness (INQ-TB) did not show any significant change in the study. This raises the question over whether the reductions observed in participants' depressive symptoms and loneliness were related to changes in social connectedness. The distinction between specific and non-specific social connectedness was discussed in Section 9.1.1. The INQ-TB is a measure of non-specific social connectedness. By contrast, descriptive analyses of the measure of specific social connectedness used in the study (SIM) indicated small average increases in this domain. In addition, participants reported in the process evaluation that group processes characterised by the CIVIC-MH framework were the main mechanisms of change in the intervention. Therefore, one possibility is that G4H-D improves depression and loneliness by increasing specific social connectedness. The mechanisms involved in G4H-D remain unclear, however, and would need to be further evaluated in a later trial.

The reduction in loneliness in the G4H-D feasibility study corresponds to a small effect size (d=-0.28) and can be compared against the large pre-post effect sizes (d=-0.86) found in the original pilot evaluation of G4H with university students (Haslam et al., 2016) and in a recent study with adults with psychological distress (d=-1.04) (Haslam et al., 2019). Table 9.2 shows the study designs and results of these two G4H studies and the G4H-D feasibility study.

Table 9.2 Comparison of G4H and G4H-D study evaluations and results on loneliness and depression outcomes

	G4H pilot study (Haslam et al., 2016)	**G4H RCT (Haslam et al., 2019)**	**G4H-D feasibility study**
Design	Single group, pre-post	RCT	Single group, pre-post
Inclusion criteria	• Score ≤15 on Friendship Scale • Score ≥25 on Kessler Psychological Distress Scale	• Score ≥5 on PHQ-9 OR mental illness diagnosis from a health professional (including GP)	• Aged 18-65 • Score >6 on UCLA-3 • Clinical diagnosis of depression
Country	Australia	Australia	UK
Setting	University	University and community	Secondary care mental health services
Attrition	33%	36%	31%
n[a]	56	120	19
Participants *Age (mean)* *Gender (% female)*	 21 65	 31 64	 48 69
Intervention	G4H: 5 group sessions over 2 months	G4H: 5 group sessions over 2 months	G4H-D: 1 one-to-one session and 5 group sessions over 6 weeks
Outcome measures *Loneliness* *Depression*	 Roberts UCLA Scale Depression, Anxiety, and Stress Scale	 Roberts UCLA Scale Depression, Anxiety, and Stress Scale	 UCLA-8 PHQ-9
Results *Loneliness* *Depression*	 d=-0.86, p<0.001 d=-0.29, p<0.046	 G4H: d=-1.04[b] TAU: d=-0.33[b] p<0.001[c] G4H: d=-0.63[b] TAU: d=-0.34[b] p=0.108[c]	 d=-0.28, p=0.046 d=-0.79, p<0.001

[a]Sample size used in analysis; [b]pre-post effect sizes: no G4H vs TAU effect sizes reported in the study; [c]p-value from mixed effects repeated measures analysis (time x condition)

There are at least four possible explanations for why the reduction in loneliness found in the G4H-D study was lower than that found in the G4H evaluations. First, it is possible that the adaptations made to G4H in this thesis compromised the fidelity of the intervention model and therefore G4H-D is less effective at reducing loneliness as a result. It is argued here that this is unlikely given that the major adaptations involved making additions to the intervention (e.g. adding a one-to-one session) rather than omitting or changing key existing components. Furthermore, the developer of G4H was consulted on the adaptations to ensure that these would not compromise the fidelity of the model.

Second, different measures of loneliness were used in the G4H studies (Roberts UCLA Scale) and the G4H-D study (UCLA-8). Both measures are brief, eight item versions of the 20 item UCLA loneliness scale (Russell et al., 1980). The Roberts UCLA Scale (Roberts et al., 1993) is designed specifically for adolescents whereas the UCLA-8 measure is designed for the general population, which may partly explain the discrepancy in findings between the studies. Nonetheless, given that these two measures are both derived from the same larger measure and share four of the same items, it seems unlikely that the discrepant results can be fully explained by the different measures used.

Third, the G4H intervention is two weeks longer than G4H-D. Therefore, a time effect on loneliness outcomes at post-intervention assessment may partly explain the different results.

Fourth, different inclusion criteria were used for the G4H studies and the G4H-D study. First, the two G4H studies focused on community samples. The feasibility study of G4H recruited university students whilst the G4H RCT for adults with psychological distress recruited participants from community rather than clinical settings. The inclusion criteria for this trial used a cut-off score of ≥5 on the PHQ-9 whereas 'caseness' for depression is normally indicated by scores of ≥10

(Kroenke et al., 2001), or a diagnosis by a health professionals, including GPs. By contrast, participants in G4H-D had received psychiatric diagnoses with scores on the PHQ-9 ranging from moderate to severe. They had also been accessing mental health services for at least a decade on average, though this is an under-estimate. Therefore, it is not clear that the two community samples used in the G4H studies are directly comparable to the secondary care service users recruited into the G4H-D feasibility study.

In particular, it seems likely that the participants in the G4H-D study had greater psychosocial needs than those in the G4H studies. For example, the length of time spent accessing mental health services is positively associated with loneliness (Wang et al., 2019). Given the differences in the study samples it can be noted that adults accessing secondary care services may need a longer period of support to meet their psychosocial needs compared to general population samples. Partial support for this proposal comes from the findings of the sub-studies used to inform the development of G4H-D, which indicated that the intervention needed to be considerably longer (see Chapter 6). The process evaluation findings also indicated that the intervention needed to be longer to meet participants' needs. It is therefore likely that G4H-D will need to be extended with additional sessions and new content added to the intervention manual in order to effectively target loneliness. The next section compares G4H-D against other approaches which have been used to tackle loneliness in order to highlight how the intervention manual might be further refined.

9.2. Other approaches to tackle loneliness

Very few loneliness interventions have been evaluated for adults with mental disorders (see Section 2.6.1, p.42). However, a wide variety of interventions have been used in the general population to tackle loneliness. Theorists and review authors have described five types of intervention: improving social skills;

changing dysfunctional interpersonal dispositions (e.g., fear of rejection); removing practical barriers to socialising (e.g. transportation); providing opportunities for social contact; and social support (de Jong Gierveld et al., 2016; Masi et al., 2011). Each of these five types of intervention will be discussed in relation to G4H-D.

9.2.1. Improving social skills

The first strategy for loneliness reduction in the general population, improving participant's social skills, is not a component of G4H-D. This may indicate that this could be an area for future development. However, there are three reasons why social skills training may not be appropriate to incorporate into G4H-D. First, although adults with depression do show poorer social skills on average, these deficits disappear with a reduction of depression which suggests that they are mood-congruent behaviours rather than a genuine skill deficit (Petty et al., 2004; Wichers et al., 2010; Zeiss & Lewinsohn, 1988). Second, it was assumed that helping people with their socials skills may be best achieved indirectly. That is, G4H-D aims to support people to have real life experience of connecting with others so that they are motivated and have the opportunity to develop skills, rather than didactically teaching specific skills before encouraging any real social interaction. This approach is similar to psychosocial interventions which support adults with mental disorders to gain employment and independent accommodation, in which people are first placed on the job or in their apartments and then supported in those settings (Corrigan, 2001). Successful interventions such as Individual Placement and Support (Kinoshita et al., 2013; Modini et al., 2016) and Housing First (Stergiopoulos et al., 2015) have thereby challenged the notions of 'work-readiness' and 'housing-readiness' which suggest individuals must be trained before they can access new resources. It is similarly possible that 'social-readiness' may be unnecessary for social connectedness interventions. The final reason not to focus on social skills was that a meta-analysis of intervention

studies found that social skills training did not lead to significantly reduced feelings of loneliness in general population samples (Masi et al., 2011). Therefore, social skills training may not be a promising area for refining G4H-D.

9.2.2. Changing dysfunctional interpersonal dispositions

The second approach to tackling loneliness in the general population is addressing unhelpful interpersonal dispositions such as heightened fears of rejection. G4H-D addresses such dispositions in two ways. First, the intervention group itself is intended to provide a positive social experience which may foster helpful interpersonal dispositions. There is some preliminary evidence for this assumption. For example, two longitudinal studies (n=76 and 92) have found that positive experiences of social groups reduced 'cognitive schemas' related to social isolation (Cruwys, Dingle, et al., 2014). Similarly, one study of a group intervention designed to model positive interactions amongst women with eating disorders (n=87) found that increases in group attachment predicted improvements in individual attachment security one year later (Keating et al., 2014). The second way in which G4H-D addresses unhelpful interpersonal dispositions is by discussing participants' beliefs, expectations, and anxieties and identifying adaptive strategies to manage these. Participants are encouraged to share adaptive strategies between themselves as a means of social support.

It may be possible to further enhance the G4H-D manual by incorporating particular strategies from clinical and positive psychology interventions which aim to promote participants' interpersonal functioning. An example from clinical psychology may be to reduce social *safety behaviours*, behaviours which are intended to prevent feared outcomes but in fact maintain anxiety (Clark & Wells, 1995). Positive psychology interventions using gratitude (Algoe, 2012) and compassion-based exercises (Hutcherson et al., 2008) have also been found to increase pro-social behaviours and perceptions of social connectedness.

Introducing components from positive psychology into G4H-D may be appropriate given the recent preliminary evidence that positive psychology interventions may reduce loneliness amongst adults with mental disorders (Lim, Gleeson, et al., 2019; Lim, Penn, et al., 2019). These topics and strategies could be incorporated into new sessions added to G4H-D.

9.2.3. Removing practical barriers to socialising

The third approach to tackling loneliness in the general population, reducing external barriers to social participation, did not feature within G4H-D. This may be a pertinent omission as some of the reasons that potential participants declined to take part in the G4H-D feasibility study were related to financial or mobility constraints. Unfortunately, there was no funding to offer suitable transportation to address these needs. More fundamentally, even where participants can access the intervention, G4H-D focusses primarily on motivating participants to socially re-engage and by addressing some of the interpersonal barriers to doing so. There is no support given for other types of barriers participants might face. Addressing personal level concerns without addressing structural barriers is a common limitation of mental health interventions. One option for the future development of G4H-D is therefore to develop links with social care and third sector services which seek to address some of the structural disadvantages people face.

Another option would be to deliver G4H-D using an online interface. The use of digital interventions in healthcare has been increasing given the advantages they can offer compared to traditional forms of care, such as increased accessibility (World Health Organization, 2019). Indeed, digital interventions targeted at specific groups, such as housebound older adults, have shown some promise in addressing some of the practical barriers to social connectedness (Fokkema & Knipscheer, 2007). However, it is argued here that G4H-D may be more effective as a face-to-face intervention. There are mixed views on whether digital

interventions could be used to tackle loneliness (e.g. Choi et al., 2012; Sbarra et al., 2019). There have been conflicting empirical findings on the association between loneliness and internet usage, and *how* the internet is used appears to be the key moderating factor (Nowland et al., 2017). Some people use the internet as a means of enhancing communication within existing relationships and identifying new social contacts. However, internet browsing and social media are also used as a means of social withdrawal. Importantly, lonely people tend to use the internet in ways which displace face-to-face social activities. Some researchers have therefore concluded that interventions should be designed to teach participants new behavioural strategies for using social media in ways which increase their online connectivity (Nowland et al., 2017). However, the fact that lonely people often use the internet as a means of social withdrawal suggests that an important source of their difficulties is located in face-to-face interactions. Therefore, it is possible that face-to-face interventions may address participants' more salient social needs, whilst online interventions could inadvertently reinforce the processes of social withdrawal and avoidance.

Moreover, face-to-face contact may be uniquely important. Some theorists have argued that social bonding requires the non-verbal cues involved in face-to-face contact (Nie, 2001) and there is now some evidence that real life interactions facilitate greater feelings of social belonging and enjoyment than online interactions (Sacco & Ismail, 2014). In summary, it is argued here that face-to-face interventions such as G4H-D may both address participants' needs and, unlike digital interventions, avoid simultaneously encouraging behaviours which may reduce social connectedness.

9.2.4. Providing opportunities for social contact

A fourth approach to reduce loneliness is simply to increase people's opportunities for social contact. Interventions which use this approach typically involve setting

up groups focussed on a particular activity such as sports or choral singing. The intention and theory-base of G4H-D did not centre on providing an opportunity for social contact within the group. One reason for this was that whilst these types of interventions appear to be effective at reducing isolation (Anderson et al., 2015; Masi et al., 2011), they do not appear to be effective at reducing loneliness (Masi et al., 2011). This is consistent with theoretical perspectives on loneliness which suggest that it is primarily the quality of people's relationships which matters, not the quantity (Peplau & Perlman, 1982), and the empirical finding that contact time with others is only weakly associated with loneliness (Pinquart & Sörensen, 2003). Hence, it is unlikely that G4H-D could be further improved by incorporating elements from the social opportunities approach.

9.2.5. Social support

The final approach to reducing loneliness identified in the literature is to enhance access to social support. This could be provided either within peer groups or one-to-one befriending. One-to-one befriending was not incorporated into the G4H-D design and this type of intervention does not appear to reduce loneliness amongst adults with mental disorders (Siette et al., 2017). By contrast, the G4H-D intervention has a lot of overlap with peer support groups. The G4H-D logic model and the findings from the feasibility study process evaluation suggest that many of the important mechanisms of change arise out of supportive interactions between group members. It is possible that these interventions are functionally equivalent and differ only in their stated purpose and rationale. Given the overlap between G4H-D, peer support groups and group psychotherapy, one option for the future development of G4H-D would be to review the literature on effective components of these other interventions. It is also possible that peer-delivered G4H-D might support the mechanisms of change and increase the effectiveness of the intervention. This hypothesis could be examined in evaluative research comparing clinician-delivered and peer-delivered G4H-D groups.

9.3. Implications for future research and practice

There are two key research implications of the findings of this thesis: (1) G4H-D could be further refined to meet the needs of adults with depression; and (2) a clinical trial of G4H-D is warranted. This section will discuss how these two implications may be addressed in future research.

9.3.1. G4H-D refinement

The next step in the development and evaluation of G4H-D is to assess whether additional refinements could be made to the intervention. It is possible that G4H-D may improve outcomes in addition to depression, loneliness in particular, but the feasibility study findings suggest that further development of G4H-D would be needed to effectively target this outcome domain. For instance, the effect size for loneliness was small, only marginally significant (p=0.046), and the process evaluation suggested that the intervention was too short to help participants improve their social connectedness outside of the intervention group.

In Section 9.2, three strategies were identified for refining the intervention: adopting exercises from clinical and positive psychology; developing local links with social care and the third sector; and adopting approaches found to be effective in group psychotherapy and peer support groups. In addition, there are two further areas of potential development for G4H-D. First, strategies to reduce self-stigma may be useful given that stigma emerged in this thesis as a barrier to social connectedness within the CIVIC-MH framework. Second, strategies to increase behavioural activation and social behaviour change could be incorporated as there was relatively little evidence of behaviour change outside of the intervention group.

Given the broad array of potential refinements to G4H-D, the first step may be to conduct a scoping review of interventions related to each of the above mentioned

approaches. Once potential refinements are identified, the second step could be to conduct interviews with expert stakeholders to determine if, and how, these refinements could be incorporated into G4H-D. Ethnographic field methods such as participant observation could also be used in particular mental health settings which target social outcomes to examine how these outcomes are targeted in routine practice. This may have the additional benefit of helping to tailor G4H-D to the practice environments in which it is intended to be delivered and support the later implementation of the intervention (Webber, 2014). Following the refinements to the intervention a small pilot study could be conducted, similar to the sub-study reported in Chapter 6, in order to examine the acceptability of the additional intervention components to the target population. Assuming the new components of G4H-D were acceptable to participants, a clinical trial could then proceed.

9.3.2. Clinical trial of G4H-D

Developing a full trial protocol of G4H-D in line with the SPIRIT guidelines (Chan et al., 2013) is beyond the scope of this thesis. Instead, some of the key considerations for the development of a protocol and clinical trial registration will be discussed here.

Clinical trials randomly assign participants to two or more arms of a trial, thereby balancing the known and unknown confounding factors. The design features of randomisation and using a comparator group are intended to ensure that the only remaining difference between the groups is whether they received the intervention. Changes in PHQ-9 score were not associated with any of the social or clinical characteristics measured in the feasibility study. Therefore, a simple randomisation procedure rather than stratified randomisation would be appropriate as there are no known confounding variables for G4H-D.

The choice of comparator group is an important decision for evaluations of complex interventions and depends on the overall aim of a trial. For instance, non-inferiority and equivalence trials will tend to use an established intervention against which to compare the new intervention (Chow & Liu, 2008). Non-inferiority trials aim to show that a new intervention is not significantly worse than a standard intervention. Equivalence trials aim to show that a new intervention is not significantly inferior or superior to an established intervention. It was discussed in Section 9.1.5 that G4H-D would need to be compared against a neutral comparator in order to determine the mechanisms of action of the intervention. However, before exploring causal mechanisms it needs to be first established that the intervention is effective. G4H-D has not yet been shown to be superior to routine care alone. Therefore, the most appropriate trial design for the next stage of evaluation may be a superiority design using treatment-as-usual as the control arm compared against treatment-as-usual plus G4H-D using a 1:1 allocation ratio to maintain statistical power (Hey & Kimmelman, 2014).

A pragmatic trial examining the effectiveness of G4H-D in routine clinical practice may be more appropriate than an explanatory trial evaluating the efficacy of G4H-D under ideal conditions. The focus for developing G4H-D in this thesis was directed towards a pragmatic trial evaluating the effectiveness of the intervention in clinical practice. In particular, no exclusion criteria were used in the feasibility study and the inclusion criteria specified either a primary or secondary diagnosis of depression in order to maximise the relevance of the findings to clinical settings in which comorbidity is common (Kessler et al., 2005).

The feasibility study used a single group design. This meant that it was not possible to evaluate participants' willingness to be randomised. It is sometimes the case that patients have such strong treatment preferences that they refuse randomisation. The remaining participants may then not be representative of the

target population and the results of the clinical trial would not be generalisable (Torgerson & Sibbald, 1998). For participants randomised to the control group there may also be a problem of demoralisation and poor compliance with the study which may bias the results. On the other hand, the limitation of incorporating a patient preference approach into a clinical trial is that it will either increase the risk of confounding factors or necessitate a much larger sample size (Torgerson & Sibbald, 1998). As G4H-D is a new type of psychosocial intervention which is not routinely delivered within secondary care and with which potential participants would be unfamiliar, it may be assumed that potential participants would not have a strong preference for the intervention compared to treatment-as-usual. Therefore, it is proposed that a patient preference approach is unnecessary for a superiority trial of G4H-D.

An economic evaluation should also be incorporated into a trial of G4H-D. Loneliness is associated with increased healthcare costs (Mihalopoulos et al., 2019). Meanwhile, increases in social connectedness have been associated with reduced attendance of primary care services (Cruwys et al., 2018), though a reduction in GP visits was not observed in the recent G4H RCT (Haslam et al., 2019). A measure of service use, such as the Client Service Receipt Inventory (Beecham & Knapp, 2001), could be included within the G4H-D trial assessment battery. Costs may thereafter be calculated from the UK annual compendium of service costs produced by the Personal Social Services Research Unit (Curtis & Burns, 2018) for use in an economic evaluation.

9.3.3. Implications for practice and policy

There are limited implications for clinical practice or policy stemming from this thesis. The feasibility study was not designed to have the internal validity required to evaluate the effectiveness of G4H-D. Therefore, it is unknown whether

the intervention would be effective in practice and it cannot be recommended that G4H-D be commissioned or delivered in clinical settings at this stage.

Nonetheless, there has been some preliminary impact of the thesis findings. First, the Specialist Depression Service at NHFT is now implementing a version of G4H-D within their service. Second, a local authority team is developing a group programme for young, black, unemployed and depressed men using theory and material from G4H-D. Given the absence of an evidence base in this area, it may be recommended that careful attention is paid to safety monitoring and implementation is evaluated in any service which adopts G4H-D.

9.4. Strengths and limitations of the thesis

9.4.1. Strengths

A particular strength of this thesis was the systematic use of theory in the development of G4H-D. Many existing loneliness interventions have not been developed in accordance with a clearly defined theory. This lack of theoretical development has been suggested to partly account for the slow progress made in this field (Dickens et al., 2011; Victor et al., 2018). The development of the CIVIC-MH framework is thus one of the key knowledge contributions of this thesis. This framework represents the first systematic mapping of the subjective dimensions of social connectedness for adults with mental disorders. As well as providing a foundation for the development of new interventions and measures, this framework may help to integrate disparate literatures such as that of social support (Thoits, 2011a), social identity theory (Haslam et al., 2018) and interpersonal closeness (Berscheid et al., 2004).

A second strength was the collaboration with different stakeholders throughout the G4H-D development process, including adults with mental disorders, clinicians, and academics. As a complex intervention, the development of G4H-D

benefited from the input of stakeholders with such a diverse set of expertise. Similarly, the involvement of a PPI co-researcher in the qualitative study of people's experiences of social connectedness incorporated an important lived experience perspective into the analysis. This level of PPI involvement is not yet the norm for many research studies (Jennings et al., 2018).

A third strength was the use of different methods to gather data on a complex phenomenon (social connectedness) and a complex intervention (G4H-D) which would not otherwise have been adequately described and evaluated using a single method (Creswell & Clark, 2011).

9.4.2. Limitations

The demographic profile of each of the study samples reported in this thesis largely consisted of White British participants. Convenience sampling strategies were also used. Taken together, this limits the external validity of the studies and the extent to which the overall findings of the thesis may be applicable to population groups not represented within the studies. For example, social connectedness may have different meanings for different cultural groups and the CIVIC-MH framework may not be universally relevant. In addition, minority groups may face additional barriers in achieving social connectedness due to the lack of culturally appropriate groups and community services. Additional components may need to be included into the G4H-D intervention, such as community asset mapping (Selamu et al., 2015), to accommodate these needs.

This thesis focussed at an individual level of analysis, which limits both the theory and the development of G4H-D. For example, the CIVIC-MH theory base for G4H-D was developed in terms of a first-person subjective account. In other words, the CIVIC-MH framework focused on individual perceptions of the psychological bond of social connectedness itself. This focus does not encompass factors at other levels which may influence this experience. For example, at the

interpersonal level, processes such as equality and reciprocity have been identified by adults with mental disorders as being important for their relationships (Topor et al., 2006). At the community level, cultural factors such as norms for relationships and living arrangements will influence how loneliness and social connectedness are experienced and understood by different groups. The individual-level perspective also limited the development of G4H-D itself. In particular, this perspective restricted the focus on the types of barriers to social connectedness most salient for adults with mental disorders. For instance, G4H-D primarily addresses intrapersonal psychological barriers to social connectedness, such as social anxiety and unhelpful interpersonal beliefs. This ignores the many structural and interpersonal barriers people face.

Furthermore, locating the problem of loneliness at the individual level obscures the fact that loneliness may be fundamentally a social-cultural problem. Historians have noted that loneliness in the UK is in fact a relatively recent phenomenon which first arose due to a conflux of social, economic and ideological changes that occurred during European industrialisation (Alberti, 2019; Smith, 2015). The term 'loneliness' only entered the English language around 1800 and was predated by the concepts of solitude and 'oneliness', which conveyed the state of being alone but did not imply an emotional lack (Alberti, 2019). Viewing loneliness from this historical perspective suggests that much deeper cultural shifts would be necessary to fully address the problem and that individual-level interventions may only have a limited impact.

9.5. Ethical considerations

In Chapter 3, a number of ethical considerations for the design and conduct of this thesis were discussed. Two further ethical issues which arose during the conduct of the G4H-D feasibility study will now be considered.

First, some participants in the G4H-D feasibility study began discussing issues related to their mental health which were unrelated to the topic of the group session. This raised a difficulty for G4H-D facilitators in deciding whether to allow such self-disclosures and off-topic discussion in order to support participants or to keep the group on task. This was addressed in the guidance for facilitators by suggesting that facilitators should first seek to validate participants' difficult experiences and second to try to relate those experiences to the session topic where appropriate.

Second, the use of self-disclosure by G4H-D facilitators raises some ethical issues. In certain circumstances, self-disclosure can lead to improved working relationships between clinicians and service users (Priebe et al., 2011). Self-disclosure by clinicians can also encourage service users to self-disclose themselves (Henretty & Levitt, 2010), which supports the G4H-D logic model and intended processes of change within the group. However, self-disclosure is not always appropriate and can adversely affect service users. For example, some disclosures may risk shifting the focus of attention onto the clinician (Roberts, 2005). Therefore, the training for G4H-D facilitators may need to include further guidance on the appropriate use of self-disclosure to participants.

Self-disclosure by clinicians can also increase the intimacy of their relationships with service users (Pinto-Coelho et al., 2016). Close or emotional relationships between G4H-D facilitators and participants could raise ethical challenges given that there is an inherent power imbalance in these relationships. For example, the facilitators asked one participant to leave the study. In the context of a close relationship with facilitators, participants may experience the clinical responsibilities of G4H-D facilitators, such as safeguarding, as a betrayal of trust. Whilst safeguarding responsibilities are often discussed at the start of clinical interventions, it may be important for G4H-D facilitators to communicate these

again at later stages of the intervention when closer relationships are likely to have formed.

9.6. Reflections on the thesis

The philosophical basis of this thesis is that of critical realism, a position which calls upon researchers to be aware of the personally and socially constructed nature of the theories that they develop about the world. It therefore seems appropriate to conclude with some deeper reflections about my own personal journey and learning through the PhD, the impact this had on the conduct of the thesis, and the potential implications for my future research.

The key thing I have learnt during the course of this PhD is that the narratives we construct about the world and each other are important not simply in terms of their accuracy but also in terms of their ability to influence a range of other personal and social outcomes. Narratives are understood here to be stories or accounts of events or experiences which may or may not be true. Ostensibly this learning point has very little to do with the subject matter of this thesis but hopefully its relevance will become clearer as I describe my PhD journey as follows.

I was very lonely in the first year of this PhD. I was working most evenings and weekends and so I rarely saw my friends and family. During this year I also encountered theories by prominent researchers which suggested that loneliness is a biological phenomenon and others suggesting that it is a personality trait. These theories seemed to imply that the difficult subjective experiences I was having at the time were either biologically fixed or due to some kind of character flaw. This gave me my first insight into the power of narrative. These loneliness narratives made me reflect on a past experience of being given a narrative within a mental health context which has been far more enduring. I was reminded of being a

depressed young man aged 20 undergoing cognitive therapy in the NHS. The therapist at the time explained to me that my troubles were due to 'maladaptive cognitive schemas' located somewhere in my unconscious. I believed this explanation and, given that it was explaining a very salient part of my subjective experience, it became enveloped into my personal identity. The notion that I had some kind of cognitive propensity to depression remained a part of my identity long after the therapy had ended and any feelings of low mood had faded away. The result was that when I began this PhD, nearly a decade following my experience of depression, I felt obliged to inform my supervisors that I was very vulnerable to depression and that this might impact upon my work. It is difficult to judge precisely how this self-conception has influenced my self-esteem and behaviour over the years but I have no doubt that it has done so.

The reason I've reflected on and shared these personal experiences is because they touch upon a number of different areas which seem relevant to the development of theories in mental health and for the development of psychosocial interventions in particular. These experiences have highlighted an important point for me, namely that social narratives shape the way that we think and impact upon our wellbeing in different ways, particularly when delivered to us by people in authority.

This understanding about the power of narrative guided my conduct during this PhD and the decisions I made. For instance, it is partly why I made an explicit point of rejecting both the biological and personality approaches to loneliness (alongside the reasons given in Chapter 2). It is also partly why I chose to develop the intervention around a positively-framed theory of social connectedness rather than to focus on loneliness. In critical realist terms, my personal experiences and values guided which aspects of reality I ultimately emphasised in this thesis.

For critical realists it is important for researchers to be aware of their liability to be influenced in this manner in order to highlight the limitations or the biases inherent in their work. I might add that it is important for researchers to be aware of the various impacts that their theories might occasion beyond the phenomenon of interest. The act of research, whether to develop a theory or to test an intervention, will create stories which will influence others in both positive and negative ways. For instance, conceptual models of mental disorder focus on elucidating the nature of disorder but are also linked to other attitudes and behaviours, such as stigma (Lebowitz & Appelbaum, 2019), prognostic expectations (Kvaale et al., 2013), perceived agency (Lebowitz & Ahn, 2015) and clinician-patient relationship factors (Lebowitz et al., 2015). Therefore, researchers have an ethical requirement to consider the implications of the stories we create in our work.

There are implications of this understanding of narrative for my future research. If there was one thing I would have done differently in this PhD, it would have been to pay more attention to the explanatory model of the intervention. Explanatory models are defined here as the explanation provided to recipients of an intervention which describes the source of their distress or unmet need along with the corresponding rationale for the intervention. For example, the explanatory model of cognitive therapy focuses upon cognitive schemas. Most, if not all, interventions depend upon providing some form of explanatory model to participants and persuading them of the model's applicability to their situation. For example, in cognitive therapy this process is called *socialising into the model* and in traditional psychiatric services this is called *promoting insight*. Existing frameworks for the development of complex interventions do not currently offer guidance for how to construct and communicate such explanatory models. The evaluation of complex interventions typically focuses on identifying the 'active ingredients' of structural features or particular techniques in a given context

(Craig et al., 2008; Moore et al., 2015). Less thought has been given to the embedded assumptions and implicit messages communicated by these interventions.

Prominent theorists have argued that one of the most potent active ingredients of psychosocial interventions is the explanatory model itself (Frank & Frank, 1991). If I am able to continue to develop such interventions then I plan to pay particular attention to the construction and communication of these models. Theorists have already highlighted the necessity of developing explanatory models which have two particular characteristics: plausibility (Wampold, 2015) and cultural relevance (Benish et al., 2011). These two characteristics are important primarily for the purpose of increasing the believability of the particular model and therefore increasing participants' engagement with the intervention and expectation of change. The focus, therefore, is on using explanatory models to enhance the effectiveness of the intervention for its primary outcome, typically a reduction in mental health symptomatology. My experiences of the impact of narrative suggest to me that other outcomes are sensitive to explanatory models and thus additional characteristics of these models should be considered.

There are quite a range of outcomes which different narratives might influence. Some examples relate to stigma, hope, and empowerment. For example, it has been found that biogenetic explanations of mental disorder reduce blame yet increase pessimism, avoidance, and the belief that affected people are dangerous and unpredictable (Haslam & Kvaale, 2015). These explanations are also associated with increased pessimism and helplessness among affected people and reduce the empathy their treating clinicians feel for them. Such findings may suggest that psychosocial explanations may be broadly less stigmatising and instil more hope in people than biogenetic explanations. However, the exact characteristics of narratives which lead to different outcomes are unclear. My own

experiences of cognitive therapy suggest that particular explanatory models within the broad psychosocial approach may be associated with undesirable outcomes. In addition, it seems plausible that intervention recipients could have idiosyncratic responses to the same explanatory model.

It is further possible that narrative characteristics might also influence the effectiveness of particular intervention exercises. To my knowledge very little research has been conducted with regards to this possibility. One recent exception concerns the role of metaphor on goal-setting. Goal-setting is central to many types of psychosocial mental health interventions though evaluation of this exercise typically focuses on technical features such as their specificity (Dickson & Moberly, 2013). Narrative may also play a role however. Across six studies involving over 1,600 people in different countries researchers found that participants who were asked to frame their goal strivings as part of a 'journey' were subsequently more likely to continue their goal-aligned behaviour following the intervention than participants framing goals as a 'destination' (Huang & Aaker, 2019). In G4H-D participants were asked to set themselves small social goals to complete during the intervention with the intention that they would continue to pursue such goals following the intervention. However, as already noted, beyond the goal setting exercise there was relatively little evidence of behaviour change outside of the intervention group. Future research might therefore also consider how particular intervention exercises might best be framed and communicated as a means of increasing their effectiveness.

For the development and evaluation of new psychosocial interventions it may therefore be useful to view explanatory models and other narrative characteristics of the intervention as important components which require careful consideration. For instance, two features of explanatory models could be evaluated. First, the narrative characteristics of models could be categorised and examined for their

association with different outcomes. As an example, the characteristics of malleability (suggesting a problem is changeable) or immutability (the problem is fixed) could be assessed in process evaluations in relation to outcomes such as hope or empowerment. Second, the degree to which explanatory models are negotiated between clinicians and patients and ultimately adopted by patients could be assessed as a moderating factor of any observed associations.

9.7. Conclusion

This is the first study to adapt an intervention to reduce loneliness amongst adults with depression using a systematic and theory-driven approach. This thesis makes three main knowledge contributions: the CIVIC-MH framework; the modification of G4H to G4H-D; and the feasibility evidence that G4H-D warrants further investigation. It is not clear that the findings generalise to service user populations not studied in this thesis, in particular ethnic minority groups in the UK. The development of interventions to reduce loneliness in clinical populations may need to be tailored to meet the particular needs of different groups of service users. At the same time, it is possible that G4H-D provides a general model which could be adapted for this purpose. Overall, the findings support progress towards the goal of decreasing loneliness for people living with depression.

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Appendix 1. Search Strategy for MEDLINE (Ovid)

1. (((mental* or psychologic*) adj2 (health or disorder* or disease* or deficien* or illness or problem* or distress)) or (psychos* or obsessive-compulsive or "obsessive compulsive" or anxiety or depress* or panic or phobi*)).ti,ab. or exp Affective Disorders/ or exp Mental Disorders/ or exp Panic Disorder/ or exp Obsessive Compulsive Disorder/ or exp Generalized Anxiety Disorder/ or exp Phobias/ or exp Psychosis/

2. exp cohort analysis/ or cohort studies/ or Case-Control Studies/ or Control Groups/ or Matched-Pair Analysis/ or ((case* adj5 control*) or (case adj3 comparison*) or (case* adj2 series) or control group*).ti,ab. or longitudinal studies/ or follow-up studies/ or prospective studies/ or retrospective studies/ or epidemiologic methods/ or cohort.ti,ab. or longitudinal.ti,ab. or prospective.ti,ab. or retrospective.ti,ab. or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))) or Cross-Sectional Studies/ or Prevalence/ or (cross-sectional or "cross sectional" or survey or prevalence or transversal).ti,ab. or (scale or validation or "construct validity" or "content validity" or "test-retest" or "internal consistency" or psychometric*).ti,ab.

3. ("social connectedness" or companionship or relatedness or "sense of belonging" or "social belonging" or "group membership" or "group identi*" or "social identi*").ti,ab. or exp social identification

4. ((("semi-structured" or "semi structured" or semistructured or unstructured or informal or "in depth" or "in-depth" or indepth or "face to face" or "face-to-face" or structured or guide) adj3 (interview* or discussion* or questionnaire*)) or (focus group* or qualitative or ethnograph* or fieldwork or "field work" or "key informant" or "content analysis" or "grounded theory" or "narrative analysis" or "narrative inquiry" or phenomolog* or "communication analysis" or "framework analysis" or "thematic analysis" or "discourse analysis")).ti,ab. or interviews as topic/ or focus groups/ or narration/ or qualitative research/ or exp qualitative research/ or exp grounded theory/ or exp interviews/ or exp observation methods/ or exp interviews/ or exp interview schedules/

5. 1 and 2 and 3

6. 5 not 4

7. limit 6 to English

Appendix 2. Qualitative study interview topic guide

Connectedness in depression interview topic guide
Version 1.0. 14 December 2017

Preparation
Before the participant arrives, allocate a unique identifier (UID) to the participant, and write it into a blank Informed Consent Form. Ensure that a copy of the CIVIC framework and G4H intervention manual has been sent to participants prior to the intervention and that printed copies are available for use during the intervention.

Introduction
- Introduce the interviewer
- Ensure the participant has read the information sheet and understands that participation is voluntary and that they are free to withdraw at any time
- Explain the aims and purpose of the activity and give a brief description of the interview structure. In particular, highlight that the purpose of the interview is to examine whether the CIVIC framework and G4H intervention are suitable or need to be adapted or not used.
- Provide an opportunity for participant to ask any questions, and then obtain written consent through the Informed Consent Form
- Describe digital recording of the interview. Turn on the recorder. Read out the UID so that it is recorded

Questions: Lived experience participants

Section 1: Experiences of social connectedness

Ask the participant to describe their own understanding of social connectedness. Give them plenty of time. Use minimal prompts if needed (e.g. 'Do go on').

Ask them how social connectedness can be improved.

Ask them what barriers they face in achieving social connectedness.

Section 2: Views on the CIVIC framework

Provide the participant with printed material describing the CIVIC framework. Describe each dimension of the framework verbally. Ask participants' view on each dimension and the framework as a whole.

Considerations: Is the dimension meaningful? Does it fit with your experiences? Are the dimensions related to each other or separate? Anything missing from the framework? How would you change the framework?

Section 3: Views on the G4H intervention

Give a summary of the rationale, goal, format (group, face-to-face, number of sessions), facilitation, location, and general activities used in the G4H intervention. Describe it verbally. Provide an opportunity for the participant to ask any questions.

Ask the participant to draw on their own experiences to provide feedback on what has been shown to them.

Considerations for general structure: number/length/frequency of sessions, location, time of day, number/background of facilitators, group format, suitability for adults with depression, considerations to take into account for this group.

Provide the participant with printed material describing the first session of the G4H intervention including the materials, procedures, and specific activities planned for the session and homework.

Ask the participant to draw on their own experiences to provide feedback on what has been shown to them.

Considerations for adaptations: Does the group programme look relevant to social connectedness? Are the format and content appropriate for adults with depression / mental health difficulties? Are the exercises potentially useful? Would participants adapt the programme in any way to improve outcomes?

Considerations for mechanisms: What do you think the outcomes might be for the group? How do you think the group might support social connectedness? What might change for participants?

Repeat for other sessions of the G4H intervention.

Questions: Staff participants

Section 1: Experiences of social connectedness

Ask the participant to describe their experience of working with adults with depression and other mental health problems.

Ask the participant to describe their own understanding of social connectedness. Give them plenty of time. Use minimal prompts if needed (e.g. 'Do go on').

Ask them about how social connectedness is experienced by the people they work with.

Ask them how social connectedness can be improved for the clients they work with.

Ask them what barriers their clients face in achieving social connectedness.

Section 2: Views on the CIVIC framework

Provide the participant with printed material describing the CIVIC framework. Describe each dimension of the framework verbally. Ask participants for their view on each dimension and the framework as a whole.

Considerations: Is the dimension meaningful? Does it fit with your experiences? Are the dimensions related to each other or separate? Anything missing from the framework? How would you change the framework?

Section 3: Views on the G4H intervention

Give a summary of the rationale, goal, format (group, face-to-face, number of sessions), facilitation, location, and general activities used in the G4H intervention. Describe it verbally. Provide an opportunity for the participant to ask any questions.

Ask the participant to draw on their own experiences to provide feedback on what has been shown to them.

Considerations for general structure: number/length/frequency of sessions, location, time of day, number/background of facilitators, group format, suitability for adults with depression, considerations to take into account for this group.

Provide the participant with printed material describing a session of the G4H intervention including the materials, procedures, and specific activities planned for the session and homework.

Ask the participant to draw on their own experiences to provide feedback on what has been shown to them.

Considerations for adaptations: Does the group programme look relevant to social connectedness? Are the format and content appropriate for adults with depression / mental health difficulties? Are the exercises potentially useful? Would participants adapt the programme in any way to improve outcomes?

Considerations for mechanisms: What do you think the outcomes might be for the group? How do you think the group might support social connectedness? What might change for participants?

Repeat for other sessions of the G4H intervention.

Distress: All participants
If the participant becomes distressed during the interview, ask if they would like to take a break or stop. If the participant reveals information which is of concern and may need reporting i.e. potential risks to another person or to themselves, or criminal behaviour, then continue the interview if you feel comfortable to, but discuss these with the PI at the earliest opportunity and where appropriate report accordingly.

End of interview
Explain the interview is now over and ask if the participant has any final questions. Give information about timeline for the study and how publications can be accessed. Thank the participant for their participation.

Appendix 3. List of suggested adaptations to G4H from interviews and piloting (n=50) and decisions to adopt or submit for expert consultation

Suggested adaptations submitted for expert consultation

1. Extend the length of the programme and include more sessions
2. Have a one-to-one session before the first group session
3. Reduce the length of the sessions from 1.5 hours to 45 minutes
4. Include fun activities (e.g. painting/music)
5. Use a collaborative approach with input from individual members into the running of the group
6. Alter goal-setting exercise to focus on setting one small goal
7. Supported socialisation: facilitator should support people to enact goals
8. Shorten month-long gap between sessions 4 and 5
9. Drop the quiz about risk factors for health
10. Alter 'self-concept reflection exercise' by dropping reference to 'aspirations' and 'personality'

Suggestions already incorporated into G4H

11. Focus on social connectedness rather than mental health problems
12. Involve people's own interests as part of group activities
13. Establish a common purpose and identity for the group
14. Provide practical examples of potential benefits
15. Show videos or testimonial from past participants on the benefits
16. Keep to the normal weekly schedule
17. Signpost participants to other sources of support
18. Facilitator needs to make it clear that participating in the group is a way of practicing key social skills (e.g. getting to know people, sharing experiences, opening up and self-disclosing) and some of the activities (e.g. discussing reciprocity) are to highlight positive social behaviours
19. Suggest other peer-led or facilitated groups
20. Facilitator should encourage a group discussion about people's experience of doing the exercise
21. Encourage mutual support within the group

Suggestions adopted as best practice for group facilitation

22. Acknowledge that two months may not be long enough for change

23. Check that people do not finish the programme feeling that they have failed
24. Acknowledge and support people for difficult experiences
25. Debrief at the end of sessions to support people
26. Liaise with professionals to check that unsupported relapses had not occurred
27. Normalise anxiety about new situations
28. Use icebreakers, activities and 'softeners'
29. Provide support for anxiety
30. Highlight the link between social connectedness and wellbeing
31. Frame G4H-D in an understandable way
32. Reassure participants that being part of few groups is common and the purpose of the group is to build these up (best practice)
33. Facilitator to model self-disclosure where appropriate
34. Don't expect everyone to self-disclose
35. Allow gradual disclosure
36. Identify people's interests early on to support them
37. Encourage people to have an open mind about socialising
38. Frame goal tasks in such a way as to take the pressure off
39. Ask people to help each other to pursue their goals
40. Identify someone in the group who might coordinate ongoing group activities
41. Give people the option of talking in a group or pairing up
42. Go round in a circle rather than open discussion as this is the norm for mental health groups
43. Facilitate so that quieter, more anxious members get a chance to speak
44. Facilitator should acknowledge how difficult the exercise is; both cognitively in terms of thinking through the complexity of the questions and emotionally if there are any gaps or negatives in the map
45. Rephrase unclear questions
46. Use a large example map to highlight where each of the scores should go
47. Facilitator should acknowledge that people naturally make (negative) social comparisons during this exercise
48. Facilitator needs to be careful to focus on people who are still alive
49. Need to clarify instructions in easier language
50. Have participants who are struggling with this exercise refocus on thinking about the groups they might want to join in the future

Appendix 4. Excerpt of expert consultation online survey

Proposed adaptation 2: Structural: Between sessions four and five reduce the time interval from a month to 2 weeks. **Rationale:** Participants with mental health difficulties need more regular, intensive input and are more likely to lose motivation and drop out over a month interval. * *Required*

- ○ Agree
- ○ Disagree (please describe why)

If you selected Disagree, please specify:

Proposed adaptation 3: Adopt a shared decision-making approach wherever possible (e.g. whether to talk in a group or in pairs; deciding how much time to give to different exercises within sessions). **Rationale:** A collaborative approach may help to build a sense of ownership and identity with the group. * *Required*

- ○ Agree
- ○ Disagree (please describe why)

If you selected Disagree, please specify:

Proposed adaptation 4: In session 1 drop the quiz about risk factors for health and focus on the 'benefits of social connectedness' rather than the 'risks of loneliness'. **Rationale:** Focussing on the health risks of loneliness may be anxiety-provoking and

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Appendix 5. Summary of exercises in G4H-D

Structure

The G4H-D intervention consists of five modules, delivered within five group sessions across two months.

One module a week will be delivered for the first four consecutive weeks, with a two week gap between the fourth module and the final, fifth module.

Each module session last 1.5 hours. Participants are asked to engage in 'reflection tasks' between sessions.

Two facilitators run the group. A facilitators' manual for the intervention will be followed.

All participants will be provided with a workbook on the first session of the intervention which gives details on the exercises and space to complete them.

Sessions

Session 1 (Schooling)
This module raises awareness of the beneficial effects that social group memberships have for health. It highlights the costs of ignoring the social dimensions of health and points out that failure to use all the social resources at our disposal generally leads to sub-optimal health outcomes. However, the module also makes the point that it is within people's power to counter these effects by learning how best to develop, maintain and harness group-based social resources.

Exercises in module 1:

1. Listing all groups a participant is a member of
2. Describing benefits of being part of social groups
3. Quiz: ranking different factors (e.g. social integration, smoking) for their association with health outcomes
4. Describing ways in which groups have helped participants currently or in the past
5. Ranking listed social groups for their importance and support provided

Reflection task: Reflect on past challenges experienced and how groups did, or could have helped meet these challenges.

Session two (Scoping)
This module focuses on the range of group-based resources that people have, or ideally should have at their disposal, to optimize health. This module engages participants in the process of 'social identity mapping'. This mapping tool was developed to explore respondents' social identities, in order to assess their current social functioning and develop a sense of how they would ideally like to function in the future.
Exercises in module 2:

1. Create a 'social identity map': listing all social groups and rating their importance, level of support, how representative a participant believes themselves to be of other group members, how positively they view each group, how similar and compatible they believe their different social groups are

Reflection task: add any groups that were left out in the session and reflect on whether there are any social needs not being met

Session 3 (Sourcing)
This module focuses on identifying and strengthening existing valued social identities with a view to optimizing and sustaining these in the longer term.

Exercises in module 3:

1. Creating a guest list and seating plan for a hypothetical social event
2. Identify two groups from the guest list and describe the things which are important to each group, how each group is compatible to other groups, and how they are incompatible
3. Discussing barriers to get more from our existing and new social connections
4. Discussing expectations from social connections and whether groups are always perfect
5. Reflecting on ways of managing difficult interactions with others
6. Reflecting on self-care strategies
7. Discussing the importance of reciprocity and strategies to maintain reciprocity
8. Discussing strategies to manage feelings such as shyness/awkwardness

Reflection task: reflecting on whether any existing gaps in social networks could be filled by new group memberships, noting down potential new groups and motivations for joining each one.

Session four (Scaffolding)
This module uses the G4H group as a model for establishing and embedding new social group connections whilst at the same time exploring strategies to identify which connections to develop and enact through a social plan of action. The goal is to trial these social plans between this and the final module, which takes place at least one month later.

Exercises in module 4:

1. Reflect on how participants see themselves as a person (their self-concept)
2. Drawing a pie chart to depict the relative important of each aspect of a person's self-identity
3. Reflecting on which aspects of one's self-identity is not well represented by their groups
4. Developing a social plan: goal setting to join new groups over the following month
5. Reflecting on how to build a shared identity with others
6. Noting learning points from the session

Reflection task: follow the goal setting plan developed during the session.

Session 5 (Sustaining)
This is a booster session held one month later that aims to troubleshoot any difficulties that have arisen in the course of implementing these social plans. It also revisits social identity maps, created in Module 2, to see how they have developed in the course of the programme. The social foundations that have been identified and developed in the preceding four modules are also reviewed with a view to encouraging their long-term maintenance.

Exercises in module 5:

1. Reflecting on positive social experiences during the course of the intervention
2. Discussing strategies to manage challenges of getting more from existing social ties and in developing new ties
3. Repeating the social identity mapping procedure completed in module 2

GROUPS 4 HEALTH
Module 1: Schooling

Why are we here?

Why should I care about groups?

What makes up a group?

How can groups help me?

Social relationships and health

Social groups as a psychological resource

Multiple groups as multiple resources

Preparation for Module 1

Module aims

1. Initiating rapport and developing relationships in the **G4H** group.
2. Raising awareness of the role that social groups play in our lives.
3. Thinking about the health effects of group membership.
4. Highlighting the value of groups as a psychological resource.

Module content

Key issues: **GROUPS 4 HEALTH** rationale

Why should I care about groups? (introductions and group rules) What makes up a group?

Activity 1: Defining social groups: Who and what are they? Activity 2: The groups in your life

How can groups help me?

Activity 3: The benefits of social groups

Social relationships and health

Activity 4: What do we believe is good for our health?
Activity 5: What is it about groups that enable them to protect health?
Activity 6: How have groups helped you in the past?

Social groups as a psychological resource

Activity 7: Which groups matter most for our health?

Multiple groups as multiple resources

Session summary: Learning points and reflection task

Module aims

1. To raise awareness of the role that social groups play in our lives.
2. To learn about the health effects of social group membership.
3. To discover how social groups can be a psychological resource.

What makes up a group?

When you think of social groups, who and what do you think of?

What are social groups?

When we talk about social groups, what do we mean? What is a group? A social group is made up of people who matter to you and with whom you bond. This could be with one other person or with hundreds of other people. It could take the form of a family group, a sports group, an informal coffee group, or formal membership of a club or association. A group can also be based on shared beliefs, common roles or similar perspectives – as a vegetarian, a Christian, a parent, or a football club supporter. All these different social connections form our social worlds and in turn shape who we are as individuals.

Use the space below to jot down some examples of groups that you come up with.

What kinds of social groups are out there?

The groups in your life…

Now list all the groups that *you* are part of in the table below.

Group membership

Feminist?

Parent

British?

Environmentalist?

Volunteer?

Dog walker?

Appendix 8. G4H-D process evaluation interview topic guide

Interview topic guide: G4H-D process evaluation

Version 1.0, 8 November 2018

PREPARATION

- Before the participant arrives write their unique identifier (UID) into a blank Consent Form.
- Ensure that copies of the Participant Workbook are available to use.
- Ensure the participant has read the information sheet and understands that participation is voluntary and that they are free to withdraw at any time.
- Explain the aims and purpose of the activity and give a brief description of the interview structure.
- Provide an opportunity for participant to ask any questions, and then obtain written consent through the Consent Form.
- Describe digital recording of the interview.
- Turn on the recorder. Read out the UID so that it is recorded.

INTRODUCTION

Thank you for participating in the Groups4Health programme. This interview is to learn about what you think about the group programme you have taken part in over the last 2 months.

We will cover:

1. What you have experienced during the group
2. How group worked
3. How we should do things in the future

There are no right or wrong answers - we are interested in your personal view. What you say will help us to further understand how the group works and how we can improve it. The interview is being recorded on audiotape. Any personal details will be removed during transcription, and the tapes destroyed after transcribing. Everything you say will be kept confidential.

INTERVIEW QUESTIONS

Section 1: Intervention components

Q1: Was there anything that you particularly liked? Examples?

Q2: Is there anything you particularly disliked?

Q3: What did you think of…

- One-to-one meeting: Meeting before the group?
- Session 1: Meeting the group and discussing benefits of social connectedness?
- Session 2: Social identity mapping?
- Session 3: Strategies to (re)connect with old/current friends?
- Session 4: Strategies to connect with new groups?
- Session 5: Addressing challenges of social connectedness

Q4: What did you think of the reflection exercises? Any changes?

Q5: What did you think of the Participant Workbook? Any changes?

Q6: What did you think of the handouts in the sessions?

Q7: What did you think about the way the group was delivered? *[e.g. understandability, group length, group size, facilitator characteristics and interaction]*

Section 2: G4H-A model

Q8: Overall do you think attending this group has made a difference for you? In what ways? What has changed for you? Please explain.

Q9: What, if anything, did you find helpful about coming to the group?
Q10: Do you feel that the group became cohesive? What helped with this? How?
Q11: Did you feel supported within the group? What helped with this?
Q12: Did you feel accepted within the group (welcomed, understood, not judged)? What helped with this?
Q13: Do you feel that the group helped you to develop your knowledge and social skills? What helped with this? How?
Q14: Did you feel able to share your experiences within the group? What were your experiences of disclosing things in the group?

Section 3: Implementation
Q15: What did you think of the questionnaires you were asked to complete? Did they feel relevant? Were there any important things that the questionnaires missed out?

Q16: Did you miss any sessions? If yes, could you say why? What might have

helped you to come to more of the sessions?

Q17: Was there anything outside of the group which supported your involvement in the group or the benefits you got from it?

Q18: Was there anything outside of the group which hindered your involvement in the group or the benefits you got from it?

Q19: Any other comments?

End of interview

Explain the interview is now over and ask if the participant has any final questions. Give information about timeline for the study and how publications can be accessed. Thank the participant for their participation.

Appendix 9. Comparison of the G4H-D feasibility study and the Morriss et al. trial (2016) study designs

Study design	**Feasibility study, completers (n=20)**	**Morris et al. (2016) treatment as usual arm (n=94)**
Inclusion criteria	• Aged 18-65 • Diagnosis of depression • UCLA3 Score ≥6	• Aged 18+ • Diagnosis of depression • Hamilton Depression Rating Scale ≥16 • Global Assessment of Function score ≤60 • Not responded to ≥6 months of treatment
Site	Single site: Nottingham	Multisite: Nottingham (73% participants); Derby (11%); Cambridge (16%)
Age, mean	49 (13.4)	46 (11.3)
Gender, % female	69	64
Diagnosis	Clinical diagnosis of major depressive disorder; Primary (70% of sample) or secondary diagnosis (30%)	Structured clinical interview for DSM-IV diagnosis of major depressive disorder; Primary diagnosis only
Baseline severity of depression (PHQ-9), mean (SD)	19.15 (4.46)	19.34 (5.09)
Follow-up period	2 months	3 months

Appendix 10. Final, amended G4H-D logic model