

# **Research Project Portfolio**

University of Nottingham

School of Medicine

Division of Psychiatry and Applied Psychology

## **Doctorate in Clinical Psychology**

**2018**

**Effectiveness of Acceptance and Commitment Therapy self-help for carers of people with multiple sclerosis: A feasibility randomised controlled trial.**

**Kristy-Jane Martin, MSc, BSc (Hons)**

Submitted in part fulfilment of the requirements for the

**Doctorate in Clinical Psychology**

## **Acknowledgements**

I'd like to thank my research supervisors for all their greatly appreciated help and support throughout the study and subsequent write-up. In particular, for taking the time to talk through more challenging aspects of the study and for sharing their extensive expertise.

I would like to extend my thanks to each and every participant, for without you, none of this would be possible!

In addition, to my father, Pete, for being a proof-reader extraordinaire, as well as my entire family for their continued support, listening skills (really, telephone counselling!) and many cups of tea.

Finally, to Luke, for everything you have done. Without you I may not have got here...

## Table of Contents

<b>THESIS ABSTRACT</b> .....	<b>1</b>
<b>Statement of Contribution</b> .....	<b>3</b>
<b>JOURNAL PAPER</b> .....	<b>4</b>
<b>Abstract</b> .....	<b>4</b>
<b>Introduction</b> .....	<b>6</b>
<b>Multiple Sclerosis</b> .....	<b>6</b>
<b>Carers for PwMS</b> .....	<b>6</b>
<b>Carer Strain</b> .....	<b>7</b>
<b>Acceptance and Commitment Therapy</b> .....	<b>8</b>
<b>Self-help</b> .....	<b>9</b>
<b>Method</b> .....	<b>11</b>
<b>Participants</b> .....	<b>11</b>
<b>Measures</b> .....	<b>12</b>
<b>Procedure</b> .....	<b>14</b>
<b>Intervention</b> .....	<b>15</b>
<b>Control</b> .....	<b>15</b>
<b>Analysis</b> .....	<b>17</b>
<b>Results</b> .....	<b>18</b>
<b>Sample</b> .....	<b>18</b>
<b>Feasibility</b> .....	<b>19</b>
<b>Effectiveness</b> .....	<b>5</b>
<b>Sample Size Estimates</b> .....	<b>10</b>
<b>Discussion</b> .....	<b>10</b>
<b>Feasibility</b> .....	<b>10</b>
<b>Effectiveness</b> .....	<b>15</b>
<b>Strengths and Limitations</b> .....	<b>15</b>
<b>Research implications</b> .....	<b>16</b>
<b>References</b> .....	<b>18</b>
<b>EXTENDED PAPER</b> .....	<b>24</b>
<b>1. Extended Introduction</b> .....	<b>24</b>
<b>1.1 Multiple Sclerosis</b> .....	<b>24</b>

1.2 Caring for someone with MS .....	25
1.2.1 Carer strain in MS.....	26
1.3 Psychological Interventions and Support Services for Carers .....	28
1.4 Acceptance and Commitment Therapy (ACT) .....	29
1.4.1 Theory .....	30
1.4.2 ACT evidence base .....	31
1.4.3 ACT for carers .....	33
1.4.4 Rationale for ACT for carers of people with MS .....	34
1.5 Self-help .....	35
1.5.1 Self-help vs. face-to-face therapy .....	38
1.5.2 Rationale for self-help for carers of people with MS.....	39
1.5.3 Rationale for ACT self-help for carers of people with MS.....	40
1.6 Feasibility Randomised Controlled Trials .....	41
1.6.1 Primary Aims .....	41
1.6.2 Secondary Aims .....	42
<b>2. Extended Method .....</b>	<b>43</b>
2.1 Recruitment .....	43
2.2 Sample Size .....	44
2.3 Inclusion & Exclusion Criteria.....	44
2.4 Measures.....	45
2.4.1 Zarit Burden Interview .....	45
2.4.2 Modified Carer Strain Index.....	46
2.4.3 CAREQOL-MS.....	47
2.4.4 Acceptance and Action Questionnaire.....	47
2.4.5 Comprehensive Assessment of Acceptance and Commitment Therapy .....	48
2.4.6 Service Use Questionnaire .....	48
2.5 Feedback interviews .....	49
2.6 Randomisation .....	50
2.7 Intervention.....	50
2.7.1 Self-help book.....	50
2.7.2 Weekly telephone calls .....	51
2.7.3 Fidelity of weekly telephone calls.....	51

2.8 Analysis .....	52
2.8.1 Quantitative analyses .....	52
2.8.1.1 Controlling for baseline variables.....	53
2.8.1.2 Multiple comparisons .....	53
2.8.2 Qualitative analyses.....	54
<b>3. Extended Results.....</b>	<b>55</b>
3.1 Recruitment .....	55
3.2 Comparisons of Eligible and Not Eligible Participants.....	55
3.3 Service Use Questionnaire.....	57
3.4 Attrition .....	57
3.5 Assessment of Fidelity to ACT Model .....	58
3.6 Individual Change Analyses.....	59
3.6.1 Case Exemplars.....	62
3.7 Effect Size Calculations.....	63
<b>4. Extended Discussion.....</b>	<b>65</b>
4.1 Comparison of Eligible and Non-Eligible Participants.....	65
4.2 Recruitment .....	66
4.3 Randomisation .....	67
4.4 Self-Help Text .....	68
4.5 Support Calls.....	69
4.6 Attrition .....	69
4.7 Measures.....	71
4.8 Effectiveness .....	74
4.9 Sample Size Estimates .....	76
4.10 Extended Strengths .....	76
4.11 Extended Limitations .....	77
<b>5. Reflective Section.....</b>	<b>79</b>
<b>References .....</b>	<b>84</b>
<b>Appendix A- Ethics Approval Letter.....</b>	<b>99</b>
<b>Appendix B- Ethics Amendment Approval Letter.....</b>	<b>101</b>
<b>Appendix C- Participant Information Sheet.....</b>	<b>103</b>
<b>Appendix D- Consent Form .....</b>	<b>110</b>
<b>Appendix E- Service Use Questionnaire.....</b>	<b>111</b>

<b>Appendix F- Weekly Telephone Script.....</b>	<b>114</b>
<b>Appendix G- Semi- Structured Interview Schedule .....</b>	<b>115</b>
<b>Appendix H- CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial.....</b>	<b>116</b>
<b>Thesis Poster .....</b>	<b>119</b>

## THESIS ABSTRACT

**Objective:** Acceptance and Commitment Therapy (ACT) may be a feasible, accessible and effective intervention to 'informal' carers of people with Multiple Sclerosis (MS) who may be experiencing strain as a result of their caring duties. The aim of this study was to assess the feasibility of randomised controlled trial (RCT) of ACT self-help, telephone-supported ACT self-help, compared to usual care (UC). Study objectives related to feasibility and acceptability of the study design and the two chosen interventions and assessing potential effectiveness at both individual and group level.

**Design:** This study was a feasibility, mixed-methods, parallel three-armed RCT design. The three arms were: (1) ACT self-help workbook (SH), (2) ACT self-help workbook alongside weekly telephone calls (SH+), and (3) usual care. The SH group received an ACT self-help text over eight weeks, with chapters sent week-by-week via email or post. Those in the SH+ group received the intervention as those in the SH group, with the addition of weekly telephone support calls to guide them through the self-help text. Participants across all groups completed measures at baseline, at three-months and six-months post randomisation. Measures included were two measures of carer strain (Zarit Burden Interview; (ZBI) and Modified Carer Strain Index; (MCSI)), carer health-related quality of life measure (CAREQOL-MS) alongside two ACT process measures (Acceptance and Action Questionnaire; AAQ-II) and Comprehensive Assessment of Acceptance and Commitment Therapy; (CompACT). All participants randomised to the two intervention groups were invited to complete a feedback interview, which was analysed using a framework analysis to inform feasibility of the study.

**Results:** Twenty-four self-defined primary carers of people with MS were randomised to one of the three groups previously described above. Overall, participants found the RCT design of the study to be feasible, although there were difficulties with the self-help text itself, as well as the timing of the intervention. The measures were predominantly feasible with one notable

difficulty, whereby a measure of service use was omitted from the analysis and was deemed not feasible in its current form. A mixed linear model analysis showed improvement on only one outcome measure for the SH group (ZBI at 6-month follow-up), and participants reported difficulties engaging with the SH intervention in its current format. The SH+ group showed improvements on both measures of carer strain (consistent across both follow-ups) and attributed improvements both to the text as well as the telephone support. Both groups showed multiple significant improvements on process measures.

**Conclusions:** A full trial of ACT-based, telephone-supported self-help is warranted, further to significant changes to the study design and protocol. Notably, the SH group (without telephone support) was not deemed a feasible intervention to progress to a full scale RCT, and therefore a two-armed RCT is recommended. Further work needs to be completed ahead of progressing to full trial, the major changes required would be to the intervention material and recruitment strategy. An internal pilot would, therefore, be necessary in order to assess the feasibility of the study after the suggested changes had been made. Personal reflections on the research process, chosen methodology, and intervention are offered.



## **Statement of Contribution**

Professor Roshan das Nair (RdN) and Drs Nima Moghaddam (NM) and Nikos Evangelou (NE) assisted with trial design and application for ethical approval. Jacqui Mhizha-Murira (JMM), PhD student at the University of Nottingham, conducted feedback interviews. Professor Roshan das Nair and Dr. Nima Moghaddam assisted with data analysis and study write-up.

## JOURNAL PAPER

### Abstract

**Objective:** Acceptance and Commitment Therapy (ACT) may be a feasible intervention for carers of people with Multiple Sclerosis (PwMS) experiencing carer-related strain. This study assessed feasibility of an RCT of ACT self-help (SH), telephone-supported ACT self-help (SH+), compared to usual care (UC). Study objectives related to feasibility and acceptability of study design and interventions.

**Design:** A mixed-method, parallel three-armed feasibility RCT. The SH group received an ACT self-help text, whereas the SH+ group additionally received weekly telephone support. All participants completed measures at baseline, three-month and six-month post-randomisation. Carer Strain was measured using Zarit Burden Interview (ZBI) and Modified Carer Strain Index (MCSI). A health-related quality of life measure (CAREQOL-MS) alongside two ACT process measures (Acceptance and Action Questionnaire; AAQ-II and Comprehensive Assessment of Acceptance and Commitment Therapy; CompACT) were also completed and a sample of participants were interviewed.

**Results:** Twenty-four carers of PwMS were randomised. Participants found the design to be feasible, but highlighted difficulties with the self-help text and timing of the intervention. An exploratory, group-level analysis indicated effectiveness for the SH+ group on measures of carer strain (consistent across both follow-ups) but only one significant improvement for the SH group (on one outcome measure, at 6-month follow-up) and no reported qualitative changes.

**Conclusions:** A full trial of ACT-based, telephone-supported self-help is warranted, further to significant changes to study design. Notably, the SH group was not deemed a feasible intervention. An internal pilot would be necessary to assess the feasibility of the study after the suggested changes are incorporated.

**Key Words:** Acceptance and Commitment Therapy, Carers, Multiple Sclerosis, Randomised Controlled Trial, Self-Help, Guided Self-Help

## **Research and Implications Statement**

- This paper provides provisional evidence that ACT-based guided self-help interventions are feasible and potentially effective for informal carers of people with Multiple Sclerosis.
- A full trial of telephone-supported ACT-based self-help is warranted, if significant changes to study design are made.

## **Introduction**

### **Multiple Sclerosis**

Multiple Sclerosis (MS) is a chronic neurological condition that affects the brain and spinal cord, resulting in wide-ranging disabilities. It affects around 100,000 people in the UK (Mackenzie, Morant, Bloomfield, MacDonald, & O’Riordan, 2014). Most people are diagnosed when they are 20-30 years old, and the prevalence is higher in women (Mackenzie et al., 2014). The disabilities experienced by people with MS (PwMS) depend on a number of factors, such as which parts of the nervous system are affected, or the illness type (Jones, Pohar, Warren, Turpin, & Warren, 2008)<sup>1</sup>.

### **Carers for PwMS**

For the purpose of this research, we use the following definition of carer: “anyone who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support” (Carers Trust, 2015; Department of Health, 2014). Therefore, this research focusses only on carers as defined above, and does not include professional or paid carers.

The UK MS Society estimated that 71% of PwMS receive care from an ‘unpaid carer’, i.e. a friend or relative (MS Society, 2013). It is estimated that carers spend between 4.6 and 12 hours a day providing care to the person with MS, with activities ranging from help with mobility to personal care (e.g., support with self-catheterisation, hygiene) (Carton, Loos, Pacolet, Versieck, & Vlietinck, 2000). The amount of care provided has been shown to increase incrementally as the level of disability increases (Murphy et al., 1998), although few details of the specific activities or nature of caring responsibilities were addressed by this study.<sup>2</sup>

---

<sup>1</sup> See Extended Introduction 1.1 for further details on MS.

<sup>2</sup> See Extended Introduction 1.2 for further details on caring for someone with MS.

## **Carer Strain**

The conceptualisation of carer strain is varied amongst studies, and terms such as carer strain or burden are often used interchangeably. Indeed, one paper sought to conceptualise and operationalise the different terminology and highlighted that burden is more related to the level of care and support, whereas strain additionally refers to the psychological impact of this role (Hunt, 2003). For the purposes of this paper the term carer strain is used and refers to both physical and/or emotional strain experienced as a result of caring responsibilities (Chipchase & Lincoln, 2001; Corry & While, 2009).

There is widespread research highlighting the needs of carers of PwMS (Corry & While, 2009; Topcu, Buchanan, Aubeeluck, & Garip, 2016). Importantly, there is research highlighting the positive impacts of caring, specifically around caring as a rewarding experience with opportunities for growth (Cheung & Hocking, 2004; Heward, Molineux, & Gough, 2006), and there is no suggestion that all carers will experience distress as a result of their caring responsibilities. However, reviews suggest a high prevalence of strain as a result of caring for someone with MS (Corry & While, 2009; Topcu et al., 2016). Indeed, caring has been linked to impact on social, psychological and physical wellbeing of the carer (McKeown, Porter-Armstrong, & Baxter, 2003) as well as reduced quality of care delivered (Kasuya, Polgar-Bailey, & Takeuchi, 2000) and a lowered quality of life both for the carer and the person with MS (Khan, Pallant, & Brand, 2007).

Levels of carer strain have been associated with multiple factors; Corry and While (2009) found that the health status of the person with MS, specifically level of disability, is correlated with carer strain. Other studies demonstrated correlations with specific symptomology of the PwMS; cognitive and psychiatric symptoms (Figved, Myhr, Larsen, & Aarsland, 2007; Khan et al., 2007), memory difficulties and reduced activities of daily living (Chipchase & Lincoln, 2001),

motor problems and incontinence (Knight, Devereux, & Godfrey, 1997), or perception of the burden to the carer themselves (Kasuya et al., 2000).<sup>3</sup>

These findings, taken together, suggest complex interactions between the care recipient's disability levels, specific physical, psychological and cognitive difficulties and the carer's own characteristics (Buchanan & Huang, 2012) that relate to carer strain. However, what is clear is that some carers do experience strain when caring for a person with MS, and that strain can negatively affect both the carer and the PwMS. Currently, support for carers of PwMS in the UK tends to focus on practical aspects, such as obtaining paid carers and respite care (Freeman & Thompson, 2000; MS Society, 2013), rather than offering psychological support. However, evaluations of structured supports for carers of people with other conditions (e.g., Alzheimer's Disease or Dementia) show promising effectiveness of psychological therapy to reduce carer strain and burden (see Dickinson et al., 2017 for a meta-review of systematic reviews).<sup>4</sup>

### **Acceptance and Commitment Therapy**

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999), a '*third wave*' of traditional cognitive behavioural therapies (CBT), is an acceptance and mindfulness-based psychological therapy (Hayes, 2004). ACT is inherently trans-diagnostic and theorises that psychological distress results from psychological inflexibility and experiential avoidance (Hayes, Pistorello, & Levin, 2012). ACT posits that to improve functioning, people must learn to accept, rather than avoid, unwanted and painful thoughts and feelings, thus allowing them to commit to actions in line with their values, rather than attempting to avoid these painful private events (Hayes et al., 1999).<sup>5</sup>

---

<sup>3</sup> See Extended Introduction 1.2.1 for further details on carer strain

<sup>4</sup> See Extended Introduction 1.3 for further details on psychological interventions and support services for carers

<sup>5</sup> See Extended Introduction 1.4 for further details on ACT

There is considerable research evidence supporting the effectiveness of ACT for a range of clinical diagnoses (A-Tjak et al., 2015); and some evidence for carer populations, showing promising results for parents of children with autism (Blackledge & Hayes, 2006), although the foci of this study was primarily related to adjustment, rather than carer-related stress or strain and was labour-intensive in that the intervention was delivered across a 14-hour two-day workshop, something potentially not feasible to a population caring for someone with MS. However, a qualitative study of group-based ACT for carers of people who had suffered a traumatic brain injury also showed some promising results with family carers (Williams, Vaughan, Huws, & Hastings, 2014), although again this was completed in a group format. This exploratory study found that participants were prioritising their caring responsibilities over their own psychological wellbeing; providing some preliminary ('proof-of-principle') support for the use of ACT with carers.<sup>6</sup>

ACT is perhaps well-suited to address strain and suffering in the context of caring for someone with a chronic, incurable, and unpredictable condition, wherein efforts by carers to 'solve' or exert control over difficulties may be unfeasible and ultimately counterproductive. Given ACT is inherently trans-diagnostic (Hayes, Luoma, Bond, Masuda, & Lillis, 2006; Lundgren, Dahl, Melin, & Kies, 2006) it is, arguably, appropriate for a population without a clinical diagnosis.<sup>7</sup>

### **Self-help**

Self-help intervention (often called bibliotherapy) allows for psychologically guided intervention to be accessible to a large population at potentially relatively little cost to the NHS. Bibliotherapy, in its true form, is completed independently (without therapist support), although it can be supplemented with telephone-delivered therapy (often called *teletherapy*).

---

<sup>6</sup> See Extended Introduction 1.4.2 & 1.4.3 for further details on ACT evidence base and ACT for carers

<sup>7</sup> See Extended Introduction 1.4.4 for rationale for ACT for carers of PwMS

Evidence either supporting or refuting the effectiveness of bibliotherapy for carers is somewhat scarce, and tends to focus on carers for people with mental health difficulties. Indeed, studies have evaluated bibliotherapy interventions for carers of people with psychosis and found promising results, highlighting the therapeutic and economic value of bibliotherapy for this population (Chien, Thompson, Lubman, & McCann, 2016; McCann et al., 2013).

ACT has also been used in a self-help format, with a recent systematic review evaluating effectiveness of ACT self-help for depression, anxiety, and psychological flexibility, finding small significant effect sizes favouring intervention across all three outcomes (French, Golijani-Moghaddam, & Schröder, 2017). Furthermore, interventions with increased therapist contact improved outcomes, supporting the use of therapist-guided ACT self-help.<sup>8</sup>

ACT may, therefore, be an appropriate intervention for carers of PwMS, although, as far as the authors are aware, no studies are yet to test or evaluate ACT in a self-help format for any carer population. Furthermore, given the nature of caring responsibilities, self-help would give necessary flexibility to fit around their caring duties, something that has been highlighted as a barrier to engagement in psychological intervention for carers (Winter & Gitlin, 2007).

The primary aim of this study was to examine the feasibility of completing a three-armed randomised-controlled trial (RCT) of ACT self-help (either with or without telephone support), compared to a usual care group. Within this, the specific aims were to:

- Highlight levels of attrition across all three arms of the study
- Estimate sample size requirement for a full-scale RCT
- Explore practicalities and acceptability of the chosen intervention and highlight potential barriers

---

<sup>8</sup> See Extended Introduction 1.5 for further details on self-help



- Assess the fidelity of the weekly telephone support calls in relation to ACT<sup>9</sup>

## Method

A feasibility, mixed-methods, parallel three-armed RCT design was used. The three arms were: (1) ACT self-help workbook (SH), (2) ACT self-help workbook alongside weekly telephone calls (SH+), and (3) usual care. This study was given favourable opinion by the Faculty of Medicine and Health Sciences Research Ethics Committee (reference G14112016), University of Nottingham, UK. The trial was registered on ClinicalTrials.gov (reference NCT03077971).

## Participants

Information regarding the study was posted on relevant online and print publications/media to facilitate self-referral. The study was also presented at the 'Living with MS' research day at the University of Nottingham. A database of people who had consented to being informed of research undertaken by the research group was also used. Potential participants were asked where they heard about the study to assess the feasibility of recruitment streams<sup>10</sup>. For feasibility studies, there has been some discussion regarding adequate sample size, in particular some conflation of differences in pilot and feasibility studies, or 'proof of concept' studies (Thabane et al., 2010). Thabane et al. (2010) acknowledge that of key importance when determining a sample size is that it is *a priori*, and transparent in relating to the specific aims of the study. Other articles are more prescriptive in determining sample size and explore this in relation to confidence intervals of quantitative findings (Hetzog, 2008), although this is highlighted as of less importance for feasibility/ proof of concept studies which are less focussed on quantitative findings (Yin Yin, 2002). Twelve participants per arm has been consistently recommended as sufficient in order to assess feasibility parameters (Julious, 2005), suggesting a sample size of 36.

---

<sup>9</sup> See Extended Introduction 1.6 & 1.7 for further details on aims

<sup>10</sup> See Extended Methods 2.1 for further details on recruitment

Whilst this is at the modest end of some recommendations, it balances the ability to assess aspects related to feasibility, whilst losing statistic power, which is arguably not an aim of a feasibility study. To allow for potentially high levels of attrition (50%), we aimed for a sample of 54 participants<sup>11</sup>.

For inclusion into the trial, potential participants needed to be: over 18 years old (because the intervention was designed for an adult population as the needs of young carers may be different), the primary carer for a person with MS, English speaking (because the intervention and assessments were in English), and able to give informed consent. Participants needed to score at least 21 on the Zarit Burden Interview (ZBI; Zarit, Orr, & Zarit, 1985), demonstrating a minimum level of “mild distress”.

People were excluded from the study if they themselves had a diagnosis of MS, or had a psychiatric diagnosis. We felt that these exclusions were justified because the outcomes of the interventions may have been directly influenced by these diagnoses. Finally, carers were excluded if they felt they were unable to commit to the intervention.<sup>12</sup>

## **Measures**

Participants completed the screening and baseline questionnaires either online (using the Bristol Online Survey tool), over the telephone, or by post. For ease of completion, the ZBI was completed alongside all other baseline questionnaires. Participants completed all questionnaires at baseline, as well as at follow-ups at 3- and 6-months post-randomisation.<sup>13</sup>

*Screening measure:* As far as the author is aware, there is no validated measure of carer strain specifically related to PwMS. Therefore, we used the ZBI because it is widely used as a measure of carer strain and has pre-defined

---

<sup>11</sup> See Extended Methods 2.2 for further details on sample size

<sup>12</sup> See Extended Methods 2.3 for further details on inclusion and exclusion criteria

<sup>13</sup> See Extended Methods 2.4 for further information about study measures

thresholds defining differing levels of strain (e.g. mild, moderate etc.). It has 22 questions and caregivers are asked to endorse each item using a 5-point scale. Response options range from 0 (Never) to 4 (Nearly Always).

*Outcome measures:* We used the Modified Carer Strain Index (MCSI; Robinson, 1983; Thornton & Travis, 2003) to assess aspects of caring and the impact this has on various life domains, and the CAREQOL-MS (Benito-Leon et al., 2011), which is a health-related quality of life scale designed and validated specifically for carers of people with MS. A higher score on the MCSI indicates more strain, and a higher score on the CAREQOL-MS indicates a better quality of life. We also administered a Service Use Questionnaire (SUQ) (see Appendix E) to give an indication of current healthcare utilisation, needed to evaluate cost-effectiveness in a future Phase III trial. Whilst this SUQ is not a published questionnaire, similar SUQs have been used in RCTs of complex interventions (das Nair et al., 2015; Lincoln et al., 2015).

*Process measures:* We included these to reflect any changes in ACT-related process; the Acceptance and Action Questionnaire (AAQ-II; Bond et al., 2011) is a 7-item self-report questionnaire used to assess experiential avoidance and psychological inflexibility, and the Comprehensive Assessment of Acceptance and Commitment Therapy (CompACT; Francis, Dawson, & Golijani-Moghaddam, 2016) is a complementary measure of additional important processes of ACT, such as 'self as context' and 'committed action'. Higher scores reflect greater psychological flexibility etc., across both measures.

We invited all participants from the intervention groups who had consented to being interviewed to a semi-structured feedback interview after their 3-month follow-up, to get further information about the acceptability of the intervention. These interviews were completed by a researcher independent to the study.<sup>14</sup>

---

<sup>14</sup> See Extended Methods 2.5 for further information about feedback interviews.

## Procedure

Potential participants were sent via email (or post if requested) a participant information sheet and were offered a telephone or email discussion with KJM to discuss the study further. Participants were given at least 24 hours to read the information. Those who wished to continue were given a participant identification number and sent a link to the online survey; this allowed participants to complete questionnaires without uploading any identifiable information to the online platform. Consent (taken through this online survey tool), was obtained prior to completion of the questionnaires. If participants did not consent, they were 'screened out' of the survey and did not progress to completion of measures.

On completion of the screening and baseline measures, the ZBI was scored to assess eligibility for inclusion into the study. Both eligible and ineligible participants were contacted via email or telephone (dependent on their preferred method of contact) and informed of their eligibility. Those who were ineligible were told why they could not take part and were thanked for their time.

Those who were eligible were randomly allocated using a computer generated random number sequence on a 1:1:1 ratio, with block randomisation using randomly selected block sizes of 3, 6, 9 and 12. The randomisation sequence was developed by NM, and the sequence was not known by the other researchers. We informed those allocated to the usual care group that they did not need to do anything further until we contacted them to collect the outcome data. Those allocated to both intervention groups were sent the chapters for the first week via email (no participants requested these via post). Times for the weekly support calls were also arranged for those allocated to self-help plus telephone support.<sup>15</sup>

---

<sup>15</sup> See Extended Methods 2.6 for further information about the randomisation.

All participants were asked to complete the same questionnaires used at baseline again at 3- and 6-months post-randomisation. Due to the nature of the intervention, participants and the person delivering the intervention could not be blinded. Outcomes were blinded as far as possible insofar as they were largely self-completed by the participants. See Figure 1 for a CONSORT diagram of participants' journey through the study.

## **Intervention**

Participants in the intervention group received chapters each week from the ACT self-help text "*Get out of your mind and into your life- the new Acceptance and Commitment Therapy*" (Hayes & Smith, 2005). Permission to use the book was granted by the author. Participants were sent chapters weekly for eight weeks. Those allocated to the SH group did not receive any additional support associated with reading the chapters, and the only contact with the researchers was via email when they were sent the relevant chapters. Those allocated to the SH+ group also received a weekly telephone support call from the lead researcher (KJM – a clinical psychology trainee with expertise in the provision of structured support), so as to promote understanding and engagement with the text (see Appendix F for the weekly support call script). These calls were recorded and assessed for fidelity to the ACT model by NM using published recommendations (Plumb & Vilardaga, 2010).<sup>16</sup>

## **Control**

Participants in the control group received usual care. We did not anticipate that any of the participants would be receiving any 'treatment' for their carer strain, but they may have been receiving informal support from other carers or friends. We documented their use of healthcare services on the Service Use Questionnaire (SUQ).

---

<sup>16</sup> See Extended Methods 2.7 for further information about the intervention.

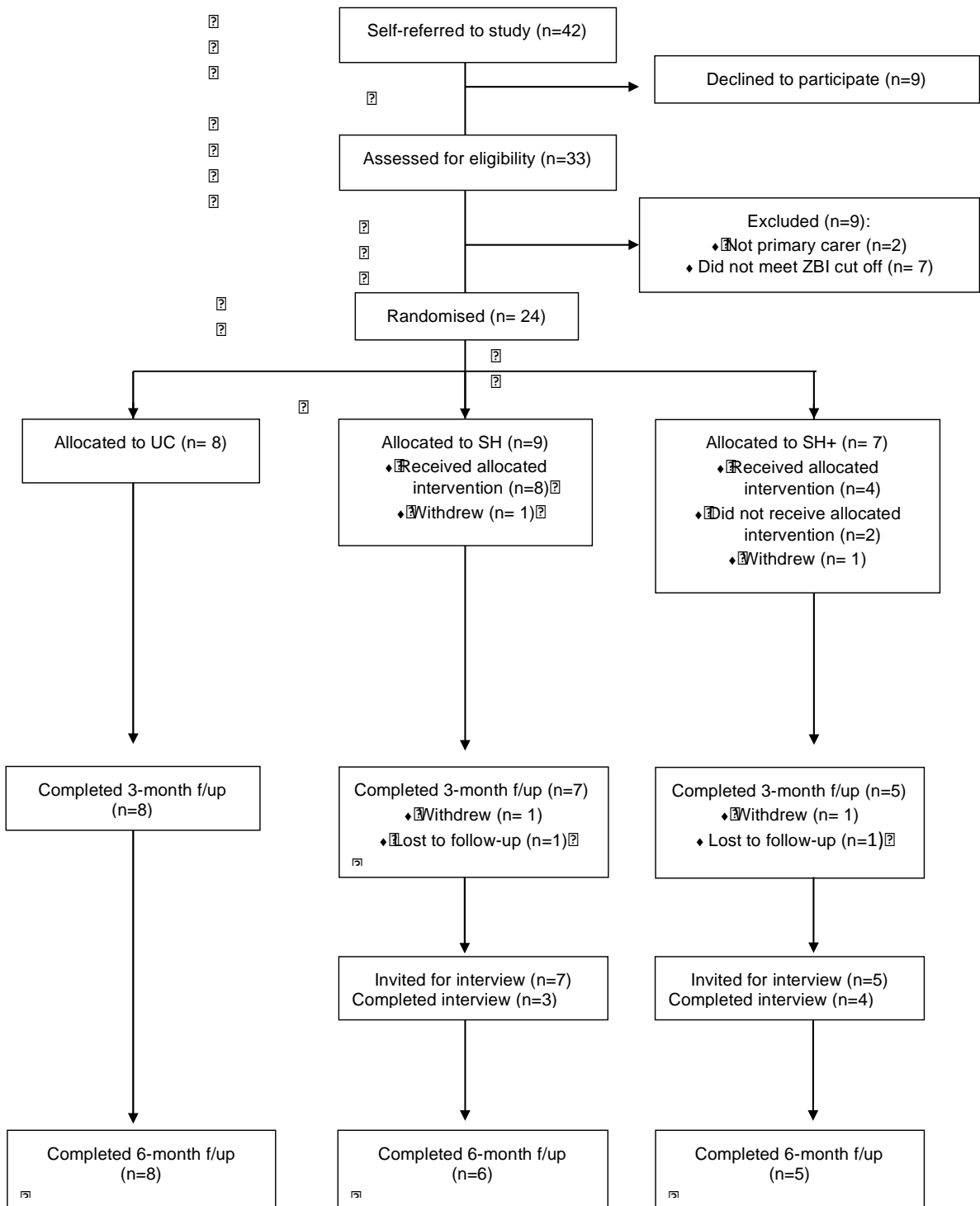


Figure 1: CONSORT diagram showing participants flow through the study

## Analysis

Quantitative analyses used a mixed linear model comparing baseline to 3-month follow-up within and between the three allocation groups; secondarily, this model was extended to include 6-month follow-up data, and thereby explore longitudinal effects. As a feasibility study, these analyses were completed to give an estimate of effect sizes for a larger, fully powered, trial. A mixed linear model was chosen as it allows for all the data to be used meaningfully, especially pertinent when there is a small sample size. Individual change analyses were also completed for individuals who completed the outcome measures at 3-month follow-up. These were completed using the Reliable Change Index (RCI; Jacobson & Truax, 1991; Jacobson, Roberts, Berns, & McGlinchey, 1999); an analysis to identify if any changes are greater than expected with measurement imprecision (Wise, 2004). This analysis allowed us to acknowledge individual changes for each participant, as well as looking for patterns within individual data across the groups and individual measures. Ten per cent of all data was audited to ensure accuracy; the lead researcher extracted the data, summed individual items (where appropriate) and reanalysed the data, comparing to the completed analysis to highlight any discrepancies.<sup>17</sup>

Descriptive data are presented to give an overview of those enrolled in the study across all three allocation groups. It was decided, *a priori*, that any variables found to be significantly different between groups at baseline would not be added as co-variables, as this process could yield misleading results (Bland & Altman, 2011).

Feasibility interviews were analysed using Framework Analysis (Ritchie, Spencer, & O'Connor, 2003). This method was chosen as it is useful in deductively answering a research question, and is frequently used for semi-structured interviews in health settings (Gale, Heath, Cameron, Rashid, &

---

<sup>17</sup> See Extended Methods 2.8.1 for further information on quantitative analyses

Redwood, 2013). This method allowed us to specify pre-defined codes to assess specific research questions related to feasibility of the study. The data was first transcribed by someone independent of the study and then assessed against and organised into a frame of these predefined codes by the lead researcher KJM.<sup>18</sup>

## **Results**

An example of the framework analysis is first presented in table 1. Results for both the qualitative and quantitative aspects of the study are also presented together, where appropriate, to give a more nuanced and integrated narrative of the study findings. Interviews were completed for 7 participants; 3 in the self-help group and 4 in the self-help plus telephone support group.

## **Sample**

In total, 42 people requested further information about the study<sup>19</sup>, with 31 consenting to participate in the study and completing baseline measures; 24 of whom were eligible for the trial.<sup>20</sup> In total, seven people were interviewed from the two intervention groups; three from the self-help group and four from the self-help plus telephone support group. Interviews varied in length, from 22 to 64 minutes.

The characteristics of the sample's demographic scores, split by group, can be seen in table 2 and 3. The groups appeared comparable on most variables, but the usual care group reported spending significantly more hours per week completing caring activities compared to the intervention groups.

---

<sup>18</sup> See Extended Methods 2.8.2 for further details on the qualitative analysis

<sup>19</sup> See Extended Results 3.1 for a breakdown of sources

<sup>20</sup> See Extended Results 3.2 for more information about those not eligible for the study.



## **Feasibility**

### *Recruitment*

Recruitment was open between February and August 2017. Predominantly, participants found out about the study online, through charitable organisations (e.g. MS Society, MS Trust online publications, and their social media channels) or social media support groups. Of the 42 people who requested further information about the study, the largest proportion reported hearing about the study through a Facebook support group for carers of people with MS. Of those interviewed, the majority spontaneously commented that they only heard about the study from the one source. None of those interviewed reported any negative aspects about the recruitment strategy, and reported that the information and process of consent/ enrolment was clear. The sample, even when including those who declined to take part or were not eligible, was considerably smaller than expected, suggesting that the current recruitment strategy if used alone would not yield sufficient numbers for a larger trial.

### *Randomisation*

No objections were noted due to randomisation process and there was not significant attrition from those who did not receive the intervention, indicating this as an acceptable methodology. Analysis of baseline demographic and outcome data give an indication of the feasibility of the randomisation process. Given the lack of differences (with the exception of one variable discussed above) between the three groups, alongside the normality and homogeneity of variance of data, this suggests the randomisation procedure is feasible, although there were unequal group sizes.

Feasibility Category	Participant quotes
Recruitment	"I was basically trawling the internet for support...and I came across it on a website search basically."
Measures	"I am aware that I was in a worse place when I saw that questionnaire then I am today. And I remember thinking that at the time; I wasn't feeling great... I do remember feeling a little bit frustrated that it was a bit 'Yes, No'."
Self-help text	"... it didn't feel written in a kind of basic practical enough way for the type of situation we're talking about... and yeah it was just a little bit ... there was times when it felt a bit turgid." "I found it too much; there was too many activities. It was too ... it was too intense for where I was at in my life, so I found I didn't do quite a few of the exercises"
Support Calls	"I think the phone calls were important because they made me do it. They made me read it and they helped me solidify what I got from it." "I wouldn't have kept the momentum going and I wouldn't have cemented ...you know ... and you were saying ... I wouldn't have cemented the concepts in my brain if I hadn't been asked questions to reflect on and ... you know ... had the space to create these little images in my head and stuff. And I don't think I would have done that if [researcher] hadn't phoned me actually. I don't."
Changes	"I feel I am able to come through that and come back to a place of stability faster than I would have if I hadn't done this. I really do. And I feel less like what I used to feel. I used to feel like I'm going mad, so the negative voice in my head has quietened down dramatically..."
Acceptability	"I was just going to say that I'd said to [researcher] that some of my friends would have put it down at ... half-way through chapter one..."
Evaluation	"So the very first chapter I found really powerful because it just kind of expressed really clearly everything that was going on in my head. And that then made me go 'I really want to break this'."
Future study feasibility	"I think I would have spaced it at maybe at a fortnight rather than a week"

Table 1: An example Framework Analysis from a participant in the SH+Call group

		UC (n=8)	SH (n=9)	SH+ (n=7)	
		n	n	n	p
Age	Mean (SD)	58.4 (9.4)	53.52 (12.6)	50.23 (7.0)	0.316a
Gender	Women (%)	8 (100%)	7 (77.8%)	4 (57.1%)	0.170b
Employment status	Employed full time	3 (37.5%)	2 (22.2%)	1 (14.3%)	0.294c
	Employed part time	1 (12.5%)	1 (11.1%)	2 (28.6%)	
	Self employed	1 (12.5%)	0	2 (28.6%)	
	Retired	3 (37.5%)	4 (44.4%)	0	
	Not working due to caring responsibilities	0	1 (11.1%)	2 (28.6%)	
	Other	0	1 (11.1%)	0	
	Relationship to person with MS	Partner	8 (100%)	7 (77.8%)	
	Parent	0	1 (11.1%)	1 (14.3%)	
	Other	0	1 (11.1%)	0	
Type MS	RR	3 (37.5%)	4 (44.4%)	4 (57.1%)	0.612c
	PP	3 (37.5%)	3 (33.3%)	1 (14.3%)	
	SP	2 (25%)	2 (22.2%)	2 (28.6%)	
Years since Diagnosis	Mean (SD)	14.0 (8.7)	14.3 (6.0)	14.4 (9.0)	0.994a
	Range	6-32	1-21	1-28	
Time been a carer	Mean (SD)	8.1 (3.6)	10.4 (8.0)	7.1 (6.0)	0.555a
	Range	5-14	1-21	1-17	
Average hours/week caring	Mean (SD)	112.9 (69.0)	37.6 (17.5)	67.7 (69.8)	0.033*a
	Range	4-168	10-60	9-168	
Barthel Index	Mean (SD)	7.88 (5.14)	11.4 (6.0)	7.1 (6.8)	0.312a

a = Independent t-test, b = Fisher's exact test, c = Pearson's chi-squared; UC = usual care, SH = self-help, SH+ = self-help and call.

Table 2: Demographic information

Measure		UC (n=8) Mean (SD)	SH (n=9) Mean (SD)	SH+ (n=7) Mean (SD)	p
ZBI		45.1 (12.0)	45.0 (10.0)	55.0 (17.7)	0.334
MCSI		15.9 (5.7)	15.9 (5.0)	18.4 (5.2)	0.575
CAREQOL-MS		65.9 (16.7)	59.6 (14.3)	60.0 (14.7)	0.685
AAQ-II		16.6 (5.6)	21.3 (9.5)	21.4 (6.4)	0.135
CompACT	Total	66.5 (21.9)	68.6 (20.6)	58.1 (20.9)	0.605
	OE	26.6 (9.7)	26.8 (13.2)	22.4 (10.1)	0.704
	BA	11.0 (5.9)	14.3 (5.5)	9.6 (6.7)	0.277
	VA	28.9 (7.8)	27.4 (7.6)	26.1 (8.2)	0.797

ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOI-MS, AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action

Table 3: Baseline scores on the measures

### *Measures*

All participants completed the measures online, with the exception of one participant who completed these over the telephone with a researcher. Participants' reported ability to complete the measures online varied. Some participants reported difficulties completing these online, and reported that they would have preferred to receive, and been quicker to respond to, measures by post. Most participants felt the online platform for completing the measures was not user friendly; specifically having to scroll up constantly to review rating categories. Most participants reported that the measures could be improved in terms of wording and highlighted that they would have liked free text options. One questionnaire (Service Use Questionnaire) was highlighted as particularly confusing, with KJM receiving a number of questions from participants concerned they had filled this out incorrectly. In particular, participants were unsure what would count as use of services for 'caring responsibilities' and participants varied as to whether they included all appointments attended with their care recipient, or solely those related to the carer's wellbeing. After reviewing the answers given, as well as reviewing the participant feedback and the questions raised, we decided to omit this questionnaire from the analysis, as we felt that the data obtained were unreliable and that the questionnaire was not a feasible measure to gauge service use <sup>21</sup>. Participants did not highlight anything specific that they felt the questionnaires missed; however, reviewing the telephone support calls, the most commonly discussed emotion was 'anxiety', which was not assessed as a distinct outcome within administered measures in their current format.

### *Attrition*

At the 3-month follow-up, 20 participants completed the online measures (16% attrition). One participant from the SH+ group completed the measures, but withdrew from the intervention because of caring responsibilities. Two other participants (one from each intervention group) formally withdrew, and declined to

---

<sup>21</sup> See Extended Results 3.3 for further information regarding the Service Use Questionnaire

complete follow-up measures; both reported the intervention was not appropriate for them. A further participant from the self-help plus telephone support group was 'lost' following week 5 of the intervention, whereby they did not respond to the telephone calls. Therefore, the self-help plus telephone support group had an attrition level of 29%. At the 6-month follow-up, 19 completed the questionnaires, showing an overall attrition level of 21%.<sup>22</sup>

### *Self-help text*

Participants reported reading an average of 25-50% of the chapters each week for the self-help group, with the SH+ group reporting reading between 50-75% of the text. Of those interviewed, all participants in the SH group reported finding the text inaccessible and "losing hope" after a few weeks. Despite it not being directly asked, all interviewees from this group suggested that a telephone call, or an email conversation would have improved their engagement with the text.

All interviewees from the SH+ group reported continuing with the text until the end of the intervention, with the exception of one participant who had not finished the text but had planned to once their care recipient's MS relapse had remitted. Only one participant who engaged with the intervention did not complete an interview, or a follow-up, therefore their engagement with the self-help text could not be assessed.

All interviewees commented on difficulties with the language of the text and that it was difficult to apply the concepts presented in the text to their own life situations. All participants reported that the amount of reading each week was "too much", given their caring responsibilities. Some interviewees would have liked a shorter summary to accompany/replace the text, and all interviewees reported that examples for carers would have been useful. Some interviewees also highlighted difficulties in understanding some of the basic concepts of ACT and requested a glossary of terms.

---

<sup>22</sup> See Extended Results 3.4 for further information about attrition

### *Support calls*

Fifty-six support calls were arranged, five calls were 'missed', six were rearranged, and two were cancelled. The average length of call was 17 minutes (range 8 to 33 minutes). The support calls were assessed for fidelity to the ACT model and showed good adherence to the ACT model. Notably, this assessment highlighted the skill of the call handler at appropriately managing often distressing call content, that was not always specific to caring but was a necessity to manage therapeutic rapport.<sup>23</sup>

All participants interviewed who had the weekly support calls commented that the support calls helped to motivate them to complete the reading in time for the next scheduled call. They all felt the calls were of an appropriate duration, and that the call handler was warm and friendly. Some interviewees reported they would have liked more information about what could be discussed during the calls; it is unknown whether this was solely for support with the text, or more of a wish for more therapeutic intervention.

### **Effectiveness**

#### *Perceived changes assessed qualitatively*

No interviewees in the SH group identified any changes as a result of the intervention. All interviewees in the SH+ identified positive changes following the intervention, which they attributed both to skills-based learning as well as the relational aspects of the weekly telephone calls.

#### *Individual-level change*

Tables 4 and 5 give a summary of the reliable change for individuals according to group allocation at three and six-month follow-up respectively.<sup>24</sup>

---

<sup>23</sup> See extended Results 3.5 for further information on the fidelity assessment

<sup>24</sup> See Extended Results 3.6 for more detail on individual change analyses

		UC		SH		SH+	
		Improvement	Deterioration	Improvement	Deterioration	Improvement	Deterioration
ZBI		1	4	1	1	3	0
MCSI		0	1	0	2	2	0
CAREQOL		0	3	1	2	3	1
AAQ-II		0	1	3	1	3	0
CompACT	Total	2	2	4	0	4	0
	OE	2	2	5	1	4	0
	BA	0	1	1	0	3	0
	VA	0	1	3	1	3	0

Table 4: Number of participants showing reliable improvement or deterioration comparing baseline to 3-month follow-up

		UC		SH		SH+	
		Improvement	Deterioration	Improvement	Deterioration	Improvement	Deterioration
ZBI		0	5	3	0	4	0
MCSI		0	0	1	1	3	0
CAREQOL		0	2	2	2	2	1
AAQ-II		1	2	4	0	3	1
CompACT	Total	0	0	4	0	5	0
	OE	1	0	5	0	5	0
	BA	0	1	5	0	4	0
	VA	0	1	3	1	4	0

Table 5: Number of participants showing reliable improvement or deterioration comparing baseline to 6-month follow-up. ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOL: Carer Quality of Life AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action



### *Exploratory group-level changes*

Plots for normality of residual errors were inspected and found to be normal therefore a mixed linear model was deemed appropriate. Table 6 shows the intention-to-treat mixed linear model analysis which revealed significant allocation-by-time interaction effects. Subsequent simple-contrast analyses showed no differences between groups at either follow-up but statistically significant within-group changes within the SH+ intervention group in particular: this group demonstrated improvement on the ZBI, MCSI, CompACT Total, CompACT OE and CompACT BA comparing baseline to 3-month follow-up, and additionally CompACT VA at baseline to 6-month comparison. In contrast, SH group showed no changes on outcome measures at 3-month follow-up, but significant improvement on the ZBI and all process measures with the exception of CompACT VA, on comparisons of baseline to 6-month follow-up. The UC group demonstrated no change on these measures. Effect-size estimates for between-group contrasts were small, with wide confidence intervals, and none were statistically significant<sup>25</sup>. Within-subjects effect sizes were also calculated for the two intervention groups, see table 7. Specifically, for the SH+ group, multiple within-group contrasts were found to be statistically significant (i.e., those for ZBI, MCSI, CompACT Total, CompACT OE, CompACT BA and additionally CompACT VA at 6-month follow-up); these effects were estimated to be of medium to large magnitude.

---

<sup>25</sup> See Extended Results 3.7 for further information on effect size calculations

Measure	T <sub>0</sub>			T <sub>1</sub>			T <sub>2</sub>			F value (p)
	UC	SH	SH+	UC	SH	SH+	UC	SH	SH+	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
ZBI	45.13 (12.00)	47.00 (10.02)	55.00 (17.69)	50.00 (17.25)	47.86 (10.09)	48.80 (15.55)	50.75 (15.39)	42.14 (12.10)	43.40 (20.03)	<b>6.586 (0.002**)</b>
MCSI	15.88 (5.74)	15.89 (5.04)	18.43 (5.16)	16.63 (6.57)	19.29 (4.23)	14.20 (6.18)	16.75 (5.82)	16.00 (5.32)	13.80 (7.82)	<b>3.943 (0.016*)</b>
CAREQOL-MS	65.88 (16.75)	59.56 (14.31)	64.00 (14.69)	71.13 (20.13)	68.14 (12.76)	57.40 (16.70)	69.62 (17.15)	57.86 (20.20)	56.60 (22.13)	2.143 (0.107)
AAQ-II	16.63 (5.58)	21.33 (9.51)	24.71 (6.40)	19.50 (6.77)	20.71 (7.74)	22.80 (8.53)	17.75 (7.46)	13.14 (5.76)	19.60 (10.83)	1.692 (0.193)
CompACT Total	66.50 (21.88)	68.56 (20.62)	58.14 (20.90)	63.38 (20.93)	72.29 (13.61)	74.00 (22.31)	68.38 (25.34)	88.57 (15.29)	88.40 (20.98)	<b>6.858 (0.001**)</b>
OE	26.63 (9.71)	26.78 (13.20)	22.43 (10.13)	26.88 (9.05)	30.57 (10.10)	27.80 (11.56)	29.75 (11.55)	38.14 (9.63)	35.80 (11.17)	<b>3.578 (0.024*)</b>
BA	11.00 (5.88)	14.33 (5.48)	9.57 (6.68)	9.00 (4.75)	13.86 (6.87)	13.00 (7.42)	11.38 (5.95)	19.86 (4.53)	15.80 (6.98)	<b>5.656 (0.003**)</b>
VA	28.88 (7.77)	27.44 (7.59)	26.14 (8.17)	27.50 (8.47)	32.57 (12.87)	33.20 (5.98)	27.25 (10.31)	30.58 (7.57)	36.80 (5.76)	2.071 (0.113)

\* refers to significance at p<0.05, \*\* refers to significance at p<0.01

Table 6: Mixed linear model with interaction effects (T<sub>0</sub> is baseline, T<sub>1</sub> is 3-month follow-up, T<sub>2</sub> is 6-month follow-up)  
ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOL: Carer Quality of Life AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action

Measures	SH				SH+				
	T <sub>0</sub> -T <sub>1</sub>		T <sub>0</sub> -T <sub>2</sub>		T <sub>0</sub> -T <sub>1</sub>		T <sub>0</sub> -T <sub>2</sub>		
	Effect size (95% CI)	p	Effect size (95% CI)	p	Effect size (95% CI)	p	Effect size (95% CI)	p	
ZBI	0.15 (-0.67 to 0.96)	0.727	1.10 (0.11 to 2.09)	<b>0.032</b>	1.62 (0.53 to 2.71)	<b>0.016</b>	2.23 (1.04 to 3.41)	<b>0.000</b>	
MCSI	0.83 (-0.03 to 1.68)	0.610	0.90 (-0.60 to 1.17)	0.950	1.33 (0.29 to 2.36)	<b>0.007</b>	1.48 (0.41 to 2.54)	<b>0.007</b>	
CAREQOL-MS	0.50 (-0.36 to 1.36)	0.257	0.07 (-0.71 to 0.84)	0.868	0.57 (-0.33 to 1.48)	0.200	0.55 (-0.37 to 1.47)	0.228	
AAQ-II	0.37 (-0.54 to 1.28)	0.429	1.28 (0.35 to 2.21)	<b>0.007</b>	0.65 (-0.43 to 1.73)	0.312	0.89 (-0.14 to 1.93)	0.073	
CompACT	Total	0.83 (-0.06 to 1.71)	0.690	2.64 (1.28 to 4.01)	<b>0.030</b>	1.45 (0.40 to 2.5)	<b>0.003</b>	3.43 (1.95 to 4.92)	<b>0.000</b>
	OE	1.02 (0.11 to 1.92)	<b>0.028</b>	2.84 (1.37 to 4.32)	<b>0.000</b>	0.98 (-0.04 to 2.00)	<b>0.037</b>	2.83 (1.49 to 4.18)	<b>0.000</b>
	BA	0.39 (-0.55 to 1.34)	0.421	1.88 (0.75 to 3.02)	<b>0.001</b>	1.46 (0.39 to 2.53)	<b>0.007</b>	2.58 (1.30 to 3.87)	<b>0.000</b>
	VA	0.69 (-0.17 to 1.55)	0.124	0.52 (-0.35 to 1.39)	0.248	0.77 (-0.17 to 1.71)	0.107	1.39 (0.39 to 2.38)	<b>0.007</b>

Table 7: Effect sizes with p values for the two intervention groups (T<sub>0</sub> is baseline, T<sub>1</sub> is 3-month follow-up, T<sub>2</sub> is 6-month follow-up). p values in bold refer to significance at p>0.05

ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOL : Carer Quality of Life AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action

## **Sample Size Estimates**

Research has suggested that for measures without a published clinically significant difference (such as the ZBI), that 0.5SD can be considered clinically meaningful (Belle et al., 2006), which estimates that a decrease in score in excess of 6.68 would be considered a minimally important difference. Therefore, eighty-four participants would be needed to have a 90% chance (at 5% significance level) of detecting a decrease in strain on the ZBI. For a two-armed RCT, therefore, the sample size needed would be 168, increasing to 218 to account for potential attrition (using the highest level of attrition across the groups, (SH+) at 29%).

## **Discussion**

Eldridge et al. (2016) suggests that a feasibility study asks, “whether something can be done, should we proceed with it, and if so, how” (p.1). We have used this definition as a starting point to determine the progression criteria for this feasibility trial. In the absence of specific guidance for progression criteria for *feasibility trials*, we use Avery et al.’s (2017) guidance for progression criteria for *internal pilot trials*, and consider the traffic light system of green (go), amber (amend), and red (stop) as preferable to a simple stop/go approach in determining whether or not a trial is feasible.

Based on these criteria, we believe that overall, this study highlighted that use of ACT self-help with telephone support is feasible as an intervention to reduce carer strain in those who care for someone with MS, and therefore a full trial is warranted to highlight whether this is effective. That said, there are some aspects which would require considerable amendments before progressing to a larger trial.

## **Feasibility**

Typically, the three key aspects to consider for progression to a full trial are: trial recruitment, protocol adherence, and completeness of outcome data (Avery et

al., 2017). In the following section, we address these aspects in determining the feasibility of this study.

### *Recruitment*

The recruitment strategy for the current study was limited and would need to be adapted for a larger trial. We relied on participants self-referring to the study from information spread predominantly via social media, online forums, and word of mouth. Therefore, it is impossible to know how many people saw the publicity material, and thereby accurately assess the 'response rate'.

We did not have any funding or endorsements from relevant MS charities to support our recruitment strategy, and with funding and endorsements, we may have been able to reach a wider group of people by having a dedicated study website and social media advertising. We also believe that recruitment can be improved by presenting the study at national events where carers of people with MS are likely to attend (e.g., the *MS Life* conference). Recruiting carers by placing advertisements at NHS MS clinics would be a viable addition to the current strategy.<sup>26</sup>

What is encouraging, which is one of the reasons we have coded this criterion as amber, is that 78.5% of those who approached us consented to participate in the study.

### *Randomisation*

There was no indication from the qualitative data that participants objected to being randomised or dropped out of the trial as a result of not being allocated to their preferred group. The groups appeared largely well-balanced, with the exception of hours per week of caring.<sup>27</sup>

---

<sup>26</sup> See Extended Discussion 4.2 for a further discussion regarding recruitment

<sup>27</sup> See Extended Discussion 4.3 for a further discussion regarding randomisation

### *Protocol adherence*

Protocol adherence usually refers to adherence to the intervention (Avery et al., 2017). We, therefore, consider the acceptability of the self-help text and the telephone calls separately.

### *Self-Help Text*

The self-help text, in its current format, would not be feasible for use with this population. All participants reported difficulties in ‘translating’ the self-help text into lay-friendly language and difficulties with applying concepts conveyed in the text to their unique life situations; which was a major focus within the support calls. The amount of reading per week was also highlighted as being too labour-intensive for carers. One participant reported that, during the reading of one page, they were interrupted seven times, making it hard to engage with the text. Participants requested further flexibility to adapt the spacing of the intervention to maximise their ability to engage in light of their caring responsibilities, which might change dramatically week to week. All participants who received the text alone reported negative experiences and could not highlight any positive personal changes as a result of the text; suggesting this is not a feasible intervention group without the additional support calls. We believe that the text needs to be shortened, with the key ACT terms described well, and with MS carer-specific information and examples added to make the text usable for this group.<sup>28</sup>

### *Support Calls*

Participants’ engagement with the support calls was generally consistent. The calls were longer than expected but this may be due to the aforementioned difficulties participants had with the self-help text. There were a number of calls that needed to be cancelled or rearranged. One participant reported missing a call as the person they cared for had fallen over and therefore they were unable to answer the call. The flexibility of the call-handler is key to ensuring continued engagement, because, given the nature of the population involved in the study,

---

<sup>28</sup> See Extended Discussion 4.4 for a further discussion regarding self-help text

it is likely that calls may need to be rearranged/cancelled at short notice. Furthermore, we believe that, given the varied nature of the call content, any call-handlers should be appropriately trained clinicians able to manage unexpected and potentially distressing discussions. Call handlers should also be well trained in the ACT model, and have the ability to use their skills to go beyond examples in the book to help promote participants understanding and engagement.<sup>29</sup>

Taken together, we considered this criterion to be amber, because if the self-help text is adapted for use with this group and there is flexibility in making/receiving the telephone calls, we believe this is a feasible intervention. However, we do not consider the use of the self-help text alone (without the telephone support) as a viable intervention, and would not recommend taking this forward as an intervention in a phase III trial.

#### *Attrition*

Overall levels of attrition across the study were lower than expected. However, there were higher levels of attrition across the two intervention groups compared with UC, with the highest level of attrition in the SH+ group. This may be related to the higher level of contact between participants and researchers in this group; participants formally withdrew early in the intervention when researchers attempted to arrange telephone support calls, with reasons relating to the acceptability of the material. This acknowledges an area for improvement; the participant information sheet might not fully prepare participants for the type of the intervention content. There were also a considerable number of suggestions regarding the content and presentation of the intervention text itself.<sup>30</sup>

---

<sup>29</sup> See Extended Discussion 4.5 for a further discussion regarding support calls

<sup>30</sup> See Extended Discussion 4.5 for further discussion regarding attrition

### *Completeness of outcome data*

As a whole, based on the qualitative data and the completeness of the questionnaires, we believe that the number and foci of the measures was right, with the removal of the SUQ. Participants found the SUQ difficult to complete and appeared to interpret the questions in various different ways. Therefore, the SUQ in its current form is not usable. From reviewing the support calls, participants spent much of these calls discussing anxiety, which was not assessed as a separate domain. The measures of carer strain were not validated for a population of carers for people with MS and therefore, these may not have captured carer strain accurately. Indeed, measures of symptom severity may not be apt to highlight any changes as a result of the ACT intervention, as (theoretically) ACT does not aim to change the presence of 'symptoms' (reflecting strain/burden), but rather the impact of them. There was also no measure of how the person with MS was functioning at time of follow-up (i.e. number of relapses since baseline, current disability level); one participant reported that the person they care for was having a relapse during completion of 3-month follow-up which they reported affected their answers given.<sup>31</sup>

Participants commented on preferring to have hard copies of the questionnaires, which was an option but was not requested. This suggests that questionnaire completion options should be more explicit and participants should be given an overt decision point, rather than trial researchers setting a default position of completion of the questionnaire online.

Taken together, we believe the outcome measures, with the exception of the SUQ, are relevant and easy to complete, with high rates of completeness. A separate study assessing the acceptability and comprehension of a SUQ is needed. We would recommend adding a short measure of anxiety and, if available, using a carer strain measure that is specific to MS. We therefore rate this criterion as amber.

---

<sup>31</sup> See Extended Discussion 4.7 for a further discussion regarding measures



## **Effectiveness**

The individual change analyses show promising results for the use of telephone-supported ACT self-help for carers of PwMS, with the SH+ group showing more favourable results than the usual care or SH. The exploratory group analyses, whilst not powered for statistical significance, support the findings from the individual level analyses. The results show significance on two measures of symptom severity (ZBI and MCSI) and three indices from an ACT-specific process measure (the CompACT Total score, OE and BA subscale-scores) with a fourth additional index at 6-month follow-up (CompACT VA). The lack of statistical significance for the *between-groups* analyses may reflect the small sample size; the small effect sizes and the large confidence intervals (which cross the line of no effect) suggest that the current sample size may be too small to detect any change between groups. However, the *within-groups* analyses, which are statistically significant for ZBI and MCSI, show large effect sizes<sup>32</sup>.

## **Strengths and Limitations**

A strength of the study is the RCT design, adopting mixed methods to help triangulate findings. This could be further improved by detailed analysis of the telephone support calls to give further insight into participants' journeys, although this was beyond the scope of this study.

The main limitation for the study was the recruitment strategy, followed by our choice of measures. When we designed this study, we could not find any validated measure of carer strain in MS. The service use questionnaire was included to give an estimate of cost-effectiveness in a definitive trial, which could not be analysed due to the poor completion rates and participants' confusion of how to complete this measure. The exclusion of people with a mental health diagnosis may also reduce the clinical utility of this study and therefore we recommend that this be removed for a larger study, which may

---

<sup>32</sup> See Extended Discussion 4.8 for further discussion regarding effectiveness

make the findings more generalisable. Furthermore, whilst we can assess potential negative effects of the intervention in the individual change scores (e.g. those showing a deterioration), it is possible that further negative effects were not assessed, particularly those outside of the measurement parameters. It may be that there were further negative effects that were missed by the potentially narrow measurement strategy (e.g. questionnaire focussed on strain, quality of life) and it is entirely possible that positive and negative effects on the participants' ability to care effectively were not measured.<sup>33</sup>

In conclusion, a full trial of ACT-based, telephone-support self-help is warranted, further to significant changes to the study design and protocol. This feasibility study showed preliminary evidence for the effectiveness of the intervention for carers of PwMS. Further work needs to be completed ahead of progressing to full trial, with predominant changes made to the intervention material as well adapting the measures used. An internal pilot would, therefore, be necessary in order to assess the feasibility of the study with the suggested changes made.

### **Research implications**

- Overall, a fully powered randomised controlled trial is warranted.
- The utility of a self-help group, without telephone support, is not demonstrated and therefore the larger trial should be a two-arm trial, comparing self-help plus telephone support arm with a usual care arm, or another comparator.
- A measure of carer strain specific to, and validated for, carers of people with MS would improve the measurement of carer strain in this population and for related trials.
- A measure of anxiety should be included, given the prominence of this as a discussion during telephone support.

---

<sup>33</sup> See Extended Discussion 4.9 & 4.10 for a further discussion regarding strengths & limitations

- Participants should be given more explicit choices regarding receiving the self-help book as a hard copy.
- The intervention should be adapted to be specific to a carer population and language made more lay-friendly.
- The spacing of the time allocated for reading should be increased, and participants be allowed flexibility to give them a greater ability to complete the reading required whilst maintaining their caring responsibilities.

**Word Count: 6636**

This paper was prepared for submission to Rehabilitation Psychology, see <http://www.apa.org/pubs/journals/rep/?tab=4> for the full instructions to authors.

## References

- A-Tjak, J. G. L., Davis, M. L., Morina, N., Powers, M. B., Smits, J. A. J., & Emmelkamp, P. M. G. (2015). A meta-analysis of the efficacy of acceptance and commitment therapy for clinically relevant mental and physical health problems. *Psychotherapy and Psychosomatics*, *84*(1), 30–36. <https://doi.org/10.1159/000365764>
- Avery, K. N. L., Williamson, P. R., Gamble, C., Francischetto, E. O., Metcalfe, C., Davidson, P., ... Blazeby, J. M. (2017). Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open*, *7*(2), e013537.
- Belle, S. H., Burgio, L., Burns, R., Coon, D., Czaja, S. J., Gallagher-Thompson, D., ... Zhang, S. (2006). Enhancing the Quality of Life of Dementia Caregivers from Different Ethnic or Racial Groups: A Randomized, Controlled Trial. *Annals of Internal Medicine*, *145*(10), 727–738. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2585490/>
- Benito-Leon, J., Rivera-Navarro, J., Guerrero, A. L., De Las Heras, V., Balseiro, J., Rodriguez, E., ... Martinez-Martin, P. (2011). The CAREQOL-MS was a useful instrument to measure caregiver quality of life in multiple sclerosis. *Journal of Clinical Epidemiology*, *64*(6), 675–686. <https://doi.org/10.1016/j.jclinepi.2010.08.003>
- Blackledge, J., & Hayes, S. (2006). Using Acceptance and Commitment Training in the Support of Parents of Children Diagnosed with Autism. *Child & Family Behavior Therapy*, *28*(1), 1–18. [https://doi.org/10.1300/J019v28n01\\_01](https://doi.org/10.1300/J019v28n01_01)
- Bland, J. M., & Altman, D. G. (2011). Comparisons against baseline within randomised groups are often used and can be highly misleading. *Trials*, *12*, 264. <https://doi.org/10.1186/1745-6215-12-264>
- Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., ... Zettle, R. D. (2011). Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. *Behavior Therapy*, *42*(4), 676–688. <https://doi.org/10.1016/j.beth.2011.03.007>

- Buchanan, R. J., & Huang, C. (2012). Caregiver perceptions of accomplishment from assisting people with multiple sclerosis. *Disability and Rehabilitation*, 34(1), 53–61. <https://doi.org/10.3109/09638288.2011.587091>
- Carers Trust. (2015). *What is a carer?* Retrieved September 11, 2017, from <https://www.carers.org/whats-a-carer>
- Carton, H., Loos, R., Pacolet, J., Versieck, K., & Vlietinck, R. (2000). A quantitative study of unpaid caregiving in multiple sclerosis. *Multiple Sclerosis Journal*, 6(4), 274–279. <https://doi.org/10.1177/135245850000600409>
- Cheung, J., & Hocking, P. (2004). Caring as worrying: the experience of spousal carers. *Journal of Advanced Nursing*, 47(5), 475–482. <https://doi.org/10.1111/j.1365-2648.2004.03126.x>
- Chien, W. T., Thompson, D. R., Lubman, D. I., & McCann, T. V. (2016). A Randomized Controlled Trial of Clinician-Supported Problem-Solving Bibliotherapy for Family Caregivers of People With First-Episode Psychosis. *Schizophrenia Bulletin*, 42(6), 1457–1466. Retrieved from <http://dx.doi.org/10.1093/schbul/sbw054>
- Chipchase, S., & Lincoln, N. (2001). Factors associated with carer strain in carers of people with multiple sclerosis. *Disability and Rehabilitation*, 23(17), 768–776. <https://doi.org/10.1080/09638280110062158>
- Corry, M., & While, A. (2009). The needs of carers of people with multiple sclerosis: A literature review. *Scandinavian Journal of Caring Sciences*, 23(3), 569–588. <https://doi.org/10.1111/j.1471-6712.2008.00645.x>
- das Nair, R., Lincoln, N. B., Ftizsimmons, D., Brain, N., Montgomery, A., Bradshaw, L., ... Pink, A. (2015). Rehabilitation of memory following brain injury (ReMemBrIn): study protocol for a randomised controlled trial. *Trials*, 16, (6). <https://doi.org/10.1186/1745-6215-16-6>
- Department of Health. (2014). Care Act 2014: *Factsheet 8 - Carers*. Retrieved November 8, 2017, from [http://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/366089/Factsheet\\_8\\_-\\_Carers.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/366089/Factsheet_8_-_Carers.pdf)
- Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining Feasibility and Pilot Studies

- in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PLoS ONE*, 11(3), e0150205. <https://doi.org/10.1371/journal.pone.0150205>
- Figved, N., Myhr, K.-M., Larsen, J.-P., & Aarsland, D. (2007). Caregiver burden in multiple sclerosis: the impact of neuropsychiatric symptoms. *Journal of Neurology, Neurosurgery, and Psychiatry*, 78(10), 1097–102. <https://doi.org/10.1136/jnnp.2006.104216>
- Francis, A. W., Dawson, D. L., & Golijani-Moghaddam, N. (2016). The development and validation of the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT). *Journal of Contextual Behavioral Science*, 5(3), 134–145.
- French, K., Golijani-Moghaddam, N., & Schröder, T. (2017). What is the evidence for the efficacy of self-help acceptance and commitment therapy? A systematic review and meta-analysis. *Journal of Contextual Behavioral Science*.
- Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13(1), 117.
- Hayes, S. (2004). Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behavior Therapy*, 35(4), 639–665. [https://doi.org/10.1016/S0005-7894\(04\)80013-3](https://doi.org/10.1016/S0005-7894(04)80013-3)
- Hayes, S., Luoma, J., Bond, F., Masuda, A., & Lillis, J. (2006). Acceptance and commitment therapy: model, processes and outcomes. *Behaviour Research and Therapy*, 44(1), 1–25. <https://doi.org/10.1016/j.brat.2005.06.006>
- Hayes, S., Pistorello, J., & Levin, M. (2012). Acceptance and Commitment Therapy as a Unified Model of Behavior Change. *The Counseling Psychologist*, 40(7), 976–1002. <https://doi.org/10.1177/0011000012460836>
- Hayes, S., & Smith, S. (2005). *Get Out Of Your Mind And Into Your Life: The New Acceptance and Commitment Therapy*. New Harbinger.
- Hayes, S., Strosahl, K., & Wilson, K. (1999). *Acceptance and Commitment Therapy: An experiential approach to behavior change*. New York:

Guildford Press.

- Heward, K., Molineux, M., & Gough, B. (2006). A Grounded Theory Analysis of the Occupational Impact of Caring for a Partner who has Multiple Sclerosis. *Journal of Occupational Science*, 13(2–3), 188–197. <https://doi.org/10.1080/14427591.2006.9726515>
- Hunt, C. K. (2003). Concepts in Caregiver Research, 27–32.
- Jacobson, N., Roberts, L., Berns, S., & McGlinchey, J. (1999). Methods for Defining and Determining the Clinical Significance of Treatment Effects: Description, Application , and Alternatives. *Journal of Consulting and Clinical Psychology*, 67(3), 300–307. <http://doi.org/10.1037/0022-006X.67.3.300>
- Jacobson, N. S., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, 59(1), 12–19
- Jones, C. A., Pohar, S. L., Warren, S., Turpin, K. V. L., & Warren, K. G. (2008). The burden of multiple sclerosis: a community health survey. *Health and Quality of Life Outcomes*, 6, 1. <https://doi.org/10.1186/1477-7525-6-1>
- Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics*, 4(4), 287–291. <https://doi.org/10.1002/pst.185>
- Kasuya, R. T., Polgar-Bailey, P., & Takeuchi, R. (2000). Caregiver burden and burnout. A guide for primary care physicians. *Postgraduate Medicine*, 108(7), 119–123. <https://doi.org/10.3810/pgm.2000.12.1324>
- Khan, F., Pallant, J., & Brand, C. (2007). Caregiver strain and factors associated with caregiver self-efficacy and quality of life in a community cohort with multiple sclerosis. *Disability and Rehabilitation*, 29(16), 1241–1250. <https://doi.org/10.1080/01443610600964141>
- Knight, R., Devereux, R., & Godfrey, H. (1997). Psychosocial consequences of caring for a spouse with multiple sclerosis. *Journal of Clinical and Experimental Neuropsychology*, 19(1), 7–19. Retrieved from [http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed4&N\\_EWS=N&AN=1997085641](http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed4&N_EWS=N&AN=1997085641)
- Lincoln, N., das Nair, R., Bradshaw, L., Constantinescu, C. S., Drummond, A. E.

- R., Erven, A., ... Morgan, M. (2015). Cognitive Rehabilitation for Attention and Memory in people with Multiple Sclerosis: study protocol for a randomised controlled trial (CRAMMS). *Trials*, 16(1), 1–9. <https://doi.org/10.1186/s13063-015-1016-3>
- Lundgren, T., Dahl, J., Melin, L., & Kies, B. (2006). Evaluation of acceptance and commitment therapy for drug refractory epilepsy: a randomized controlled trial in South Africa--a pilot study. *Epilepsia*, 47(12), 2173–2179. <https://doi.org/10.1111/j.1528-1167.2006.00892.x>
- Mackenzie, I. S., Morant, S. V., Bloomfield, G. A., MacDonald, T. M., & O’Riordan, J. (2014). Incidence and prevalence of multiple sclerosis in the UK 1990-2010: a descriptive study in the General Practice Research Database. *Journal of Neurology, Neurosurgery, and Psychiatry*, 85(1), 76–84. <https://doi.org/10.1136/jnnp-2013-305450>
- McCann, T. V., Lubman, D. I., Cotton, S. M., Murphy, B., Crisp, K., Catania, L., ... Gleeson, J. F. M. (2013). A Randomized Controlled Trial of Bibliotherapy for Carers of Young People With First-Episode Psychosis. *Schizophrenia Bulletin*, 39(6), 1307–1317. Retrieved from <http://dx.doi.org/10.1093/schbul/sbs121>
- McKeown, L. P., Porter-Armstrong, a P., & Baxter, G. D. (2003). The needs and experiences of caregivers of individuals with multiple sclerosis: a systematic review. *Clinical Rehabilitation*, 17, 234–248. <https://doi.org/10.1191/0269215503cr618oa>
- MS Society. (2013). *A lottery of treatment and care - MS services across Scotland and the UK*. Retrieved from <http://mslottery.mssociety.org.uk/wp-content/uploads/2013/04/UK-ms-lottery.pdf>
- Murphy, N., Confavreux, C., Haas, J., Konig, N., Roullet, E., Sailer, M., ... C., Y. (1998). Economic evaluation of multiple sclerosis in the UK, Germany and France. *Pharmacoeconomics*, 13(5 II), 607–622. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed4&N=EWS=N&AN=1998162600>
- Plumb, J. C., & Vilardaga, R. (2010). Assessing treatment integrity in acceptance and commitment therapy: Strategies and suggestions. *International Journal of Behavioral Consultation and Therapy*. Plumb,



- Jennifer C.: Department of Psychology, University of Nevada, Reno, Mail Stop 298, Reno, NV, US, 89557-0062, jcplumb@gmail.com: Joseph D. Cautilli. <https://doi.org/10.1037/h0100912>
- Ritchie, J., Spencer, L., & O'Connor, W. (2003). Carrying out qualitative analysis. *Qualitative research practice: A guide for social science students and researchers*, 2003, 219-62
- Robinson, B. C. (1983). Validation of a Caregiver Strain Index. *Journal of Gerontology*, 38(3), 344–348
- Thornton, M., & Travis, S. S. (2003). Analysis of the reliability of the modified caregiver strain index. *J Gerontol B Psychol Sci Soc Sci.*, 58. <https://doi.org/10.1093/geronb/58.2.S127>
- Topcu, G., Buchanan, H., Aubeeluck, A., & Garip, G. (2016). Caregiving in Multiple Sclerosis and Quality of Life: A Meta-synthesis of Qualitative Research. *Psychology & Health*, 446(February), 1–31. <https://doi.org/10.1080/08870446.2016.1139112>
- Williams, J., Vaughan, F., Huws, J., & Hastings, R. (2014). Brain injury spousal caregivers ' experiences of an acceptance and commitment therapy ( ACT ) group. *Social Care and Neurodisability*, 5(1), 29–40. <https://doi.org/10.1108/SCN-02-2013-0005>
- Winter, L., & Gitlin, L. N. (2007). Evaluation of a telephone-based support group intervention for female caregivers of community-dwelling individuals with dementia. *American Journal of Alzheimer's Disease & Other Dementias®*, 21(6), 391–397.
- Wise, E. A. (2004). Methods for analyzing psychotherapy outcomes: a review of clinical significance, reliable change, and recommendations for future directions. *Journal of Personality Assessment*, 82(1), 50–59. [http://doi.org/10.1207/s15327752jpa8201\\_10](http://doi.org/10.1207/s15327752jpa8201_10)
- Zarit, S., Orr, N. K., & Zarit, J. M. (1985). *The hidden victims of Alzheimer's disease: Families under stress*. NYU Press.

## **EXTENDED PAPER**

### **1. Extended Introduction**

This extended introduction gives further details on caring for someone with Multiple Sclerosis (MS), and associated carer stress/ strain. This section offers an in-depth review of Acceptance and Commitment Therapy (ACT), bibliotherapy and teletherapy, and discusses study aims/ objectives in more detail alongside the epistemological position of the study.

#### **1.1 Multiple Sclerosis**

Multiple Sclerosis (MS) is caused by the demyelination of axons; which can result in a wide range of symptoms dependent on the location of the damage to the nerves (Smith & McDonald, 1999). This demyelination can result in scar tissue building up around axons, causing nerve damage. These are often referred to as lesions, or plaques. The damage to the myelin, or the lesions, can cause the nerve signals to slow down or to be blocked completely. The location of the demyelination or lesions can be in the brain or the spinal cord. Therefore, the range of symptoms associated with MS can vary significantly between people, and is dependent on the level of demyelination, the location of demyelination/ lesions, and the severity of damage to the nerve itself (Keegan & Noseworthy, 2002; Smith & McDonald, 1999). Research estimates that more than 30% of PwMS experience moderate-to-severe plasticity, most commonly in legs, and 90% report bladder dysfunction and fatigue. Other common symptoms include sensory disturbances, constipation and sexual dysfunction (Goldenberg, 2012).

The cause of demyelination is currently unknown (Smith & McDonald, 1999). Although there are numerous theories and a number of contributing factors, including genetics, infectious diseases and a Vitamin D deficiency (Gilden, 2017), there has been no widely acknowledged causal factor(s) (Keegan & Noseworthy, 2002).

There are three subtypes of MS; relapsing remitting (RR), primary progressive (PP) or secondary progressive (SP). A fourth type of MS (Benign) also exists, although this refers to MS where the person has no symptoms (or shows little to no disability) for many years; generally recognised as a lack of symptoms for more than 15 years (Lassmann, Brück, & Lucchinetti, 2001). The subtype of MS is categorised by the presence of symptoms and course of the MS. RR MS is characterised by symptoms that can appear suddenly, which lasts on average 2-6 weeks, and then the symptoms decrease/remit completely (Rejdak, Jackson, & Giovannoni, 2010). Approximately 85% of people with MS (PwMS) are initially diagnosed with relapsing-remitting (RR) type, characterised by symptomology developing during a relapse. Symptoms must be present for a period of at least 24 hours, and cannot otherwise be explained by infection or disease. The specific symptoms are dependent on the location of lesions, and can be new, can be the re-emergence of previous symptoms, or symptoms presenting in new parts of the body. PP MS refers to a disease trajectory in which symptoms present and are progressive from onset, whereas SP MS starts its course as RR and then becomes progressive (Calabresi, 2004; Lassmann et al., 2001; Murray, 2006).

## **1.2 Caring for someone with MS**

The MS Society estimates that currently over 71% of PwMS receive care, support or assistance from a family member or friend (MS Society, 2013), and one in three report that they rely solely on care and support from these 'informal carers' (Redfern-Tofts, Wallace, & Mcdougal, 2016). Indeed, despite health and social care provisions for people with MS, one study highlighted, across all levels of disability, that people with MS were more likely to have received care and support in the preceding 24 hours from family, than from health or social care services (O'Hara, De Souza, & Ide, 2004).

Given the variation in the symptomology of MS, as well as the level of disability and trajectory of disease, it is hard to get a nuanced picture of the specific

activities involved in caring for someone with the illness (Carton et al., 2000). However, research has highlighted that caring responsibilities can vary dramatically; from household chores and support with finances, to personal care being provided by these informal carers, as opposed to being provided by health or social care services (Aronson, Cleghorn, & Goldenberg, 1996; Buchanan, Radin, Chakravorty, & Tyry, 2010; Corry & While, 2009; O'Hara et al., 2004). Research has also shown that the level of caring behaviour increases alongside any increases in the sufferers' level of disability (Murphy et al., 1998). Given the unpredictability of the disease course and potential presence of relapses and remissions, this is not a linear relationship (Carton et al., 2000), and is likely to be mediated by the environment and resources of the individual and their family/ carer (Kersten et al., 2000). Furthermore, research suggests that it is illness type and not just the severity of disability that is predictive of caring roles and specific behaviours associated with these caring roles (Jones et al., 2008). Research further suggests that, whilst the majority of this care is provided by a spouse or partner, many carers report caring for a friend or neighbour (Carton et al., 2000), which may impact the topography of caring behaviours.

The caring duties can have both a positive, and negative, impact on a carer's health, wellbeing, as well as potential impacts on their financial situation; with as many as four in ten informal carers of working age reducing their working hours in order to provide this care (Buchanan, Radin, Chakravorty, & Tyry, 2009). The experience of caring as positive, negative, or more likely a mixture of both, has been theorised to be mediated both the objective and subjective experiences of caring (Kersten et al., 2000).

### **1.2.1 Carer strain in MS**

Not all carers experience stress/ strain as a result of their caring responsibilities (Cheung & Hocking, 2004; Heward et al., 2006), indeed as many as two-thirds describe caring as a rewarding experience (Buchanan, Radin, Chakravorty, & Tyry, 2009). However, research has consistently shown that carers report

feeling strain day to day as a result of caring, and highlight a plethora of unmet needs (Corry & While, 2009; Kersten et al., 2000; Lorefice et al., 2013).

Given the difficulty in describing the topography of behaviour associated with caring for someone with MS, the strain associated can be as varied as the presentation of the disease itself. Indeed, carers have reported that they can have periods without feeling any strain, and times where this might become overwhelming (Peters, Jenkinson, Doll, Playford, & Fitzpatrick, 2013b). Historically, literature of carer strain has focussed on the elderly, or those with a dementia (Pearlin, Mullan, Semple, & Skaff, 1990), highlighting the role of the carer's own ageing and changing resources, physically, emotionally, and financially as a contributor to experiences of caring as stressful. Recently, there is a growing body of literature that focusses on carers for people with MS as a heterogeneous group, looking beyond purely spousal carers as well as differences in those caring for people at different points in their lifespan (Corry & While, 2009). Indeed, grief has been highlighted as a mediating factor in levels of strain; the caregiver may experience grief for the perceived loss of the person, or their relationship as it was, prior to the MS (O'Brien, Wineman, & Nealon, 1995), something found to be particularly pertinent in spousal carers (Cheung & Hocking, 2004).

Levels of psychological distress and strain in carers has been found to be correlated to a number of factors related to the health of the person with MS (Corry & While, 2009). This review highlighted that it is most commonly level of disability that is predictive of the level of strain reported by the carer (Corry & While, 2009); whereas other research has argued that it is not the level of disability, but the unpredictability of the disease that carers reports as being the most difficult to manage (Bhuse, 2008; Khan et al., 2007; Rivera-Navarro et al., 2009). Importantly, these are not necessarily distinct concepts; the unpredictable nature of the disease course and fluctuating nature of the condition might be related to both the planning and control of responsibilities and also the level of disability of the individual that impact upon carer strain. Interestingly, research has not acknowledged the indirect effect of the distress

carer strain might cause the individual with MS, which, in turn, may then be further impacting on the carer; especially given the number of people who care for a family member. Indeed, one study highlighted the experiences of carers and the person with MS when they were given the change in diagnosis from relapsing-remitting to secondary-progressive and the impact this has on both the mental health of the individual with MS, and subsequent experiences of strain by the carer, particularly when planning for the future (Davies et al., 2015).

Other research suggests that it is the *type* of disability, rather than the *level* that is most predictive of carer strain. Figved, Myhr, Larsen and Aarsland (2007) found that psychiatric and cognitive difficulties were most strongly correlated with the caregiver's distress. Peters et al. (2013a) found that the number of problems reported by carers was correlated with carer strain, even when caregiving variables (e.g., level of disability) are corrected for. Furthermore, research has highlighted the correlation between characteristics of the carer themselves and their perceived burden from caring, highlighting the importance of understanding the carer strain as related to the person with MS, as well as the strengths and personal resources available to the carer (Buchanan & Huang, 2012).

### **1.3 Psychological Interventions and Support Services for Carers**

There is a distinct lack of evidence around interventions for carers of people with MS. There is a larger body of evidence focussing on other degenerative neurological conditions; a recent meta-review of thirteen systematic reviews highlighted the effectiveness of psychosocial multicomponent interventions for carers of people with Dementia (Dickinson et al., 2017), noting the considerable potential of technology-based interventions. Currently, support for carers of PwMS in the UK tends to focus on practical aspects, such as obtaining paid carers and respite care (Freeman & Thompson, 2000; MS Society, 2013), which, whilst providing immediate relief, serves to perpetuate a cycle of potentially costly respite services, and does not promote behavioural change.

Indeed, one study highlighted that carers, and the individual with MS, felt they are 'left to get on with it' (Davies et al., 2015).

A UK survey which looked at experiences of carers across a number of neurological conditions (including MS, Motor Neurone and Parkinson's Disease) highlighted that 70% of carers felt that they lacked any opportunity to discuss difficulties they were experiencing related to caring (Peters et al., 2013b). Respondents also highlighted that where services were accessible, they tended to be generic services within mental health and social care and not specific to the needs of carers. This lack of targeted care reduced the respondents' belief that there was any genuine understanding of their problems amongst the healthcare professionals with whom they were dealing or that there was insufficient flexibility within the services themselves to allow adaption of these services to meet the specific circumstances encountered by the carers. Indeed, a study completed in Australia showed more positive outcomes for carers (across a number of neurological conditions) where the service was developed specifically for carers (Kristjanson, Aoun, & Yates, 2006), highlighting that current service provisions may not be best suited to the complex and unique needs of carers.

#### **1.4 Acceptance and Commitment Therapy (ACT)**

In short, ACT (Hayes et al., 1999), a '*third wave*' of traditional cognitive behavioural therapies (CBT), focusses on accepting the things that are out of our control, and committing our actions in line with our values (Hayes, 2004). ACT is a model of *behavioural change*, and aims to help people discover their true values and then find ways to change their actions in line with these values (Hayes et al., 2012). ACT teaches people to respond more effectively to difficult thoughts and feelings, so that these difficult thoughts no longer act as a barrier to living a full and enjoyable life.

### 1.4.1 Theory

Fundamentally, ACT is steeped in behaviourism. Relational Frame Theory (RFT; Hayes, Barnes-Holmes, & Roche, 2001), a behavioural account of human language and cognition, forms the underpinnings of the ACT model.

In brief, RFT posits that language and cognition is based on learned relationships between stimuli (events). Multiple exemplar training allows for humans to derive novel relations between stimuli – even in the absence of direct experience, and independently of formal or physical stimulus relations – based on arbitrary contextual cues (e.g., sound combinations [‘words’] produced in the social environment) – an ability that conceptually accounts for the generativity of language. RFT further posits that humans respond to stimuli according to the learned relations among them: given the human propensity to derive relations between stimuli (i.e., form ‘relational frames’), enabling the functions of one stimulus to transform functions of another, this has important implications for understanding human behaviour and its language-mediated nature (Roche, Barnes-Holmes, Barnes-Holmes, Stewart, & O’Hora, 2002). One implication is that the psychological functions of stimuli can transfer to the words or images that are coordinated with them; of clinical relevance, this means that verbal and cognitive stimuli can come to invoke the same responses as the external events that they relate to – for example, verbal awareness of past aversive events may elicit pain and attempted avoidance. The pervasiveness of language and verbal awareness enables experiential contact with pain (unwanted thoughts and feelings) across situations, and even in the absence of external stressors; advocates of RFT and ACT posit that attempts to control these unwanted thoughts and feelings ultimately lead to an internal struggle which can prevent the individual from living a full and valued life.

Philosophically, ACT is rooted in Functional Contextualism (Biglan & Hayes, 1996; Hayes, 2004); a pragmatic variation on traditional Contextualism which aims to achieve both prediction and influence of events, viewing psychological events as ongoing and situationally defined. Central to the ACT model is,



therefore, the notion of workability, and that psychological pain is mediated by contextual factors (or, the relational frame). Therefore, attempts to challenge thoughts and feelings are not necessary to change behaviours, if we can change the context in which these thoughts and feelings are causally linked to behaviours (Hayes et al., 2006).

Taken together, these form the foundations of the ACT model; through a series of learnt experiences, humans create complex relational frames which are then arbitrarily applied to form the basis of human responding. In the context of psychotherapy, this proposes that previously neutral thoughts, feelings, memories, bodily sensations etc., can become aversive stimuli in themselves, shaping behaviours. Importantly, ACT rejects the notion of a 'healthy normality' and theorises 'destructive normality', the notion that suffering arises from processes which are common amongst humans, resultant of these relational frames (Hayes et al., 1999). Therefore, ACT works towards acceptance of these thoughts and feelings and focusses on the committing actions towards valued-based goals; attempts to control unwanted thoughts, feelings, memories, sensations etc., only further reinforces these relational frames and seeks to increase psychological distress.

The ACT model is formed around six core processes, often referred to as the 'Hexaflex'; acceptance, cognitive defusion, being present, self-as-context, values and committed action. Together, these processes are theorised to improve psychological flexibility; the ability to engage consciously in the present moment and respond accordingly in line with values (Hayes et al., 2006).

#### **1.4.2 ACT evidence base**

The evidence base for ACT, across a number of different difficulties and disorders, is promising. Although, perhaps unsurprisingly, is in relative infancy compared to more traditional psychotherapies. It is beyond the scope of this thesis to give a complete and nuanced picture of the current ACT evidence-base. However, ACT has been listed as a "research-supported" treatment

approach by the American Psychological Association (APA) for chronic pain, depression, anxiety, obsessive-compulsive disorder and psychosis, with chronic pain having the most extensive and strong research base (Levant et al., 2006).

Whilst the evidence is promising, there have been critical reviews contesting the potential effectiveness of ACT as compared to other treatment options, and differing estimates of potential effect sizes. One author has sought to estimate the effectiveness of ACT across a number of psychiatric conditions, somatic disorders as well as for workplace stress. Most recently, this found a small effect size (0.42) following a meta-analysis of 60 RCTs totalling 4234 participants (Öst, 2014), although interestingly this effect size has deteriorated from the previous iteration of this meta-analysis which showed an effect size of 0.68 (Öst, 2008). These also showed no statistically significant difference between ACT and CBT. However, Ruiz (2012) completed a systematic review and meta-analysis of 16 articles which directly compared ACT to CBT. Mean effect sizes were found to favour ACT (Hedge's  $g = 0.40$ ), and it was noted that eleven of the sixteen included studies had at least one outcome where ACT outperformed CBT, whereas only two where CBT was shown to outperform ACT. Interestingly, the author highlighted that these 'head-to-head' studies were predominantly authored by researchers with an interest in ACT (Ruiz, 2012). All these reviews have highlighted distinct methodological criticisms of those included articles, and acknowledged potential epistemological difficulties with use of symptom reduction as a measurement of intervention 'success' (Öst, 2008, 2014; Ruiz, 2012).

Interestingly, a recent analysis focussed on anxiety and depression, used a sequential meta-analysis to highlight, and critically appraise, the sufficiency of the ACT evidence base (Hacker, Stone, & MacBeth, 2016). This also demonstrated at least moderate pre-post effect sizes for ACT when compared to no treatment, but concluded 'insufficient evidence' for both anxiety and depression, when comparing ACT to an active control, or other treatment option. This gives a fairly rounded overview of the current evidence for ACT; there is a solid evidence base when comparing ACT to a no-treatment control,

and some evidence when comparing to other interventions. However, the current evidence base is not at a level in which to satisfy 'sufficiency' that ACT should be offered as a first-line of treatment for governing bodies such as NICE to change its guidance (Hacker et al., 2016). Regardless, as ACT has consistently demonstrated as least a small effect size across a number of clinical and non-clinical conditions (such as stress), suggesting it may be an applicable approach for a carer population.

### **1.4.3 ACT for carers**

There is a distinct paucity of studies of any intervention for carers of people with MS, or indeed for 'informal' carers of other conditions, and fewer still using ACT approaches. One study for carers of people with a Traumatic Brain Injury (TBI) used a group-based ACT intervention and found that participants reported an increased awareness of their own psychological difficulties, which, for a small proportion of participants, resulted in a negative outcome. However, other participants found that this increased awareness, whilst 'painful' at times, allowed them to identify their own needs and start integrating ACT principles into their lives (Williams et al., 2014). This study, whilst showing some preliminary evidence for the applicability of ACT to a caring population, focused only on qualitative outcomes and did not assess effectiveness of the intervention. Therefore, whilst participants may have reported changes resultant of the intervention, there is no evidence to support whether these were reflective of any change in stress/ strain. Furthermore, there was no follow-up period to this study, and therefore it is impossible to highlight whether any potential changes were indicative of change in longer-term functioning. Indeed, the study acknowledges that even those who showed an increase in awareness of 'painful' emotions, it concludes that this allowed participants to start integrating ACT principles into their lives, without sufficient data to support or refute this.

One RCT compared CBT and ACT for carers of people with Dementia, with those randomised to ACT showing significantly lower levels of anxiety at post-treatment than those randomised to receive the CBT intervention ( $d=0.5$ ,  $p<0.05$ ), however this was not maintained at a longer-term follow-up (Losada et al., 2015). Individual analyses showed that 36% of those who received an ACT intervention showed clinically significant change at post-intervention, compared with 23% of those receiving CBT, and at follow-up 36% of those receiving ACT and 26% of those receiving CBT were deemed 'recovered' (Losada et al., 2015). This study shows that both may be viable treatment options for carers, although it is important to note that the focus of the study was on anxiety and depression rather than carer-related strain. There is already widespread evidence supporting the use of ACT and CBT for people with anxiety and depression, and therefore whilst the study was novel in that it focused only on those who are carers for people with MS, it did not look at this from a carer strain perspective and did not acknowledge it as a distinct phenomenon. Indeed, those included in the study may well be experiencing depression or anxiety that is entirely related, or unrelated to their caring duties. Arguably, from an ACT perspective, it may not be expected that people would be aiming for 'recovery' as measures included in this study focus on symptom reduction and not on impact of symptoms and experiences on day-to-day life; more consistent with ACT theory.

#### **1.4.4 Rationale for ACT for carers of people with MS**

Carers of people with MS report difficulties in coping with the unpredictability of the disease (Bhuse, 2008; Khan et al., 2007; Rivera-Navarro et al., 2009); ACT would see this as an attempt to assert control, and argues that unwanted thoughts and feelings arise when there is a threat to this illusion of control. Theoretically, ACT is, therefore, well-suited to addressing suffering in the context of caring for someone with a chronic and unpredictable condition, wherein efforts to 'solve' or exert control over difficulties may be unfeasible and ultimately counterproductive; ACT is inherently response focused rather than antecedent-focused as in CBT (Hofmann & Asmundson, 2008). CBT would

promote use of cognitive challenging techniques, whereas, in a caring population, the beliefs or thoughts about the symptoms may be well be true, and it is the attempts to assert control which is contributing to the strain experienced by the carers. Indeed, ACT aims to help people adopt a psychological flexibility and learn to accept those things that are out of our control (i.e. the disease, its progression and the associating thoughts and feelings) and commit our action to those 'workable actions'. ACT works on developing acceptance (coming to terms with difficult thoughts and feelings, in order to achieve meaningful engagement in valued activities) and may represent a realistic, adaptive approach to managing the apparently intractable emotional demands of caring (through building general resilience).

Research has also highlighted the correlation between the personal characteristics of the carer themselves, and the level of perceived burden. For example, Buchanan and Huang (2011) found that carers who felt that their caring responsibilities were emotionally draining was indicative of poorer mental health, suggesting that it is, therefore, possible to improve carer strain by focussing on the carer's perception of caring as a burden. Furthermore, researchers have argued that because ACT aims to teach generic positive psychological skills, rather than targeting specific unwanted experiences and feelings, it is inherently trans-diagnostic, and has been shown to be of value across many physical, and mental health conditions, even in the absence of a diagnosis (Dindo, Van Liew, & Arch, 2017).

### **1.5 Self-help**

The definition of 'self-help' can vary dramatically (Cavanagh, Strauss, Forder, & Jones, 2014; Lewis et al., 2003), and can also be referred to as 'self-care', 'self-management', 'self-instruction' or even 'psychoeducational' interventions (Lewis et al., 2003). Cuijpers (1997) offered a definition focussed on the individual 'helping' or 'improving' themselves without therapist input. This definition separates psychoeducation from 'self-help', in that providing information alone is not sufficient; a more structured approach, involving skills-based techniques

that allow the individual to make active change, is necessary. Furthermore, the extent to which self-help involves therapist guidance can vary; from those which are purely self-help to those involving differing levels of guidance or support (Cavanagh et al., 2014; Newman, Erickson, Przeworski, & Dzus, 2003; Newman, Szkodny, Llera, & Przeworski, 2011).

A growing body of research exploring the use of psychological interventions delivered in a self-help format, both for people with a diagnosed psychiatric disorder and for general psychological distress in non-clinical populations, is emerging. Self-help therapies have been increasingly recommended as a first-line intervention (NICE, 2017), and allow for psychologically guided interventions to be accessible to a large population at potentially relatively little cost to the NHS. Given the current emphasis on cost-saving and austerity in the United Kingdom, it is perhaps unsurprising that self-help interventions may be developed as a first line of treatment (NICE, 2009, 2011, 2017). Although, interestingly, high quality RCTs have consistently been shown to lack data, or to not report data, on the cost-effectiveness of self-help interventions (Lewis, Pearce, & Bisson, 2012). However, two articles based in the United States estimated savings of \$540-\$630 per client when compared with standard CBT (Newman, Consoli, & Taylor, 1999; Newman, Kenardy, Herman, & Taylor, 1997). It is important to note, however, that neither article was an RCT nor were they based in the UK; hence they were not included in the Lewis and colleagues review. More recently, a systematic review of the economic impact of 'third wave' therapies highlighted no self-help studies which reported data on cost-effectiveness, or other economic analyses (Feliu-Soler et al., 2018). Regardless, some economists have argued that self-help therapies would inherently pay for themselves by reducing other costs associated with more intensive psychological interventions (therapist time etc.) and increase productivity and subsequently improve return to work figures (Layard, Clark, Knapp, & Mayraz, 2007). However, it is important to note that, whilst this may seem like common sense, there is a paucity of research supporting these claims, especially in long-term follow-up studies.

The evidence base for the effectiveness of self-help therapies is promising, although it has predominantly focused on anxiety, depression or stress. Indeed, Bower and Gilbody (2005) conducted a review examining a stepped care model for psychological interventions and recommended further research into both the acceptability and cost-effectiveness of self-help therapies. Interestingly, one meta-analysis on 'minimal contact therapies' (including both self-help and guided self-help) found that none of the 31 included RCTs reported data on acceptability of these interventions, to clients (Lewis et al., 2012). With regards to effectiveness, this showed overall effectiveness when compared to a wait-list control, but highlighted that face-to-face individual therapy was more effective than use of self-help (self-help compared to face-to-face therapy will be discussed in more detail in extended introduction 1.5.1). Whilst there are calls for further research into the cost-effectiveness and acceptability of self-help therapies, there is considerable evidence supporting use of self-help as a first line treatment; with a comprehensive review demonstrating effectiveness for clients with anxiety and/ or depression (den Boer, Wiersma, & van den Bosch, 2004).

Many of the self-help treatments evaluated have focussed on CBT interventions, and therefore the evidence base for non-CBT, or 'third-wave' therapies, in a self-help format is still in its infancy. However, a recent meta-analysis (Cavanagh et al., 2014) focussed on mindfulness-based self-help interventions and showed a statistically significant decrease in symptoms of anxiety and depression. This meta-analysis demonstrated the use of these third wave interventions when delivered in a self-help format.

Furthermore, systematic reviews of self-help has historically included both interventions with some (but minimal) therapist contact, alongside those that are purely self-help (e.g. Cavanagh et al., 2014). NICE guidance supports use of 'self-help' for depression, as an example, but refers to telephone-supported self-help, with the use of weekly telephone contact with a therapist (NICE, 2009). Despite deeming this as the first stage within the stepped care model, it is entirely possible that therapies with no therapist contact at all could be clinically

effective (e.g. Cuijpers et al., 2011; Lewis et al., 2012), and relatively cost-effective. Therefore, it is necessary to investigate both self-help involving no therapist contact as well as therapist-guided self-help as potentially effective alternatives to face-to-face therapy.

### **1.5.1 Self-help vs. face-to-face therapy**

There is a mixed evidence base surrounding the effectiveness of self-help when compared to face-to-face interventions. As discussed earlier, Lewis and colleagues (2012) found that self-help was less effective than face-to-face interventions for anxiety disorders. Yet other research has not supported this; one study showed no statistically significant difference in effectiveness of guided self-help compared with face-to-face treatment for treatment for anxiety or depression (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010). Indeed, small (but not statistically significant) effect sizes favouring guided self-help were shown. Importantly, the authors highlight that participants included in this study consented to randomisation to either self-help or face-to-face and that there were no significant differences between the two modalities in regard to attrition. This may not be representative of all those seeking help with anxiety or depression; not all those seeking help for anxiety/ depression would accept a fifty percent chance of receiving a self-help treatment. Therefore, whilst this research highlights that self-help may be appropriate for *some* people seeking help for anxiety or depression, it gives little insight into *for whom* self-help might be most appropriate or acceptable, or *when* in their journey. Furthermore, this study focussed only on guided self-help and, whilst systematic reviews of non-guided self-help have found it to be effective in reducing anxiety (Lewis et al., 2012) and depression (Cuijpers et al., 2011), effect sizes for non-guided interventions were lower than those for guided self-help treatments.

As far as we are aware, there is no evidence comparing effectiveness of these interventions for carers of people with MS, although there is support for the use of telephone-administered CBT for depression with people with MS (Mohr et al., 2000). Furthermore, one review of technology-based CBT for carers of people



with dementia highlighted effectiveness equal to that expected in face-to-face CBT at reducing symptoms of depression (Scott et al., 2016). This review highlights a lack of long-term outcomes in this population, as well as a lack of understanding of the mechanisms of change, although they did acknowledge the potential cost-savings of the interventions included in the review. Importantly, this did not include studies with telephone contact with a therapist. Given that previous studies have highlighted improvements in self-help interventions associated with therapist guidance, as compared to those without (e.g. French, Golijani-Moghaddam, & Schröder, 2017); this provides a solid proof-of-principle base for the use of both self-help, and guided self-help, as a potentially effective intervention modality in a caring population.

Predominantly, evidence on the effectiveness of self-help as compared to face-to-face treatments has focussed on anxiety or depression. This is perhaps unsurprising; people without a mental health difficulty/ diagnosis would not routinely be offered treatment (at least within NHS services) and therefore meaningful comparisons cannot be made. Indeed, the Scott et al. (2016) review highlighted the potential for self-help therapies as a potentially effective intervention for carers of people with Dementia, this focussed on clinical depression, rather than carer strain and as a unique and distinct focus of the intervention.

### **1.5.2 Rationale for self-help for carers of people with MS**

Given the focus on carer strain rather than a diagnosis-driven phenomenon, self-help interventions (as opposed to face-to-face psychological therapies) may be entirely appropriate for two key reasons. Firstly, service provisions for psychological therapies are already under increasing strain. The already present requirement to demonstrate symptomology 'cut-offs' for services in order to gain a referral would preclude many carers from accessing psychological therapies. Carers simply may not reach clinical levels of any measures of symptomology. Furthermore, using self-help interventions as the first stage within a stepped care model is in keeping with recommendations to

apply interventions in the least intrusive manner (Andersson et al., 2005). This is particularly pertinent in mild to moderate or non-clinical populations that may require some level of support but without potentially costly and highly intensive psychological therapy. Secondly, in the context of carer strain, these interventions may be more appropriate than the more potentially costly high-intensity interventions as carers may actually struggle to attend or engage with these higher intensity therapies due to the practicalities of their caring responsibilities (e.g. organising respite care for the person with MS to allow the carer to attend appointments).

### **1.5.3 Rationale for ACT self-help for carers of people with MS**

Predominantly, self-help interventions have focussed on CBT-based interventions, although there is preliminary evidence supporting both use of ACT (French et al., 2017), and mindfulness delivered in a self-help format for anxiety, depression and stress (Martin, Golijani-Moghaddam, & das Nair, 2018). Furthermore, a review highlighted that mindfulness-based self-help interventions (including ACT, DBT and other integrative approaches using a mindfulness component) showing effectiveness at reducing symptoms of anxiety, depression and stress (Cavanagh et al., 2014).

As discussed earlier (see extended introduction 1.4.4), ACT is theoretically potentially well-suited to a carer population, particularly in those without a clinical diagnosis who may struggle to access traditional mental health services within the NHS. Furthermore, given the move towards lower intensity therapies as a first line of intervention, as well as the practical difficulties which carers may face in accessing and engaging with services, ACT in a self-help format warrants further research to highlight its acceptability and potential effectiveness in the carer population.

## **1.6 Feasibility Randomised Controlled Trials**

Given the numbers of carers for people with MS, and the lack of appropriate services designed for this population, this study will assess the feasibility of conducting a larger phase III RCT to evaluate the effectiveness of ACT self-help and ACT guided self-help for carers of people with MS. In line with the latest Medical Research Council (MRC) guidance on developing and evaluating complex interventions (Moore et al., 2015), a feasibility trial is warranted as it is first necessary to address whether the trial can be conducted, alongside addressing any potential threats to the validity, or barriers to a successful phase III RCT (Tickle-Degnen, 2013).

### **1.6.1 Primary Aims**

The primary aims relate to feasibility aspects. Therefore, the proposed study will aim to:

- Determine the recruitment potential and highlight levels of attrition across all three arms of the study.
- Explore the practicalities of using the chosen intervention and to highlight any barriers to intervention effectiveness, including practical issues relating to using online questionnaires and weekly telephone support.
- Estimate sample size requirement for a full-scale RCT.
- Assess participants' perceptions of the acceptability of the self-help book alongside acceptability of taking part in the trial and any barriers to their involvement or engagement with the trial and intervention material.
- Assess the fidelity of the weekly telephone support calls in relation to ACT.
- Assess adherence to the intervention and highlight the practicalities of completing the self-help programme and the weekly telephone support calls.
- Explore the potential cost of a full scale RCT and highlight the potential cost-effectiveness of the intervention.

### **1.6.2 Secondary Aims**

Secondary aims are to conduct group-level exploratory analyses to obtain estimates of effect sizes and, individual change analyses to highlight changes to an individual's scores from baseline to follow-up. This will allow for a preliminary (although statistically underpowered) analysis of the intervention to assess its effectiveness for individuals within the trial, and at a group-level.

### **1.7 Epistemology**

The proposed research has been developed from a post-positivist approach. This combines both theory and practice and does not ignore the researcher's own motivation and expectations, including questions regarding the neutrality of knowledge. Indeed, post-positivism is arguably the dominant paradigm for conducting research into psychotherapy (McLeod, 2017). This approach allows for the use of mixed research methods in attempting to understand complex phenomena, but does not ascertain independence from the data retrieved. This has been taken into account when designing the study and potential researcher biases have been reduced as much as is practicable.

## **2. Extended Method**

This extended introduction gives further details on the recruitment process, details about the psychometrics and measures used, proposed sample size, and the randomisation procedure.

### **2.1 Recruitment**

Participants were not directly approached for the study. Instead, researchers placed details of the study in various MS related locations and provided contact details for the research team, for those who felt they may wish to participate in the study and wanted further information. The sources were predominantly internet-based services, although some written publications (e.g. local MS Society quarterly newsletters) were used to increase potential recruitment figures. NHS recruitment was not sought as there is currently no carer specific services for those who care for someone with MS.

Information about the study was also posted on online forums (e.g. MS-UK) with the permission of forum administrators. The MS Society and MS Trust highlighted the study on their websites and the MS Trust posted information about the study on their social media pages. One participant also reported that they had posted the study information on a social media support page and a number of participants subsequently self-referred having seen this social media post.

The study was also presented at a conference in October 2015; those interested in the study left their details with the lead researcher. One researcher (RdN) was involved in a separate large scale RCT for PwMS and those whom had consented to being contacted for future studies were contacted by a member of the study's team to seek permission to pass their details on and for the lead researcher (KJM) to contact them. Outcomes assessors for this study also passed participant information sheets (PIS) to PwMS whom could then chose to pass these onto their carer if they wished to do so.

All information about the study listed the lead researcher's contact details, giving potential participants the means to get in touch should they wish to gain further information, or to take part in the trial. This was deemed a non-coercive manner of recruitment as potential participants were not directly contacted, merely given information and the means to complete the self-referral process.

## **2.2 Sample Size**

For pilot and feasibility trials, statistical power to determine effectiveness of the intervention is not necessary. Indeed, the aim of a feasibility study is to highlight whether a larger, fully-powered, study would be warranted as well as investigating, in a cost-effective manner, the feasibility of current protocol (Eldridge et al., 2016), and as such, a smaller sample size than that required for a full trial is acceptable. Twelve participants per arm has been identified as sufficient to estimate relevant feasibility parameters with adequate precision (Julious, 2005). To allow for possible attrition, a sample size target was set at 18 per arm, totalling 54 across the study. Although this sample size might seem high, a review of attrition in RCTs have shown attrition levels around 31% (Hewitt, Kumaravel, Dumville, & Torgerson, 2010), and a similar study evaluating ACT self-help for chronic pain showed an even higher attrition of 42% (Johnston, Foster, Shennan, Starkey, & Johnson, 2010). Therefore, a recruitment target was set to allow for a 50% level of attrition.

## **2.3 Inclusion & Exclusion Criteria**

Recommendations for feasibility studies dictate that inclusion and exclusion criteria should be less restrictive than might be expected in a fully powered RCT, to allow for criteria to be refined as part of feasibility aims (Moore et al., 2015; Tickle-Degnen, 2013). Therefore, inclusion criteria for the present study aimed to promote inclusivity. There were three criteria for inclusion into the study; participants must define themselves as a carer for someone with MS, carers must be over 18 years-old and score at least a mild level of distress as

measured by the Zarit Burden Interview (ZBI; Zarit, Reever, & Bach-Peterson, 1980). In the participant information sheet carers were presented with the definition of a carer used in this paper and were asked whether they defined themselves in this way. When participants questioned whether they would meet the criteria or not, the research team reinforced that it is the potential participant's *identity* as a carer that is important to consider, rather than having a predefined checklist for 'what is a carer'. The requirement for participants to be over 18 years-old arose because previous research has highlighted that the needs of 'young carers' may be different to those of adult carers (Dearden & Becker, 2004). Addressing these potentially differing needs was beyond the scope of the present study and young carers were, therefore, excluded. Finally, participants' level of distress was included as an inclusion measure to prevent possible ceiling effects.

Exclusion criteria for the study were defined in order to create as homogenous a sample of carers as possible, with the foci of the intervention on caring stress/strain, rather than other clinical or psychiatric problems for which carers may already be receiving care. Participants were also excluded if they were unable to commit to the intervention; this criterion was designed to ensure that participants entered the study with an understanding and commitment to the intervention, with the aim being to reduce possible attrition. Participants were made aware that they could withdraw from the study at any point.

## **2.4 Measures**

### **2.4.1 Zarit Burden Interview**

The Zarit Burden Interview (ZBI; Zarit, Reever, & Bach-Peterson, 1980) is a 22-item Likert scale questionnaire which takes around 10 minutes to complete and measures the extent to which the caregivers perceive their emotional, physical, social, and financial status as a result of caring. This questionnaire gives an overall score for the level of burden, which corresponds to a mild, mild to moderate, moderate to severe, or severe level of burden. The ZBI measure was

originally developed for carers of older adults in the community, it has, however, since been validated for carers of people with a number of conditions including stroke (Schreiner, Morimoto, Arai, & Zarit, 2006) and dementia (Wang et al., 2008). One study validated its use with carers across a number of neurological conditions (TBI, stroke, brain infection, hypoxia and other disorders) and found reliability ranged from  $\alpha=.80$  to  $\alpha=.82$ ; (Siegert, Jackson, Tennant, & Turner-Stokes, 2010). As far as the author is aware, this measure has not been validated for carers of people with MS; however no other validated measure of carer strain specific to people with MS has been identified and other studies of carers for people with MS have used this measure (Morales-Gonzales, Benito-Leon, Rivera-Navarro, Mitchell, & Group, 2004). Therefore, the ZBI measure was used in addition to a secondary measure of carer strain, (see 2.4.2 “Modified Carer Strain Index”) in order to ensure as far as possible that aspects of caring specific to MS are not missed due to the lack of a validated measure specific to this population. The reliability of the ZBI in this study (at baseline, including all those who completed baseline measures) was found to be  $\alpha=0.96$ .

#### **2.4.2 Modified Carer Strain Index**

The Modified Carer Strain Index (Robinson, 1983; Megan Thornton & Travis, 2003) assesses the impact of caring on different life domains. It is a 13-item self-report questionnaire, with responses of ‘yes’, ‘sometimes’, and ‘no’. A higher score on the MCSI indicates a higher burden to the carer. The questionnaire has been validated in various carer populations including Alzheimer’s’ (Diwan, Hougham, & Sachs, 2004), stroke survivors (Post, Festen, van de Port, & Visser-Meily, 2007), elderly people (Megan Thornton & Travis, 2003) and cancer patients (Ugur & Fadiloglu, 2010). Although this measure has not been validated with carers of people with MS, as discussed above, there is no validated measure of carer strain specific to people with MS. However, this measure has been widely used in studies of carer strain for people with MS (Chipchase & Lincoln, 2001; Khan, McPhail, Brand, Turner-Stokes, & Kilpatrick, 2006; Lincoln et al., 2002; Peters et al., 2013b) and therefore was included as an additional measure to the ZBI. The psychometric properties of this measure



have been consistently shown as reliability, ranging from  $\alpha=.77$  (cancer patients; Ugur & Fadiloglu, 2010) to  $\alpha=.90$  (caregivers of elderly people; Thornton & Travis, 2003). The reliability of the MCSI in this study, at baseline across all those who completed online measures was found to be  $\alpha=0.91$ .

### **2.4.3 CAREQOL-MS**

The CAREQOL-MS (Benito-Leon et al., 2011) is a health-related quality of life scale, chosen for inclusion as it was designed and validated specifically for carers of people with MS. The measure is a 24-item questionnaire with four subscales. The internal reliability for the total score is  $\alpha=.96$  and the measure was validated across a sample of 286 carers of people with MS (Benito-Leon et al., 2011). The four subscale scores are as follows: physical burden/global health, social impact, emotional impact, and need for help/emotional reactions. A higher total score on the CAREQOL-MS indicates a worse quality of life. The reliability of the CAREQOL-MS in the current sample was found to be  $\alpha=0.95$ .

### **2.4.4 Acceptance and Action Questionnaire**

The Acceptance and Action Questionnaire (AAQ-II; Bond et al., 2011) is a 7-item self-report questionnaire used to assess experiential avoidance and psychological inflexibility. This measure uses a Likert scale where participants rate how true each of the 7 statements are for them, the scales reflect 1 as *never true* and 7 as *always true*. The scores from each individual item are added together to give a total score. The minimum score is 7 and the maximum is 49, with lower scores reflecting greater psychological flexibility. This measure has been validated across a large sample size showing a good reliability score of  $\alpha=.84$  (Bond et al., 2011). Questions have been raised regarding the face, content and construct validity of the AAQ-II, arguing that the questionnaire items are measuring psychological distress rather than psychological flexibility and avoidance (Wolgast, 2014). However, the AAQ-II remains the current 'gold standard' and most widely used general ACT process measure (Cavanagh et al., 2014; Gloster, Klotsche, Chaker, Hummel, & Hoyer, 2011). Therefore, using

this measure will allow for the findings of the proposed study to be related to broader ACT literature, but an additional ACT-process measure was also included, given the criticisms raised above. The reliability of the AAQ-II in the current sample was found to be  $\alpha=0.93$ .

#### **2.4.5 Comprehensive Assessment of Acceptance and Commitment Therapy**

The Comprehensive Assessment of Acceptance and Commitment Therapy (CompACT; Francis, Dawson, & Golijani-Moghaddam, 2016) is a questionnaire that has been developed recently in response to criticisms of the AAQ-II as discussed earlier in this paper. The CompACT is distinct from (and complementary to) the AAQ-II in that it measures additional important processes of ACT, such as 'self as context' and 'committed action'. The CompACT is a 23-item measure, using a seven-point Likert scale ranging from 0, strongly disagree, to 6, strongly agree. The CompACT shows a total score alongside scores for 'openness to experience', 'behavioural awareness' and 'valued action'. Higher overall scores reflect greater psychological flexibility, and higher subtest scores reflect greater openness to experience, behavioural awareness and valued action. The reliability of the AAQ-II in the current sample was found to be  $\alpha=0.91$ .

The analysis of the AAQ-II and CompACT will give insight into changes to experiential avoidance/psychological inflexibility pre- and post-intervention, as well as between groups. This will, therefore, provide insight into the processes behind the intervention and whether it helps foster better acceptance.

#### **2.4.6 Service Use Questionnaire**

The SUQ asks participants to record the frequency with which they access NHS services, such as visits to general practitioners and other health and social care professionals, as well as access to services provided by charities. Current medication and medications used over the previous three months will also be

recorded. Whilst this is not a published questionnaire, similar SUQs have been used in RCTs of complex interventions (das Nair et al., 2015; Lincoln et al., 2015) and give a good indication of the number and scale of services accessed by participants. This measure can give an indication of the cost-effectiveness of this intervention.

## **2.5 Feedback interviews**

The aim was to complete interviews with 6 participants in each intervention group, with maximum variation sampling to ensure a variety of typical and non-typical experiences of the study. Participants were invited to complete the interviews on completion of the 3-month follow-up data. Given lower than expected recruitment numbers, and a number of participants declining an interview when invited, all participants (in the two intervention groups) who consented to a feedback interview were invited to complete an interview.

Feedback interviews were completed by a researcher who was otherwise not involved in the study. All interviews were recorded and transcribed verbatim using an independent transcriber. A semi-structured interview protocol was developed (see Appendix G) designed to assess feasibility aspects of the study as well as incorporating some questions relating to change resultant of taking part in the intervention. The questions on the interview schedule were purposefully selected to relate directly to the various aspects of feasibility, as suggested by Eldrige and colleagues (2016). Further questions regarding changes were also included, developed around the framework from a change interview (Elliott, Slatick, & Urman, 2001). This framework has been recommended as a method of feedback for psychological intervention in order to qualitatively highlight positive and negative changes, as well as asking participants to hypothesise on which aspects of the intervention they attribute any changes to (Castonguay, 2011; Clarke, Rees, & Hardy, 2004; Klein & Elliott, 2006), the framework has been used in similar studies on self-help (Bendelin et al., 2011; Cuijpers et al., 2011). One strength of this framework is that it allows for explicit questions regarding negative aspects of intervention, to

support participants to feel more able to give negative feedback (Castonguay et al., 2010).

## **2.6 Randomisation**

A randomisation sequence was produced by one researcher (NM) who was not involved in the recruitment, screening or baseline measures process. This researcher was blind to group allocation. The randomisation sequence was computer-generated, on a 1:1:1 ratio. Randomly selected block sizes (3, 6, 9, 12 etc.) were added to encourage even group allocation at various points in case recruitment did not reach expected levels. The other researchers were blind to the randomisation sequence, including the block sizes, thus removing this as a potential source of bias. Participants were notified via email or telephone of their group allocation (dependent on their preferred method of communication). Participants were notified of the next steps for the study, which were dependent upon this allocation. Blinding of participants to allocation was not possible due to the nature of the intervention.

## **2.7 Intervention**

### **2.7.1 Self-help book**

Participants in both intervention arms received the same chapters from the self-help book each week, using the published ACT manual “*Get out of your mind and into your life –The new Acceptance and commitment Therapy*” (Hayes and Smith 2005). Table 8 provides an overview of the chapters sent to participants each week.

<b>Week</b>	<b>Chapters</b>	<b>Topic(s)</b>
1	Introduction 1, 2	Human Suffering and Language
2	3, 4	Avoidance and Letting Go
3	5	Introduction to Thoughts
4	6, 7	Defusion and the Observing- Self
5	8	Mindfulness
6	9, 10	Willingness
7	11, 12	Values
8	13, Conclusion	Commitment

Table 8: Breakdown of chapter sent to participants each week

### **2.7.2 Weekly telephone calls**

Participants allocated to the self-help plus telephone support arm of the study received weekly telephone support calls from the lead researcher (KJM). All telephone support calls were recorded for assessment of fidelity to the intervention. The length of call, as well as the number of calls missed, cancelled, or rearranged were also recorded to assess adherence to the intervention as well as feasibility of the support calls. Wherever possible the reasons for the miss, cancellation or re-arrangement of the calls were also recorded. The focus of the calls was to promote participants' understanding of the self-help text, in order to help them engage with ACT and to reduce the potential for lack of understanding or difficulty getting attuned to the ACT model which may have caused a barrier to engagement with the intervention.

### **2.7.3 Fidelity of weekly telephone calls**

All calls were recorded and assessed for fidelity to the intervention and the ACT model. Thirty percent of total calls were randomly selected and assessed for fidelity by NM, using Plumb and Vilardaga's recommended strategies for

assessing treatment integrity in ACT (Plumb & Vilardaga, 2010), therefore the following questions were used as a basis for the fidelity assessment:

1. Did the researcher 'check in' with the participant?
2. Did the researcher focus on domains as per the telephone support call guide?
3. Were discussions (guided to be) congruent with the ACT model?
4. Was any researcher advice antithetical to ACT (e.g., thought challenging)?  
[Reverse-scored]
5. Was the researcher suitably flexible and responsive to issues raised by the participant?

Ratings were on a three-point Likert scale, where 0= no, 1= partially, 3= yes; therefore, a higher score reflects greater fidelity (question 4 is reverse scored to allow for this).

## **2.8 Analysis**

### **2.8.1 Quantitative analyses**

As the study is not a phase III trial, statistical power would be not met. Quantitative analyses were included regardless to give estimates of effect sizes to highlight exploratory indication of potential effectiveness.

Two follow-up periods were included; at three- and six-month post-randomisation. These were to give a post-intervention assessment (allowing for some flexibility in the intervention due to missed, cancelled, or rearrangements telephone calls), as well as an indication of any longer-term impact of the intervention. Longer follow-ups (in excess of six months) may have given a better indication of the stability of changes, particularly in light of the nature of MS as a potentially fluctuating condition; however, practicalities regarding the length of study confined this to six-months post-randomisation.

The primary outcome measure was the ZBI, with secondary and process measures analysed in order to identify feasibility of other measures and impact outside of carer strain (particularly in light of the lack of validation of current measures of carer strain in this population). Data was analysed using SPSS, with 10% of all data audited to ensure accuracy. Audit of data was completed by the lead researcher (KJM), by downloading the data from the online platform in a separate file, and then questionnaires were scored manually through SPSS (as opposed to the use of codes written and created by lead researcher); these were then checked for consistency across the two files. This would also give an ability to assess the feasibility of using pre-written codes to aid data analysis.

Individual level analyses were completed in order to highlight possible changes, as well as looking more closely at any individual changes which could be triangulated against qualitative data and adherence.

#### **2.8.1.1 Controlling for baseline variables**

All outcome measures were also completed at baseline, as was the recording of demographic and data related to caring and specifics regarding the disease type and disability level of the person with MS. This data was recorded in order to give an indication of the sample and its generalisability to wider population, as well as to highlight the feasibility of the randomisation process. It was decided, a priori, that baseline variables would not be controlled, as researchers have suggested that controlling for any statistical differences noted at baseline can be misleading (Bland & Altman, 2011), and using a mixed model would highlight within group effects, potentially mitigating the need for these statistics regardless.

#### **2.8.1.2 Multiple comparisons**

This study included six different measures. Standard practice is to correct for multiple comparisons to prevent the increase in possibility of a type I error; the more measures in a study, the higher likelihood of making a type 1 error. There

are a number of different statistical methods available to correct for this increase in the potential for a type 1 error; the Bonferroni method, a conservative method for controlling for this type of error, is commonly used. This would define that statistical significance would be 0.05 divided by 6, giving a p value for significance at 0.0083. However, it was decided that, given this study is not intended to achieve statistical power, the potential for a type I error should be prioritised over making a type II error (failing to acknowledge an effect, when there is indeed one). Indeed, the recommendations for feasibility studies do not suggest an assessment of effectiveness as a necessity of feasibility studies (National Institute for Health Research, 2016), but suggests that they can be included in order to estimate standard deviations or effect sizes for a larger trial. Therefore, adjustments for multiple comparisons were not made and the p value assigned for statistical significance for the study remained at 0.05.

### **2.8.2 Qualitative analyses**

The feasibility interviews were analysed using Framework Analysis (Ritchie et al., 2003), a method of qualitative analysis that takes a deductive, manifest level approach; common amongst semi-structured interviews in health-related research (Gale et al., 2013). This method of analysis uses a pre-defined framework against which the transcripts are assessed, particularly useful when answering specific questions relating to feasibility. This method was chosen as compared to other approaches which assume an inductive approach to data analysis such as thematic or content analysis. As the focus of the interviews was to answer specific questions, a deductive approach was deemed appropriate.

Analysis of the interview began with the researcher listening to the audio files alongside the written transcriptions of the data. NVivo was used to initially organise and code the data, with a code assigned to each phrase of text. These were then analysed to identify any patterns within the data and arranged within the pre-defined framework of feasibility (see journal paper for example).



### 3. Extended Results

The extended results section provides further details on participants who did not meet eligibility criteria for the study and provides additional analyses of the data, including individual change analyses.

#### 3.1 Recruitment

In total, 42 people expressed an interest in the study, see table 9 for a breakdown of recruitment sources. No information regarding the number of people who were 'invited' or 'the reach' of the recruitment strategy was collected, as the recruitment process was predominantly conducted online and therefore it was not possible to estimate the reach of the strategy.

Source	n
Facebook support group	12
Previous research trial	9
Word of mouth	8
MS Trust Social Media	3
Conference	4
Trials register	2
MS Society website	2
MS Society newsletter	2

Table 9: Breakdown of recruitment sources

#### 3.2 Comparisons of Eligible and Not Eligible Participants

Table 10 compares those who did and do not meet the ZBI cut-off for eligibility. Statistical analyses show that there was a significant difference for both gender and age for those who reached the ZBI cut-off compared to those who did not; there were significantly more older males who were not eligible on the ZBI. No other variables were significantly different between the groups.

		Not eligible (n=7)	Eligible (n=24)	p
Age	Mean (SD)	65.7 (7.3)	54.3 (10.3)	0.011*a
Gender	Female	2 (29%)	19 (79%)	0.022*b
Employment status	Employed full time	2 (29%)	6 (25%)	0.873c
	Employed part time	2 (29%)	4 (17%)	
	Self employed	0	2 (8%)	
	Retired	3 (34%)	7 (29%)	
	Not working due to caring responsibilities	0	4 (17%)	
	Other	0	1 (4%)	
Years identified as a carer	Mean (SD)	15.2 (11.4)	8.7 (6.1)	0.051a
	Range	2-37	1-23	
Average hours/week caring	Mean (SD)	58.0 (75.4)	71.1 (62.4)	0.644a
	Range	7-168	4-168	
Relationship	Partner	7 (100%)	21 (88%)	0.713c
	Parent	0	2 (8%)	
	Other	0	1 (4%)	
Type of MS	RR	2 (29%)	11 (46%)	0.695c
	PP	3 (43%)	7 (29%)	
	SP	2 (29%)	6 (25%)	
Years since diagnosis	Mean (SD)	20.4 (11.2)	14.7 (7.8)	0.130a
	Range	9-37	1-32	

a= Independent t-test, b= Fisher's exact test, c= Pearson's chi-squared. \* denotes significance at p<0.05

Table 10: Baseline demographics for eligible and not eligible participants

### **3.3 Service Use Questionnaire**

The Service Use Questionnaire (SUQ) was omitted from the analysis, due to concerns over the internal consistency. Of the 31 people who completed the baseline measures, 5 people made contact with the researcher (16%) on submission of the online measures to question whether they had completed this questionnaire correctly. Concerns were raised whether 'contacts due to caring responsibilities' were specific to the individual seeking advice about carer strain, or included accompanying the individual with MS to appointments. On review of the answers, some participants reported multiple contacts with services and in the free-text responses these were unrelated. Therefore, it was deemed that the responses given by participants may not be comparable across the groups.

### **3.4 Attrition**

Of the two participants who withdrew from the study, both cited similar reasons. Both participants reported that the trial had not been what they had expected and felt it was too much "like therapy". Both participants declined to complete a feedback interview, or to complete the measures. One participant withdrew from each intervention group.

One further participant withdrew from the intervention (self-help plus telephone support) but consented to continuing completion of measures. The reason given by this participant was that the participant had recently had changes to their social care package and felt they could not engage in the intervention at that point in time due to their caring responsibilities. The participant did ask if they could delay the study and continue their participation later, unfortunately this was not feasible due to practicalities of the study.

One participant from the intervention group (self-help plus telephone support) requested to delay the telephone call one week due to the fact that the person for whom they cared had become seriously ill and been admitted to a hospice.

This participant agreed to continue with the study but did not arrange further calls and was subsequently lost to follow-up.

One participant in the self-help group did not complete the 3-month outcome measures, but subsequently made contact with the lead researcher and agreed to complete the 6-month follow-up and a feedback interview. This participant's disengagement with the study was predominantly focussed on a reported high burden of responsibility, both caring and otherwise, alongside a fundamental disagreement with the ACT theory presented in the book.

Overall, study attrition was lower than expected, although attrition was higher in the intervention groups, being highest in the self-help plus telephone support. This may be related to the increased contact with researchers thus making researchers more aware of a participant's level of engagement with the intervention/ study.

### **3.5 Assessment of Fidelity to ACT Model**

In total, eight telephone calls were assessed for fidelity; a mixture of calls were assessed across different participants and different time-points within the intervention. All of the recordings reviewed showed the maximum scores for fidelity on the 3-point Likert scale. The researcher (NM) reviewing the recordings also commented on the skill of the clinician at managing often difficult and distressing content, and highlighted the fact that the clinician needed to be adequately trained in order to allow for flexibility with these support calls. It was noted, in terms of call content, that a lot of time was spent helping participants to make sense of the ACT concepts and terminology, as well as supporting participants to apply these to their own personal circumstances.

### 3.6 Individual Change Analyses

Table 11 shows the individual change analyses according to group allocation. The data highlights any change in participants scores, calculated using the alpha coefficients for the measures as computed for the baseline sample (see Extended Methods sections 2.4 for further details).

Only one participant (20%) in the self-help plus telephone support group showed any reliable deterioration on any outcome measure, compared to 4 in the usual care group (50%) and 3 in the self-help group (50%). Furthermore, of those showing reliable deterioration in the self-help and treatment as usual groups, the deterioration was often across multiple outcomes.

All participants in the self-help plus telephone support group showed reliable improvement across one of the outcomes. Four of the five participants in the self-help and telephone support group showed reliable improvement on one of the primary or second outcomes, with one participant only showing improvement on the process measures. Of the four that showed a reliable improvement in one of the measures of carer strain, or quality of life, all four also showed an improvement on one of the ACT process measures.

Of those participants in the self-help group, five of six (83%) showed improvement on the ACT process measures, although only three participants (50%) showed reliable improvements on the measures of carer strain or quality of life.

	Participant	ZBI			MCSI			CAREQOL		
		T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>
UC	1	49	50	49	17	14	16	72	66	69
	3	59	<b>72↓</b>	<b>73↓</b>	24	24	24	88	92	93
	8	50	<b>65↓</b>	<b>63↓</b>	18	<b>24↓</b>	22	70	<b>83↓</b>	<b>79↓</b>
	12	50	<b>63↓</b>	<b>60↓</b>	13	16	13	60	<b>84↓</b>	<b>73↓</b>
	26	30	29	35	4	4	6	36	34	40
	27	45	<b>53↓</b>	<b>53↓</b>	15	13	14	77	77	77
	28	54	<b>45↑</b>	48	20	17	20	75	<b>84↓</b>	77
	31	24	23	25	18	18	18	49	49	49
SH	7	38	<b>28↑</b>	<b>23↑</b>	13	16	10	62	<b>51↑</b>	<b>22↑</b>
	9	58	53	58	21	21	23	75	79	<b>84↓</b>
	13	49	46	44	10	14	10	50	56	44
	14	54	47	49	16	<b>23↓</b>	18	60	<b>69↓</b>	<b>74↓</b>
	23	54	47	<b>44↑</b>	24	<b>18↑</b>	<b>13↑</b>	81	75	<b>62↑</b>
	29	47	<b>60↓</b>	<b>29↑</b>	17	17	<b>22↓</b>	55	61	61
SH+	6	78	<b>45↑</b>	<b>49↑</b>	25	<b>16↑</b>	<b>20↑</b>	86	<b>66↑</b>	80
	10	79	75	75	25	24	24	82	80	80
	16	36	42	<b>24↑</b>	11	8	<b>6↑</b>	47	<b>56↓</b>	43
	18	54	<b>34↑</b>	<b>30↑</b>	18	<b>12↑</b>	<b>8↑</b>	60	<b>36↑</b>	<b>32↑</b>
	19	56	<b>48↑</b>	<b>39↑</b>	15	11	11	63	<b>49↑</b>	<b>48↑</b>

Table 11a: Individual change analyses for outcome measures; those in bold refer to reliable change, where ↑ denotes reliable improvement & ↓ denotes reliable deterioration. ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOL : Carer Quality of Life

		AAQ			CompACT			CompACT OE			CompACT BA			CompACT VA		
	Participant	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>2</sub>
UC	1	14	<b>26↓</b>	<b>23↓</b>	41	42	32	18	17	15	4	5	4	19	20	13
	3	25	28	26	51	49	41	22	23	24	10	6	<b>5↓</b>	19	20	<b>12↓</b>
	8	15	19	<b>8↑</b>	97	<b>69↓</b>	101	39	<b>26↓</b>	<b>49↑</b>	22	<b>12↓</b>	19	36	31	33
	12	19	21	<b>24↓</b>	52	<b>36↓</b>	60	17	18	23	6	1	10	29	<b>17↓</b>	27
	26	16	16	16	67	72	79	25	<b>32↑</b>	27	13	12	<b>19↑</b>	29	28	33
	27	17	18	17	61	<b>67↑</b>	62	24	22	23	7	10	8	30	35	32
	28	21	22	22	61	<b>70↑</b>	70	24	<b>33↑</b>	<b>33↑</b>	10	10	10	27	27	26
	31	6	6	6	102	102	102	44	44	44	16	16	16	42	42	42
SH	7	23	<b>14↑</b>	<b>10↑</b>	52	<b>81↑</b>	<b>95↑</b>	19	<b>31↑</b>	<b>36↑</b>	15	18	<b>21↑</b>	18	<b>32↑</b>	<b>38↑</b>
	9	31	<b>7↑</b>	<b>14↑</b>	56	<b>94↑</b>	<b>102↑</b>	20	<b>46↑</b>	<b>50↑</b>	17	<b>24↑</b>	16	19	24	<b>36↑</b>
	13	24	22	<b>7↑</b>	80	80	90	28	<b>42↑</b>	<b>46↑</b>	15	17	<b>25↑</b>	37	<b>21↓</b>	<b>19↓</b>
	14	31	<b>25↑</b>	<b>19↑</b>	44	<b>60↑</b>	<b>65↑</b>	7	<b>22↑</b>	<b>24↑</b>	10	11	<b>17↑</b>	27	<b>60↑</b>	24
	23	22	21	21	51	<b>73↑</b>	<b>84↑</b>	20	<b>30↑</b>	<b>33↑</b>	14	16	<b>20↑</b>	17	<b>27↑</b>	<b>26↑</b>
	29	26	28	28	65	<b>59↓</b>	75	22	20	28	9	6	<b>14↑</b>	34	31	33
SH+	6	26	<b>20↑</b>	27	36	<b>79↑</b>	<b>86↑</b>	19	<b>37↑</b>	<b>39↑</b>	0	<b>12↑</b>	<b>13↑</b>	17	<b>30↑</b>	<b>34↑</b>
	10	29	33	<b>34↓</b>	26	<b>49↑</b>	<b>53↑</b>	3	<b>11↑</b>	<b>17↑</b>	4	5	5	19	<b>33↑</b>	<b>31↑</b>
	16	31	<b>25↑</b>	<b>18↑</b>	65	<b>83↑</b>	<b>105↑</b>	24	<b>32↑</b>	<b>44↑</b>	6	<b>16↑</b>	<b>18↑</b>	35	35	<b>43↑</b>
	18	27	10↑	<b>9↑</b>	75	<b>104↑</b>	<b>100↑</b>	25	<b>38↑</b>	<b>35↑</b>	12	<b>24↑</b>	<b>22↑</b>	38	42	43
	19	28	26	<b>10↑</b>	51	55	<b>98↑</b>	21	21	<b>44↑</b>	10	8	<b>21↑</b>	20	<b>26↑</b>	<b>33↑</b>

Table11b: Individual change analyses for process measures; those in bold refer to reliable change, where ↑ denotes reliable improvement & ↓ denotes reliable deterioration. AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action

### 3.6.1 Case Exemplars

RCTs can be criticised for failing to highlight individual participant journeys throughout the study. Therefore, two case exemplars have been chosen to highlight two different participant journeys throughout the study, using the individual change analyses alongside qualitative data and adherence to intervention. Given the difficulty in understanding adherence to the intervention in the SH group, two extreme cases were chosen from the SH+ group, and will be discussed below.

Participant 16 was the only participant in the SH+ group to show any reliable deterioration on any of the outcomes measures. They showed no improvement at 3-month follow-up on either of the measures of carer strain, and showed a reliable deterioration in the quality of life measure. Interestingly, this participant showed a reliable improvement on both process measures, and two of the three CompACT subscales (showing no reliable change on the valued action). This participant completed all the telephone calls and was considered to have engaged consistently with the study. The participant gave feedback following completion of the 3-month follow-ups that the person they care for had suffered a serious relapse just days prior to completion of outcomes. This participant reported positive experiences of the study and reflected a good understanding of the ACT model and application to their experiences. From their 6-month follow-up, the scores show a different picture; the participant showed a reliable improvement on both the ZBI and MCSI, and no change on the quality of life measure as compared to baseline. Using the reliable change criterion, this would have demonstrated a reliable improvement if calculated from 3-month to 6-month follow-up, perhaps unsurprising given the sharp deterioration at the 3-month follow-up. As no qualitative data is available for the 6-month follow-up, and it did not form part of the outcome measures, the health status of the person they care for is not available. Their scores of the process measures also showed reliable improvement at 6-month follow-up.



Participant 18 also completed the intervention per protocol, and engaged consistently throughout the intervention. This participant showed reliable improvement across both time-points and on all outcome measures, and both process measures, alongside the CompACT subscales for openness to experience and behavioural awareness. This participant gave extensive positive feedback regarding their experience of the intervention, specifically highlighting that they acknowledged an avoidance of completing activities that they valued for fear of possible negative emotions that may associate this, e.g. worry about leaving the person they care for, and the guilt for wanting to engage in activities without the PwMS. This participant did acknowledge some practical difficulties with the intervention but highlighted that the overall approach was “completely unexpected” and “changed the way I view things”.

### **3.7 Effect Size Calculations**

Despite the lack of differences between groups on outcome measures at baseline, the means show there were slight differences between groups at baseline. For example, as can be seen from table 4 in the Journal Paper, the means at baseline on the ZBI show the UC group scored better (i.e. less carer strain) than those on the SH+, whereas the opposite is true for the follow-up. Therefore, between group analyses (used for traditional effect size calculation) would not acknowledge that the trajectory of groups is very different, as the starting points were not equal (although not statistically significant, in such a small sample size this might make a meaningful change). It was, therefore, deemed appropriate to use the Mean Difference, and Standard Error of the Mean Difference, rather than post intervention data for calculating between-groups effect sizes, in accordance with published guidance (Faraone, 2008; Lakens, 2013; Sullivan & Feinn, 2012). The effect sizes were calculated for between groups at 3-month (T1) and 6-month follow-up (T2), which showed a range of effect sizes, although all showed large confidence intervals and none were statistically significant (see table 12).

Measure	T <sub>1</sub>			T <sub>2</sub>			
	Effect Size (95% CI's at post intervention)			Effect Size (95% CI's at post intervention)			
	UC- SH	UC- SH+	SH-SH+	UC- SH	UC- SH+	SH-SH+	
ZBI	0.21 (-1.17 to 1.74)	-0.46 (-1.46 to 0.54)	-0.30 (-1.32 to 0.72)	0.72 (-0.27 to 1.70)	0.82 (-0.24 to 1.87)	0.10 (-0.89 to 1.09)	
MCSI	0.32 (-0.63 to 1.28)	-0.55 (-1.56 to 0.45)	-0.99 (-2.07 to 0.081)	0.16 (-0.80 to 1.12)	0.55 (-0.48 to 1.59)	0.38 (-0.61 to 1.38)	
CAREQOL-MS	0.14 (-0.82 to 1.09)	-0.45 (-1.45 to 0.55)	-0.70 (-1.74 to 0.35)	0.58 (-0.39 to 1.55)	0.76 (-0.28 to 1.81)	0.19 (-0.80 to 1.18)	
AAQ-II	-0.32 (-1.28 to 0.64)	-0.47 (-1.47 to 0.53)	-0.11 (-1.12 to 0.91)	0.63 (-0.03 to 1.60)	-0.02 (-1.04 to 0.99)	-0.59 (-1.60 to 0.42)	
CompACT	Total	0.23 (-0.72 to 1.19)	0.58 (-0.43 to 1.59)	-0.67 (-1.71 to 0.38)	-1.12 (-2.15 to -0.10)	-1.22 (-2.33 to -0.12)	-0.11 (-1.09 to 0.88)
	OE	0.23 (-0.73 to 1.18)	0.34 (-0.66 to 1.33)	0.09 (-0.92 to 1.11)	-0.98 (-1.99 to 0.03)	-0.81 (-1.86 to 0.25)	0.16 (-0.83 to 1.15)
	BA	0.18 (-0.77 to 1.14)	0.58 (-0.43 to 1.59)	0.40 (-0.62 to 1.43)	-1.28 (-2.33 to -0.24)	-1.08 (-2.16 to 0.01)	0.19 (-0.80 to 1.18)
	VA	0.49 (-0.48 to 1.45)	0.71 (-0.31 to 1.71)	0.15 (-0.87 to 1.16)	-0.42 (-1.38 to 0.55)	-1.10 (-2.19 to -0.01)	-0.64 (1.65 to 0.38)

Table 12: Between group effect size calculations at T<sub>1</sub> (3-month follow-up) and T<sub>2</sub> (6-month follow-up)

ZBI: Zarit Burden Interview, MCSI: Modified Carer Strain Index, CAREQOL : Carer Quality of Life AAQ-II: Acceptance and Action Questionnaire, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy; OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action

## **4. Extended Discussion**

This section provides a further in-depth discussion of the study findings, alongside consideration of the strengths and weaknesses of the study.

### **4.1 Comparison of Eligible and Non-Eligible Participants**

Analysis of those who were eligible at baseline compared to those who did not meet the cut-off on the ZBI (i.e. did not demonstrate at least a mild level of disability) shows that there were significant differences in eligibility for both gender, and age. These results show that those who were not eligible (on ZBI) were significantly older, and male, compared to those who showed at least a mild level of strain. It is important to note that the sample size is small and therefore we must acknowledge that this may not be representative for the wider population. Indeed, reflecting on the recruitment of those individuals who were not eligible (on the ZBI); these were predominantly contacted through a database of PwMS who were involved in a previous research study, as opposed to the majority of those eligible who saw the study advertised online or in print media and self-referred to the study. It is, therefore, entirely possible that those who did not reach the cut-off on the ZBI agreed to take part in the study for different reasons than those who sought out the study independently, and we may, therefore, expect their levels of strain to be lower.

Of those not eligible for the study (based on the ZBI), significantly more were male (and all reported they were caring for a partner). On the contrary, for those eligible for the study, there were significantly more females than males (although most also reported caring for a partner). Given that previous research has shown a high proportion of people with MS are female, this would fit with the prevalence of male spousal carers found in this study and oftentimes documented in research (Kristiansen, Bigby, Johnson, & Traustadottir, 2005). However, research has highlighted that there are differences in gender regarding who might adopt a more substantial role in caring for the person with MS (Perrin et al., 2015), which may potentially affect their experiences of caring as a strain. Importantly, whilst the data shows a significant difference in gender

between those eligible on the ZBI compared to those not eligible, we only know the gender of the carer, and not the person that they care for, something which should be included in a full-scale RCT.

Gender differences in experiences of caring for someone with MS have been demonstrated in previous research (Lee, Pieczynski, DeDios-Stern, Simonetti, & Lee, 2015). Specifically, this study found that male spousal carers reported lower levels of strain, lower perceived social support and a lower need for emotional support. Importantly, gender differences in expressing emotional needs are inherently implicated in the measures of carer strain; is there a true relationship between reported carer strain and actual strain, or merely a relationship between the willingness or ability to express or report strain? An ACT hypothesis may theorise that this inability to express emotional discomfort is, in fact, an avoidance strategy which may become counterproductive, and would, therefore, argue that using the ZBI as an inclusion measure might preclude these individuals from a potentially effective intervention. On the other hand, the Lee et al. (2015) found an inverse relationship between expressed emotional needs and quality of life, highlighting that those expressing less strain have higher quality of life, suggesting the intervention may not be warranted and that the use of a carer strain measure as a tool for inclusion is feasible.

## **4.2 Recruitment**

The recruitment strategy used in this study, whilst feasible, would not be viable as the sole stratagem for a larger trial. All participants who were interviewed reported only finding out about the study from one strategy, despite participants stating that they were also a member of a local MS society, or that they followed a social media page/ charity website on which the study had also been promoted. As is common with social media strategies, they are fast-paced; whilst this allows lots of people to be accessed quickly, it also highlights the potential for people to miss the information.

Should the recruitment strategy be widened, and more direct methods of alerting potential participants to the study be adopted, it is entirely possible that those who enrolled in the current study may not be representative of any future study. Indeed, it could be argued that those who have sought out this study may be more willing than others to engage with some form of psychological intervention. This, in turn, may suggest that a full trial might show a higher level of attrition than was experienced in this study (see extended discussion 4.6 for further discussion). However, given published figures of the number of people currently caring for someone with MS, and the high prevalence of carer stress/strain in this population, the strategy used by this study is lacking. Importantly, high attrition rates are not uncommon across RCTs; one large systematic review which looked into recruitment in RCTs highlighted that 63% of the 113 studies included reported difficulties with recruitment (McDonald et al., 2006). This factor alone demonstrates the importance of conducting a feasibility study ahead of a larger trial; such a study could well help to mitigate potential recruitment difficulties before conducting a larger, and potentially costly, phase-III trial.

### **4.3 Randomisation**

The randomisation procedure was practical for the researchers involved, and no participants objected to being the subject of this randomisation, nor cited this as any reason for withdrawal. This suggests that this approach to randomisation is a feasible and acceptable procedure for a full trial. The between groups analyses at baseline suggests differences between groups on hours per week spent caring. It can be argued that adjusting for baseline variables can be misleading, (Bland & Altman, 2011) and, due to the mixed linear model analysis chosen in this study, it was not necessary but such adjustments could be potentially problematic in a future trial. Indeed, between groups analyses are commonly used in definitive trials to demonstrate effectiveness. Such use, should there be significant differences between groups at baseline, may potentially confound results. Furthermore, given the research suggesting that both level of MS disability and hours-per-week spent caring are contributory to

the level of carer strain, we recommend that in any future trial randomisation stratified against these variables should be considered. Furthermore, whilst in this study there were no significant differences between groups on the type of MS, stratifying randomisation to ensure equal numbers of MS type across the groups, would help to highlight possible sub-group effects by MS type.

#### **4.4 Self-Help Text**

A significant amount of feedback provided was related to the self-help text itself, indicating that this particular text, in its current format, would not be feasible for a larger trial. The book was chosen due to the interactive nature of the text and the plethora of activities and exercises designed to help participant translate their reading into practice. Whilst interviewees reported that the exercises were on the whole useful, carers in the SH group reported that there were specific exercises that they could not understand the reasoning behind. These reports would seem to support the use of the support calls to help promote trial subjects' understanding and reasoning of the text and exercises. Those interviewed also reported that the volume of material they were required to engage with each week was too much to be practical for them, given their caring responsibilities. Interestingly, those interviewed from the SH+ group acknowledged that they would not necessarily like two weeks between sections, because they felt the weekly telephone calls promoted their continued adherence to the book, but that they would like less volume.

All those interviewed also reported that the text could be enhanced by being related to caring more generally, if not specific to carers of people with MS. Indeed, one participant highlighted that they wrote one page summaries for themselves for each chapter, to help them go back and make the most of the reading, in a more manageable approach. Interviewees also expressed difficulty with the language used; that the language felt 'Americanized' and not always lay-friendly. From a therapeutic perspective, if participants felt they were managing alone (without telephone support) and were alienated by the overuse of scientific language, or the complexity of the material, this could account for

the negative feedback of those in the SH group from the study. Indeed, those in the SH group did not show any statistically significant group-level changes on any outcome or process measure, with the exception of one sub-test of the CompACT, supporting the notion that without the telephone support the text itself did not improve participants' psychological flexibility, possibly related to lack of understanding of the ACT concepts. This highlights the necessity to adapt the language, content and volume of the current material, but any such adaptation must be done carefully, ensuring adherence to the ACT model.

#### **4.5 Support Calls**

The telephone support calls were shown to have good fidelity to the ACT model and participants reported finding these a positive, rewarding and useful experience. On review of the telephone support calls (for the fidelity assessment), the assessor noted that, as the intervention progressed, participants' use of ACT terminology and processes were increasingly used to discuss their difficulties. It was also noted that those who received the support calls showed a greater understanding and use of ACT when completing the telephone interview. However, this was not formally assessed and the researcher who noted this greater familiarity was also involved in the intervention and therefore there is definite potential for assessor bias. Notwithstanding this potential bias it does, however, highlight the utility of reviewing the telephone calls as a process measure, as it is quite possible that this may give further insight into mechanisms of change for participants in this intervention group.

#### **4.6 Attrition**

At three-month follow-up, there was an attrition level of 16%, increasing to 21% at six-month follow-up, considerably lower than expected. However, the level of attrition was highest amongst the SH+ group (29% at 3-month and 6-month follow-up). However, due to the block randomisation process, this group had a slightly smaller sample size than the other two groups. Therefore, any

individuals withdrawing would have a larger impact than for the other two groups. Furthermore, given that this group had the most contact with the researcher, it would suggest that participants are more likely to formally withdraw rather than simply not adhere to the intervention. One participant completed some of the intervention, subsequently rearranged support calls due to a severe decline in the health of the person they care for and subsequent admission to end-of-life-care. Following this they did not complete questionnaires or make any further contact with the study. Two participants formally withdrew, both of whom related this withdrawal to the intervention itself, stating that they had expected the intervention to be more practical and less like a psychological intervention. Both suggested that the participant information, and subsequent discussions with the researcher, had not made this adequately clear. Both these participants were offered the chance to complete the follow-up questionnaires, but both declined and withdrew from the intervention. Whilst this level of attrition high, we believe that given the changes suggested elsewhere within this paper; more flexibility and more comprehensive information about what to expect, this could be reduced in a phase III trial.

Furthermore, one participant requested to delay the intervention due to ongoing difficulties with social care support workers and lack of time to engage, requesting a substantial delay. It was explained that this would not be possible due to practicalities of the study. Indeed, participants were asked, at time of questionnaire completion, if they were able to engage in the intervention, but this example shows that circumstances can change between completion and randomisation. Therefore, this participant continued with the study but did not complete the intervention and therefore was not counted in levels of attrition, and highlights the need for flexibility, perhaps arguing that the follow-up periods should be related to completion of the intervention, allowing for people to delay the start if necessary.



## 4.7 Measures

Predominantly, the measures chosen were deemed feasible, with the exception of the SUQ, which was excluded from analysis due to poor completion. The difficulties in the SUQ related to a subjectivity of what would be deemed a contact with a health or social care service as *related* to caring responsibilities. For example, questions were raised by participants about whether a visit accompanying the person with MS, where the aim of the visit was related to the person with MS, would deem a contact, or if the definition for the purposes of the SUQ referred only to visits made to address changes in the carers own physical/ mental health related to their role as a carer for a PwMS. Indeed, some carers also reported that the person whom they cared for had concurrent severe and enduring mental health problems and the carers were unsure whether these would be appropriate to report. One participant reported that the person they care for became an inpatient during the study, due to a mental health crisis, which the carer believed was intrinsically related to their MS, and therefore they queried whether contacts related to this episode should also be recorded. It highlights the complexity of the caring relationship and the difficulty in compartmentalising aspects of caring responsibilities and duties. Therefore, the utility of the SUQ in its current format as a means of assessing cost-effectiveness was not deemed feasible.

Another difficulty with the measurement of carer strain is the lack of any validated measure specific to carers of PwMS. Two measures of carer strain were chosen for the study as neither had been validated in MS, and therefore it was decided that the use of a single published measure of carer strain might not adequately assess aspects of caring unique to caring for someone with MS. However, it is still possible that the measures included will not reflect carer strain in this population. Indeed, given variations in: caring needs, type and level of disability of the MS sufferer, varying experiences of caring as positive, negative or a mixture of both, and themes surrounding carers' feelings of loss and grief it is hardly surprising that conceptualising carer strain as a unique and distinct concept is difficult. Yet, the ZBI has been shown as an internally valid

measure of carer strain in community-dwelling older adults, as well as for carers of people with Dementia, suggesting that it might be possible, although quite difficult, to use this measure. Regardless, the current measures have not been validated in this population and questions remain as to their ability to accurately reflect the strain experienced by carers of PwMS. Therefore, prior to conducting a full-scale study, the validity of current published measures of carer strain (i.e. ZBI, MCSI) should be thoroughly researched in order to test their validity in this population. Should the validity of current measures prove unsatisfactory, a measure of carer strain designed specifically for carers of PwMS should be developed and validated.

There was no measure of the functioning of the individual with MS at either follow-up; this was only assessed at baseline, and was solely related to level of disability, not the presence of current symptoms or the time since relapse if applicable. Given the unpredictability of the condition, these would probably impact on the level of strain experienced by the carer at the time of follow-up assessment. Indeed, in the final feedback telephone call, one participant in the self-help with telephone support group stated that the person they cared for had had a relapse during the intervention period. In their final feedback, they subsequently acknowledged that the relapse of the PwMS for whom they cared had seriously affected them at the time of the three-month follow-up. It could be argued that the intervention is designed to help carers manage these relapses and that, should their results show significantly higher levels of strain, this is important information regarding the effectiveness of the intervention. However, ACT would not posit to eliminate the strain and, should the person with MS be relatively stable at baseline, and then have a relapse during the follow-up periods, it would unrealistic to suggest that this would not skew potential results, even if the participant had made significant improvements as a result of the intervention. A more in-depth discussion of ACT and measures of symptomology follows later in this paper. Furthermore, it may be that the ability to manage the impact of a relapse could be different at the first follow-up, as compared to the longer-term follow-up; indeed, many interventions recommend a consolidation period following a psychological therapy and improvements

beyond the initial follow-up would not be unusual. It would, therefore, be useful to assess level of disability and time since relapse across all time points. Similarly, there was no assessment of the type and amount of caring activities; carers self-reported average hours/week spent caring but there was no formal reporting measure for the type of activities involved. As discussed in the introduction, it is not necessarily the time but also the nature of duties which can be most indicative of strain. Therefore, we propose the inclusion of a measure, such as that used by Pakenham and colleagues (Pakenham, 2007); this being a psychometrically sound measure which could give further insight into the changes in caring activities engaged by the carer.

Importantly, use of symptom reduction measures is not theoretically consistent with ACT theory. ACT posits that it is not the presence or severity of a symptom (or a thought/ feeling in the specific measures used in this study) that is important regardless of the 'success' of any intervention. Rather, it is the impact of the symptoms on a person's life and the extent to which they prevent valued-based living. Looking specifically at the ZBI, there are items which ACT would not target. For example, "I am embarrassed by my relative's behaviour"; ACT would not seek to address the presence/ level of embarrassment, but the impact of it. By way of example, it may be that a carer feels embarrassment as a result of behaviours exhibited by their care recipient which, in turn, leads the carer to isolate themselves in an attempt to reduce potential embarrassment. Currently, the carer is adopting avoidance-based strategies, which may leave them feeling isolated and alone. Importantly, ACT would not seek to reduce this embarrassment, but rather to highlight the impact of this avoidance on their life and values. So, it would be more helpful to measure the impact that this embarrassment has, i.e. whether this leads to the carer not inviting people round.

The example given above relates to a weekly support call where a participant discussed not going on holiday, or having friends and family to the house, leading to a socially isolated existence. Throughout the intervention, the participant reflected on their 'depression' at their current existence and the

'anxiety' they felt in social situations, through fear of judgement about their skills as a carer, as well as highlighting embarrassment at their care recipients' level of disability and lack of inhibition. ACT allowed this participant to look at the avoidance as a strategy that was leading to other difficulties. They avoided the embarrassment but were left feeling isolated and dissatisfied with life, and harboured feelings of anger towards their care recipient and which then led to guilt over this anger. An important part of their ACT journey was highlighting their values and learning to accept the feelings and ensuring they did not impact on them living their life in accordance with these values. This would not be addressed by the ZBI as an outcome.

Finally, social support has been consistently shown to mitigate strain, (Adelman, Tmanova, Delgado, Dion, & Lachs, 2014; Almberg, Grafstrom, & Winblad, 2000) something which was not assessed in the current study. Current life events and stressors formed a part of the feedback interview and produced salient information about the impact of the PwMS's mental health, which subsequently impacted the carers strain. This may be something which could form part of an informed service use questionnaire (indeed, one could be completed for both the carer and the person that they care for), and could extend to include social and external support outside of health and social care services. However, there is a risk of 'over-measurement' or 'survey fatigue' and a balance between trying to measure every possible aspect of a carers context and the need to keep questionnaires timely without adding unnecessary burden to the carer who is ultimately already under strain due to their inclusion in the study.

#### **4.8 Effectiveness**

Importantly, effectiveness of interventions is not deemed a primary aim of a feasibility study (National Institute for Health Research, 2016), but was included to demonstrate standard deviation of measures alongside estimates of effect sizes that can be used to help guide designs for a larger trial. Therefore, it is important to note that this data should be interpreted with caution.

In terms of the ACT model, this research adds little to the understanding of the ACT model as applied to this, or any other, population. However, the data in this study does show proof-of-principle evidence that ACT, delivered in a guided self-help form, *may be* an effective intervention to help support carers of PwMS. Inherently, the calculations of group-level and individual-level analyses show that ACT self-help with telephone support is worth investigating at a larger, more definitive level trial.

The use of both process measures, alongside the symptomology outcomes, gives some insight into the possible attribution of changes in outcomes to the ACT intervention. Although, it cannot be certain that this (i.e. ACT self-help) mediates the outcomes; outcomes may be related to other factors, for example therapeutic alliance, some placebo effect of receiving any intervention or an interaction of the two. Interestingly, at 3-month follow-up, there were few people in the SH group who improved on the measures of carer strain, but a greater number showed an increase on process measures, suggesting that increases in overall psychological flexibility is not enough to reduce carer strain. Importantly, this group showed a group level improvement on one subscale of the CompACT (at 3-month follow-up, multiple improvements on the CompACT were demonstrated at 6-month follow-up), therefore suggesting that there is more than a simplex linear relationship between process measures and symptom reduction measures. Partly, this should be taken in light of criticisms raised regarding the use of symptom measures. However, in addition, more people in the SH+ showed improvement on these measures and also showed improved psychological flexibility. Therefore, we cannot conclude for this group (SH+ group) that the improvement of ACT process measures was a causal factor for symptom reduction, and then discount the interaction for the reverse in the SH group. It is possible that there is an aspect of the therapeutic relationship that mediates this finding, but also that perhaps the increases are reliable at an individual level, but not at a group level (to mitigate the lack of change, or reliable deterioration for others within the group). This highlights a key discrepancy between results shown and possible conclusions at a group,

versus individual level. Regardless, it is important that these are acknowledged as hypotheses at this stage, given the distinctly small sample size and lack of statistical power.

#### **4.9 Sample Size Estimates**

Sample size estimates for a future study comparing the SH+ group to the UC group, taking the highest estimate of attrition, suggest a sample size of 216 in order to detect a minimal important difference on the ZBI. However, given the highlighted concerns and recommendations for a validated measure of carer strain specific to this population, this might not also be a representative sample size for a study to be powered for an alternative measure of carer strain. Therefore, it is recommended that as part of the internal pilot, the minimally important difference be computed for the pilot data, which can be used to adapt the sample size, using the above as an estimated starting point. A sample size calculation based on the MCSI, which was the secondary measure of carer strain included, would estimate that a sample of 220 be needed, similar to that by estimate using the ZBI. It may, therefore, be expected that the sample size would not differ dramatically from these estimates and could feasibly form part of the internal pilot study.

#### **4.10 Extended Strengths**

The methodological design of this study is strong; RCTs allow for an intervention to be trialled and tested against a control/ usual care group which increases the potential accuracy of any results so as to mitigate the possibility of a placebo effect. The use of a mixed-methods RCT further improves the design, allowing for triangulation of findings and to give a richer depth to the data to highlight changes across groups. Having two intervention arms also gives methodological rigour as it allows the self-help intervention to be evaluated as a unique and stand-alone intervention, but also acknowledges the need for additional support (i.e. the telephone calls).

Exploratory group level analyses help to give an indication of the effect sizes which may be expected for a larger trial. This, coupled with individual level and interview data, allows for triangulation of findings which is useful to explore both feasibility and possible effectiveness of the intervention(s). The use of individual change analyses allows for the estimation of possible changes for individuals within the study and helps to map their individual journey, without relying on between-group statistical significance, which is arguably less relevant for individuals within the study. Indeed, the use of the individual change analyses also allows for patterns across individuals within a certain group to be mapped, and can be extrapolated to highlight differences between groups.

#### **4.11 Extended Limitations**

The main limitation of this study was the recruitment strategy, which led to a much lower than expected level of recruitment. The strategy adopted predominantly focussed on use of social media and other online outlets. Whilst possibly 'reaching' a wide audience this clearly did not translate into an adequate number of people taking part. Indeed, one of the social media channels posted details of the study on their page, which had tens of thousands of followers, but only three people made contact as a result of this post. Arguably, not all those who follow the page may have viewed the post, and not all of those who viewed the post may have been carers, therefore whilst these pages were potentially viewed by a great number of people, it does not necessarily lead to recruitment of the targeted individuals required for the study.

Given the low levels of recruitment, this also limited the usefulness of the quantitative findings; using published recommendations for the numbers of participants needed for feasibility studies, we randomised significantly less than the number recommended for full trial parameters to be estimated (Julious, 2005). This, coupled with the number of changes recommended before moving to a phase III trial, indicate that an internal pilot should be carried out as the first stage of a phase III trial.

The measures chosen, whilst not entirely within the control of the researchers, were another major limitation of the study. The lack of validated questionnaires to measure carer strain for carers of PwMS leaves questions regarding the internal validity of the measures in this population. The use of symptom reduction measures has been discussed extensively and, whilst a certain level of pragmatism is necessary and warranted, it does raise questions for both this and wider trials of ACT interventions, of how to reliably measure effectiveness whilst retaining theoretical and epistemological coherence. The difficulties encountered with measuring cost-effectiveness also highlight the need for further work before moving to a phase III trial.

There are also limitations on what this study can add to the current literature and evidence base for ACT; RCTs are less focussed on mechanisms of change and processes compared with quantifying effectiveness. Use of mixed-methods attempts to mitigate this by use of change-process interview questions and process measures, but further changes could be adopted which might seek to highlight mechanisms of change and whether these are related to the use of ACT itself. Use of the telephone support recordings could be a rich and interesting data source for a phase III trial which could give this insight.



## 5. Reflective Section

This section provides a critical reflection of my experience throughout the research process. I start by reflecting on what drew me to this research project and design, moving through to the implementation of the study and subsequently the process of writing this thesis. I will reflect on both the chosen methodology and experiences of the research process, alongside my own views towards the chosen intervention modalities.

Beginning my research process, I felt a level of confidence at designing and implementing an RCT design. Prior to beginning the course, I had worked on two large, multi-centre phase-III RCTs and therefore I felt more comfortable in working with this methodology. Interestingly, I felt more confident in relation to quantitative over qualitative methodologies and did not initially want to adopt a mixed-method approach, something which I think has been the greatest journey for myself as a researcher and a clinician throughout this process (which, I will discuss in greater detail later in this reflection). Reflecting on my expectations of the research process, I have come to see that I had high expectations that were, fundamentally, unrealistic. In the initial design of the study, it was expected that two trainees would collaborate together for this project; which was initially explored but did not come to fruition. On reflection, this was an important turning point for myself and the study. I did not make changes to reduce the labour intensity in order to suit one trainee, instead adding in a six-month follow-up which, whilst I believe this aspect transpired to be a particular strength of the project (perhaps impacting my identity as a researcher), it shows a lack of understanding and self-awareness (impacting my identity as a future clinical psychologist managing appropriate work-life boundaries). Interestingly, I have always reflected throughout the research process of this as a 'blessing in disguise' as I subsequently felt more ownership over the project and had the ability to work at my own pace. On writing this reflection, I have to wonder about whether this is, in fact, a reflection of my own urge to control. Given that I did not attempt to find another trainee to share the project, this could show my

experiential avoidance of my own discomfort at the prospect of relying on others to help build my success, something which is central to my identity. This has led me to think about my future as a researcher, as projects cannot be conducted in isolation and team collaboration is necessary. This in turn brings about a certain level of anxiety in me regarding my potential role in future research, although it is possible that the level of anxiety I experienced was more intense as a result of course deadlines (and indeed success on the course).

Another source of reflection for me has been the recruitment strategy. When designing the study, I liaised at length with a representative from a national charity, and was given assurances about their level of involvement with the study. Subsequently, due to staff changes and restructuring, these were not offered. This left me feeling frustrated at myself for not pursuing this participation in a more formal manner and getting written assurances, and also for not having a back-up plan. This was opposing to my own view of myself as someone who is very methodical and has changed how I practice; I subsequently always follow a telephone call with an email confirming the content. Furthermore, the length of the recruitment period was around six-months, and I felt completely out of control in regard to this aspect of the trial. Short of resubmitting to NHS ethics, I could not formulate a feasible and practical change to strategy that would be possible within the course parameters which would still allow me to meet deadlines. This tapped into my urge to control and given I felt this whole area was out of my control, left me feeling anxious and somewhat resentful towards the study; I began to question my identity as a researcher and choice in project.

A key reflection that I have taken from this process relates to my hopes for the study to be 'successful', something I had not previously experienced to this degree, potentially due to the level of ownership I had over this study. The study was designed using a post-positivist epistemology, acknowledging the researcher's own biases and motivations. I had taken steps to ensure that the impact of these were reduced as much as possible, but I, perhaps, had not acknowledged just how present these might be. In particular, I found myself

looking for justifications behind any lack of change, or deterioration, in the SH+ group, but accepting of any improvements. This was particularly pertinent when looking at the individual change data; I noticed myself looking for extraneous factors that might have influenced participants who had not demonstrated reliable improvements, particularly with the SH+ group, with whom I had developed meaningful relationships. I found it interesting that despite acknowledging this as a potential bias, I found myself falling into this trap. Even with regards to the feedback interviews there is a tendency to look for negative life events which may have impacted the study and the level of tenacity is not applied to positive life events that may have provided a false improvement on measures! Indeed, when suggesting changes to the study design it was noted that there were some important factors not recorded, such as the presence of a relapse or symptoms at each time point. The urge behind this was to understand any potential deterioration, but surely this must apply the other way; a carer might present as less strained at a follow-up if the health of the person with MS is improved to the measurement at baseline? Moving beyond the health of the person with MS, there may be a plethora of factors that could improve someone's score on the questionnaires; anything extraneous to the study. This leaves me wondering about the utility of an RCT to give any individual indication of a participant's journey, as there are just a few time points in which these concepts are measured and there are a multitude of factors which could have influenced these. Given my initial drives towards quantitative methodology, this study has shown me the value and richness of gathering qualitative data as a way of gaining insight into what is such a complex phenomenon; measuring someone's psychological wellbeing with a universal questionnaire.

The ACT model is perhaps, the only part of the study that I have not found myself doubting throughout the process. During my first year, when developing the study, I used the self-help text myself and therefore I found myself using my own experiences of the text as a tool for supporting participants. The ACT model has in itself, helped me to frame much of this reflection and my own anxieties around control and the necessity to accept those things that are out of

our control and instead concentrate on the workable actions that are within my control. This did bring about some interesting feelings for me when receiving the feedback from one participant who fundamentally disagreed with the ACT model. This was something I took to supervision and had discussions around this urge to 'defend' the ACT model. This does highlight a reflection regarding whether I am so wedded to this model that I struggle to see that it might not be the best fit for some participants, and brings me back to my epistemological position and the necessity to notice and mitigate researchers' own biases such as this.

Finally, when designing the project, I was keen to use teletherapy as part of the evaluation; my experiences working with carers of people with MS prior to starting the course highlighted the extensive logistics involved in attending clinics etc. Theoretically, and practically, this is still a distinctly important decision and something that was fed back to have improved the acceptability of the intervention for a number of those involved. However, for myself, as the therapist, it was difficult to manage; it felt like I was *powerless* as a therapist on the end of the phone to an often-distressed person. The unclear boundaries regarding what was and was not to form part of the telephone support meant that I was often grappling between my own urge as a therapist to give the client the time they need and extend the content beyond the specificities of the book, but I was constantly aware that these were supposed to be structured around the content of the self-help text. This clearly extended to the participants, as this was fed back by a number of those in the SH+ group, and something which would need to be further discussed for a full-scale trial. On reflection, I began to think about ways to manage this dilemma; the aim of the intervention design is to allow flexibility and to minimise the practical barriers for carers, thus supporting teletherapy. Nonetheless, to have the flexibility to respond in the moment, to the person on the telephone, it is important to be able to stray from the content to ensure a therapeutic alliance and maximise the potential of the call.

One reflective article by Binnie (2015) provided a critical account of working within an IAPT service, entitled “Do you want therapy with that?”. This discussed the ‘McDonaldisation’ of mental health services in the UK, which I think summarises much of my own concerns regarding the intervention methodology; it can feel like a factory style conveyor belt of therapy. This can feel depersonalised, but equally might be sufficient for many people seeking support. Regardless, the use of the text gave a structure for the content of the calls, and I noted that some participants stuck strictly to this content and came each week with a list of difficulties and aspects which they had not understood. Others took a more free-flowing approach and would look to me for more guidance for the call use. I recall one call where a participant began to discuss a difficult experience and then interrupted themselves to say this was not relevant or what not what we were ‘supposed’ to be talking about. I found this a hard balance as my urge was to remain client-centred and have this flexibility, but I was aware these were being recorded and would be reviewed by my supervisor and therefore I felt the urge to stick stringently to the text by way of a manual.

Importantly, I can acknowledge both the strengths, and the weaknesses of the methodology and its necessity alongside more in-depth single case designs or at least triangulation with qualitative interviews. It leaves me with a number of key reflections that will help me develop both myself as future Clinical Psychologist with a dual researcher and clinician role, but also to evaluate and improve the study itself.

Portfolio Word Count: 24341 (excluding abstract, figures, tables and appendices)

## References

- Adelman, R. D., Tmanova, L. L., Delgado, D., Dion, S., & Lachs, M. S. (2014). Caregiver burden: a clinical review. *Jama*, *311*(10), 1052–1060.
- Almberg, B. E., Grafstrom, M., & Winblad, B. (2000). Caregivers of relatives with dementia: experiences encompassing social support and bereavement. *Aging & Mental Health*, *4*(1), 82–89.
- Andersson, G., Bergstrom, J., Hollandare, F., Carlbring, P., Kaldo, V., & Ekselius, L. (2005). Internet-based self-help for depression: randomised controlled trial. *The British Journal of Psychiatry: The Journal of Mental Science*, *187*, 456–461. <https://doi.org/10.1192/bjp.187.5.456>
- Aronson, K. J., Cleghorn, G., & Goldenberg, E. (1996). Assistance arrangements and use of services among persons with multiple sclerosis and their caregivers. *Disability and Rehabilitation*, *18*(7), 354–361.
- Bendelin, N., Hesser, H., Dahl, J., Carlbring, P., Nelson, K. Z., & Andersson, G. (2011). Experiences of guided Internet-based cognitive-behavioural treatment for depression: a qualitative study. *BMC Psychiatry*, *11*(1), 107.
- Benito-Leon, J., Rivera-Navarro, J., Guerrero, A. L., De Las Heras, V., Balseiro, J., Rodriguez, E., ... Martinez-Martin, P. (2011). The CAREQOL-MS was a useful instrument to measure caregiver quality of life in multiple sclerosis. *Journal of Clinical Epidemiology*, *64*(6), 675–686. <https://doi.org/10.1016/j.jclinepi.2010.08.003>
- Bhuse, M. (2008). Assessment of caregiver burden in families of persons with multiple sclerosis. *The Journal of Neuroscience Nursing: Journal of the American Association of Neuroscience Nurses*. M. Buhse, School of Nursing, State University of New York at Stony Brook, Stony Brook, NY, USA. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed8&N EWS=N&AN=18330407>
- Biglan, A., & Hayes, S. (1996). Should the behavioral sciences become more pragmatic? The case for functional contextualism in research on human behavior. *Applied and Preventive Psychology*, *5*(1), 47–57.
- Binnie, J. (2015). Do you want therapy with that? A critical account of working

- within IAPT. *Mental Health Review Journal*, 20(2), 79–83.
- Bland, J. M., & Altman, D. G. (2011). Comparisons against baseline within randomised groups are often used and can be highly misleading. *Trials*, 12, 264. <https://doi.org/10.1186/1745-6215-12-264>
- Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., ... Zettle, R. D. (2011). Preliminary psychometric properties of the Acceptance and Action Questionnaire-II: a revised measure of psychological inflexibility and experiential avoidance. *Behavior Therapy*, 42(4), 676–688. <https://doi.org/10.1016/j.beth.2011.03.007>
- Bower, P., & Gilbody, S. (2005). Stepped care in psychological therapies: access, effectiveness and efficiency. Narrative literature review. *The British Journal of Psychiatry: The Journal of Mental Science*, 186, 11–7. <https://doi.org/10.1192/bjp.186.1.11>
- Buchanan, R. J., & Huang, C. (2011). Informal caregivers assisting people with multiple sclerosis: factors associated with the strength of the caregiver/care recipient relationship. *International Journal of MS Care*, 13(4), 177–87. <https://doi.org/10.7224/1537-2073-13.4.177>
- Buchanan, R. J., & Huang, C. (2012). Caregiver perceptions of accomplishment from assisting people with multiple sclerosis. *Disability and Rehabilitation*, 34(1), 53–61. <https://doi.org/10.3109/09638288.2011.587091>
- Buchanan, R. J., Radin, D., Chakravorty, B. J., & Tyry, T. (2009). Informal care giving to more disabled people with multiple sclerosis. *Disability and Rehabilitation*, 31(15), 1244–1256.
- Buchanan, R., Radin, D., Chakravorty, B. J., & Tyry, T. (2010). Perceptions of informal care givers: health and support services provided to people with multiple sclerosis. *Disability and Rehabilitation*, 32(6), 500–510. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med5&NEWS=N&AN=19852704>
- Calabresi, P. A. (2004). Diagnosis and management of multiple sclerosis. *American Family Physician*, 70(10), 1935–1944.
- Carton, H., Loos, R., Pacolet, J., Versieck, K., & Vlietinck, R. (2000). A quantitative study of unpaid caregiving in multiple sclerosis. *Multiple*

- Sclerosis Journal*, 6(4), 274–279.  
<https://doi.org/10.1177/135245850000600409>
- Castonguay, L. G. (2011). Psychotherapy, psychopathology, research and practice: Pathways of connections and integration. *Psychotherapy Research*, 21(2), 125–140.
- Castonguay, L. G., Boswell, J. F., Zack, S. E., Baker, S., Boutselis, M. A., Chiswick, N. R., ... Morford, M. (2010). Helpful and hindering events in psychotherapy: a practice research network study. *Psychotherapy: Theory, Research, Practice, Training*, 47(3), 327.
- Cavanagh, K., Strauss, C., Forder, L., & Jones, F. (2014). Can mindfulness and acceptance be learnt by self-help?: A systematic review and meta-analysis of mindfulness and acceptance-based self-help interventions. *Clinical Psychology Review*, 34(2), 118–129.  
<https://doi.org/10.1016/j.cpr.2014.01.001>
- Cheung, J., & Hocking, P. (2004). Caring as worrying: the experience of spousal carers. *Journal of Advanced Nursing*, 47(5), 475–482.  
<https://doi.org/10.1111/j.1365-2648.2004.03126.x>
- Chipchase, S., & Lincoln, N. (2001). Factors associated with carer strain in carers of people with multiple sclerosis. *Disability and Rehabilitation*, 23(17), 768–776. <https://doi.org/10.1080/09638280110062158>
- Clarke, H., Rees, A., & Hardy, G. E. (2004). The big idea: Clients' perspectives of change processes in cognitive therapy. *Psychology and Psychotherapy: Theory, Research and Practice*, 77(1), 67–89.
- Corry, M., & While, A. (2009). The needs of carers of people with multiple sclerosis: A literature review. *Scandinavian Journal of Caring Sciences*, 23(3), 569–588. <https://doi.org/10.1111/j.1471-6712.2008.00645.x>
- Cuijpers. (1997). Bibliotherapy in Unipolar Depression: a Meta-Analysis. *Studies*, 28(2), 139–147. [https://doi.org/10.1016/S0005-7916\(97\)00005-0](https://doi.org/10.1016/S0005-7916(97)00005-0)
- Cuijpers, Donker, T., Johansson, R., Mohr, D. C., van Straten, A., & Andersson, G. (2011). Self-guided psychological treatment for depressive symptoms: A meta-analysis. *PLoS ONE*, 6(6).  
<https://doi.org/10.1371/journal.pone.0021274>
- Cuijpers, Smit, F., Bohlmeijer, E., Hollon, S. D., & Andersson, G. (2010).



- Efficacy of cognitive-behavioural therapy and other psychological treatments for adult depression: meta-analytic study of publication bias. *The British Journal of Psychiatry: The Journal of Mental Science*, 196(3), 173–178. <https://doi.org/10.1192/bjp.bp.109.066001>
- das Nair, R., Lincoln, N. B., Ftizsimmons, D., Brain, N., Montgomery, A., Bradshaw, L., ... Pink, A. (2015). Rehabilitation of memory following brain injury (ReMemBrIn): study protocol for a randomised controlled trial. *Trials*, 16, 6. <https://doi.org/10.1186/1745-6215-16-6>
- Davies, F., Edwards, a, Brain, K., Edwards, M., Jones, R., Wallbank, R., ... Wood, F. (2015). “You are just left to get on with it”: qualitative study of patient and carer experiences of the transition to secondary progressive multiple sclerosis. *BMJ Open*, 5(7), e007674. <https://doi.org/10.1136/bmjopen-2015-007674>
- Dearden, C., & Becker, S. (2004). Young carers in the UK: the 2004 report.
- den Boer, P. C. A. M., Wiersma, D., & van den Bosch, R. J. (2004). Why is self-help neglected in the treatment of emotional disorders? A meta-analysis. *Psychological Medicine*, 34(6), 959–971.
- Dickinson, C., Dow, J., Gibson, G., Hayes, L., Robalino, S., & Robinson, L. (2017). Psychosocial intervention for carers of people with dementia: What components are most effective and when? A systematic review of systematic reviews. *International Psychogeriatrics*, 29(1), 31–43.
- Dindo, L., Van Liew, J. R., & Arch, J. J. (2017). Acceptance and Commitment Therapy: A Transdiagnostic Behavioral Intervention for Mental Health and Medical Conditions. *Neurotherapeutics: The Journal of the American Society for Experimental NeuroTherapeutics*, 14(3), 546–553. <https://doi.org/10.1007/s13311-017-0521-3>
- Diwan, S., Hougham, G. W., & Sachs, G. A. (2004). Strain experienced by caregivers of dementia patients receiving palliative care: findings from the Palliative Excellence in Alzheimer Care Efforts (PEACE) Program. *Journal of Palliative Medicine*, 7(6), 797–807. <https://doi.org/10.1089/jpm.2004.7.797>
- Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining Feasibility and Pilot Studies

- in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PLoS ONE*, 11(3), e0150205. <https://doi.org/10.1371/journal.pone.0150205>
- Elliott, R., Slatick, E., & Urman, M. (2001). Qualitative change process research on psychotherapy: Alternative strategies. *Psychological Test and Assessment Modeling*, 43(3), 69.
- Faraone, S. V. (2008). Interpreting Estimates of Treatment Effects: Implications for Managed Care. *Pharmacy and Therapeutics*, 33(12), 700–711. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2730804/>
- Feliu-Soler, A., Cebolla, A., McCracken, L. M., D'Amico, F., Knapp, M., López-Montoyo, A., ... Luciano, J. V. (2018). Economic Impact of Third-Wave Cognitive Behavioral Therapies: A Systematic Review and Quality Assessment of Economic Evaluations in Randomized Controlled Trials. *Behavior Therapy*, 49(1), 124–147. <https://doi.org/https://doi.org/10.1016/j.beth.2017.07.001>
- Figved, N., Myhr, K.-M., Larsen, J.-P., & Aarsland, D. (2007). Caregiver burden in multiple sclerosis: the impact of neuropsychiatric symptoms. *Journal of Neurology, Neurosurgery, and Psychiatry*, 78(10), 1097–1102. <https://doi.org/10.1136/jnnp.2006.104216>
- Francis, A. W., Dawson, D. L., & Golijani-Moghaddam, N. (2016). The development and validation of the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT). *Journal of Contextual Behavioral Science*, 5(3), 134–145.
- Freeman, J. A., & Thompson, A. J. (2000). Community services in multiple sclerosis: still a matter of chance. *Journal of Neurology, Neurosurgery & Psychiatry*, 69(6), 728–732. <https://doi.org/10.1136/jnnp.69.6.728>
- French, K., Golijani-Moghaddam, N., & Schröder, T. (2017). What is the evidence for the efficacy of self-help acceptance and commitment therapy? A systematic review and meta-analysis. *Journal of Contextual Behavioral Science*.
- Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13(1),

- Gilden, D. H. (2017). Infectious causes of multiple sclerosis. *The Lancet Neurology*, 4(3), 195–202. [https://doi.org/10.1016/S1474-4422\(05\)01017-3](https://doi.org/10.1016/S1474-4422(05)01017-3)
- Gloster, A. T., Klotsche, J., Chaker, S., Hummel, K. V, & Hoyer, J. (2011). Assessing psychological flexibility: what does it add above and beyond existing constructs? *Psychological Assessment*, 23(4), 970–982. <https://doi.org/10.1037/a0024135>
- Goldenberg, M. M. (2012). Multiple Sclerosis Review. *Pharmacy and Therapeutics*, 37(3), 175–184. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3351877/>
- Hacker, T., Stone, P., & MacBeth, A. (2016). Acceptance and commitment therapy—Do we know enough? Cumulative and sequential meta-analyses of randomized controlled trials. *Journal of Affective Disorders*, 190, 551–565.
- Hayes, S. (2004). Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behavior Therapy*, 35(4), 639–665. [https://doi.org/10.1016/S0005-7894\(04\)80013-3](https://doi.org/10.1016/S0005-7894(04)80013-3)
- Hayes, S., Barnes-Holmes, D., & Roche, B. (2001). *Relational frame theory: A post-Skinnerian account of human language and cognition*. Springer Science & Business Media.
- Hayes, S., Luoma, J., Bond, F., Masuda, A., & Lillis, J. (2006). Acceptance and commitment therapy: model, processes and outcomes. *Behaviour Research and Therapy*, 44(1), 1–25. <https://doi.org/10.1016/j.brat.2005.06.006>
- Hayes, S., Pistorello, J., & Levin, M. (2012). Acceptance and Commitment Therapy as a Unified Model of Behavior Change. *The Counseling Psychologist*, 40(7), 976–1002. <https://doi.org/10.1177/0011000012460836>
- Hayes, S., Strosahl, K., & Wilson, K. (1999). *Acceptance and Commitment Therapy: An experiential approach to behavior change*. New York: Guildford Press.
- Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Research in nursing & health*, 31(2), 180-191.
- Heward, K., Molineux, M., & Gough, B. (2006). A Grounded Theory Analysis of

- the Occupational Impact of Caring for a Partner who has Multiple Sclerosis. *Journal of Occupational Science*, 13(2–3), 188–197. <https://doi.org/10.1080/14427591.2006.9726515>
- Hewitt, C. E., Kumaravel, B., Dumville, J. C., & Torgerson, D. J. (2010). Assessing the impact of attrition in randomized controlled trials. *Journal of Clinical Epidemiology*, 63(11), 1264–1270. <https://doi.org/http://dx.doi.org/10.1016/j.jclinepi.2010.01.010>
- Hofmann, S. G., & Asmundson, G. J. G. (2008). Acceptance and mindfulness-based therapy: new wave or old hat? *Clinical Psychology Review*, 28(1), 1–16.
- Johnston, M., Foster, M., Shennan, J., Starkey, N. J., & Johnson, A. (2010). The effectiveness of an Acceptance and Commitment Therapy self-help intervention for chronic pain. *The Clinical Journal of Pain*, 26(5), 393–402. <https://doi.org/10.1097/AJP.0b013e3181cf59ce>
- Jones, C. A., Pohar, S. L., Warren, S., Turpin, K. V. L., & Warren, K. G. (2008). The burden of multiple sclerosis: a community health survey. *Health and Quality of Life Outcomes*, 6, 1. <https://doi.org/10.1186/1477-7525-6-1>
- Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics*, 4(4), 287–291. <https://doi.org/10.1002/pst.185>
- Keegan, B. M., & Noseworthy, J. H. (2002). Multiple sclerosis. *Annual Review of Medicine*, 53, 285–302. <https://doi.org/10.1146/annurev.med.53.082901.103909>
- Kersten, P., McLellan, D. L., Gross-Paju, K., Grigoriadis, N., Bencivenga, R., Beneton, C., ... Thompson, A. J. (2000). A questionnaire assessment of unmet needs for rehabilitation services and resources for people with multiple sclerosis: results of a pilot survey in five European countries. *Clinical Rehabilitation*, 14(1), 42–49.
- Khan, F., McPhail, T., Brand, C., Turner-Stokes, L., & Kilpatrick, T. (2006). Multiple sclerosis: disability profile and quality of life in an Australian community cohort. *International Journal of Rehabilitation Research*, 29(2). Retrieved from [http://journals.lww.com/intjrehabilres/Fulltext/2006/06000/Multiple\\_sclerosis](http://journals.lww.com/intjrehabilres/Fulltext/2006/06000/Multiple_sclerosis)

\_\_disability\_profile\_and\_quality.1.aspx

- Khan, F., Pallant, J., & Brand, C. (2007). Caregiver strain and factors associated with caregiver self-efficacy and quality of life in a community cohort with multiple sclerosis. *Disability and Rehabilitation*, 29(16), 1241–1250. <https://doi.org/10.1080/01443610600964141>
- Klein, M. J., & Elliott, R. (2006). Client accounts of personal change in process-experiential psychotherapy: A methodologically pluralistic approach. *Psychotherapy Research*, 16(1), 91–105.
- Kristiansen, K., Bigby, C. M., Johnson, K., & Traustadottir, R. (2005). *Deinstitutionalization and people with intellectual disabilities: In and out of institutions*. Jessica Kingsley Publishers.
- Kristjanson, L. J., Aoun, S. M., & Yates, P. (2006). Are supportive services meeting the needs of Australians with neurodegenerative conditions and their families? *Journal of Palliative Care*, 22(3), 151–157.
- Lakens, D. (2013). Calculating and reporting effect sizes to facilitate cumulative science: a practical primer for t-tests and ANOVAs. *Frontiers in Psychology*, 4, 863. <https://doi.org/10.3389/fpsyg.2013.00863>
- Lassmann, H., Brück, W., & Lucchinetti, C. (2001). Heterogeneity of multiple sclerosis pathogenesis: implications for diagnosis and therapy. *Trends in Molecular Medicine*, 7(3), 115–121.
- Layard, R., Clark, D., Knapp, M., & Mayraz, G. (2007). CEP Discussion Paper No 829 October 2007 Cost-Benefit Analysis of Psychological Therapy, (829).
- Lee, E.-J., Pieczynski, J., DeDios-Stern, S., Simonetti, C., & Lee, G. K. (2015). Gender differences in caregiver strain, needs for support, social support, and quality of life among spousal caregivers of persons with multiple sclerosis. *Work*, 52(4), 777–787.
- Levant, R. F., Barlow, D. H., David, K. W., Hagglund, K. J., Hollon, S. D., Johnson, J. D., ... Directorate, P. (2006). Evidence-Based Practice in Psychology, 61(4), 271–285. <https://doi.org/10.1037/0003-066X.61.4.271>
- Lewis, Anderson, L., Araya, R., Elgie, R., Harrison, G., Proudfoot, J., ... Williams, C. (2003). Self-help interventions for mental health problems. *Report to the Department of Health R&D Programme*.

<https://doi.org/10.1037/e616692007-001>

- Lewis, Pearce, J., & Bisson, J. I. (2012). Efficacy, cost-effectiveness and acceptability of self-help interventions for anxiety disorders: Systematic review. *British Journal of Psychiatry*. <https://doi.org/10.1192/bjp.bp.110.084756>
- Lincoln, N., das Nair, R., Bradshaw, L., Constantinescu, C. S., Drummond, A. E. R., Erven, A., ... Morgan, M. (2015). Cognitive Rehabilitation for Attention and Memory in people with Multiple Sclerosis: study protocol for a randomised controlled trial (CRAMMS). *Trials*, *16*(1), 1–9. <https://doi.org/10.1186/s13063-015-1016-3>
- Lincoln, N., Dent, A., Harding, J., Weyman, N., Nicholl, C., & Blumhardt, L. D. (2002). Evaluation of cognitive assessment and cognitive intervention for people with multiple sclerosis. *J Neurol Neurosurg Psychiatr.*, *72*. <https://doi.org/10.1136/jnnp.72.1.93>
- Lorefice, L., Fenu, G., Sardu, C., Frau, J., Melis, M., Marrosu, M. G., ... Neurology, B. (2013). What do multiple sclerosis patients and their caregivers perceive as unmet needs? *BMC Neurology*, *13*. <https://doi.org/10.1186/1471-2377-13-177>
- Losada, A., Márquez-González, M., Romero-Moreno, R., Mausbach, B. T., López, J., Fernández-Fernández, V., & Nogales-González, C. (2015). Cognitive–behavioral therapy (CBT) versus acceptance and commitment therapy (ACT) for dementia family caregivers with significant depressive symptoms: Results of a randomized clinical trial. *Journal of Consulting and Clinical Psychology*, *83*(4), 760.
- Martin, K.-J., Golijani-Moghaddam, N., & das Nair, R. (2018). Mindfulness self-help interventions for symptoms of depression, anxiety and stress: Review and meta-analysis. *International Journal of Therapy & Rehabilitation*, *24*.
- McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., ... Roberts, I. (2006). What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials*, *7*(1), 9.
- McLeod, J. (2017). Science and Psychotherapy: Developing Research-Based Knowledge That Enhances the Effectiveness of Practice. *Transactional*

*Analysis Journal*, 47(2), 82–101.  
<https://doi.org/10.1177/0362153717694885>

- Mohr, D. C., Likosky, W., Bertagnolli, A., Goodkin, D. E., Van Der Wende, J., Dwyer, P., & Dick, L. P. (2000). Telephone-administered cognitive-behavioral therapy for the treatment of depressive symptoms in multiple sclerosis. *Journal of Consulting and Clinical Psychology*, 68(2), 356.
- Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., ... Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, 350. <https://doi.org/10.1136/bmj.h1258>
- Morales-Gonzales, J. M., Benito-Leon, J., Rivera-Navarro, J., Mitchell, A. J., & Group, G. S. (2004). A systematic approach to analyse health-related quality of life in multiple sclerosis: the GEDMA study. *Multiple Sclerosis (Houndmills, Basingstoke, England)*, 10(1), 47–54. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med5&NEWS=N&AN=14760952>
- MS Society. (2013). *A lottery of treatment and care - MS services across Scotland and the UK*. Retrieved from <http://mslottery.mssociety.org.uk/wp-content/uploads/2013/04/UK-ms-lottery.pdf>
- Murphy, N., Confavreux, C., Haas, J., Konig, N., Rouillet, E., Sailer, M., ... C., Y. (1998). Economic evaluation of multiple sclerosis in the UK, Germany and France. *Pharmacoeconomics*, 13(5 II), 607–622. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed4&NEWS=N&AN=1998162600>
- Murray, T. J. (2006). Diagnosis and treatment of multiple sclerosis. *BMJ: British Medical Journal*, 332(7540), 525.
- National Institute for Health Research. (2016). Feasibility and pilot studies: a guide for NIHR Research Design Service advisors. Retrieved from [https://www.rds-eastmidlands.nihr.ac.uk/resources/Guide to Supporting Feasibility and Pilot Studies MAY 2016 FIANAL.pdf](https://www.rds-eastmidlands.nihr.ac.uk/resources/Guide%20to%20Supporting%20Feasibility%20and%20Pilot%20Studies%20MAY%202016%20FINAL.pdf)
- Newman, Consoli, A. J., & Taylor, C. B. (1999). A Palmtop Computer Program for the Treatment of Generalized Anxiety Disorder. *Behavior Modification*, 23(4), 597–619. <https://doi.org/10.1177/0145445599234005>
- Newman, Erickson, T., Przeworski, A., & Dzus, E. (2003). Self-help and

- minimal-contact therapies for anxiety disorders: Is human contact necessary for therapeutic efficacy? *Journal of Clinical Psychology*. <https://doi.org/10.1002/jclp.10128>
- Newman, Kenardy, J., Herman, S., & Taylor, C. B. (1997). Comparison of palmtop-computer-assisted brief cognitive-behavioral treatment to cognitive-behavioral treatment for panic disorder. *Journal of Consulting and Clinical Psychology*, *65*(1), 178–183.
- Newman, Szkodny, L. E., Llera, S. J., & Przeworski, A. (2011). A review of technology-assisted self-help and minimal contact therapies for drug and alcohol abuse and smoking addiction: Is human contact necessary for therapeutic efficacy? *Clinical Psychology Review*. <https://doi.org/10.1016/j.cpr.2010.10.002>
- NICE. (2009). CG90: Depression in adults. *NICE Clinical Guideline*, (April 2007), 67. Retrieved from [guidance.nice.org.uk/cg90](http://guidance.nice.org.uk/cg90)
- NICE. (2011). Anxiety (CG22).
- NICE. (2017). Computerised cognitive behaviour therapy for depression and anxiety.
- O'Brien, R. A., Wineman, N. M., & Nealon, N. R. (1995). Correlates of the caregiving process in multiple sclerosis. *Scholarly Inquiry for Nursing Practice*, *9*(4), 323–342. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med3&NEWS=N&AN=8820593>
- O'Hara, L., De Souza, L., & Ide, L. (2004). The nature of care giving in a community sample of people with multiple sclerosis. *Disability and Rehabilitation*, *26*(24), 1401–1410.
- Öst, L.-G. (2008). Efficacy of the third wave of behavioral therapies: A systematic review and meta-analysis. *Behaviour Research and Therapy*, *46*(3), 296–321.
- Öst, L.-G. (2014). The efficacy of Acceptance and Commitment Therapy: an updated systematic review and meta-analysis. *Behaviour Research and Therapy*, *61*, 105–121.
- Pakenham, K. I. (2007). The nature of caregiving in multiple sclerosis: development of the caregiving tasks in multiple sclerosis scale. *Multiple*



*Sclerosis Journal*, 13(7), 929–938.

- Pearlin, L. I., Mullan, J. T., Semple, S. J., & Skaff, M. M. (1990). Caregiving and the Stress Process: An Overview of Concepts and Their Measures<sup>1</sup>. *The Gerontologist*, 30(5), 583–594. Retrieved from <http://dx.doi.org/10.1093/geront/30.5.583>
- Perrin, P. B., Panyavin, I., Paredes, A. M., Aguayo, A., Macias, M. A., Rabago, B., ... Arango-Lasprilla, J. C. (2015). A disproportionate burden of care: Gender differences in mental health, health-related quality of life, and social support in Mexican multiple sclerosis caregivers. (G. Forbes Kraft, Gray-Little, Spielberger, Spielberger, Jenkinson, White, Requena Hernandez, Bailey, Gallagher-Thompson, Ehde, Gimenez, Schmitt, Nicholas, Good, Panitz, Diener, Andrade, Khan, Atienza, Patti, Arciniega, Galanti, Alonso, Arango-Lasprilla, Coh, Ed.), *Behavioural Neurology*. Arango-Lasprilla, Juan Carlos: University of Deusto, Bilbao, Spain, 48007, jcarango@deusto.es: Hindawi Publishing Corporation. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc11&N EWS=N&AN=2015-47363-001>
- Peters, M., Jenkinson, C., Doll, H., Playford, E. D., & Fitzpatrick, R. (2013a). Carer quality of life and experiences of health services: a cross-sectional survey across three neurological conditions. *Health and Quality of Life Outcomes*, 11, 103. <https://doi.org/10.1186/1477-7525-11-103>
- Peters, M., Jenkinson, C., Doll, H., Playford, E., & Fitzpatrick, R. (2013b). Carer quality of life and experiences of health services: a cross-sectional survey across three neurological conditions. *Health and Quality of Life Outcomes*, 11(1), 103. <https://doi.org/10.1186/1477-7525-11-103>
- Plumb, J. C., & Vilardaga, R. (2010). Assessing treatment integrity in acceptance and commitment therapy: Strategies and suggestions. *International Journal of Behavioral Consultation and Therapy*. Plumb, Jennifer C.: Department of Psychology, University of Nevada, Reno, Mail Stop 298, Reno, NV, US, 89557-0062, jcplumb@gmail.com: Joseph D. Cautilli. <https://doi.org/10.1037/h0100912>
- Post, M. W. M., Festen, H., van de Port, I. G., & Visser-Meily, J. M. A. (2007). Reproducibility of the Caregiver Strain Index and the Caregiver Reaction

- Assessment in partners of stroke patients living in the Dutch community. *Clinical Rehabilitation*, 21(11), 1050–1055. <https://doi.org/10.1177/0269215507079140>
- Redfern-Tofts, D., Wallace, L., & Mcdougal, A. (2016). *My MS My Needs 2016 : access to treatment and health care Technical report*.
- Rejdak, K., Jackson, S., & Giovannoni, G. (2010). Multiple sclerosis: a practical overview for clinicians. *British Medical Bulletin*, 95(1), 79–104. Retrieved from <http://dx.doi.org/10.1093/bmb/ldq017>
- Ritchie, J., Spencer, L., & O'Connor, W. (2003). Carrying out qualitative analysis. In *Qualitative Research Practice* (pp. 219–262). London: Sage.
- Rivera-Navarro, J., Benito-Leon, J., Oreja-Guevara, C., Pardo, J., Dib, W. B., Orts, E., ... Group, C. Q. of L. in M. S. (CAREQOL-M. S. (2009). Burden and health-related quality of life of Spanish caregivers of persons with multiple sclerosis. *Multiple Sclerosis (Houndmills, Basingstoke, England)*, 15(11), 1347–1355. Retrieved from <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med5&NEWS=N&AN=19797453>
- Robinson, B. C. (1983). Validation of a Caregiver Strain Index. *Journal of Gerontology*, 38(3), 344–348.
- Roche, B., Barnes-Holmes, Y., Barnes-Holmes, D., Stewart, I., & O'Hora, D. (2002). Relational frame theory: A new paradigm for the analysis of social behavior. *The Behavior Analyst*, 25(1), 75–91. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2731595/>
- Ruiz, F. J. (2012). Acceptance and commitment therapy versus traditional cognitive behavioral therapy: A systematic review and meta-analysis of current empirical evidence. *International Journal of Psychology and Psychological Therapy*, 12(3).
- Schreiner, A. S., Morimoto, T., Arai, Y., & Zarit, S. (2006). Assessing family caregiver's mental health using a statistically derived cut-off score for the Zarit Burden Interview. *Aging and Mental Health*, 10(2), 107–111.
- Scott, J. L., Dawkins, S., Quinn, M. G., Sanderson, K., Elliott, K.-E. J., Stirling, C., ... Robinson, A. (2016). Caring for the carer: a systematic review of pure technology-based cognitive behavioral therapy (TB-CBT) interventions

- for dementia carers. *Aging & Mental Health*, 20(8), 793–803.  
<https://doi.org/10.1080/13607863.2015.1040724>
- Siebert, R. J., Jackson, D. M., Tennant, A., & Turner-Stokes, L. (2010). Factor analysis and Rasch analysis of the Zarit Burden Interview for acquired brain injury carer research. *Journal of Rehabilitation Medicine*, 42(4), 302–309.
- Smith, K. J., & McDonald, W. I. (1999). The pathophysiology of multiple sclerosis: the mechanisms underlying the production of symptoms and the natural history of the disease. *Philosophical Transactions of the Royal Society of London. Series B, Biological Sciences*, 354(1390), 1649–1673.  
<https://doi.org/10.1098/rstb.1999.0510>
- Sullivan, G. M., & Feinn, R. (2012). Using Effect Size—or Why the P Value Is Not Enough. *Journal of Graduate Medical Education*, 4(3), 279–282.
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., ... & Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how. *BMC medical research methodology*, 10(1), 1
- Thornton, M., & Travis, S. S. (2003). Analysis of the reliability of the modified caregiver strain index. *The Journals of Gerontology. Series B, Psychological Sciences and Social Sciences*, 58(2), S127–S132.  
<https://doi.org/10.1093/geronb/58.2.S127>
- Tickle-Degnen, L. (2013). Nuts and bolts of conducting feasibility studies. *The American Journal of Occupational Therapy: Official Publication of the American Occupational Therapy Association*, 67(2), 171–176.  
<https://doi.org/10.5014/ajot.2013.006270>
- Ugur, O., & Fadiloglu, C. (2010). “Caregiver Strain Index” validity and reliability in Turkish society. *Asian Pacific Journal of Cancer Prevention: APJCP*, 11(6), 1669–1675.
- Wang, G., Cheng, Q., Wang, Y., Deng, Y., Ren, R., Xu, W., ... Bai, L. (2008). The metric properties of Zarit caregiver burden scale: validation study of a Chinese version. *Alzheimer Disease & Associated Disorders*, 22(4), 321–326.
- Williams, J., Vaughan, F., Huws, J., & Hastings, R. (2014). Brain injury spousal caregivers’ experiences of an acceptance and commitment therapy (ACT

- ) group. *Social Care and Neurodisability*, 5(1), 29–40.  
<https://doi.org/10.1108/SCN-02-2013-0005>
- Wolgast, M. (2014). What Does the Acceptance and Action Questionnaire (AAQ-II) Really Measure? *Behavior Therapy*, 45(6), 831–839.  
<https://doi.org/http://dx.doi.org/10.1016/j.beth.2014.07.002>
- Yin, Y. (2002). Sample size calculation for a proof of concept study. *Journal of biopharmaceutical statistics*, 12(2), 267-276.
- Zarit, S. H., Reever, K. E., & Bach-Peterson, J. (1980). Relatives of the impaired elderly: correlates of feelings of burden. *The Gerontologist*, 20(6), 649–655.

## Appendix A- Ethics Approval Letter



E-mail: [FMHS-ReschEthics@nottingham.ac.uk](mailto:FMHS-ReschEthics@nottingham.ac.uk)

10<sup>th</sup> January 2016

Kristy-Jane Martin  
Trent Doctorate in Clinical Psychology (DClinPsy)  
c/o Professor Roshan dasNair  
Professor of Clinical Psychology & Neuropsychology  
Division of Psychiatry and Applied Psychology  
Room C22 Institute of Mental Health  
Jubilee Campus  
Wollaton Road  
Nottingham  
NG8 1BB

### Faculty of Medicine and Health Sciences

Research Ethics Committee  
C/o Faculty PVC Office  
School of Medicine Education Centre  
B Floor, Medical School  
Queen's Medical Centre Campus  
Nottingham University Hospitals  
Nottingham  
NG7 2UH

Dear Ms Martin

<b>Ethics Reference No:</b> G14112016 – <b>please always quote</b>	
<b>Study Title:</b> Effectiveness of Acceptance and Commitment Therapy Self-Help for Carers of People with Multiple Sclerosis: A Feasibility Randomised Controlled Trial. <b>Short Title:</b> ACT Carers Study	
<b>Chief Investigator/Supervisor:</b> Professor Roshan dasNair, Professor of Clinical Psychology & Neuropsychology, Division of Psychiatry and Applied Psychology.	
<b>Lead Investigators/student:</b> Kristy-Jane Martin, Trent Doctorate in Clinical Psychology.	
<b>Other Key Investigators:</b> Dr Nima G Moghaddam, Research Clinical Psychologist Trent DClinPsy Programme, University of Lincoln, Dr Nikos Evangelou, Clinical Associate Professor Neurology, Division of Neurosciences.	
<b>Type of Study:</b> Pilot Study/questionnaires, quantitative/qualitative	
<b>Proposed Start Date:</b> 12/2016	<b>Proposed End Date:</b> 30/09/2017 12mths
<b>No of Subjects:</b> 54	<b>Age:</b> 18+years
<b>School:</b> Medicine	

Thank you for submitting the above application which was considered by the Committee at its meeting on 14<sup>th</sup> November 2016 and the following documents were received:

- ACT Carers Study application form and documents v1.0 date 28/10/2016

These have been reviewed and are satisfactory and the study is approved.

Approval is given on the understanding that the conditions set out below are followed:

1. You must follow the protocol agreed and inform the Committee of any changes using a notification of amendment form (please request a form).
2. You must notify the Chair of any serious or unexpected event.
3. This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.

4. An End of Project Progress Report is completed and returned when the study has finished  
(Please request a form).

Yours sincerely



**Professor Ravi Mahajan**  
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee

# Appendix B- Ethics Amendment Approval Letter



E-mail: [FMHS-ReschEthics@nottingham.ac.uk](mailto:FMHS-ReschEthics@nottingham.ac.uk)

17<sup>th</sup> February 2017

Kristy-Jane Martin  
Trent Doctorate in Clinical Psychology (DClinPsy)  
c/o Professor Roshan dasNair  
Professor of Clinical Psychology & Neuropsychology  
Division of Psychiatry and Applied Psychology  
Room C22 Institute of Mental Health  
Jubilee Campus  
Wollaton Road  
Nottingham  
NG8 1BB

## Faculty of Medicine and Health Sciences

Research Ethics Committee  
C/o Faculty PVC Office  
School of Medicine Education Centre  
B Floor, Medical School  
Queen's Medical Centre Campus  
Nottingham University Hospitals  
Nottingham  
NG7 2UH

Dear Ms Martin

<b>Ethics Reference No:</b> G14112016 – please always quote	
<b>Study Title:</b> Effectiveness of Acceptance and Commitment Therapy Self-Help for Carers of People with Multiple Sclerosis: A Feasibility Randomised Controlled Trial.	
<b>Short Title:</b> ACT Carers Study	
<b>Chief Investigator/Supervisor:</b> Professor Roshan dasNair, Professor of Clinical Psychology & Neuropsychology, Division of Psychiatry and Applied Psychology.	
<b>Lead Investigators/student:</b> Kristy-Jane Martin, Trent Doctorate in Clinical Psychology.	
<b>Other Key Investigators:</b> Dr Nima G Moghaddam, Research Clinical Psychologist Trent DClinPsy Programme, University of Lincoln, Dr Nikos Evangelou, Clinical Associate Professor Neurology, Division of Neurosciences.	
<b>Type of Study:</b> Pilot Study/questionnaires, quantitative/qualitative	
<b>Proposed Start Date:</b> 12/2016	<b>Proposed End Date:</b> 30/06/2018 21mths
<b>No of Subjects:</b> 54	<b>Age:</b> 18+years
<b>School:</b> Medicine	

Thank you for notifying the Committee of amendment no 1: 27.01.2017 as detailed in the attached Notice of amendment form. The following documents were received:

- ACT Carer Study Protocol V2 27.01.17
- ACT Carer Study Consent Form V2 27.01.17
- ACT Carer Study Participant Information Sheet V2 27.01.17
- ACT Carer Study Baseline Covering Letter V2 27.01.17
- ACT Carer Study Baseline Questionnaires V2 27.01.17
- ACT Carer Study 3 Month Follow-Up Covering Letter V2 27.01.17
- ACT Carer Study 3 Month Questionnaires V2 27.01.17
- ACT Carer Study 6 Month Follow-Up Covering Letter V2 27.01.17
- ACT Carer Study 6 Month Questionnaires V2 27.01.17

These have been reviewed and are satisfactory and the study amendment no 1: 27.01.2017 is approved.



Approval is given on the understanding that the conditions set out below are followed:

1. You must follow the protocol agreed and inform the Committee of any changes using a notification of amendment form (please request a form).
2. You must notify the Chair of any serious or unexpected event.
3. This study is approved for the period of active recruitment requested. The Committee also provides a further 5 year approval for any necessary work to be performed on the study which may arise in the process of publication and peer review.
4. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

**Professor Ravi Mahajan**  
**Chair, Faculty of Medicine & Health Sciences Research Ethics Committee**



## Appendix C- Participant Information Sheet



UNITED KINGDOM · CHINA · MALAYSIA

### Participant Information Sheet

(Version 2: 27.01.2017)

**Title of Study:** Effectiveness of Acceptance and Commitment Therapy self-help for carers of people with multiple sclerosis: A feasibility randomised controlled trial.

**Name of Researcher(s):** Kristy-Jane Martin, Roshan dasNair, Nima Moghaddam, Nikos Evangelou

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

#### **What is the purpose of the study?**

A lot of care is currently being provided to people with MS by family members and loved-ones. Some of these carers of people with MS sometimes experience difficulties as a result of their caring duties. Currently, help is available through generic NHS services only, or by information provided by charities such as the MS Society and MS Trust. We would like to assess whether a self-help book can help carers to reduce the strain they experience and improve their own psychological wellbeing.

The self-help book uses an Acceptance and Commitment Therapy (ACT) approach to help people better manage the strain of caring and improve their quality of life. The aims of ACT are to help people to learn to accept that there are things in life that cannot be controlled, like our thoughts and feelings, but

that we can control our actions. The book aims to help people learn techniques to cope more effectively with thoughts and feelings, and work towards living a life more in line with their values.

### **Why have I been invited?**

You are being invited to take part because you are a carer for somebody with MS. We are inviting 54 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. If you do decide to take part you will receive this information sheet to keep (electronically) and be asked to complete a consent form online. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

### **What will happen to me if I take part?**

If you agree to take part in the study, you will be sent a link to an online survey. The online survey will ask you to consent to taking part and then to complete some questionnaires. You can request the questionnaires and consent via post, should you prefer to complete this in this way, rather than online. If you request the consent and questionnaires via the post, you will be asked to sign a consent form, and return it in a prepaid envelope. Should you have any difficulties completing the questionnaires, we can arrange for someone to help you with these. All of the data will be anonymised, and only accessible by those in the research team. Your contact details will be kept on a password protected document on the University of Nottingham system, only accessible by the research team that will need to contact you to inform you of your allocation. To take part in the study, your results on the questionnaire must indicate that you have at least a mild level of carer burden; therefore, once you have completed the questionnaires, a researcher will be in touch within two weeks to let you

know whether you are eligible to take part. If your results indicate you do experience at least a mild level of distress, you will be randomly allocated to one of three groups: ACT self-help, ACT self-help plus telephone support, or usual care. The reason that we have a usual care group is to allow the research team to compare the outcomes of those in the two ACT groups to those in the usual care group; this is sometimes called the comparison group, or control group. The reason we randomly allocate people to one of the three groups is because this is the fairest way to do it, so everyone has an equal chance of being in one of the groups. Neither you nor the researcher will be able to choose which group you are allocated to. The random allocation will be done by a computer.

If you're allocated to ACT self-help, we will send you a chapter of the ACT book each week for eight weeks. If you're allocated to ACT self-help plus telephone support, we will send you a chapter of the ACT book each week and arrange weekly support calls. The researcher will arrange a convenient time to contact you each week. These telephone support calls are to help you complete the self-help book and should last no more than 15 minutes. The self-help book will last for 8 weeks. If you are allocated to usual care, you will not receive the self-help book, but you will still be involved in the study.

3 months after starting the study, we will send you a web-link for you to complete the same questionnaires as at the beginning of the study. Again, you can receive these questionnaires through the post should you prefer. You will then be reminded about the possibility of taking part in a feedback interview. Only some people will be asked to give further feedback, so even if you consent you may not be contacted. The purpose of these interviews is for you to give further feedback about aspects of the study that were useful, as well as those that were less useful. This interview will help us develop the intervention in any future trials. If you are chosen to take part in this, a different researcher will get in touch. This researcher will not be involved in any other part of the study, and therefore we would welcome your feedback about any positives or negatives of taking part in the study. This researcher will arrange a convenient time to

complete this interview, which will be done either over the phone or on Skype, should you prefer this.

You will be sent a web-link to complete the same questionnaires one final time, 6 months after starting the study. Again, you can receive these questionnaires through the post, should you prefer. This will be the final part of the study.

### **Expenses and payments**

Participants will not be paid an inconvenience allowance to participate in the study. There will be no necessity for participants to travel as a result of this study, and interviews can be completed over Skype or telephone.

### **What are the possible disadvantages and risks of taking part?**

There are no particular risks of taking part in the study. It is possible that some carers may experience distress as a result of taking part in the study. Whilst this is not likely, previous research has found that some people may become more aware of their own needs and how these are not currently being met. We would recommend contacting your GP should this arise.

### **What are the possible benefits of taking part?**

We cannot promise the study will help you, but the information we get from this study may help us to offer care that is better suited to the needs of carers for people with MS.

### **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you

remain unhappy and wish to complain formally, you can do this by contacting the primary research supervisor for this study: Prof Roshan dasNair ([roshan.dasnair@nottingham.ac.uk](mailto:roshan.dasnair@nottingham.ac.uk)).

### **Will my taking part in the study be kept confidential?**

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

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people 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.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the university will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (name, address, telephone number) will be kept for 12 months after the end of the study so that we are able to contact you about the findings of the study. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

### **What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis up until that point.

### **What will happen to the results of the research study?**

We plan to publish the results of this study in a scientific journal. However, you will not be identified in any publication. If you wish, we can send you a summary of the study results.

This study will also be written up as part of the primary researcher's thesis for the qualification of Doctorate in Clinical Psychology, and this will be published in the University of Nottingham's repository of theses.

### **Who is organising and funding the research?**

This research is being organised by the University of Nottingham and is being funded as part of a Doctorate in Clinical Psychology research project.

### **Who has reviewed the study?**

All research carried out through the University of Nottingham is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Faculty of Medicine and Health Sciences Research Ethics Committee, reference G14112016.

### **Further information and contact details**

Kristy-Jane Martin: [kristy.martin@nottingham.ac.uk](mailto:kristy.martin@nottingham.ac.uk)



**Appendix D- Consent Form**



**CONSENT FORM  
(Version 2: 27.01.2017)**

**Title of Study:** Effectiveness of Acceptance and Commitment Therapy self-help for carers of people with multiple sclerosis: A feasibility randomised controlled trial.

**REC ref: G14112016**

**Name of Researcher:** Kristy-Jane Martin

**Please initial box**

1. I confirm that I have read and understand the information sheet 27.01.17 (Version 2.0) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis up to that point.
3. I understand that relevant sections of data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential.
4. I am willing to be contacted for a follow-up interview (optional). 

<b>Yes</b>	<b>No</b>
<input type="checkbox"/>	<input type="checkbox"/>
5. If interviewed, I understand that the interview will be recorded and that anonymous direct quotes from the interview may be used in the study reports.
6. I would like a copy of the results at the end of the study (optional). 

<b>Yes</b>	<b>No</b>
<input type="checkbox"/>	<input type="checkbox"/>
7. I agree to take part in the above study.
8. I would like to be informed of other similar studies (optional)

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature



## Appendix E- Service Use Questionnaire

Use of health and social-service questionnaire	
We would like to know a little about any contacts with the health services listed below in the last 3 months that were due to caring responsibilities.	
If you had no contact please mark "00" in the boxes otherwise put the number of times as appropriate.	
<i>Due to caring responsibilities, have you had contact (in the last 3 months) with:</i> General practice and community nursing services	
Number of times you saw a GP at the surgery	<input type="text"/> <input type="text"/>
Number of times you saw a GP at your home	<input type="text"/> <input type="text"/>
Number of times you spoke to a GP on the telephone	<input type="text"/> <input type="text"/>
Number of times you saw a nurse at the surgery	<input type="text"/> <input type="text"/>
Number of times you saw a nurse at your home	<input type="text"/> <input type="text"/>
Number of times you saw a counsellor at the surgery	<input type="text"/> <input type="text"/>
Number of contacts with anyone else from the surgery	<input type="text"/> <input type="text"/>
Who did you see? _____	
<i>Due to caring responsibilities, have you had contact (in the last 3 months) with:</i> Hospital and Community Services	
Number of times you saw a neurologist at the hospital	<input type="text"/> <input type="text"/>
Number of times you saw a MS nurse in the hospital	<input type="text"/> <input type="text"/>
Number of times you saw a MS nurse at your home	<input type="text"/> <input type="text"/>
Number of time you called an MS nurse	<input type="text"/> <input type="text"/>

<b>Use of health and social-service questionnaire cont.</b>	
<b>We would like to know a little about any contacts with the health services listed below in the last 3 months that were <i>due to caring responsibilities</i>.</b>	
<b>If you had no contact please mark "00" in the boxes otherwise put the number of times as appropriate.</b>	
<b><i>Due to caring responsibilities</i>, have you had contact (in the last 3 months) with: Therapy Services</b>	
Number of contacts with occupational therapist	<input type="text"/> <input type="text"/>
Number of contacts with a psychologist	<input type="text"/> <input type="text"/>
Number of contacts with a pharmacist	<input type="text"/> <input type="text"/>
Number of times you contacted the NHS 111 service	<input type="text"/> <input type="text"/>
<b><i>Due to caring responsibilities</i>, have you had contact (in the last 3 months) with: Social Services</b>	
Number of times you saw a social worker	<input type="text"/> <input type="text"/>
Number of times you saw a home help	<input type="text"/> <input type="text"/>
Number of times you saw a care assistant	<input type="text"/> <input type="text"/>
Number of times you had respite care	<input type="text"/> <input type="text"/>
Number of contacts with anyone else from Social Services	<input type="text"/> <input type="text"/>
<b>Who did you see?</b> _____	
<b><i>Due to caring responsibilities</i>, have you had contact (in the last 3 months) with: Other services</b>	
Number of times you have accessed support from a charitable organisation (e.g. MS Society)	<input type="text"/> <input type="text"/>
Number of times you have accessed support from other organisations?	<input type="text"/> <input type="text"/>
<b>Which organisations? What help/support was given?</b> _____ _____	

Use of health and social-service questionnaire cont.											
<b>Medication</b>											
Are you currently on any medication? (If YES, please list all medications)			<input type="checkbox"/> Yes <input type="checkbox"/> No								
1		4									
2		5									
3		6									
Have you started and/or stopped any medication in the last 3 months? (If YES, please list medication)			<input type="checkbox"/> Yes <input type="checkbox"/> No								
<i>Medication started within the last 3 months:</i>		<i>Medication stopped within the last 3 months:</i>									
Are you suffering from any other complaints or illnesses? (If YES, please list any serious illnesses and year of diagnosis)			<input type="checkbox"/> Yes <input type="checkbox"/> No								
			<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Y</td> <td>Y</td> <td>Y</td> <td>Y</td> </tr> </table>					Y	Y	Y	Y
Y	Y	Y	Y								
			<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Y</td> <td>Y</td> <td>Y</td> <td>Y</td> </tr> </table>					Y	Y	Y	Y
Y	Y	Y	Y								
			<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Y</td> <td>Y</td> <td>Y</td> <td>Y</td> </tr> </table>					Y	Y	Y	Y
Y	Y	Y	Y								

## **Appendix F- Weekly Telephone Script**

1. How have you found the book this week?
2. Was there anything you found difficult to understand, or struggled with?
3. Have you managed to complete all the chapters this week?
  - a. If no, is there anything outside of the study that prevented you completing these this week, or was it the study material that you struggled with?
4. Was there anything particularly useful about the chapters this week?
5. Are there aspects from these exercises this week that you will continue moving forward?
  - a. If yes, what is it about these exercises that you have found useful?
  - b. If no, what is it about these exercises that were not so useful?

## Appendix G- Semi- Structured Interview Schedule

1. What did you find most useful about using the self-help book?
  - a. Were there any weeks or topics you found particularly useful?
2. What did you find least useful about using the self-help book?
  - a. Were there any weeks or topics you struggled to engage with?
  - b. Were there any weeks or topics you felt were not relevant to you?
3. What changes, if any, have you noticed in yourself, since starting the book?
  - a. (If identify some spontaneously, if not, move to Q4) what do you attribute these changes too?
  - b. (SH + TELEPHONE ONLY) Do you believe any changes are related to the relational aspect of the telephone calls, or the skills side of the book, or both?
4. Have you learnt any new skills as a result of using this book?
  - a. Have any of these impacted on your life/caring responsibilities?
5. Were there any parts of the book that you would like to change?
6. Were there any things going on in your life during the time you were taking part in the study? (e.g. worsening of MS symptoms of people with MS, if relapsing-remitting, people with MS in relapse or remitting stage?)
7. Do you feel the questionnaires you completed online captured anything that may have changed as a result of taking part in the study?
8. Is there anything you would like to change about the study?
9. Did you find the weekly telephone calls useful? (if applicable)
  - a. Is there anything that would have been more useful about these calls?
10. Did you feel the amount of reading each week was acceptable?
11. Did you feel you had enough time each week to complete the exercises?
12. Were there any weeks that you had to skip?
13. Is there anything else you would like to feedback?

Appendix H- CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial



**CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\***

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	Title page
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6-10
	2b	Specific objectives or research questions for pilot trial	10
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	14
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	12
	4b	Settings and locations where the data were collected	14
	4c	How participants were identified and consented	14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	15
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	12 & 13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	30

Sample size	7a	Rationale for numbers in the pilot trial	11 & 12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	14 & 15
	11b	If relevant, description of the similarity of interventions	15
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	17 & 18
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	16
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	18
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	21 & 22
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	16
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	29
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	26
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	35 & 36
	19a	If relevant, other important unintended consequences	n/a

<b>Discussion</b>			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	35 & 36
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	35
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	35 & 36
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	30-34
<b>Other information</b>			
Registration	23	Registration number for pilot trial and name of trial registry	11
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	n/a
	26	Ethical approval or approval by research review committee, confirmed with reference number	11

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).



## Thesis Poster

# ACT for Carers of People with Multiple Sclerosis: A Feasibility RCT

Kristy-Jane Martin<sup>1</sup>, Nima Moghaddam<sup>1</sup>,  
Nikos Evangelou<sup>2</sup>, Roshan dasNair<sup>1</sup>



University of Nottingham  
UK | CHINA | MALAYSIA

<sup>1</sup>Trent Doctorate in Clinical Psychology, Universities of Nottingham & Lincoln, <sup>2</sup>Division of Clinical Neurosciences, University of Nottingham



## Background

Approximately 71% of people with multiple sclerosis (MS) receive care from an 'unpaid carer', i.e. a friend or relative<sup>1</sup>, many of whom report negative impacts of their social, emotional and physical wellbeing<sup>2</sup>. Currently, support for carers of people with MS in the UK tends to focus on practical aspects, such as obtaining paid carers and respite care, rather than offering psychological therapy or support<sup>3</sup>. Low intensity therapies, such as self-help or guided self-help, might be an appropriate first line of treatment for strained carers of people with MS, as these can offer the flexibility to fit around the already busy lives of carers<sup>4</sup>. Acceptance and Commitment Therapy (ACT)<sup>5</sup> focusses on accepting the things that are out of our control, and committing our actions in line with our values<sup>6</sup>. Given many carers of people with MS report difficulties in coping with the unpredictability of the disease<sup>7</sup>; theoretically, ACT is well-suited to addressing suffering in the context of caring for someone with a chronic and unpredictable condition, wherein efforts to 'solve' or exert control over difficulties may not be feasible and ultimately counterproductive.

## Objectives

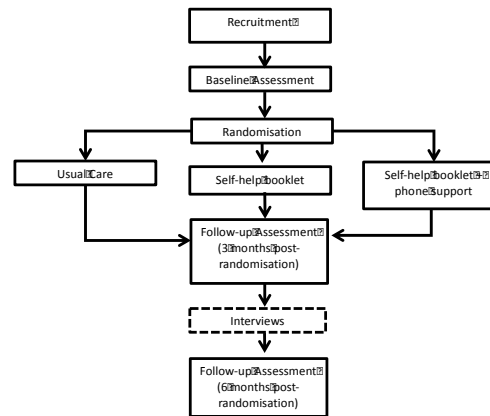
Related to feasibility aspects, specifically to assess:

- Recruitment potential and levels of attrition
- Practicalities of the intervention, assessment tools, and weekly support
- Estimate effect sizes
- Acceptability of intervention
- Fidelity of the support calls to ACT

Secondary objectives to assess effectiveness at individual and group level

## Method

A feasibility, mixed-methods, parallel three-armed RCT design was used. The three arms were: (1) ACT self-help workbook (SH), (2) ACT self-help workbook alongside weekly telephone calls (SH+), and (3) usual care. Those randomised to groups 1 or 2 were emailed a set of chapters each week for eight weeks, those in the group 2 additionally received a weekly telephone call. Three months and six-months post-randomisation, all participants completed outcome measures which will include the same questionnaires used as baseline. Participants in the two intervention groups were invited to complete a telephone feedback interview.



Measures	Results Summary
<b>Carer Strain:</b> Zarit Burden Interview (ZBI) Modified Carer Strain Index (MCSI)	<b>Feasibility area</b>   Progression
<b>Quality of Life:</b> CAREQOL-MS	<b>Recruitment</b>   Amber
<b>ACT Process Measures:</b> Acceptance and Action Questionnaire (AAQ-II) Comprehensive Assessment of Acceptance and Commitment Therapy (CompACT)	<b>Attrition</b>   Amber
	<b>Measures</b>   Amber
	<b>Self-Help Book</b>   Amber
	<b>Support Calls</b>   Green

## Results

**Feasibility:**

**Recruitment & Attrition:**

	UC	SH	SH+	Total
% of Expected	44%	50%	39%	44%
Attrition at 3-month f/up	0%	22%	43%	20%

**Measures:**  
Online platform not user friendly, SUQ not analysed  
**Self-Help Book:**  
SH group reported reading average 25-50% book, SH+ 50-75%  
Amount of reading too much, language not lay-friendly  
**Support Calls:**  
Average call length: 17 minutes (range 8 to 33 minutes)  
Reported to increase adherence to intervention

**Effectiveness:**

**Individual Change:**  
Percentage of reliable change (improvement) at 3-month follow-up

	UC	SH	SH+
ZBI	13%	14%	60%
MCSI	0	0	40%
CAREQOL	0	14%	60%
AAQ-II	0	43%	60%
CompACT	25%	57%	80%

**Exploratory Group Level**  
Significant improvement for ZBI, MCSI, CompACT in SH

## Discussion

Full scale RCT is warranted with significant changes to study protocol:

- Recruitment strategy should be widened and include clinic recruitment
- Adapt study information sheets and assess whether participants are able to engage in intervention prior to randomisation
- Reconsider measures chosen
- Reduce reading per week, adapt self-help text

## References

1. MS Society. A lottery of treatment and care - MS services across Scotland and the UK. 2013. Available from: <http://mslottery.mssociety.org.uk/wp-content/uploads/2013/04/UK-ms-lottery.pdf>
2. Corry M, While A. The needs of carers of people with multiple sclerosis: A literature review. *Scand J Caring Sci.* 2009;23(3):569-88.
3. Freeman JA, Thompson AJ. Community services in multiple sclerosis: still a matter of chance. *J Neurol Neurosurg Psychiatry* [Internet]. 2000 Dec 1;69(6):728-32.
4. Edmonds P, Vivat B, Burman R, Silber E, Higginson JJ. "Fighting for everything": service experiences of people severely affected by multiple sclerosis. *Mult Scler. England*; 2007 Jun;13(5):660-7.
5. Hayes S, Strosahl K, Wilson K. *Acceptance and Commitment Therapy: An experiential approach to behavior change.* New York: Guilford Press; 1999.
6. Hayes S. Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behav Ther.* 2004;35(4):639-65.
7. Bhuse M. Assessment of caregiver burden in families of persons with multiple sclerosis. *The Journal of neuroscience nursing : journal of the American Association of Neuroscience Nurses*; 2008; 40: 25-31.

## Contact

Kristy-Jane Martin  
Trent Doctorate in Clinical Psychology,  
Universities of Nottingham & Lincoln  
Email: [kristy.martin@nottingham.ac.uk](mailto:kristy.martin@nottingham.ac.uk)