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A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

A multiple single-case experimental design

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Thesis Abstract

Objective: Individuals diagnosed with fibromyalgia are reported to have reduced levels of physical activity which is a key focus of treatment guidelines. Acceptance and commitment therapy (ACT) has previously been shown to increase value-consistent behaviour and levels of activity in individuals with other chronic health conditions. Research into ACT for fibromyalgia has so far been limited but has reported a range of positive outcomes. A key aim of this study was to examine levels of activity utilising activity trackers, and to investigate possible relationships between levels of activity and psychological flexibility (a key process in ACT). In addition the study set out to investigate relationships between psychological flexibility, its core processes, and levels of psychological health, functional ability, symptom severity and the overall impact of fibromyalgia, to identify any possible mechanisms of change.

Methods: This study utilised a non-concurrent mixed-method case-series design (SCED) to explore the effectiveness of an eight-week supported self-help ACT predicated intervention (delivered via bibliotherapy) for six participants diagnosed with fibromyalgia. Multiple levels of analysis focussed on baseline stability, difference between phases, reliable and clinically significant change, individual and overall effect size.

Results: Levels of physical activity were not found to be reduced for this population with no measurable change across the intervention. However, participants reported an increase in meaningful activity. Reliable, clinically significant and beneficial change was shown in psychological flexibility for all participants which was maintained at follow up. Beneficial change was also reported for all participants in psychological distress, functional ability and disorder impact. Symptom severity increased for half of the participants.

Conclusions: The ACT self-help intervention appeared to benefit all six participants in terms of increasing psychological flexibility and meaningful activity. However, levels of physical activity did not increase, and the results suggest the levels of activity reported for individuals diagnosed with fibromyalgia require further investigation. The intervention also appeared to benefit the psychological and functional wellbeing of individuals with fibromyalgia although no clear pattern to infer a mechanism of change emerged from the results. The findings of this study are coherent with ACT theory but

call into question assumptions about low levels of activity within a fibromyalgia population.

Keywords: Fibromyalgia; activity; case series; acceptance and commitment therapy; self-help

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This work is dedicated to ‘Marmite’ and crop rotation in the 14th century!

Statement of contribution

I, Carla Rainbow, declare that this thesis is the product of my own original work, which I have carried out whilst enrolled on the Trent Doctorate in Clinical Psychology. I have received regular input and supervision from my supervisors, Dr Dave Dawson and Dr Mark Gresswell through the course of this research and throughout the three years of the course. I undertook the systematic review and the small-scale research under their supervision and I prepared the main thesis research protocol and applied for ethical approval with their assistance. After ethics were approved, I recruited the participants, fitted them with an activity tracker and sent them the weekly intervention via both e-mail and post. I carried out the weekly telephone contacts and completed the data collection and analysis for this study. Two fellow doctoral students, Megan Mellor and Sarah Shaw, conducted the change interviews, but these were transcribed, analysed and written up by me. Dr Dave Dawson and Dr Mark Gresswell offered consultation during all stages of the research and checked the qualitative elements of data.

Table of contents

Thesis Abstract 1
Acknowledgments 3
Statement of contribution 4
Systematic review 10
Abstract 12
Background 13
Rationale and review objectives 16
Method 16
Results 19
Discussion 35
Limitations 38
Conclusions 38
Implications for practice and future research 39
References 40
Journal paper 45
Abstract: 46
Highlights 47
Background 48
Aims 51
Method 52
Design 52
Recruitment 52
Measures 53
Procedure 55
Intervention 55
Analysis 56
Results 59
Sample 59
Baseline stability 61
Levels of activity – measured as bi-pedal motion with the Fitbit flex 61
Psychological distress – measured by the DASS-21 65
Total fibromyalgia impact –measured by the FIQ-R 66
Psychological flexibility – measured as CompACT total score 69
Conceptualised self –measured by the SEQ 70

RCI, CSC and PEM(DC) results, ... 71
Tau-U analysis ... 75
Framework analysis ... 76
Outcome summary ... 78
Discussion ... 79
Conclusions ... 81
References ... 83
Extended Paper ... 92
1.0 Extended background ... 92
1.1 Diagnosis ... 92
1.2 Aetiology ... 93
1.3 Epidemiology ... 94
1.4 Impact of the disorder ... 95
1.5 Treatment ... 95
1.6 Exercise and increased activity for fibromyalgia ... 97
1.7 Acceptance and Commitment Therapy ... 98
1.8 Relational Frame Theory ... 98
1.9 Rule governance ... 100
1.10 Psychological Flexibility and the six core processes ... 102
Rationale for utilising an ACT based intervention for this research ... 110
Supported self-help interventions ... 111
Extended aims and purpose of investigation ... 111
Extended epistemological position ... 114
2.0 Extended Method ... 115
2.1 Design and rationale ... 115
2.3 SCRIBE reporting ... 116
2.4 Recruitment ... 117
2.5 Sample size ... 119
2.6 Measures ... 119
2.7 Maturation, familiarity and autocorrelation ... 124
2.8 Procedure ... 124
2.9 The intervention ... 127
2.10 Weekly telephone calls ... 129
2.11 Fidelity ... 129

2.12 Analysis 130
Extended ethical considerations and approval 133
Data collection, storage & protection 134
3.0 Extended Results 134
3.1 Participants 134
3.2 Sociodemographic information 134
3.3 Generalisability of sample 135
3.4 External events and extrinsic variability 135
3.5 Telephone calls 136
3.6 Fidelity 136
3.7 Subscales of the DASS-21 137
3.8 Subscales of the FIQ-R 142
3.9 Subscales of the SEQ 145
3.10 Individual change for the dyadic processes of ACT – measured by subscales of the CompACT 148
3.11 Summary of dyadic processes as measured by the CompACT and SEQ 155
3.12 Participant summaries 157
3.14 Overall summary 162
3.13 Framework analysis 165
3.14 Results summary 169
4.0 Extended discussion including limitations and strengths 172
4.1 Discussion in context of theory 174
4.2 Opinion and original consideration 175
4.3 Applicability and clinical relevance 177
4.4 Conclusions 177
4.5 Future recommendations 178
5.0 Critical reflection 179
Extended references 183
Appendices 205
Poster 234
Small Scale Research Project 235
Abstract 237
Background 238
Aims and purpose of investigation 242
Method 242

Results 245
Discussion 246
Conclusions 250
Limitations 250
Recommendations 251
References 252
Tables for SSRP 257
Figure for SSRP 282
Appendix for SSRP 284

List of Tables

Table 1: Selection Criteria 17
Table 2: List of studies reviewed 20
Table 3: Study characteristics 21
Table 4: Acronyms, measures and outcomes 25
Table 5: Outcome measures 29
Table 6: Mediation analysis 34
Table 7: Summary of measures 54
Table 8: Intervention schedule 56
Table 9: Rationale and levels of analysis 58
Table 10: Participant sociodemographic information 60
Table 11: Baseline stability calculations for levels of activity and psychological flexibility 61
Table 12: Pre, post and follow up scores, RCI, CSC and PEM(DC) analysis 73
Table 13: TAU-U analysis across phases A & B1 and phases A & (B1 + B2) controlling for baseline trend 75
Table 14: Qualitative responses to changed behaviour 77
Table 15: Summary of EULAR recommendations for fibromyalgia 97
Table 16: Summary of questions, sources of evidence and hypotheses 113
Table 17: SCRIBE guidelines and adherence 118
Table 18: Clinical interpretation of DASS scores 121
Table 19: Clinical interpretation of the FIQ-R 122
Table 20: Weekly exercises of the intervention 128
Table 21: Telephone call frequency and duration 136
Table 22: Summary of dyadic processes and the corresponding elements of the intervention 155
Table 23: Contrast in subscales of the FIQ-R from baseline to follow up for participant 2 158
Table 24: Contrast in subscales of the FIQ-R from baseline to follow up for participant 4 159
Table 25: Contrast in subscales of the FIQ-R between baseline and follow up for participant 5 160
Table 26: Contrast in subscales of the FIR-R from baseline to follow up for participant 6 161
Table 27: Results summary table 170

Systematic review

Examining the effectiveness of Acceptance and Commitment Therapy for Fibromyalgia: A systematic review

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Abstract

Background: Fibromyalgia is a condition that is characterised by chronic widespread pain with an accompanying range of somatic symptoms. Treatment for Fibromyalgia has been inconsistent and potentially ineffective. Recent developments in Cognitive Behavioural Therapy have led to Acceptance and Commitment Therapy, a third wave trans-diagnostic therapy that has shown promise in a range of conditions including chronic pain. Acceptance and Commitment Therapy research for Fibromyalgia is limited but has shown promise. The validity and generalisability of findings appears to be negatively affected by trial and outcome measure heterogeneity and methodological flaws. Therefore, this review set out to systematically review the effectiveness of Acceptance and Commitment Therapy for Fibromyalgia.

Method: Systematic online and hand searches with the application of selection and quality criteria revealed 110 trials of which 34 were duplicates, 6 were assessed and passed eligibility and were reviewed.

Results: Evidence supported the effectiveness of Acceptance and Commitment Therapy in a range of symptom reduction domains for Fibromyalgia.

Conclusion: Low and medium quality evidence supports the effectiveness of Acceptance and Commitment at reducing the overall impact for FM, pain disability and psychological inflexibility. There is low quality evidence to support psychological inflexibility as a mediator of pain disability, FM impact, self-efficacy, depression, and state and trait anxiety but the conflicting and unsupported evidence is insufficient to support pain acceptance as process of change for ACT within an FM population

Background

Fibromyalgia (FM) is a Medically Unexplained Symptom (MUS) syndrome which is primarily characterised by chronic widespread pain (Jay & Barkin, 2015). The widespread pain is often accompanied by a range of debilitating somatically manifested symptoms including: fatigue (Watson, Buchwald, Goldberg, Noonan, Ellenbogen, 2009); impaired cognition, colloquially termed 'fibro-fog (Glass, 2008); disrupted and non-restorative sleep (Holman, 2008) and Irritable Bowel Syndrome (Wolfe, Michud, Li & Katz, 2010). Individuals diagnosed with FM also have a high prevalence of psychological co-morbidities such as depression and anxiety, which are known to develop and perpetuate chronic pain (Miró, Martínez, Sánchez, Prados, & Medina, 2011) and are often targeted in FM research (Thieme, Turk & Flor, 2004). There is increasing evidence to support a biopsychosocial model of causation (Glombiewski et al, 2010) although the aetiology of FM remains unknown and disputed (Wolfe, Brahler, Hinz, Hauser, 2013). Diagnosis for FM is based on subjective self-reported symptoms and within the general population in Western Countries, the estimated prevalence of FM is escalating from between 2-4% in 2009 (Spaeth, 2009), to between 5.4% and 8% in 2016 (Menzies, 2016) with women nine times more likely to be diagnosed (Staud, 2009).

FM appears to be debilitating to the individual with high levels of symptom severity (Matarín Jiménez et al, 2017) and losses in daily functioning (Segura-Jiménez et al, 2017). FM patients also report damage to their intimate and social relationships (Armentor, 2017). Significantly, the overall impact of FM on the sufferer's global quality of life has been reported to be only secondary to those with end stage renal failure (Wolfe et al, 2010b). The level of individual impact perhaps goes some way to explain the high levels of healthcare utilization for FM patients, which has been the focus of several FM studies (Ljotsson et al, 2013; Luciano et al, 2017). On average individuals in the U.K. diagnosed with FM required 25 medical appointments and 11 prescriptions, in the year prior to diagnosis compared with 12 visits and 4.5 prescriptions per year in controls (Hughes, Martinez, Myon, Taïeb, & Wessely, 2006). Increased utilisation of healthcare provision by FM sufferers continues after diagnosis (Perrot et al, 2012) suggesting current treatment is ineffective and the prognosis for FM is considered poor (Häuser, Perrot, Clauw & Fitzcharles, 2018).

Practitioner knowledge about FM was reported as being low by Ortiz, de la Cruz and Jiméneza (2016) potentially because FM is not recognised as an illness by the European Union. Subsequently there is currently no medication or treatment specifically approved for FM in the U.K. (Jay & Barkin, 2015). Current treatment guidelines for FM are limited and inconsistent with only three countries worldwide; Canada, Germany and Israel having specific treatment guidelines. Other guidelines are developed by professional non-government bodies utlising systematic reviews and meta-analysis to inform them (The American Pain Society, 2005; The Association of the Scientific Medical Societies in Germany, 2012); The Canadian Pain Society, 2013), and The European League Against Rheumatism, 2016) Thieme, Mathys, and Turk (2017) found discrepancies between treatment recommendation within the FM guidelines, which they attributed to inclusion criteria of the studies, the quality of the studies themselves, weighting of results and the composition of the review panels.

Whilst guidelines gave different weight to their recommended treatments; the consistent recommendation is that exercise and Cognitive Behavioural Therapy (CBT) should be the recommended treatment for FM. Pharmacological treatments are perceived as ineffective for FM (Martinez, Myon, Tatob & Wessely, 2006) and should only be prescribed as part of a multi-modal approach (Nüesch, Häuser, Bernardy, Barth and Jüni, 2013). CBT also the most widely researched psychological therapy for FM. Not surprisingly for a diagnosis that is characterised by chronic pain, the primary outcome measure in CBT for FM research, is pain intensity, with physical functioning and depression the main secondary outcomes (Bernardy et al, 2010). Results between studies were reported to be inconsistent (Glombieski et al, 2010) with positive outcomes in these listed domains reported as significant but ranging from small to large effects (Bernardy, Füber, Köllner & Häuser, 2010).

Advances in CBT have led to the development of Acceptance and Commitment Therapy (ACT) a third wave, trans-diagnostic psychotherapy. At the time of previous guideline development, ACT had only a very small evidence base for FM and was not included in any of them. ACT is an action-oriented therapy that is grounded in behavioural theory (Lu and McCracken, 2016). Hayes, Luoma, Bond, Masuda & Lillis (2006) outline how ACT proposes that attempts to supress and control painful

experiences including emotions, psychological or physical experiences (experiential avoidance) can ultimately lead to more distress. In contrast to 'typical' CBT interventions that may seek to change the content of troubling cognitions, ACT seeks to alter the context in which they occur. Rather than attempt to avoid or control sources of pain, ACT attempts to teach clients that human suffering is a common and an appropriate response to some life events and a valued life can co-exist with pain. Clients commit to behaviour change consistent with their own values, independent of how they are feeling (Öst, 2014).

ACT aims to increase Psychological Flexibility (PF), which is the ability to live in the service of creating a rich and meaningful life, in line with individual values, even in the presence of unpleasant experiences. ACT incorporates 6 self-related and intertwined core processes within the PF model (Hayes et al, 2006). (1) Acceptance of things as they are, juxtaposed to experiential avoidance of unwanted private experiences; (2) cognitive defusion, which is untangling thoughts from dominating the awareness and reducing their influence; (3) self as context (SAC) which is becoming aware of how we see ourselves and stepping away from rigid and unhelpful constructions of identity; (4) being aware and present in the here and now, sometimes described as being mindful; (5&6) values and committed action, which is understanding how we want to live our lives to make them meaningful and committing to take action to achieve value driven goals. Whilst PF itself has been reported as a mediator of change within the ACT model (McCracken & Gutiérrez-Martínez, 2011), acceptance as a process has also been found to be a mediator for change within other chronic pain conditions (Cederberg, Cernvall, Dahl, von Essen & Ljungman, 2016)

A meta-analysis for ACT and chronic pain conditions found it to be effective for outcomes such as depression, anxiety, pain interference, pain intensity and illness disability (Veehoff, Trompetter, Bohlmeijer & Schreurs, 2016). ACT studies specifically for FM have been limited but show positive outcomes in a variety of primary outcomes such as reducing the overall impact of FM (Carbonell-Baeza, 2011, Luciano et al, 2014 & Ljotsson et al, 2014), pain disability (Wicksell et al, 2013) and valued living (Steiner et al, 2013). Significant effects have also been demonstrated in domains such as anxiety, depression, cognitive fusion, pain acceptance, pain catastrophising, pain intensity, pain management, fatigue, fear of movement,

psychological flexibility, sleep, self-esteem, self-efficacy and even the cost of healthcare utilisation within the same studies.

Rationale and review objectives

Whilst studies report promising results in terms of significance and effect size, methodological flaws are evident within the evidence such as lack of randomisation (Carbonell-Baeza et al, 2011) and the lack of blinding to participants across all studies. Variations in sample sizes and a diversity of measures utilised to assess a myriad of outcomes make generalisability hard to ascertain. Non-standardised and incomplete ACT intervention formats, heterogeneity in the frequency and duration of treatments, together with the lack of focus on measuring ACT specific elements bring in to question what is being assessed.

The purpose of this review is to systematically identify and assess current research on the effectiveness of ACT-based interventions for individuals with Fibromyalgia. This review could inform future guideline development of treatment for FM. Despite showing initial promise there appears to be a lack of further research in this area and this review might highlight future research developments.

This review aims to answer the following –

- Are ACT-based interventions effective for Fibromyalgia?
- Do ACT-based interventions increase psychological flexibility in individuals diagnosed with Fibromyalgia?
- What are the processes of change within ACT for Fibromyalgia?
- What is the quality of research into ACT for Fibromyalgia?

Method

This systematic review was developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist (Scells et al, 2017) (Appendix A). No protocol exists for this review.

Literature Search

A systematic search of publications was conducted across 5 databases. The first 3; Medline (inception to current date); PsychINFO (19thc to present); CINAHL (Complete 1981 to present) utilised the EBSCO interface. Scopus (inception to present) was on Elsevier and PubMed on the engine of The National Center for Biotechnology Information. Searches on all databases took place on or before 09.08.18. and no date limit was imposed. The following search syntax was used (''Fibromyalgia''[MeSH] OR ''Fibromyalgia'') AND (''Acceptance and Commitment Therapy''[MeSH] OR ''Acceptance and Commitment Therapy'' OR ''ACT''. English language was selected as a search criterion and ''Fibromyalgia'' was selected as a Major subject heading where possible. The search strategy is detailed in Appendix B

Study selection criteria.

Following the systematic search of the literature 107 articles were identified and hand searching of text and forward and reverse citation searching identified another 3 articles. 34 duplicates were removed. The remaining 76 titles and abstracts were reviewed for suitability following a set inclusion criterion based on the PICO framework (Table 1).

Table 1: Selection Criteria

	Criteria	Rationale
P	Fibromyalgia – study must be 100% FM population only	Must be population specific to assess the effectiveness of ACT for FM
I	Intervention studies only	To adequately assess the effectiveness of ACT interventions
	Intervention must be ACT-based and outline ACT processes utilised	To assess quality of the intervention delivered follows ACT principles & processes.
C	No set comparison was specified	For the purposes of inclusivity and because the amount of literature was estimated to be limited
O	No specific outcome measure	After reviewing the literature there was no single measure utilised in ACT for FM research
	English text only	Pragmatically insufficient resources for translation
	Peer-reviewed articles	To increase quality of papers for review required by scientific community

After initial application of the inclusion criteria, 6 potential studies were identified. Full-text articles were obtained. Despite a possible risk of publication bias, it was decided to specify the use of peer-reviewed journals only. Whilst the efficacy of the peer review process is contested and open to the subjectivity of the reviewer, inconsistencies, biases and ethical transgressions by reviewers (Resnik & Elmore, 2016)**,** it is still the standard by which the scientific community respects the quality of submission.

Consideration to grey literature was made when the number of suitable papers was limited however further tentative searching revealed only one possible dissertation paper (Steiner, 2013) which, upon inspection appears to be related to a paper already selected for inclusion (Steiner, Bogusch & Bigatti, 2013). Clarification was sought via e-mail from the primary author but at the time of writing no response had been received. Grey literature was therefore not included.

Methodological quality and risk of bias assessment

Five out of the 6 studies included in this review are randomised control studies (RCT's) and one was an uncontrolled pilot study. Therefore, rather than use a generic quality assessment tool that could potentially fail to assess elements of the study that are specific and essential to the quality of the design (Boland, Cherry & Dickson, 2017) two separate but comparable tools were utilised from the same academic source. The Scottish Intercollegiate Guidelines Network (SIGN, 2018) has compiled a set of appraisal tools for a range of study designs based on the principles of improving standards. The checklists cover selection; allocation; performance; detection, attrition and reporting bias and examines areas such as confounding variables within the study. Both checklists were adapted to account for the quality of an ACT-based intervention (Appendix C).

Data Extraction

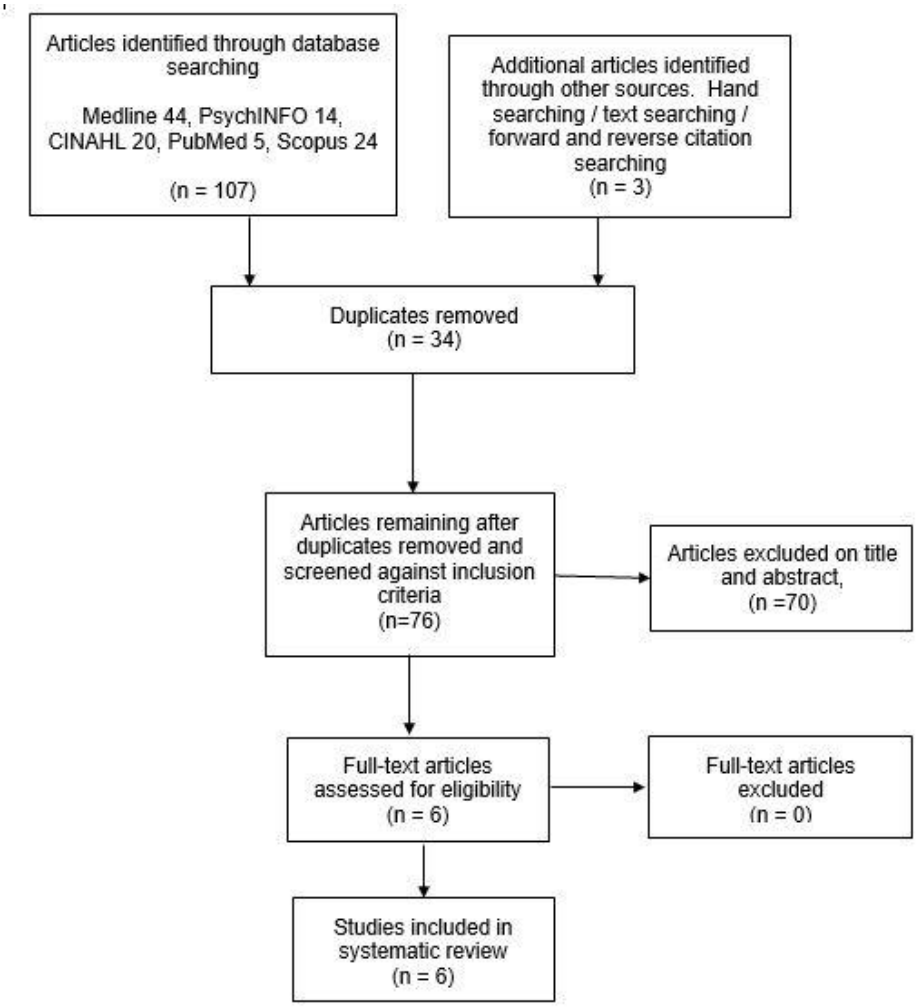
Using a customised data extraction form the following characteristics were collected from each study: Author, date and study location; Sample-size; Mean age; Gender; Study Design; Comparison (where applicable); Intervention delivery; ACT processes; Primary and secondary outcome measures; Timings of measures taken.

Results

Literature Search Outcome & Selection Criteria

The process and outcome of the search strategy is outlined using a PRISMA flow diagram (Figure1). A total of 107 trials were identified from 5 databases and a further 3 from hand text searches. Of these 110, 34 were duplicates which left 76 abstracts to be reviewed for inclusion criteria. Of the 76 only 6 were selected for further eligibility assessment. Those that were rejected were studies that focussed on chronic pain rather than FM or were not ACT-based interventions. 2 papers were secondary analysis of the same study.

Figure 1: PRISMA flow diagram



All 6 studies passed the selection criteria, which is acknowledged as broad, allowing for as much literature on ACT for FM to be reviewed due to the limited amount of studies into ACT for FM. The studies have been tabulated for information purposes (Table 2).

Table 2: List of studies reviewed

1	Carbonell-Baeza, A., Aparicio, V. A., Chillón, P., Femia, P., Delgado-Fernandez, M., & Ruiz, J. R. (2011). Effectiveness of multidisciplinary therapy on symptomatology and quality of life in women with fibromyalgia.
2	Wicksell, R. K., Kemani, M., Jensen, K., Kosek, E., Kadetoff, D., Sorjonen, K., Ingvar & Olsson, G. L. (2013). Acceptance and commitment therapy for fibromyalgia: a randomized controlled trial..
3	Steiner, J. L., Bogusch, L., & Bigatti, S. M. (2013). Values-based action in fibromyalgia: results from a randomized pilot of acceptance and commitment therapy.
4	Luciano, J. V., Guallar, J. A., Aguado, J., López-del-Hoyo, Y., Olivan, B., Magallón, R., ... & Garcia-Campayo, J. (2014). Effectiveness of group acceptance and commitment therapy for fibromyalgia: a 6-month randomized controlled trial
5	Ljótsson, B., Atterlöf, E., Lagerlöf, M., Andersson, E., Jernelöv, S., Hedman, E., ... & Wicksell, R. K. (2014). Internet-delivered acceptance and values-based exposure treatment for fibromyalgia: a pilot study.
6	Simister, H. D., Tkachuk, G. A., Shay, B. L., Vincent, N., Pear, J. J., & Skrabek, R. Q. (2018). Randomized Controlled Trial of Online Acceptance and Commitment Therapy for Fibromyalgia.

Methodological quality and risk of bias assessment

The results of the assessment and listed sources of bias are shown in Table 3 The lower the quality of the paper, the higher the risk of bias. Quality assessment was used to inform the weight of evidence within the discussion and conclusion of this review rather than as an exclusion criterion. Ratings on two of the studies (Wicksell et al, 2013 & Luciano et al, 2014) were found to be consistent with a systematic review of ACT for chronic pain (Simpson, Mars & Esteves, 2017).

Study Characteristics

Study characteristics are summarised in Table 3

Table 3: Study characteristics

	Author & Location	Sample size	Mean age	Gender balance	Study Design	Comparison	Intervention	ACT processes	Primary outcome measures	Secondary outcome measures	Timing of measures	Source of bias	Quality of evidence rating
1	Carbonell-Baeza et al, 2011 Spain	75 41- ACT 34-WL	51.4 SD 7.4	100% Female	RCT	Waiting List	Group 12 weeks 40 mins	Acceptance Being Aware Values Committed Action	FIQ	SF-36 HADS VPMI RSES	Pre Post No follow up	No randomisation Allocation concealment not reported Lack of blinding to participants Only 4/6 ACT processes Multi-disciplinary	Low
2	Wicksell et al, 2013 Sweden	40 23-ACT 17-WL	45 SD 6.6	100% Female	RCT	Waiting List	Group 12 weeks 90 mins	Acceptance Cognitive Defusion Being Aware Values Committed Action	PDI PIPS	FIQ SF-36 SES BDI STAI SPS	Pre Post 3-4 months (mean 108.7 – SD 17.0)	Allocation concealment not reported Lack of blinding to participants Only 5/6 ACT processed	Low
3	Steiner et al, 2013 U.S.A	28 18-ACT 10-PED	48 SD 13	100% Female	RCT	Pain Management Education	1:1 session 12 weeks 1 hour	Acceptance Cognitive Defusion Being Aware Self as Context Values Committed Action	CPVI	n/a	Pre Post 12 weeks	No randomisation process reported Allocation concealment not reported Lack of blinding of participants Attrition not accounted for during intervention Not all measures taken are reported	Low
4	Luciano et al, 2014 Spain	156 51-ACT 53-WL 52-RPT	48	96.17% Female	RCT	Waiting List Recommended pharmacological treatment	Group 8 weeks	Acceptance Cognitive Defusion Being Aware Self as Context Values Committed Action	FIQ	MINI HADS PCS CPAQ PVAS EQ5D AES	Pre Post 3 months 6 months (only 6 month analysed)	Lack of blinding to participants Educational status of participants and number of depressed participants varied at baseline	Medium
5	Ljotsson et al, 2014 Sweden	41 41-ACT	52 SD 9.0	100% Female	Pilot Study	N/A	Internet delivered 10 weeks	Acceptance Cognitive Defusion Being Aware Self as Context Values Committed Action	FIQ	PDI PIPS HADS SF-12 FSS TIC-P	Pre Post 6 months	Lack of blinding of participants No comparison between full participants and those lost to follow up	Medium
6	Simister et al, 2018 Canada	67 33-ACT 34-TAU	39.7 SD 9.36	95% Female	RCT	Treatment as Usual	Internet modules & Treatment as Uusual 3 months	Acceptance Cognitive Defusion Being Aware Self as Context Values Committed Action	FIQ-R	CES-D SF-MPQ PSQI 1 SST 6 WT CPAQ-R FFMQ CFQ VLQ	Pre Post 3 month	Lack of blinding of participants Attrition not reported	Medium

Year and location

Carbonell-Baeza et al, 2011) report the first ACT study for FM, although it is multi-disciplinary and therefore Wicksell et al (2013) is often credited as the first ACT for FM study. Steiner et al also published in 2013 with both Luciano et al and Ljotsson et all publishing in 2014. There is then a jump until 2018 until the next published ACT study for FM by Simister et al. There is currently no U.K. study published with Spain, Sweden, Canada and The United States of America hosting these published studies.

Sample sizes

Total sample sizes ranged from 28 (Ljotsson et al, 2014) to 156 (Luciano et al, 2014) with large variations also shown in the range of sample sizes assigned to the ACT based conditions (range 18-51) and controls (10-51). Participants had a confirmed diagnosis of FM.

Mean age and Gender

The mean ages of participants ranged from 39.7 to 52. Four of the studies had all female participants (Carbonell-Baeza et al, 2011; Wicksell et all, 2013; Steiner et al, 2013 & Ljotsson et al, 2014) with the other two studies had high ratios of female participants of 96.17% (Luciano et al, 2014) and 95% (Simister et al, 2018)

Study Design

One study was a pilot (Ljotsson et al, 2014), the other 5 studies are RCT's and 3 of these (Carbonell-Baeza et al, 2011; Wicksell et al, 2013; Luciano et al, 2014) utilised a waiting list control. One trial used pain management education as its control (Steiner et al, 2013) and no detailed information was provided as to what this entailed. A further study utilised treatment as usual as a control. Treatment as usual was also continued in the ACT based group but varied widely from prescription drugs, exercise programmes to spinal blocks or physiotherapy. Only one study utilised an active control and this was in conjunction with a wait list control (Luciano et al, 2014). The active control was recommended pharmacological treatment which varied in prescription and dosage: pregabalin (300-600 mg/d); duloxetine (60-120 mg/d); analgesics; benzodiazepines and hypnotics.

Intervention

There was no consistent ACT intervention across all 6 studies with delivery methods including 1:1 sessions (Steiner et al, 2013), group-based therapy (Carbonell-Baeza et

al, 2011; Wicksell et al, 2013; Luciano et al, 2014) and internet delivered modules (Ljotsson et al, 2014 and Simister et al, 2018). Intervention length ranged from 8 weeks to 3 months with reported weekly exposure ranging from not specified to as little as 40 minutes to a maximum of 90 minutes. Only three studies included intervention fidelity checks (Wicksell et al, 2013, Steiner et al, 2013 & Luciano et al, 2014).

ACT processes

ACT has six core processes (acceptance, cognitive defusion, being aware, self as context, values and committed action). Only 4 of the studies report delivering all 6 processes (Steiner et al, 2013; Ljotsson et al, 2014; Luciano et al, 2014 and Simister et al, 2018). Carbonell-Baeza et all (2011) delivered just 4 processes with Wicksell et al, (2013) delivering 5. Whilst most components are listed specifically it was noted that being aware was also termed as contact with the present, mindfulness and being present. Within this review it is referred to as 'being aware'. Only Wicksell et all (2013) specified giving summary sessions of missed components and it is unclear in the remaining studies which components were missed by participants.

Timing of measures

One study took only pre and post intervention measures with no follow up (Carbonell-Baeza et al, 2011); one study specified follow up measures at 12 weeks in addition to the pre and post measures (Steiner et al, 2013) whilst Wicksell et al (2013) and Simister et al (2018) outline an approximate 3 month follow up. Luciano et al (2014) state that 3 and 6-month measures were taken but that only the 6-month measure was used for analysis. Ljotsson et al (2014) took follow up measures at 6 months.

Outcome measures

Outcome measure information is outlined in Table 4.

There is no consistent primary outcome measure or single measure that encompassed all 5 studies but the Fibromyalgia Impact Questionnaire (FIQ) and its revised version (FIQ-R) was utilised in 5 of the 6 studies (Carbonell-Baeza et al, 2011; Wicksell et al, 2013; Luciano Ljotsson et al, 2014; Luciano et al, 2014 and Simister et al, 2018). A total of 31 measures were used (2 were revised versions), measuring a range of 23 outcomes; adverse (side) effects; anxiety; depression; cognitive fusion; cost impact of healthcare utilisation; fatigue; fear of movement; mindfulness; overall impact; pain

acceptance; pain catastrophising; pain disability; pain intensity; pain management; physical ability; psychological flexibility; quality of life; sleep; self-esteem; self-efficacy and valued living. Overall impact (FIQ & FIQ-R) and depression (BDI, CES-D & HADS) were the most commonly measured outcomes with only Steiner et al, 2013 not measuring these outcomes. Unsurprisingly for a condition which is characterised by chronic pain 7 separate measures generated a lot of data which focussed on differing aspects of pain.

Results of Outcome Measures

Outcome measure results are summarised in Table 5. Where available p values and cohen d's values are reported together with confidence intervals.

Overall impact and quality of life

To examine the overall impact and quality of life for individuals diagnosed with FM, four studies (Carbonell-Baeza et al, 2011, Wicksell et al, 2013, Luciano et al, 2014 & Ljotsson et al, 2014) utilised the Fibromyalgia Impact Questionnaire (FIQ) with Simister et al (2018) using the revised version (FIQ-R). Both versions are divided into 3 subscales; functional, overall, symptomology. Significant effects were reported in the overall score for these five studies. No effect size was reported for Carbonell-Baeza et al (2011), but in the low-quality study Wicksell et all (2013) reported small to medium effect at post treatment measure which was sustained at follow up.

Table 4: Acronyms, measures and outcomes

Acronym	Measure	Measuring	Papers					
			1	2	3	4	5	6
1 SST	1 min sit stand test	Physical ability						S
6 WT	6 minute walk test	Physical ability						S
AES	Assessment of adverse effects	Adverse (side) effects				S		
BDI	Becks depression inventory	Depression		S✓				
CES-D	Centre for epidemiological studies for depression	Depression						S✓
CFQ	Cognitive fusion questionnaire	Cognitive fusion						S✓
CPAQ	Chronic pain acceptance questionnaire	Pain acceptance				S		
CPAQ-R	Chronic pain acceptance questionnaire – revised	Pain acceptance						S✓
CPVI	Chronic pain values inventory	Values living with pain			P✓			
EQ5D	EuroQoL visual analogue scale	Quality of Life (QoL)				S		
FFMQ	Five facet mindfulness questionnaire	Mindfulness						PR
FIQ	Fibromyalgia impact questionnaire	Impact	P✓	S✓		P✓	P✓	
FIQ-R	Fibromyalgia impact questionnaire – revised	Impact						P✓
FSS	Fatigue severity scale	Fatigue					S✓	
HADS	Hospital anxiety and depression scale-	Depression and Anxiety	S			S	S✓	
PCS	Pain catastrophising scale	Pain catastrophising				S✓		PR
PDI	Pain disability index	Pain disability		P✓			S✓	
PIPS	Psychological inflexibility in pain scale	Psychological inflexibility		PR ✓			S✓	
PSQI	Pittsburgh sleep quality index	Sleep						S
PVAS	Pain visual analogue scale	Pain intensity				S✓		
RSES	Rosenberg self-esteem scale Spanish version	Self-esteem	S					
SES	Self-efficacy scale	Self-efficacy		S✓				
SPS	Self-reported pain intensity numeric scale	Pain intensity		S✓				
SFMPQ	McGill pain questionnaire	Pain – affect & sensory						S✓
SF-12	Short form health survey	Mental and Physical QoL					S✓	
SF-36	Health related survey	Mental l QoL	S✓	S✓				
	(SF-36 separated for clarity)	Physical QoL	S✓	S				
STAI	Spielberger trait-state anxiety inventory	Anxiety – State and trait		S✓ ✓				
TIC-P	Trimbos & institute of medical technology assessment cost questionnaire for psychiatry	Cost impact of healthcare					S✓	
TSK-11	Tampa scale for Kiniesiophobia	Fear of movement						PR ✓
VLQ	Valued living questionnaire	Values						PR ✓
VPMI	Vandebilt Pain Management	Pain Management	S✓					

P=primary outcome measure S=secondary outcome measure PR=reported as process variable
✓= significant change reported

In the three medium quality studies Ljotsson et al, 2014 reported a medium to large effect which increased at follow up and both Luciano et al (2014) and Simister et al (2014) reported large effects at post measures which was sustained at follow up.

In addition to the FIQ Luciano et al (2014) used the EuroQoL visual analogue scale (EQ5D) to ascertain overall quality of life which showed no significant effect.

Physical and mental wellbeing

Eight different measures were used to examine differing aspect of physical and mental wellbeing. Only one paper (Simister et al, 2018) tested functional physical ability by assessing a 6-minute walk and 1-minute sit stand test. There was no significant effect reported.

The Hospital Anxiety and Depression Scale (HADS) was used in three papers (Carbonell-Baeza, 2011, Luciano et al, 2014 & Ljotsson et al, 2014). No significant effect was reported by the low-quality study of Carbonell-Baeza et al (2011) and results were inconsistent in the medium quality studies as Luciano et al (2014) also reported no significant effect but a significant medium to large effect which increased at follow up was reported by Ljotsson et al, 2014).

Depression was also measured using the Becks Depression Inventory (BDI) by Wicksell et al (2013) and the Centre for Epidemiological Studies for Depression scale (CES-D) (Simister et al, 2018). In both cases a significant effect was shown. In the low-quality paper (Wicksell et al, 2013) effect size diminished at follow up but the opposite was shown in the medium quality paper.

Anxiety was measured by the Spielberger trait-state anxiety inventory by Wicksell et al (2013) and significant improvements were shown in both state and trait dimensions of this scale with the medium effects sustained at follow up.

The Short Form Health Questionnaire was used in its full version (SF-36) (Carbonell-Baeza et al, 2011, Wicksell et al, 2013) and the short version (SF-12) (Ljotsson et al, 2014). All reported a significant effect for mental quality of life that was either sustained or increased at follow up. Only Ljotsson et al (2014) reported a significant

effect for physical quality of life but one that decreased from large to medium at follow up.

Pain

Five different aspects of pain (acceptance; catastrophising; disability; intensity; management) were assessed using eight measures (Table 4) including a revised version of the Chronic Pain Acceptance Questionnaire (CPAQ & CPAQ-R).

Pain acceptance

Luciano et al (2014) used the CPAQ and Simister et al (2018) used the CPAQ-R to measure pain acceptance within a FM population. Only Simister et al (2018) report a significant condition x time change (p=0.012). Both medium quality studies use this as a measure of the acceptance process within ACT.

Pain catastrophising

Two medium quality studies (Luciano et al, 2014 & Simister et al, 2018) employed the Pain Catastrophising Scale (PCS) and this time only Luciano et al (2014) report the effect as being significant.

Pain disability

The Pain Disability Index (PDI) was used as a primary outcome measure by Wicksell et al (2103) and a secondary outcome measure by Ljotsson et al (2014). Both studies report significant effects (Wicksell et al – medium/large & Ljotsson et al – large) at post treatment measure that were sustained at follow up.

Pain intensity

Three separate measures were used to measure pain intensity. Two of these were visual analogue scales (Pain Visual Analogue Scale (PVAS) & Self-Reported Pain Intensity Scale (SES). Luciano et al (2014) used the PVAS in their medium quality study where participants self-report their levels of pain intensity on a scale of 0-10cm rule line (0= no pain 100= worse pain) and reported a significant medium effect at post treatment which decreased slightly at follow up. Wicksell et al (2013) also reported a decreasing significant effect using the SES a self-report numeric 0-10 rating scale. In their medium quality paper, Simister et al (2018) used the McGill Pain Questionnaire (SFMPQ) and the findings mirror the previous studies by reporting a significant but decreasing effect from post to follow up (Large – small effect).

Pain management

The Vanderbilt Pain Management Inventory (VPMI) assesses active and passive coping strategies (active where participants function despite of their pain: passive – where participants relinquish control of their pain to others) and was used in the low quality Carnobell-Baeza et al (2011) study. A significant effect is reported but no effect sizes are given.

Fibromyalgia symptoms

In addition to overall impact and chronic pain, FM sufferers report other symptoms including fatigue (Watson, Buchwald, Goldberg, Noonan, Ellenbogen, 2009) and disrupted and non-restorative sleep (Holman, 2008). Ljotsson et al (2014) assessed the effect of ACT on fatigue and found a significant medium to large effect that slightly decreased at follow up (medium). Utilizing the Pittsburgh Sleep Quality Index (PSQI), Simister et al (2018) detail similar conclusions on sleep quality.

Self-esteem

Carbonell-Baeza et al (2011) examined self-esteem by utlising the Rosenberg Self-esteem Scale (RSES Spanish version) and found no significant effect.

Table 5: Outcome measures

	Author	Statistical analysis	Results of primary outcome measures	Measure	Results of secondary outcome measures	Measure
1	Carbonell-Baeza et al, 2011	t-test and chi-square to compare demographic variables 2 factor (group*time) ANCOVA repeated measures to examine intervention effects on outcome variables. P values reported Intention to treat analysis	ACT: Significant interaction effect (group*time) reported on overall impact on pre and Post measures pre 72.5 (SD2.2); Post 63.3 (SD2.5) (p=<0.001) WL: significant worsening reported on overall impact score on pre and Post measures – pre 70.5 (SD2.3) – Post 74.7 (SD2.6)	FIQ	SF-36: ACT reported significant Post treatment improvement in Physical QoL (p=0.001); Bodily pain (p=0.003); Vitality (p=0.003); Social functioning (p=,0.001); Mental QoL (p=0.008). WL reported significant decrease in social functioning (p=0.019) HADS: ACT no significant Post treatment change reported VPMI: ACT reported significant Post treatment improvement in passive coping (p=0.005) RSES: ACT no significant Post treatment change reported	SF-36 HADS VPMI RSES
2	Wicksell et al, 2013	1 way ANOVA to identify pre-treatment differences between conditions Linear mixed-effects model analysis. Cohen's d with point estimates and 95% confidence intervals reported Bivariate correlations and mediation analysis Intention to treat analysis	ACT: reports statistically significant group x time interaction in pain disability (p<0.001) and reports significant improvement at both Post and Follow up compared to control group; Post d=.75 (0.04: 1.44) Follow up d=0.73 (-0.00: 1.44) WL: No significant effect reported in the comparison group.	PDI	FIQ: ACT: reports statistically significant group x time interaction on FMS impact (p=0.047). ACT vs WL: Post d=.41 (-0.29: 1.11) Follow up d=0.66 (-0.06: 1.37). SF-36: ACT: reports statistically significant group x time interaction in mental quality of life (p=0.030). ACT vs WL: Post d=.84 (0.08: 1.57) Follow up d=1.06 (0.28: 1.82). ACT: There was no statistically significant group x time interaction in physical quality of life (p=0.775). ACT vs WL: Post d=0.19 (-0.52: 0.91); Follow up d=0.28 (-0.45: 1.00) SES: ACT: reports statistically significant group x time interaction in self-efficacy (p=0.049). ACT vs WL; Post d=0.74 (0.03: 1.43); Follow up d=0.38 (-0.33: 1.08) BDI: ACT; reports statistically significant group x time interaction in for depression (p=0.005). ACT vs WL Post d=0.44 (-0.28: 1.14); Follow up d=0.64 (-0.08: 1.35) STAI: ACT; reports statistically significant group x time interaction in both state (p=0.021) and trait (p=0.003) anxiety. ACT vs WL State Post d=0.51 (-0.018: 1.20) Follow up d=0.55 (-0.17: 1.26). Trait Post d=0.73 (0.03: 1.43) Follow up d=0.74 (0.01: 1.46) SPS: ACT; no statistically significant group x time interaction in pain intensity (p=0.066). ACT vs WL Post d=0.38 (0.32: 1.07) Follow up d=0.82 (-0.08: -1.54) PIPS: ACT; reports statistically significant group x time interaction in psychological inflexibility (p=0.008). ACT vs WL Post d=1.06 (0.32: 1.79) Follow up d=0.72 (-0.01: -1.43)	FIQ SF-36 SES BDI STAI SPS PIPS
3	Steiner et al, 2013	ANCOVA used to assess group differences at baseline Paired sample t-tests to examine within group differences	Confidence Intervals were not reported ACT: reports statistically significant positive change in family relationships at Post (p=0.005) and Follow up (p=0.003). Post t(17)=3.19 d=0.75 Follow up t(17)=3.43 d=0.81 PED: reports no statistically significant change in family relationships at Post (p=0.089) or Follow up (p=0.057). Post t(9)=1.91 d=0.60 Follow up t(9)=2.18 d=0.69 ACT: reports statistically significant positive change in intimate relationships at Post (p=0.015) and Follow up (p=0.036). Post t(17)=2.70 d=0.64 Follow up t(17)=2.27 d=0.53	CPVI	N/A	N/A

			PED: reports no statistically significant change in intimate relationships at Post (p=0.798) or Follow up (p=0.357). Post t(9)=0.26 d=0.08 Follow up t(9)=0.97 d=0..31 ACT: reports statistically significant positive change in work at Post (p=0.014) but not at Follow up (p=0.532). Post t(17)=2.75 d=0.64 Follow up t(17)=0.64 d=0.15 PED: reports no statistically significant change in work at Post (p=1.000) or Follow up (p=0.413). Post t(9)=0.00 d=0.00 Follow up t(9)=0.86 d=0.27			
4	Luciano et al, 2014	1 way ANOVA to identify pre-treatment differences between conditions with Post hoc Tukey on baseline measures Linear mixed-effects model analysis Bonferroni to adjust significant levels of pairwise contrasts Bivariate Pearson correlations and mediation analysis Intention to treat analysis	ACT: reports statistically significant group x time interaction effect on overall impact p=.036 GACT vs RPT – Post d=1.43 (1.12: 1.75); Follow up d=1.43 (1.08: 1.78) GACT vs WL - Post d=2.35 (1.98: 2.72); Follow up d=2.11 (1.69: 2.54) RPT vs WL - Post d=.55 (0.22: 0.88); Follow up d=0.34 (-0.02: 0.71)	FIQ	PCS: ACT: reports statistically significant group x time interaction effect on pain catastrophising p=.042. GACT vs RPT – Post d=0.76 (0.60: 0.93); Follow up d=0.69 (0.53: 0.84) GACT vs WL - Post d=0.89 (0.73: 1.06); Follow up d=0.72 (0.57: 0.88) RPT vs WL - Post d=.14 (-0.03: 0.30); Follow up d=0.04 (-0.12: 0.19) PVAS: ACT: reports statistically significant group x time interaction effect on pain intensity p=.0.15. GACT vs RPT – Post d=0.62 (0.42: 0.83); Follow up d=0.47 (0.26: 0.68) GACT vs WL - Post d=0.93 (0.74: 1.12); Follow up d=0.80 (0.61: 0.99) RPT vs WL - Post d=..37 (0.17: 0.57); Follow up d=0.38 (0.18: 0.58) HADS: ACT: reports no significant group x time interaction effect on depression and anxiety p=.662 GACT vs RPT – Post d=0.36 (0.15: 0.57); Follow up d=0.39 (0.17: 0.61) GACT vs WL - Post d=0.77 (0.57: 0.96); Follow up d=0.85 (0.65: 1.06) RPT vs WL - Post d=..46 (0.25: 0.67); Follow up d=0.52 (0.29: 0.74) CPAQ: ACT: reports no significant group x time interaction effect on acceptance of pain p=.119 GACT vs RPT – Post d=1.05 (0.85: 1.25); Follow up d=1.01 (0.81: 1.20) GACT vs WL - Post d=1.21 (1.03: 1.40); Follow up d=1.14 (0.95: 1.33) RPT vs WL - Post d=.23 (0.04: 0.42); Follow up d=0.19 (0.001: 0.38) EQ5D: ACT: reports no significant group x time interaction effect on acceptance of pain p=.070 GACT vs RPT – Post d=0.85 (0.60: 1.10); Follow up d=0.66 (0.38: 0.94) GACT vs WL - Post d=1.06 (0.83: 1.29); Follow up d=0.84 (0.58: 1.10) RPT vs WL - Post d=.31 (0.04: 0.59); Follow up d=0.26 (0.05: 0.57) AES: ACT none reported. RPT: Nausea 25%, Dry mouth 23.1%, Drowsiness 21.2%, Constipation 19.2%, Headache 21.2% and Fatigue 21.2% (5 participants left due to AE's). WL: none reported	PCS PVAS HADS CPAQ EQ5D AES
5	Ljotsson et al, 2014	Dependent sample t-tests on pre to post and post to follow up. Dependent t-tests on post to follow up Multiple linear regression analysis to assess further healthcare seeking on follow up	ACT reports statistically significant decrease in overall impact and in the FIQ pain subscale. ACT: Within group effect size FIQ overall Post d=0.71 (0.46: 0.97) Follow up d=0.96 (0.66: 1.27) FIQ pain Post 0.62 (0.29: 0.95) Follow up 1.22 (0.81: 1.63)	FIQ	ACT: significant decreases on all measures from pre to post treatment, t(36.60-38.13)=4.70-10.46, all ps<.001 and from pre to follow up, t(35.31-38.07=4.33-11.64, all ps<.001 Within group effect sizes PDI: Post d=0.82 (0.56: 1.09); Follow up d=0.87 (0.55: 1.19) SF-12^{m}*: Post d=0.63 (0.33: 0.93); Follow up d=0.93 (0.86: 0.48) SF-12^{p}*: Post d=0.85 (0.56: 1.14); Follow up d=0.69 (0.33: 1.03) HADS ^{a}:: Post d=0.75 (0.40: 1.10); Follow up d=0.90 (0.52: 1.27) HADS ^{d}: Post d=0.80 (0.52: 1.08); Follow up d=1.03 (0.64: 1.43)	PDI SF-12 HADS FSS PIPS

		controlling for post scores. Not reported in this review			FSS: Post d=0.75 (0.47: 1.02); Follow up d=0.62 (0.38: 0.87) PIPS: Post d=1.56 (1.11: 2.01); Follow up d=1.63 (1.20: 2.07) *higher scores indicate better health. Sign of effect changed for clarity	
6	Simister et al, 2018	Linear mixed effects modelling to analyse the effects of treatment compared with control. Longitudinal mediation analysis if a significant condition x time interaction found. Bootstrap resampling	ACT: A significant condition time effect demonstrating improvement in FM impact (p<.001). Between Condition effects Post: d=1.26 (0.70: 1.80) Follow up d=1.59 (1.00: 2.16)	FIQ-R	CES-D: ACT: A significant condition x time effect demonstrating improvement in Depression (p=.020). ACT vs TAU Post: d=0.87 (0.34: 1.39) Follow up d=0.56 (0.04: 1.07) SF-MPQ: ACT: A significant condition x time effect demonstrating improvement in Pain (p=.010). ACT vs TAU Post: d=0.84 (0.32: 1.36) Follow up d=0.11 (-0.39: 0.62) PSQI: ACT: No significant condition x time effect was reported for sleep (p=.055). ACT vs TAU Post: d=0.79 (0.26: 1.31) Follow up d=0.53 (-0.02: 1.04) 6WT: ACT: No significant condition x time effect was reported for the walking test (p=.126). ACT vs TAU Post: d=0.06 (-0.44: 0.56) Follow up d=0.28 (-0.22: 0.79) 1SST: ACT: No significant condition x time effect was reported for the sit stand test (p=.277). ACT vs TAU Post: d=0.06 (-0.44: 0.56) Follow up d=0.10 (-0.40: 0.60) CPAQ-R: ACT: A significant condition x time effect was reported in pain acceptance relative to TAU (p=0.012). ACT vs TAU Post: d=0.84 (0.31: 1.36) Follow up d=0.80 (-0.25: 0.76) FFMQ: ACT: No significant condition x time effect was reported for Mindfulness (p=.980). ACT vs TAU Post: d=0.29 (-0.21: 0.80) Follow up d=0.26 (-0.40: 0.60 CFQ: ACT: A significant condition x time effect was reported for cognitive fusion (p=.007). ACT vs TAU Post: d=0.25 (-0.25: 0.75) Follow up d=0.65 (-0.13: 1.16) VLQ: TAU: A significant condition x time effect was reported for values (p=.027). ACT: ACT vs TAU Post: d=0.19 (-0.31: 0.70) Follow up d=0.46 (-0.05: 0.97) TSK-11: ACT: A significant condition x time effect was reported for kinesiophobia (p<.001). ACT vs TAU Post: d=0.95 (-0.41: 1.47) Follow up d=0.64 (0.12: 1.15) PCS: ACT: No significant condition x time effect was reported for pain catastrophising (p=.051). ACT vs TAU Post: d=0.36 (-0.14: 0.87) Follow up d=0.26 (-0.24: 0.76)	CES-D SF-MPQ PSQI 6WT 1SST CPAQ-R FFMQ CFQ VLQ TSK-11 PCS

d=0.2 (small effect), d=0.5 (medium effect), d= (large effect) (Cohen, 1988)

Self-efficacy

Wicksell et al (2013) examined self-efficacy by utilising the Self-efficacy Scale (SES). It was reported that a significant medium/large effect at post treatment measure decreased to small effect at follow up.

Cost of healthcare utilisation

Luciano et al (2014) utilised the Trimbos & Institute Medical Technology Assessment Cost Questionnaire for Psychiatry (TIC-P) to assess the effect of healthcare utilisation and its cost following the ACT intervention and report significant reductions at both post (p=.002) and follow up (p=.04) were reported. Another study (Luciano et al, 2017) further examined the cost effectiveness of the ACT intervention based on this study.

ACT measures

Only three ACT processes were measured directly (Cognitive defusion, Mindfulness (Being aware) and Values) by Simister et al (2018) who also measured fear of movement (kiniesiophobia), which indirectly links to experiential avoidance but is not an ACT process measure. Psychological Flexibility which is the target of ACT is measured dichotomously by the Psychological Inflexibility in Pain Scale (PIPS) in only two of the six studies (Wicksell et al, 2013 & Ljotsson et al, 2014) and is not approached in the other four.

Cognitive fusion

Simister et al (2018) engaged the Cognitive Fusion Questionnaire (CFQ) to measure cognitive fusion. A significant positive condition x time effect was reported with small effect size at post treatment measure increasing at follow up.

Mindfulness

Simister et al (2018) used the Five Facet Mindfulness Questionnaire (FFMQ) and found no significant effect.

Values

Simister et al (2018) examined values with the Valued Living Questionnaire (VLQ). An increase in valued living was reported and the significant effect increased between post and follow up treatment measures (small to medium effect).

The Chronic Pain Values Inventory (CPVI) is the sole measure in the low-quality Steiner et al (2013) study. It purports to measure the effects of chronic pain on a

person's values in 6 single item domains. The six domains are family, intimate relations, work, friends, health and personal growth but only the former three are reported within the study. Importance of values is rated 0-5 (0=not important 5=extremely important) and then participants also rate their success in these domains 0-5 (0=not successful 5=extremely successful. In the three domains that were reported (Family, intimate relationships and work) Steiner et al (2013) report significant effects. In the family domain the effect increased slightly at follow up (medium/large – large), in intimate relationships a medium effect was sustained at follow up and in the work domain a medium effect decreased to small effect at follow up.

Fear of movement

Simister et al (2018) used the Tampa Scale for Kiniesiophobia to measure fear of movement. A significant large effect was reported at post treatment effect which decreased at follow up.

Psychological inflexibility

Wicksell et al (2013) and Ljotsson et al (2014) measure psychological inflexibility using the Psychological Inflexibility in Pain Scale (PIPS). Both studies, the former a low quality and the latter a medium quality study, report significant effects. Wicksell et al (2013) detail a large effect which decreases to medium large at follow up and Ljotsson et al (2014) report a large effect at post treatment which was sustained at follow up.

Mediation analysis

Mediation analysis is summarised in Table 6

Psychological inflexibility

In a low-quality study Wicksell et al (2013) report that significant relationships between pre and post changes in psychological inflexibility and pain disability, FM impact, self-efficacy, depression, and state and trait anxiety.

Pain acceptance

Two medium quality studies examined pain acceptance as a mediator for change. Luciano et al (2014) found there to be no mediating relationship between pain acceptance and any of the outcome measures using the CPAQ as the measure for pain acceptance. In contrast Simister et al (2018) using the CPAQ-R and reported a significant mediating relationship between pain acceptance and FM impact but no other measure.

Table 6: Mediation analysis

	Author	Statistical analysis	Results of mediation	Measures
1	Carbonell-Baeza et al, 2011	N/A	N/A	N/A
2	Wicksell et al, 2013	Mediation analysis Bivariate correlations* Bootstrap analysis for indirect effects	*Mediation analysis restricted to outcome variables with significant time x condition interactions. *Significant relations between pre and post changes in psychological inflexibility and pre and follow up changes in pain disability (r=0.62, p<0.001), FM impact (r=0.40, p= 0.03), self-efficacy (r= -0.70, p<0.001), depression (r=0.54, p=0.002), state (r=0.61, p<0.001) and trait (r=0.35, p<0.05)	PIPS PDI FIQ SES BDI STAI
3	Steiner et al, 2013	N/A	N/A	N/A
4	Luciano et al, 2014	Mediation analysis Path analysis models Bivariate correlations	No statistically significant differences in pain acceptance between the ACT and RPT at baseline (p=.39). Both increased significantly from baseline to after assessment (ACT p=<.001 RPT p=<.001) but pain acceptance did not mediate changes in functional status, pain catastrophising, pain intensity, anxiety and depression but did mediate QoL	CPAQ FIQ HADS-A PVAS EDQ-50
5	Ljotsson et al, 2014	N/A	N/A	N/A
6	Simister et al, 2018	Mediation analysis Longitudinal mediation analysis if a significant condition x time interaction found.	Increases in pain acceptance from pre to post treatment mediated the effects of treatment on pre-treatment to follow up improvements in FM impact (FIQ-R, a x b=-3.58, p=.005, 995 CI= -10.69: -0.03. Changes in pain acceptance did not mediate improvements in any of the other outcome variables. A second mediation analysis in kinesiophobia did not mediate improvements in FM impact (TSK-11; a x b= -.14, p=.949, 95%CI= -5.86: 5.09)	CPAQ-R FIQ-R CES-D SF-MPQ CFQ VLQ TSK-11

Outcome variable	Indirect effect	Bootstrapped bias corrected
PDI – pain disability	-3.65	*-11.52: -0.54
FIQ - impact	-3.18	**-10.67: -0.03
SES – self efficacy	15.80	*1.83: 43.34
BDI - depression	-1.98	**-4.81: -0.42.
STAI - State	-5.08	*-14.82: -0.57
STAI – trait	-.2.71	*-8.16: -0.06

*99% CI p<0.01 **95% CI p<0.05

Outcome variable	Indirect effect (Standardised)	Bootstrapped bias corrected 95% CI
FIQ	-1.07 (-0.04)	-5.41; 2.91
PCS	-1.08 (-0.10)	-2.70;0.20
HADS-A	-0.67 (-0.10)	-1.76; 0.44
PVAS	-2.21 (-0.07)	-7.98; 2.73
EQ-5D	4.53 (0.17)	0.65; 8.82

Discussion

This systematic review set out to examine the effectiveness of ACT for Fibromyalgia, to ascertain if ACT increases psychological flexibility in FM, to identify processes of change and to assess the quality of research that the current evidence for ACT for FM rests upon. Heterogeneity across outcome measures, the ACT interventions and risk of bias inhibit meta-analysis. Consideration was made in respect of the FIQ measure which is utilised in its original or revised form across five of the six studies but again differences in version, delivery method, follow up and study type precluded further analysis.

Effectiveness of ACT for Fibromyalgia

As Bernardy et al (2010) found with CBT interventions for FM, there is a large focus on symptom reduction and pain in ACT research for FM. Whilst symptom reduction is not a target for ACT interventions it is of obvious interest to participants and researchers alike and what really matters for individuals living with the condition. Four of the six studies utilised the FIQ (Carbonell-Baeza, 2011, Wicksell et al, 2013, Luciano et al 2014 and Ljotsson et al, 2014) and Simister et al (2018) the FIQ-R to examine the effect of ACT on the overall impact of FM. There was a good correlation between the total scores for the FIQR and the FIQ ($r = 0.88$, $P < 0.001$) so it should be possible to make reasonable comparisons between papers reporting the original FIQ and those reporting the FIQ-R (Bennett et al, 2009). Whilst the FIQ has received criticism for ethnoculturalism and under reporting of functional impairment (Wicksell et al, 2013) which were addressed in the FIQ-R, there still appears to be an apparent lack of ecological validity. However, the FIQ and FIQ-R are still the most frequently used outcome measure in FM research. A significant effect was reported for all five studies and whilst Carbonell-Baeza et al (2011) did not report effect sizes and did not take follow up measures the other studies report medium / large effects at post that were either sustained or increased at follow up. The Carbonell-Baeza et al's (2011) study was mutli-disciplinary and incorporated ACT and exercise. Therefore, it is impossible to ascertain if the results are due to the ACT intervention, the exercise or a combination of both.

Whilst significant effects are also demonstrated in a range of other symptom related areas such as; depression (Wicksell et al, 2013 & Simister et al, 2018 & Ljotsson et

al, 2014); family, intimate relationships and work (Steiner et al, 2103); fatigue (Ljotsson et al, 2014); pain catastrophising (Luciano et al, 2014); pain disability (Wicksell et al, 2013 & Ljotsson et al, 2014); pain intensity (Wicksell et al, 2-13 & Luciano et al, 2014); pain coping (Simister et al, 2018); mental quality of life (Carbonell-Baeza et al, 2011, Wicksell et al, 2013 & Ljotsson et al, 2014); physical quality of life (Carbonell-Baeza, 2011 & Ljotsson et al, 2014); anxiety (Wicksell et al, 2013); fear of moving (Simister et al, 2018) and pain management (Carbonell-Baeza, 2011), inconsistencies and contradictions make it hard to assess the effectiveness of ACT for FM in these outcomes. It is hard to make comparisons when only six outcome measures (FIQ (R), HADS, PDI, SF-36, PCS, PIPS) were used more than once. The HADS was used in three papers (Carbonell-Baeza et al, 2011, Luciano et al, 2014 & Ljotsson et al, 2014), where only the medium quality paper of Ljotsson et al, 2014) found a significant effect, contradicting the low quality Carbonell-Baeza et al (2011) study and the medium quality Luciano et al (2014) study so that no real conclusion can be made. In addition to the FIQ (&R) consensus was met on only two further measures (PDI & PIPS) which were both used by Wicksell et al (2013) & Ljotsson et al (2014). Both studies report significant effects in both pain disability and psychological inflexibility, which would be expected as the outcomes have been shown to be correlated (Wicksell, Lekander, Sorjonen & Olsson, 2010).

Psychological flexibility and change mechanisms of ACT for individuals diagnosed with Fibromyalgia

The target of ACT interventions is to increase Psychological Flexibility and yet only two studies (Wicksell et al, 2013 & Ljotsson et al, 2014) attempt to measure this construct. The Psychological Inflexibility in Pain Scale (PIPS) is used by both studies to measure Psychological Inflexibility and yet Bond et al (2011) put forward the case that flexibility is defined by the ability to contact the moment in service of valued living where inflexibility is defined as the fusion to evaluative and self-descriptive cognitions. Whilst two sides of the same coin, they represent the difference between acceptance and experiential avoidance and therefore measuring the juxtaposed position is not the same thing. Whilst both a low and medium quality study found a significant effect of ACT on psychological inflexibility there was no measure for psychological flexibility.

Combined with this is the lack of measurement of ACT processes which makes assessment of the effectiveness of ACT hard to quantify. Acceptance is measured in

two medium quality studies using the CPAQ (Luciano et al, 2014) and its revised version the CPAQ-R (Simister et al, 2018) offering contradictory result with only Simister finding a significant effect. There is also the argument here that again the measure is not coherent to the outcome as the CPAQ does not only measure the ACT process of acceptance. Within ACT acceptance is also referred to as willingness which accounts for only one of the subscales of the CPAQ, however full scores and not subscales are reported in these studies which Simpson et al (2017) highlight could be unreliable or misleading. Only Simister et al (2018) attempts to measure other ACT processes and reports significant effects for cognitive fusion (CFQ), being aware (Mindfulness FFMQ) and valued living (VLQ).

Mediation analysis is focussed on psychological inflexibility and pain acceptance and in a low-quality study Wicksell et al (2013) report that significant relationships between pre and post changes in psychological inflexibility and pain disability, FM impact, self-efficacy, depression, and state and trait anxiety. Both Luciano et al (2014 - CPAQ) and Simister et al (2018 – CPAQ-R) analysed pain acceptance as a mediator of change. The findings were again contradictory with Luciano et al (2014) reporting no mediating relationship. Simister et al (2018) report a mediating relationship for pain acceptance only in FM impact (FIQ-R) which would support the findings of previous studies in to chronic pain (Cederberg et al, 2016).

Quality of research into ACT for Fibromyalgia

After quality assessment, three papers (Carbonell-Baeza, 2011, Wicksell et al, 2013 and Steiner, 2013) were rated as low-quality studies with fundamental flaws to the studies such as lack of randomisation, concealment and blinding within an RCT. The other three studies were rated as medium quality (Luciano et al, 2014, Ljotsson et al, 2014 & Simister et al, 2018). It is the later studies that rate more highly, and this could translate that the standard of reporting is more rigorous due to increased standards of the scientific community rather than the standard of the study, as items listed as sources of bias are in some cases not reported rather than reported as deviant. Wood et al (2009) found that effect estimates were overly exaggerated in higher risk studies particularly when outcomes were subjective and self-reported as in the case of all six studies within this review, however overall this was not supported by this review

When assessing the quality of each study the assessment tool was also adapted to include the quality of the intervention delivered as the 6 processes of ACT are inter-related. Carbonell-Baeza et al (2011) and Wicksell et al (2013) fail to deliver all six core processes of ACT with Carbonell-Baeza et al (2011) omitting cognitive defusion and both studies omitting the self as context process despite recent findings to suggest that it predicts pain related interference in FM (Yu, Norton, Almarzooqi & McCracken, 2017).

In addition, variations in the control arms that are not accounted or controlled for such as differences in medication, multi-discipline studies, fundamental flaws to study designs such as lack of randomisation and the lack of any active control comparing ACT with CBT (the recommended psychological treatment for FM), result in a lack of high quality research on ACT for FM. The lower the quality of the paper, the higher the risk of bias and therefore the less generalisable the results of the study.

Limitations

The review is limited to English language publications and there is no Grey Literature included which could lead to a risk of publication bias. The first author initiated and carried out the literature search and applied both the selection criteria and quality assessment. The selection criterion is acknowledged as broad due to the limited amount of evidence on ACT for FM. No meta-analysis was carried out and the review is therefore narrative.

Conclusions

Medium and low-quality evidence suggests that the ACT interventions that were delivered were effective for a range of symptom reductions but more robustly suggest ACT is effective at reducing the overall impact for FM, pain disability and psychological inflexibility.

There is low quality evidence to support psychological inflexibility as a mediator of pain disability, FM impact, self-efficacy, depression, and state and trait anxiety but conflicting and unsupported evidence is insufficient to support pain acceptance as process of change for ACT within an FM population.

Implications for practice and future research

Whilst ACT for FM show promise there is a clear need for high quality research that utilises standard ACT interventions and standardised measures that capture ACT process, which are the target of ACT interventions and not symptom reduction, such as the CompACT measure (Francis, Dawson & Golijani-Moghaddam, 2016). To capture both change mechanisms and outcome measures more reliably the utilisation of single case design studies would be appropriate.

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Journal paper

Abstract:

Objective: Individuals diagnosed with fibromyalgia are reported to have reduced levels of physical activity which is a key focus of treatment guidelines. Acceptance and commitment therapy (ACT) has previously been shown to increase value-consistent behaviour and levels of activity in individuals with other chronic health conditions. A key aim of this study was to examine levels of activity, utilising activity trackers, and to investigate possible relationships between levels of activity and psychological flexibility (a key process in ACT).

Methods: This study utilised a non-concurrent mixed-method case-series design to explore the effectiveness of an eight-week supported self-help ACT predicated intervention (delivered via bibliotherapy) for six participants diagnosed with fibromyalgia.

Results: Levels of physical activity were not found to be reduced for this population with no measurable change across the intervention. However reliable, clinically significant and beneficial change was shown in psychological flexibility for all participants which was maintained at follow up. Participants reported an increase in meaningful activity.

Conclusions: The ACT self-help intervention appeared to benefit all six participants in terms of increasing psychological flexibility and meaningful activity. However, levels of physical activity did not increase, and the results suggest the levels of activity reported for individuals diagnosed with fibromyalgia require further investigation.

Keywords: Fibromyalgia; activity; case series; acceptance and commitment therapy; self-help

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Highlights

- Fibromyalgia sufferers are reported to have low levels of physical activity, but this appears disputed.
- A supported Acceptance and Commitment Therapy (ACT) predicated self-help intervention increases psychological flexibility in people with fibromyalgia.
- Individuals with fibromyalgia report increased functional ability even in the presence of pain following the ACT based intervention.
- Beneficial increases in psychological flexibility could mediate reductions in psychological distress and functional impairment in a fibromyalgia population.

Background

Fibromyalgia is perhaps one of the most contested disorders of modern times with continuing debates surrounding its classification (Hyland, Bacon, Lanario & Davies, 2019), its diagnosis (Häuser, Sarzi-Puttini & Fitzcharles, 2019), its aetiology (Bellato *et al*., 2012) and even its legitimacy (Wolfe, 2009). Suggested mechanisms for fibromyalgia include but are not limited to; functional somatic disorder (Mayou & Farmer, 2002); personality types (Torres *et al*, 2013): central nervous system hypersensitivity or dysfunction (Coppieters *et al*., 2015); small fibre prevalence (Grayston *et al*., 2019); and insulin resistance (Pappolla *et al*., 2019). Fibromyalgia is perhaps best conceptualised as a medically unexplained chronic pain condition which often includes a range of heterogeneous, somatic manifestations that accompany the widespread pain including: moderate to severe fatigue (Watson, Buchwald, Goldberg, Noonan & Ellenbogen, 2009); disrupted and non-restorative sleep (Holman, 2008); Irritable Bowel Syndrome (Wolfe, Michaud, Li & Katz, 2010a); and impaired cognition – often colloquially termed 'fibro fog' (Glass, 2008). Fibromyalgia also has a high prevalence of overlapping psychological co-morbidities such as depression and anxiety (Del Paso, Pulgar, Duschek & Garrido, 2012) which are known to play a significant role in both the development and perpetuation of chronic pain (Miró, Martínez, Sánchez, Prados, & Medina, 2011).

The personal impact of fibromyalgia appears to be multi-faceted and debilitating. Individuals diagnosed with fibromyalgia demonstrate losses to their daily functioning with Mcloughlin, Colbert, Stegner and Cook (2011) reporting significant reductions in activity compared to healthy controls. Reduced activity in fibromyalgia has been associated with higher levels of pain and fatigue and a reduction in daily functioning (Segura-Jiménez *et al*, 2017). Fibromyalgia patients also report damage to their intimate and social relationships (Armentor, 2017) which Matarín Jiménez *et al*, (2017) related to high levels of symptom severity[1]. Treatment guidelines from a globally limited range of sources such as The American Pain Society (APS, 2005; Burckhardt *et al*., 2005); The Canadian Pain Society (CPS, 2013; Fitzcharles *et al*., 2013), and The European League Against Rheumatism (EULAR, 2016; McFarlane *et al*., 2017) gave different weight to their recommendations for fibromyalgia. Exercise and

[1] Further background information on fibromyalgia is provided in the extended paper

Cognitive Behavioural Therapy (CBT) are the primary recommended treatments with the consistent message of fostering non-pharmacological and healthy active lifestyle approaches[2].

Recent fibromyalgia research has focussed on increasing activity in line with treatment recommendation and more specifically on exercise. Nüesch, Häuser, Bernardy, K., Barth, and Jüni, (2013) reported in their meta-analysis that exercise had a positive effect on pain intensity, physical functioning and well-being for those diagnosed with fibromyalgia. However, prescriptive exercise interventions for fibromyalgia are reported to have low adherence rates (Dobkin *et al*, 2006) potentially because exercise feels counterintuitive when the presenting issue is chronic widespread pain that sufferers believe will increase with movement. Fibromyalgia sufferers report common accusations of not being believed or even malingering made against them (Paxman, 2019) and Ghavidel-Parsa *et al* (2015) suggest that fibromyalgia patients may also fear that their health status may be questioned if they are seen engaging in exercise when they report being unable to carry out daily tasks. Mist, Firestone and Jones, (2013) put forward in their meta-analysis that any type of increased activity is beneficial to fibromyalgia sufferers which could suggest it is the change in behaviour rather than any specific exercise that has a positive effect[3].

CBT has been the most widely researched psychological treatment for fibromyalgia and within this paradigm, lack of activity is viewed as a resulting consequence of unhelpful beliefs and thought patterns formed as an initial response to symptoms (Luciano *et al*, 2014). The primary outcome measure in CBT for fibromyalgia research has been pain intensity, with physical functioning and depression the main secondary outcomes (Bernardy, Füber, Köllner & Häuser, 2010). Results between studies were reported to be inconsistent (Glombieski *et al*, 2010) with positive outcomes reported as significant but ranging from having small to large effects (Bernardy *et al*., 2010). Steiner, Bigatti, Slaven and Ang (2017), suggest these inconsistencies might be accounted for not only by the difference between studies but by the correlation between the outcome measures of pain intensity, physical functioning and depression.

[2] Further information on treatment is provided in the extended paper
[3] Further comment on activity and exercise in fibromyalgia can be found in the extended paper

Increasing physical activity, in turn reverses or reduces deconditioning and subsequently decreases pain intensity. The authors also found depression was a partial mediator of the relationship between pain intensity and physical functioning in fibromyalgia.

Advances in CBT have led to the development of Acceptance and Commitment Therapy (ACT) a third wave, trans-diagnostic psychotherapy aimed at increasing value-consistent behaviour. At the time of previous fibromyalgia guideline development ACT had only a very small evidence base and was not included as an individual therapy. ACT is an action-oriented therapy that is grounded in behavioural theory (Yu & McCracken, 2016) and is founded upon the principle of Functional Contextualism[4], a field developed from radical behaviourism (Biglan & Hayes, 1996). Hayes, Luoma, Bond, Masuda & Lillis (2006) detail how ACT proposes that attempts to supress and control painful emotions or psychological experiences can ultimately lead to more distress by restricting behavioural and psychological responding to experiences. ACT attempts to teach clients that human suffering is both common and an appropriate reaction to some life events. Individuals are invited to commit to behaviour change consistent to their own values, independent of how they are currently feeling and even in the presence of unpleasant experiences. Unlike CBT that focusses primarily on unhelpful cognitions, ACT examines the influence of internal content within a given context and only deems it problematic when it results in behaviour which undermines values-based action (Yu & McCracken, 2016).

The aim of ACT is to increase Psychological Flexibility (PF), the ability to contact the present without activating defence strategies in the service of creating a rich and meaningful life for the client. ACT incorporates 6 self-related and intertwined core processes within the PF model (Hayes *et al*, 2006): (1) Acceptance of things as they are, juxtaposed to experiential avoidance of unwanted private experiences; (2) cognitive defusion, which is untangling thoughts from dominating the awareness of an individual and reducing their influence on behaviour; (3) self as context (SAC) which is becoming aware of how we see ourselves and stepping away from rigid and unhelpful constructions of identity; (4) being present in the here and now (being mindful); (5&6)

[4] Additional information on functional contextualism is provided in the extended paper

values and committed action, which is understanding how we want to live our lives to make them meaningful, and committing to take action to achieve value driven goals. A meta-analysis for ACT and chronic pain conditions found the approach to be effective for outcomes such as depression, anxiety, pain interference, pain intensity and illness disability (Veehoff, Trompetter, Bohlmeijer & Schreurs, 2016). A recent study by Roche, Dawson, Moghaddam, Abey & Gresswell, (2017) found that ACT increased levels of activity for individuals with Chronic Fatigue Syndrome even when activity was not specifically targeted.[5]

Fibromyalgia sufferers reportedly demonstrate decreased levels of activity (McLoughlin *et al*, 2011) which has been linked to reduced levels of functioning and increased levels of pain and fatigue (Segura-Jiménez *et al*, 2017). Therefore, there is the potential that a psychological therapy such as ACT, that has been reported to increase activity in the pursuit of individual values (Roche *et al*., 2017), could have some real benefit for those diagnosed with fibromyalgia. Self-help interventions are increasingly being utilised as a more cost-effective way to deliver therapeutic skills and knowledge that would have traditionally been delivered face to face or in group interventions. The self-help genre could potentially aid inclusion to stigmatised or less mobile client groups (Levin, Potts, Haeger, & Lillis, 2018) such as individuals diagnosed with fibromyalgia. Previous ACT studies specifically for fibromyalgia have been limited in both number and quality but show positive outcomes in a variety of domains such as pain catastrophising and improved physical and psychological functioning (Steiner, Bogisch, Hernandez, Lydon-Lam & Johnston, 2013; Wicksell *et al* 2013**;** Luciano *et al*, 2014; Ljótsson *et al*, 2014**)**. The limited self-help-based intervention research examining ACT for fibromyalgia have reported a range of positive outcomes (Steiner *et al*., 2013, Ljótsson *et al*, 2014) but suggest further investigation.

Aims

The principal aim of this study was to investigate the efficacy of an ACT guided self-help intervention for individuals with fibromyalgia. Specifically we wanted to examine the impact of ACT on the level of physical activity, psychological distress, daily functioning, symptom severity and disorder impact within this population.

[5] Further discussion surrounding ACT is provided in the extended paper

As ACT posits psychological flexibility as the facilitator of value based behavioural change this study additionally set out to examine the relationship(s) between the above behavioural and psychological outcomes and psychological flexibility (and its components) to identify any potential mechanisms of change. The research also aimed to further understand participants' experience of the intervention such as the acceptability of the intervention and change attribution via post-intervention change interviews.

Method

Institutional ethical approval was obtained from the University of Nottingham[6].

Design

A mixed method non-concurrent multiple single case phased AB design was utilised for this study (SCED). The AB aspect refers to the two phases of this study although there are in effect two stages to the B phase (B1 & B2). Phase A refers to the repeated baseline measures (before intervention) of the dependent variables; B1 is the intervention phase, with ACT, the independent variable, expected to alter the context in which clients see both themselves and their pain and therefore cannot be withdrawn or reversed. Phase B2 represents a follow up, after intervention, to ascertain if change had been sustained.[7]

Recruitment

The study was advertised in fibromyalgia specific social media support groups and detailed information was sent to those expressing an interest. Potential participants who met the following inclusion criteria were recruited to the study: a) over 18 and able to give informed consent; b) having a good level of literacy and comprehension in English (assessed during initial meeting); were computer literate; c) had a formal diagnosis of fibromyalgia; d) were not allergic to rubber (due to wearing of activity trackers) and e) who lived within the counties of Derbyshire, Nottinghamshire or Lincolnshire. In order to meet criteria for effective SCED research, recruitment continued until the recommended number of six participants was reached allowing for five replications (Smith, 2012)[8].

[6] Additional ethical consideration is provided in the extended paper
[7] Further design information is provided in the extended paper
[8] Further information on recruitment and sample size is provided in the extended paper

Measures

Measures shown in Table 7 were chosen following a review of extant literature into both ACT and fibromyalgia research. Levels of activity were monitored using 'Fitbit' trackers. Consideration was made for population specific measures that would provide complete data with the least burden on participants and so a short form measure of psychological distress was chosen (DASS-21, Lovibond & Lovibond, 1997). The Fibromyalgia Impact Questionnaire – revised (FIQ-R, Bennett *et al*, 2009) is used extensively in Fibromyalgia research (Williams & Arnold, 2011) and includes the subjective experiences of pain, cognitive impairment (fibro fog), tenderness and environmental sensitivity that typifies fibromyalgia. Whilst the acceptance and action questionnaire-II (AAQ-II, Bond *et al*, 2011) has been cited as the most widely used measure of psychological flexibility in ACT research, it does not cover the self-as-context or committed action processes (Frances, Dawson & Golijani-Moghaddam, 2016) and previous research has raised concerns relating to its discriminant validity and construct (Wolgast, 2014; Gamez *et al*., 2014; Frances *et al*., 2016; Ong, Pierce, Woods, Twohig, & Levin, 2019). Subsequently a decision was taken to use the CompACT (Francis *et al*., 2016) which incorporates the committed action process although its authors note that it does not measure the self-as context construct. Exploration into the self-as-context process within ACT is limited. This study utilised the Self-Experience Questionnaire (SEQ, Yu, McCracken & Norton, 2016) to measure the process. Use and validation data of this new scale is limited (Yu, Norton, Almarzooqi & McCracken 2017) but despite this its reported α is .94. Together the CompACT and the SEQ measure psychological flexibility and the six core processes of ACT.[9]

[9] Further measurement information is included in the extended paper

Table 7: Summary of measures

Measure / timing	Total Q's	Overall measure	Domain 1 measure	Domain 2 Measure	Domain 3 Measure	Scoring	Notes	Psycho-metric	Example items
FITBIT **Daily**	N/A	Level of activity measured as steps taken	N/A	N/A	N/A	N/A	N/A	N/A	N/A
DASS-21, **Weekly** (Lovibond & Lovibond, 1997)	21	Psychological distress Sum of all 21 questions x2 to equal DASS 42 Scores range 0-6=3 (x2)=126	Depression = D 7 questions Q's – 3, 5, 10, 13, 16, 17, 21 Scores range 0-21 x2=42	Anxiety = A 7 questions Q's – 2, 4, 7, 9, 15, 19, 20 Scores range 0-21 x2=42	Stress = S 7 questions Q's – 1, 6, 8, 11, 12, 14, 18 Scores range 0-21 x2=42	0 - Did not apply to me at all 1 - Applied to me to some degree or some of the time 2 - Applied to me a considerable degree or a good part of the time 3 - Applied to me very much or most of the time	Scores are timesed by 2 to equate to the DASS 42. Higher scores demonstrated higher rates of symptoms / distress	D α = .96 A α = .92 S α = .95 Overall α = .93	'Depression - 'I felt I had nothing to look forward to' Anxiety - 'I was aware of dryness of my mouth' Stress - 'I found it hard to wind down'
FIQ-R **Weekly** (Bennett *et al*, 2009)	21	Impact of FMS The sum of all 3 domains Scores range from 0-100	Functioning 9 questions Qs 1-9 Range is 0-30	Overall impact 2 questions Q's 10-11 Range 0-20	Symptoms of FMS 10 questions Q's 12-21 Range is 0-50	Scaled Domain 1 - 0=No difficulty to 10=Very difficult Domain 2 – 0=Never to 10=Always Domain 3 0=low impact to 10=high impact	Scores divided by 3 in domain 1 and by 2 in domain 3 Higher scores indicate higher negative impact	Function α = .92 Overall α = .92 Symptom α = .96 FIQ-R α = .91	Function = 'How difficult was it for you to brush or comb your hair' Overall = 'Fibromyalgia prevented me from accomplishing goals for the week' Symptoms = 'please rate your level of pain'.
CompACT, **Weekly** (Francis, Dawson, Golijani-Moghaddam, 2016)	23	PF = Psychological flexibility Sum of all questions (after reversed scored) Scores range from 0-138	OE = Openness to experience (Acceptance & Cognitive defusion) 10 questions Q's – 2,4,6,8,11,13, 15,18,20,22 Scores range 0-60	BA = Behavioural awareness (Contact with the present) 5 questions Q's – 3, 9, 12, 16, 19 Scores range 0-30	VA = Valued action (Values & Committed action) 8 questions Q's – 1, 5, 7, 10, 14, 17, 21, 23 Scores range 0-48	0 = Strongly disagree 1 = Moderately disagree 2 = Slightly disagree 3 = Neither agree nor disagree 4 = Slightly agree 5 = Moderately agree 6 = Strongly agree	12 questions were reversed Q's - 2, 3, 4, 6, 8, 11, 13, 15, 18, 20, 22 Higher scores = greater psychological flexibility	OE α = .90 BA α = .87 VA α = .90 PF α = .91	OE = 'One of my big goals is to be free from painful emotions' BA - "I find it difficult to stay focussed on VA = "I act in ways that are consistent with how I wish to live my life'
SEQ **Weekly** (Yu, McCracken & Norton, 2016)	15	Contextual Self The self as context Sum of all questions Scores range from 0-90	Self as distinction 7 questions Q's - 1, 2, 3, 4, 5, 6, 7 Scores range from 0-42	Self as observer 8 questions Q's - 8, 9, 10, 11, 12, 13, 14, 15 Scores range from 0-48	N/A	Scaled 0 = Never true to 6 = Always true	Positively scored with higher rates indicating more positive aspects to conceptualised self	SEQ α = .91	Self as distinction ='I can actually see that I am not my thoughts' / Self as observer = "I am able to step back from my emotions and observe them from a separate point of view'

Fitbit = Activity Tracker, Depression, Anxiety and Stress Scale = DASS – 21, Comprehensive Assessment of ACT Processes = CompACT, Self-Experiences Questionnaire = SEQ, Fibromyalgia Impact Scale – Revised = FIQ-R

Procedure

Participants were fitted with activity trackers to their non-dominant wrists at the initial meeting and asked to complete baseline questionnaires of the online measures. Online measures were then taken weekly until the end of phase B2 (follow up). Approximately one week after the initial meeting weekly support telephone calls began which ascertained extrinsic events that might impact the results of the study. The support calls continued during phase B1 when they also allowed for clarification of the intervention by participants and for the researcher to check adherence fidelity. Telephone calls ceased at the end of the intervention phase (B1).

At follow up either four or six weeks after the intervention, a change interview (adapted from Elliot, 2002) was conducted by researchers not connected with the study to reduce bias. The interview was to ascertain participants' views of the effectiveness and acceptability of the self-help intervention and their perception of any changes experienced during the intervention, including change attribution[10].

Intervention

The intervention was a bibliotherapy called 'Living Beyond Your Pain' (Dahl & Lundgren, 2006), which is an ACT predicated self-help resource that was developed specifically to target individuals living with chronic pain conditions and is now considered a key ACT text. The use of the resource has previously been reported to increase functioning and decrease pain intensity in chronic pain populations (Johnston, Foster, Shennan, Starkey & Johnson, 2010: Thorsell *et al*, 2011). Table 8 below outlines the content and ACT process of each chapter which were delivered in order. Participants received the intervention weekly in both electronic and paper form during phase B1[11]. Holidays and periods of illness for P3, P4, P5 and P6 that extended the intervention phase were noted[12].

[10] Further procedural details are provided in the extended paper
[11] Further information about the intervention is provided in the extended paper
[12] Further detail on extrinsic events is noted in the extended paper

Table 8: Intervention schedule

Session	Chapter(s)	ACT Process / Content
Orientation session		Overview of ACT
1	Introduction &1	Overview of ACT
2	2	Creative Hopelessness & Experiential Avoidance
3	3	Values
4	4	Cognitive Defusion
5	5	Being Present /Self as Context
6	6	Acceptance
7	7	Committed Action
8	8 & Conclusion	Summation / Review / Going Forward

Chapters from 'Living Beyond Your Pain' (Dahl & Lundgren, 2006)

Analysis

Details of analysis are shown in Table 9. Visual graphical inspection of data is the primary form of analysis and considered the 'Gold Standard' within SCED (Kazdin, 2019). Therefore the repeated outcome measures are displayed using single-case data graphs. The graphs were inspected for differences and changes in trend between phases with attention given to stability of baseline data. Baseline stability is often reported as the hallmark and benchmark for interpreting effects in SCED's (Lane & Gast, 2014). Despite this Tate *et al*., (2016) reported that 22% of SCED studies failed to be open and transparent about baseline data. Baseline stability for the primary outcome and process measure was calculated using the stability window method as outlined by Lane and Gast (2014) with up to 30% variation considered stable.

It is however acknowledged that visual inspection is open to subjective interpretation and the potential increase of both Type 1 and Type 2 errors by Busk and Marascuilo, (2015) who outlines that multiple methods of analysis should be used to give a deeper understanding and greater confidence in the results. Therefore, further visual aids in the form of baseline regression trend lines and lines of data progression are provided for some graphs with further analysis provided using the Percentages Exceeding the Median (PEM) (Ma, 2006) dual criterion (DC) method (Fisher, Kelley & Lomas, 2003) for additional reliability and validity.

As advocated by Kratochwill *et al*, (2014), further statistical analysis was carried out on pre, post and follow up scores to assess if both reliable and clinically significant changes had been made, utilising the Reliable Change Indices (RCI) and Significant Change Criterion (CSC) (Jacobson & Truax, 1991).. Both reliable and clinically significant change was calculated using Excel spreadsheets utilising data from DASS-21 (Ronk, Korman, Hooke & Page, 2013), CompACT (Potts, 2018), SEQ (Yu, Norton & McCracken, 2017) and FIQ-R (Williams & Arnold, 2011). This study used criterions a and c for calculating CSC depending on available comparative data.

This research also used Tau-U analysis (Parker, Vannest, Davis & Sauber, 2011) to examine the generalisability of this intervention with statistical control of potentially confounding baseline trends. Analysis was carried out via an online calculator specific to Tau-U (http://www.singlecaseresearch.org/calculators/tau-u). Tau-U analysis is reported as the percentage of treatment scores that exceed the baseline scores once the baseline has been adjusted for trend (Pustejovsky, 2016)[13].

[13] Further information on statistical analysis is reported in the extended paper

Table 9: Rationale and levels of analysis

Analysis	Analysis method	Focus of analysis	Rationale	Potential limitation
Visual analysis ***Primary form of analysis***	Data graph plots	Baseline stability Difference between phases and between individuals	Gold standard in SCED design gives clear representation of the data within and between participants and between phases	Subjective nature of visual inspection particularly in relation to baseline stability
Baseline stability calculation	Percentage windows (0-10%, 10-20%, 20-30%, 30%+) from the median of the baseline range (Lane & Gast 2014)	Baseline stability	To address subjectivity of visual analysis and allows for reporting of baseline data	Cannot always establish stable baseline across multiple measures
Reliable Change (RCI)	Subtracting premeasurement scores from the post or follow up scores and dividing the difference by the standard error of difference for that measure. The standard error of difference is calculated using the internal consistency of a measure and the standard deviation. If the resulting value is ± >1.96 then the change is deemed reliable (95% confidence interval).	Reliability and validity of change	To assess if change is statistically reliable or due to chance or measurement variability	Reliability indexes vary
Clinically significant change (CSC)	Criterion A: if an individual's post / follow up treatment score is 2 standard deviations from the mean of the clinical group. Where non-clinical data is available this is the criterion that should be used. Criterion B: if an individual's post / follow up treatment score is 2 standard deviations within the mean of a non-clinical group. Criterion C: if an individual's post / follow up treatment score is closer to the mean of the non-clinical group	Clinical levels of change	To assess if change is between clinical and non-clinical levels	Can miss individual meaningful change. Symptom reduction is not a specific target in ACT
Percentages exceeding the median - Dual criterion- (PEM/DC)	PEM - visual line from the median in the baseline phase across successive phases DC - the baseline trend was also accounted for by drawing a regression line from the baseline trend stretched forward over the intervention phase. Only data points that fell above (or below dependent on direction of improvement) both lines (the baseline median and the baseline trend line) are counted	Individual effect size	To assess individual effect sizes and to enable comparison with previous research	PEM - insensitivity to the magnitude of the data points that exceed the median or when there is a particularly strong baseline trend hence using the DC method
Tau-U Analysis	Calculations of the effect size for each selected phase contrast with the respective standard errors are made and then (via multi-tiered analysis) an omnibus effect size across all phases of the intervention is determined.	Overall effect size	To assess overall effect size adjusting for confounding baseline trends and to enable comparison with previous research	Varying interpretive guidelines

Qualitative data from the interviews were analysed using framework analysis and utilised in conjunction to support or refute findings within the quantitative data. *A Priori* themes already generated by the questions within the semi-structured interviews were expanded in an inductive approach. A five-step process was followed as outlined by Srivastava and Thomson, (2009): 1) Familiarization of the data including listening and transcribing; 2) Identifying thematic framework from priori themes; 3) Indexing sections of the data that correspond to the themes; 4) Charting the indexed data; and 5) Mapping and interpreting the key characteristics of the indexed information[14].

Results

Sample

Six participants enrolled in the study and despite expectations of a potentially high rate of attrition which had been reported in existing literature (Ong, Lee & Twoking, 2018) there was 100% retention. Table 10 details demographic details of the participants. The six participants reported a formal diagnosis of fibromyalgia and were all white women aged between 31 and 64 (mean = 44); four of the participants were married, four were in employment and four were educated to A 'Level standard or above. These demographics are all similar to the samples reported by Wallit, Katz, Bergman, & Wolfe, (2016). In addition to fibromyalgia all six participants reported having a formal diagnosis of depression and five participants reported a diagnosis of anxiety which reflects the observations of Del Paso *et al*, (2012) about co-morbid psychological issues. Whilst three participants had previously engaged in psychotherapeutic interventions they reported this was for other issues such as depression and the therapy did not focus on the fibromyalgia. All participants self-reported reduced levels of functioning and activity due to their fibromyalgia[15].

[14] Further information on framework analysis is provided in the extended paper
[15] Further sample information is provided in the extended paper

Table 10: Participant sociodemographic information

	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6
Gender	Female	Female	Female	Female	Female	Female
Age	50	40	31	40	39	64
Marital Status	Separated	Single	Married	Married	Married	Married
Employment Status	Part-time	Full-time	Part-time	Part-time	Unemployed due to fibro	Retired on ill health
Level of Education	Degree	Degree	A level	GCSE	GCSE	Post Grad
Mental Health Diagnosis	Anxiety & Depression	Depression	Anxiety & Depression	Anxiety &Depression	Anxiety & Depression	Anxiety & Depression
Physical Health Diagnosis	Fibromyalgia Rheumatoid arthritis [1,] Sjogren's syndrome	Fibromyalgia	Fibromyalgia Raynaud's syndrome [2] Hypermobility [3]	Fibromyalgia	Fibromyalgia	Fibromyalgia, Asthma
Time since symptoms emerged	17 years	20 years	16 years	19 year	6 years	19 years
Time since diagnosis	15 years	10 years	8 years	5 years	4 years	1 year
What have you tried for fibro	Drug treatments	Drug treatments	Drug treatments	Drug treatments	Drug treatments	Drug treatments. Changing diet
Previous Psychological Therapy	Talking therapy but not for the fibro	CBT for depression	CBT for depression	None	None	None
Current medication	Citalopram [F] Levothyroxine Lafutidine Amitriptyline [F] . Benacarly	Ramipril Citalopram [F]	Dihydrocodeine [F]	Gabapentin [F] Naproxen [F] Thyroxin, Amitriptyline [F] Codeine [F] Sertraline [F]	Gabapentin [F] , Amitriptyline [F] Duloxetine [F] Naproxen [F] Omeprazole Co-codamol [F]	Amitriptyline [F] Citalopram [F]

1. Rheumatoid arthritis and Sjogrens syndrome are both inflammatory auto immune disorders .
2. Raynaud's syndrome is a disorder affecting the blood supply to hands, feet and other extremities.
3. Hypermobility affects the range of movement in the joints.
4. F = Medication reported to be prescribed specifically for the participants fibromyalgia

Baseline stability

Baseline stability calculations for levels of activity and psychological flexibility are shown in Table 11. There are 21 data points for levels of activity and 4 data points for psychological flexibility at baseline before the introduction of the intervention which exceeds recommendation (Horner *et al*, 2005). Each participant reached the minimum level of baseline stability for levels of activity and five out of the six participants reached the required threshold for stability for psychological flexibility (<30%). One participant did not reach the minimum desired level of baseline stability for psychological flexibility, however as the participant had reached a very acceptable threshold for levels of activity (<10%) this was noted for information purposes to inform the results and discussion but did not give reason to extend the baseline phase.

Table 11: Baseline stability calculations for levels of activity and psychological flexibility

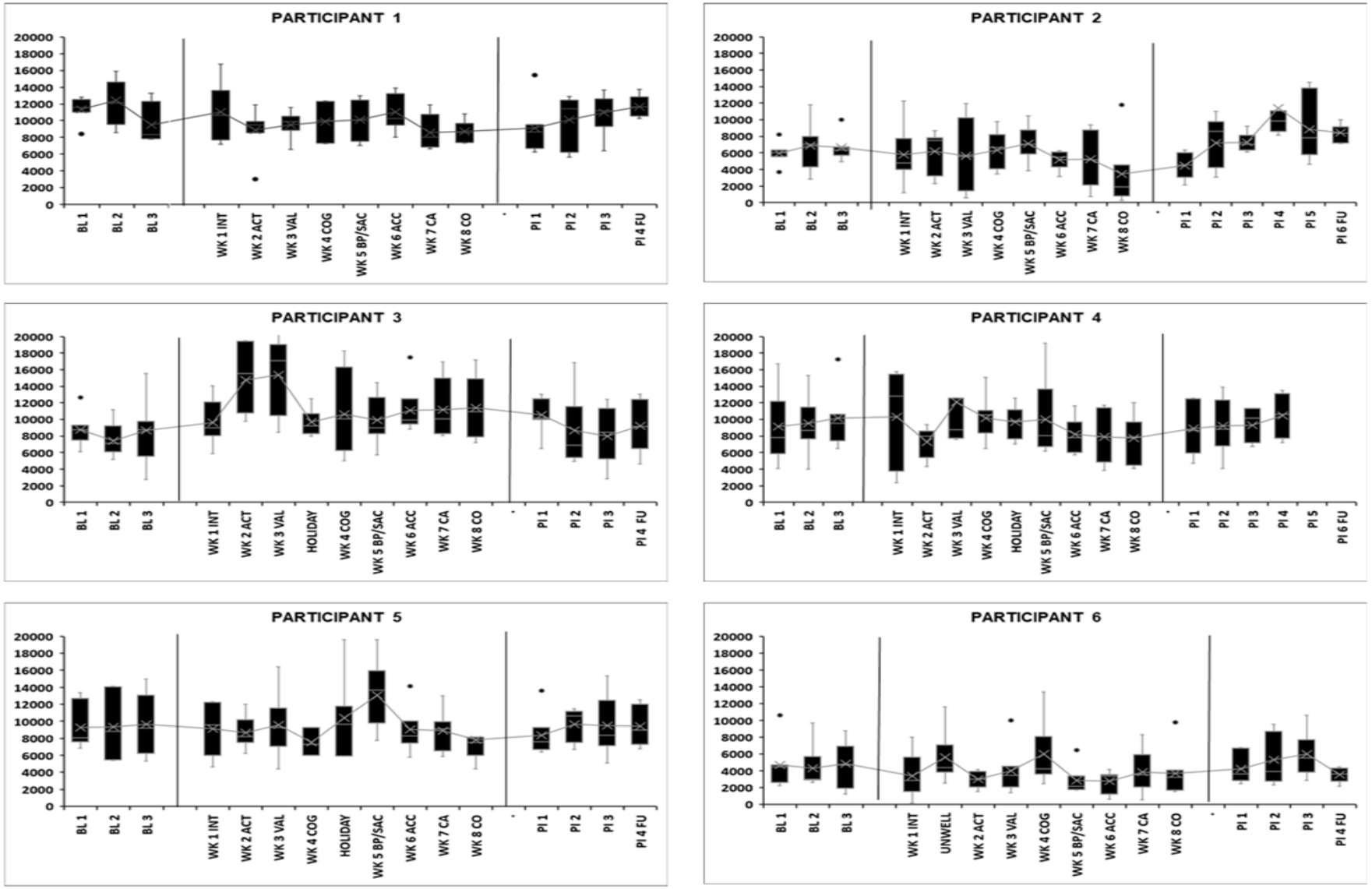
	Level of Activity				Psychological Flexibility			
Participant	**Mean**	**Median**	**Range**	**Percentage Stability Met**	**Mean**	**Median**	**Range**	**Percentage Stability Met**
1	11084	11319	9532 - 12403	10 - 20%	69.75	69	66 - 75	0 - 10%
2	6485	6644	5947 - 6644	10 - 20%	50	48	44 - 60	20 - 30%
3	8280	8652	7451 - 8736	10 - 20%	71.25	71	66 - 70	0 - 10%
4	9607	9532	9167 -10123	0 - 10%	66.75	66.50	63 - 71	0 - 10%
5	9420	9342	9271 - 9647	0 - 10%	88.25	87.50	85 - 93	0 - 10%
6	4630	4722	4283 - 4885	0 - 10%	54.75	49	43 - 74	30%+

Stability of baseline was calculated using the median for the baseline measures of levels of activity and psychological flexibility. Levels are reported as up to 10% = very acceptable, 11-20% = reasonable, 21-30% = acceptable and >30% questionable.

Levels of activity – measured as bi-pedal motion with the Fitbit flex

There was a high variability of levels of activity both within and between all participants across all phases of the intervention. Figure 2 demonstrates the range, outliers and the mean levels of activity (steps taken) for each participant each week. The Fitbit for participant 4 stopped sending data for the last two weeks of the intervention but she was out of the intervention phase (in follow up phase) when this happened, and she

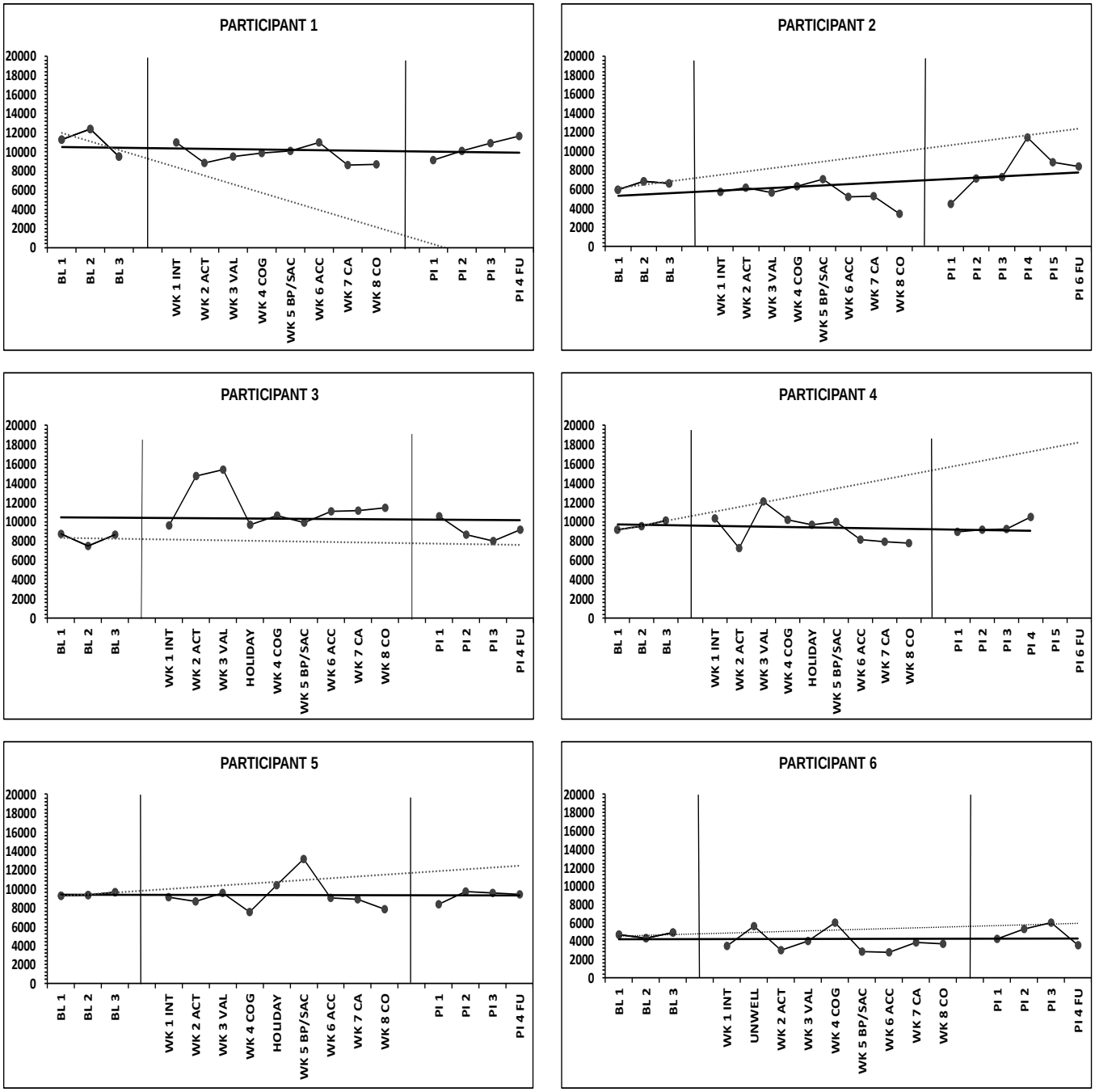
continued to complete the online questionnaires until the change interview. Therefore, all possible data for her is displayed.



Y axis is steps taken. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Increase demonstrates improvement

Figure 2: Daily steps shown as weekly range, mean line and outliers for each participant across all phases of the intervention

Due to the large variation in levels of activity, weekly steps were averaged and graphed for the purposes of simplifying further analysis as shown in Figure 3



Y axis is steps taken. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Increase demonstrates improvement. Dotted line indicates baseline trend whilst solid black line indicates overall trend

Figure 3: Average weekly steps taken including baseline and overall trendlines for each participant across all phases of the study

Participants 1, 2, 3, 4 and 5 all fell well within the normative population range for levels of bi-pedal activity outlined by Tudor-Locke *et al* (2011). Whilst participant 6 had a

lower rate of activity she was still above the expected range for a normative lower-active group as she was a retired older adult. Both visual analysis and stability window calculations demonstrate a stable baseline for levels of activity for each participant. The addition of an overall trend line best demonstrates that levels of activity for all participants remained relatively stable across all phases and does not appear to offer any inference between the intervention as a whole or any of its individual elements for influencing levels of activity. PEM/DC average was .27 at both post and follow up and therefore deemed not effective which supports the Tau-U analysis which found the overall effect size of change in the level of physical activity at both post and follow up to be non-beneficial (Tau-U=-.23 at post and Tau-U=-.10 at follow up) and not statistically significant in either case.

Psychological distress – measured by the DASS-21

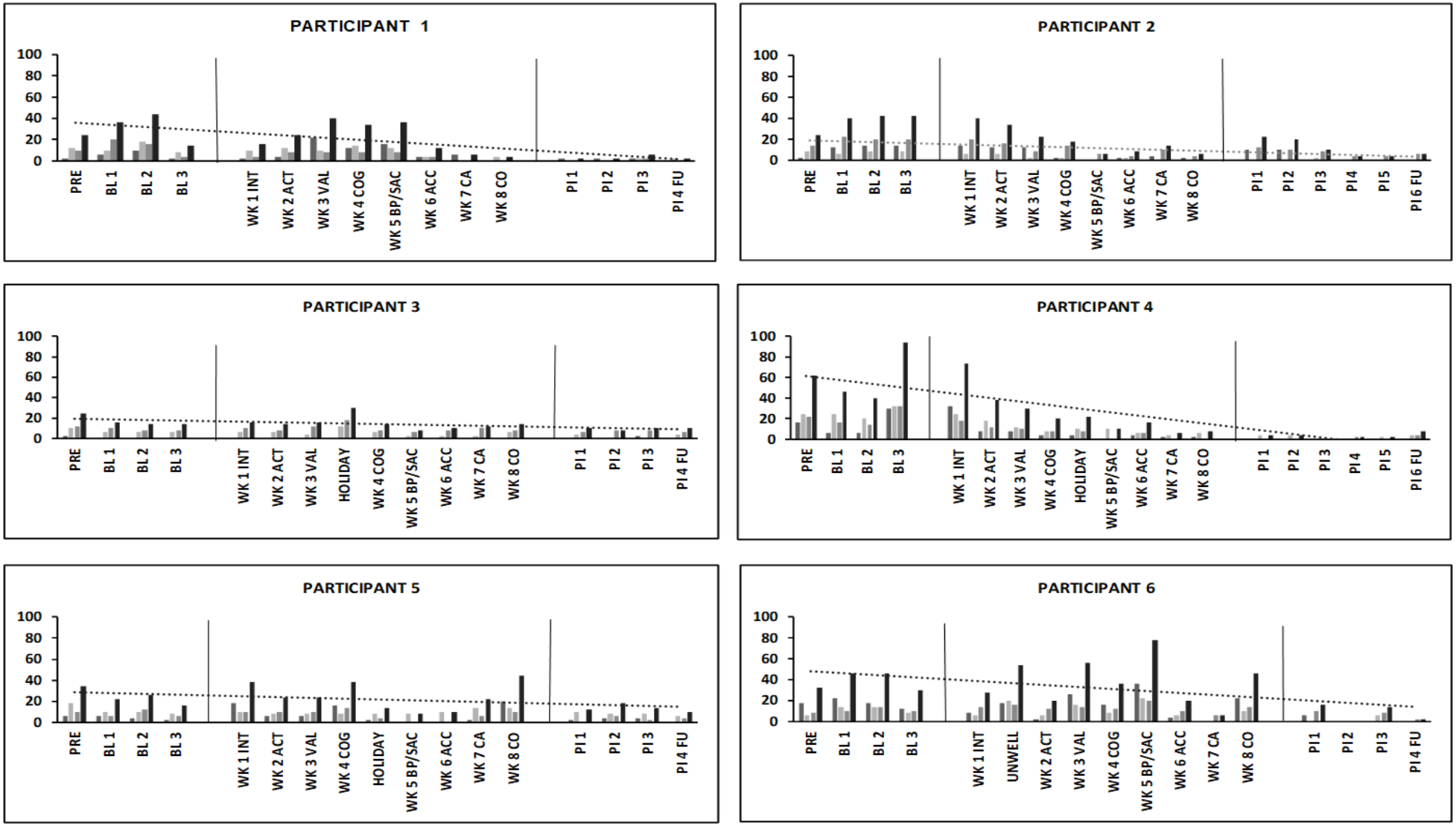
Visual inspection (Figure 4) demonstrates variation in the baseline for Participants 1,4 and 6. However, there is a beneficial decline in overall psychological distress for all participants across the research period although the change for P1 and P3 was neither reliable nor effective. Participant 2's beneficial change was not found to be reliable or clinically significant, however PEM/DC analysis found it to be highly effective at both post and follow up. Participant 4 demonstrated reliable, clinically significant and highly effective beneficial change at both post and follow up, whilst participant 5 reported reliable and clinically significant beneficial change at follow up although this was found to be not effective by PEM/DC analysis. Participant 6 demonstrated a slight non-beneficial increase in levels of psychological distress at post which could potentially be accounted for by reported extrinsic factors. However P6 then reported reliable and clinically significant beneficial change at follow up from pre intervention scores which was mildly effective. The PEM/DC average for all six participants at post was .45 and .47 at follow up which is considered not to be effective. However Tau-U calculations found the overall effect size of change in the level of psychological distress to be beneficial and statistically significant at both post (Tau-U=-0.41 $p<0.05$) and follow up (Tau-U=-.60 $p<0.005$). The difference between PEM/DC and Tau-U analysis can be accounted for by the baseline trend data within the measure as the PEM/DC accounts for baseline trends but does not adjust for them in the way that the Tau-U does.[16].

[16] Further analysis on the subscales of the DASS-21 is provided in the extended paper

Total fibromyalgia impact –measured by the FIQ-R

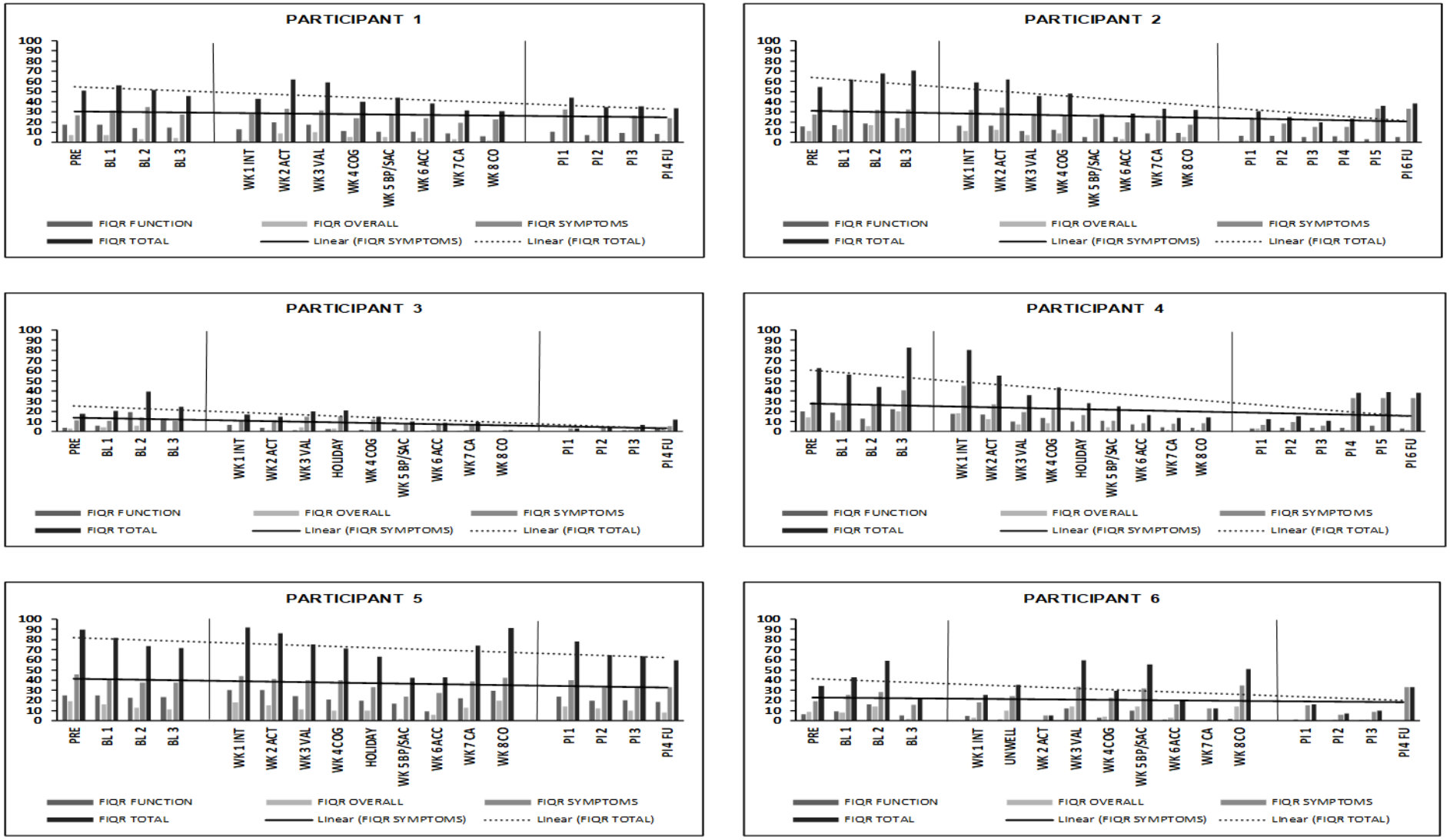
As the symptom subscale accounts for 50% of the total impact of fibromyalgia as measured by the FIQ-R it therefore heavily influences the outcome measure. Visual analysis (Figure 5) indicates an overall reduction in the total impact of fibromyalgia and functional ability for all six participants despite symptom levels remaining relatively stable or increasing over the period of the study. The increase in functional ability in the presence of pain suggests that symptoms had less impact on participants' functioning. PEM/DC average for all six participants was found to be mildly effective at post (.53) and at follow up (.54). The PEM/DC result was supported by the Tau-U analysis which reported that the percentage of treatment scores that exceed the baseline scores once the baseline has been adjusted for trend (Pustejovsky, 2019) was 53% at post and 66% at follow up. Both effect sizes were found to be significant ($p<0.005$). These results suggest that the total impact of fibromyalgia was reduced by the ACT intervention[17].

[17] Further analysis on the subscales of the FIQ-R is provided in the extended paper



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement.

Figure 4: Psychological distress, subscales of DASS-21 and overall trend line for overall psychological distress across all phases of the study for each participant

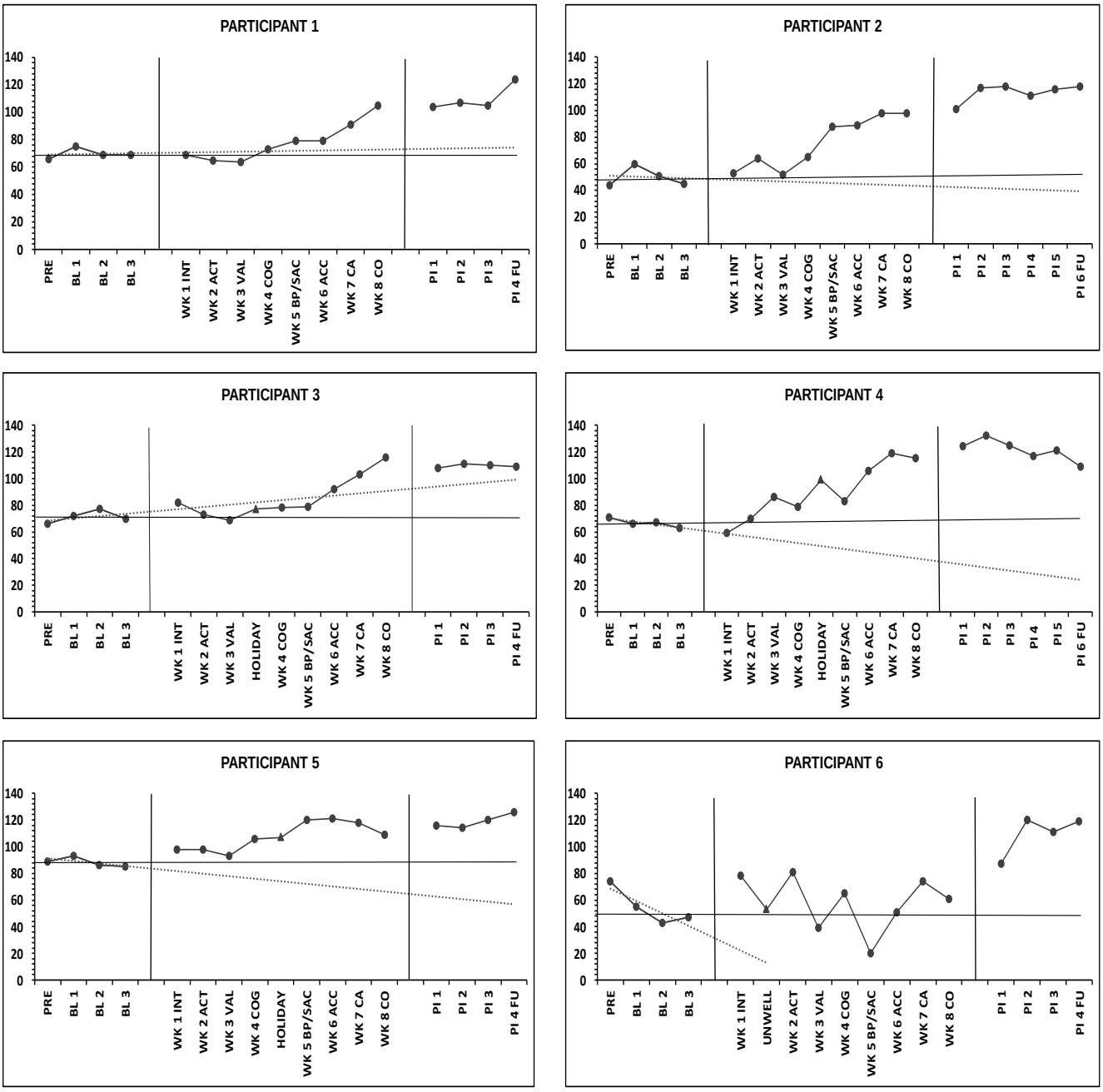


PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement.

Figure 5: Total impact and the subscales of the impact of fibromyalgia with overall trend for total impact and symptom impact – measured by the FIQ-R across all phases for each participant

Psychological flexibility – measured as CompACT total score

Visual analysis from the baseline trend indicates all 6 participants demonstrated positive increases in their level of psychological flexibility at both post and follow-up (Figure 6).



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Increase demonstrates improvement Dotted line = baseline trend Solid black line = baseline median line

Figure 6: Psychological flexibility and baseline trend – measured by total scores of the CompACT for each participant across all phases of the intervention with baseline median line to demonstrate PEM/DC analysis.

Further analysis supports visual inspection as the positive changes in psychological flexibility at follow up were found to be reliable, clinically significant and effective (as measured by RCI, CSC and PEM/DC) for all participants (mildly effective for P1 and P3, moderately effective for P6 and highly effective for P2, P4 and P5). Reliable and clinically significant change was reported for five out of the six participants (P1, P2, P3, P4 & P5) at post measurement scores and PEM/DC analysis found this change to be effective (ranging from mildly to highly effective) except for participant 3 whose change was deemed to be ineffective. Although the baseline trend for participant 6 indicated a deterioration she did not deteriorate as sharply as expected and follow up suggests a beneficial improvement from premeasurements scores. Overall the average PEM/DC score was .77 at post and .84 at follow up which is considered moderately effective. The PEM/DC result is supported by the Tau-U analysis which found the overall effect size of change in the level of psychological flexibility to be beneficial (Tau-U = .64) and statistically significant ($p<0.005$) at both post and follow up.

Despite all six participants demonstrating a positive increase in psychological flexibility there does not appear to be the emergence of any clear pattern as to which element of the intervention most influenced its development[18]. The increase in psychological flexibility appears to be an individual and cumulative process and does not appear related to levels of activity as measured by step count.

Conceptualised self –measured by the SEQ

Visual analysis of Figure 7 shows that participant 5 met the ceiling effect at the end of the baseline phase and remained there with only minor fluctuation throughout the remainder of the intervention. Results for participant 5 for this measure should therefore be interpreted with caution. The remaining five participants all demonstrated a reliable and clinically significant beneficial increase in their conceptualised self by follow up and this was deemed effective for participants 1,2,3 and 6. Only change for participant 6 was reliable, clinically significant and effective at post. PEM/DC average showed ineffective change at post but mildly effective change at follow up. The PEM/DC analysis is heavily influenced by participant 5 reaching a ceiling effect for the majority of the intervention. Tau-U analysis reported that the overall effect of the intervention on

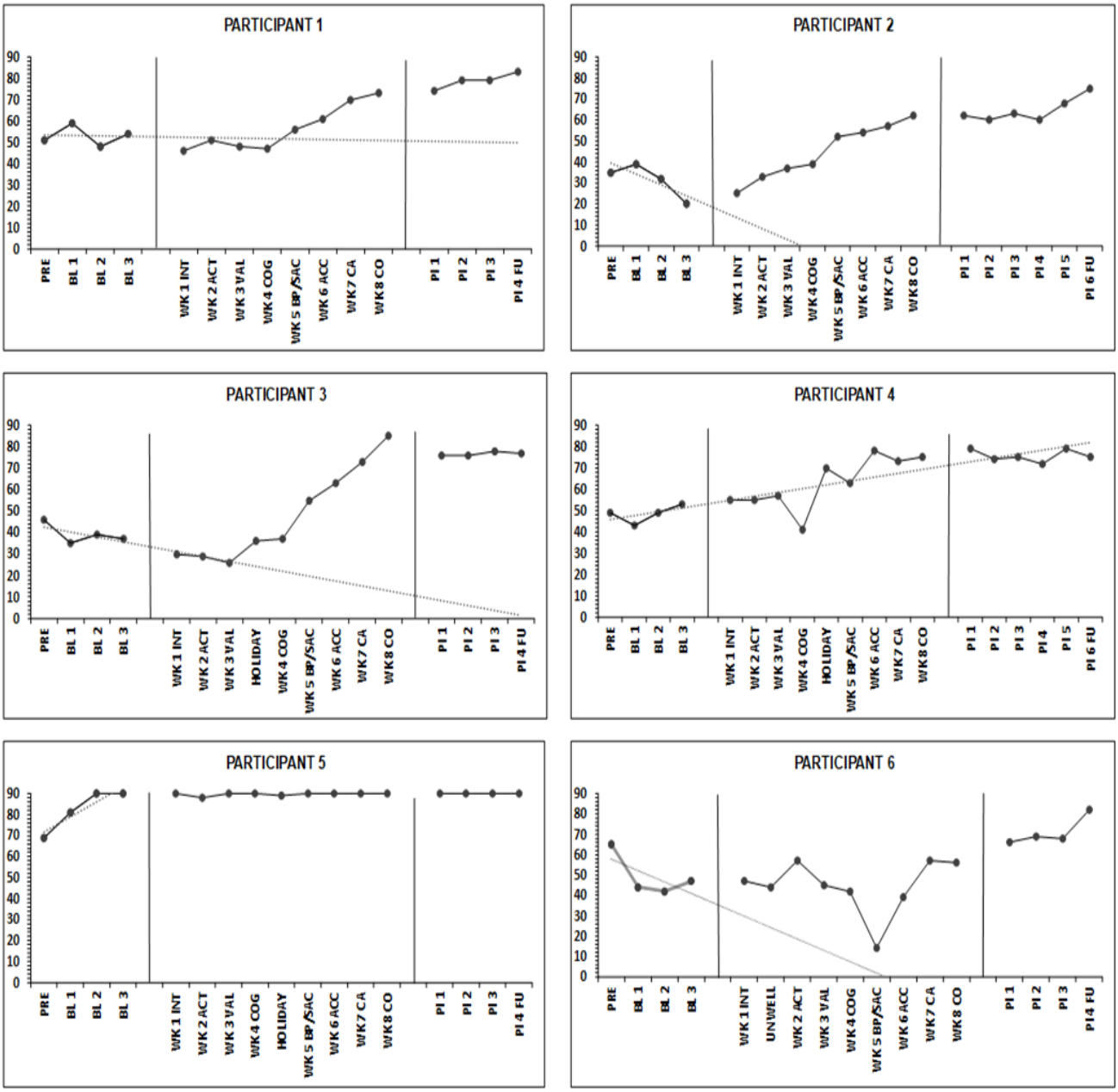
[18] Further analysis of the CompACT and the dyadic processes measured within it are discussed in the extended paper

the conceptualised self was beneficial at both post and follow up Tau-U = .29 at post & .50 at follow up) but was only statistically significant at follow up ($p<0.005$)[19].

RCI, CSC and PEM(DC) results,

A full analysis of reliable and clinically significant change with the percentage exceeding the median analysis (dual criterion method) for pre, post and follow up measures are shown in Table 12.

[19] Further analysis of the subscales of the SEQ are reported in the extended paper



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Increase demonstrates improvement Dotted line = baseline trend

Figure 7: The self-as-context (conceptualised self) and baseline trend – measured by the SEQ across all phases for each participant

Table 12: Pre, post and follow up scores, RCI, CSC and PEM(DC) analysis

		ACTIVITY	DASS - 21				CompACT				SEQ	FIQ-R			
Participant	**Time period**	**Activity daily average**	**Depression**	**Anxiety**	**Stress**	**Overall**	**OE scale**	**BA scale**	**VA scale**	**Psychological Flexibility**	**SEQ**	**Function**	**Overall**	**Symptoms**	**Overall impact**
Participant 1	Pre	11319	2	12 R+C+	10 R+	24	24	9 R+C+	33	66 R+C+	51	17 R+C+	7	27	51
	Post	9146	0	4	0	4	39	24	42	105	73	6	2	23	31
	Follow up	11685	0	2 R+C+	0 R+	2	51 R+C+	27 R+C+	46 R+C+	124 R+C+	83 R+C+	8	2	24	34
	PEM at Post	.38	.63	.63	.38	.38	.63	.63	.25	.50	.50	0	0	.75	0
	PEM Follow up	.50	.75	.75	.58	.25	.75	.75	.50	.67	.67	0	0	.75	0
Participant 2	Pre	5947	2	8 R+C+	14 R+	24	7 R+C+	8 R+C+	29	44 R+C+	35 R+C+	16	11	28 R+C+	54
	Post	4476	2	0	4	6	44	20	34	98	62	9	5	18 R-C-	32
	Follow up	8416	0	0 R+C+	6	6	52 R+C+	25 R+C+	41	118 R+C+	75 R+C+	5 R+C+	0	33	38
	PEM at Post	0	.88	.75	1.0	1.0	.50	1.0	.50	1.0	.75	1.0	1.0	.38	1.0
	PEM Follow up	0	.93	.86	1.0	1.0	.57	1.0	.71	1.0	.86	1.0	1.0	.43	1.0
Participant 3	Pre	8736	2	10	12	24	17 R+C+	11	38	66 R+C+	46 R+C+	3	3	11 R+C+	17
	Post	10537	0	6	8	14	51	17	48	116	85	0	0	1	1
	Follow up	9196	0	4	6	10	49 R+C+	12	48	109 R+C+	77 R+C+	3	3	6	12
	PEM at Post	1.0	0	0	0	0	.33	.22	0	.44	.44	1.0	.22	.56	1.0
	PEM Follow up	.86	0	0	0	0	.54	.38	0	.61	.62	1.0	.15	.69	1.0

Participant 4	Pre	9167	16 R+C+	24 R+C+	22 R+C+	62 R+C+	21 R+C+	8 R+C+	42	71 R+C+	49 R+C+	20 R+C+	14 R+C+	29 R+C+	63 R+C+
	Post	8918	0	4	0	4	49	30	45	124	79	3	3	7 R-C-	13
	Follow up	10472	0 R+C+	4 R+C+	4 R+C+	8 R+C+	47 R+C+	24 R+C+	38	109 R+C+	75 R+C+	3 R+C+	2 R+C+	33	38
	PEM at Post	0	.89	1.0	1.0	.89	.78	.89	.44	.89	.44	1.0	.89	.89	.89
	PEM Follow up	0	.94	1.0	1.0	.93	.87	.93	.60	.93	.33	1.0	.94	.73	.93
Participant 5	Pre	9271	6 R-C-	18	10	34	47	14	28 R+C+	89	69	25	19	46	90
	Post	8360	20 R+C+	14 R+C+	10	44 R+C+	40	22	47	109	90	29	20 R+C+	42	91 R+C+
	Follow up	9425	0	6 R+C+	4	10	48	30 R+C+	48 R+C+	126 R+C+	90	19	8 R+C+	33 R+C+	60 R+C+
	PEM at Post	.11	0	0	.23	0	.89	.78	.78	1.0	0	.22	0	0	0
	PEM Follow up	.08	0	0	.15	0	.85	.69	.85	1.0	0	.15	0	0	0
Participant 6	Pre	4722	18	6	8	32	31 R-C-	15	28	74	65	6	9	19 R-C-	34
	Post	4241	22 R+C+	10 R+C+	14	46 R+C+	17 R+C+	20	24	61 R+C+	56	2	14	35	51
	Follow up	3558	0 R+C+	0	2 R+	2 R+C+	46	30 R+C+	43 R+C+	119 R+C+	82 R+C+	0	0	33 R-C-	33
	PEM at Post	.23	.22	.67	.11	.44	.56	.44	.78	.78	.44	.78	0	.22	.33
	PEM Follow up	.15	.15	.77	.31	.62	.69	.62	.85	.85	.61	.85	0	.31	.31

Change indicated next to pre scores denotes change pre to post; change indicated next to post measures denotes change post to follow up; change indicated next to follow up measures denotes change pre to follow up.

R = denotes Reliable Change. C =denotes Clinically Significant Change (from clinical to non-clinical range) at p<.05. + or - indicates improvement or deterioration respectively. (N.B. all scales used criterion C for clinical cut offs except the DASS-21 which used criterion A). Effect size was calculated using percentage exceeding the median analysis using the dual criterion method (PEM or PEM/DC). PEM-scores range from 0-1 ≥.90 highly effective, ≥.70 <.90 moderately effective, .50-.69 mildly effective (questionable), < .50 ineffective.

Tau-U analysis

Table 13 shows the Tau-U analysis for the totals of all measures across the intervention i.e.; post = phase B1 and follow up = phase B2

Table 13: TAU-U analysis across phases A & B1 and phases A & (B1 + B2) controlling for baseline trend

Measure	Baseline Phase Mean (SD)	Intervention Phase to end of B^1 - Mean (SD)	Intervention Phase to end of B^2 - Mean (SD)	Tau-U	Var-Tau	Z value	Confidence Interval - 95%
Fitbit Flex Levels of Activity	8251.11 (2221.56)	8248.15 (2980.24)		-0.23^	0.16	-1.34	-0.5519<>0.0933
			8316.88 (2732.08)	-0.10^	0.16	-0.64	-0.4042<>0.2060
CompACT Psychological Flexibility	66.79 (13.80)	82.92 (22.23)		0.64**	0.15	4.31	0.3478<>0.9283
			93.90 (23.94)	0.64**	0.15	4.31	0.3478<>0.9283
DASS-21 Psychological Distress	34.50 (17.67)	23.92 (16.78)		-0.41*	0.15	-2.77	-0.7003<>-0.1198
			18.32 (15.95)	-0.60**	0.14	-4.31	-0.8671<>-0.3250
FIQ-R Fibromyalgia Impact	53.46 (19.90)	39.37 (23.26)		-0.53**	0.15	-3.57	-0.8187<>-0.2383
			36.00 (22.46)	-0.66**	0.14	-4.81	-0.9358<>-0.3938
SEQ Contextualised Self	50.71 (17.21)	58.10 (20.30)		0.29	1.15	1.92	-0.0052<>0.5752
			64.11 (19.00)	0.50**	0.14	3.60	0.2260<>0.7681

*p<0.05 **p<0.005 ^non-beneficial result
The Tau-U effect size ranges from -1 to 1, with a Tau-U of 0 indicating 0% improvement/decline and a Tau-U of +/-1 indicating 100% improvement/decline.

Framework analysis

A priori framework developed to interpret data from the change interview focussed on the three following domains. The identification of an expanded framework based on these themes can be seen in Figure 8.

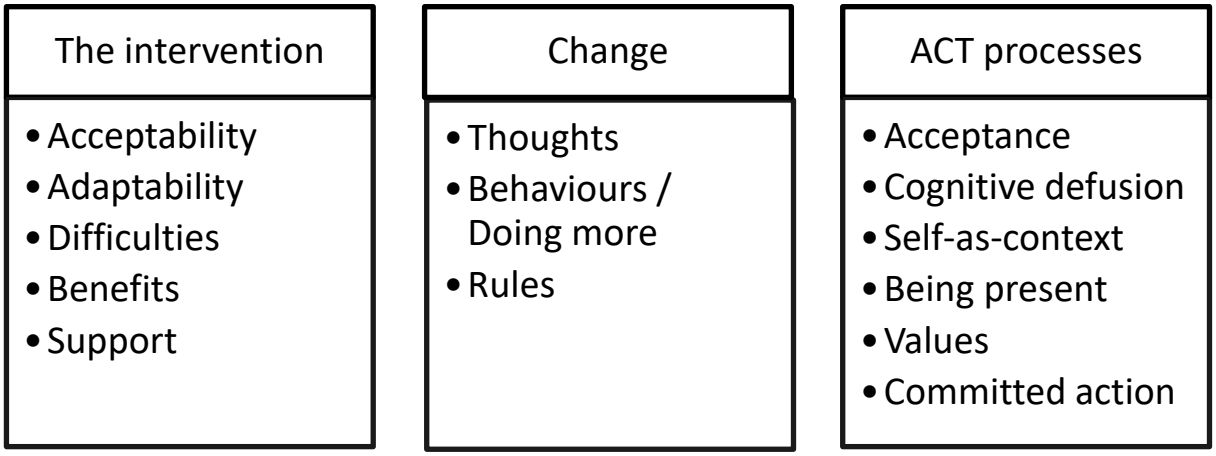


Figure 8: Expanded themes from framework analysis

All six participants reported they found the intervention acceptable with the caveat that two participants found it 'Americanised' and four participants commented on the adaptability of the intervention into other aspects of their lives. Barriers and difficulties mainly focussed on finding the time to engage with the material between weeks as a result of being busy and in one case of the 'brain fog' reported by fibromyalgia sufferers (Glass, 2008). The consensus of all six-participants was that the telephone support was beneficial and an integral part of the intervention. The relationship between the researcher and the participants could be considered a non-specific factor which could influence the outcome of this study. Therapeutic relationships have been reported to increase engagement, adherence to interventions and influence therapeutic outcomes (Blasko, Serran, & Abracen, 2018). Whilst all participants reported finding the telephone support helpful most positive outcomes were sustained or improved upon between post and follow up in the absence of the calls. The cohort reported changes to their thought processes and behaviours in line with their values which is coherent with the ACT model (Hayes *et al*., 2006). Whilst levels of activity measured by the

trackers did not appear to increase, the participants reported 'doing more' which predominantly focused on increasing social and pleasurable engagement (Table 14)[20].

Table 14: Qualitative responses to changed behaviour

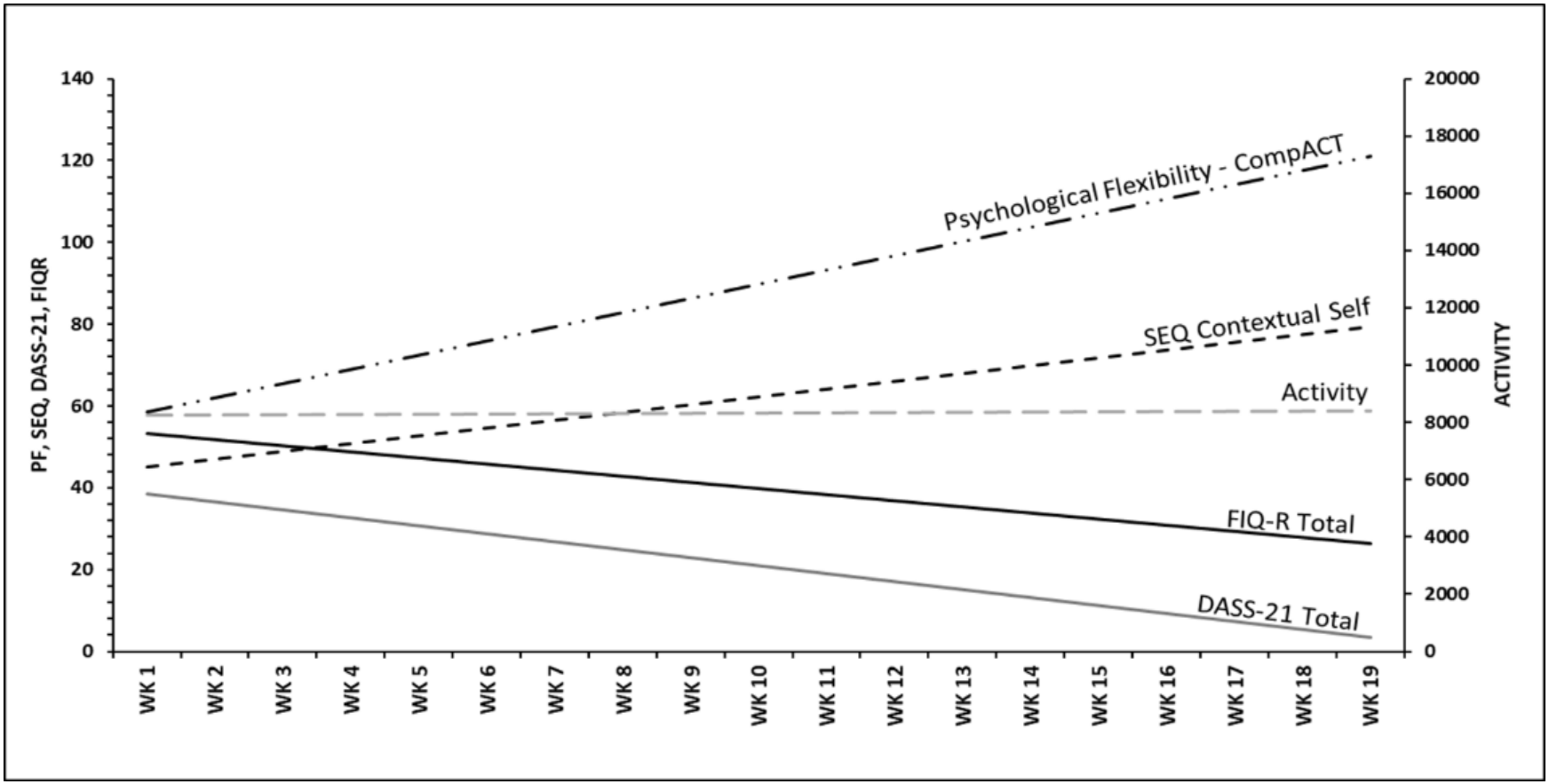
Participant	Response in relation to behaviour changes
P1	''My friends have all been very good and lots of people with long term conditions have people that abandon them or move on and leave them whereas my friends let me dip in and dip out, so I have decided to dip in a little bit more''
P2	''I guess like I said I am doing more at weekends. I think pretty much every weekend I've done something whereas before I would have kind of wanted to do it, but I'd have gone you know what I can't I'm too tired or I'm in too much pain. I think every weekend since, I've done something I wanted to do which has been a massive massive change and it's giving me something to look forward to during the week because I know at the weekend I've always got something''. ''I see far more of my best friend than I've seen in ages I've kept in touch and got back in touch with people that kind of drifted apart from because I just couldn't be bothered to go and meet them for a drink or go and have tea before I started back at work I was going for coffees and cake so yeah it really has changed and a shift in my thinking as well I think it's alright you know'' I'm using far less pain killers far less pain killers I'm far less bothered by far less upset by it it's not stopping me from going out and doing things and I'm not thinking about it and the pain is coming and it's there in my background''
P3	''The couch to 5 K & I did successfully complete that. The intervention helped me to complete that'' ''actually my level of activity and variety of things that I'm doing and how involved I get with things has increased''
P4	''I have dropped quite a few of my painkillers which has been quite good - because I was having 8 paracetamol and four codeine everyday whereas now I don't think I've had any paracetamol or codeine apart from the odd time when I come back from the gym but I've been fine again the next day'' ''yeah I'm even started going to some exercise classes at the gym'' ''I mean there are some days when I was taking the kids to school in my pyjamas and id just come home and get on the sofa but I don't remember the last time I did that so that's got to be a good thing''
P5	''I'm doing more but it's not even about doing more if somebody had said do you want to go out for lunch I'd be like no kind of thing like there's no point me doing that because it will just be well I'll be poorly tomorrow but now be like yeah I'll come so now I am doing more I suppose'' ''like I say you know I've been on holiday I haven't been for 4 or 5 years because every time I went it was like the first few days of being bad and I think by the time I'm better I'm gonna be going home and be back to square while what's the point of going but we did we went and it was amazing'' ''I've started going swimming and enjoying the local leisure club''
P6	''I've been generally much more positive and generally much better doing more things'' ''I have also come off my medication my amitriptyline and citalopram, so I am just hoping that because I have felt more in control of things that I have felt able to do that because obviously I don't want to stay on medication forever''

Responses were in relation to behaviour change that participants attributed to the intervention

[20] Further detailed information relating to the framework analysis can be found in the extended paper

Outcome summary

The overall aggregated levels of increase / decrease in all outcomes are demonstrated using overall trend lines in Figure 9[21].



Dotted lines = increase denotes benefit Solid line = decrease denotes benefit

Figure 9: Aggregated overall trend lines for all measures across the intervention for all participants

[21] Further summary information is provided in the extended paper

Discussion

This study set out to investigate: a) the efficacy of an ACT guided self-help intervention for individuals with fibromyalgia, with specific focus on physical activity, psychological flexibility, daily functioning, quality of life, symptom severity, and psychological distress and b) to examine the relationship(s) between these psychological and behavioural outcomes and psychological flexibility.

It was hypothesised that as a result of participants engaging with more value laden behaviours their levels of activity would increase. However, whilst all six participants reported 'doing more', levels of activity that could be measured in terms of steps taken, did not increase across participants over the course of this study. There appear three apparent explanations for this; a) activity including exercise was not the specific focus of the intervention despite the hypothesis that levels of activity would increase, having previously done so under similar circumstances in other chronic health conditions (Roche *et al*., 2017); b) 'doing more' in value guided terms is idiosyncratic and only two participants reported that behaviours in line with their values had a physical activity theme and; c) the focus within extant literature on increasing levels of activity appears to be driven by the reduced levels of activity reported within a fibromyalgia population and y*et al*l six participants fell within the normative range for levels of activity with four of the six participants consistently above the optimum levels outlined by Tudor-Locke *et al*., (2011). Potentially this could raise a question about the sample within this research however McLoughlin *et al*., (2011) recommended the use of trackers rather than self-report measures to assess daily activity as they found large variations between self-reported and actuary levels of activity for individuals diagnosed with fibromyalgia. All six participants reported reductions in their activity due to their fibromyalgia symptoms at the start of the study. Houdenhove, Neervickx, Onghena, Lysens and Vertonnen, (2001) found that individuals with fibromyalgia had overly high levels of pre-morbid activity and in addition Galvez-Sánchez, Duschek, and del Paso (2019) suggested that individuals diagnosed with fibromyalgia have high levels of perfectionism which has also been linked to higher levels of psychological inflexibility (Crosby, Bates, Twohig, 2011). It is therefore reasonable to suggest that whilst lower levels of activity are often reported by fibromyalgia sufferers this may be in comparison to former levels of activity or to their own high standards rather than comparative to a normative population. The findings of this study could therefore call in to question that individuals with fibromyalgia have reduced levels of activity.

There were increased levels of psychological flexibility across the span of the intervention which were sustained at follow up for all participants. Analysis did not identify any clear pattern between the processes of ACT and the increase in psychological flexibility. Whilst increasing psychological flexibility does not appear to have impacted the actual level of activity for fibromyalgia sufferers, all six participants report 'doing more' in terms of activity that was meaningful to them. Psychological flexibility is described as the ability to contact the present moment and consciously choose to change or persist in behaviours in line with individual values (Fletcher & Hayes, 2005). Whilst participants detail choosing to engage in meaningful behaviours which enhance their quality of life, it would appear that increasing physical activity is a lifestyle choice that not everyone would identify as important to them. Previous research aimed at increasing activity often focused solely on exercise with reports of limited success in eliciting the required behaviour change with high attrition rates (O'Dwyer *et al*., 2019) and low adherence (Dobkin *et al*., 2006). It is not too hard to conclude that these results might stem from exercise not being viewed as meaningful or value consistent to individuals with fibromyalgia. Whilst treatment guidelines for fibromyalgia (APS, 2005, CPS, 2013 and EULAR, 2016) have recommended exercise, the CPS (2013) guidelines highlighted the need to increase 'normal' activity which includes increasing social activity and the results of this study appear to support this. Ultimately ACT is a behavioural therapy and behavioural change has been shown to be more likely and sustainable over time when it is consistent with the values of an individual (Anderson & Funnel, 2002). It is reasonable to see this is because the behaviour change can then be experienced as beneficially reinforcing rather than an abstract increase in activity not important to the individual.

All participants also demonstrated beneficial changes in their levels of psychological distress. Miro *et al*., (2011) highlighted that depression and anxiety both play a significant role in the development and maintenance of chronic pain with Tsuji, Matsudaira, Sato, & Vietri, (2016) highlighting that higher levels of depression are associated with higher levels of pain. In addition, Mease and Seymour (2008) and Segura-Jimenez *et al*., (2017) reported that levels of pain were responsible for the reduced levels of activity and the reduced quality of life for fibromyalgia sufferers. However the results of this study appear to refute these findings, at least partially, as whilst levels of symptom severity at times remained the same or increased, there was no direct link between the levels in symptom severity, psychological distress and the level of activity. In addition there was a reduction in the impairment to functioning and the overall impact of fibromyalgia for five of the six participants even in the presence of

sustained or increased symptoms. Whilst perhaps counter-intuitive these findings are in line with ACT which does not directly target symptom reduction. In addition Steiner *et al*., (2017) had identified a correlation between the outcome measures in previous CBT research (pain, functioning and depression) and the outcomes in this study therefore allow the inference that psychological flexibility could be the active mediator to improved psychological and functional outcomes for individuals living with fibromyalgia even in the presence of pain[22].

The ACT supported self-help intervention appears to have successfully targeted both psychological flexibility and value-consistent meaningful activity. However, no clear pattern emerged between elements of the intervention and psychological flexibility or its core processes. This study acknowledges limitations in measuring potential mechanisms of change as although the timing of the delivery of the intervention could be controlled, when it was engaged with and to what degree it was engaged with could not be controlled. It would be hard to say if any change was due to a specific process or a carryover effect which was in fact inferred in the qualitative responses of this research[23].

The results of this single-case series study are entirely consistent with ACT theory but appear to have implications for both future research and the treatment of fibromyalgia. Treatment guidelines and extant research is predicated on the assumption that fibromyalgia sufferers have reduced levels of activity in comparison to controls. This study has highlighted a disparity with these findings. Whilst the sample within this study did not increase their level of activity as a result of the intervention they attributed meaningful change directly to it, with a range of positive outcomes. This suggests that prescriptive therapies and interventions based solely on increasing levels of activity and specifically exercise may not be beneficial to individuals diagnosed with fibromyalgia and it is the change to more meaningful activity that could be of most benefit and should be the target for future interventions.

Conclusions

Direct replication in this multiple single-case design and consistency between participant outcomes and between the different forms of analysis, suggests the potential for generalisability of the results generated by the current study though further systematic replication is suggested. Overall, the ACT supported self-help intervention

[22] Further discussion in terms of theory and extant literature can be found in the extended paper
[23] Further discussion on the strengths and limitations of this study are presented in the extended paper

appears well received and effective in a range of positive outcomes such as increasing psychological flexibility and reducing psychological distress. Therefore, this study supports the use of ACT based supported self-help interventions for a fibromyalgia population.

However, the findings outlined could be further supported by; a) re-defining levels of activity in a large sample of fibromyalgia sufferers using activity trackers versus self-report and; b) replication of this study utilizing longer follow-up periods to see if levels of psychological flexibility, psychological distress and functioning in a fibromyalgia population are sustained[24].

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Journal paper word count – 5999/6000 excluding Tables, Figures, references and directions to the extended paper

[24] Further suggestions for future recommendations are provided in the extended paper

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Extended Paper

1.0 Extended background

Fibromyalgia has been described in medical literature since the 1800's when it was originally termed neurasthenia (Sumpton & Moulin 2014). Neurasthenia was reported to have been a common diagnosis, providing both patients and clinicians with a framework for unexplained symptoms that might otherwise have been interpreted contemporaneously as hypochondriasis, malingering and even insanity (Sicherman, 1977). In 1904 neurasthenia was renamed fibrositis, and more recently the name fibromyalgia has been utilised, which is an amalgam of fibro-myo-algia meaning fibrous tissue, muscles and pain (Rahm *et al*, 2015). Fibromyalgia was previously considered to be a rheumatic and musculoskeletal disease and so the diagnostic criteria for fibromyalgia was developed by the American College for Rheumatology (ACR) (Wolfe *et al*., 2019). More recent evidence indicates that fibromyalgia is a non-inflammatory illness (Williams & Clauw, 2009, Vargas-Alcaron *et al*, 2012, Wolfe *et al*., 2019) with Wolfe, Walitt and Hauser (2014) claiming that the assumption of rheumatic causation has now been totally discounted. Fibromyalgia is currently considered solely a pain disorder within rheumatology communities and is perhaps best conceptualised within the broader spectrum of an idiopathic, non-progressive and non-degenerative, medically unexplained syndrome (Jay & Barkin, 2015). Symptoms in fibromyalgia are generally stable but with diurnal and individual variation (Wolfe *et al*, 2011). In addition to co-existing depression and anxiety there is also evidence to support high levels of other psychiatric co-morbidities such as borderline personality disorder, neuroticism, perfectionism and alexithymia (Galvez-Sanchez, Duschek & Reyes del Paso, 2019). All co-existing symptoms are considered secondary to the chronic pain, which is the defining feature of fibromyalgia.

1.1 Diagnosis

The ACR took responsibility for the diagnostic criteria for fibromyalgia which has been subject to major revisions since 1990 when it was intended for research rather than clinical purposes (Wolfe *et al*., 2011). At that time the focus of diagnosis was solely on the pain symptomology (Williams & Clauw, 2009) and involved the examination of 18 tender points (Wolfe *et al*, 1990). Diagnosis of fibromyalgia could be made if pain lasting longer than three months was found in 11 out of the 18 tender points. Criticisms surrounding the criteria included that the tender point test was inherently arbitrary, thus rendering it open to misdiagnosis and that the criteria did not address the range of

symptoms, other than pain, that affected fibromyalgia patients (Moyano. Kilstein & de Miguel, 2015). Revisions by the ACR in 2010 took account of fatigue, cognition and the other somatic symptoms and the ACR made further revisions in 2011 whereby they totally eradicated the tender point examination (Sumpton & Moulin, 2014). Diagnosis is currently focused on the self-reported severity and tolerance of pain and the adaptive coping strategies available to an individual (Wolfe *et al*, 2011) using the symptom severity scale (SS) (Wolfe *et al*., 2010), and the widespread pain index (WPI) (Wolfe *et al*., 2011). There are no physical or biological markers for fibromyalgia and therefore diagnosis is one of exclusion to other disease. Catoggio (2015), claims that since this criterion change, diagnosis has become more widespread and less specific. Wolfe *et al* (2015) reported that 25% of patients diagnosed on the new guidelines would not have met the 1990 criteria which may go some way to explaining the increase in prevalence rates (see section 1.3).

Individuals diagnosed with fibromyalgia indicate unsympathetic and unknowledgeable physicians as an important problem (Kumbhare, Ahmed, Sander, Grosman-Rimon, & Srbely, 2018). This is supported by Ghavidel-Parsa, Bidari, Maafi and Ghalebaghi, (2015) who reported that awareness about fibromyalgia is low with a distinct lack of knowledge about fibromyalgia and its diagnostic criteria amongst clinicians. Walitt, Katz, Bergman and Wolfe (2016) found clinician knowledge was so low that the diagnostic criteria for fibromyalgia were often either not used or used solely as a guide rather than a diagnostic tool, with up to 75% of some clinicians' patients being mis-diagnosed.

1.2 Aetiology

There is continual debate as to the aetiology and taxonomy of fibromyalgia with a wide range of casual factors suggested (Wolfe, 2017). There is also a large overlap of psychologically determined co-morbidities with fibromyalgia such as depression (Thiagarajah, Guymer, Leech & Littlejohn, 2014) anxiety and stress (Hallberg & Carlsson (1998) which could be suggestive of aetiological links although bi-directionality is reported to play a significant role (Wolfe & Walitt, 2013). Population cohort studies have identified various complex triggers which are reported to contribute to the emergence of symptoms such as, child abuse, long term physical and emotional stressors and even lower education levels (Creed & Barksy, 2004, Creed *et al*, 2012).

The lack of definitive aetiological causation appears to lead to fibromyalgia being a contested and 'invisible' illness with sufferers often deemed to be lazy and malingering

(Paxman, 2019). Armentor, (2017) reported how individuals diagnosed with fibromyalgia often felt disbelieved, judged and marginalised by family members, friends and employers but most of all by health care professionals who often express that they don't believe fibromyalgia even exists (Griffith & Ryan, 2015). Fibromyalgia sufferers often seek information from the internet potentially due to the lack of practitioner knowledge or definitive agreement on causation. A recent study by Basavakumar, Flegg, Eccles and Ghezzi (2019) highlighted the inaccuracy and inadequacy of internet provided information in relation to the symptoms, aetiology and treatment of fibromyalgia. The authors also suggested that the lack of information clarity led to patients attributing the aetiology of fibromyalgia to a range of causal factors often totally unrelated to the illness.

Of note for this research study, is the lack of judgement in relation to causal aetiology of fibromyalgia. The determination of aetiology of fibromyalgia is not within the remit of this work and as will be explained in the section of this thesis dedicated to the epistemological position of functional contextualism, the aetiology of fibromyalgia could be considered as irrelevant for the purposes of this study. The pragmatic truth for the individuals involved in this study is that they have a diagnosis of fibromyalgia and they struggle with pain and a variety of other associated symptoms.

1.3 Epidemiology

There is large variation in reports of the prevalence of fibromyalgia. Within the general population in Western Countries, the estimated prevalence of fibromyalgia appears to be escalating exponentially with reported rates between 2-4% in 2009 (Spaeth, 2009), to between 5.4% and 8% in 2016 (Menzies, 2016) and up to a potential 11% in 2018 (Wolfe, Walitt, Perrot, Rasker & Häuser, 2018). These rates are heavily disputed with both Wolfe *et al* (2019) and Srinivasan *et al* (2019) highlighting the previously discussed issues with both the diagnostic criteria and the lack of physician knowledge for this variation. Over 90% of individuals diagnosed with fibromyalgia are women (Wallit *et al*., 2016) and in epidemiological findings, women's pain and other fibromyalgia related symptoms were often considered to have psychological causation and therefore treated with anti-depressants. Men's pain and symptoms were often deemed physiological and treated with pain control medication (Sabik, 2010; Katz, Mamyrova, Guzhva & Furmark, 2010) which may contribute to some of the gender differential in diagnostic levels. A recent sociodemographic study reported that the mean age of fibromyalgia sufferers was 49.3 years (Martini *et al*., 2019) mirroring similar findings from an older study which also reported that 64.2% of sufferers were married, 84.8% were educated to at least

college standard and 49.5% were in employment (Cronan, Serber, Walen & Jaffe, 2002). Apart from the level of education, the sociodemographic of a fibromyalgia population do not appear remarkably different from a normative population sample. Cronan *et al* (2002) also reported that symptomology in fibromyalgia decreased with age, which was supported by Shillam, Jones & Miller, (2011).

1.4 Impact of the disorder

An increasing fibromyalgia population with high healthcare utilisation creates a substantive impact on healthcare provision. Diagnosis for fibromyalgia is based on subjective self-reported symptoms but usually generates expensive and exhaustive testing. Whilst these tests are solely exclusionary as there are no confirmatory markers for fibromyalgia, they are necessary to rule out other physiological conditions (Wolfe *et al*, 2013). On average individuals in the U.K. diagnosed with fibromyalgia required more than double the amount of medical appointments and prescriptions, in the year prior to diagnosis compared with general population controls (Hughes, Martinez, Myon, Taïeb, & Wessely, 2006). Increased utilisation of healthcare provision by fibromyalgia sufferers continues after diagnosis (Perrot *et al*, 2012) suggesting current treatment is ineffective and there are continuing unmet care needs. Fibromyalgia sufferers were reported to miss more workdays than those diagnosed with any other illness and have higher unemployment rates compared to individuals with other chronic pain conditions (Leadley, Armstrong, Lee, Kleijnen, 2012). Wolfe, *et al*., (2010), claim impairment to life quality for fibromyalgia sufferers is only secondary to individuals with end-stage renal failure when measured on the Quality of Life Scale.

Given all of the above fibromyalgia could be considered a label with socially constructed negativity and stigma attached to it (Undelan & Malterud, 2007). Sufferers of medically unexplained and contested illnesses are reported to be involved in identity crisis and self-stigmatisation (Nettleton, 2006) and there is evidence to suggest that internalising stigma is directly related to compromised treatment outcomes (Yanos, Lysaker & Roe, 2010). In addition, Armentor (2017) reported that lack of understanding about fibromyalgia led sufferers to avoid social interactions in the attempt to hide from the stigma associated with an invisible and contested illness which subsequently leads to further isolation and lack of activity.

1.5 Treatment

Current treatment guidelines for fibromyalgia are limited and inconsistent with only three countries worldwide; Canada, Germany and Israel having specific treatment

guidelines. The guidelines provided by other professional non-government bodies such as The American Pain Society (APS, 2005; Burckhardt *et al*., 2005); The Canadian Pain Society (CPS, 2013; Fitzcharles *et al*., 2013), and most recently and geographically relevant (as often referred to within the U.K.), The European League Against Rheumatism (EULAR, McFarlane *et al*., 2017) have used systematic reviews and meta-analyses to formulate their own fibromyalgia treatment recommendations. Thieme, Mathys, and Turk (2017) found discrepancies between treatment recommendations within the fibromyalgia guidelines, which they attributed to the inclusion criteria of the studies, the quality of the studies themselves, weighting of results and the composition of the review panels.

Jay and Barkin (2015) reported there were no medications or treatments specifically approved for fibromyalgia in the U.K. and this remains true at the time of writing. Treatment for fibromyalgia is therefore inconsistent and often based on pharmacologic symptom amelioration, even though this is against the limited recommendation (Russell *et al*, 2008). Only 3 drugs have been approved for fibromyalgia worldwide. In 2007 Lyrica (pregablin), a neuralgesic and central nervous system depressant, often prescribed as an anti-convulsant, was the first drug approved by the Food and Drug Administration (FDA) although EULAR found only weak evidence to support its use to treat fibromyalgia. In 2008 Duloxetine (Cymbalta), and in 2009 Milnacipran (Savella) were approved, which are both serotonin and norepinephrine reuptake inhibitors, more commonly associated with the treatment of depression (Sabik, 2010) and again EULAR only gave a weak recommendation for these drugs. Nüesch, Häuser, Bernardy, Barth and Jüni's (2013) meta-analysis of fibromyalgia treatments recommended that medication for fibromyalgia should only be prescribed as part of a multi-modal approach. A summary of the EULAR guideline recommendations for psychopharmacological treatment in fibromyalgia can be seen in Table 15.

Table 15: Summary of EULAR recommendations for fibromyalgia

Class of medication	Brand names	EULAR recommendation
Anti-depressants	e.g. Amitriptyline or other tricyclic antidepressants;	Weak recommendation only for Duloxetine and Milnacipran
	Duloxetine, Milnacipran, Mirtazapine or other serotonin-norepinephrine reuptake inhibitors	Both approved
Selective serotonin reuptake inhibitors (SSRI's)	e.g. Citalopram, Sertraline,	Weak recommendation against all SSRI's
		None approved
Anti-epileptics	e.g. gabapentin, pregabalin, topiramate	Weak recommendation only for gabapentin which is
		Not approved
Nonsteroidal anti-inflammatory drugs (NSAIDs)	e.g. diclofenac, ibuprofen, naproxen	Weak recommendation against all NSAID's
		None approved
Opioids	e.g. morphine, oxycodone, tramadol, codeine, dihydrocodeine	Strong recommendation against all opioids
		Contra-indicative

As treatment of fibromyalgia is non-curative and aimed solely at reducing symptoms, this may explain why in the U.K. over-medication and indiscriminate polypharmacy prescription for fibromyalgia is reported to be rife as doctors prescribe a range of drugs to treat both the pain and psychological symptoms (Jay & Barkin, 2015). Over 90% of fibromyalgia patients are prescribed medication (Wolfe *et al*, 2011), including strong opioids, which are deemed contra-indicative (Arnold, 2009). This high level of ongoing prescribing is despite pharmacological treatments being perceived as ineffective for fibromyalgia (Martinez, Myon, Taïeb & Wessely, 2006). It was reported that most fibromyalgia sufferers prescribed psychopharmacology, reported little lasting impact to their pain and often reported side-effects from the medication, yet they continued to take what was prescribed (Taylor *et al*., 2019).

1.6 Exercise and increased activity for fibromyalgia

A recent Cochrane review supported treatment guidelines surrounding increased exercise (Winkelman, 2019) and treatment options such as Acceptance and Commitment Therapy (ACT) that might increase activity in line with individual values is therefore worthy of investigation. Whilst it appears increased activity has benefit for

those suffering with fibromyalgia a recent systematic review by O'Dwyer, Maguire, Mockler, Durcan and Wilson (2019) on behavioural change interventions that target physical activity, found only limited success at eliciting the necessary behaviour change in adults with fibromyalgia. The authors also reported in their review that attrition rates were a minimum of 6.4% for this population.

1.7 Acceptance and Commitment Therapy

ACT assumes that human suffering is a normal psychological function. Non-humans respond predictably to the exposure of aversive stimuli, in a time-limited manner that is directly linked to the presence of that stimuli (returning to baseline levels soon after the removal of that stimuli). Humans have developed the ability to remember past events or predict future events as if aversive stimuli were currently present (even in their absence) by creating relationships between situations and events (Houwer, Hughes & Barnes-Holmes, 2016). According to ACT, the human ability to introduce past and future contexts to the present, is tied solely to our use of language (symbolic activity). Language is reported to have evolved as a categorisation and evaluation tool giving humans the ability to problem solve and communicate on an external social level. Symbolic activity can become problematic due to human introspection, when individuals apply the useful technique of problem-solving to an inappropriate target i.e. attempting to solve psychological pain (Guinther & Dougher, 2015). Before outlining ACT as an intervention, it is important to discuss the theoretical premise on which ACT is based, known as Relational Frame Theory (RFT).

1.8 Relational Frame Theory

RFT is a process-oriented, contextual behavioural theory of human symbolism, language and cognition (Barnes-Holmes, Barnes-Holmes, Hussey & Luciano, 2015). The term 'language' refers to any form of symbolic activity including written and verbal words, sounds, imagery, pictures and gestures. According to Hayes, Strosahl and Wilson (2012), the principle tenet of RFT is that people learn to relate differing stimuli under arbitrary contextual control via operant conditioning (the association of behaviours and subsequent consequences), influenced by multiple and repetitive social cues. The arbitrary nature of association allows derived relationships to be inferred between stimuli including those with differing sensory profiles i.e. sound and appearance, including relationships that have not been directly taught. This means that a verbal stimulus can have the same psychological impact as the physical presence of an object because the sound and the object are in the same equivalence class (Berens

& Hayes, 2007). People don't need to directly experience something to learn from it as connections between stimuli are made within 'relational frames'. The term 'relational frame' is figurative and descriptive of the relationships which may exist between stimuli. Any event / item that participates in a relational frame is considered a stimulus.

The simplest form of relational framing is naming something (Lindstedt, 2018) so that a word directly corresponds to an object (correspondence framing) and subsequently a stimulus equivalence class can be established e.g. teaching a child that an apple is called an apple. The child will then be able to pick out an apple from the word and they will learn to say the word when shown an apple. This bi-directional learning is understood to underpin basic human language acquisition. Eventually a child will then learn that an apple is a fruit and that other items such as pears are in the same equivalence class, where there is an assumption of shared characteristics despite the stimuli being separate entities. This naming and learning within an equivalence class can be problematic in the case of contested and stigmatised illnesses such as fibromyalgia. Sufferers can be placed in a negatively framed equivalence class judged by the socially inferred relations of being lazy (Paxman, 2019), being disabled and by not being believed (Armintor, 2017) simply by being labelled by the fibromyalgia diagnosis.

Bordieri, Kellum, Wilson and Whiteman (2016) outline that relational framing is learned behaviour that has 3 main properties;

1) Mutual entailment, which is the assumption that relations in one direction also work in the opposite direction e.g if A is shorter than B, then B is taller than A.
2) Combinatorial entailment, which dictates that mutual entailments combine e.g. If A is shorter than B and B is shorter than C this must mean that C has a contextual relationship to A and is taller than A even though this hasn't been stated.
3) Stimulus functions can be arbitrary or non-arbitrary and can be transformed via relational frames. A stimulus function is the operantly learned behaviour elicited by the stimulus e.g. To be fearful of a spider. Non-arbitrary functions are based on inherent characteristics of a stimuli so in the previous example a non-arbitrary function would be that A is the shortest. Arbitrary functions apply learned experience judgements to a stimulus, which can be contextually altered e.g. whilst A is the shortest, the term may hold less value if you were picking players in a basketball team where tallest might be viewed as more desirable. Therefore, being short now holds a negative function and C, being the tallest would hold most value within this context and the stimulus function is therefore transformed.

Relational frames work by addition and not subtraction so that changes to the frame require new information rather than any attempts to remove information from the frame. According to Hayes, Pistorello and Levin, (2012) only three types of relational frame are required; 1) frames that co-ordinate events and words; 2) before and after frames; and 3) comparative frames. Comparative relational frames can alter behavioural processes e.g an individual can become fearful of a situation even if they have not experienced it if it is in a relational frame and can be compared to another experience (Berens & Hayes, 2007). It is important to note that according to RFT there can be an arbitrary application of relational frames which means that individuals can form comparative relational frames even when stimuli do not share formal properties. This then offers a potential explanation why individuals with fibromyalgia who have experienced chronic pain on one occasion can fear experiencing further pain in an apparently non-related way if the event is within that relational framework.

1.9 Rule governance

Verbal stimuli can be combined into elaborate verbal rules that then regulate behaviour and this is termed rule governed behaviour (Törneke, Luciano & Salas, 2008). Rule governed behaviour does not require direct learning but is governed by the specificity of contingencies i.e. it enables an individual to respond effectively and precisely when direct learning is either not possible or potentially dangerous (Barnes-Holmes, Barnes-Holmes, McHugh & Hayes, 2004) e.g. individuals don't need to touch an electric cable to understand that this is not a behaviour they should engage in. Intuitively within relational frame theory if a rule is applied to an event it can, by the three properties of relational frame theory (mutual and combinatorial entailment and the transformation of stimuli) be applied to other stimuli to which a relational frame has been established. When an individual is being governed by rules they are less precise in tracking environmental changes and this is known as the insensitivity effect. This means that individuals will keep repeating behaviours that potentially once worked even if the behaviour no longer works and even if the behaviour subsequently has negative consequences. In the case of individuals with fibromyalgia this could potentially be applied to many of the failed strategies they report to have tried to manage their symptoms including taking contra-indicative medication that they report as ineffective (Taylor *et al*., 2019) and restricting their activities in an attempt to avoid pain.

There are three types of rule governed behaviours; pliance, tracking and augmentation.

1) The term pliance refers to verbal rules that are based on socially monitored historical consequences between a rule and prior behaviour and are often learnt in terms of social pleasing. Hayes *et al* (2012) offer the example of a child being told to wear a coat in case it is cold outside where a child's compliance to wear the coat could be based more on pleasing the parent than keeping warm. Pliance rules tend to be rigid and often narrow behavioural response options as upholding this type of rule reduces sensitivity to environmental contingencies e.g even when it isn't cold the child will still wear the coat. Pliance rules in fibromyalgia sufferers may even include how to behave when unwell. As children they may have received the social contingency that when unwell they must withdraw socially and take up the 'sick role' to be believed and/or cared for (Mengshoel & Heggen, 2004).

2) Tracking is where instead of complying to social contingencies a verbal rule is followed because a link has been made between a rule and a natural contingency e.g if the child wore the coat and it turned out to be cold, so they understood the benefit to them and subsequently choose to repeat the behaviour to keep warm. Tracking allows a more flexible and adaptive approach to behaviour change particularly when of benefit or value to the individual (Kissi *et al*., 2017). However, tracking can be problematic when individuals follow contingency based rules. Tracking in fibromyalgia may reinforce isolation and inactivity behaviours as sufferers follow the rule that going out can lead to increased pain and is therefore experienced as punishing and staying in prevents an increase in pain so that a relationship between inactivity and symptom reduction is built and is negatively reinforced.

3) Augmenting is when an individual follows a rule because there is a personal incentive to behave that way and can alter the extent to which an event functions as a consequence (Stewart, Barnes-Holmes, Barnes-Holmes, Bond & Hayes, 2006). Augmenting does this in one of two ways; 1) Formative augmentals which establish new consequences e.g. staying in may relieve symptoms, but it also increases social isolation and; 2) Motivative augmentals which alter the strength of an existing functional consequence i.e. An event may still occur, but it will have

less importance and therefore the strength of the consequence will have altered (Fagerstrøm, Foxall & Arntzen, 2010) e.g. an individual may still experience pain, but that experience may become less important if another experience becomes more important for example spending time with family. Values have augmental functions because they allow an individual to choose how much focus to give to an experience. ACT therefore seeks to encourage an individual to evaluate and prioritise meaningful action in line with their values.

The ability to change rule governed behaviours is related to psychological flexibility which is fundamental to ACT as an intervention.

1.10 Psychological Flexibility and the six core processes

According to ACT psychological flexibility is an explanatory model of human functioning and adaptability'' (Scott & McCracken, 2015). ACT posits that pain is a natural human response to some of life's negative experiences but that humans can often cause themselves unnecessary additional suffering when verbal and cognitive processes narrow their behavioural repertoires in key areas (McHugh, Sandoz & Hooper, 2016). The psychological flexibility model is simultaneously a model of health and intervention (Hayes *et al*, 2012). The processes of health (Figure 10) counter the processes of dysfunction (Figure 11) so that theoretically psychological flexibility leads to adapted and useful strategies and is juxtaposed to psychological inflexibility which has been reported to predict psychopathology (Woodruff *et al*, 2014). Psychological inflexibility is hypothesised to cause rigidity in responding and the inability to adapt to situations.

Psychological flexibility is reported to consist of six processes.

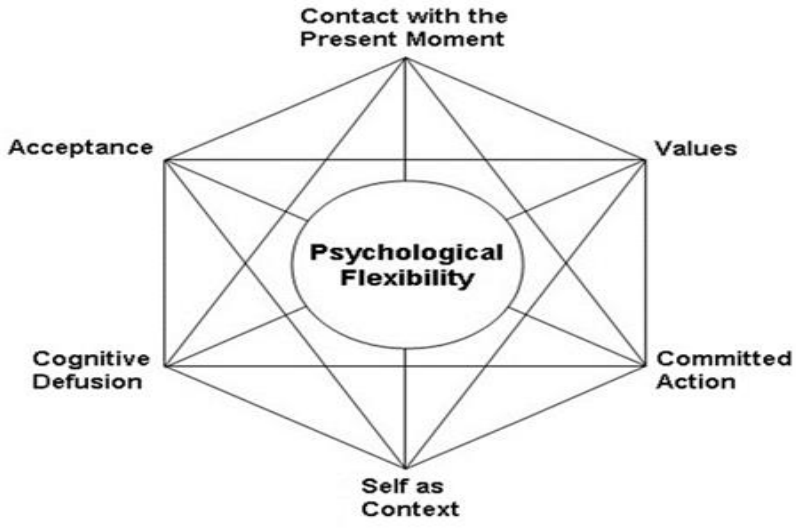


Figure 10: Psychological Flexibility Model

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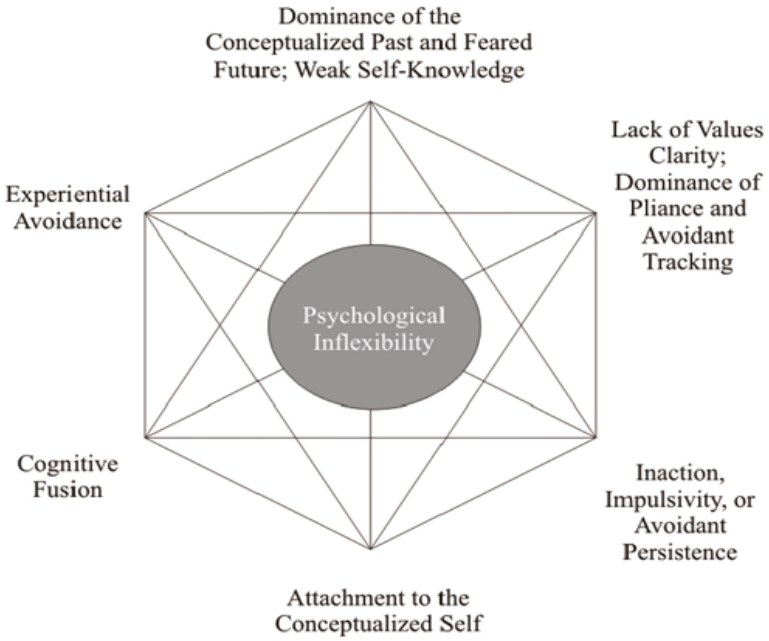


Figure 11: Psychological Inflexibility Model

Psychological flexibility has been reported to have a mediating role in a range of positive outcomes such as reducing pain catastrophizing, psychological distress and increasing quality of life (Cassar *et al*.,2018). A systematic literature review reported that there was growing evidence to support psychological flexibility as the mechanism of change in ACT (Scott & McCracken, 2015).

Experiential avoidance / Acceptance

The mutual entailment / bi-directionality and stimulus function transformation outlined in relational frame theory are important in understanding experiential avoidance. When an individual, thinks about, or reports an aversive event, the stimulus function between the event and the thought or report is transformed so that some of the original functions of the event will appear in the thought or report. In turn the thought or report itself becomes aversive. Experiential avoidance occurs when a person is unwilling to remain connected to any private experience (thoughts, feelings, memories, bodily sensations etc) in relation to an aversive event and attempts to alter or avoid the experience rather than stay connected to it (Kirk, Meyer, Whisman, Deacon & Arch, 2019). Over time it is not just the event or experience that is avoided but any stimuli within the relational frame as their function will have also become aversive.

Emotions are a particular target of experiential avoidance, as humans are often socially programmed to experience emotions (their own and others) as aversive. Pliance rules are communicated from an early age with the elimination of emotions often highlighted as a goal and a child's worth evaluated on their ability to suppress their emotions e.g. 'don't cry'; 'don't be afraid' and 'they are a good baby they don't cry much' (Hayes *et al*, 2006). Paradoxically it has been reported that attempts to supress an event (thought or emotion) can often lead to an increase in both the frequency and the intensity of the event (Wang, Luppi, Fawcett, & Anderson, 2019) as attempts at suppression often reference the item to be repressed e.g. when trying not to focus on the pain, the word pain is used in the instruction not to focus on the pain and thus it is automatically brought to mind. In this way avoidance strengthens the underlying relational frame as a repetitive cue and increases psychological inflexibility. Attempts at experiential avoidance often hold hoped for desirable outcomes as a false promise of getting rid of the bad experience eg ''If I didn't feel pain I could go out and enjoy life'' with the bi-directional thought that pain must therefore be avoided. This results in the shrinkage of life experiences as individuals attempt to avoid more and more painful events.

The opposite to experiential avoidance is acceptance which can be divided in to two co-existent but distinct entities; 1) behavioural willingness which can be described as voluntarily choosing to enable or sustain contact with private experiences based on your own values and; 2) psychological acceptance which is intentionally taking up an open, flexible and non-judgemental posture to in the moment experiences (Butler *et al*., 2016). Monestès *et al*. (2016) report that experiential avoidance is a common psychological process in European cultures and it has been associated with a wide range of psychopathologies and behavioural problems such as eating disorders (Skinner, Rojas & Veilleux, 2017), anxiety disorders (Spinhoven, van Hemert & Penninx, 2017) and personality disorders (Wall, Ahmed & Sharp 2019). Conversely positive outcomes related to acceptance such as behavioural regulation and psychological distress have been reported (Hamill, Pickett, Amsbaugh & Aho, 2015). Individuals with fibromyalgia have reportedly benefitted in terms of coping with pain and daily functioning from acceptance-based interventions (Rodero *et al*., 2011).

Cognitive fusion / Defusion

With language and therefore cognitions central to the underpinning theory behind the psychological flexibility model there is a direct link to the core process of cognitive fusion / defusion and Hayes *et al* (2006) state that because of this, a key purpose in ACT is to

target cognitive fusion. Cognitive fusion might best be described as the process by which verbal events (language and cognitions) exert such a strong control over the response to stimuli that it excludes all other variables i.e. individuals believe the literal contents of their mind so strongly they become 'fused' with their cognitions and cannot distinguish narrative from fact (Solé *et al*., 2016). Therefore individuals believe that thoughts are facts so then rules must be concrete and adhered to. Experiential avoidance is an immediate consequence of cognitive fusion because being tied strongly to beliefs encourages attempts to supress, control or eliminate experiences that an individual expects to experience as distressing (Bardeen & Fergus, 2016). In the fused state, behaviour becomes increasingly driven by derived stimulus relations, where direct experience plays less of a role, as individuals respond to their thoughts as if they were real. For example, if an upcoming event is constructed within an individual's mind as fearful (anxiety provoking), their response to that event will be as if all their fears are present and real, despite the event not having taken place yet or indeed it may never take place. Relational frame theory outlines that this is because cognitive fusion allows the functional properties of the stimulus to be strongly present with the cognition (Berens & Hayes, 2007).

ACT dictates that it is not thoughts that are the problem but fusion to the thoughts i.e. as language has evolved in many ways to keep us safe it is ok to think about potential fears in relation to a situation, but the thought is just a thought and that by altering the cues and contexts to the stimuli the thought need not lead to behaviours incongruent with an individual's values. Pliance and adherence to socially transmitted instructions is high in the state of fusion. Fibromyalgia sufferers may have a strong belief cognition such as ''I can't go out and enjoy myself until I get rid of my pain'' which would severely inhibit behaviour if they were fused to this thought and applied it literally. This shows how closely cognitive fusion is to experiential avoidance and how the bi directionality of thoughts can further reinforce both processes.

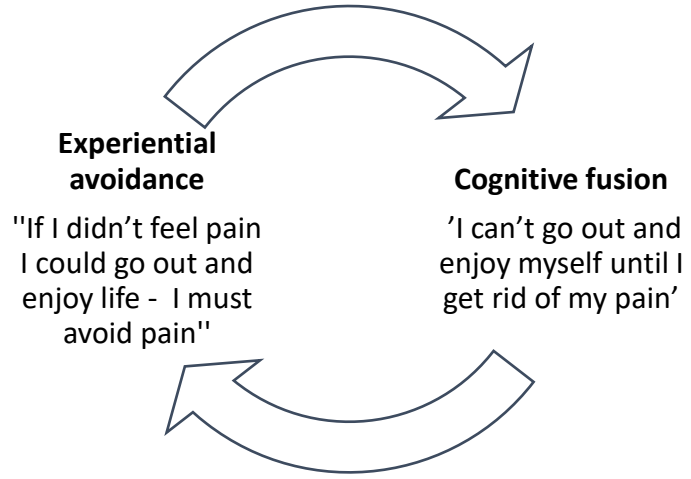


Figure 12: Bi directionality of thought

The alternative to fusion is defusion, which is when an individual is conscious of their thoughts but has control over their interpretation and how to respond to them (Schumacher, Kemps, & Tiggemann, 2018). Unlike traditional cognitive therapies that would attempt to change the content of thoughts, ACT attempts to alter the context in which the thought has impact, so the individual can experience thoughts and feelings as thoughts and feelings and not as facts. An example of this is changing the thought ''I would like to go out BUT I am in pain'' to ''I would like to go out AND I'm in pain (Dahl & Lundgren, 2006). Bramwell and Richardson (2018) recently reported that cognitive defusion played a role in the reduction of psychological distress in the general population. Adults with autism, who are reported to be high in cognitive fusion, reported a reduction in distressing thoughts utilising cognitive defusion techniques (Maisel, Stephenson, Cox & South, 2019).

Attachment to Conceptualised Self / Self-As-Context

The self-as-context process within ACT is constructed of three distinct yet overlapping entities which can be understood as three differing types of self-knowledge (Moran, Almada & McHugh, 2018):

1) The self as content; is the 'conceptualised self'; the categories, evaluations and content of thoughts, feelings, memories and behaviours constructed to understand personal experience and the concept of self that an individual identifies with (Hayes *et al*, 2012). The conceptualised self is a direct by-product of the self-story we construct to offer a coherent identity to ourselves and society.

The self as content includes derived cause and effect explanations so expands from dispositional to descriptive e.g. 'I am' starts to include the justifications of 'I am because' e.g. 'I am disabled because I have fibromyalgia'. Once an individual identifies with a particular self-conceptualisation it is less likely for other alternatives to be considered. Threats to the self-concept will be defended as if the physical self were being threatened as it is seen as vital to existence (Yu, Norton, Harrison & McCracken, 2015).

2) The self as process; is the 'experiencing self' that has an awareness of an experience separate from cognitions and without being unduly influenced by them e.g. can note what is present without cognitive fusion and without the need to defend (Hayes *et al*, 2006). Societal learning teaches individuals to have an awareness of what they are saying in live time e.g. they are often able to regulate what they are saying but this is not naturally extended to a behavioural or cognitive awareness. The self as process is synonymous with mindfulness or present moment awareness. Whereas the conceptual self requires these verbal descriptions to make sense of events, the self as process requires nothing more than noting the descriptions (Gillard, Flaxman & Hooper, 2018). The self as process is the aspect of self that is least affected by relation frames when in the mindful mode.

3) The self as context: Perhaps somewhat confusingly the self-as-context process contains an element with the same name. For the purposes of clarity within this research when referring to the process, self-as-context will be hyphenated and un-hyphenated when referring to the element within the process. Self as context has been described as a 'transcendent or observing self', far removed from the problem-solving mind it is a mind that is 'not looked at but looked from' (Yu *et al*., 2017a). Self-identity is the identity that we construct about ourselves and yet we do not exist in isolation and therefore need other perspectives from which to make the comparisons and evaluations to construct an identity. It is within the self as context that we become aware of our interrelatedness. The self as context is based upon deictic relationships which are key verbal relationships in the development of perspective taking and are taught experientially (García-Zambrano, Rehfeldt, Hertel & Boehmert, 2019). Key deictic relations are I/you, here/there and now/then. To truly understand these relationships, you need both perspectives as we only truly become aware of ourselves when we understand

how others are aware of us (Montoya-Rodríguez, Molina & McHugh, 2017). Perspective taking leads to increased salience surrounding aspects of our being with the increase of self-statements defending that identity to the social world. It could be argued that self as context is the aspect of self-knowledge that is therefore most affected by the stigma of a contested illness. Fibromyalgia is reported to be a label with socially constructed negativity and stigma (Undelan & Malterud, 2007; Volkmann, 2018) and individuals with fibromyalgia report not being believed about their illness and feeling judged. In response this becomes a more salient aspect of their self-identity.

Within the self-as-context process of ACT, problems are understood to arise when, assisted by cognitive fusion, an individual becomes trapped in their 'conceptualised self' (self-as-content), believing that their thoughts about themselves are true facts rather than merely metacognitions (Yu *et al*., 2017a). Reduced levels of activity were reported when individuals believed themselves to be unable to do something with cognitions such as 'I am disabled because I have fibromyalgia' (Yu *et al*., 2017b). Descriptions about themselves then form a story which can vary dependent on the context. For instance, Yu, Norton, Almarzooqi and McCracken (2017b) reported a strong identification to the conception of 'I am a fibromyalgia sufferer'. The function of being a fibromyalgia sufferer could then alter dependent on context e.g. individuals might see themselves as survivors within the safety of a support group, may see themselves as unbelieved or burdensome when relating with healthcare professionals or when applying for benefit funding, or may see themselves as a failure as a family member or friend unable to engage in family / social life due to their pain. Previous research has suggested a potential association between self-as-context and functioning, including reduced levels of activity, in fibromyalgia sufferers (Yu *et al*., 2017b) which makes it worthy of further investigation.

Dominance of past and future / Being in the present moment

It may sound like stating the obvious, but things only occur in the present moment. Just seconds before an event, that event hasn't happened and just moments later that event has passed with a 'lag' between an event and any symbolic activity (Hayes *et al*, 2012). Individuals lose contact with the present and become past and future orientated as they attempt to problem solve by going over past events to see where it all went wrong or attempting to predict future events so they can prevent future failures. This leads to difficulties in responding to the current social context as the stimulus control of past and future thoughts can be so overwhelming that it inhibits behaviour and responding.

Individuals then lose the ability to notice experiences that happen in the moment, including positive ones that could alter relational frames as they are so focussed on avoiding negative experiences even those that don't actually exist in the here and now. ACT attempts to teach individuals attentional control, that is to have the ability to choose to focus their attention, even when drawn elsewhere, back to the present moment. This control is often referred to as being mindful and can be described as attending to what is present in a focussed, voluntary and flexible way (Braun, Kinser, Carrico & Dow, 2019). Being mindful has been linked to positive outcomes in life satisfaction and affect (Felsman, Verduyn, Ayduk & Kross, 2017). However, a systematic review by Bawa *et al*., (2015) reported that there is limited evidence to support the effectiveness of solely mindfulness-based interventions for patients with chronic pain.

Loss of clarity with values / Values

As previously outlined experiential avoidance and cognitive fusion lead to a range of aversively controlled behaviours that can restrict an individual's ability to live life to their full potential (Bramwell & Richardson, 2018). This means that individuals can easily lose touch with what is intrinsically important to them (values) generating a loss of motivation on all levels which can subsequently lead to further restrictive behaviours. The emphasis on individual values is an anomalous concept for ACT in comparison to most traditional cognitive and behavioural therapies but values must be freely chosen, verbally constructed with an evolutionary and dynamic pattern of activity culminating from them (Raftery-Helmer, Moore, Coyne & Reed, 2016). Hayes *et al* (2012) state that it is the values process within ACT that makes sense of the processes of acceptance, cognitive defusion and committed action for an individual. Values act as augmentals (both formative and motivational) to rule governed behaviours and as indirect reinforcers to behavioural change (da Silva Ferreira, Simões, Ferreira & dos Santos, 2019). The ACT intervention attempts to re-engage an individual with their personal values, but this must not be based on reasoning or an attempt to problem solve, values must reflect the true essence of the individual and be rooted in living in the present moment. Values are not an end point, so they are hard to measure and research as a process, although goals established in line with values can be measured in terms of workability (Kasser, 2016). Vowles, Sowden, Hickman and Ashworth (2019) report valued based activity was predictive of eliciting behaviour change in a range of psychosocial outcomes which is encouraging in a population that has previously been reported to be resistant to behaviour change.

Inaction / Committed action

Throughout explaining the processes of ACT there has been discussion about restricted behaviours under aversive control. This rigid pattern of ineffective behavioural responding and subsequent inaction is a culmination of experiential avoidance, cognitive fusion, being stuck in the conceptual self, being stuck in the past or future and loss of contact with values (Gilpin, Stahl & McCracken, 2019). Rigidity in behaviours can be avoidant or excessive but either way the behavioural response attempts to reduce or eliminate contact with unpleasant experiences (Harris, 2019). Committed action refers to '*'valued based action designed to create a pattern of action that is itself values based*'' (Hayes *et al*, 2012. p.95). i.e. behaviour change in line with values in the service of living well. Committed action is the antithesis to inaction and the effects of experiential avoidance and cognitive fusion. According to O'Connor, Tennyson, Timmons and McHugh (2019) it is the committed action that stems from values that act as 'predominant reinforcers' and which make sustained behaviour change more likely. This is because by engaging in valued laden actions new information can be added to the relational frame. Committed action is not necessarily an overt behaviour or physical activity as action may well be private experiences such as committing to stay connected to unpleasant experiences. Committed action is the 'achievable object' within ACT and the culmination of the other processes. Galán *et al* (2019) examined associations between committed action, physical health and functioning in individuals with fibromyalgia and reported it explained some of the variance of pain disability, physical health and mental health.

Rationale for utilising an ACT based intervention for this research

Whereas CBT for chronic pain conditions is usually aimed at symptom reduction and altering the content of cognitions (Robinson, Wicksell & Olsson, 2004), ACT encourages living well even in the presence of painful symptoms. ACT seeks to alter the function of thoughts and feelings using experiential learning to create value consistent behaviour change (Hayes, Pankey & Gregg, 2002). Ong, Lee and Twohig, (2018) report dropout rates for ACT exclusive interventions to be around 15.8% compared to CBT interventions which demonstrate up to 24.9% attrition. The authors suggest this may be due to lower participant burden and in addition Johns *et al*, (2016) report a high acceptability for ACT in general. There is increasing research examining the impact of ACT and its core processes on a range of both physical and mental health outcomes.

Öst (2014) reported in his systematic review that ACT is probably effective for a range of conditions including tinnitus, depression, psychotic symptoms, obsessive compulsive disorder, anxiety, drug abuse, and stress at work. Glombiewski *et al*, (2010) highlighted that further investigation is required into the process mechanisms of change in psychological treatments for fibromyalgia and ACT has distinct processes that can be delivered in individual phases, allowing potential change mechanisms in a fibromyalgia sample population to be examined. This would make ACT an appropriate intervention for potentially increasing levels of activity and examining process mechanisms of change within a fibromyalgia population.

Supported self-help interventions

There has been an exponential rise in the last decade of self-help literature (and research to assess its effectiveness), for a wide range of issues such as depression (Andersson *et al*., 2005) and anxiety (Furmark *et al*., 2009) in an ever-increasing range of modalities such as CBT, Compassion Focussed Therapy and ACT (Hirai & Clum, 2006). Gellatly *et al*'s., (2007) meta-analysis of self-help interventions for depressive symptoms reported that self-help was more effective when accompanied by additional support and Cuijpres, Donker and van Straten, (2010) reported that supported versions of self-help interventions for depression and anxiety were comparable with face to face interventions. Despite this there has been a reported ambivalence towards self-help interventions, with reports of low uptake and adherence to the interventions, and high attrition rates (Khan, Bower & Rogers, 2007). However, Ong *et al*., (2018) report that whilst dropout rates for ACT exclusive interventions are around 15.8% they are lower when participants don't have to attend the intervention. Previous studies have demonstrated encouraging evidence to support the efficacy for self-help interventions for a range of conditions including for chronic pain (Johnston *et al*., 2010) and for a fibromyalgia population (Ljótsson *et al*., 2014). Bernardy, Klose, Welsch and Hauser (2010) reported that the internet was an effective treatment delivery method for fibromyalgia sufferers. Therefore, an internet delivered supported self-help intervention was deemed an appropriate choice for this research study.

Extended aims and purpose of investigation

Given the significant personal impact of fibromyalgia, research that aims to examine the effectiveness of psychological therapies and improve daily functioning for individuals living with fibromyalgia has clear clinical relevance. Examining the efficacy of a self-help ACT intervention for a fibromyalgia population could have potential relevance to those who don't wish to or are unable to access formal services and an internet

supported self-help intervention could potentially offer a comparatively low-cost treatment option. Examining the mechanisms of change within this ACT intervention could potentially inform future research and practice for therapy for individuals with fibromyalgia. The aims of this study can be seen as a number of questions shown in Table 16.

Table 16: Summary of questions, sources of evidence and hypotheses

Questions	Sources of evidence	Hypotheses
1) Does the primary outcome demonstrate change? • Do levels of activity change?	Number of steps taken daily as measured by the activity tracker measured at pre, post and follow up.	It is expected that the intervention will increase levels of physical activity
2) Does the primary process outcome demonstrate change? • Do levels of psychological flexibility change?	Pre, post and follow up scores of the total CompACT	It is expected that the intervention will increase levels of psychological flexibility – tested using RCI, CSC and PEM/DC and Tau-U
3) Are changes in the primary outcome measure linked to changes in the primary process variable? • Are changes in levels of activity linked to changes in psychological flexibility?	Number of steps taken daily as measured by the activity tracker Weekly scores of the total CompACT	It is expected that an increased level in psychological flexibility is linked to an increase in physical activity.
4) Do the secondary outcomes demonstrate change? • Has the level of psychological distress changed? • Has the level of functional impairment in a fibromyalgia sufferer changed? • Has the impact of fibromyalgia changed? • Has the severity of symptoms for fibromyalgia changed? • Has the overall impact of having fibromyalgia changed?	Pre, post and follow up scores of the total and individual elements of the DASS – 21 Pre, post and follow up scores of the total and individual elements of the FIQ-R	It is expected that the intervention will decrease the level of psychological distress and the impact of fibromyalgia – tested using RCI, CSC and PEM/DC and Tau-U As ACT does not specifically target symptom reduction there is no hypothesis in relation to the functional impairment or symptom severity of fibromyalgia.
5) Do the ACT process variables change? • Are there changes to levels of experiential avoidance? • Are there changes to levels of cognitive fusion? • Are there changes to the conceptual self? • Are there changes to the level of losing contact with the present? • Are there changes to the levels of connection with values? • Are there changes to the levels of inaction?	Pre, post and follow up scores of the subscales of the CompACT Pre, post and follow up total scores of the SEQ Change interview	It is expected that following the intervention there will be increased levels in acceptance, cognitive defusion, free conceptual self, being present, contact with values and committed action.
6) Are outcome changes linked to individual elements of the intervention? • Are any changes observed in the primary outcome linked to an ACT process variable as delivered by the intervention?	Number of steps taken daily as measured by the activity tracker Weekly scores of the subscales of the CompACT Weekly total scores of the SEQ	No hypothesis
7) Do the process variables within ACT change following the introduction of the corresponding elements of the intervention? • Are any changes observed in the ACT process variables linked to the weekly intervention?	Weekly scores of the subscales of the CompACT Weekly total scores of the SEQ Mapped to the introduction of intervention chapters	No hypothesis

RCI=reliable change indices, CSC=clinically significant change, PEM/DC=percentages exceeding baseline median dual criterion analysis, Tau-U=Tau-U analysis

Extended epistemological position

ACT is founded upon the principle of Functional Contextualism, a field developed from radical behaviourism (Biglan & Hayes, 1996) and consequently functional contextualism is the epistemological stance taken for this research. The explicit aims of functional contextualism include the prediction and influence of behavioural and psychological events (including thoughts and feelings) i.e. defined by whether a particular activity achieved a stated goal (workability), using empirically based concepts (Colley & Scott, 2018). Within functional contextualism the core analytic unit is the act-in-context i.e. The act can be any type of behavioural or psychological activity with the caveat that it must have the capacity to be observed (including internal observations), predicted and influenced (Boone, Mundy, Morrissey Stahl & Genrich, 2015). The whole act is focussed on and individual elements are only abstracted when it would be useful to do so. The act is defined by its intended consequence and not by the form the act takes e.g. the act of writing this thesis is in the context of fulfilling the requirements of the doctorate research module. It would be irrelevant whether I used a pen, or typewriter or laptop, it is the act of completing the thesis that is important.

From a functional contextual position, epistemological truth is sought pragmatically. The focus is on successful working and achievement of the function of the goal of analysis. Within ACT an individual's goals are defined by their values and achievement is defined by whether a behaviour has been beneficial in terms of working in the service of those values. Scientific paradigms often have both an epistemological and ontological position, where epistemology dictates how truth is sought and ontology dictates the nature of the existence of that truth. Within the framework of functional contextualism, truth exists pragmatically for the sake of being right or wrong, not contingent on any further explanation or understanding. This has led to functional contextualism being termed a-ontological (Barnes-Holmes, 2005), although Hayes *et al* (2012) are keen to point out that this is very different from being anti-ontological.

There was consideration given to use alternative epistemologies for this study such as taking a socially constructionist position as there has been research on the social construction of medically unexplained illnesses including fibromyalgia (Wolfe, 2018). Social constructionism outlines that truth and knowledge are socially created whereby the development of fibromyalgia from neurasthenia to the illness understood contemporarily has been generated via societal construction rather than medical discovery. The social construction epistemology accounts for the subjective interpretation of what having a diagnosis of fibromyalgia might mean for the individual

within a social context and indeed aligns itself in many ways with the interpretive nature of language as outlined in RFT. However, it was decided to continue with the functional contextual approach in which the founders of ACT situated the intervention as there is then no judgement about the aetiology of fibromyalgia.

2.0 Extended Method

2.1 Design and rationale

Randomised control trials (RCT) are often cited as the 'gold standard' by which to examine variables as RCTs attempt to control for a range of potential biases, however they are not without limitation (Rothwell, 2005). A critique that is often thrown at RCTs is their aggregation of results, where meaningful change for an individual can be lost within the data. Single Case Experimental Design (SCED) allows for the systematic manipulation of variables via the arrangement of phases to examine idiosyncratic change and could therefore be considered more ecologically valid (Swoboda, Kratochwill & Levin, 2010). Whilst RCTs can compare two different conditions (control and comparison), SCEDs also have the ability to do this but within an individual instead of between individuals. SCEDs are able to offer this comparison between conditions by establishing a stable baseline for an individual whereby they can effectively act as their own control. Repeated observations of the outcome measures under the same conditions allow causal inferences to be made and causal mechanisms to be identified. Replication of the treatment / intervention between subjects from this within subject design, suggests that a treatment has potential to be generalised to similar populations (Kratochwill *et al*., 2010). SCEDs are not without their own methodological challenges such as managing the nonindependence of sequential observations (i.e., autocorrelation, the need for multiple baseline measures and appropriately addressing the matter of missing observations (Smith, 2012).

This research utilised a multi participant SCED, phased AB design, as part of a mixed method approach as Smith's (2012) systematic review of SCEDs found evidence to support their use to investigate both outcomes and processes for psychological interventions. Mixed methods can be described as the explicit use of both quantitative and qualitative methodology within the same study so that verbal data can enhance numerical data thus increasing an individualised understanding of any change which is coherent with the SCED design (Creswell & Clark, 2017). Triangulating methodologies is reported to increase the depth of understanding to the phenomena under investigation, particularly to less or unexplored topics (Hussein, 2009). As ACT for

fibromyalgia currently has a limited evidence base this suggests that a mixed method approach utilising a SCED design is an appropriate design for this study.

Phase A refers to the repeated baseline measures (before intervention) of the dependent variables which are; levels of physical activity (measured by activity trackers); levels of psychological distress (measured by the DASS-21); daily functioning, disability perception, symptom severity and overall impact of fibromyalgia (measured by the FIQ-R); psychological flexibility as measured by the total score of the Comprehensive Assessment of ACT Processes (CompACT); and the individual processes of ACT (measured by the CompACT subscales and the SEQ). Apart from levels of activity the measures were taken via self-reported questionnaires (see section 2.6). Baseline stability focussed primarily on physical activity and then psychological flexibility. Phase B1 is the intervention phase, where the ACT based intervention was delivered to the participants. Measures continued to be taken during phase B1 and were also taken again during phase B2 which represents a follow up period lasting four to six weeks after intervention, to ascertain if change has been sustained. Whilst maturation effects (natural temporal variations) are hard to control against, the delivery of the intervention as a phase with individual elements, allows for observation of potential effects. Qualitative data were collected during discussion in the initial and the weekly interviews that took place between the participant and researcher using a semi-structured schedule (Appendix D) and in a further semi-structured change interview which took place between four- and six-weeks post intervention with a non-related research associate (Appendix E).

2.3 SCRIBE reporting

For the quality of the design and the standard of research to be assessed it has become common place for reporting guidelines to outline good practice of what should be included for the reader to make informed decisions regarding the validity and weighting of the results. The Consolidated Standards of Reporting Trials (CONSORT) issued guidelines for reporting randomised control trials (Bennett, 2005) and a Cochrane review found that when journals endorsed CONSORT the completeness of reporting was improved although still required improvement (Turner, Shamseer, Altman, Schulz & Moher, 2012). Tate *et al*., (2016) recently published ‘’The Single-Case Reporting Guideline in Behavioural Interventions’’ (SCRIBE) and outlined in that guideline how frequently information pertinent to the design such as baseline data and visual analysis

was often unreported. SCRIBE reporting guidelines were used as a template for this research and adherence is shown in Table 17.

2.4 Recruitment

There are limited commissioned fibromyalgia services within the U.K. and none within the local areas of the Trent Doctorate Programme. Participants needed to be in travelling distance of the Doctorate programme (Derbyshire, Nottinghamshire and Lincolnshire) as fitness trackers were to be fitted. Recruitment took place using advertisements and online messages to localised support groups and online support forums within the three counties of the doctorate programme (Appendix F). In total five support groups were identified, and the administrators of those groups were messaged to obtain consent to post in the group (shown in Appendix G). Following consent, the advert was posted in four of the five groups. Interested participants e-mailed a university e-mail address and they were offered more detailed information about the study and given a chance to ask questions (Appendix H). If participants met the selection criteria and were still happy to continue then an appointment was then arranged to fit the activity trackers and to take the chargers to each participant taking part in the study and informed consent was sought (Appendix I).

Table 17: SCRIBE guidelines and adherence

CATEGORY	TOPIC & NUMBER	DESCRIPTION	COMMENT
Title and Abstract	1. Title	Identify the research as a single-case experimental design in the title	✓
	2. Abstract	Summarize the research question, population, design, methods including intervention/s (independent variable/s) and target behaviour/s and any other outcome/s (dependent variable/s), results, and conclusions design in the title	✓
Introduction	3. Scientific background	Describe the scientific background to identify issue/s under analysis, current scientific knowledge, and gaps in that knowledge base	✓
	4 Aims	State the purpose/aims of the study, research question/s, and, if applicable,	✓
METHOD Design	5 Design	Identify the design (e.g., withdrawal/reversal, multiple-baseline, alternating-treatments, changing-criterion, some combination thereof, or adaptive design) and describe the phases and phase sequence (whether determined a priori or data-driven) and, if applicable, criteria for phase change	✓
	6 Procedural changes	Describe any procedural changes that occurred during the course of the investigation after the start of the study	✓
	7 Replication	Describe any planned replication	✓
	8 Randomization	State whether randomization was used, and if so, describe the randomization method and the elements of the study that were randomized	✓
	9 Blinding	State whether blinding/masking was used, and if so, describe who was blinded/masked	Not applicable for this type of study
Participant/s	10 Selection criteria	State the inclusion and exclusion criteria, if applicable, and the method of recruitment	✓
	11 Participant characteristics	For each participant, describe the demographic characteristics and clinical (or other) features relevant to the research question, such that anonymity is ensured	✓
Context	12 Setting	Describe characteristics of the setting and location where the study was conducted	✓
Approvals	13 Ethics	State whether ethics approval was obtained and indicate if and how informed consent and/or assent were obtained	✓
Measures / Materials	14 Measures	Operationally define all target behaviours and outcome measures, describe reliability and validity, state how they were selected, and how and when they were measured	✓
	15 Equipment	Clearly describe any equipment and/or materials (e.g., technological aids, biofeedback, computer programs, intervention manuals or other material resources) used to measure target behaviour/s and other outcome/s or deliver the interventions	✓
Intervention	16 Intervention	Describe the intervention and control condition in each phase, including how and when they were actually administered, with as much detail as possible to facilitate attempts at replication	✓
	17 Procedural fidelity	Describe how procedural fidelity was evaluated in each phase	✓
Analysis	18 Analyses	Describe and justify all methods used to analyse data	✓
Results	19 Sequence completed	For each participant, report the sequence actually completed, including the number of trials for each session for each case. For participant/s who did not complete, state when they stopped and the reasons	✓
	20 Outcomes and estimation	For each participant, report results, including raw data, for each target behaviour and other outcome/s	✓
	21 Adverse events	State whether or not any adverse events occurred for any participant and the phase in which they occurred	✓
Discussion	22 Interpretation	Summarize findings and interpret the results in the context of current evidence	✓
	23 Limitations	Discuss limitations, addressing sources of potential bias and imprecision	✓
	24 Applicability	Discuss applicability and implications of the study findings	✓
Documentation	25 Protocol	If available, state where a study protocol can be accessed	Not published
	26 Funding	Identify source/s of funding and other support; describe the role of funders	✓

Adapted from Tate *et al* (2016) guidance on SCED reporting to allow comments on adherence

2.5 Sample size

Consensus on sample size for similar SCED studies varies, with Kratochwill *et al*, (2010) detailing in the What Works Clearing House a recommendation of at least 2 replications and therefore a sample size of 3, with Smith (2012) outlining a total of 6 participants. This study aimed to have 6 participants complete the phased intervention which would mean 5 replications. Due to previous studies in psychological interventions in fibromyalgia demonstrating low adherence rates (O'Dwyer *et al*., 2019), recruitment aimed to overcompensate. Cavanagh, Strauss, Forder and Jones (2014) suggest that the ratio for completion of guided self-help intervention is two-thirds and therefore a minimum of 9 participants were potentially required to meet this target. This study aimed to allow time for additional recruitment if attrition was high. If participants withdrew from the study but allowed their data to be used it would have been included in any analysis.

2.6 Measures

Daily - Fitbit flex - These are owned by the University of Lincoln and were borrowed for the purposes of this study. Data are recorded as steps taken and was collected by electronic download. The rationale for using the activity trackers is that Mcloughlin *et al*. (2011) recommended not using self-report to measure levels of activity within a fibromyalgia population due to the variability in self-report related to actual levels of activity compared to healthy controls. In addition this reduced participant burden from having to engage with daily measures. Whilst there has been concerns about the accuracy of activity trackers, Evenson, Goto and Furberg (2015) reported that in laboratory-based studies using step counting to compare tracker-assessed steps with reality that accuracy was high for the Fitbit, with correlation coefficients > = 0.80.

Fitbits measure bi-pedal locomotion (steps) and Tudor-Locke *et al*., (2011) reported a wide variation in average daily steps taken within a normative population ranging between 4,000-18,000. Their findings noted that low-active populations such as older adults or those with illness had an average daily range of between 2000 and 2500. Overall Tudor-Locke *et al*., (2011) recommended between 7000 and 8000 steps per day as an optimum for healthy living within a normal population.

Weekly - The following measures were completed after the initial meeting and then on a weekly basis by clicking a personalised electronic link that was sent to each individual at the same time each week via Qualtrics (a standard online questionnaire

platform https://www.qualtrics.com/uk). Qualtrics was also programmed to send reminder e-mails to participants who had not completed the measures within three days. The total questionnaire comprised a total of 80 questions which could be accessed via computer or smart phone for ease of access.

Depression, Anxiety and Stress Scale – 21

Whilst individuals with fibromyalgia report high levels of symptom severity and reduced functioning this is often reported to be linked to psychopathologies such as depression and anxiety (Del Paso *et al*., 2012) and is therefore worthy of investigation in any fibromyalgia research. The Depression, Anxiety and Stress Scale -21 (DASS-21) *(Lovibond & Lovibond, 1997)* is a short form of the Depression, Anxiety and Stress Scale (DASS-42 (Lovibond & Lovibond, 1995)), which was a 42-item self-reported measure examining overall psychological, depression, anxiety, and stress. The DASS-21 is a self-report scale, measuring overall psychological distress and composed of three subscales: depression, anxiety, and stress. The DASS-21 measures the three conditions in relation to an individual's experience over the previous week.

Crawford, Cayley, Lovibond, Wilson and Hartley (2011) report a number of advantages of the DASS-21 over the full-length version (DASS-42) which include the reduced time it takes to complete, and the subsequent reduced participant burden compared to the DASS-42 which was a consideration when choosing the scale. In addition Crawford *et al* (2011) report that the DASS-21 has a cleaner factor structure than the DASS-42 due to the superiority of the items retained. However it is also noted that the downside of the DASS-21 in comparison to the DASS-42 is a slightly lowered reliability according to Henry and Crawford (2005), though more recent validation studies have found reliability to be more similar than previously thought (Ronk, Korman, Hooke & Page, 2013). Clinical levels of the DASS-21 are reported in Table 18.

The Hospital Anxiety and Depression Scale (HADS) was considered as an alternative measurement of psychological distress, depression and anxiety but a systematic review had raised concerns about the clarity of the latent structure of the measure so that it was hard to differentiate between the constructs of depression and anxiety (Cosco, Doyle, Ward & McGee, 2012). Coyne and Sonderen (2012) go as far as to say that alternatives to the HADS should be sought. In addition to the concerns about the HADS, the DASS-21 measure includes the stress subscale which acknowledges the influence of life events and individual responses to them. The DASS-21 has already been shown

to demonstrate reliability and validity in measuring depression, anxiety and stress within chronic pain conditions (Wood, Nicholas, Blyth, Asghari & Gibson, 2010).

Table 18: Clinical interpretation of DASS scores

Depression	Anxiety	Stress	Interpretation
0-9	0-7	1-14	Normal range
10-13	8-9	15-18	Mild
14-20	10-14	19-25	Moderate
21-27	15-19	26-33	Severe
28+	20+	34+	Extremely severe

Fibromyalgia Impact Questionnaire – Revised

The fibromyalgia impact questionnaire – revised (FIQ-R: Bennett *et al*, 2009) is an updated revision of the Fibromyalgia Impact Questionnaire (Burckhardt, Clark & Bennet, 1991) and is used extensively in Fibromyalgia research (Williams & Arnold, 2011). The FIQR is another self-report measure and consists of 21 questions relating to the previous seven-day period. Questions in the FIQ-R cover three domains; functional ability (9 questions and 30% weighted); overall perception of disability due to fibromyalgia (2 questions and 20% weighted); and symptom severity (10 questions and 50% weighted). Combined these subscales then give an overall score representing the impact of fibromyalgia to the individual and quality of life. It is worthy of note that the FIQ-R closely mirrors the SS and WPI scales that are used in the diagnosis of fibromyalgia.

Several deficiencies relating to gender bias and ecological validity were identified in the original FIQ that the FIQ-R set out to resolve (Srifi *et al*., 2013). The functional domain within the FIQ-R examines difficulty performing daily activities such as personal grooming, grocery shopping, preparing meals and changing beds. These items were chosen by a focus group of fibromyalgia patients as being particularly pertinent to their daily functioning which add to its ecological validity (Bennet *et al*., 2009). However whilst the FIQ-R was deemed more valid than the FIQ there is perhaps an argument for a contemporary update, as preparing homecooked meals and sweeping floors might be considered less relevant in today's society. The assumption of who performs such functions may still hold an element of gender bias. There are 2 questions in the 'overall'

(disability perception) domain, which has significance to this study as it examines the things that participants believe fibromyalgia prevents them from doing and how overwhelmed they feel by the fibromyalgia. Finally the last domain of 'symptoms' contains 10 questions about fibromyalgia symptoms and this section has been adapted to include the subjective experiences of memory, balance, tenderness and environmental sensitivity that typifies fibromyalgia and is often missed in other scales. The overall total score of the FIQ-R measures the total impact of fibromyalgia on sufferers. The FIQ-R has a good discriminatory quality between fibromyalgia, Rheumatoid Arthritis, Systemic Lupus and Major Depressive Disorder which are often co-morbid (Carrillo-de-la-Peña *et al*., 2015). The FIQ-R is consistently reported to have good internal consistency with the functional domain having a Cronbach Alpha of .92, the overall impact reported to be α=.92, the symptom severity domain to be α=.96 and the overall impact of fibromyalgia as measured by the FIQ-R to be α= .91 (Salgueiro *et al*., 2013).

Table 19: Clinical interpretation of the FIQ-R

Mild	Moderate	Severe	Extreme
0-42	43-59	60-74	75-100

Total scores on FIQ-R measure

No other measure appears to offer an evaluation of the full spectrum of issues that fibromyalgia sufferers report impacts their lives. When examining the extant literature in relation to fibromyalgia and in particular in relation to ACT and fibromyalgia (Carbonell-Baeza, 2011; Luciano *et al*, 2014; Ljótsson *et al*, 2014; Wicksell *et al*, 2013; Steiner *et al*, 2013) it is apparent that the FIQ and more recently the FIQ-R is the most prevalently used measure in fibromyalgia research. As research into ACT and fibromyalgia is currently so limited, the rationale for using the FIQ-R was that a) it was most relevant to the population being studied and b) it would potentially allow for comparison of results between studies.

Comprehensive Assessment of ACT Processes

There is a proliferation of measures for the individual processes of ACT such as experiential avoidance (Hayes *et al*., 2004; Gámez, Chmielewski, Kotov, Ruggero & Watson, 2011); cognitive defusion (Forman *et al*., 2012; Gillanders *et al*, 2014); being present (Walach, Buchheld, Buttenmüller, Kleinknecht & Schmidt, 2006) and values

(Wilson, Sandoz, Kitchens & Roberts, 2010). However there has been less development towards an overall measure of psychological flexibility that also incorporates the ACT core processes. As previously discussed in the journal element of this thesis there have been concerns raised about the AAQ-II (Bond *et al*., 2005). The AAQ-II was originally constructed as a measure of experiential avoidance and acceptance with a heavy focus on the constructs of experiential avoidance and cognitive defusion within its scales (Tyndall *et al*., 2019).

The CompACT (Francis, Dawson, Golijani-Moghaddam, 2016) reports to be designed to counter the criticisms of the AAQ-II (Bond *et al*., 2011). The CompACT was developed utilising the Delphi method of consensus with a panel of ACT experts to refine questions to 23 items. The CompACT has a stable and coherent three factor structure covering the 3 'dyadic' processes of Openness / Acceptance (OE α=.90), Being Present / Mindful (BA α=.87) and Values & Committed Action (VA α=.90) within ACT. The CompACT also claims to measure overall psychological flexibility. The convergent validity of the CompACT to the AAQ-II was reported as r=.79 (Francis *et al*, 2016). Whilst both the face and content validity of the CompACT were enhanced by using a panel of experts in its construction, the developers of the CompACT highlight that one of its limitations is that the self-as-context process is not included (though technically part of the BA scale), acknowledging ambiguity over the self-as-context process and the lack of previously established measure (Francis *et al*., 2016).

Self-Experiences Questionnaire

The self-experience questionnaire (SEQ; Yu *et al*., 2017b) is a 15 item (reduced from 29) self-report measure of the self-as-context process. Each item of the SEQ is positively scored with higher sores indicating a more flexible conceptualised self-i.e. an improved state. The SEQ was specifically devised in an attempt to reduce ambiguity surrounding the self-as-context process within ACT which both the AAQ-II and CompACT fails to measure. However Yu *et al*., (2017a) acknowledge that whilst the self-as-context process is a concept of three elements (self as content, self as process and self as context) the SEQ is only a two factor construct measuring the self as distinction (self as content) and self as observer (self as process) which is then an overall measure of the conceptual self. Yu *et al*.,(2017b) propose the failure to capture all the elements of the process are potentially down to the lack of original questions targeting the self as context element and the high correlation between the three concepts of self-knowledge. In addition it could be hypothesised that the self as context

element examines the deictic relationships and would therefore require a measure of interpretation into how others perceive the individual. For the purposes of this study the overall construct representing the self-as-context process will be used. Use and validation data of this new scale is very limited (Yu and, McCracken, 2016; Yu *et al*., 2017a) but its reported Cronbach Alpha is .94.

2.7 Maturation, familiarity and autocorrelation

A potentially undesirable consequence of taking repeated measures is that changes in responses may be due to the natural passing of time (maturation), familiarity with the measure or due to autocorrelation (where a previous response influences the next response) rather than being dependent on the intervention (Busk & Marascuilo, 2015). Whilst these issues are inherent in single case design where measures are repeated, the weekly nature of the responses potentially mitigates as much as is plausible an individual remembering their response from the previous week. Stability at baseline suggests that participants did not change their responses based on familiarity with the measures but were responding to the measures. Repeated baseline measures allowed for examination of potential maturation.

2.8 Procedure

Initial stage

Participants responding to the advertisements were given further information about the study (Appendix H) and an appointment was made to go and individually meet those expressing a wish to continue and who met inclusion criteria. At this initial meeting participants were verbally and textually made aware that their participation was entirely voluntary, and they could withdraw from the project at any time, with no repercussions and that they could remove data up to two weeks after each data set was collected. Potential participants were given the opportunity to ask any further questions and an orientation and brief psychoeducation overview of ACT and the study was provided. If individuals expressed that they still wished to continue then signed informed consent was sought (Appendix I). Activity trackers were fitted and instructions were given on how to recharge them and how to ensure that data were downloaded to the internet by synching the tracker with their smartphones. Internet access was checked. Sociodemographic information was collected, and the participants were sent their first personalised link to the questionnaire measures and asked to complete them. Participants were given fifteen pounds at this stage. The study was non-concurrent as participants began their interventions at differing times when ready which will have

increased ecological validity. Contact details of the researcher and supervisors were given in case participants had further questions, any problems with the equipment or wished to make a complaint.

Baseline phase

The baseline phase followed the initial meeting. During this phase participants were asked to wear their activity trackers constantly and note any prolonged periods (apart from when charging) that the tracker was not on their wrists. Participants were also asked to make a note of any external event that they felt might impact their participation in the study. Approximately one week after the initial meeting each participant began receiving a weekly telephone call from the primary researcher at a pre-arranged but conveniently variable time. During this call a semi-structured interview (Appendix D) took place to ascertain if there had been or were expected to be any influencing uncontrolled variables or to answer questions. Calls started during this phase, so contact with the researcher didn't become a new variable in the intervention phase.

Smith (2012) suggests that at least 3 stable (or worsening) data points of the primary outcome measure are taken at baseline which is essential if inferences are to be made and established. This study intended to take 21 baseline measures of levels of activity and four measures of the other outcome measures to allow for baseline stability and a clear baseline trend to be established in the primary outcome (levels of activity) and for psychological flexibility. The high number of activity data points was also to reduce any potential Hawthorne effect (McCarney *et al*., 2007). The Hawthorne effect might change trial participants' behaviour due to the awareness of being in a research study and to monitoring their own activity, which is particularly relevant to this study as participants were wearing activity monitoring bands. The activity bands used did not visually display activity data (they were just a solid black band) to reduce self-monitoring processes but participants could access their data via their phone apps. Whilst the data were sent from the Fitbits via weekly e-mail to a specifically generated university e-mail address that participants had no access to, they were able to look at the data via the app on their phones if they wished to.

Intervention phase

The criterion to start the intervention phase was a stable baseline across the primary outcome measure of level of activity and a period of three weeks was chosen for this. The intervention was delivered in a self-help format, broken down into psychoeducation and the core processes of ACT which were delivered on a weekly basis. Delivery of the

intervention material was done both electronically (via e-mail) and a second copy was sent in paper format by post to the participant's home address. The reasoning behind sending the intervention in two formats was two-fold. Firstly each week within the intervention there were exercises and worksheets for the participants to engage with, which could have been costly for the participant to print. Secondly there was psychoeducational text to engage with which individuals with fibromyalgia may have struggled to manage if they had to sit at a computer screen for prolonged periods of time or engage with during periods of 'fibro fog'. Each week participants received new information and experiential exercises (non-physical tasks) and were asked to engage with the material. Weekly telephone calls as outlined in the baseline phase continued but now included a fidelity check to ensure the chapters had been read and the exercises engaged with. Participants continued to wear their activity trackers, to note any adverse external events and to complete the weekly questionnaires.

Delivering the intervention in process order follows guidelines (Hayes, 2005) and allowed changes to be tracked and inferences made. To ensure clarity of the results of the weekly measures, participants received the intervention information after they received that week's questionnaires and were specifically asked not to engage with the material until after they had completed that week's questions. Therefore any change in that week's measures would not be attributed to another week's intervention material.

Post-Intervention phase

Post-intervention the weekly telephone contacts ceased although participants could contact the researcher via e-mail if necessary and the participants were asked to continue to wear activity trackers and to complete the weekly questionnaires. Interviews based on The Change Interview (Elliot, 2002) were carried out by one of two trainee clinical psychologists from the Trent Doctorate programme, not otherwise involved in this study, to reduce potential bias. Whilst based on Elliot's (2002) change interview the questions were adapted to the relevance of this research and a copy of the questions can be found in Appendix E. These interviews focussed on the participant's experience of the intervention as a whole, its individual elements, change and what they found helpful/unhelpful. Participants were also asked about the acceptability of the intervention as previous studies had raised concerns over its use (Akiens, 2016). Interviews took place between four- and six-weeks post intervention dependent on participant and interviewer availability. The interviews were recorded for analytic purposes. At this time participants returned their Fitbit equipment and no further

questionnaires were sent out or completed. Participants were left with a final payment of ten pounds at this stage.

2.9 The intervention

The introduction and first chapter give an overview of ACT. Chapter 2 is based on creative hopelessness which is an ACT therapeutic technique aimed at confronting the participants agenda of emotional control. The participants' are encouraged to review what they have previously tried (and potentially failed) to eradicate their suffering particularly in the way of experiential avoidance and to open their minds to an alternative way of improving their lives. Chapter three examines values (loss of values and clarifying them), chapter four is based on cognitive fusion/defusion, chapter five is based on being present and the self-as-context (and the dichotomous elements), chapter six examines acceptance (avoidance) and chapter seven identifies inaction and calls for committed action. The conclusion is a summation of the text and an examination of any obstacles to moving forward. In addition to written psychoeducational text, each chapter contains exercises to engage the participants on an experiential level which Hayes *et al* (2006) states is a vital element of ACT as a therapeutic intervention as this allows the addition of information to relational frames. The exercises and their targeted ACT processes are itemised in Table 20.

Whilst the 'Living Beyond Your Pain' (Dahl & Lundgren, 2006) bibliotherapy can be used as a standalone text, for the purposes of this research it was accompanied by weekly telephone calls (see section 2.10). Previous concerns about the level of complexity within the text and the length of the intervention causing high rates of attrition had been raised (Akiens, 2016; Johnston, Foster, Shennan, Starkey, & Johnson, 2010) and this was monitored during the intervention via questioning and observation for the purposes of this study. The authors of the book (Dahl & Lundgren, 2006) were contacted for their permission to use the text for research purposes and were informed that results would potentially be published in a peer reviewed journal. Lundgren replied and consent was given.

Table 20: Weekly exercises of the intervention

Week of intervention	Exercise	Description / ACT process
1	Experience of pain management	Creative hopelessness
2	Clean and dirty pain diary	Creative Hopelessness & Experiential Avoidance
2	Pain chain	Creative Hopelessness & Experiential Avoidance
3	Exploring values	Values
3	Attending your own funeral	Values
3	Building values compass	Values
4	Distance from thoughts	Cognitive defusion and Self-as-context
4	Rules about pain	Cognitive defusion
4	Chocolate ice cream	Cognitive defusion
4	Painful thinking diary	Cognitive defusion
4	Arrogance of words	Cognitive defusion
4	Thought observer	Self-as-context
4	This is me thinking	Self-as-context
4	Kick your buts	Cognitive defusion
5	Conceptualised self	Self-as-context
5	Locating the observer self	Self-as-context
5	Battle of action versus protection	Being Present
5	Being in the moment	Being Present
5	Mindful journaling	Being Present
6	Turn up the acceptance dial	Acceptance
6	Create a pain monster	Acceptance
6	Stressful situations	Acceptance
7	Values compass points the way	Values and committed action
7	Testing for vitality	Committed action
7	The bullseye	Values
7	Support team	Committed action
8	Identifying obstacles	Committed action
8	Identifying and coping strategies	Committed action
8	Develop committed action for obstacles	Committed action
8	Strategies for passengers on the bus	Values and committed action

There are no specific exercises in the introduction or conclusion of Living Beyond Your Pain

2.10 Weekly telephone calls

The weekly phone calls started at baseline phase and continued throughout both the baseline and intervention phases. The weekly calls were not intended as teletherapy but as supportive and therefore limited to -

- Check in including any problems with downloading data / filling in questionnaires / wellbeing
- Discussion of external events during the past week
- Potential barriers to participation in the next week
- Question session re: intervention and tasks – this was to allow participants to clarify elements of the intervention and for the researcher to ascertain if the materials had been engaged with.

Participants were notified that questions relating to the fidelity of the intervention were not a test nor would there be any repercussions if they hadn't engaged with the materials. The length of each call was recorded together with details of any missed or cancelled calls. When calls were missed participants would review two week's engagement at the next call or they would e-mail details of their engagement instead. Participants were always reminded that if they had any concerns they could contact the researcher via the university e-mail address, and they would be responded to as soon as possible. This e-mail address was checked on a daily basis. Telephone calls were recorded with permission on all occasions except three when the recording device failed. Handwritten notes taken during these sessions were then referred to. The decision to record the calls was made on the basis of participant and researcher safety in case any issues arose.

2.11 Fidelity

The intervention is a standard text that has been already assessed as being a key ACT text and therefore fidelity was assessed regarding engagement to the intervention via the weekly telephone calls or e-mails. Participants were asked to describe the exercises they had engaged with and whilst they were not encouraged to use the calls as an extended therapy session they often reflected on their difficulties / enjoyment / confusion of the exercises. This was noted. .

2.12 Analysis

Data were downloaded from the Qualtrics website via a comma separated values (CSV) file. CSV files cannot deal with leading zero values and therefore a numeric one is added to all scores. Using excel spreadsheets all scores were converted to correct this and then checked against text versions of the participants responses for accuracy. Excel spreadsheets were then used to score the responses in line with each measure's guidelines. Random hand scoring checks were completed.

Baseline stability

Stability of the baseline is important so that a trend can be established. Trend is the direction the data pattern of a measure is taking over time and allows the participant to effectively act as their own control for evaluating change (Wolery, Gast & Hammond, 2010). There are a number of outcome and process measures used within this study and it would have been an unrealistic task to gain stability across all measures at baseline. As the level of activity was the primary outcome measure, baseline stability in this measure was sought as a priority. Variation in the baseline was calculated using the more robust measure of median as the mean can be affected by extreme scores. Baseline stability for the primary outcome measure was calculated using the stability window method as outlined by Lane and Gast (2014). Percentage windows (0-10%, 10-20%, 20-30%, 30%+) from the median were examined to see where range scores at baseline for the measure fell. Variation in the baseline measures is described by Morley (ref; p:81) as up to '' *10% variation acceptable, 10-20% reasonable, 20-30% borderline acceptable and values beyond questionable"* so that up to 30% would be considered stable. A maximum of 20% variation was sought within the primary outcome measure. Baseline stability using the same method was also calculated for psychological flexibility and a maximum of 30% variation was sought for this measure.

In addition the start of the intervention phase was randomly selected to be at the end of three weeks of baseline as it added additional control to the design of the experiment. Morley (2017) states that a random start of intervention together with a stable baseline measure is the ideal for this type of research. Consideration was given to a complete randomisation of baseline start with varying lengths of baseline for each participant as this would have increased internal validity. However a decision was taken to minimise the baseline for all participants for pragmatic and ethical reasons as this reduced the additional burden of further questionnaires in a population with a chronic health

condition. Therefore this research acknowledges that some compromise was made to facilitate engagement and for practical purposes.

Percentage exceeding the median and dual criterion method (PEM/DC)

Data in SCEDs often doesn't meet the parametric assumption of the independence of residual data due to the successive measurements in intra-subject design (Parker & Hagan-Burke, 2007). Subsequently a method known as percentage of non-overlapping data (PND) (Scruggs, Mastropieri, Cook & Escobar, 1986) had previously been used as a statistical analysis of effect size in SCEDs. However Ma (2006) highlighted that PND is susceptible to ceiling or floor data within the baseline phase leading to the risk of a type-II error i.e. accepting a false null hypothesis – no effect size found when visual analysis clearly demonstrates there is one. Ma (2006) proposed a new method of individual effect size calculation for SCED designs known as percentage exceeding the median (PEM), which Wolery, Busick, Reichlow and Barton (2010) report eliminates the confounding condition relating to extreme outlier data in the PND. In the PEM the null hypothesis is based on the binomial formula that if treatment has no effect then the data points within the treatment phase will fluctuate 50/50 above and below the median of the previous baseline phase. The PEM is therefore calculated by stretching a visual line from the median in the baseline phase across successive phases and counting the data points that exceed that line (above the line if an increase indicates a positive outcome and below the line if a decrease indicates a positive outcome). The number of points above expectation are then compared to the number of possible points in that phase to gain a percentage of points exceeding the median. Effect size for PEM is comparative to the PND (Scruggs *et al*., 1986) and whilst Ma (2006) altered the categories in his original paper, later papers (Chen & Ma, 2007: Ma, 2009; Wolery *et al*., 2010) validate the use of the original categories of .90+ deemed highly effective, .70 - <90 = moderately effective, 50 - >70 mildly effective (questionable) and below .50 is deemed ineffective. Wolery *et al*. (2010) reported that the PEM was more reliable, particularly in relation to ceiling and floor effects, than the PND although Ma (2009) acknowledges an insensitivity to the magnitude of the data points that exceed the median or when there is a particularly strong baseline trend. Therefore in addition to the baseline median line utilised in PEM the dual criterion (DC) method outlined by Fisher, Kelley and Lomas, (2003) was used whereby the baseline trend was also accounted for by drawing a regression line from the baseline trend stretched forward over the intervention phase. Only data points that fell above (or below dependent on

direction of improvement) both lines (the baseline median and the baseline trend line) would be counted.

Reliable / clinically significant change

Whilst visual analysis can demonstrate changes between phases it cannot inform us if the change between pre and post / follow up is statistically reliable or is due to measurement variability. Reliable change indices examine changes in the pre – post/follow up scores and indicate how much change positively or negatively in order for that change to be deemed statistically significant and not as a result of chance or variability in the measure. If reliable change was identified then further analysis to check if the change was clinically significant i.e. between clinical and non-clinical scores was carried out.

Criticisms of RCI and CSC analysis include that they can discount small but meaningful change for the individual merely on the premise that they do not meet cut-off criteria at specific points of measurement (Kazdin, 2001). In addition whilst the RCI and CSC allow individual analysis of the effect of an intervention there is a heavy focus on symptom reduction with these calculations which is not a primary goal of ACT (Hayes *et al*., 2006). However the RCI and CSC still remain an alternative to group mean analysis and an effective way to investigate treatment effectiveness.

Tau-U analysis

Baseline trend in SCED design is vital to conclusion validity but can be confounding such as if the data suggest that the participant would have improved anyway without the intervention. Whilst the PEM/DC analysis accounts for baseline stability and baseline trend it does not adjust for any confounding trends within the baseline and can therefore restrict conclusions being made about the intervention. Tau-U analysis is based on the non-overlap of data between phases and is related to Kendall's Tau (correlation index between paired scores) and Mann-Whitney U (index of phase differences). The Tau-U analysis is congruent with the visual analysis and indeed should be guided by it. Tau-U is a non-parametric, distribution free way of determining the effectiveness of the intervention within single case designs (Parker & Vannest, 2012). The Tau-U effect size ranges from -1 to 1, with a Tau-U of 0 indicating 0% improvement and a Tau-U of +/- 1 indicating 100% improvement or decline.

Framework analysis

From a functional contextualism perspective introspection is a relatively unimportant focus and as such the change interviews provided supplemental information to the quantitative data rather than unique insight into psychological change. Framework analysis is a qualitative methodology, a form of content analysis, that was developed by Ritchie and Spencer (1994) particularly relevant for examining both similarities, differences and relational themes within semi-structured interviews (King, Horrocks & Brooks, 2018). Unlike some other qualitative methodologies such as grounded theory or interpretative phenomenological analysis, framework analysis is not naturally aligned with any specific epistemological approach (Gale, Heath, Cameron, Rashid & Redwood, 2013) and is therefore appropriate to use within the pragmatic functional contextual approach.

Extended ethical considerations and approval

This study has been produced with consideration to the code of human research ethics outlined by The British Psychological Society (2014) and did not commence until ethical approval had been received from the Research Ethics Committee of The University of Nottingham. A letter confirming ethical approval was granted on 16.10.18 can be found in Appendix J.

The primary researchers search of the extant literature could find no reported contra-indication or long-term negative impact of ACT so risk to participants was deemed low. However any psychological intervention has the potential to elicit individual distress and so a check in with the participants was added to the weekly phone calls made during the research to signpost the participants to appropriate services if necessary. Participants were reminded at the end of each call they could contact the researcher via university e-mail if they had any concerns at any time and they would be responded to as soon as possible The numbers of appropriate support agencies were provided in the information sheet (Appendix H) together with the contact details of the researcher and the supervisors overseeing the study. Informed consent was only sought after two opportunities to be given further information and to ask further questions.

During the early stages of the study one participant experienced a major bereavement which raised an ethical dilemma about her continued participation in the study. Firstly it was made explicitly clear to her that there was no pressure for her to make any decisions or to carry on and it was reiterated that she was free to withdraw from the study at any time and she would be supported in any decision she chose to make. The

participant was adamant that she wanted to continue in the study as she felt it might benefit her at that time. Consultations with supervisors took place to ensure it would be ok to proceed and if the adequate support was available if the participant needed it. The primary researcher has experience in bereavement counselling, and it was felt that the participant's potential support needs could be assessed in an ongoing process and therefore her wishes could / should be followed. The participant remained in the study although she took a week out to give herself some space to process events at the request of the researcher.

Risks to the researcher and those undertaking the change interviews were considered low but were mitigated by lone working procedures when visiting the participants at home and by the support and assistance provided from the university supervisors.

Data collection, storage & protection

All appropriate precautions were taken to maintain confidentiality. Identifying data including signed consent forms were kept in a locked cabinet at The University of Nottingham and stored separately from other information. Participants allocated their own identifying code and all data were coded with this to protect their anonymity. Electronic data were encrypted, and password protected on secure memory sticks in line with GDPR legislation. Paperwork and all electronic data will be destroyed securely in line with university requirements.

3.0 Extended Results

3.1 Participants

A total of 18 individuals showed initial interest and after further information was sent out via university e-mail, 12 of those individuals expressed that they would like to take part in the study. One participant checked and discovered that she would be unable to wear the tracker during the working week due to her job and decided not to continue. Of the remaining 11 participants the first six were chosen to take part in the study in a first come first served basis as they all met the inclusion criteria. Of the remaining five applicants, three consented their agreement to be placed on a waiting list in case of attrition.

3.2 Sociodemographic information

There was a mean of nine years between symptom emergence and diagnosis with the range of time since symptoms emerged being between 6-20 years. Valentini, Fetter &

Orbell (2019) recently examined treatment preferences in fibromyalgia patients and reported an increasing openness towards psychological options the longer the time since diagnosis. All six participants were regularly taking prescribed medication specifically for their fibromyalgia which included a range of approved and non-approved anti-depressants, anti-convulsants and painkillers including opioids which are deemed as contra-indicative. In several cases (participants 1,4,5 and 6) polypharmacy for fibromyalgia (multiple medications for the same thing) is evident. These results support previous findings reported by Arnold (2009), Wolfe *et al*., (2011) and Jay and Barkin (2015) regarding the use of pharmacology to treat fibromyalgia.

3.3 Generalisability of sample

Demographically the sample in this study appears to typify a representative sample of individuals diagnosed with fibromyalgia which could suggest that results could be generalised out and compared to other research into fibromyalgia. However convenience sampling can lend itself to selection bias. Of note here is that the participants in this study had lived with their symptoms and diagnosis for several years. Their willingness to participate in the study could be reflective of Valentini et al's., (2019) findings surrounding increasing openness to psychological therapy dependent on increased time since diagnosis. Therefore, further replication of this study using systematic approaches to larger sampling including people newly diagnosed with fibromyalgia would increase the external validity and generality of the intervention (Dallery, Rachel, Cassidy, Bethany, Raiff, 2013). In addition as this sample is exclusively female and over 18 years of age, it may not be generalisable to males or to children and young people who have a fibromyalgia diagnosis.

3.4 External events and extrinsic variability

During the course of the intervention participant 1 reported that she went through periods of elevated work-related stress at weeks 3,4 and 5 of the intervention phase. Participant 2 reported changing her job over the intervention phase though she reported this was not particularly stressful to her, whilst participants 3, 4 and 5 reported no adverse events during the study. Participant 6 experienced a bereavement at week one of the intervention phase, a funeral on week two of her intervention and an adverse experience in week five of her intervention. The intervention phase was expected to last 8 weeks for each participant; however four participants (P3, P4, P5, P6) took a one-week hiatus from the intervention and this phase therefore lasted nine weeks for them.

Breaks taken were reportedly due to illness or holiday. All dates and reasons were noted and are indicated in the results. Participants 3,4 and 5 all reported going on holiday during the intervention phases and all breaks are accounted for within the data.

3.5 Telephone calls

Telephone calls were usually made on a Monday or Friday due to researcher availability and participant convenience. Participant one received a call each week of the baseline and intervention phase, whilst participants five and six missed one week of the intervention due to being away. Participants two and four missed two weekly calls during the intervention phase whilst participant three missed three weekly calls during the intervention phase. Participant three expressed that sometimes she preferred to e-mail with her level of engagement and her wishes were followed. The number of calls ranged between 8 – 11 per participant and the length of call ranged from 3 minutes and 25 seconds to 15 minutes and 59 seconds. The number of calls and the frequency and duration of each call per participant can be seen in Table 21.

Table 21: Telephone call frequency and duration

Participant	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12	Total calls
1	9.57	6.23	7.45	9.33	7.24	9.12	10.01	15.59	8.39	5.39	10.26	-	11
2	9.28	5.47	6.46	15.31	-	11.05	12.2	8.31	-	8.36	8.36	-	9
3	8.14	4.37	4.29	9.24	-	5.49	3.54	-	5.01	-	-	7.36	8
4	9.48	3.58	4.32	-	7.08	7.01	-	5.13	7.35	3.25	8.39	5.01	10
5	9.35	4.58	8.51	6.24	7.36	9.34	5.09	5.51	8.32	-	4.38	8.39	11
6	9.27	5.46	7.59	8.50	15.31	12.13	-	13.09	13.52	10.26	12.18	7.56	11

Time of calls shown in minutes and seconds

3.6 Fidelity

Every participant reported engaging with each chapter and each exercise. In some cases, this was assessed by detailed e-mails about individual reflections on the exercises but this was predominantly ascertained through general discussion about that week's text during the telephone calls.

3.7 Subscales of the DASS-21

Depression

As the DASS-21 overall measure of distress is an accumulation of the three equally scored subscales of Depression, Anxiety and Stress it was considered valuable to analyse the subscales individually for the purposes of this research.

Visually (Figure 13) it appears that all 6 participants showed beneficial decreases in their levels of depression from pre to follow up measures. However only 2 participants (P4 and P6) were in the clinical range for depression at the start of the study and RCI and CSC analysis for these participants showed that pre to follow up change was reliable and clinically significant whilst PEM/DC analysis showed only participant 4's change to be effective. Participants 5 and 6 demonstrated a non-beneficial increase in the pre-post scores for depression but both demonstrated beneficial change between pre and follow up. Participant 3 had extremely low levels of depression as measured on the DASS-21 subscale and her scores hit the floor effect at baseline with little fluctuation throughout which will have impacted average based analysis. The PEM/DC average for all six participants was .44 at post and .46 at follow up which would be considered not to be effective.

There does not appear to be any clear pattern between levels of depression and the elements of the intervention although the intervention as a whole appeared to have a beneficial decrease in levels of depression for all participants.

Anxiety

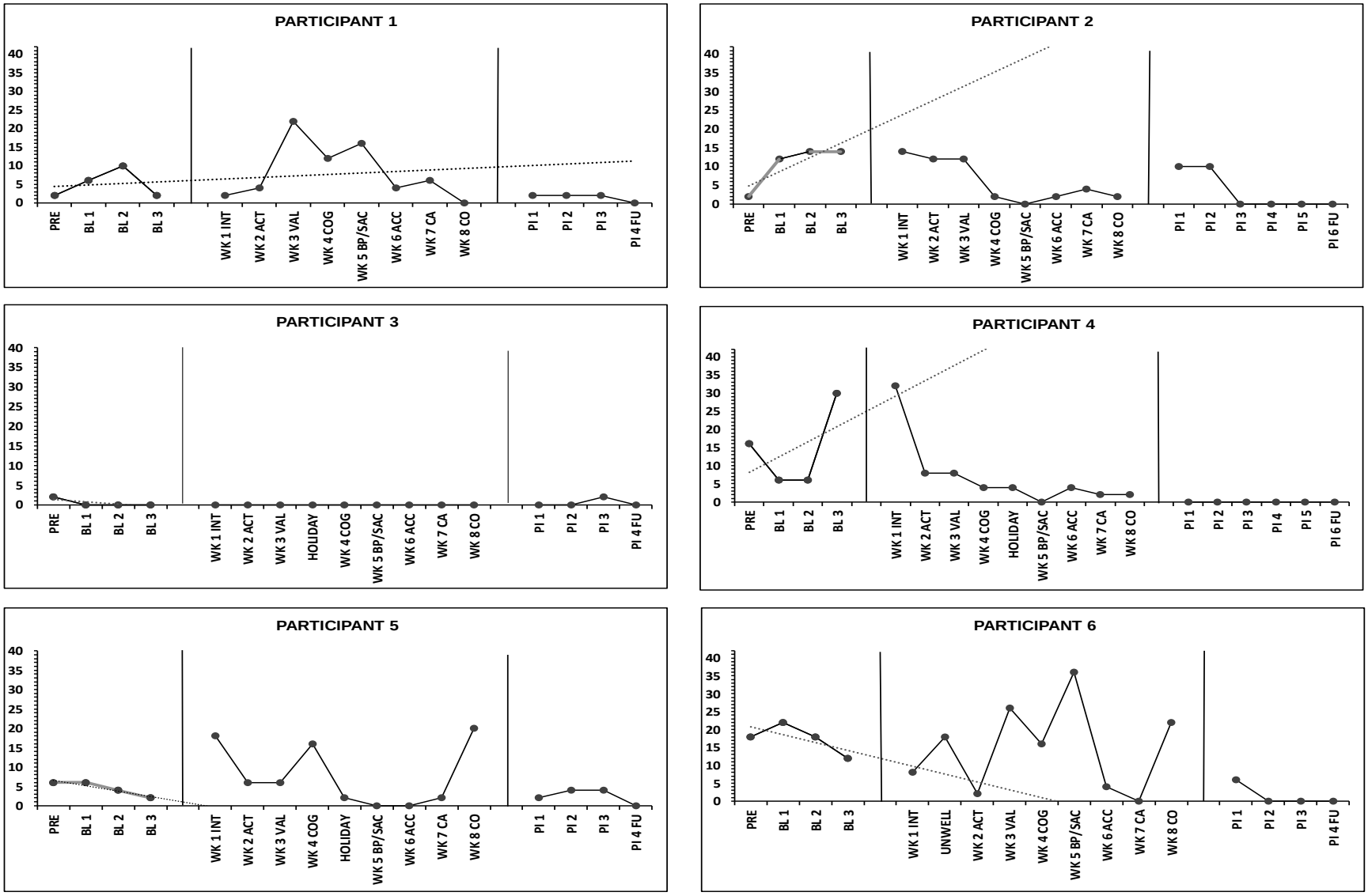
Whilst participants 1, 2, 4 and 6 demonstrate beneficial decreases in their levels of anxiety (Figure 14) at both post and follow up, participant 6 did not fall within the clinical level for anxiety at the start of the study and change was not deemed to be reliable which excluded her scores from further clinical analysis. Participants 1, 2 and 4 demonstrated reliable and clinically significant change at both post and follow up which PEM/DC analysis found to be between mildly and highly effective at post and either moderately or highly effective at follow up. Participants 3 and 5 both demonstrated a beneficial decrease in both pre to post and pre to follow up scores (P5 was both reliable and clinically significant) however levels did not fall below baseline trend or baseline median and were therefore found to not be effective.

Average PEM/DC for anxiety all 6 participants demonstrates change to be mildly effective at post (.51) and follow up (.56). Again, there is no clear pattern emerging between elements of the intervention and levels of anxiety.

Stress

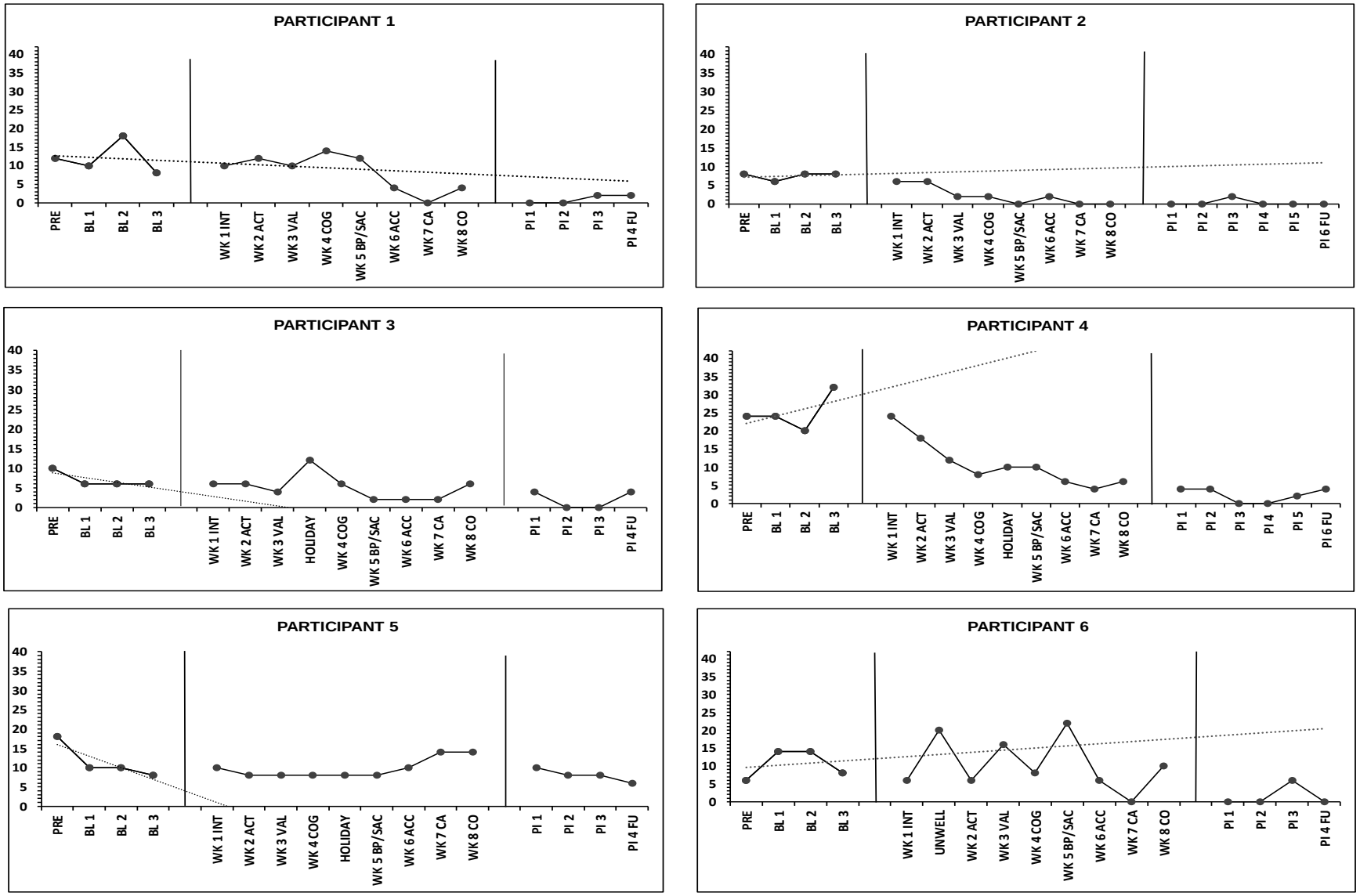
Five of the six participants (P1, P2, P3, P4 and P6) demonstrate a beneficial decline in their levels of stress (Figure 15) at both post and follow up from pre-scores. Whilst participants 1, 2 and 4 showed reliable change only participant 4's pre-measure scores fell within the clinical level for stress and could therefore be subject to further clinical analysis. Participant 4 demonstrated reliable and clinically significant change which was highly effective at both post and follow up measures. Participant 2's positive decline was found to be reliable, highly effective although not clinically significant. Participant 5 also demonstrated a beneficial decline in their level of stress but only at follow up and this was not reliable and was above the baseline trend.

The average PEM/DC score for all participants was .45 at post and therefore not effective but .51 at follow up and therefore considered mildly effective. As with the previous subscales, instability and trends within the baseline may impact this score. No pattern relating to individual elements of the intervention influencing levels of stress emerged from the data.



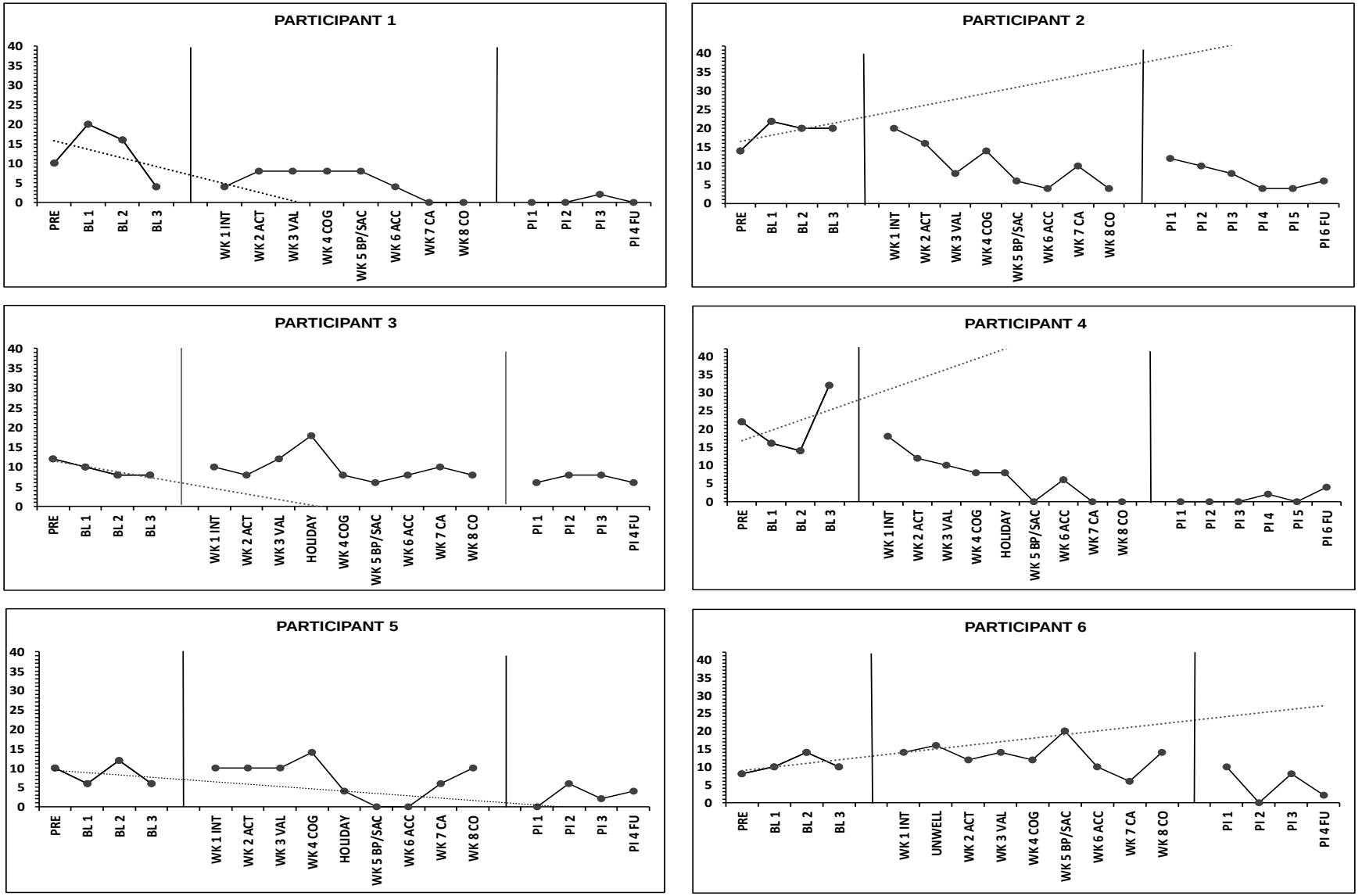
PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement

Figure 13: Level of depression and baseline trend - measured by the DASS-21 across all phases for each participant



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement

Figure 14: Level of anxiety and baseline trend - measured by the DASS-21 across all phases for each participant



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement

Figure 15: Level of stress and baseline trend – measured by the DASS-21 across all phases for each participant

3.8 Subscales of the FIQ-R

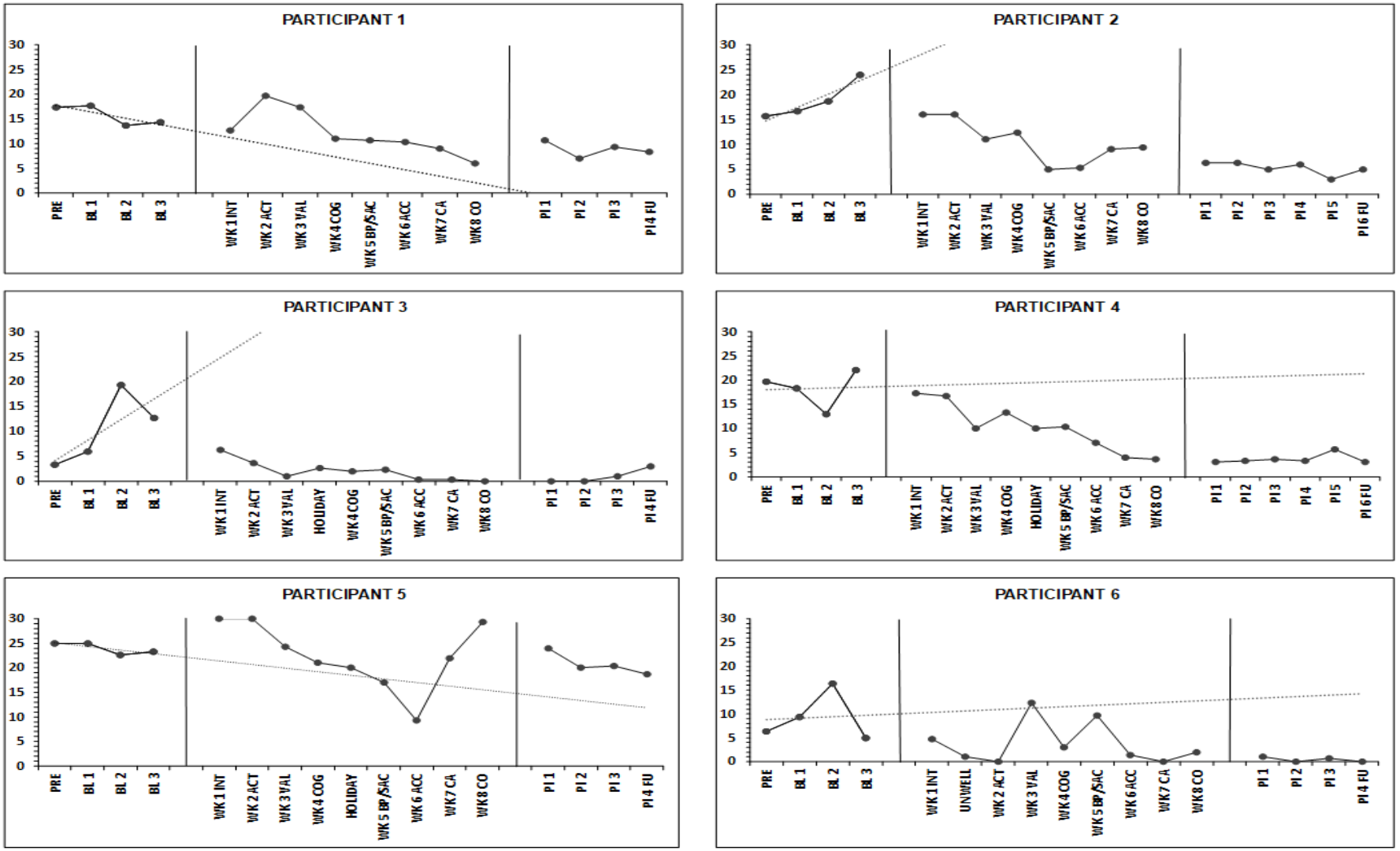
Function

From visual inspection of Figure 16, all six participants appear to demonstrate a beneficial decrease in their functional impairment due to fibromyalgia by follow up. Only change at follow up for participants 2 and 4 was found to be reliable and clinically significant whilst PEM/DC analysis found change to be highly effective for participants 2, 3, 4 and moderately effective for participant 6 at both post and follow up. PEM/DC average calculations show the effect to be mild at both post and follow up (.67). Participant 5 reported a non-beneficial increase in the overall impact of her fibromyalgia at post and whilst this beneficially declined from pre to follow up this change was above the baseline and median trends, so PEM/DC analysis found this change to be ineffective. Whilst there does not appear to be a clear pattern between elements of the intervention and the functional impairment of fibromyalgia there does appear a progressive decline of impairment over the period of the study and through follow up.

Overall – perceived disability

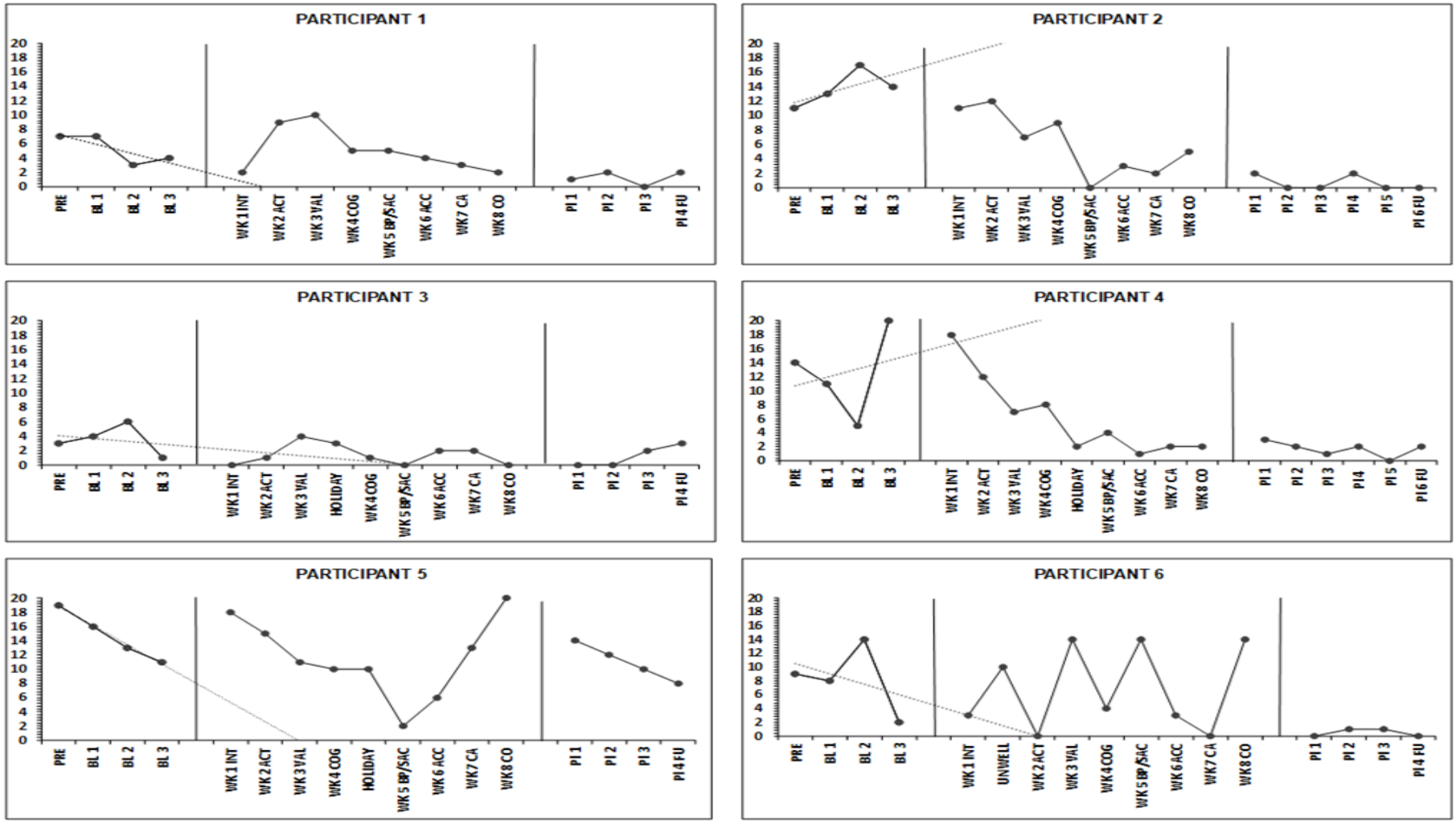
Visual analysis of Figure 17 appears to show that only participant 3 failed to show a beneficial decrease in the overall perceived disability of fibromyalgia at follow up as measured by the FIQ-R. This could be influenced by the low level reported in this scale at premeasure. Whilst participant 5 appeared to show a reliable and clinically significant beneficial change at follow up PEM/DC analysis reported this was not effective and can be best understood via the visual analysis of the variance in the data. In direct contrast the change for participants 2 and 4 was deemed to be effective at both post and follow up which was found to not be reliable. PEM/DC average for all six participants showed the change not to be effective.

No clear pattern appeared from the data as to which element of the intervention had most influence on the overall perception of disability due to fibromyalgia although for participants 2, 3 and 5 it is at its lowest in the week that being present and the self-as-context process is delivered which is coherent with the content delivered.



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement.

Figure 16: Level of functional impairment and baseline trend – measured by the FIQ-R across all phases for each participant



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement.

Figure 17: Level of overall perceived disability of fibromyalgia and baseline trend – measured by the FIQ-R across all phases for each participant

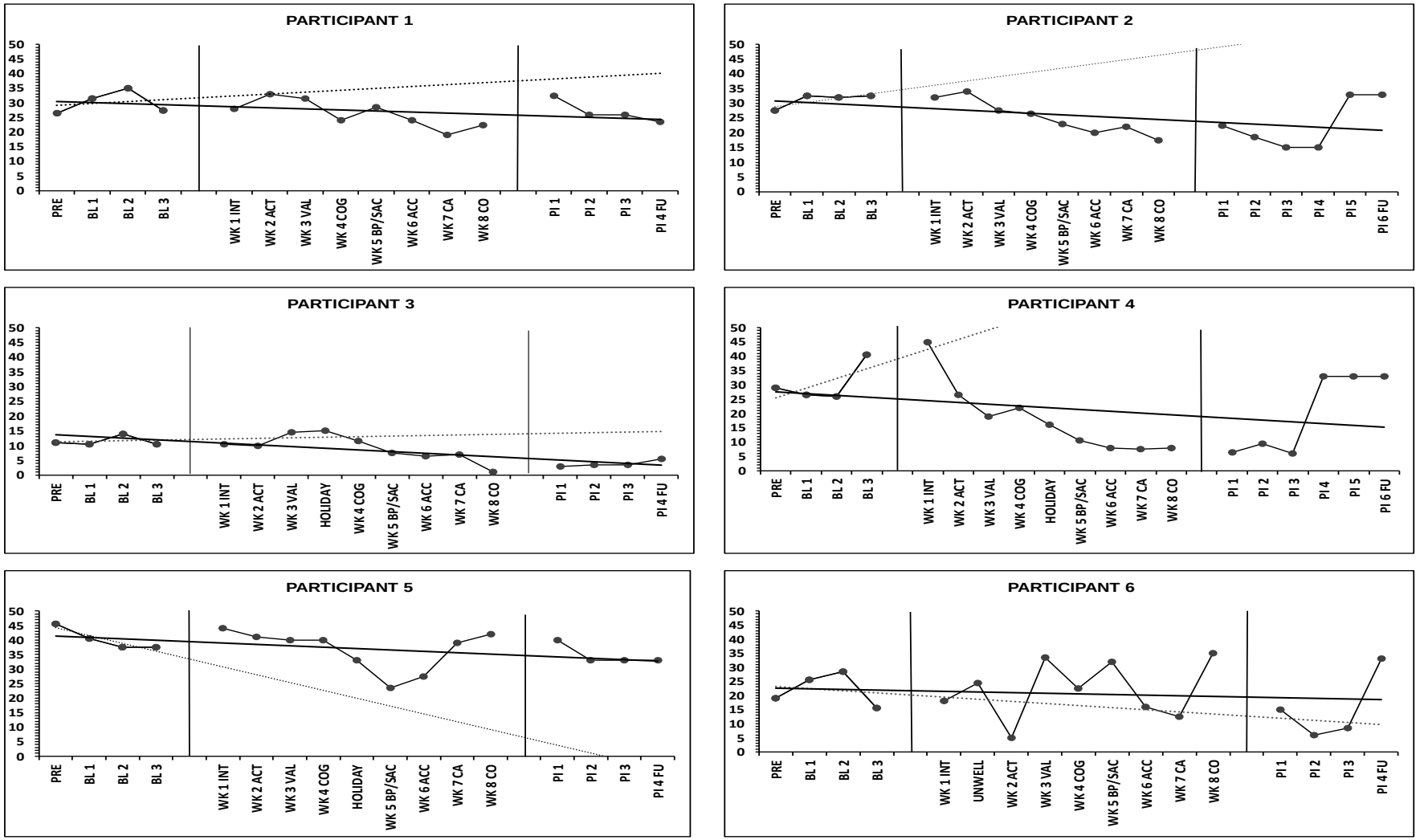
Symptoms

From visual inspection of Figure 18, participants 1,2,3 and 4 appear to demonstrate a beneficial decrease in the severity of their fibromyalgia symptoms at post as measured by the FIQ-R, and this change was found to be reliable and clinically significant for participants 2,3 and 4. Only the change shown for participants 3 and 4 was found by PEM/DC analysis to be effective. The post change for participant 1 was found to be moderately effective but not reliable. Change for participants 2 and 4 was not maintained and they both demonstrated non-beneficial increases in the symptom scale by follow up.

Participant 6 appears to show non-beneficial increases in their fibromyalgia symptoms at both post and follow up although this was neither reliable nor effective. Therefore three of the six participants had shown an increase in their symptoms by follow up. Participant 5 did demonstrate reliable and clinically significant change at post and follow up but this was not effective when assessed by PEM/DC. The average PEM/DC found the change to be ineffective at both post and follow up and this is best highlighted by the overall trend lines shown in Figure 17. No clear pattern emerged in the data to link individual elements of the intervention to symptom impact.

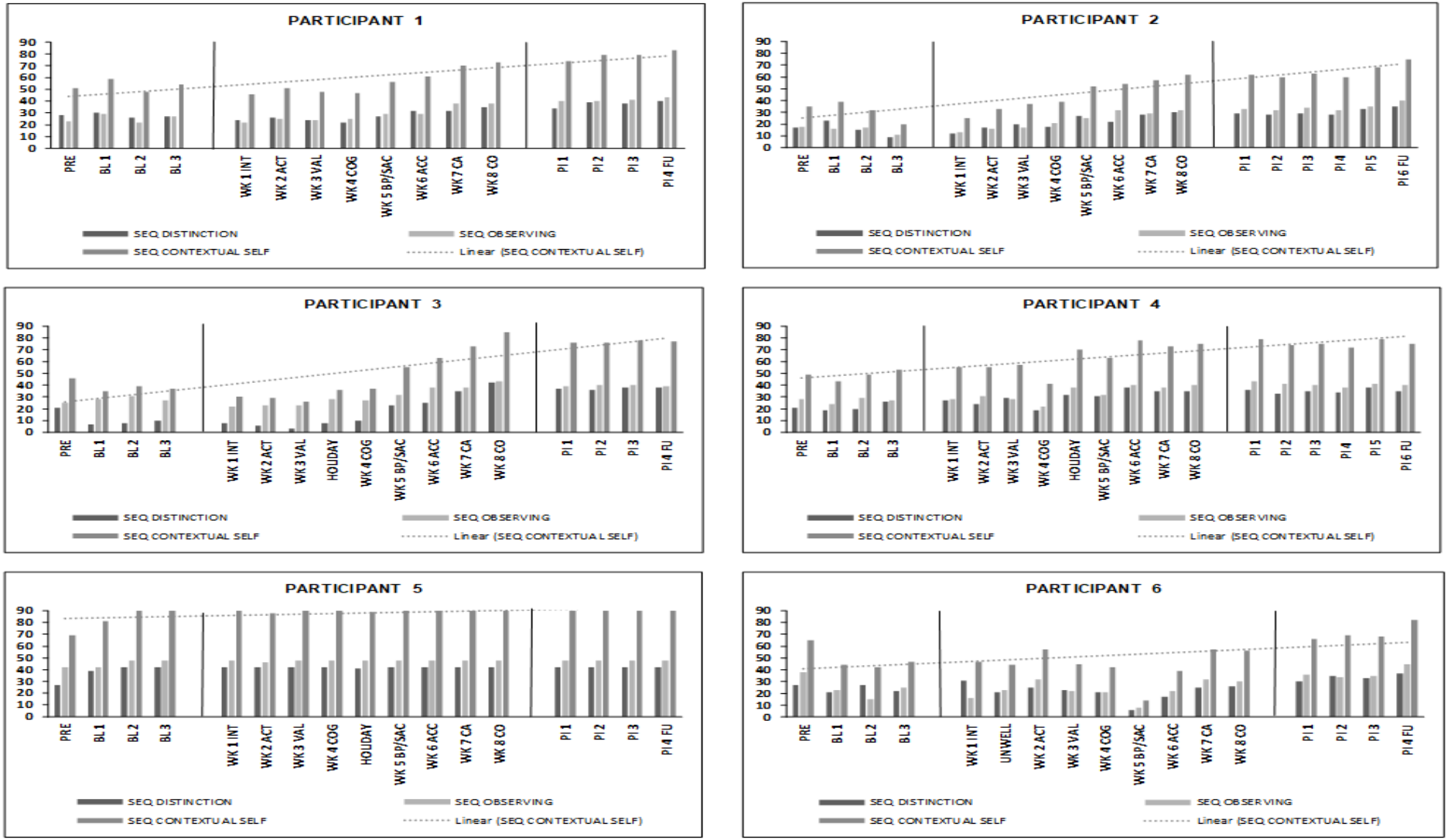
3.9 Subscales of the SEQ

There appears to be a direct increase in the conceptualised self in the week the self-as-context element was delivered for participants 1, 2 and 3 and in the week after the delivery of that element for participants 4 and 6 (Figure 7). When examining the subscales within the SEQ (self as distinction and self as observer) no clear pattern emerged as to which concept of self-knowledge is increased and therefore most influenced by the intervention (Figure 19).



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Decrease demonstrates improvement Dotted line = baseline trend solid line = overall trend

Figure 18: Level of symptom impact of fibromyalgia and baseline trend – measured by the FIQ-R across all phases for each participant



PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase. Increase demonstrates improvement Dotted line = overall trend of overall measure of contextual self

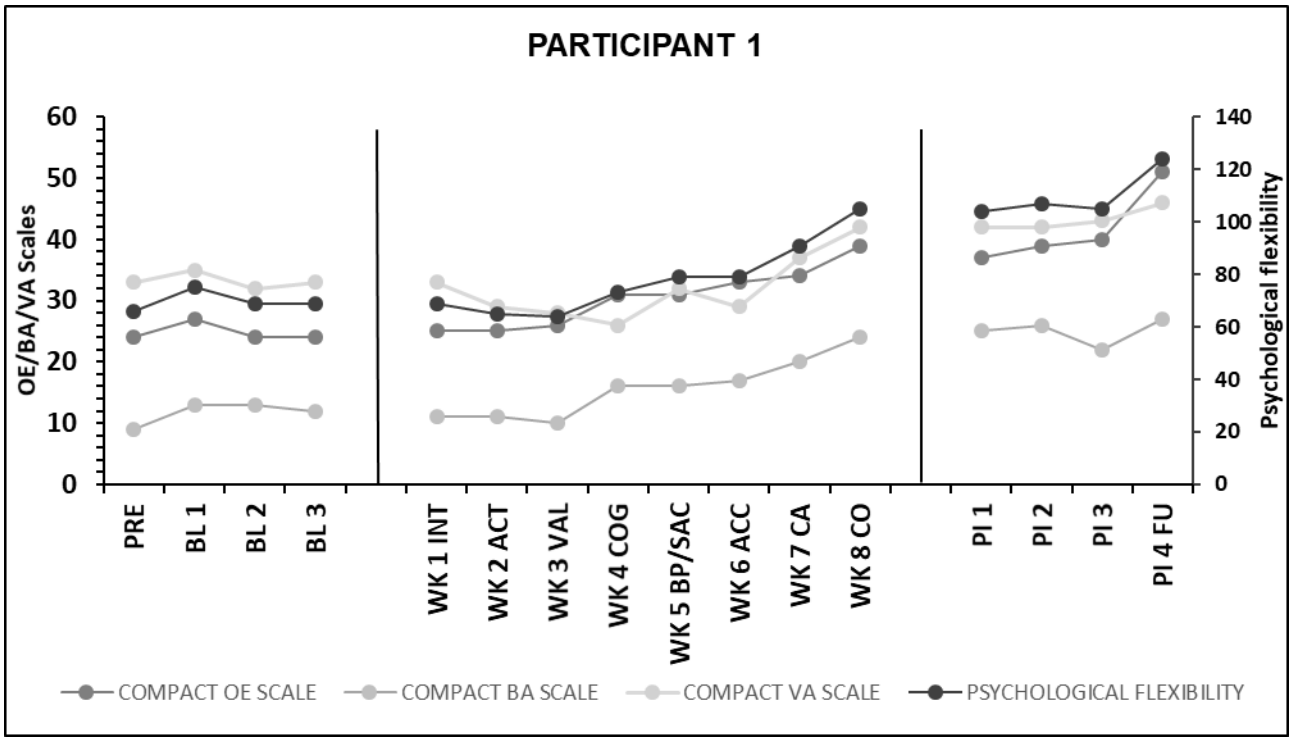
Figure 19: Self as distinction, self as observer and conceptualised self with overall trend for conceptualised self – measured by the SEQ across all phases for each participant

3.10 Individual change for the dyadic processes of ACT – measured by subscales of the CompACT

The CompACT measures the dyadic processes within ACT of openness to experience (OE = cognitive defusion and acceptance), behavioural awareness (BA = being present) and valued action (VA = values and committed action) and the overall measure of psychological flexibility. As results have already demonstrated an effective, reliable and clinically significant increase of psychological flexibility for all participants, further examination to attempt to identify which elements of the intervention may have influenced its development for each participant is worthy of investigation.

Participant 1

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 1 are shown in Figure 20.



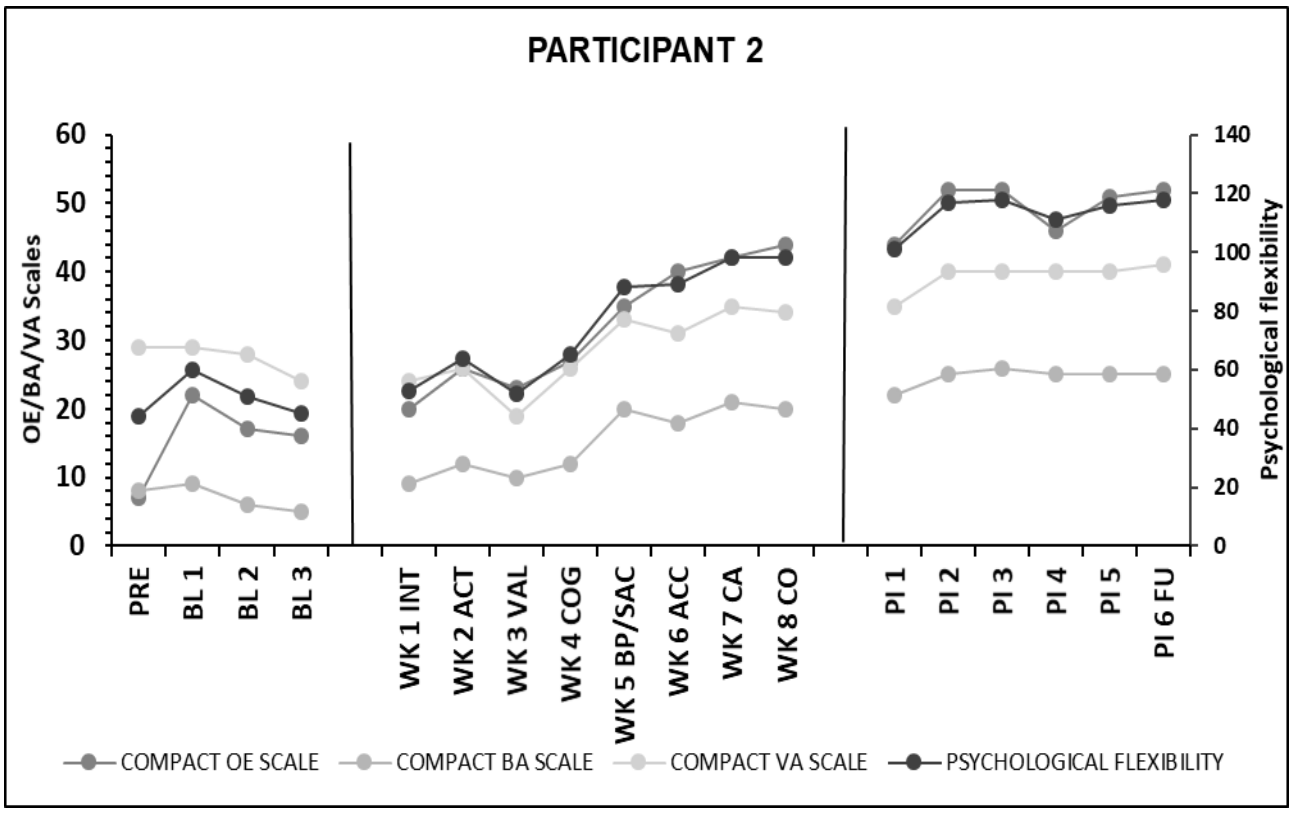
OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 20: Individual change for dyadic ACT processes and psychological flexibility – measured by the CompACT for participant 1 across all phases of the intervention

Visual analysis demonstrates a stable baseline across all measures of the CompACT for participant 1. There is an increase in the OE scale in the weeks corresponding to the delivery of the cognitive defusion and acceptance elements of the intervention. The increase in OE was found to be reliable, clinically significant and moderately effective at follow up. Whilst the increase in BA is reported as reliable, clinically significant and mildly effective at post and moderately effective at follow up there is no apparent immediate influence following the delivery of the corresponding element of the intervention. This is in direct contrast to the SEQ scale which theoretically is the other half of the dyadic process of behavioural awareness (not measured within the CompACT) which showed a clear increase above baseline trend when the relevant chapter of the intervention was delivered. Whilst the introduction of values does not appear to influence the VA scale there is an increase as the committed action element is introduced which results in reliable, clinically significant and mildly effective change at follow up and which appears to correspond with an increase in psychological flexibility.

Participant 2

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 2 are shown in Figure 21. Increases in the OE scale are reliable, clinically significant and highly effective at both post and follow up measures. Increases are shown in the weeks that the corresponding chapters of cognitive defusion and acceptance are delivered and continue to rise afterwards. Change in the BA scale is also shown as reliable, clinically significant and highly effective at post with a slight reduction to moderately effective at follow up. Participant 2 demonstrates an increase in BA in the week that the being present and self-as-context chapter is delivered which also corresponds to changes in the SEQ measure and this appears to influence the increase in psychological flexibility the most. Whilst there is an increase in the VA scale in the weeks after the values and committed action chapters are delivered there is a decrease in the actual weeks of delivery Whilst there is an increase in VA at both post and follow up the change was not reliable.

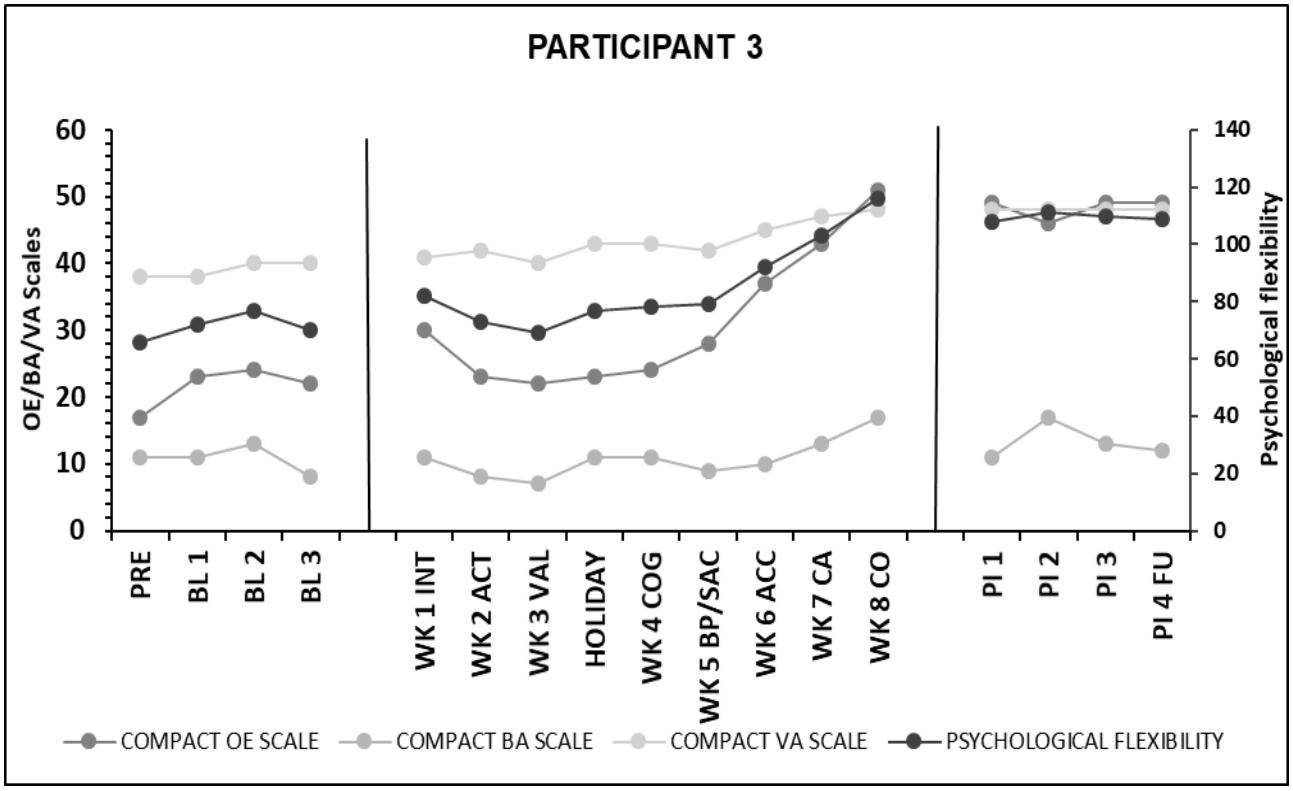


OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 21: Individual change for dyadic ACT processes – measured by the CompACT for participant 2 across all phases of the intervention

Participant 3

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 3 are shown in Figure 22. Only changes reported in psychological flexibility and openness to experience were found to be reliable, clinically significant an effective at both post and follow up. There is no increase in the week that the cognitive defusion element is delivered but there is increase in the weeks after. There is however a corresponding increase in openness to experience when the acceptance element was delivered which also aligns itself with the increase in psychological flexibility. Whilst there appears to be an increase in the weeks after the behavioural awareness element was delivered (BA scale) this is not as significant as in the SEQ scale. Whilst change for the SEQ scale was reliable, clinically significant and effective, change within the BA scale was not reliable. Change in the VA scale was not found to be reliable either as participant 3 reported high levels on the VA scale throughout.



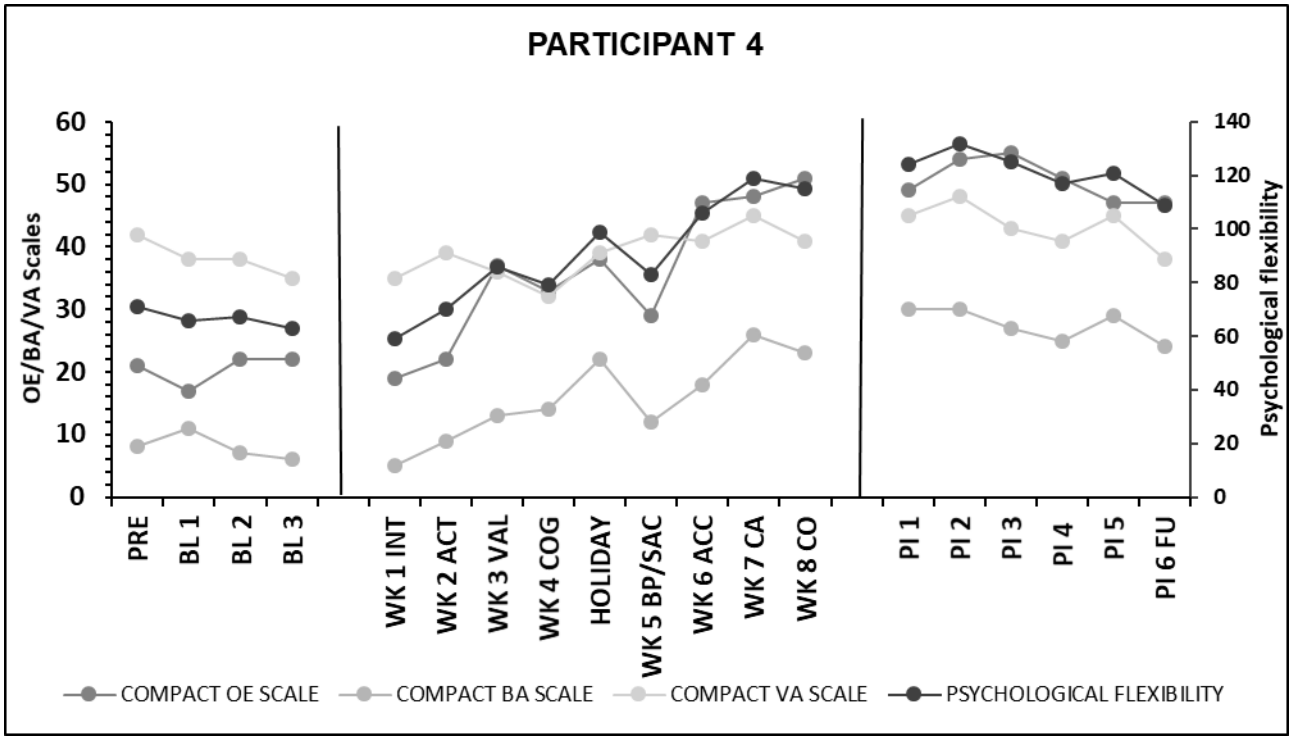
OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 22: Individual change for dyadic ACT processes – measured by the CompACT for participant 3 across all phases of the intervention

Participant 4

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 4 are shown in Figure 23. Change within the OE scale was found to be reliable, clinically significant and moderately effective at post and follow up and whilst there does not appear to be a clear impact with the delivery of the cognitive element of the intervention there is an increase directly related to the delivery of the acceptance element. This increase in the week acceptance is delivered follows a clear decline the previous week although the increase does appear to be above the phase trendline for that subscale. The BA scale demonstrates a decrease the week that the being present element is delivered which is mirrored in the SEQ scale but taking extrinsic factors into account this represents the week after a peak in all scores which is when the participant went on holiday. The increase in BA is reliable, clinically significant and moderately effective at post which

then increases to highly effective by follow up. Changes in the VA scale were not found to be reliable and did not appear to be influenced by any particular element of the intervention.

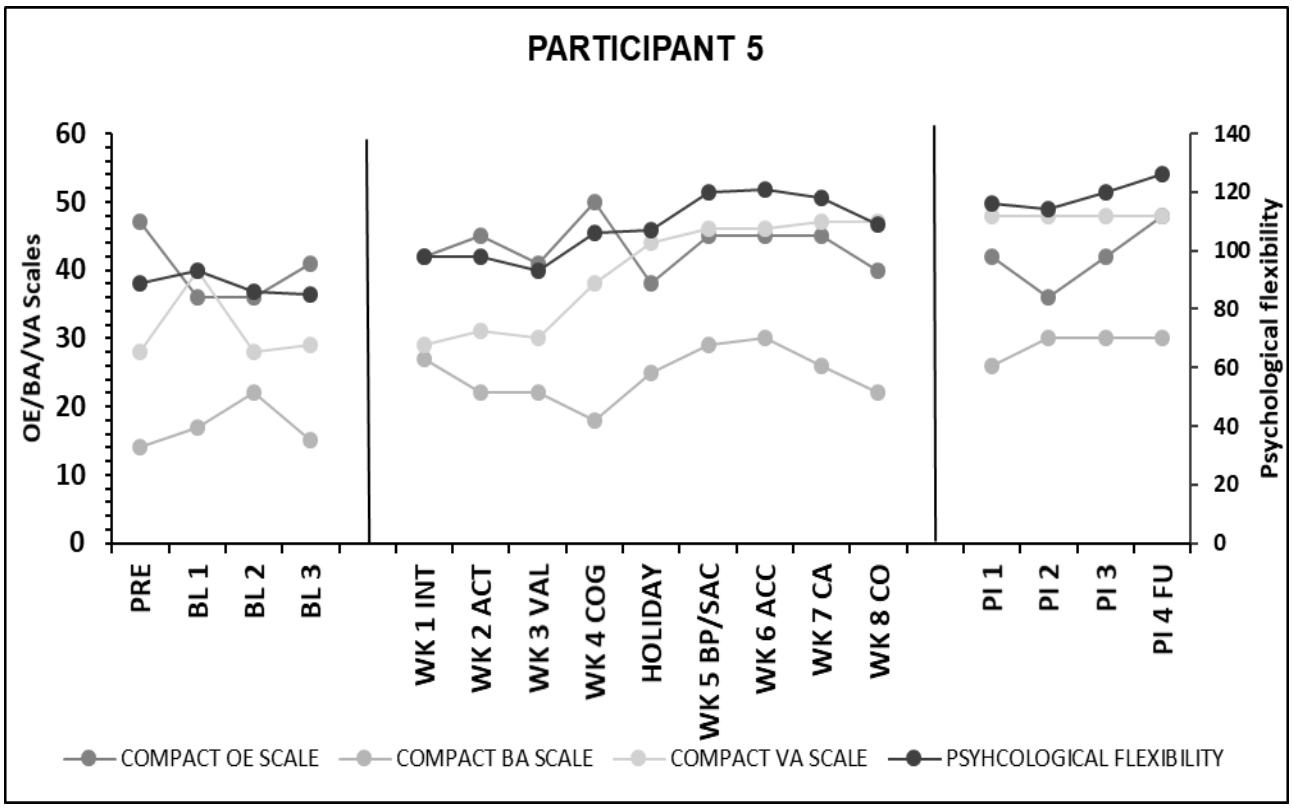


OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 23: Individual change for dyadic ACT processes – measured by the CompACT for participant 4 across all phases of the intervention

Participant 5

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 5 are shown in Figure 24. Change within the OE scale was not found to be reliable and whilst the scale appeared to be influenced by the delivery of the cognitive defusion material this was not maintained. Behavioural awareness (BA) appears to increase across the intervention and whilst change at follow up was reliable and clinically significant it was found to be ineffective. This gradual increase in BA is in contrast to the SEQ scale where participant 5 reached and maintained a ceiling effect through the majority of the intervention. Change in the VA scale for participant 5 at post and follow up is found to be reliable, clinically significant and at least moderately effective. There is no clear pattern in the increase of psychological flexibility.



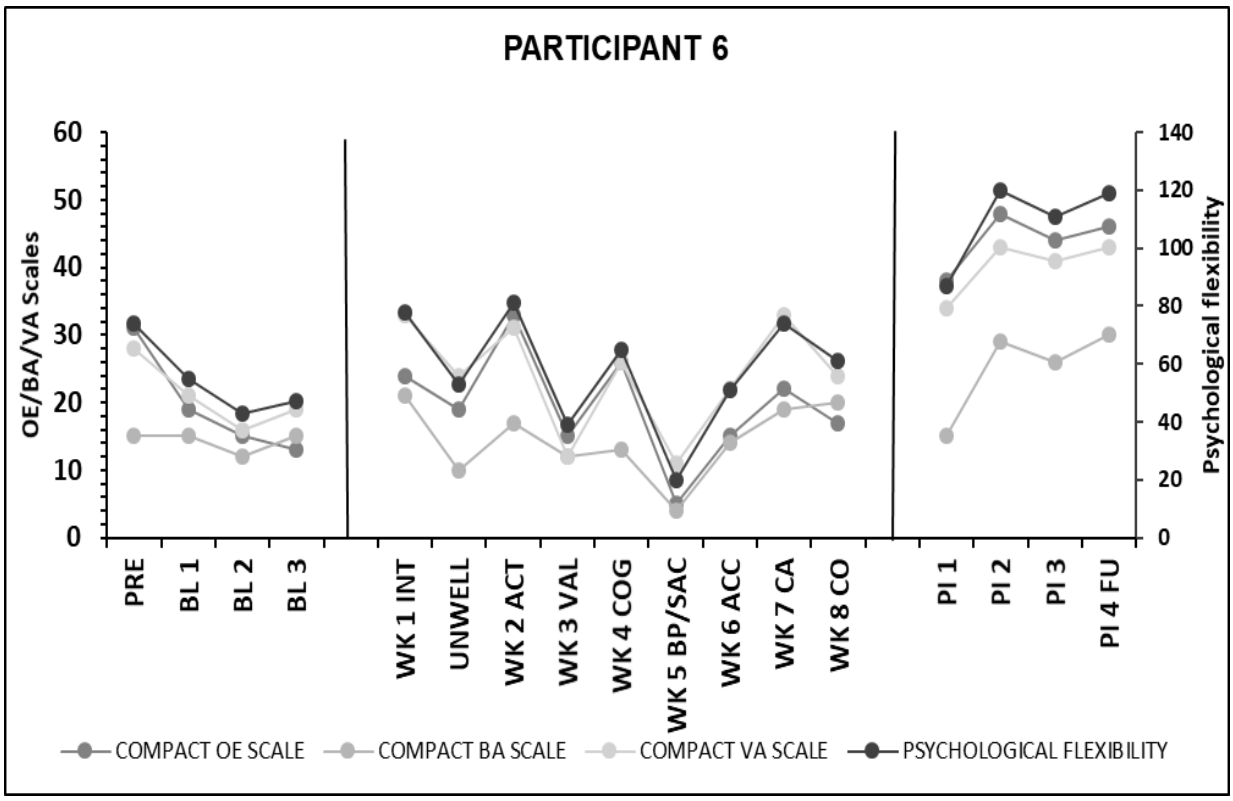
OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 24: Individual change for dyadic ACT processes – measured by the CompACT for participant 5 across all phases of the intervention

Participant 6

The total scores for psychological flexibility and the subscales of openness to experience, behavioural awareness and valued action for participant 6 are shown in Figure 25. Inspection of the OE scale visually appears to show an increase in OE at both post and follow up though further analysis shows that only the change at follow up is reliable, clinically significant and mildly effective. An apparent increase due to the influence of the introduction of cognitive defusion and acceptance is not maintained and appears to be inflated by the decreases in previous weeks. Participant 6 demonstrated

a decrease in behavioural awareness at post but demonstrated a reliable, clinically significant and mildly effective increase by follow up.



OE=openness to experience, BA=behavioural awareness, VA=valued action. Increase demonstrates improvement. PRE=Pre study measure BL=Baseline phase WK=Intervention phase (INT=Introduction, ACT=Creative Hopelessness, VAL=Values, COG=Cognitive Defusion, BP=Being present, SAC=Self-as-context, ACC=Acceptance, CA=Committed action, CO=Conclusion) PI=Post intervention phase.

Figure 25: Individual change for dyadic ACT processes – measured by the CompACT for participant 6 across all phases of the intervention

Levels of BA actually decrease the week that the relevant element of the intervention was delivered, and this matches findings within the SEQ which makes up the other half of the behavioural awareness dyad measure. There is a clear increase above baseline for the VA scale for participant 6 and whilst change was not reliable at post it was reliable, clinically significant and moderately effective by follow up. Participant 6's scores demonstrate the highest level of variation and often appear to be influenced by reported extrinsic factors. There are no clear patterns between elements of the intervention and the subscales within the CompACT and increases in psychological flexibility for participant 6.

3.11 Summary of dyadic processes as measured by the CompACT and SEQ

A summary of the individual and dyadic processes of ACT and how they influenced change in the corresponding weeks of the intervention are shown in Table 22.

Table 22: Summary of dyadic processes and the corresponding elements of the intervention

	OE Scale - CompACT		**BA Scale - CompACT**	**Conceptual self - SEQ**	**VA Scale - CompACT**	
Participant	Cognitive Defusion	Acceptance	Being Present	Self-as-context	Values	Committed Action
1	✓	✓	X	✓	X	✓
2	✓	✓	✓	✓	X	X
3	✓	✓	X	✓	X	X
4	X	✓	X	X	X	✓*
5	✓*	X	✓*	X	X	X
6	✓**	✓**	X	X	X	✓

✓= change was seen in the scale the week of the corresponding element of the intervention * = change was not sustained ** = change was preceded by decline X = no direct increase in line with delivery of the element

Openness to experience

The OE scale is targeted by the ACT processes of cognitive defusion and acceptance. Change within the OE scale of the CompACT at post was reported as reliable and clinically significant for participants 2, 3 and 4 but was not effective for participant 3 but was reliable, clinically significant and effective at follow up for participants 1-4. Participant 6 demonstrated a reliable, clinically significant but not effective non-beneficial decrease at post but then showed similar results in a beneficial direction by follow up. Participant 5 reported high levels in this scale throughout the study. Average PEM/DC analysis shows change to be mildly effective at post (.61) and moderately effective at follow up (.71). This scale appeared to be most directly influenced by the introduction of the corresponding elements (Table 22). Participants 1,2 and 3 appeared

to show an increase in the scale when both of the corresponding elements of the intervention were delivered. Participant 4 showed an increase only when the element of acceptance was delivered and whilst participant 5 showed an increase when cognitive defusion was delivered this increase was not sustained. Whilst participant 6 showed an increase in the OE scale that corresponded with the delivery of both cognitive defusion and acceptance these increases were preceded by decreases in the scale the previous weeks and only the increase after the acceptance week was sustained.

Behavioural awareness

The dyadic process within ACT is made up of being present which is measured by the BA scale of the CompACT and the self-as-context which is measured by the SEQ. The BA scale was found to be reliable, clinically significant and effective for participants 1, 2 and 4 at post and 1, 2, 4, 5 and 6 at follow up. Average PEM/DC analysis found it to be mildly effective at post (.65) and moderately effective at follow up (.72). The SEQ scale showed change to be reliable and clinically significant at post for participants 2, 3 and 4 but only effective for participant 2. Reliable and clinically significant change at follow up for participants 1, 2, 3, 4 and 6 and was effective for all except for participant 4. Average PEM/DC showed that change was not effective at post (.43) but mildly effective at follow up (.51). Participant 5 reached the ceiling effect at baseline. Only participants 2 and 5 showed an increased in the BA scale directly in line with the delivery of the being present element of the intervention and this increase was not sustained for participant 5. Increases in the SEQ scale were shown for participants 1, 2 and 3 in line with the delivery of the self-as-context element. It is important to note that the being present and the self-as-context elements are delivered in the same week and make up both elements of the behavioural awareness dyadic process.

Valued action

The valued action scale is made up by the ACT processes of values and committed action. Change within the VA scale were found to be reliable, clinically significant and moderately effective for participant 5 at post and reliable, clinically significant and at least mildly effective at follow up for participants 1, 5 and 6. Average PEM/DC analysis found change to not be effective at post (.46) and mildly effective at follow up (.59). No participants demonstrated an increase directly in line with the delivery of the values process of the intervention but participants 1, 4 and 6 showed an increase in the week

of the committed action element. However the increase was not sustained for participant 4. Worthy of note is that participants 1, 2, 3, 5 and 6 all showed a decrease in the value scale the week it was delivered.

3.12 Participant summaries

Participant 1

Participant 1 showed only a mildly effective increase in activity from an average 11319 steps per day rising to 11685 steps by follow up (+3.23%) although overall trend shows a decrease over the length of the intervention. At post participant 1's level of activity had dropped. The beneficial decrease in the level of psychological distress at post and follow up as measured by the DASS-21 was not reliable or effective. Participant 1 reported low levels of depression across the study despite a formal diagnosis of depression and taking several medications recorded as anti-depressants. It is of interest that symptom levels for participant 1 remained relatively stable across the study but beneficial decreases in the function, overall and overall impact within the FIQ-R were shown. Only the pre-post change in the function scale was reliable and clinically significant. Increase in psychological flexibility (CompACT) for participant 1 at both and follow up was shown to be reliable and clinically significant and in both cases, it was found to be mildly effective. Changes in participant 1's contextual self as measured by the SEQ were beneficial and mildly effective at both post and follow up though only change at follow up was reliable and clinically significant.

Whilst levels of activity showed little change following the intervention for participant 1, there were beneficial decreases in both psychological distress and the impact of their fibromyalgia and beneficial increases in both psychological flexibility and contextual self as seen in Figure 26. The beneficial changes made at post were either sustained or increased by follow up.

Participant 2

Whilst participant 2 showed an overall increase in levels of activity across the study (41.52% increase from pre to follow up) this was not found to be effective. The beneficial decreases in psychological distress (measured by the DASS-21) for this participant at post were sustained at follow up and were highly effective although not reliable. Participant 2 had relatively high levels of fibromyalgia symptoms (measured by the FIQ-R) throughout the study. However, participant 2 demonstrated beneficial changes in the functioning, overall attachment with the diagnosis and the overall impact of

fibromyalgia which were highly effective at both post and follow up. The difference between the subscales is highlighted by Table 23 which shows the same level of symptoms in the baseline phase and then at follow up and the contrast in scores for the other subscales between the two time periods.

Table 23: Contrast in subscales of the FIQ-R from baseline to follow up for participant 2

Period	Function	Overall	Symptoms	Overall impact
Baseline phase	17	13	33	62
Follow up	5	0	33	38

The change in psychological flexibility (CompACT) for participant 2 mirrored that of participant 1 in that it was reliable, clinically significant at both post and follow up measures and change was deemed mildly effective. The beneficial increases shown in the SEQ measure for participant 2 were reliable, clinically significant and found to be moderately effective at both post and follow up.

Whilst levels of activity did increase over the course of the study for participant 2 the increase was not effective. However, the beneficial changes in all other measures were at least moderately effective (highly effective in the CompACT, DASS-21 and FIQ-R) at both post and follow up demonstrating that beneficial change was sustained.

Participant 3

Participant 3 is the only participant to demonstrate a beneficial increase in their level of activity that was deemed effective at both post and follow up although levels decreased between post and follow up (highly effective and 20.62% increase at post & moderately effective and 5.27% at follow up). Despite this, extreme variation in the range of levels of activity (7451-15388) particularly in the earlier period of the intervention results in a downward overall trend line (Figure 26) so that visual and statistical analysis are not congruent. Participant 3 reported relatively low levels in the three subscales of the DASS-21 throughout the study so that even though change was beneficial it was not reliable or effective. Relatively low levels were also reported by participant 3 in the function, overall and symptom subscales of the FIQ-R although there was enough variation over the period of the research for highly effective beneficial change to be reported at both post and follow up for the overall subscale and the total overall impact of fibromyalgia. Mildly effective beneficial change which was reliable and clinically significant was reported at post and follow up for her fibromyalgia symptoms. Again, beneficial change in psychological flexibility (CompACT) for this participant was deemed

reliable and clinically significant at both post and follow up although this was only effective at follow up. Reliable and clinically significant change was also reported at post and follow up for the SEQ scale although this was only effective (mildly) at follow up.

For participant 3 levels of activity did show beneficial and effective increases across the course of the intervention and whilst still a beneficial increase this had reduced by follow up. All other scales showed beneficial increases (or decreases dependent on the scale) at both post and follow up that were sustained or increased in the level of effectiveness by follow up.

Participant 4

Participant 4 demonstrated a decrease in levels of activity by post which then changed to a beneficial increase by follow up (14.24%) although this was not effective and overall, there was a downward trend in the level of activity (Figure 25). This participant reported the highest levels of depression, anxiety and stress at premeasure amongst the six participants which appears to decrease directly at the start of the intervention. The beneficial decrease in the level of psychological distress as measured by the DASS-21 was reliable and clinically significant at both post (moderately effective) and follow up (Highly effective). Like participants 1 and 2, scores within the function and overall scales of the FIQ-R change in contrast to the symptom scale for participant 4. By follow up participant 4 reported higher levels of symptom severity than at premeasure, yet considerably less impact on their impact and overall disablement by fibromyalgia (Table 24). Beneficial change in function and the overall disability perception scale was reliable and clinically significant at both post and follow up and was highly effective by follow up. Whilst there was a beneficial, reliable and clinically significant change at post for the symptom scale this had changed to a moderately effective reliable and clinically significant non beneficial increase in symptoms at follow up.

Table 24: Contrast in subscales of the FIQ-R from baseline to follow up for participant 4

Period	Function	Overall	Symptoms	Overall impact
Baseline phase	20	14	29*	63
Follow up	3	2	33*	38

*Scores chosen from each phase for similarity in symptom scale for comparison

Yet again this participant demonstrated reliable, clinically significant and effective change in their level of psychological flexibility (CompACT) which for this participant

increased between post and follow up. Change within the SEQ was reliable, clinically significant but not effective at both post and follow up.

Levels of activity for participant 4 demonstrated a numerical increase, but this was not found to be effective and the overall trend appears to show a slight decrease across the period of the study. There was a non-beneficial increase in symptomology at follow up, but all other scales showed beneficial increases or decreases at both post and follow up that were sustained or increased in the level of effectiveness by follow up.

Participant 5

Whilst participant 5 showed a slight increase in their level of activity at follow up (1.66%) it had decreased at post and both changes were not effective. The overall trend for activity levels remained relatively stable (Figure 26). Levels of psychological distress measured by the DASS-21 showed a non-beneficial reliable and clinically significant increase at post which appears to be heavily influenced by the depression scale. Participant 5 reported relatively high levels of function impairment, overall disability perception and symptom severity across the intervention but as with previous particpants there was variation in the relationship between the subscales as shown in Table 25. Change across all scales of the FIQ-R were not found to be effective though changes in the overall, symptom and overall impact were deemed reliable and clinically significant at follow up.

Table 25: Contrast in subscales of the FIQ-R between baseline and follow up for participant 5

Period	Function	Overall	Symptoms	Overall impact
Baseline phase	25	16	41*	82
Intervention phase	21	10	40*	71
Follow up	24	14	40*	78

*Scores chosen from each phase for similarity in symptom scale for comparison

Increases in psychological flexibility at both post and follow up as measured by the CompACT were highly effective but only reliable and clinically significant by follow up. Participant 5 reached the ceiling effect within the SEQ scale at baseline and remained there with little variation throughout the remainder of the study. Therefore, whilst change showed a beneficial increase at post sustained at follow up this change was not reliable nor effective and should be interpreted with caution.

Levels of activity remained relatively stable throughout the study for participant 5 but only changes within the CompACT scale were found to be effective (highly effective

beneficial increase in psychological flexibility). There was variation in the relationships between the subscales of the FIQ-R.

Participant 6

Participant 6 demonstrated a decrease in their level of activity at both post and follow up (-24.65%) however this change was not effective due to the variation throughout the study and the overall trend was relatively stable (Figure 26). The DASS-21 scale showed non-beneficial increases in depression, anxiety and stress at post, but all scales had reduced beneficially from both pre and post by follow up. The reduction in overall psychological distress by follow up was reliable, clinically significant and mildly effective. Participant 6 also reported a non-beneficial increase in their symptoms as measured by the FIQ-R at post and this reliable and clinically significant change was sustained at follow up though not found to be effective. Again, there was a significant variation in the relationship between the symptoms scale and the function and overall scales which can be seen in Table 26.

Table 26: Contrast in subscales of the FIR-R from baseline to follow up for participant 6

Period	Function	Overall	Symptoms	Overall impact
Baseline phase	16	14	29*	59
Follow up	0	0	33*	33

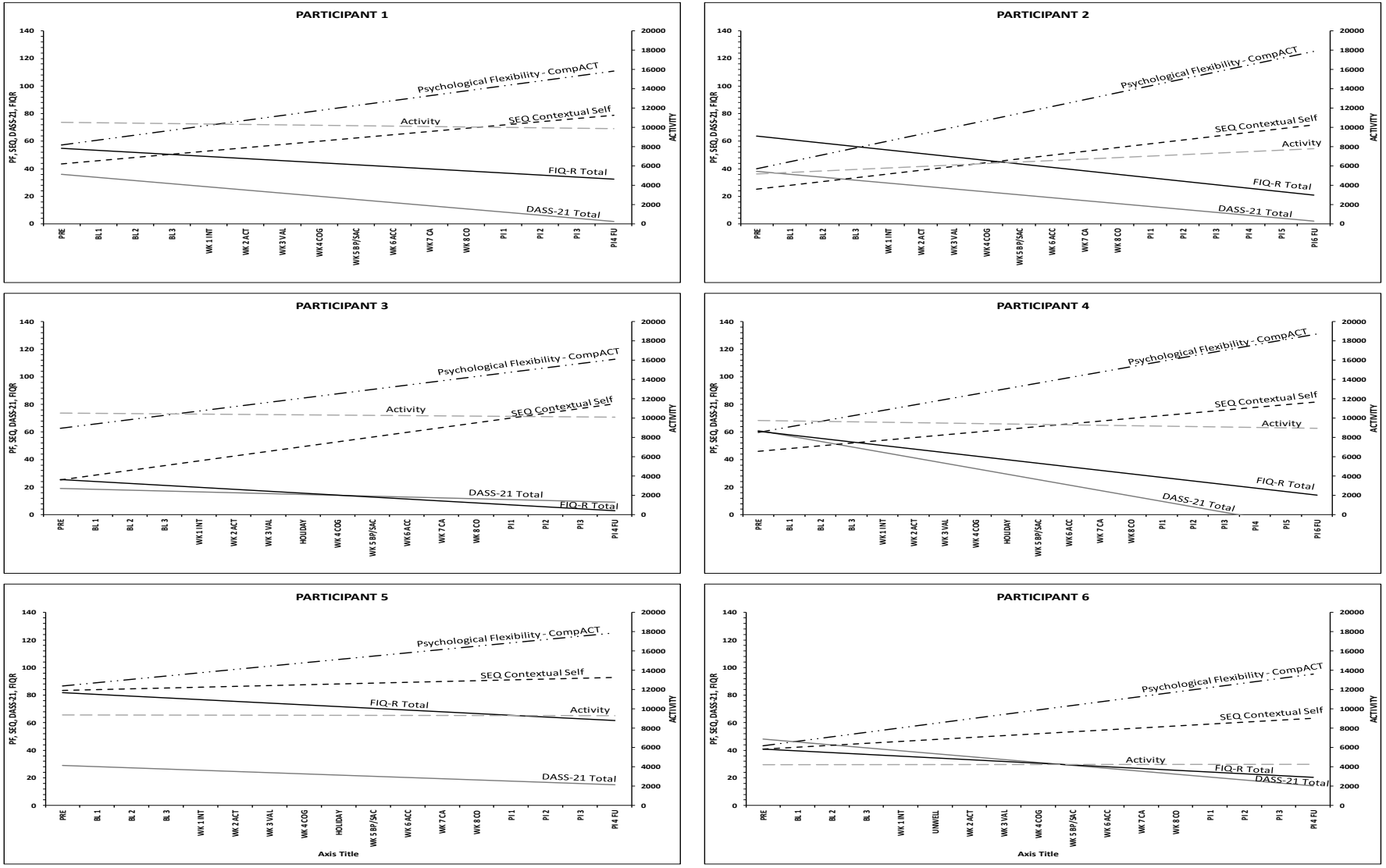
*Scores chosen from each phase for similarity in symptom scale for comparison

A moderately effective, reliable and clinically significant increase in psychological flexibility was seen at follow up although for this participant there had been a non-beneficial decrease in levels of psychological flexibility (CompACT) at post. Changes in the SEQ showed non-beneficial change at post but then improved to a beneficial increase by follow up which was reliable, clinically significant and mildly effective.

The level of activity for Participant 6 was relatively stable across the study though post and follow up measures suggest a decrease. Change at post was non-beneficial for all measures which was then resolved to a beneficial change (from pre) by follow up. This may have been influenced by external factors as there is a higher level of variance within the data than for the other participants and participant 6 reported adverse external conditions. The contrast between the symptom scale within the FIQ-R and the other scales is the starkest for participant 6.

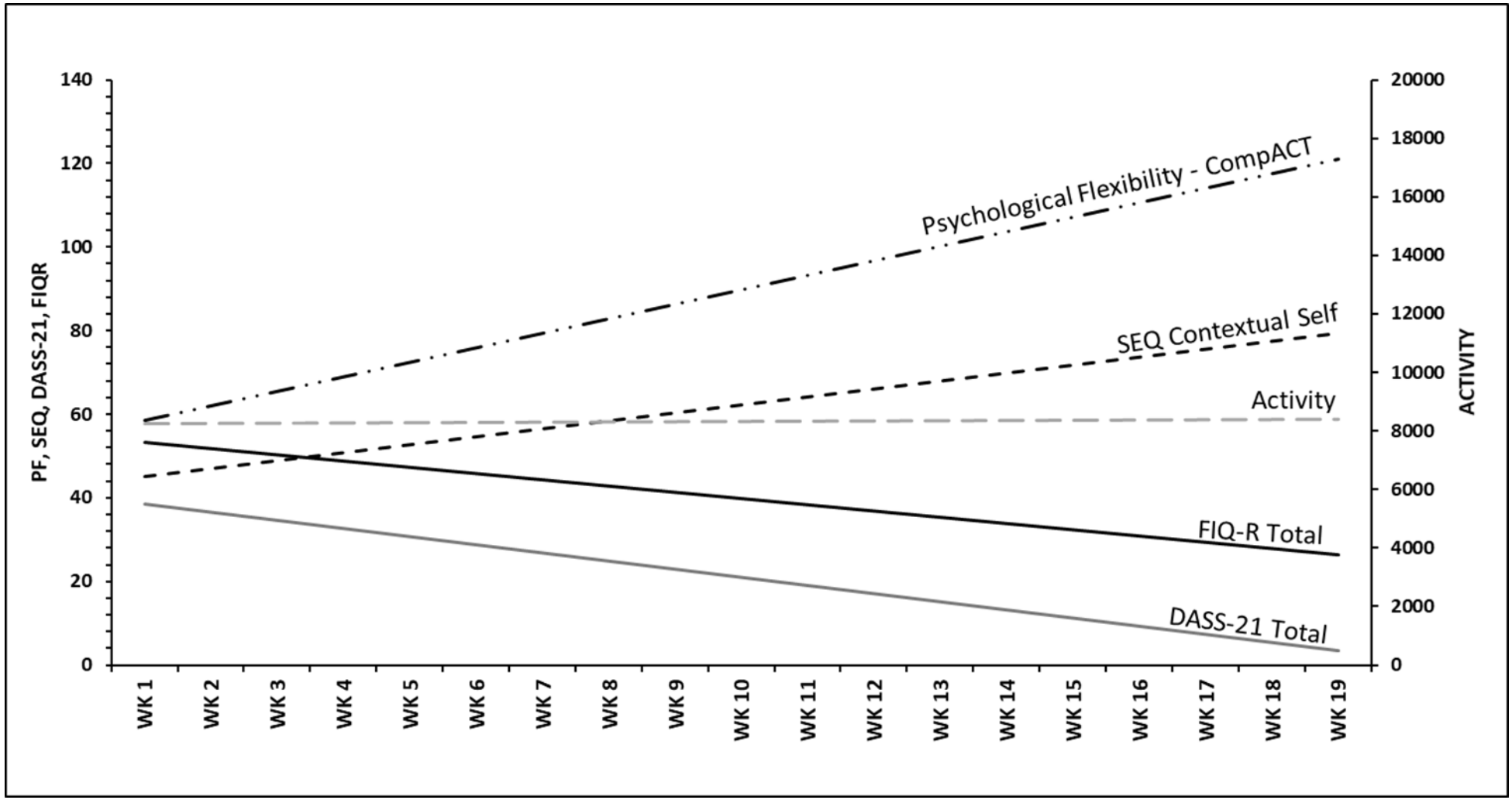
3.14 Overall summary

Levels of activity for all participants fell within the normative range with participants 1,3,5 and 6 exceeding the optimum levels of daily activity on average for their categories. Overall effect for levels of activity demonstrated a slight non-beneficial decrease at both post (Tau-U=-0.23) and follow up (Tau-U=-0.10) measured by the Fitbit. There was a beneficial statistically significant increase / decrease in levels of psychological distress (Tau-U = 41% improvement at post and 60% improvement at follow up) (measured by the DASS-21) and in psychological flexibility (Tau-U = 64% improvement at both post and follow up) (CompACT). Whilst there was a beneficial increase in the level of conceptualised self (measured by the SEQ) at both post (Tau-U = 29% improvement) and follow up (Tau-U = 50% improvement) this was only statistically significant at follow up. The overall levels of increase / decrease in these outcomes can clearly be seen using overall trend lines in Figure 27.



Dotted lines = increase denotes benefit Solid line = decrease denotes benefit

Figure 26: Aggregated overall trendlines for all measures for all participants for all phases of the study



Dotted lines = increase denotes benefit Solid line = decrease denotes benefit

Figure 27: Average overall trend lines for all measures across the intervention for all participants

3.13 Framework analysis

A priori themes generated by the change interview (Appendix E) were a) the intervention; b) change and; c) ACT processes. Immersion of the data by the primary researcher through listening and transcription then allowed the identification of an expanded framework based on these themes, which can be seen in Figure 28. Further detailed analysis including quotes can be found in Appendix K.

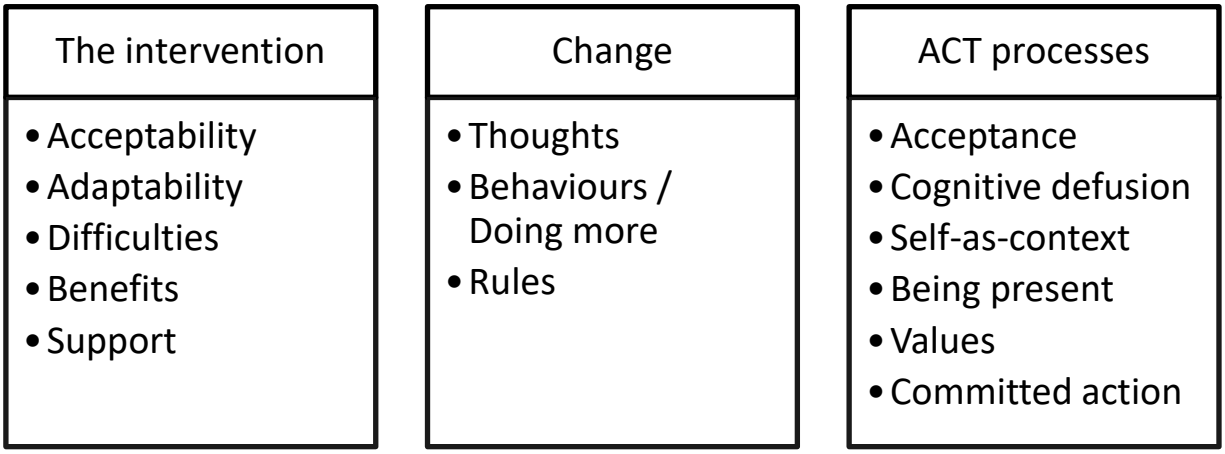


Figure 28: Expanded themes from framework analysis

The intervention

Acceptability

When asked about the acceptability of the intervention all participants specified there was no element that was unacceptable. However, participants 3 and 6 reported they found the language within the intervention to be slightly 'jargonistic' and 'Americanised'. Whilst this could have been a potential barrier to participation and mirrors some of the concerns of Akiens, (2016) and Johnston *et al*., (2010) in relation to the complexity of the text, participant 2 mentioned that they found the intervention to be well written, easy to follow and not too 'self-helpy'.

Adaptability

Four of the six participants referred to the adaptability of the intervention even though this was not directly elicited which tentatively supports the ideology of ACT being transdiagnostic. Participants 1, 2 4 and 6 felt they could apply the intervention to other aspects of their lives such as fatigue, anxiety or life stressors and not just their pain. Participant 4 felt the intervention and some of its elements would be of benefit to her friends and to her son and the situations they were facing.

Difficulties

Time was an aspect of the intervention that participants reported as difficult including finding the time between work and family life to engage with the materials (participants 2, 3 and 6) and some weeks feeling there was a lot of content and therefore feeling rushed to complete the exercises before the next week's information arrived. However, participant 4 reported that they felt there was adequate time to do the exercises and it was timed well. Participant 6 also mentioned struggling to take in the content of the intervention when feeling 'brain fogged'. Participants 1 & 4 mentioned that the experiential exercise they found most difficult was the funeral exercise but despite this they found it beneficial. Participant 6 reported struggling with visualising her pain and preferred not to write things down.

Benefits

Both participant 1 and 4 mentioned that having a paper copy of the intervention was beneficial as it allowed them to engage with the materials at their leisure and return to and organise them. Three participants found the use of metaphors useful particularly the monsters on the bus metaphor which demonstrates values and committed action (participants 4 & 5) and participant 1 found the dartboard exercise (values) the most beneficial. Participants 2, 3 and 6 recognized there was a benefit to the experiential nature of the intervention which is a key tenet of ACT and they also reported that it was an accumulative process rather than driven by any specific week or exercise which supports the findings of the increases in psychological flexibility reported in this study.

Support

When asked about the telephone support all six participants said they found them beneficial for a range of reasons such as offering the opportunity to ask questions (P6), providing a space to verbalise and cement learning (P2), and to keep the intervention fresh in the participants mind (P1). Two of the participants stated that they missed the telephone calls when they ceased at the end of phase B1 (P1 and P5) although participant 4 felt potentially that it was unnecessary for the calls to be weekly and it was just good knowing there was someone there if required. The relationship between the researcher and the participants could be considered a non-specific factor which could influence the outcome of this study.

Change

Thoughts

All six participants report a noticeable shift in their thinking, specifically away from battling their thoughts for up to ten years (P2), being consumed by their thoughts (P3) and being dragged down by them (P1). Participant 6 stated she felt her thoughts had reversed with both participants 4 & 5 noticing a change from 'can't to can' and a shift in the way they perceive their illness (see ACT processes for further detail).

Behaviours / 'doing more'

Whilst overall the level of activity measured by the Fitbit did not show an increase over the course of the intervention all six participants reported 'doing more' and having changes to their behaviour which they considered to be positive. Three of the participants (P2, P4 & P6) reported significant reductions or cessation of pain medication which they had previously reported as ineffective but were still taking which supports the findings of (Taylor *et al*., 2019). Participants 1 & 2 talked about getting back in touch with people and increasing their social activities with participant 3 talking about being more involved, Participant 3 reports that during the course of the intervention she started and successfully completed the couch to 5k task (a programme designed to get people running), participant 4 reports joining the gym and not spending days sitting on the sofa and participant 5 started swimming and went on a family holiday for the first time in 4-5 years which they all report is something they only considered because of the intervention.

Rules

All six participants reported a change in the rules they applied to their behaviours from a categorical 'I can't' mindset to an 'I can' and why not. Participant 3 identified that she believed she didn't have rules surrounding what her pain restricted her to do prior to the intervention but working through the exercises she recognized how restrictive her life could be to 'avoid the pain'. Participants 1, 2, 5 & 6 discussed that they recognised the 'pain' or tiredness would still be present, but this wasn't a reason to not engage in activities.

ACT processes

Acceptance

Participants 1, 2, 4 and 5 made comments that were coded as demonstrating avoidance / acceptance. Participant 1 discussed accepting things she recognised were beyond her control which altered the experience of stress at work, whereby participant 4 talked of taking the kids and the pain with her rather than not going out. Participant 5 had previously refused to go on holiday because she would be in pain. During the intervention she chose to go on holiday accepting that she would probably experience pain, but she would also experience being on holiday. Participant 2 discussed the paradox of experiential avoidance that the more she thought about the pain, the more she experienced it as discussed by Wang *et al*., (2019).

Cognitive defusion

Participants 1, 2, 5 and 6 made comments that were coded as cognitive fusion / defusion. All four of these participants reported recognizing thoughts as just thoughts, separating from their thoughts and not being governed by them. Participant 2 recounted the quicksand analogy used in the intervention to describe her previous struggle with her thoughts.

Self-as-context

Participants 1, 3, 5 and 6 made comments that were coded as aspects of the conceptualised self in relation to having fibromyalgia. Participants 1 and 3 talked about the things they had previously felt incapable of doing due to their fibromyalgia and how they were ill because of the fibro. Participant 1 discussed how she had then reevaluated whether perhaps she was being lazy rather than ill and participant 3 recognising that she could do these things even though she had fibromyalgia. Participant 6 detailed how she no longer considered herself to be ill but now saw herself as a capable individual who happened to have fibromyalgia. Participant 5 discussed how she had felt controlled by the fibro but was now ‘the boss’ of it.

Being present

Participants 1, 2 and 4 made comments that were coded as referring to being present. Participants 1 and 4 noticed taking time out and relaxing whilst participant 2 noted that she was no longer fixed on getting to a destination to reduce pain but was now enjoying the experience of the journeys that she took.

Values

Participants 1, 2 and 6 made comments that were coded as referring to values. All three participants reported evaluating the way they were living when they examined what was important to them and recognising that the way they were living was not placing the things that were important to them at the forefront of what they were doing.

Committed action

Participants 1, 2, 3, 5 and 6 made comments that were coded as referring to committed action. Participants 1, 2 and 5 talked about doing more, getting on with things and no longer saying no automatically. Participants 2 and 6 specified that for them 'doing more' was aligned with moving towards living in line with their values and what was important to them as individuals.

3.14 Results summary

Table 27 which has been amended from Table 3 demonstrates the outcomes posed to the original questions set out in the aims of this research.

Table 27: Results summary table

Questions	Sources of evidence	Hypothesis	Result
Does the primary outcome demonstrate change? Do levels of activity change?	Number of steps taken daily as measured by the activity tracker measured at pre, post and follow up.	It is expected that the intervention will increase levels of physical activity	Overall levels of physical activity overall did not increase An increase in meaningful activity was reported
Does the primary process outcome demonstrate change? Do levels of psychological flexibility change?	Pre, post and follow up scores of the total CompACT	It is expected that the intervention will increase levels of psychological flexibility – tested using RCI, CSC and PEM/DC and Tau-U	Levels of psychological flexibility were shown to be beneficially increased at both post and follow up for all participants at all levels of analysis
Are changes in the primary outcome measure linked to changes in the primary process variable? Are changes in levels of activity linked to changes in psychological flexibility?	Number of steps taken daily as measured by the activity tracker Weekly scores of the total CompACT	It is expected that an increased level in psychological flexibility is linked to an increase in physical activity.	No pattern emerged between psychological flexibility and levels of physical activity
Do the secondary outcomes demonstrate change? Has the level of psychological distress changed? Has the level of functional impairment in a fibromyalgia sufferer changed? Has the impact of fibromyalgia changed? Has the severity of symptoms for fibromyalgia changed? Has the overall impact of having fibromyalgia changed?	Pre, post and follow up scores of the total and individual elements of the DASS – 21 Pre, post and follow up scores of the total and individual elements of the FIQ-R	It is expected that the intervention will decrease the level of psychological distress and the impact of fibromyalgia – tested using RCI, CSC and PEM/DC and Tau-U As ACT does not specifically target symptom reduction there is no hypothesis in relation to the functional impairment or symptom severity of fibromyalgia.	Levels of psychological disease perception and the overall impact of fibromyalgia were reduced for all participants Levels of symptoms severity remained stable or increased for three participants however levels of functional impairment reduced for all participants even in the presence of pain

Questions	Sources of evidence	Hypothesis	Result
Do the ACT process variables change? Are there changes to levels of experiential avoidance? Are there changes to levels of cognitive fusion? Are there changes to the conceptual self? Are there changes to the level of losing contact with the present? Are there changes to the levels of connection with values? Are there changes to the levels of inaction?	Pre, post and follow up scores of the subscales of the CompACT Pre, post and follow up total scores of the SEQ Change interview	It is expected that following the intervention there will be increased levels in acceptance, cognitive defusion, the conceptual self, being present, contact with values and committed action.	There was a beneficial increase in the dyadic processes (measured by the CompACT & the SEQ) for all scales at post and for all except for P4 in the VA scale at follow up. The change interview appears to support these findings
Are outcome changes linked to individual elements of the intervention? Are any changes observed in the primary outcome linked to an ACT process variable as delivered by the intervention?	Number of steps taken daily as measured by the activity tracker Weekly scores of the subscales of the CompACT Weekly total scores of the SEQ	No hypothesis	No apparent link was shown between levels of activity and elements of the intervention
Do the process variables within ACT change following the introduction of the corresponding elements of the intervention? Are any changes observed in the ACT process variables linked to the weekly intervention?	Weekly scores of the subscales of the CompACT Weekly total scores of the SEQ Mapped to the introduction of intervention chapters	No hypothesis	No clear pattern of influence between the weekly process variables and the weekly intervention was reported between participants

RCI=reliable change indices, CSC=clinically significant change, PEM/DC=percentages exceeding baseline median dual criterion analysis, Tau-U= Tau-U analysis

4.0 Extended discussion including limitations and strengths

There was a beneficial increase in psychological flexibility at follow up for all six participants which included an increase from post measures for four of the six participants. There did not appear to be the emergence of any clear pattern to suggest links between particular elements of the intervention and psychological flexibility and together this could suggest that positive changes in psychological flexibility are an accumulation of the processes of ACT, developed as a longer-term outcome that can be sustained or improved upon. The assumption of an accumulation or 'carry-over' effect, which has been shown to influence therapeutic outcomes (Kessner *et al*., 2014) appeared to be supported by data from the change interviews as participants refer to the 'knock-on' effect of the intervention. This accumulation of processes could go some way to explain why studies in to ACT fail to agree on one specific ACT process as the mechanism of change for psychological flexibility or other outcomes (Hamil *et al*., 2015, Bramwell & Richardson, 2018, Yu & McCracken, 2016, Felsman *et al*., 2017, Vowles *et al*., 2019, Galan *et al*., 2019).

This study aimed to examine mechanisms of change for an ACT intervention within a fibromyalgia population. However, there were several issues that limited conclusive inferences being made in relation to the ACT processes. In terms of the dyadic processes of ACT, all six participants demonstrated a beneficial increase in openness to experience, behavioural awareness and valued action by follow up. The OE (openness to experience) scale made up of cognitive defusion and acceptance appeared to show the most promise in terms of identifying patterns in relation to increases in the process measure and the delivery of the corresponding element of the intervention. This is coherent with ACT as an intervention as Hayes *et al*., (2006) detail that cognitive fusion (defusion) and subsequently experiential avoidance (acceptance) are a key target of ACT as a therapy. However, within ACT the core processes are intertwined and cognitive defusion and acceptance are interconnected as a dyadic process as measured by the CompACT (Francis *et al*., 2016). The CompACT only measures dyadic processes and not individual core processes so it is hard to identify singular mechanisms of change just from using this measure.

Whilst overall there was a beneficial increase in the VA scale (values and committed action) across the intervention and at follow up, none of the participants demonstrated an increase in the scale in the week that the corresponding element of the value process was delivered. This was potentially influenced by the order in which the intervention

was delivered as the values process is towards the start of the intervention and directly after the creative hopelessness element which identifies failed strategies. Additionally in what could be identified as a demonstration of the paradox relating to the salience of thoughts (Wang *et al*., 2019), participants reported realising at this point (as it had been brought to their attention) that they were not living in line with their values. Potentially this paradox may go some way to explain a decrease in the VA scale for five out of the six participants at that point in the intervention. In addition to the above whilst the timing of the delivery of the intervention could be controlled, when it was engaged with and to what degree it was engaged with could not be.

This study also aimed to examine the self-as-context process which is so often omitted from ACT based research due to conceptual issues (Yu *et al*., 2017a). However whilst the other processes of ACT are distinctly targeted in their own right, the self-as-context is in fact targeted by other processes and it could then be argued then that the self-as-context is in fact a culmination of other ACT processes. Because the self-as-context as a process is ambiguous there is also a blur between the distinct processes of ACT being delivered e.g. some self-as-context exercises in the cog defusion weeks and the being mindful and self-as-context elements being incorporated in to one chapter etc. Therefore any inferences about change in relation to the self-as-context would be dependent on the result for the corresponding processes and could not be considered conclusive under these circumstances. See section 4.2 for further discussion on the self-as-context.

Considering the above it is impossible to disconnect any one ACT core process from this study to make any conclusive inference about the individual process mechanism of change.

Having highlighted some limitations of the study, the strengths of this study lie in its scientific rigor. There are multiple sources of analysis that offer consistent representations of the results and back up the primary source of visual analysis. A SCED design, whilst not the most common methodology, appears to be gaining greater use and understanding within the scientific community as it allows the measurement of individual difference by utilizing the multiple baseline design (Swoboda, Kratochwill & Levin, 2010). The SCED design also goes some way to allow generalisability due to the direct replication between particpants and further forms of analysis that are being developed (and which have been shown in this study) allowing for comparisons with other forms of research. However, this must be tempered with the understanding that

the SCED design cannot extend generality across settings and populations (Dallery *et al*., 2013). To fully claim generalisability of the intervention would require the systematic replication of this study extended to other populations (such as those newly diagnosed as previously suggested) and to other settings. The use of supported telephone calls allowed change and extrinsic events to be monitored which increased the ecological and internal validity of this study and the change interview added further meaning and understanding to the data.

4.1 Discussion in context of theory

Behaviourism dictates that all behaviour is learned through conditioning (Thieme & Turk, 2012) and Luciano *et al*., (2014) outlined that within a CBT framework lack of activity in chronic pain conditions is considered to be a result of unhelpful beliefs and behaviours that are formed as a response to symptoms such as pain. Individuals reduce their levels of activity as a natural and understandable reaction to unpleasant sensations and over time these reduced levels of activity impact social and functional abilities. Participants in this study all reported 'doing less' as a direct result of their fibromyalgia symptoms which epitomises a behavioural perspective.

Treatment guidance for fibromyalgia is based predominantly upon increasing activity and a CBT focus would be on altering cognitions or on direct behavioural change (Buckelew *et al*., 1994) to achieve this. Previous behavioural change interventions for a fibromyalgia population have been reported to be ineffective (O'Dwyer *et al*., 2019). Acceptance and commitment therapy is based on RFT, which states that conditioning occurs via repetitive environmental cues and symbolic activity (language) within relational frames. Whilst ACT also acknowledges the importance of cognitions and behaviour change, indeed the cognition 'that if I go out I will be in pain' may well be true for individuals with fibromyalgia, it is the restrictive and avoidant action that an individual engages in to avoid pain due to the fusion with those thoughts which ACT targets (Hayes *et al*., (2006). The fundamental difference between CBT and ACT appears to lie in the location and nature of reinforcers.

The concept of values as reinforcers is unique to ACT within the behavioural paradigm, which Vowles *et al* 2019 reported was the process within ACT to elicit behaviour change as the reinforcement is then experienced and meaningful and individual. Values are augmentals in that they act as indirect reinforcers (da Silva Ferreira, *et al*., 2019) but then the subsequent valued action (the change in behaviour based on values) is the

predominant reinforcer most likely to maintain the behaviour change (O'Connor, Tennyson, Timmons & McHugh, 2019). From this perspective what defines CBT from ACT and other behavioural therapies is an internal locus of motivation and Anderson and Funnel, (2002) reported that meaningful change was more likely when freely chosen in line with individual values. It is important to acknowledge that this intervention did not increase levels of physical activity. However it did appear to engage the participants so that there was no attrition and it also appeared to elicit meaningful changes in behaviour.

In both CBT and ACT it is still the new experience that is sought (Raftery-Helmer, Moore, Coyne & Reed, 2016). ACT as a therapy is fundamentally experiential so that new information can be added to relational frames, opening up the repertoires of ways in which an individual can choose to respond to situations. This is because as individuals engage in experiential avoidance the insensitivity effect makes the tracking of negative outcomes more salient and more reinforcing and new experiences allow new information into the relational frame for new relationships to be formed. The participants in this study all demonstrated increases in their openness to experience as they chose to revaluate how they were living in the presence of pain. By increasing their levels of acceptance and defusing from their thoughts about how to avoid their pain participants had engaged in new behaviours. Three participants spoke of no longer taking pain medication which Taylor *et al*, (2019) had reported fibromyalgia sufferers continued to take despite being ineffective. This potentially demonstrates an ability to now track natural contingencies to their experience. Revisiting previously enjoyable experiences even in the presence of pain, such as going on holiday or increasing levels of socialisation appears to have allowed a value driven augmental process, whereby through formative augmentals new consequences were formed or through motivative augmentals the pain became less of a focus.

4.2 Opinion and original consideration

ACT research acknowledges the difficulty and ambiguity surrounding measuring and fully understanding the self-as-context process and subsequently the lack of research focus surrounding it (Francis *et al*., 2017, Yu *et al*., 2017a). This study attempted to include the self-as-context process to address this issue and because how individuals perceive themselves is reported to be important to people with fibromyalgia (Armentor, 2017). However, from a theoretical perspective this author suggests that there appears to be a fundamental conceptual dilemma. The definition of the term 'processes' is '*'a*

series of actions directed towards an end". In the case of ACT, the core processes are hypothesised to work directly towards an end which is psychological flexibility. In the case of acceptance, cognitive defusion, being present (mindful), values and committed action, the target of the process is clear with evidence-based techniques utilised to cultivate that specific element of psychological flexibility. However, in the case of self-as-context there is no clear target or method related solely to the process.

The self-as-context is made up of three entities (content, process and context) which are reported to be targeted by the other processes in the same way that they target psychological flexibility i.e. the self as content is targeted by cognitive defusion and the self as process is targeted by mindfulness (Yu *et al*., 2017b). The self as context element of the self-as-context process is based on deictic relationships involving the understanding of others perspective of the self. Therefore, measuring this element of the self-as-context process would involve either the insight of others or the interpretation of how an individual believes others to perceive them. Whilst the SEQ (Yu *et al*., 2017a) sets out to measure the self-as-context, it too acknowledges its struggle with defining the concept and outlines how the measure is only a measure of two elements of the self-as-context process. It could therefore arguably be a combined measure of cognitive defusion and mindfulness. In later consultation with the authors of the CompACT it was reported that similar questions to those on the SEQ were discounted from the Delphi method used in the construction of the CompACT either by expert consensus or because psychometrically they did not fit.

Ciarrochi, Sahdra, Marshall, Parker and Howath, (2014) examined ACT processes in relation to psychological flexibility and weight. The study also highlighted the lack of research in to self-as-context and perhaps surprisingly for a study that focused on aspects of self-knowledge did not include it in their measures. Ciarrochi *et al*., (2014) reported that dependent on an individual's weight range (underweight, overweight and obese) there were differing profiles of experiential avoidance, cognitive fusion, loss of contact with the present, loss of contact with valued living and inaction. They concluded that psychological flexibility was not a unitary construct but was a unique balance of the processes of ACT, dependent on how an individual perceived themselves and how they believed others perceived them, which are the two aspects of the self as context element of the process. According to Ciarrochi *et al*., (2014) the process profiles changed in relation to how individuals viewed themselves and perceived others to view them with those in lower weight ranges more able to work towards goals as they were

less impacted by social influence having higher levels of acceptance. This could suggest that acceptance is the process that targets the self as context element which would then mean that all three entities of the self-as-context are targeted by other ACT processes.

This researcher therefore puts forward the opinion that the ambiguity and difficulty in measuring and quantifying the self-as-context process could be that rather than being a process of psychological flexibility the self-as-context is in fact a dimension (which is defined as 'being a property of') of psychological flexibility. Indeed, Godbee and Kangas, (2019) reported in a recent review paper that there is limited evidence to support the use of the self-as-context component as a standalone process in ACT-based interventions. The Ciarrochi *et al*., (2014) study could go some way to support the hypothesis of this researcher if indeed the self as context element is found to be targeted by the acceptance process as this would mean that all three entities of the self-as-context process are targeted by other core processes and it is therefore not a process in its own right. Therefore, examining the self-as-context as a dimension of psychological flexibility rather than a process would be worthy of future investigation.

4.3 Applicability and clinical relevance

Hughes *et al*., (2006) and Perrot *et al*., (2012) had outlined the high use of healthcare provision both before and after diagnosis in a fibromyalgia population. The present study supports that an ACT intervention is effective for increasing psychological flexibility and functional abilities for individuals with fibromyalgia, which supports the delivery of ACT in a supported self-help format. This suggests that 1:1 interventions which are high in resource and costs are not necessary for ACT to be successful within this population. The National Health Service (NHS) long term plan (2019) identifies both digitally enabled and out of hospital care as its priorities, trying to introduce more individual methods of treatment at community level. Therefore, an ACT based supported self-help intervention offers treatment that is line with NHS strategy, whilst reducing healthcare utilization and opening access for less mobile, more rural, stigmatised and marginalised groups

4.4 Conclusions

The current study and intervention have met SCED evidence standards criteria and the findings of the research provide supporting evidence that increases in psychological flexibility lead to improvements in psychological distress, functioning, disability perception and overall quality of life for individuals diagnosed with fibromyalgia.

Therefore, this study supports ACT based supported self-help interventions for a fibromyalgia population.

4.5 Future recommendations

Findings within this current study lead to the following recommendations for future research.

- As participants within the study self-reported low levels of activity which were then refuted using electronic tracking devices, future research utilizing activity trackers to assess the actual level of activity in a larger sample of fibromyalgia sufferers would be advised. This could then be compared with their levels of self-reported activity. This may have clinical relevance for treatment guidelines that are built on the meta-analysis of current research based on the premise of lower levels of activity for individuals with fibromyalgia.
- As the sample used for this study had all lived with the symptoms and diagnosis of fibromyalgia for several years, which research suggests could be influential in an openness to engage with psychologically based interventions, future replication of this study focused on a newly diagnosed population of fibromyalgia patients would allow the results to be extended more widely.
- Whilst the actual levels of activity for individuals with fibromyalgia has been called in to question in this current study, previous research has reported the benefit for increasing activity and for engaging in exercise. This study highlighted that activity and exercise might not be value laden. Therefore, an ACT based intervention that specifically targets an increase in levels of physical activity would be worthy of investigation to assess if behaviour change can be elicited when not value laden.
- As this study was unable to determine the mechanisms of change between the ACT processes, it would be beneficial to replicate this study whilst a) randomizing the delivery of the ACT processes although this may require a large re-write of the text as it builds upon previous exercises and references previous exercises and b) use individual measures of the ACT processes and a separate measure of psychological flexibility. This would allow each process to be examined in more detail and for inferences regarding any patterns of change relating to the processes to be assessed. However, the use of seven measures (one for each ACT process and one for psychological flexibility) would increase participant burden quite significantly from the current study which utilised two measures for

these processes and would therefore have to be considered carefully on ethical grounds.

- Further replication of this study could potentially use a comparison of CBT to test out the premise that anything is better than nothing. This may require a review of the methodology used in this study.
- Whilst levels of psychological flexibility appeared to increase between post and follow up for some participants, replication of this study with a longer follow up period would be advised to see if levels continue to rise or are sustained over a longer period.
- To further investigate the self-as-context as a dimension and not a process of psychological flexibility. As the self-as-context is often omitted or takes a back seat in ACT research it may be time for it to become the focus of attention particularly with a potentially new viewpoint of its purpose within the model.

5.0 Critical reflection

The following section will outline my personal reflections on the research design, personal & ethical considerations and assumptions & growth using a reflection-on-action, reflection-in-action and reflection-for-action approach so that a past, present and future focus is given.

Research design; Having limited research experience before embarking on this study I was more familiar with the concept of randomised control trials as being the way to demonstrate efficacy of change for an intervention. Therefore the SCED design was something I knew little about and whilst reading suggested it was a methodology that was gaining ground within the scientific community I had initial doubts about using it for my research. On reflection these doubts were more to do with my own ability and wanting my research to be viewed as credible and worthwhile. However the more I read, the more I believed that this was a good design to study change at an individual level, which is something I considered particularly important with a disorder like fibromyalgia which has such a heterogenous and idiosyncratic population. I was disheartened at the original response to my ethics application from the ethics board in relation to my sample not being large enough to offer statistical power. This appeared to demonstrate a lack of understanding about the design. I felt that if a research ethics panel didn't understand my methodology then perhaps I should look at a method that was more familiar to others as well as myself. I went away and did further reading on the subject and still felt that to examine individual change and change mechanisms that

the SCED design was the best fit. I had a period of reflection and made a conscious choice to stick with my convictions and to attempt to show the worth of this methodology to give others a better understanding rather than shy away from something just because it wasn't the conventional norm. The analysis phase and the overall workability of the SCED has left me happy to have stuck with the SCED for the design of my research and going forward I have learnt not only new skills and new knowledge which have a practical application in my work but also a working example of when to trust myself when informed by evidence even if it is relatively limited in comparison to other methods.

In addition as I was to be the one making the weekly telephone calls I made the decision not to look at the data from the weekly measures until the end of the study as I felt that I may have been influenced or attempted to move participants in a certain direction dependent on seeing those results. Whilst I believe this really helped me stay more impartial during those phone calls it meant that I was unable to check on anomalies or unusual events within the data such as a ceiling effect for one participant in the SEQ measure. It is hard to know if I would have done anything differently under the circumstances but on reflection this would appear to offer a case for total researcher impartiality in future studies i.e. another clinician could make the weekly phone calls so that the data could be assessed on an ongoing basis and checks made without it potentially impacting the study.

Personal and ethical considerations: The weekly telephone calls also raised personal and ethical considerations. Firstly on a personal level I wanted to ensure that my participants were happy, so they felt ok about continuing in the intervention, but I also had to take a stance where I imposed personal boundaries. I had a participant who asked me to call her over the weekend, but my study days were Fridays and Mondays. I had previously considered this might happen particularly if participants were at work themselves and whilst I wanted the research to work I also wanted to maintain a work life balance that didn't intrude on to my family life. In this case I asked if there was a particular reason for the call to be on a Saturday/Sunday and did explain to her my study days. She said she was more than happy for me to call her after work on the Friday rather than at the weekend so fortunately this issue was resolved to a mutually beneficial satisfaction but this did make me resolute to keep a distinction between my work and my home life where possible.

In addition during the calls one of the participants disclosed a bereavement and this posed an ethical dilemma for me about her participation and also my role as researcher

/ support. I am already a qualified therapist having worked for several years specialising in bereavement amongst other things, so whilst I felt qualified to support this participant I questioned how this would impact her at a personal level and also how it would impact the results of my research. I discussed this in supervision and with the participant at length. She expressed a desire to continue with the study and felt that it might be a good time to learn new skills and have a distraction from her grief. I made her right to withdraw explicit yet again and we agreed to continue, and I was very transparent about what as a researcher I could and could not offer her in terms of support. I did prepare myself that she might not continue in the study, but then this was true for all of the participants. As it was she continued right until the end and reported how beneficial she found this. Her results are visually more erratic than the other participants and I wondered if they would weaken any arguments my results suggested. However, upon reflection I feel this demonstrates ecological validity and indeed strengthens the argument for the intervention as she demonstrated beneficial change even when real life painful events occur. Going forward I will remind myself that participants really are in charge of their own participation unless it is deemed unsafe, and that being transparent manages expectations on both sides as I think without agreeing the terms of the support offered I could have been drawn in to offering bereavement counselling which would have changed my role within the study.

Assumptions and growth: When I started out with this research study I was under the assumption that individuals with fibromyalgia needed to go and do more physical activity because that is what the evidence suggested. However this study has shown me that the whole premise of ACT which is about doing things that are more meaningful to you as an individual is more important to the individual than measurable physical activity and not everything worthwhile can be measured in the way we like it to be. I think I came with the thought that for ACT to work my participants needed to be physically doing more but they were doing more but in different ways and what I now need to take forward is the understanding of defining concepts. Doing more for the purposes of the study meant moving more but my participants had other ideas. They all felt they were doing more and enjoying more even if that wasn't shown on a graph as something we could report statistically. From a research stance this might encourage me to look at alternative outcomes to the ones I am focused on and to incorporate way of measuring alternatives into the research and this is why I am glad we had the qualitative element to capture this.

During the course of the research I had thoughts about the self-as-context which led me to have a seemingly unique idea about it in relation to ACT, as I was of the opinion that it was not a process within psychological flexibility but part of psychological flexibility itself. However as a trainee I was scared to voice this probably for fear of making myself look foolish or suggesting something against established norms. I think having reflected on this I would like to be braver in my future work and so I chose to include my consideration as part of my thesis. Perhaps that will be a mistake but then I have learnt more from my mistakes, so I have left it in.

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Appendices

Appendix A – PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	2
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5 & 8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	11
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	n/a

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8 & 9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	8
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	n/a
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	9
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	21
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	24
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1

Appendix B: Search History Example - Medline



Thursday, August 09, 2018 7:18:27 AM

#	Query	Limiters/Expanders	Last Run Via	Results
S9	S3 AND S6	Narrow by Language: - english Narrow by SubjectMajor: - fibromyalgia Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	44
S8	S3 AND S6	Narrow by SubjectMajor: - fibromyalgia Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	49
S7	S3 AND S6	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	111
S6	S4 OR S5	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	384,447
S5	acceptance and commitment therapy or act	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	384,447
S4	(MH "Acceptance and Commitment Therapy")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	233
S3	S1 OR S2	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	10,487
S2	fibromyalgia	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	10,487
S1	(MH "Fibromyalgia")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Basic Search Database - MEDLINE	7,712

Appendix C – Quality Assessment Tools

Sample A – RCT

SIGN	Methodology Checklist 2: Controlled Trials

Study identification (*Include author, title, year of publication, journal title, pages*)		
Guideline topic:	Key Question No:	Reviewer:

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.	Yes ☐ No ☐ Can't say ☐
1.2	The assignment of subjects to treatment groups is randomised.	Yes ☐ No ☐ Can't say ☐
1.3	An adequate concealment method is used.	Yes ☐ No ☐ Can't say ☐
1.4	The design keeps subjects and investigators 'blind' about treatment allocation.	Yes ☐ No ☐ Can't say ☐
1.5	The treatment and control groups are similar at the start of the trial.	Yes ☐ No ☐ Can't say ☐
1.6	The only difference between groups is the treatment under investigation.	Yes ☐ No ☐ Can't say ☐
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Yes ☐ No ☐ Can't say ☐

1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
1.10	All 6 processes of ACT are delivered	Yes ☐ No ☐ Can't say ☐ Does not apply ☐

SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias? *Code as follows:*	High quality (++)☐ Acceptable (+)☐ Low quality (-)☐ Unacceptable – reject 0 ☐
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Sample 2 – Pilot study

SIGN	Methodology Checklist 3: Cohort studies

Study identification (*Include author, title, year of publication, journal title, pages*)

Guideline topic:	Key Question No:	Reviewer:

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

Please note that a retrospective study (ie a database or chart study) cannot be rated higher than +.

SECTION 1: INTERNAL VALIDITY

	In a well conducted cohort study:	***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.[i]	Yes ☐ No ☐ Can't say ☐
	SELECTION OF SUBJECTS	
1.2	The study indicates how many of the people asked to take part did so	Yes ☐ No ☐ Does not apply ☐
1.3	Comparison is made between full participants and those lost to follow up,	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
	SECTION 2: OVERALL ASSESSMENT OF THE STUDY	
1.4	The outcomes are clearly defined.[ii]	Yes ☐ No ☐ Can't say ☐
1.5	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.[iii]	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
1.6	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.[iv]	Yes ☐ No ☐ Can't say ☐
1.7	The method of assessment of exposure is reliable.[v]	Yes ☐ No ☐ Can't say ☐

1.8	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.[vi]	Yes □ No □ Can't say □ Does not apply□
1.9	Exposure level or prognostic factor is assessed more than once.[vii]	Yes □ No □ Can't say □ Does not apply □
1.10	All 6 processes of ACT are delivered	Yes ☐ No ☐ Can't say ☐ Does not apply ☐
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise the risk of bias or confounding?[viii]	High quality (++) □ Acceptable (+) □ Unacceptable – reject 0
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Yes ☐ No ☐ Can't say ☐
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Yes □ No □
2.4	**Notes.** Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Appendix D – Semi-structured weekly questionnaire



- Check in – Any problems with downloading data / filling in questionnaires etc
- Discussion of external events during the week – logged and not logged
- Problem solving re barriers to participation

In addition, during intervention phase

- Question session re intervention and tasks

Appendix E – Change interview



1. How did you find the intervention? – what was good / bad about it?
2. How helpful did you find the telephone calls?
3. What, if anything, has changed for you?
4. What have you noticed because of the intervention?
5. Was there one exercise / element / week that made a bigger difference?
6. What was the hardest thing about the intervention?
7. Was there anything about the intervention you found unacceptable?
8. How did you feel about the intervention itself?
9. In your opinion is it likely that the change was a result of the intervention?
10. Is there anything else that has happened for you that might have influenced the intervention?

Appendix F - Advert



University of Nottingham
UK | CHINA | MALAYSIA

Project Title: A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

Do you have Fibromyalgia?

We already know that you might take pain medication but still be in pain and that you might be told to exercise but feel too tired. We also know that your 'fibro fog' might stop you thinking straight but then keeps you awake at night and that Fibromyalgia can feel like it's taking over your life making the rest of your world feel smaller.

Would you like to take part in research being conducted by the Universities of Nottingham and Lincoln?

A treatment option called Acceptance and Commitment Therapy (ACT) has been successfully used by people diagnosed with cancer and other chronic pain conditions to improve daily functioning and Quality of Life. Research on ACT for Fibromyalgia is limited so what we don't know is if this might be effective to help you. That's why we are inviting you to participate in a research study to explore how this self-help strategy might help you live a more valued and meaningful life in the way you choose and not the way you currently feel Fibro dictates.

Over an approximate twelve-week period you would be asked to wear an activity tracking band, keep a diary of events in your life, complete some questionnaires, be interviewed and pivotally take part in a guided 8-week self-help-based intervention. All of this can be done from the comfort of your home, with weekly contact and support from the research team. Afterwards you will have the chance to tell us exactly what you think and what you did and didn't find helpful. Are you -

- Over 18
- Have a good level of literacy and comprehension in English.
- Computer literate and have internet access and a smartphone
- Have a formal diagnosis of Fibromyalgia.
- Live within Derbyshire, Nottinghamshire or Lincolnshire
- Not be allergic to rubber (use of activity tracker band)
- Not confined to a wheelchair or have significant reduced physical mobility

To see if you are eligible and get more detailed information please contact:

Carla Rainbow by e-mailing - msxcr7@nottingham.ac.uk

Appendix G – Consent to post in group request



University of Nottingham
UK | CHINA | MALAYSIA

Project Title: A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

Researcher/Student: Carla Rainbow – msxcr7@nottingham.ac.uk

Supervisor/Chief Investigator: Dr Thomas Schroder – Thomas.schroder@nottingham.ac.uk

I am looking to recruit participants to take part in a preliminary research study to investigate the efficacy, acceptability and feasibility of a self-help therapeutic intervention based on Acceptance and Commitment Therapy for Fibromyalgia.

Acceptance and Commitment Therapy has demonstrated reported positive outcomes in other chronic pain and physical health conditions but there has so far been limited research for Acceptance and Commitment Therapy for Fibromyalgia.

As the gatekeeper of the Fibromyalgia support group I would like to gain permission to post within the group so that members can contact me if they feel they would like to take part.

Appendix H – Information sheet

University of Nottingham
UK | CHINA | MALAYSIA

PARTICIPANT INFORMATION

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

Researcher/Student: Carla Rainbow – msxcr7@nottingham.ac.uk

Supervisor/Chief Investigator: Dr Thomas Schroder – Thomas.schroder@nottingham.ac.uk

We would like to invite you to take part in a preliminary research study to investigate the efficacy, acceptability and feasibility of a self-help therapeutic intervention based on Acceptance and Commitment Therapy for Fibromyalgia.

Acceptance and Commitment Therapy has demonstrated reported positive outcomes in other chronic pain and physical health conditions but there has so far been limited research for Acceptance and Commitment Therapy for Fibromyalgia. Before you begin, we would like you to understand why the research is being done and what it involves for you.

What is the purpose of this study?

The aim of the study is to explore if a brief self-help intervention based on Acceptance and Commitment Therapy is effective in helping people deal with the pain and other issues associated with Fibromyalgia. This study is being conducted as an academic requirement and will be included in a Clinical Psychology Doctorate thesis which will be submitted to the University of Nottingham.

Why have I been invited?

You are being invited to take part because you have indicated you have a diagnosis of Fibromyalgia, expressed an interest and because you met our shortlisting criteria. We are inviting six participants like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. Taking part is voluntary and entirely your decision. It's ok to take time to give this some thought when you understand what is involved before making any decision. If you wish to take part, you will be given this information sheet to keep and asked to sign consent forms.

You may change your mind about being involved at any time or decline to answer a particular question. You are free to withdraw at any point before or during the study without giving a reason.

What will I be asked to do?

If after you have had time to consider your involvement in this study, you decide to take part, then initially a mutually convenient time will be arranged for us to meet for an orientation discussion, where the study will be explained in more detail. Here we will go over the principles of the intervention and the kind of tasks that you will be doing to see if there any barriers to your involvement and how we might overcome them. If you wish to continue, I will check your access to the internet and fit you with a small device worn on the wrist that measures physical activity (fitbit) and explain how to download the data. I will ask you to fill in the questionnaires that you will be asked to continue to complete on a weekly basis. The questionnaires might take up to fifteen minutes each week to complete. You will again be able to ask questions. This initial session will last approximately one hour.

The study has 3 stages. In each stage you will be asked to download the data from your activity tracker, complete a weekly questionnaire online (approximately 15 mins), discuss events in your life and you can ask questions during a weekly telephone call. In addition, in the middle stage, you will be asked to take part in the self-help intervention, engaging in the reading material and tasks. You can choose to engage in the materials for as long as you choose but it would take approximately a minimum of an hour a week to read the material and to engage in the tasks. During the weekly telephone call at this stage you would have the opportunity to ask further questions and gain clarification about aspects of the intervention in addition to discussing events in your life. The intervention lasts eight weeks and you will have new material delivered each week with new tasks to build on the previous weeks. Four weeks after the intervention a final meeting will be arranged at a mutually convenient time. At this meeting the activity band will be retrieved, and a recorded interview will take place where you will be asked about your experience of the study and the intervention. This interview will be conducted by a separate researcher not involved in the study. You will also be given the opportunity to ask questions and have a debrief session about the study.

I have provided a flowchart at the end of this information sheet that represents each stage of the study and what will happen if you agree to take part.

Will the research be of any personal benefit to me?

We can't give any guarantee that participating in this study will help you, however research utilising this intervention for Fibromyalgia and other pain conditions has shown benefit to others dealing with their pain and being able to engage more in the things they found meaningful. Your participation will contribute to the scientific evidence for Fibromyalgia and may help our understanding surrounding the condition. We will provide an inconvenience payment of £15.00 for taking part in the intervention and a further £10.00 at the final interview.

Are there any possible disadvantages or risks in taking part?

If you take part in the research you will be giving up some of your time to download the data, answer the questionnaire and take part in the tasks. Some of those tasks relate to your pain, your mood and your daily functioning and that might feel uncomfortable or make you feel self-conscious. Part of this study asks you to ask yourself some questions about your illness and your life and although all your information will remain confidential, this could potentially be something you find difficult to do. Therefore, it is recommended that you give this element some considered thought before agreeing to take part in the study. If you did find yourself distressed or needing further support due to participation in the study, then further contact details have been provided and you will have the opportunity in our weekly telephone calls to discuss ongoing issues.

Samaritans (24 hours a day) 08457909090 or 116123
Website: www.samaritans.org

Trent Psychological Therapies can be contacted on

Derbyshire Head Office
Phone: 01332 265659
Post: Woodlands Lodge, 111 Uttoxeter New Road, Derby, DE22 3NL
Email : enquiries@trentpts.co.uk
Nottinghamshire Head Office
Phone: 0115 896 3160
Post: 19 The Ropewalk, Nottingham, NG1 5DU
Email : enquiries@trentpts.co.uk
Chesterfield Head Office
Phone: 01246 387 498
Post: 81 Saltergate, Chesterfield, S40 1JS
Email : enquiries@trentpts.co.uk

Lincolnshire stepts2change can be contacted on: 0303 123 4000.

Other providers are available

Alternatively, you may wish to speak to your G.P.

What will happen to the information I provide?

All information collected during this study will be kept strictly confidential. Any identifying characteristics such as your name will not be included in any published papers and all attempts will be made to remove data which might identify you indirectly such as location or demographic data. You will be allocated a randomised identity code, so your information can be anonymised and stored securely in locked filing cabinets or on password protected computers as soon as is reasonably possible. The only people with access to this data will be the researcher, their research supervisors, administration staff and other authorised persons from the Universities of Nottingham and Lincoln. All staff involved in this research project are bound to adhere to the same confidentiality agreement. If you give consent for any data to be used in another study for secondary analysis, your confidentiality would be maintained. We believe there are no known risks associated with this research study; however, as with any online activity the risk of a breach is always possible. We will do everything possible to ensure your answers in this study will remain anonymous.

Following completion of the study your data will be stored for approximately seven years in line with the university requirements and then disposed of securely.

The change interview at the end of the research will be recorded and transcribed by an approved transcriber and uploaded into a password-protected database. I would like to be able to quote what you say in my report or a publication. I will make sure that your anonymity is protected, but if you do not wish me to do so, please tell me.

There is one exception to the confidentiality agreement. If during the study you disclose something which gives a genuine concern for your safety or the safety of others, we have a duty of care to pass this information onto relevant parties.

The data collected will be analysed and then written up as part of a research portfolio for the Doctorate in Clinical Psychology at The University of Nottingham. It will also be submitted for publication in a peer-reviewed journal and presented at appropriate conferences. You will remain anonymous in any publications or presentations. You are welcome to request a copy of the findings by contacting the research team.

We will follow ethical and legal practice and all information will be handled in confidence.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

At the end of the project, all raw data will be kept securely by the University under the terms of its data protection policy after which it will be disposed of securely. The data will not be kept elsewhere

If you have any questions or concerns, please don't hesitate to ask. We can be contacted before and after your participation at the email addresses above.

What if there is a problem?

If you have any queries or complaints, please contact the student's supervisor/chief investigator in the first instance. If this does not resolve your query, please write to the Administrator to the Division of Psychiatry & Applied Psychology's Research Ethics Sub-Committee adrian.pantry1@nottingam.ac.uk who will pass your query to the Chair of the Committee.

Appendix I – Informed consent



University of Nottingham
UK | CHINA | MALAYSIA

PARTICIPANT CONSENT

STUDENT RESEARCH PROJECT ETHICS REVIEW
Division of Psychiatry & Applied Psychology

Project Title: A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

Researcher/Student: Carla Rainbow – msxcr7@nottingham.ac.uk

Supervisor/Chief Investigator: Dr Thomas Schroder – Thomas.schroder@nottingham.ac.uk

Ethics Reference Number:

- Have you read and understood the Participant Information? YES/NO
- I understand I will be asked to wear an activity tracker, have questionnaires sent to me, take part in interviews which will be recorded and participate in an Acceptance and Commitment based intervention for Fibromyalgia? YES/NO
- Do you know how to contact the researcher if you have questions about this study? YES/NO
- Do you understand that you are free to withdraw from the study without giving a reason? YES/NO
- I understand that data collected for the purposes of this study may be looked at by authorised individuals from the Universities of Nottingham and Lincoln, the research group and regulatory authorities where it is relevant to my participation. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my taking part in this study. I understand that my personal details will be kept confidential. YES/NO
- I give permission to be contacted to complete the assessments associated with this study, downloading data from activity bands, questionnaires, the self-help intervention and weekly telephone support, which will be recorded. YES/NO
- I give permission to be contacted again later to complete a follow-up interview, which will also be recorded and to complete further questionnaires. I understand that anonymised direct quotes from the interview may be used in the study reports. YES/NO

- Do you give permission for your data from this study to be shared with other researchers in the future provided that your anonymity is protected? YES/NO

- Do you understand that non-identifiable data from this study including quotations might be used in academic research reports or publications? YES/NO

- I confirm that I am 18 years old or over YES/NO

Signature of Participant ..... Date .....

Name (in capitals) .....

Appendix J – Ethical approval

University of Nottingham
UK | CHINA | MALAYSIA

University of Nottingham
UK | CHINA | MALAYSIA

DPAP Committee

16/11/2018

Supervisor: Thomas Schroder

Applicant : Carla Rainbow

Project: Project Id A mixed methods exploration of self-help Acceptance and Commitment Therapy for individuals diagnosed with Fibromyalgia

A favourable opinion is given to the above named study on the understanding that the applicants conduct their research as described in the above numbered application. Applicants need to adhere to all conditions under which the ethical approval has been granted and use only materials and documentation that have been approved. If any amendments to the study are required, an amendment should be submitted to the committee for approval. An end of study form will be required once the study is complete.

yours

David Daley

Professor David Daley

Co-Chair of DPAP Ethics Subcommittee

Amanda Griffiths

Appendix K – Table of framework analysis

Intervention					
Participant	Acceptability	Adaptability	Difficulties	Benefits	Support
P1	Nothing was unacceptable	Yes because you can apply it to absolutely anything so you know you can actually take some of the aspects from the study and you know think what could I do and what would I like to do the last few chapters as it was sort of kicking off it was almost like the chapters were relevant to what was happening in my life at the time actually the study was like no you can relate it to this and that actually made that switch in my brain thinking it's not a negative you can think of this as a new start I've had like issues with anxieties as well, so it's helped with that but I did find it really useful for the bits of life outside with the fibro as useful as well	I found the funeral thing really hard not because I had not thought of my own funeral it was more the fact that I am quite a social person but when I'm at home I don't actually see anybody so I use a lot of my energy at work and I have very little social life so it was like ooh who will come to my funeral, what friends?	I was always sort of determined that it wasn't going to have an impact on my life but over the past few years I've found that harder because I'm getting older and the fibromyalgia has become more active, so it's been harder not to wallow sometimes. So it's been nice because it's given me a good kick up the backside sort of thing to keep me focussed and not just sit there and think poor me, life is so rubbish and get out there and sort of think yeah what do I want to do. that's the nice thing having the paper version so that you can refer to it over and over again that has been a real benefit Yes and I think it was the dartboard one I found that really useful I do think without it I wouldn't be feeling so positive about my future and possibly who knows if I wasn't feeling so	I really missed speaking to her for the first two or three weeks actually they were useful and not that we talked for a long time or talked about anything in particular it was, erm it was just I think it worked nicely going side by side doing the work and having the chance to chat about it I think it gave me a better understanding of the study because one of the things I suffer with is a bit of brain fog so it kept is because I did the work on the Saturday and the phone call was on the Friday it sort of kept it fresh in my mind and it helped me ready for the next drop in of the mail the next day so it was nice doing that but it just seemed to work that it was you know you weren't just left on your own

				positive I be feeling worse physically and it possibly wouldn't without far off because it hits you mentally first and then physically doesn't it it's probably saved me from a flare up and more days off work I have found it useful	
P2	I found it very user friendly as well I kept thinking even if I've got no experience would I be able to follow this would I be able to do deliver this and explain it to somebody else and yeah and yeah I could I think it's been really useful really good it's something that I had absolutely no knowledge about And I didn't know what to expect obviously but actually it was kind of really really helpful really well written as well and it's just one sort of piece of literature, but I found it really really well written and not too self helpy	I thought I would just be looking at my pain but in fact I've been looking at a lot of aspects of my life it is quite specific to pain but I think as well but I thought about this earlier because I knew you were coming And I was thinking about the sort of fatigue side of it And I was thinking of going back and doing it again but with the fatigue in mind I'm picking up parts the bits but with fatigue in mind because there are bits I can use for that because fatigue is a massive part as well I'm looking at it for that but for pain	I really realised how much it was affecting me I think that kind of opened up a little bit a lot of emotions and a lot of overwhelming and Oh my God things id probably locked away so the first few chapters of sort of doing it it was kind of like Oh my God yeah fibro does affect me it is I can't just sit on it anymore and say I'm just fine fine everything's fine so it was quite challenging I think I've spent my life saying I've got fibro but it doesn't stop me doing anything and I'm alright I'm fine and actually I'm not or I wasn't the hardest thing for me was finding the time especially when I was at work	I don't think there was one kind of defining moment each week something came out that kind of and it all kind of knocked on from week to week so it so something that you did in week one suddenly in Week 2 you are kind of like I can going to go back to that so I don't think I could pick out one defining sort of thing the whole thing has been really good	extremely helpful yeah because I was kind of doing it on my own and all in my head and writing it and doing it it's been really good to speak to The researcher and kind of get out there and sort of discussed it and get it a bit clearer in my head And I hadn't realised what I had learned until I was talking to The researcher about it it and it was all of a sudden I thought yeah yeah I have got it could there be times that I thought none of that has gone in I've not done any of that but actually talking to The researcher I'm talking it through I thought yeah yeah so I don't think the course would be the same without those Phone calls I think for me there needs to be I needed that
P3	on how Americanised it was The tone of some of the Information within it I		the hardest week of the intervention there was one	so it's something there about the activities actually engaging with the	Very helpful for keeping me on track I'm sort of focused on this is what

	didn't like or didn't get on with it was quite emotive So to pick examples are like the clean paint dirty pain I suppose it's been cleverly done and intentionally done that way But yeah the sort of very Americanisation of the book and the tone of its writing I think if I had been given to read just as this old this book might help you I could probably see that I wouldn't finish it because I didn't get on with the tone of writing within it but Having said that obviously doing it in the sense of the study it was good that had to do it once you got into the activities they really you could see they had purpose I think it was all acceptable		week that felt particularly rushed	activities rather than just sitting and reading the introduction	I'm doing and that's sort of awareness that I need to fit this in to my daily life and stuff so yeah and it was good just to have checking in that known opportunity to say something or to just say everything's fine and thank you for checking in it was lovely
P4	Nothing was unacceptable	definitely should be made available to everybody I think in fact I was listening to some people at work the other day and they were complaining about pain and I felt like saying to them just read this this will sort you out and I suppose I could use the monster thing with them for something to get over I mean my son is starting comp this time and I know he's nervous so I could use that coz I think he's going through a bit of a strange time	the one I didn't overly like which I spoke to about on the Phone anyway was the funeral one I just couldn't sort of get my head round it really I tried to do it based on pain and then I tried to do it based on something else	the bus one i really loved the bus 1 and even now that still sticks in my head even now when I sort of feel Oh dear it just pops into my head that one about it I always tell all you've got to go over it's like the monster you carry around on your bus it's been really useful really really useful all of it has been I liked the idea of it being weekly it seems to sink in I think it's really good how you doing weekly sessions it's not too much	yeah they're alright I don't think necessarily I needed them every week personally on a personal level I mean it was nice to talk to her but I was fine I know she was at the end of an email if I needed her so but I don't think they were good but I don't think they were needed every week maybe

				to take in and it's not overwhelming I mean some weeks I kind of got it through a sort of rush thinking Oh I've not read it properly but I just went back on it because it was there for me to go back and have a look again definitely I liked the idea of it coming out in paper as well as in email if I'm honest I didn't look at the emails I waited for the paper copy My family seem to understand a bit more now coz they've been asking questions especially after I explained the monster thing to them	
P5	Nothing was unacceptable		sticking to the work when I was poorly it wasn't that it was hard it was just there Oh I've got to do that kind of thing but after few weeks it was fine again because you know it wasn't just about conforming i really wanted to do this because it was helping	I looked at it and I thought how is this, how is reading this going to do anything for my fibro but it's just amazed me but I like how just reading a few chapters has made such a difference the bit about fibro being the monster that sort of thing ruling your life kind of thing and about separating yourself from that monster at about you being in charge of the monster that's what it was And I was like yeah I'm going to do that	yeah they were really helpful um I miss them actually when they stopped I didn't really struggle with the intervention everything was fine anyway so I was okay
P6	interesting it was also quite heavy to get into I think a bit jargonistic at times	I've been generally much more positive and generally much better doing more	for me it was writing stuff down and I didn't write everything down i found	because it's a bit cumulative and they all sort of drop into place at	very helpful yes that was really good because I could ask

	it is American isn't it And I think would that be a barrier? Difficult to say but i found some of it a bit challenging I suppose in terms of the language	things and my issue is more fatigued than pain although I do get pain but it's the fatigue that tends to stop me from doing things sort of mental and physical fatigue so having little strategies to use to try and get me over that has been really useful	that quite difficult when you put something on paper it seems to make it final or to me it does I guess it's an issue I've got one of the things i really didn't get on with was trying to visualise the pain as a monster I couldn't sort of really cope with that at all that didn't work for me for me it needed more than just going through it once I needed to go back and have another look and keep revisiting things I think there is so much to take on board that it's trying to do it in a fairly restrictive time scale is perhaps more difficult I perhaps needed longer to look at it	different times I'm not really sure I can't really pinpoint one thing its sort of a combination of things and then trying to build on that	questions and if things weren't going so well I could talk about it

Change

Participant	Thoughts	Behaviours / Doing more	Rules
P1	Because I can be one of those people that just wallows and goes down and I tend to allow myself to wallow for a couple of days and then that's it because if I don't I will just keep on going down but it was nice to see that wasn't necessarily a bad thing but as long as I gave myself a limit I could still do that it has been so useful to me and made a massive change on how I feel mentally and psychologically and that then has a turn and reflects on how I feel physically	My friends have all been very good and lots of people with long term conditions have people that abandon them or move on and leave them whereas my friends let me dip in and dip out, so I have decided to dip in a little bit more	It let me think maybe if you're not feeling so well do you need to actually go and step in the bath or could you just have a quick wash or wipe down - do you need to use that energy to do that sort of thing and does it matter If I peel the potatoes or get a bag of chips out the freezer? no not today it makes no difference And I'm thinking actually no there's no reason why you can't

P2	The changes in how I think, and my thought processes are completely all down to it. I wouldn't have got there without it. I've been battling with my head for 10 years and I've just not managed it, I've not been able to do it, and this has really helped focus it so yeah definitely	I guess like I said I am doing more at weekends. I think pretty much every weekend I've done something whereas before I would have kind of wanted to do it, but I'd have gone you know what I can't I'm too tired or I'm in too much pain. I think every weekend since, I've done something I wanted to do which has been a massive massive change and it's giving me something to look forward to during the week because I know at the weekend I've always got something. I see far more of my best friend than I've seen in ages I've kept in touch and got back in touch with people that kind of drifted apart from because I just couldn't be bothered to go and meet them for a drink or go and have tea before I started back at work I was going for coffees and cake so yeah it really has changed and a shift in my thinking as well I think it's alright you know I'm using far less pain killers far less pain killers I'm far less bothered by far less upset by it it's not stopping me from going out and doing things and I'm not thinking about it and the pain is coming and it's there in my background	so I've kind of gone I can't do this because I'm in pain but no actually I can. I'm not that bad I'm going to do it so yeah it's been a massive shift - it's been great coz it's obviously not stopped the pain the pain is still there
P3	And I suppose to elaborate on that I know my beliefs but the mind chatter that go with it and now I better not do that because, because of these fears and things because that needs doing and I'm going to do that and not have that worry hanging over me because it's going to cause this or sort of pain or whatever or equally I do wake up and I'm stiff and it hurts but I'm not having it then consume my day I think there has been a lot of change directly as a result of the intervention certainly the cognitive changes and so yeah it has caused big shift in me which has been caused a shift in my actions which gets me where I am now	The couch to 5 K & I did successfully complete that. The intervention helped me to complete that. actually my level of activity and variety of things that I'm doing and how involved I get with things has increased	the rules about pain is really interesting for me because I didn't think initially when I was reading it that I had actually got that many but then doing the thinking diary around that it's sort of it did bring more awareness of well didn't think I had rules around it but then I'm aware of all these avoidance things that I do to avoid it and therefore I have all these rules around it that was interesting

P4	it's not I can't be bothered anymore it's right let's go I just seem to have this I'm gonna do things attitude whereas before I didn't as I was what's the word I'm looking for - worried about doing things before and that's a big thing I think it's been really good	I have dropped quite a few of my painkillers which has been quite good - because I was having 8 paracetamol and four codeine everyday whereas now I don't think I've had any paracetamol or codeine apart from the odd time when I come back from the gym but I've been fine again the next day yeah I'm even started going to some exercise classes at the gym I mean there are some days when I was taking the kids to school in my pyjamas and id just come home and get on the sofa but I don't remember the last time I did that so that's got to be a good thing	I still do think the odd time Oh I can't be bothered so I'll sit on the settee, but I've tended to think about things a bit more and think come on I can do this I'm gonna do it let's do it
P5	it's changed my mindset loads like when you're in pain you don't want to walk but I've started to go as much as possible because I think I enjoy doing that so why should fibro stop me	I'm doing more but it's not even about doing more if somebody had said do you want to go out for lunch I'd be like no kind of thing like there's no point me doing that because it will just be well I'll be poorly tomorrow but now be like yeah I'll come so now I am doing more I suppose like I say you know I've been on holiday I haven't been for 4 or 5 years because every time I went it was like the first few days at being bad and I think by the time I'm better I'm gonna be going home and be back to square while what's the point of going but we did we went and it was amazing I've started going swimming and enjoying the local leisure club maybe in a sauna and they help my pain loads	I'm still in a load of pain all the time but if I've got something to do I'll do it where before I was no I won't be able to do that because I won't be able to move for the next day there was always that and now I'm like no that can go away and I'll do it anyway because I'm going to be in pain anyway I'm putting fibro more at the back of everything rather than this is my life and I've got fibro and I can't do these things
P6	it's a total reversal from how I was thinking which is massive really isn't it	I've been generally much more positive and generally much better doing more things I have also come off my medication my amitriptyline and citalopram, so I am just hoping that because I have felt more in control of things that I have felt able to do that because obviously I don't want to stay on medication forever	move away from some of the things that I was doing like Oh I can't do that because I'll be too tired not thinking or I can't do something nothing I can, but I just have to adjust a little bit to do it or make a few allowances and not overdo things but not just not do stuff anymore
ACT processes			

Participant	Acceptance	Defusion	SAC	Being present	Values	Committed action
P1	so that part of my life is over, or will be, so what can I do instead and how can I change it so yes the last few chapters as it was sort of kicking off it was almost like the chapters were relevant to what was happening in my life at the time	you can just think well that's just a thought let it go Yes it's a thought not an act yes it has helped with that to be fair and it has made what could be a really horrid time for me much easier to deal with	it was nice to see the bits where I might be feeling lazy as opposed to ill And I'm thinking actually no there's no reason why you can't	noticing that actually when I first started the study I had lots of pain I had in my shoulders and it was really hard to do my hair and to lift my arms up now its not there so do you see what I mean its like little bits and you sort of see yourself getting better because you think oh actually when I first started I was over this way and now I am over that way but doing the study made me realise that it had gone	my friends let me dip in and dip out so I have decide to dip in a little bit more	it's given me a good kick up the backside sort of thing to keep me focussed and not just sit there and think poor me life is so rubbish and get out there and sort of think yeah what do I want to do
P2	I'd be sat reading it some days And I think yeah yeah if I do sit and think about pain I get more pain	With my thoughts as well I think I've always been I think from the CBT it's always been about you know changing change your thoughts change your thought process as you challenge them you know that's what you do because they're not meant to be there So that's why I've looked for the automatic negative thoughts but actually it is OK to have those thoughts it is OK to		look I thought I was good at that and id go ooh look like there's a robin there is a sparrow but that's just a checklist there's a squirrel there's this there's that there's a dog and it was just checklist And it wasn't actually me taking note of anything it was me making a list of what I'd seen so now I do actually take the time out out I don't focus on I've got to get from A to B because I'm in pain	the bit about the values scoring social life and friends really highly but then actually what do I do about that not a lot so I've been bearing that in mind a lot so I've not been saying no unless I have to say no but I've not been saying no to things I've been going out and doing things at weekends I thought yeah I do value my friendships and do value the things I	I've not been saying no unless I have to say no but I've not been saying no to things I've been going out and doing things at weekends I thought yeah I do value my friendships and do value the things I enjoy doing but I've not been doing them I guess like I said I am doing more at weekends pretty much every weekend I've done something whereas before I

		have them it's what we do with them there was an analogy about Being in quicksand the more you fight against something the further down you sink so the more I was fighting my thoughts the more they were controlling me so I'm thinking yes so what this isn't a nice thought yeah like I say everything you notice a lot more about yourself you know a lot more about you thinking when you stop challenging your thoughts you start going with them		and I'm tired and this that and the other I think no I'm gonna kind of enjoy it and if I'm out with the dog I'm going to kind of look around and often just stand so that's been quite good	enjoy doing but I've not been doing them for me the value stuff that I talked about earlier that kind of really struck a chord and made me really go hang on going out and sort of really looking at my values that would have just I would have probably just spent the summer bitting and bobbing doing bits and bobs it's all in a notebook so I can do it if I do it again it would be interesting again for me to actually redo some of the exercises now it's completely finished just to see how it's gone I haven't done the values again and I think I should I should do the values Again to see what's changed	would have kind of wanted to do it but I'd have kinda gone you know what I can't I'm too tired or I'm in too much pain. I see far more of my best friend than I've seen in ages I've kept in touch and got back in touch with people that kind of drifted apart from because I just couldn't be bothered to go and meet them for a drink or go and have tea before I started back at work I was going for coffees and cake so yeah it really has changed and a shift in my thinking as well I think it's alright you know
P3	I thought I know if there will be a set back and I'm OK with there being a setback I felt on entrance to the study that I was living my life the way I wanted to and it was sort of fulfilling but then working through the intervention highlighted to me how sort of small and restricted I've made		you think I can't physically do that I can barely run upstairs it's not going to happen, and it does, I can do it and it's been good			I do wake up and I'm stiff and it hurts but I'm not having it then consume my day or the vast proportion of my morning yes I'm aware of that but I think right get up get a shower get dressed go down for breakfast and it's sort of it's much smaller it doesn't take over as much

	my lifestyle to in my mind prevent flare up's. Then working through the intervention I challenged some of those areas and my beliefs on what I could and couldn't do in my capabilities and so at the end of the intervention I'm still in a position where flare ups are infrequent and they're quite small and I can manage them without medication					
P4	I mean come on we're going out like if I'm taking the kids I can take my pain monster with me too I don't think I'll ever get rid of my fatigue but that's ok I've realised			sit on my own and just be quiet you know and whereas before I didn't I just did everything for everybody else where is now I think no slow down a bit stop just enjoy		
P5	before I would have been like what's the point of going on holiday if I'm going to be in pain and then I was like well I may as well be on holiday and in pain rather than at home	the bit about fibro being the monster that sort of thing ruling your life kind of thing and about separating yourself from that monster at about you being in charge of the monster that's what it was And I was like yeah I'm going to do that	I'm the boss of my fibro now instead of the other way round but you know what it's like simple stuff but it's in your head and you get it in your head that you can't do this stuff and then when your reading it and you think why don't I do this			but it's changed the way I look at things like why not just go because it's not going to make your pain any worse or better because you're still going to be in pain so just go

P6		I found it hard to get hold of their concept at first but was the diffusion and coming away from my thoughts it's something I spoke to the researcher about and said I was struggling with and she explained that thoughts are just thoughts and I've used that so many times since if I'm getting into a sort of bad space or something and I think it's just a thought it's not any more real than anything else I can not get caught up in it and get some emotional distance so that's really been helpful I think	I said to my husband I don't think of myself as ill any more which i did before i had got myself into that sort if mindset where I was thinking Oh I've got fibromyalgia i'm not going to change my whole life and i'm not going to be able to do things and since doing all the interventions I'm sort of thinking well i'm not an ill person I'm perfectly capable a normal person i haven't Changed from who I am I just happen to have fibromyalgia which is a bit of a hiccup but I can still carry on doing the things that I want to do so really where it has helped I think		I think looking at values it's made me totally question everything really in a lot of ways Am I really living the life that I want and what's stopping me what's going on here And I have used that to be able to really think what's important	What I feel is important I'm moving towards that a bit so yeah that's been really helpful and really positive

Poster

ACT and levels of activity in fibromyalgia:

A mixed method single-case approach

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Carla Rainbow*, Dave Dawson & Mark Gresswell

Trent Doctorate in Clinical Psychology

UNIVERSITY OF LINCOLN

BACKGROUND

- ✓ Fibromyalgia is a chronic widespread pain condition with a range of accompanying debilitating symptoms such as fatigue and cognitive impairment (1)
- ✓ People with fibromyalgia are reported to have reduced levels of activity (2) and the limited guidelines surrounding the treatment of fibromyalgia suggest increasing levels of activity are beneficial for this population (3)
- ✓ Previous behavioural based interventions have reported limited success at eliciting changes in behaviour with high attrition rates and low adherence (4,5)
- ✓ ACT has previously demonstrated positive outcomes in other chronic pain conditions and was found to increase levels of activity in other chronic health conditions (6,7).
- ✓ The reported mechanism of change in ACT is psychological flexibility (PF) (a willingness to pursue value consistent behaviour even in the presence of pain) (8)
- ✓ There is limited research specific to ACT and fibromyalgia

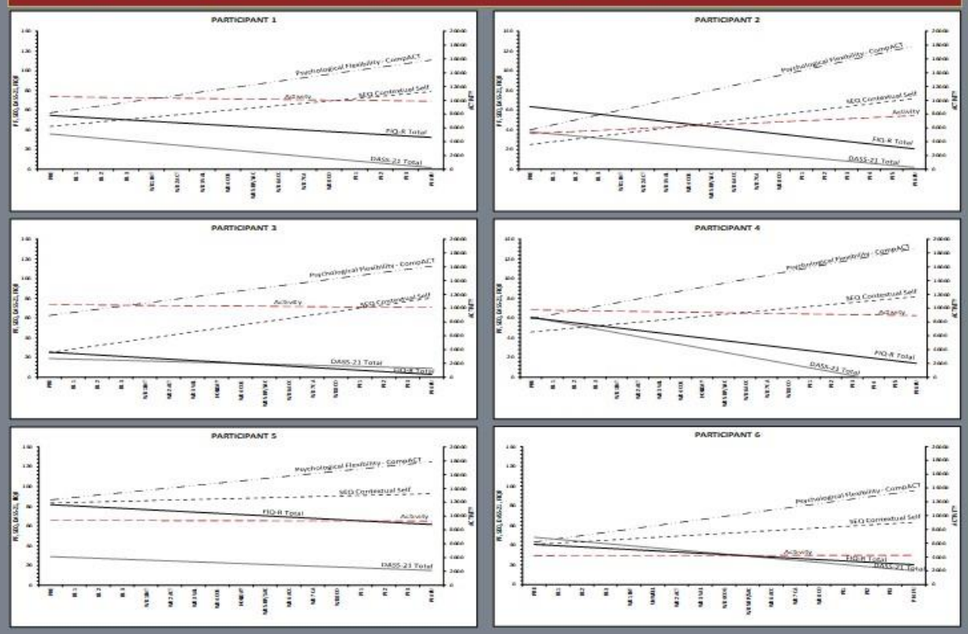
AIMS

- To examine the impact of an ACT based supported self-help intervention on the level of physical activity, psychological distress, daily functioning, symptom severity and disorder impact within this population.
- To examine the relationship(s) between the above behavioural and psychological outcomes and psychological flexibility

METHOD

- A non-concurrent mixed methods single case design was utilised (A=baseline, B1=intervention, B2 follow up after intervention)
- ACT based bibliotherapy (9) was delivered weekly for 8 weeks together with support telephone calls
- Levels of activity were monitored daily using Activity trackers (Fitbits)
- Levels of psychological distress, disorder impact, psychological flexibility and other ACT processes were measured weekly via online questionnaire (10,11,12,13)

RESULTS - AGGREGATED OVERALL TRENDLINES FOR ALL MEASURES



RESULTS SUMMARY

- Overall levels of activity did not appear to increase
- Levels of increased 'meaningful activity' were reported for all participants
- Levels of psychological distress decreased beneficially for all participants
- Levels of PF and core ACT processes showed beneficial increase for all participants
- No mechanisms of change were identified

DISCUSSION

- The reported levels of reduced activity in individuals with fibromyalgia appear disputed.
- Replication in this multiple single-case design and consistency between participant outcomes and between the different forms of analysis, suggests the generalisability of the results generated by the current study
- Overall the ACT supported self-help intervention appears well received and effective in a range of positive outcomes such as increasing psychological flexibility and reducing psychological distress.
- The results were consistent with ACT theory in relation to value based increased action being more meaningful
- This study supports the use of ACT based supported self-help interventions for a fibromyalgia population.
- Further research on the actuary levels of activity in fibromyalgia is recommended.

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Small Scale Research Project

Audit of placement supervision for the Trent Doctorate in Clinical Psychology: 2019

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Abstract

Objective(s): To establish if placement clinical supervision for trainees on the Trent Doctorate in Clinical Psychology meets the minimum standards to achieve good practice and accreditation requirements as outlined in British Psychological Society (BPS) (2010) and British Association of Behavioural and Cognitive Psychotherapists (BABCP) (2019) guidelines. To identify strengths and weaknesses from a trainee perspective.

Method: 47 current trainees across three years of study on the Trent doctorate course were invited to complete an audit questionnaire designed to match the BPS guidelines on trainee supervision. Responses were compared to audit target thresholds to identify strengths and weaknesses.

Results: Of the ten domains within the BPS (2010) guidelines there were five identified areas of comparative strength, two domains deemed borderline and three areas of comparative weakness.

Conclusions: Whilst the Trent course goes to extensive lengths to set out the provision for clinical supervision for trainees, there is a clear disparity for some trainees between expectation and reality.

Background

Clinical psychology is regarded as integral to the National Health Service (NHS) (2019), with clinicians trained as reflective scientist-practitioners to integrate theoretical and clinical knowledge and who are valued for their leadership and supervisory capabilities (Nel, Pezzolesi & Stott, 2012). Clinical psychologist practitioners can occupy consultant positions, the highest clinical grade within the NHS (Davey, Lake & Whittington, 2015) and Norcross, Sayette & Pomerantz (2018) report that it is therefore a sought-after role. The term Clinical Psychologist is a protected title[25], protected by the Health and Care Professionals Council (HCPC) who regulate health, social care and psychological professionals. To practice as a clinical psychologist it is a legal requirement to be registered with the HCPC and registration with the HCPC is dependent on reaching and maintaining minimum standards set out for each of the professions it regulates. These standards include a minimum level of education which, for a Clinical Psychologist within the United Kingdom (U.K.), is normally a Clinical Doctorate from an approved training programme (HCPC, 2019).

The British Psychological Society (BPS) acts as the representative body for psychology and psychologists in the U.K. and assesses training programmes, offering accreditation to courses meeting the required standards. Accreditation of doctorate training programmes is regarded as a threshold marker of quality, ensuring that graduates meet the required standard to register with the HCPC. To gain course accreditation, the BPS (2019) sets out a range of overarching standards in eight domains; 1) Programme Design; 2) Programme content; 3) Working ethically and legally; 4) Selection & admissions; 5) Student/trainee development & membership; 6) Academic leadership & programme delivery; 7) Discipline-specific resources and 8) Quality management & governance, which the course must meet. Within these standards, section 2.4 states that clinical supervision is an essential part of the training of Clinical Psychologists. An additional guideline (BPS, 2010) outlines the specifics under which clinical supervision for trainee clinical psychologists should take place.

In addition to requiring clinical supervision for trainees, the BPS (2019) states that the content of clinical psychology doctoral programmes must include both the teaching

[25] Designated titles are protected by law and professionals must be registered to use them. Anyone not on the register who uses a designated title may be breaking the law and could be prosecuted.

and the supervisory resources required to meet competence frameworks in terms of Cognitive Behavioural Therapy (CBT). Within the U.K. the lead organisation regulatory body for CBT is The British Association for Behavioural and Cognitive Psychotherapies (BABCP). Whilst practitioners can utilise CBT within their therapeutic work without being a member of the BABCP, many services will require a clinician to be accredited with the BABCP to supervise other CBT clinicians. The BABCP (2017 & 2019) also requires trainees to undergo clinical supervision and outlines their own guidance for the supervision required to allow a trainee to apply for accreditation after graduation.

Clinical supervision is a well-established concept that modern healthcare guidelines promote as underpinning the essence of good care (Hampson et al., 2017) and regulatory bodies support in their respective codes of conduct to develop best practice (O'Donoghue, 2015). There have been numerous definitions of clinical supervision (Wilson, Davies & Weatherhead, 2016) but for the purposes of this audit, clinical supervision will be summarised as -

> ‘’an intervention provided by a more senior member of a profession to a more junior member or members of that same profession. This relationship is evaluative, extends over time, and has the simultaneous purposes of enhancing the professional functioning of the more junior person(s), monitoring the quality of professional services offered to the clients, she, he, or they see, and serving as a gatekeeper for those who are to enter the particular profession’’
>
> (Bernard and Goodyear, 2014, p:8)

Clinical supervision is now considered a fundamental process across therapeutic modalities and healthcare disciplines (Wheeler & Richards, 2007). Britt and Gleaves (2011) highlighted that clinical supervision is vital in the training of clinical psychologists as supervisors act as the gatekeeper between the trainee’s theoretical knowledge and the integration of that knowledge into skills. However supervision is inherently personal and multi-faceted so that it is difficult to define or dissect successful elements (Milne, Pilkington, Gracie & James, 2003), although the relationship between the supervisor and supervisee has been consistently highlighted as the most important factor (Kilminster & Jolly, 2000). Lobban et al (2009) reported that positive supervisory

relationships were associated with the self-efficacy of trainees as therapists and higher perceptions of their own clinical skills. Conversely negative supervisory relationships were associated with the erosion of trainee's therapeutic skills (Brosan, Reynolds & Moore, 2006). Numerous supervisory models have been employed, although there remains limited supporting evidence for any specific model (Howard, 2018).

Whilst there is dispute in relation to supervisory models and the effective elements of supervision, Proctor (1986) outlined three functions; Normative; Formative; and Restorative for successful supervision which appear consistently and consensually in research agendas (Bishop, 2017). The 'normative' function refers to the managerial aspect of supervision, including monitoring and evaluation; 'formative' refers to the educational and guidance function for supervision; with 'restorative' referring to the support and well-being offered within the supervisory relationship. Proctor's (1986) three functions in supervision have been linked with a range of positive outcomes such as enhanced confidence, motivation, therapeutic perceptiveness and patient outcomes (Nelson & Friendlander, 2001). These functions may be particularly relevant within the trainee supervisory relationship. O'Donovan, Halford & Walters (2011) report that in addition to skill development (formative) the supervisor of a trainee is expected to monitor ethical / behavioural issues and evaluate performance (normative) and offer emotional support (restorative), thereby fulfilling all three elements of Proctors (1986) model.

However, Simpson-Southward, Waller and Hardy (2017) state that Proctor's (1986) three functions are both complementary and conflicted within trainee-supervisory relationships. There are reported power imbalances inherent within trainee relationships (Nelson & Friedlander, 2001), with non-disclosure within supervision high as trainees may perceive they will be negatively evaluated (Mehr, Ladany & Caskie, 2015). O'Donovan, Dyck and Bain (2001) reported that trainees found it hard to provide negative feedback on their supervisor potentially because they felt it would impede them passing placement with additional longer-term implications if they wanted to return to work within the same service after graduation. In addition trainees have reported that the restorative function of supervision, which Scott, Ingram, Vitanza and Smith (2000) reported was the most crucial function and is related to the supervisory relationship, could be heavily impacted by the evaluative duties of the

supervisor who ultimately holds responsibility for the trainee's development (Turner & Hill, 2011).

The Trent Doctorate in Clinical Psychology is a multi-agency three-year full-time training programme, run in collaboration between the Universities of Nottingham and Lincoln (UoN & L); Derbyshire Healthcare Foundation NHS Trust; Lincolnshire Partnership Foundation NHS Trust; and Nottinghamshire Healthcare NHS Trust to cover the training provision for Clinical Psychologists across the three counties (Derbyshire, Lincolnshire and Nottinghamshire). The current intake on the Trent doctoral programme is set at 16 trainees per year, so that over the three-year course there are a potential 48 trainees currently in training[26]. The Trent course leads to a professional qualification in Clinical Psychology (Doctor of Clinical Psychology - DClinPsy) and is approved by the HCPC and accredited by The BPS. To gain BPS course accreditation, The Trent course has implemented a comprehensive range of training, procedures and paperwork to comply with the guidance set out by the BPS guidelines (2019), including the provision of clinical supervision for trainees whilst on placement. The handbook for the Trent Doctoral Training Programme (2018; p.17) states that ''*Ample opportunities to develop practice through individual clinical supervision [is a] key feature[s] of the Trent programme''.* Whilst this ensures that the course could lead to registration with the HCPC after graduation for trainees, ideally it should also fulfil the functions of effective supervision for maximum benefit to the trainee and subsequently to the client (Abiddin, 2008).

Both the BPS (2019) and the BABCP (2019) require the clinical supervision of trainees to be formally documented and audited. An audit measures current practice against pre-determined standards and guidelines (van Gelderen, et al., 2018). Audits form part of the clinical governance process and can evaluate various aspects of practice including structural elements, processes and outcomes (Gnanalingham, Gnanalingham & Gnanalingham, 2001). An audit can be described as a systematic cyclical process, with the ongoing aim being to identify areas for development, and achieve a higher level of quality at each stage and subsequent cycle (Benjamin, 2008). Service user feedback has been identified as critical in audit and development processes (Le Var, 2002) and is ideally placed to check disparities between what

[26] This can vary due to maternity leave or deferral – There are currently 16 trainees in each year

should be happening and what is actually taking place. Therefore this audit has been aimed at the trainees currently enrolled on The Trent Doctorate in Clinical Psychology programme.

Aims and purpose of investigation

The main aim of this audit is to establish:

- If clinical supervision for trainees on placement, on the Trent Doctorate in Clinical Psychology course meets the minimum standards to achieve good practice in the supervision of clinical trainees as outlined in BPS guidelines and complies with accreditation requirements?

Secondary aims are to establish:

- If clinical supervision for trainees on placement on the Trent Doctorate in Clinical Psychology course meets the minimum standards for graduates to apply for accreditation with the BABCP and therefore be qualified to supervise CBT practitioners.
- Areas of relative strengths, weaknesses and areas of development in the supervision on placement for a Trent trainee clinical psychologist.
- Trainee perspectives of the function and purpose of placement supervision on The Trent programme.

Method

Design

This audit is based on the audit cycle. The National Institute for Clinical Excellence (NICE) (2002) outlined five stages in the audit cycle (*figure 1*); 1) Preparing for audit; 2) Selecting criteria for audit review; 3) Measuring level of performance; 4) Making recommendations and improvements; 5) Sustaining improvements. This work will outline and describe the first four elements of the audit cycle.

Participants

A questionnaire invitation was sent via e-mail to all current trainees on The Trent clinical psychology doctorate programme (16 in each year – however the author is a second-year trainee and did not participate in the responses). Therefore there were

a potential 47 respondents. In addition clarification of technical elements of clinical supervision were sought from the senior clinical tutors from the Trent Clinical Psychology Doctorate programme.

Materials

The BPS (2010) guidelines on clinical supervision for training programmes was used as the primary quality standard. The guideline is broken down in to ten domains; 1) Qualification of supervisors; 2) Supervisor workshops and meeting; 3) Allocation to clinical placements; 4) Setting up the placement; 5) Placement content; 6) Clinical supervision; 7) Quality of supervision; 8) Clinical reports and communication; 9) Review meetings and feedback; 10) Assessment of clinical competence. Similarly the BABCP (2019) guideline for supervision has comparative domains and is used as the secondary quality standard.

A questionnaire relating to the BPS (2010) and BABCP (2019) guideline criterion was developed via Qualtrics, a standard online questionnaire platform. The questionnaire generated both quantitative and qualitative data, using a mix of binary and Likert type scale responses with additional opportunity to personally comment on various aspects of the supervision.

Trent specific documentation used as sources of evidence are; a) Flowchart of placement and supervisor identification process – Trent Appendix B7 ; b) Placement contract – Trent Appendix B8 ; c) Portfolio of proficiencies – Trent Appendix B9 ; d) Client log – Trent Appendix B11 and Trainee evaluation of placement and supervision – Trent Appendix B13 (Trent handbook 1920)

Procedure

1) *Preparing for audit*; There is a provision from both the BPS (2019) and the BABCP (2019) that clinical supervision on The Trent Doctorate in Clinical Psychology course is audited. Therefore it was identified as an important area of interest.

2) *Selecting criteria for audit review*; The BPS (2010) guideline for the clinical supervision of trainees is the basis for the audit criteria. Target rates are based on the following terminology within the guideline. Where the terms; Must; Essential; Important; Obligation; and Responsibility have been used in the criteria the audit target has been set at 100%. Where the terms; Normally; Should; Generally; and Expected

have been used the audit target has been set at 75%. The term 'May' generated an audit target of 50%. Where a criterion had multiple elements each element was assessed separately to gain as thorough picture as possible. There are four criteria relating to team supervision which were not included in this audit as all trainees received mainly individual supervision. Audit targets rates were not set for the BABCP (2019) guideline as this was a secondary marker of quality, these were pass or fail.

3) *Measuring level of performance*; The questionnaire covered aspects of clinical supervision that trainees were involved in. Responses were recorded on Qualtrics. It was specified that trainee responses should be based on one supervisor in year 1 (FPA/B placement), two supervisors in year 2 (1 each for SYPA and SYPB) and two supervisors in year 3 (1 each for TYPS and TYPF). If trainees had more than one supervisor per placement they were asked to respond in relation to their primary supervisors. Further information was sought from the senior clinical tutors on The Trent Doctorate in Clinical Psychology on aspects of supervision that trainees were not involved in such as training for supervisors. Percentage responses for each criterion were then compared to quality targets to determine individual passes or fails. Pass or fails were then allocated to their respective domains and strengths and weaknesses were determined as follows –

- <75% of domain pass = weakness
- >75% of domain pass = strength

Each element was then allocated one of three functions; Normative – administrative, managerial and evaluative; Formative – teaching and guidance; or Restorative; relational and supportive. Criterion that were not assessed as it was not possible to ascertain for the purposes of this audit were noted but not counted.

4) *Making recommendations and improvements;* Once individual fails and domain weaknesses had been identified, qualitative responses were used to contextualise quantitative data and to generate discussion and recommendations. Trent policies and paperwork were also examined to assess whether there were processes in place or if fails were due to omission**.**

Results

There were a total 38 out of a potential 47 respondents meaning that there was a potential of 38 responses for questions relating to individual experience. Responses were not forced and the minimum level of response for these questions was 33 and the maximum was 38.

There were 13 respondents from year one, 14 respondents from year two and 11 respondents from the third-year trainees. Based on one supervisor in the first year and two supervisors in the second and third years there were a possible 110 responses for questions relating to experience across all placements. Responses were not forced and the minimum level of response for these questions was 95 with a maximum of 105.

Table 28: shows the full BPS (2010) guidelines for clinical supervision, the BABCP (2019) criterion, highlights the questions and evidence utilized for each criterion, outlines audit targets, the functional domain of each criterion and the audit result.

Table 29: Summarises the results and function for each domain and identifies areas of relative strengths and weaknesses.

Qualification of supervisors; This domain was considered to have a normative function. Both BPS criterion in this domain passed the audit target thresholds so this was an area of comparative strength. However the BABCP outlined three criteria for the qualification of supervisors, with the supervision that was provided failing two elements. It was not possible to ascertain the third element.

Supervisor workshops and meeting; Whilst this had a formative function for the supervisors from a trainee perspective this domain was considered to have a normative function. Of the two criterion that were assessed via consultation with the senior clinical tutor, both passed the audit target thresholds and this domain was therefore considered a comparative strength.

Allocation to clinical placements; Four of the five assessed criterion in this domain passed the audit target thresholds. It was therefore a comparative strength. All elements were considered to have a normative function.

Setting up the placement; This was an area of comparative weakness as just four of the nine assessed criteria passed the audit target thresholds. One criterion could not be assessed. All nine of the criteria were deemed to have a normative function.

Placement content; Of the five-criterion assessed, all had a normative function. The clinical supervision on The Trent programme met the audit target thresholds for all five and was therefore a comparative strength. A BABCP criterion passed the audit target.

Clinical supervision; This was identified as an area of comparative weakness as only two out of six of the assessed criteria passed the audit target thresholds. One criterion was not assessed. Of two BABCP comparable criterion, only one passed audit target threshold. All elements had a formative function, whilst the two criterion that passed also held normative functions. Therefore the four elements that did not pass audit target threshold were deemed to be solely formative.

Quality of supervision; All four of the assessed criteria passed the audit target thresholds and this was therefore considered a comparative strength. One criterion could not be assessed. Within this domain one element was normative, two were formative and the last assessed criterion was restorative with 91.53% of supervisory relationships across all placements being deemed as good.

Clinical reports and communication; This domain was a comparative weakness as only one of the two assessed criteria passed the audit target thresholds. Both elements held a formative function.

Review meetings and feedback; of the seven criterion that were assessed only four passed the audit target thresholds and this was therefore assessed as a comparative weakness. One criterion could not be assessed. All elements were considered to have a normative function.

Assessment of clinical competence; Both assessed criteria were considered to have a normative function, and both failed to meet the audit target threshold. This domain was therefore considered a comparative weakness. One criterion was not assessed.

Discussion

The primary aim of this audit was to assess if clinical supervision on placement for trainees on the Trent Doctorate in Clinical Psychology course met the minimum

standards to achieve good practice as outlined in BPS (2010) guidelines. This audit identified that the Trent course demonstrates clear process, however it appears that these processes do not always filter down effectively to the trainees and supervisors and this identified several areas of comparative weakness in the clinical supervision provided on placement. The weaknesses identified are predominantly in elements that could be assigned to trainee or supervisor responsibilities. However, responsibility ultimately falls back to the course if the clinical supervision provision does not meet accreditation standards. This audit therefore identified areas for development.

The Trent course has an extensive range of policies, procedures and paperwork aimed at complying to the BPS (2010) guidelines for clinical supervision for trainee clinical psychologists (Appendices D-H). This audit found this was a strength of the course as every criterion had been diligently targeted through these processes (*see Table 28*). However, this demonstrates a heavy reliance on paperwork to assess such a vital and transactional aspect of clinical psychology training, and a lack of direct communication of some important issues. Some trainees reported they felt that paperwork often overtook meaningful discussion around their own personal needs or experiences and whilst the portfolio of proficiency was designed to ensure competencies were met, the learning goals often pertained to previous trainees and were not relevant to their own needs.

There is a clear and understood review process, but trainees feedback supported both Nelson and Friedlander (2001) and O'Donovan, Dyck and Bain's (2001) findings that the power imbalance within the supervisory relationship impacted this process. Trainees reported feeling powerless and said they found it difficult to be honest giving placement and supervisor feedback especially when their supervisor had to sign off on their evaluation, particularly mid-placement when they had to remain there. One trainee highlighted they felt they wouldn't be heard, especially if other trainees who had been on that placement hadn't previously raised concerns and things would have to be really bad before they spoke out. In addition only 86.54% of respondents said they regularly received a minimum of one hour's supervision per week but often did not report this. This appears to hint at a potential perpetuation of bad practice by both the supervisor and the trainee and does not allow for the course or the supervisor to respond and improve.

The audit highlighted a general lack of knowledge amongst trainees regarding their own responsibilities in relation to clinical supervision on placement. The trainee contract (Trent 2020, p5) states

> *''The trainee and supervisor have responsibilities to adhere to the CTCP guidelines on supervision. It is expected that trainee and supervisor will discuss the nature of their supervisory relationship during the process of drawing up this contract.''*

Trainees are also told in a lecture in their first year teaching block and within the course handbook (UoN & L, 2018) that they are responsible for; 1) Trainee Logbooks; 2) Portfolio of Proficiencies (POP) (including ratings); 3) Client log; 4) Own development: strengths and learning needs; 5) Supervision received: Supervision log; and 6) Trainee's evaluation of the placement. Theoretically this shifts the responsibility relating to some of the trainee's concern's in relation to the portfolio of proficiency not being individual, the quality and quantity of supervision they receive, and the need to evaluate both the placement and supervision away from the course and the supervisor and places it firmly back with the trainee. However most trainees failed to recall this training, and it could be argued that one slide during an intense period of information intake and one section within a 300-page handbook (UoN & L, 2018) could be overlooked and is not sufficient for such a vital aspect of training. Some trainees reported very limited experience and confidence in the use of supervision prior to starting on the course and the consensus was that more extensive training on the use of supervision would be beneficial and potentially more memorable.

Whilst much of the focus in relation to placement clinical supervision is on the evaluation of trainees, there appears to be limited attention given to the ability and evaluation of the supervisor other than an assumption of competence through qualification (O'Donovan, Halford & Walters, 2011). The Trent course has recently (2019) introduced its own training provision for supervisors having previously utilised courses held jointly with other training establishments. Potentially in-house training will now ensure that new supervisors are acquainted with the specific requirements of The Trent course as well as the overarching requirements of supervision. In the past the Trent course has held workshops for supervisors to learn about the trainee assessment process, however trainees report extremely low attendance at these

workshops which may account why some trainees felt their supervisors failed to understand the assessment process and the criterion for passing or failing. With limited contact with the university and potentially just 1 or 2 trainees a year, each supervisor may have a limited source of normative reference for what is or isn't competent, particularly in the use of CBT, which trainees report their supervisors do not utilise as their primary modality. Gonsalvez and Freestone (2007) reported a leniency bias on the part of supervisors evaluating trainees, with trainee failure rates reported as being extremely low, which could be considered disconcerting when the supervisor is ultimately responsible for the trainee passing and then working beyond their competencies.

This audit also aimed to examine if the clinical supervision provided on placement for a Trent trainee met the three effective functions of supervision (Proctor, 1986). There seemed to be a high pass rate of normative elements to supervision, particularly those in relation to the aspects that The Trent course is responsible for such as the allocation of placements and ensuring that processes were in place. Where the normative function appears to fall down is in the elements for which the supervisor holds responsibility such as arranging inductions and case work, which trainees reported could severely impact the selection of material for case studies. There was a divided rate of passes and failures in relation to the formative function of supervision with trainees reporting a lack of opportunity to read relevant clinical literature or to observe their supervisors despite this having been identified as a critical element to training (Britt & Gleaves, 2011). Whilst the majority of trainees found clinical supervision on placement to have a restorative function, the findings of Simpson-Southward et al. (2017) were supported, as trainees reported that when normative issues took precedence, such as when trainees were placed on review, that supervision could became a punitive process and impacted the supervisory relationship negatively.

A secondary aim of the audit was to establish if the clinical supervision met the minimum standards set out by the BABCP (2019). The clinical supervision of trainees on The Trent Doctorate in Clinical Psychology would fail the criterion to allow trainees to apply for accreditation after graduation. Whilst supervisors are HCPC registered, the majority are not BABCP accredited supervisors which is a requirement of the BABCP. Trainees expressed frustration knowing that whilst CBT was being taught and promoted, they could not utilise the supervision provision from training to apply

for accreditation. It is not a course requirement for supervisors to hold BABCP accreditation and would significantly reduce placement opportunities if it was introduced. However the BPS (2019) continues to insist on CBT being a main modality taught on clinical psychology doctorate courses despite trainees reporting an apparent strong preference amongst clinical psychologists for an alternative range of modalities.

There appears to be a limited choice of placements for trainees to complete core placements. Nel, Pezzolesi and Stott (2012) highlighted that the supervisory capabilities of a clinical psychologist are one of the reasons that clinical psychology is considered an integral part of the NHS, allowing practitioners to hold high ranking clinical roles. Indeed both the NHS (2018) and BPS (2012) guidelines on activities for clinical psychologists highlights the need to supervise as part of the role, specifically supervision for trainee psychologists. It is therefore not surprising that most clinical supervisors utilised on placement by the Trent course are HCPC registered clinical psychologist practitioners. It is less understood, why then there are not more placement supervision offers which would allow both trainees and the course administration more choice.

Conclusions

The results of this audit appear to indicate there is a disparity from what should be happening and what is happening in relation to clinical supervision for some Trent trainees. Whilst the Trent course goes to extensive lengths to meet the guidelines set out by the BPS (2010) what is happening on placement sometimes falls short of good practice, often because of issues of responsibility allocated to the supervisor or trainee. Whilst the supervision provided appeared to meet all three functions of effective supervision (Proctor (1986) this varied between individuals which is to be expected due to the idiosyncratic nature of the supervisory relationship. The supervision does not meet BABCP (2019) standards for individual accreditation after graduation.

Limitations

This audit was being conducted by a current trainee of the Trent doctoral programme, although they did not contribute towards the data, they were responsible for generating the questionnaire and there is therefore a potential conflict of interest. Not all trainees responded, and this work only covers the first four phases of the audit cycle. Whilst

recommendations have been made there is no guarantee that changes could or would be implemented or for re-audit to assess if any changes have been beneficial and sustained. It was impossible to ascertain the level of experience, knowledge and views of the supervisors who have offered placements on the Trent Doctorate in Clinical Psychology programme over the previous three years and therefore the audit is incomplete and from a trainee perspective.

Recommendations

- Based on trainee feedback the major recommendation would be for The Trent Doctorate in Clinical Psychology to offer training to trainees on the use of supervision including making their responsibilities within the supervisory role more explicit.
- There is the potential to allow a more private method of giving feedback or alternatively to make giving supervisor feedback a summative exercise where critical and detailed feedback is a standard requirement and to be expected by all parties. A further study in to how to increase trainee feedback may be worthwhile.
- To make supervisor attendance at workshops compulsory within a specified time frame, potentially once every two to three years for supervisors to stay abreast of current assessment processes and course requirements.
- To provide alternative restorative supervision during any review processes.
- To complete the fifth element of the audit cycle with the potential for further work to examine making and sustaining improvements to clinical supervision.

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Tables for SSRP

Table 28: Supervision guidelines - audit markers and results

Guidance Domain	BPS	BABCP	Quantitative Questions	Qualitative Questions	Additional Evidence OR Lack of evidence	Target	Functional Domain	Questionnaire and Audit result
Qualification of supervisors	1.1 Trainees must be supervised either by: (i) A clinical psychologist who is registered with the Health Professions Council, and/or who holds Chartered Membership of the Society and full membership of the Division of Clinical Psychology, who has at least two years' post-qualification experience, and who has clinical responsibilities in the unit in which the work is carried out; *or* (ii) Any other appropriately qualified and experienced psychologist who is registered with the Health Professions Council, and/or who holds Chartered Membership of the Society; *or* (iii) An appropriately qualified and experienced member of another profession who is registered with a		5	9	HCPC registration numbers given in Placement contract – Trent appendix B8 Confirmation of additional monitoring carried out by clinical tutors	100%	Normative	Total responses – 104 Confirmation of additional monitoring carried out by clinical tutors for non HCPC supervisor All supervisors were suitably qualified **- 100% PASS**

	professional or statutory body which has a code of ethics, and accreditation and disciplinary/complaints procedures. In case of (ii) or (iii) above, the quality and quantity of supervision that is received by the trainee must be monitored carefully by the Programme Director or Clinical Tutor.							
Qualification of supervisors	1.2 Supervision should normally be provided by a supervisor who has clinical responsibilities in the unit or service in which the work is carried out.		6	9		75%	Normative	101 responses 98.9% of supervisors held clinical responsibility within the placement service - **PASS**
Qualification of supervisors		Trained and qualified in CBT post grad diploma level (or meet minimum standards) – Supervision during the period of training for both assessment and therapy, carried out by a Cognitive and/or Behavioural Therapist who	7	9			Normative	104 responses 1.92% of 104 respondents said their supervisor had post graduate training in CBT or met minimum standards

		meets the BABCP criteria for Practitioner or Supervisor Accreditation.						
Qualification of supervisors		Should currently practice CBT with 50% of their own practice	8	9			Normative	106 responses Only 19.23% of 104 respondents said their supervisor used CBT for at least 50%
Qualification of supervisors		Receive specific CBT supervision					Normative	Unable to ascertain if supervisors received specific CBT supervision
Supervisor workshops and meetings	2.1 Programmes must organise regular supervision workshops to train supervisors in methods of supervision; these should be designed with the needs of new as well as experienced supervisors in mind. Supervisors are expected to attend workshops on supervision. There should also be regular meetings at which supervisors have an opportunity to share information and discuss problems. Where programmes make use of team supervision, viz. where the ratio of trainee					100%		Until recently Trent shared supervision training with The University of Leicester but now provide their own in-house training – 100% **PASS**

	to supervisor is other than 1:1, the programme must ensure that appropriate guidance is given to supervisors and trainees on the procedures that are necessary for good team supervision. It will probably be necessary to establish supervisor workshops related specifically to team supervision.							**Not assessed**
Supervisor workshops and meetings	2.2 Suggested learning objectives for introductory supervisor training are provided at www.bps.org.uk/accreditation/downloads. Programmes that have developed supervisor training that reflects these objectives are able to seek approval for their training from the Society's Learning Centre (www.bps.org.uk/learningcentre), enabling supervisors who successfully complete the training to apply for entry to the Society's Register of Applied Psychology Practice Supervisors					100%		The course supervision training meets the learning centre requirements and those attending the course are eligible to apply for accreditation – 100% **PASS**
Supervisor workshops and meetings	2.3 It is important that supervisors keep abreast of theoretical, research and professional developments in their fields of work and participate in continuing professional development.							**Not assessed** HCPC registration requires CPD but unable to ascertain
			11	14		75%	Normative	

Allocation to Clinical Placements	3.1 There should be an explicit procedure for allocating trainees to clinical placements. All trainees and supervisors involved should understand the procedure and know how to influence decisions about clinical placements. The person responsible for arranging placements should give primacy to general training requirements and competency development needs but should also take account of the needs of individual trainees. Information should be provided about the experience obtainable in the various placements to help trainees and programme staff to make placement decisions.		12 13 16	15 19	Flowchart of placement supervision identification process – Trent Appendix B7 (Appendix D) Specialist placement fairs	75% 75% 75%	Normative Normative Normative	Flowchart of placement supervision identification process – Trent Appendix B7 (Appendix D) – **100% PASS** 37 responses Only 27.02% of respondents felt they understood the procedure and 13.51% felt they knew how to influence the procedure - **FAIL** Successful completion of core placements of Trent trainees 100% - **PASS** 38 responses Core placements allocated without prior information to the trainee, but

								emails sent before placement – **84% - PASS**
Allocation to Clinical Placements	3.2 The Programme should try to ensure effective co-working for trainees who are sharing the same placement. This is especially important where there is team supervision, with two trainees allocated to one supervisor, or when two or more trainees receive supervision from a team of supervisors, within the same placement.		17 18	19		75%	Normative	38 responses – 4 said they had shared a placement Those respondents who shared placement found it effective - **100% PASS**
Setting up the Placement	4.1 Both trainee(s) and supervisor(s) must have an opportunity to meet either before, or at the very beginning of the placement to discuss the range of experience, which is to be provided, and the expectations (hours, days of work, etc) of the trainee(s). The general aims of the placement should normally be agreed within the first two weeks of the placement and a clinical contract should be written. Attention must be paid in the clinical contract to the range of opportunities available in the placement, and to the		21 22 23 24 25 26		Introductory e-mails Placement contract – Trent Appendix B8 (Appendix E) Portfolio of proficiencies – Trent Appendix B9 (Appendix F)	100% 75% 100% 75%	Normative Normative Normative Normative	104 responses - 92.31% of respondents said they had an opportunity to meet their supervisor prior to or at the start of placement with 91.26% managing expectations and experience at the beginning. – **FAIL** 104 responses - 91.35% of respondents said

	needs, interests and previous experience of the trainee. Particular efforts should be made to fill major gaps in the trainee's experience, and records of the trainee's previous experience should be available for this purpose. The Programme Director or Clinical Tutor will have played a major role in the assessment of the trainee's strengths and needs and in the sequence of placements.				Portfolio of proficiencies – Trent Appendix B9 (Appendix F)			they agreed the placement aims within 2 weeks and 99.1% said this was agreed in their placement contract – **PASS** 104 responses - 92.31% felt their needs, interests and previous experience was considered in the clinical contract – **FAIL** 104 responses - 97.12% of respondents felt their portfolio of proficiencies clearly outlined their learning - **PASS**
Setting up the Placement	4.2 In cases where there is more than one supervisor involved in a trainee's placement (team supervision) a primary supervisor must be identified for each		27	34	Placement contract – Trent appendix B8 (Appendix E)	100%	Normative	36 responses - 88.46% of respondents said that when they had

	trainee who will take responsibility for the planning and co-ordination of that trainee's placement, supervision and assessment, and for liaison with Programme staff.							more than 1 supervisor a primary supervisor was clearly identified - **FAIL**
Setting up the Placement	4.3 The supervisor must plan an induction for the trainee, arrange for cover in the event of annual or other leave and should plan casework well in advance.		28 29 30 31	34	Placement contract – Trent appendix B8 (Appendix E)	100%	Normative	104 responses - Only 80.77% of respondent's supervisors had arranged an induction at the start of placement with only 76.92% of 105 responses indicating that supervisors had arranged cover. Of 36 responses 33.33% of respondent trainees had at some point been left without supervision for a period. 104 responses - 30.77% of respondent's supervisors did not appear to have

								planned casework in advance - **FAIL**
Setting up the Placement	4.4 Care should be taken to ensure that the trainee has access to (at least) shared office space, telephone and a desk. There must be adequate arrangements for secretarial and IT support for placement work and trainees must be given guidance on the facilities available.		32	34	Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	75% 100%	Normative Normative	104 responses - 94.23% - **PASS** 104 responses - 94.23% - **FAIL**
Setting up the Placement	4.5 Supervisors must remember that they have clinical and legal responsibilities for their trainees throughout the training period. It is good practice for supervisors to be insured, for trainees to be aware of relevant legal boundaries (e.g. re. the Data Protection Act, the Children Act). It is essential that trainees have appropriate (substantive or honorary) contracts that allow them to work in their placement.		33	34	Teaching on Trent programme on relevant ACTs	100%	Normative	Unable to ascertain if supervisors held private insurance. All Trent trainees have substantive contracts – 100% **PASS**
Placement Content	5.1 Programmes must develop, in consultation with the Division of Clinical Psychology's Faculties and Special Interest Groups and local supervisors, guidelines on the required experience in		36	42	Placement contract – Trent appendix B8 (Appendix E)	100%	Normative	The course has developed a guideline which states 6-8 clients at

	clinical placements, recommending an appropriate amount of clinical work.							any one time – 100% **PASS** 36 responses - Only 77.78% of respondents were aware of these guidelines.
Placement Content	5.2 The local guidelines on placement content should be taken into account in the provision of placement experience for the trainee. The level of his/her experience and expertise and the stage of training will determine the particular balance of work for each individual trainee.		38	42	Placement contract – Trent appendix B8 (Appendix E)	75%	Normative	104 responses - 85.58% of those who replied felt the level of work reflected their level of training and experience - **PASS**
Placement Content	5.3 Supervisors should ensure that trainees undertake an appropriate quantity of clinical work. There are dangers in both extremes: too little work reduces the opportunity for learning and too much may reduce trainees' capacity for planning or reflecting upon the work. Supervisors should monitor the balance of time spent by the trainee on work at different levels (direct client work, indirect and organisational work). This balance will vary according to the stage of training and the type of placement.		37 39	40 42	Placement contract – Trent appendix B8 (Appendix E)	75% 75%	Normative Formative Normative	104 responses - 83.65% of respondents assessed the quantity of work on placement was just right – **PASS**

	Supervisors should be alert to the dangers of time being lost at the start of the placement through suitable work not being available and should take this into account in preparing for the arrival of the trainee.							104 responses - 86.54% of respondents said work was available at the start of their placement - **PASS**
Placement Content	5.4 A log must be kept of the work a trainee has done in a clinical placement. The programme must ensure that the Clinical Tutor appropriately uses these records in planning future placements and by future clinical supervisors in discussing what experience they should provide.	It is recommended that records of all supervision sessions are kept.	41	42	Client log – Trent Appendix B11 (Appendix G) Portfolio of proficiencies – Trent Appendix B9 (Appendix F)	100%	Normative	36 responses - All trainees complete a client log and have portfolios of proficiencies – 100% **PASS**
Placement Content	5.5 With team supervision, the programme should give clear guidelines about the experience to be acquired so that the placement may be planned to make optimal use of others involved in providing supervision.							**Not assessed**
Clinical Supervision	6.1 There must be a formal, scheduled supervision meeting each week that must be of at least an hour's duration. Longer supervision will sometimes be needed, especially where team or group supervision is used.	For a full-time clinical practice, this should a minimum of one and a half hours per month of	44 92 93	47 49	Placement contract – Trent Appendix B8 (Appendix E)	100% 75%	Normative, Formative & Restorative	103 responses - Only 85.43% of respondents felt they regularly received a minimum of at least one hour

	In addition, supervisors should try to make themselves available for informal discussion of matters that arise between formal supervision sessions. The total contact between the trainee(s) and supervisor(s) must be at least three hours a week and will need to be considerably longer than this time at the beginning of training.	individual supervision. This can mean an average, providing the contact is regular. For those working less than half time clinical work, it is acceptable to pro-rata the overall amount of supervision time to 45 mins or one hour.				100%	Normative & Formative Normative, Formative & Restorative	of supervision per week - **FAIL** 95 responses - 89.47% of respondents said they received informal supervision in addition - **PASS** 95 responses - Only 51.58% of respondents said their formal and informal supervision added up to a minimum of 3 hours per week - **FAIL**
Clinical Supervision	6.2 In cases of team or group supervision, trainees must always receive, in addition, an appropriate amount of individual supervision. Individual supervision must provide opportunities to discuss personal issues, professional development, overall workload and organisational difficulties as well as on-going casework.		48	49				**Not assessed**
Clinical Supervision			48	49	Placement contract – Trent	100%	Formative	35 responses - Only 80% respondents

	6.3 Adequate time for clinically relevant reading must be made available to the trainee on placement. In addition, supervisors have a crucial role in contributing to the integration of the academic and practical aspects of the Programme. They should discuss literature relevant to the clinical work in hand and suggest suitable reading to the trainee. In general they should help trainees to develop a scholarly and critical approach to their clinical work.				appendix B8 (Appendix E)	75%	Formative	said they were given time for clinically relevant reading - **FAIL** 35 responses - 94.29% of respondents said their supervisors discussed relevant literature - **PASS**
Clinical Supervision	6.4 In addition to discussing clinical work, it is essential that the trainees and supervisors have opportunities to observe each other at work: the trainee can learn much more from this and it is essential in order for the supervisor to give the trainee accurate and constructive feedback. Placements differ in the most appropriate opportunities for such direct contact: some may use joint clinical work of some kind; others may prefer audiotape, videotape or a one-way screen. Some form of mutual observation of clinical work is regarded as essential.	Practitioners should have regular episodes of live sampling in supervision.	48	49	Placement contract – Trent Appendix B8 (Appendix E) Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	100%	Restorative	35 responses - 88.58% of respondents were able to observe their supervisor and of 35 responses 94.29% said they were observed - **FAIL**
	7.1 The quality of the supervision that is provided for the trainee will depend upon		51 53	52	Trainee evaluation of	75%	Normative, Formative	105 responses - 88.58 of

Quality of Clinical Supervision	many factors. The care taken in the early stages to build up a good relationship will enhance the quality of the clinical supervision		54		placement and supervision – Trent Appendix B13 – (Appendix H)		& Restorative	respondents said their supervisors took care to build a good relationship whilst from 104 responses 95.19% said they took care themselves to build the relationship with the supervisor. - **PASS**
Quality of Clinical Supervision	7.2 Supervisors should be prepared to adapt their style of supervision to the stage of the programme a trainee has reached. It is necessary to be prepared to describe basic clinical procedures in detail and to ensure that trainees have an adequate grasp of techniques they are asked to use. Detailed training in techniques should also be available to more experienced trainees if required.		55 56	52	Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	75% 75%	Formative	104 responses - 78.85% of respondents agreed their supervisor adapted their styles in accordance with the trainee's level of training – **PASS** 105 responses - 86.67% of respondents said their supervisor gave detailed training and technique instruction - **PASS**

Quality of Clinical Supervision	7.3 Trainees and supervisors may find that they have a different orientation and interests. Where this happens tolerance should be shown on both sides. Trainees should be helped to see that they might learn much that is valuable from a supervisor whose approach they may not ultimately wish to adopt. On the other hand, supervisors should see it as one of their functions to help trainees develop their own interests in an appropriate way. Where supervisors decide they must overrule the way the trainee wishes to work, they should explain their reasons with care, rather than simply asserting that this is how things should be done.		57 59 61 62	52 62	Trainee evaluation of placement and supervision – Trent Appendix B13 –	75%	Formative	34 respondents - Only 2% of respondents said they were actively discouraged from using a preferred modality – **PASS** **Not assessed**
Quality of Clinical Supervision	7.4 Supervisors should be prepared to discuss seriously and sympathetically any general issues of relationships with patients or staff that arise in the programme of clinical work. They should be sensitive to any personal issues that arise for the trainees in relation to clients and be prepared to discuss these in a supportive way when they are considered to affect the trainee's work. The range of personal issues that can be raised by clinical work is wide and includes, for example, over-involvement, dealing with		54	52	Trainee evaluation of placement and supervision – Trent Appendix B13 –	75%	Normative, Formative & Restorative	From 104 responses 91.53% said they felt they developed good relationships with their supervisor However unable to assess supervisory intent

	anger and despair, workload and time management problems.							
Clinical Reports and Communication	8.1 Communication with other members of clinical teams and networks involves both written and verbal reports. Verbal reporting and discussion are often more important than formal written reports in terms of their effects on clinical decisions and action. Since the relative importance of written and oral communication is likely to vary between settings, supervisors will need to identify the most important channels of communication in their placement and teach the trainee to use these channels effectively and efficiently. Training in effective communication will involve both observation of the supervisor's behaviour, and practice by the trainee with ample opportunity for feedback.			64 65	Trainee evaluation of placement and supervision – Trent Appendix B13 –	75%	Formative	29 responses - Only 44.83% of respondents said they had had any training on communication - **FAIL**
Clinical Reports and Communication	8.2 There is a wide variation within the profession in how clinical reports are written and presented, particularly with respect to the amount of detailed information provided. Trainees need to be acquainted with a variety of report and letter writing styles. If there is agreement about minimal requirements of clarity and			66	Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	75%	Formative	31 responses - 80.65% of respondents were encouraged to develop their report writing skills - **PASS**

	relevance in reports, exposure to individual differences between supervisors is more likely to be constructive than confusing. Trainees should be encouraged to write reports that are appropriate to the recipient (whether this is a professional colleague or a client), avoid jargon, distinguish clearly between fact and opinion, and provide consistent clarity of expression. Both supervisor and trainee should be aware of the potential conflict between communicating fully to professional colleagues and maintaining confidentiality.							
Review Meetings and Feedback	9.1 There must be a formal process during each placement whereby the Programme team monitors the clinical experience of trainees and the supervision provided and helps to resolve any problems that may have arisen. The aims of this are: a) to review the progress of the clinical Contract b) to give feedback to the trainee on his/her clinical performance c) to allow the trainee to comment on the adequacy of the placement d) to set targets based upon the above for the remainder of the placement		67 70	69 71	Portfolio of proficiencies – Trent Appendix B9 (Appendix F)	100%	Normative	Of 35 responses - 100% of respondents had an initial placement review with 94.29% also receiving a mid- placement review and 94.11 receiving an end of placement review – 51.42% reviewed their contract during meetings, 97.14% received feedback, 94.29% commented

	e) to give feedback to the supervisor on his/her performance.							on the adequacy of the placement and 100% set targets Only 65.72% of respondents gave supervisor feedback There is clearly a formal process during placement - **PASS**
Review Meetings and Feedback	9.2 When a trainee is involved with some form of team supervision, the programme must ensure that each trainee's experience is monitored on an individual basis. Other review or feedback of meetings that may be held at the beginning and end of a placement should also allow for individual time allocation for each trainee. If possible, all team supervisors involved with any single trainee should be involved in the monitoring process (and beginning and end of placement meetings). Where it is not possible for all a trainee's supervisors to be present at a key review meeting, one designated supervisor should seek views from other team supervisors prior to the							**Not assessed**

	meeting and provide feedback after the meeting.							
Review Meetings and Feedback	9.3 Matters such as the physical resources available to the trainee (room space, secretarial backup, etc) and theory-practice links may also be usefully discussed at this time. Supervisors and trainees may find it helpful in the review to go through the rating forms that will be used at the end of the placement.		70	71 77	Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	50%	Normative	35 responses - 94.29% of respondents commented on the adequacy of the placement during review meetings and 100% set targets - **PASS**
Review Meetings and Feedback	9.4 In general, it is expected that the programme staff member conducting the monitoring will hold discussions with the trainee and supervisor separately and then hold a joint discussion. In this way more accurate feedback about the trainee's performance and about the quality of the supervision provided may be obtained. The timing of the monitoring is important if sufficient time is to be left for improvements to be made. A plan and timetable for the review should be agreed at the start of the placement.		70	71 77		75%	Normative	35 responses - 94.29% of respondents were seen alone or given the opportunity - **PASS**
Review Meetings			70 75	71 77		100%		35 responses - 97.14% of

and Feedback	9.5 Mid placement qualitative feedback is essential both for the supervisor and the trainee. Supervisors should try to set aside positive or negative personal feelings about trainees when making evaluations. Feedback should be detailed and constructive and designed to help trainees develop a range of effective and appropriate skills; thus, feedback should be critical but not wholly negative.					75%	Normative & Formative Normative & Formative	respondents said they received feedback and only 65.72% of respondents gave supervisor feedback – **FAIL** 33 responses - Only 69.70% of respondents felt that their feedback was detailed and constructive - **FAIL**
Review Meetings and Feedback	9.6 If seriously dissatisfied about aspects of a trainee's performance, supervisors should regard themselves as under an obligation to the profession to indicate this to the programme staff.		72	73 77			Normative	35 responses - 8.57% of respondents said they had been placed on placement review due to supervisor concerns – unable to ascertain if supervisors had concerns they did not report.
Review Meetings	9.7 The trainee also has a responsibility to the programme and to the profession to		70	71 77	Trainee evaluation of	100%	Normative	All trainee's complete evaluation

and Feedback	give feedback to the programme staff about the quality of the placement and the supervision.				placement and supervision – Trent Appendix B13 – (Appendix H)			of placement and supervision forms - **PASS**
Review Meetings and Feedback	9.8 At the end of the placement the supervisor must give the trainee full feedback on his/her clinical performance. The trainee must see the supervisor's written assessment. Any major points that the supervisor is concerned about should normally have been raised well beforehand, at least during the formal monitoring process, to allow the trainee time to improve. The trainee must also have ample opportunity to comment on the placement, for example, on the experience and the supervision received. The trainee's views should be recorded formally as part of the general evaluation of the placement. Feedback forms and forms for rating clinical competence should always be completed at the time of the end of placement review and returned promptly.		70 74	71 77	Portfolio of proficiencies – Trent Appendix B9 (Appendix F) Trainee evaluation of placement and supervision – Trent Appendix B13 – (Appendix H)	100% 100%	Normative Normative	34 responses - Only 29.41% of respondents reported seeing their supervisors' reports with the same number not knowing – **FAIL** All trainee's complete evaluation of placement and supervision forms however of 35 responses only 65.72% of respondents report giving supervisor feedback - **FAIL**
			75	77		75%		

Review Meetings and Feedback	9.9 The points made in section 9.5 concerning the provision of balanced, constructive and detailed feedback to the trainee also apply to the end of placement review. The supervisor should, in addition, help the trainee to identify gaps in his/her experience to facilitate planning for subsequent placements. It is important for the supervisor and trainee to forward this information to the person responsible for co-ordinating placements.		76		Portfolio of proficiencies – Trent Appendix B9 (Appendix F)		Normative & Formative	35 responses - Only 69.70% of respondents felt that their feedback was detailed and constructive - **FAIL**
Assessment of Clinical Competence	10.1 It is important that supervisors are familiar with the examination and continuous assessment requirements for trainees and the guidelines and regulations for these.		76	77		100%	Normative	34 responses - Only 67.65% of respondents felt their supervisor understood the assessment criterion - **FAIL**
Assessment of Clinical Competence	10.2 In cases of team supervision, all supervisors who have been involved with the trainee(s) must be familiar with the programme's assessment procedure and must give feedback on the trainee(s) clinical competence.							**Not assessed**

Assessment of Clinical Competence	10.3 Supervisors must be familiar with the specific criteria for passing and failing in the assessment of clinical competence set by the programme. In addition, supervisors should be aware of appeals procedures. In cases where trainees have displayed unsatisfactory behaviour, such as regular and serious lateness for clinical appointments, professional misconduct, or failure to acquire an adequate level of clinical competence, trainees must be left in no doubt about the problem. The supervisors should discuss with the Clinical Tutor what action should be taken and it may be helpful to have a member of the programme staff present at the time of the end of placement review.		76	77	Supervisors workshop – held in first year	100% 75%	Normative	34 responses - Only 67.65% of respondents felt their supervisor understood the assessment criterion - **FAIL**

Table 29: Summary of results and identification of strengths and weaknesses

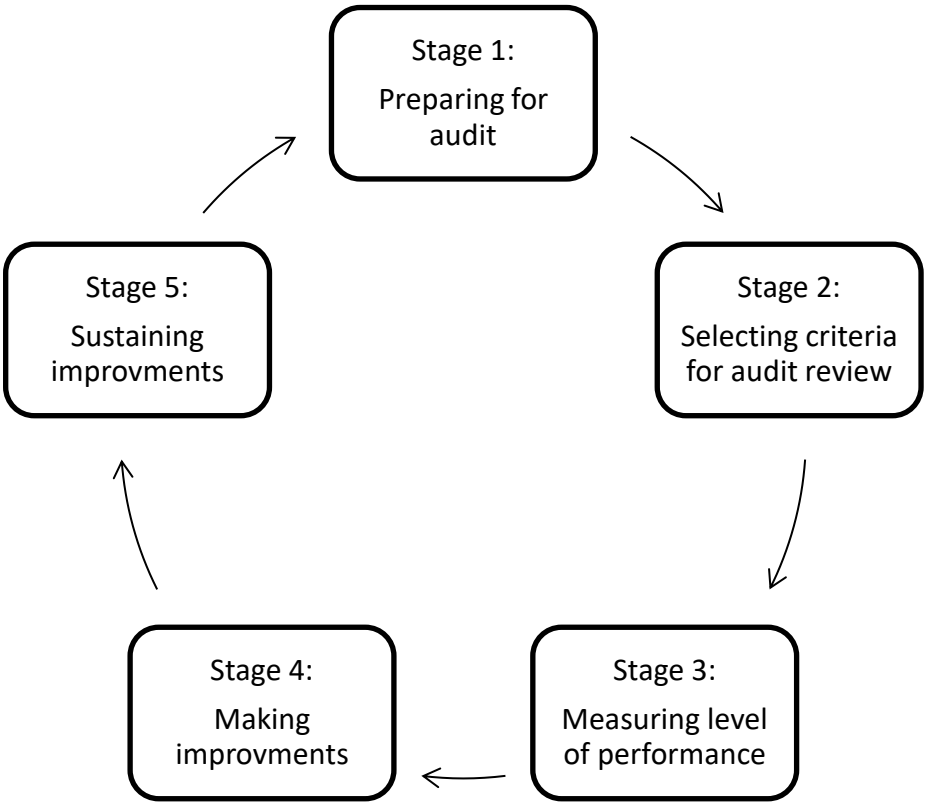
Guidance Domain	Status	Elements	Function	Relative strength / weakness
Qualification of supervisors	Passes	Suitably qualified supervisors	Normative	2/2 – 100%
		Supervisors hold clinical responsibility within the service	Normative	Strength
Supervisor workshop	Passes	The Trent course organises the training of supervisors	Normative	2/2 – 100%
		The training provided meets the required standard to allow application to the BPS Register of Applied Psychology Practice Supervisors	Normative	Strength
Allocation to placement	Passes	Explicit procedure for allocation	Normative	4/5 – 80%
		Completion of core placements	Normative	Strength
		Placement information made available	Normative	
		Effective co-sharing of placements	Normative	
	Fails	Trainees did not understand the procedure for allocation or how to influence the decision	Normative	
Setting up the placement	Passes	Placement aims agreed within 2 weeks	Normative	4/9 – 44.44%
		Gaps in learning were identified	Normative	Weakness
		Trainees had shared access to office space, telephone and a desk	Normative	
		Trainees had substantive contracts	Normative	
	Fails	Opportunities for trainees and supervisors to meet prior to placement	Normative	
		Trainees needs, interests and previous experiences were not accounted for	Normative	
		A primary supervisor was not always allocated	Normative	
		Supervisors did not always arrange inductions and plan case work	Normative	

		There was not always adequate secretarial or IT support	Normative	
	Unable to ascertain	If supervisors held private insurance		
Placement content	Passes	The guideline for the quantity of clinical work	Normative	5/5 – 100%
		The actual level of clinical work	Normative	Strength
		The work being reflective to the level of training	Normative	
		Work was available at the start of placement	Normative	
		Keeping client logs	Normative	
	Not assessed	Team supervision guidelines		
Clinical supervision	Passes	Informal supervision was generally available	Normative & Formative	2/6 – 33.33%
		Supervisors discussed relevant literature	Formative	Weakness
	Fails	There was not always a minimum of 1 hour's supervision per week	Normative & Formative	
		Informal and informal supervision did not add up to 3 hours per week	Normative & Formative	
		Time was not always given for clinically relevant reading	Formative	
		Trainees did not always have the opportunity to observe or be observed	Formative	
	Not assessed	Additional team supervision		
Quality of supervision	Passes	Supervisors adapted to the needs of the trainee	Normative	4/4 – 100% Strength
		Detailed training and technique instruction were given	Formative	
		Tolerance to differing modalities was shown	Formative	

		The quality of relationship in the supervisory relationship was considered good	Restorative	
	Unable to ascertain	The reasons why a trainee would be discouraged from using a modality		
Clinical reports and communication	Passes	Supervisors encouraged trainees to develop their report writing skills	Formative	½ - 50% Weakness
	Fails	Training in verbal and written communication was not given	Formative	
Review meetings and feedback	Passes	There was a clear formal review process	Normative	4/7 – 57.14%
		Adequacy of placement usually discussed	Normative	Weakness
		Most trainees were seen or given the chance to be seen alone	Normative	
		Trainees had a formal process to give feedback on placement and supervision	Normative	
	Fails	Trainees reported not giving their supervisors feedback	Normative	
		Trainees reported they did not see their supervisors report	Normative	
		Trainees did not feel feedback was detailed or constructive	Normative	
	Not assessed	Team supervision		
Assessment of clinical competence	Fails	Trainees often felt that supervisors were not familiar with the examination and continuous assessment process	Normative	0/2 – 0% Weakness
		Trainees often felt supervisors didn't understand the criteria for passing or failing competences	Normative	
	Not assessed	Team supervisors		

Figure for SSRP

Figure 1: The audit cycle


Stage 1:
Preparing for audit
Stage 2:
Selecting criteria for audit review
Stage 3:
Measuring level of performance
Stage 4:
Making improvments
Stage 5:
Sustaining improvments

Appendix for SSRP

Appendix A – Questionnaire

Q2

Please indicate which year of training you are currently in

- ○ Year 1 (1)
- ○ Year 2 (2)
- ○ Year 3 (3)

Q3 Please indicate you experiences of supervision prior to starting on The Trent Doctorate

	Not at all (1)	Not very (2)	Neutral (3)	Somewhat (4)	extremely (5)
How experienced did you consider yourself in the use of supervision (1)	○	○	○	○	○
How confident did you feel in the use of supervision (2)	○	○	○	○	○
How able were you to be open and reflective in supervision (3)	○	○	○	○	○

Q4

Qualification of Supervisors

Please note:

Please answer the following questions to best of your knowledge.

If you have been allocated more than one supervisor per placement the questions will relate to your primary supervisor, although you are free to comment where applicable on any of your placement supervisors. Therefore the questionnaire is based on the premise that you had one supervisor in year 1 and two supervisors per year in years 2 and 3.

Please answer applicable questions where the option has been provided for each supervisor over the course of your training.

Q5 Was your supervisor a clinical psychologist registered with the Health Proffesions Council and / or holds a Chartered Membership of the Society and full membership of the Division of Clinical Psychology?

	Yes (1)	NO (2)
FPA / FPB supervisor (1)	○	○
SYPA supervisor (2)	○	○
SYPB supervisor (3)	○	○
TYPS supervisor (4)	○	○
TYPF supervisor (5)	○	○

Q6 Does / did your supervisor have clinical responsibility in the unit or service in which the work you have done carried out?

	Yes (1)	No (2)
FPA / FPB supervisor (1)	○	○
SYPA supervisor (2)	○	○
SYPB supervisor (3)	○	○
TYPS supervisor (4)	○	○
TYPF supervisor (5)	○	○

Q7 Does / did your supervisor hold a post graduate qualification in CBT

	Click to write Column 1

	Yes (1)	No (2)	Don't know (3)
FPA / FPB supervisor (1)	○	○	○
SYPA supervisor (2)	○	○	○
SYPB supervisor (3)	○	○	○
TYPS supervisor (4)	○	○	○
TYPF supervisor (5)	○	○	○

Q8 Was CBT your supervisors main modality eg Did your supervisor appear to use CBT for a minimum of 50% of their caseload

	Yes (1)	No (2)	Don't know (3)
FPA / FPB supervisor (1)	○	○	○
SYPA supervisor (2)	○	○	○
SYPB supervisor (3)	○	○	○
TYPS supervisor (4)	○	○	○
TYPF supervisor (5)	○	○	○

Q9 Please feel free to comment on the level of qualification of your supervisors - particularly in their use (or lack of) CBT

Q10 **Allocation to Clinical Placements**

Q11 Do you feel you understand the procedure for allocation of trainees to clinical placement?

- Yes (1)
- No (2)

Q12 Do you know how to influence the decision in relation to allocation of placements?

- Yes (1)
- No (2)

Q13 Have you ever requested a specific placement (other than specialist options)

- Yes (1)
- No (2)

Q14 If yes - was your request for a specific placement granted and if not was the decision discussed with you? Please comment

Q15 Please give brief description of why you requested that placement e.g travelling time, learning requirement, personal reasons

Q16 Have you been given details of your placement supervisors and placements in advance

- Yes (1)
- No (2)

Q17 Have you shared the same supervisor with another trainee on placement?

- Yes (1)
- No (2)

Q18 If you shared a supervisor did you experience this as effective?

- ○ Yes (1)
- ○ No (2)

Q19 Please comment further if you wish to do so on the allocation of placements

Q20

Setting up the placement

Please respond for each supervisor / placement where applicable

Q21 Did you have the opportunity to meet your supervisor either prior to or at the very start of placement?

	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q22 Did you discuss experience and expectations eg hours / days of week etc?

	Yes (1)	No (2)

FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q23
Did you agree the aims of the placement within the first two weeks of the placement?

	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q24
Did you receive a written clinical contract? Trent paperwork included in this answer

	Yes (1)	No (2)

FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q25

In your opinion was your previous experience and training needs taken into consideration?

	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q26

Did your portfolio of proficiency sent at the start of each placement clearly outline your learning needs?

	Yes (1)	No (2)

FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q27

If you were allocated more than one supervisor per placement was a primary supervisor clearly outlined?

	Yes (1)	No (2)	Not applicable (3)
FPA/ FPB (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q28

Had your supervisor planned an induction?

	Yes (1)	No (2)

FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q29
Did your supervisor arrange cover for annual or other leave?

	Click to write Column 1	
	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q30 Were there times when you were left with no supervision?

○ Yes (1)

○ No (2)

Q31

Was your casework planned in advance of you starting?

	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q32

Did you have access to a shared office space, desk and telephone and adequate secretarial and IT support

	Yes (1)	No (2)
FPA/ FPB (1)	○	○
SYP A (2)	○	○
SYP B (3)	○	○
TYP S (4)	○	○
TYP F (5)	○	○

Q33

If you have worked out of your host trust were you offered an honorary contract?

	Yes (1)	No (2)	Don't know (3)	Not applicable (4)
FPA/ FPB (1)	○	○	○	○
SYP A (2)	○	○	○	○
SYP B (3)	○	○	○	○
TYP S (4)	○	○	○	○
TYP F (5)	○	○	○	○

Q34 Please comment further if you wish to do so about the structural and contractual element of your placement

Q35

Placement content

Please generalise responses further detail can be given at the end of this section

Q36 Are you aware of the guidelines relating to the appropriate amount of clinical work on placement?

	Yes (1)	No (2)
1 (1)	○	○

Q37 Do you feel the quantity of work on clinical placement has been -

	Too little (1)	Too much (2)	About right (3)

FPA / FPB (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q38 Do you feel the level of work reflected the level of training you were at?

	Yes (1)	No (2)	Don't know (3)
FPA / FPB (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q39 Was clinical work available when you started placement?

	Yes (1)	No (2)	Don't know (3)

FPA / FPB (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q40 If you answered no please comment on how this impacted you and your placement

Q41 Have you completed the following for each placement?

	Yes (1)	No (2)	Don't know (3)
Portfolio of proficiency (1)	○	○	○
Client log (2)	○	○	○
Supervision log (3)	○	○	○

Q42 Please comment further if you wish to do so about the levels and availability of clinical work undertaken on placement

Q43 **Clinical Supervision**

Q44 Have you received a minimum of one hour per week scheduled supervision?

	Yes (1)	No (2)	Don't know (3)

FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP F (6)	○	○	○
TYP S (7)	○	○	○

Q92 Was informal supervision open to you in addition to the scheduled supervision?

	Yes (1)	No (2)	Don't know (3)
FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP F (6)	○	○	○
TYP S (7)	○	○	○

Q93 Did formal and informal supervision add up to a minimum of three hours per week?

	Yes (1)	No (2)	Don't know (3)

FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP F (6)	○	○	○
TYP S (7)	○	○	○

Q47 Please feel free to comment on the quantity of supervision received

Q48
Please answer yes or no to the following questions - if the answer is no for one or all placements then answer no, if the answer is yes for all placements then answer yes

	Yes (1)	No (2)
Did your supervisor/s discuss relevant literature (1)	○	○
Were you given time for clinically relevant reading? (2)	○	○
Did you get to observe your supervisor (any observation method) (3)	○	○
Were you observed by your supervisor (any observation method) (4)	○	○
Did you receive group or team supervision in addition (5)	○	○

Q49 Please comment further if you wish on the academic content of your supervision - if you have answered no to the previous questions please elaborate

Q50 **Quality of supervision**

Q51 Do you feel your supervisor took care to build a good relationship with you?

	Yes (1)	No (2)	Don't know (3)
FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q52 Please comment further - what was good or what could have been done differently?

Q53 Do you feel you took care to build a good relationship with your supervisor?

	Yes (1)	No (2)	Don't know (3)

FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q54 Do you feel you had a good working relationship with your supervisor?

	Yes (1)	No (2)	Don't know (3)
FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q55 Did your supervisor give detailed training and technique instruction in supervision relative to your level of training?

	Yes (1)	No (2)	Don't know (3)

FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q56 In your opinion do you feel your supervisor adapted their supervision to accommodate the level of training you were at?

	Yes (1)	No (2)	Don't know (3)
FPA / B (1)	○	○	○
SYP A (2)	○	○	○
SYP B (3)	○	○	○
TYP S (4)	○	○	○
TYP F (5)	○	○	○

Q57 Please list the modalities that your supervisors have supported you with over your time on placements.

Q58 Please list any models of supervision that you have used and comment on what you found effective.

Q59 In relation to year one supervision, did your supervisor encourage you to work using CBT

- Actively encouraged (1)
- neither encouraged or discouraged (2)
- Actively discouraged (3)

Q60 What preferred modality did your first year supervisor have (if known via discussion)
Q61 If you have ever discussed using a preferred modality do you feel you have been -

- Actively encouraged (1)
- neither encouraged or discouraged (2)
- Actively discouraged (3)

Q62 Please comment on the use of modalities in supervision with particular attention to supervisor and CBT

Q63 **Clinical reports and communication**

Q64 Please comment on the level of training whilst on placement in relation to letter writing

Q65 Please comment on the level of training whilst on placement in relation to effective communication

Q66 Please comment on the level of training whilst on placement in relation to report writing
Q67 **Review meetings and feedback**

Q68 For each placement have you received the following -

	Yes (1)	No (2)
Initial placement meeting (1)	○	○
Mid placement review (2)	○	○
End of placement review (3)	○	○

Q69 If no please detail

Q70 During each meeting have you -

	Yes (1)	No (2)	Dont know (3)
Reviewed your clinical contract (1)	○	○	○
Received feedback on your clinical performance (2)	○	○	○
commented on the adequacy of the placement (3)	○	○	○
Set targets for the remainder of your placement (4)	○	○	○
Given feedback to your supervisor on their performance (5)	○	○	○
Were you / or given the chance to be seen alone? (6)	○	○	○

Q71 If you answered no to any of the previous question please detail

Q72 Have you ever been placed on placement review?

- Yes (1)
- No (2)
- Prefer not to say (3)

Q73 If yes were you given adequate time and support to make changes? please comment further if you wish to do so

Q74 At the end of each placement did you see your supervisors report?

- Yes (1)
- No (2)
- Dont know (3)

Q75 Did you feel feedback was constructive and detailed for each placement?

- Yes (1)
- No (2)
- Dont know (3)

Q76 Do you feel your supervisors understood the assessment process and the criteria for passing / failing clinical competencies?

- Yes (1)
- No (2)
- Dont know (3)

Q77 Please comment further on the feedback and review process in supervision

Q78 **Additional information**

Q79 Please comment on the level of training you have received on the Trent Doctorate Course in relation to how to use supervision - please detail any changes to the training and 'what you wish you had know about using supervsion'

Q80 In relation to how you feel about supervision NOW

	Not at all (1)	Not very (2)	Neutral (3)	Somewhat (4)	Extremely (5)
How experienced do you consider yourself in the use of supervision? (1)	○	○	○	○	○
How confident do you feel in the use of supervision? (2)	○	○	○	○	○
How able are you to be open and reflective in supervision (3)	○	○	○	○	○

0-1 Sources of bias = high quality – low risk of bias
2 Sources of bias = medium quality – medium risk of bias
3-5 Sources of bias = low quality – high risk of bias
6+ Sources of bias = should not be included