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Acceptance Based Telephone Support around the time of Transition to Secondary Progressive Multiple Sclerosis: A Feasibility Randomised Controlled Trial

Christopher Meek, MSc, BSc (Hons)

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Doctorate in Clinical Psychology

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Thesis Abstract

Introduction: Multiple Sclerosis (MS) is the most common neurological disease in young adults, and it contains different stages. Transitioning to Secondary Progressive Multiple Sclerosis (SPMS) is a difficult time for patients, fraught with psychological uncertainty and an increase in physical disability. In parallel, healthcare appointments become less frequent, disease modifying treatments are withdrawn, and social contacts typically become more difficult to maintain. The aim of this study was to assess whether providing a brief, Acceptance and Commitment Therapy (ACT) based telephone supported bibliotherapy intervention during transition to SPMS is feasible, effective and valued by participants. A separate questionnaire study was conducted as an adjunct to the project to determine the strength of relationship between psychological flexibility and distress in SPMS.

Method: A single centre, mixed-methods, two-arm feasibility randomised controlled trial (RCT), comparing (i) Acceptance Based Support + treatment as usual (TAU) to (ii) TAU for those who had transitioned to SPMS was conducted. Feasibility, signal of efficacy and acceptability were assessed in both groups by self-report measures at 3 timepoints (Baseline, 8 weeks, 12 weeks), and feedback interviews analysed using framework analysis following the completion of the study. The questionnaire study recruited participants through the MS Register, a large existing database of MS patients. Those with SPMS were invited to complete a single psychological flexibility questionnaire, which was paired with a previously completed anxiety/depression questionnaire to observe correlation direction and strength.

Results: The recruitment strategy was not feasible: 14 of 40 were recruited (35%) during the four-month time period. Mean sample age of 53, ten women. The data collection procedures and trial processes were feasible and acceptable to participants, reflected through all measures being completed, no attrition, and positive participant interview feedback. The intervention did not demonstrate efficacy, with no practically important differences between baseline and 8-week or 12-week follow up for anxiety (d = 0.00 [-1.60, 1.60]), depression (d = 0.00 [-1.60, 1.60]), or psychological flexibility (d = 0.42 [-1.20, 2.04]). The control group showed a significant reduction in anxiety at 12-week (d = 1.91, [-0.03, 3.83], p = .04), but not at 8-week but was due to one outlier. Comparisons between control and intervention groups showed no significant difference in anxiety (F = 3.21, p = .10), depression (F = 0.12, p = .89) or psychological flexibility (F = 0.36, p = .56) scores. Positive interview feedback suggested potential impact not being captured through self-report measures. The questionnaire study (n = 688) found psychological flexibility was negatively correlated with distress (r = -0.65), anxiety (r = -0.58) and depression (r = -0.56).

Discussion: A future trial with those transitioning to SPMS using a similar ACT-based telephone supported bibliotherapy intervention and this methodology is not feasible, due to an unsuccessful recruitment strategy and a lack of evidence of efficacy. A more efficient recruitment strategy, or longer recruitment period is needed to recruit a large enough sample. Adapting the ACT intervention is also needed to ensure that it targets psychological flexibility, which could include changing the workbook or session delivery. The questionnaire study finding that psychological flexibility is negatively correlated with distress provides justification for using a psychological flexibility focussed intervention, such as ACT in SPMS.

Statement of Contribution

Professor Roshan das Nair (RdN), Dr Nima Moghaddam (NM), Dr Gogem Topcu (GT) and Dr Nikos Evangelou (NE) helped with trial design and applying for ethical approval. Lloyd Oates (LO), DClinPsy student conducted feedback interviews. Sophie Harrison, MSc student helped with interview transcription and coding. Dr Rod Middleton (RM) and Dr Nikos Evangelou (NE) provided access to MS Register data. Professor Roshan das Nair and Dr Nima Moghaddam assisted with data analysis and write up.

Journal Paper

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Acceptance Based Telephone Support around the time of Transition to Secondary Progressive Multiple Sclerosis: A Feasibility Randomised Controlled Trial

Christopher Meek, Nima Moghaddam, Gogem Topcu, Nikos Evangelou, Rod Middleton, Lloyd Oates, Sophie Harrison, Roshan das Nair

Abstract

Introduction: Multiple Sclerosis is the most common neurological disease in young adults, and it contains different stages. Transitioning to Secondary Progressive Multiple Sclerosis is a difficult time for patients, fraught with psychological uncertainty and an increase in physical disability. In parallel, healthcare appointments become less frequent, disease modifying treatments are withdrawn, and social contacts typically become more difficult to maintain. The aim of this study was to assess whether providing a brief, ACT-based telephone support intervention during transition to SPMS is feasible, effective and valued by participants.

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Discussion: A future trial with those transitioning to SPMS using a similar ACT-based telephone supported bibliotherapy intervention and this methodology is not feasible, due to an unsuccessful recruitment strategy and a lack of evidence of efficacy. A more efficient recruitment strategy, or longer recruitment period is needed to recruit a large enough sample. Adapting the ACT intervention is also needed to ensure that it targets psychological flexibility, which could include changing the workbook or session delivery.

[1] See Appendix U for full author guidelines

Highlights

- Many need emotional support after diagnosis of secondary progressive MS
- An ACT-based telephone support RCT contained acceptable procedures
- Recruitment was not feasible, and 12-months is required to achieve the sample
- ACT-based telephone support did not demonstrate efficacy a larger trial is not indicated
- Future trials could use successful elements to achieve low attrition and missing data

Acceptance Based Telephone Support around the time of Transition to Secondary Progressive Multiple Sclerosis: A Feasibility Randomised Controlled Trial

Multiple Sclerosis (MS) is the most common inflammatory neurological disease in young adults, with a worldwide prevalence of approximately 2.2 million, with 106,000 in the United Kingdom (Wallin et al., 2019). Symptoms of MS can be physical (e.g. numbness, weakness, visual impairment, loss of balance, dizziness, urinary bladder urgency), and also psychological (e.g. fatigue, depression) (Calabresi, 2004). For around 85% of people with MS, it presents initially as a series of relapses, each followed by a period of recovery (McKay et al., 2015). When there is a lack of disease progression between these relapses; this is referred to as Relapsing-Remitting MS (RRMS).

Approximately 80% of those with RRMS develop a progressive disorder with an absence of relapse then recovery, but more typically a gradual decline in function. This is called Secondary Progressive Multiple Sclerosis (SPMS), and is defined by progressive accumulation of disability after an initial RRMS course; which may or may not contain sharp episodes of decline during progression (Lublin et al., 2014). A gradual worsening of symptoms, lack of clear recovery and an increased severity and presence of new symptoms are markers for this stage of the disease. This accompanies greater negative impact on quality of life, and a reduction in work, activities and social relationships (Ziemssen, Tolley, et al., 2020). SPMS has a high personal cost: those with MS already experience a higher prevalence of clinical depression and anxiety than the general population (Boeschoten et al., 2017), and those with progressive forms of MS are most severely affected (Jones et al., 2012). SPMS also carries a large societal impact because of inability to work and healthcare costs, which increases in tandem with disease severity (Kobelt et al., 2017).

Medication for RRMS has progressed in the last few decades with the advent of Disease Modifying Treatments (Auricchio et al., 2017). This contrasts with the few effective medications available for SPMS (Metz & Liu, 2018), and therefore clinicians instead focus on symptom management and improving quality of life through pharmacological and non-pharmacological treatments (Fox et al., 2012).

The progression from RRMS to SPMS usually takes around 20 years from initial diagnosis (Koch et al., 2010; Manouchehrinia et al., 2016). However, identifying progression objectively presents a significant clinical challenge for health professionals (Ziemssen, Piani-Meier, et al., 2020). Subsequently, receiving a new diagnosis can take an average of almost three years after onset of progressive symptoms (Katz Sand et al., 2014). From a psychosocial perspective, this can be a time of great distress and anxiety for the patient (Janssens et al., 2003), fraught with uncertainty (Edwards et al., 2008; Wilkinson & das Nair, 2013), and mirroring their experience of receiving their initial RRMS diagnosis (Deibel et al., 2013). Unsurprisingly, this period has been described as a "fear point" of MS (Davies et al., 2015, p. 8) and transition to SPMS a "devastating and demoralising" experience (Thorne et al., 2004, p. 18).

Understanding the needs of people around the point of transition to SPMS is important in designing appropriate interventions. A meta-synthesis found that successful adjustment to SPMS depended primarily on individuals' coping strategies, sense of independence, and healthcare and social support systems. Those with SPMS who are able to accept or adjust to their diagnosis and disease progression, tended to fare better than those who ignored their increasing difficulties, or restricted and reduced their lives too readily (Meek et al., 2020). Healthy coping strategies and perceived social support in MS adjustment are key (Bassi et al., 2019), and a clear plan to maintain these during transition is needed (Giovannetti et al., 2020). These studies on MS adjustment mirror a unified

working model of adjustment to chronic illness, which refers to the chronic illness as disrupting a person's *emotional equilibrium* (Moss-Morris, 2013). Successful adjustment necessitates a return to equilibrium (e.g. through acceptance, good self-efficacy, problem-focused coping, maintenance of activity), whereas difficult adjustment is characterised by ongoing disequilibrium (e.g. through denial, helplessness, coping through avoidance, reduction in activity).

However, despite the needs of those with SPMS and the range of stressors associated with transition (Malcomson et al., 2008), input from healthcare providers reduces after transition to SPMS. Those with SPMS are given fewer neurology appointments and feel downgraded from when they had RRMS (Croft et al., 2016). The lack of contact with services and rushed appointments that do not address patients' needs are experienced as frustrating and abandoning (Davies et al., 2015). Psychosocial resources to help with the significant emotional response of SPMS transition are recognised as a current deficit in NHS services. A key finding from the MS Trust (Croft et al., 2016) is that SPMS patients have a shortage of access to psychological services, with 45% of MS specialists reporting that current psychological services are insufficient in their area (Mynors et al., 2016).

A psychological intervention would be of benefit to this client group, and there have been several studies which have shown benefit in similar populations. For example, there is evidence that Cognitive Behavioural Therapy (CBT) approaches may help with depression (Mohr et al., 2001), fatigue (van den Akker et al., 2016) and reducing distress short-term around the initial MS diagnosis (Moss-Morris et al., 2013). Reduction of distress is important, but across chronic illness it is recognised that self-efficacy – a sense of being able to manage (Bishop et al., 2008), along with accepting coping styles and social support are the key determinants of successful adjustment to SPMS (Bassi et al., 2019; Moss-Morris, 2013).

The focus on reducing distress in CBT has been criticised by some, who feel the cognitive reappraisal mechanism can feel invalidating when negative illness beliefs and distress may be entirely logical due to the debilitating nature of their condition. In response to this, some authors have trialled Third Wave Behavioural therapy approaches, such as Acceptance and Commitment Therapy (ACT) in long term, degenerative conditions (Angiola & Bowen, 2012). ACT (Hayes, 2016) is a mindfulness and acceptance based psychological therapy, which attributes psychological distress to the result of experiential avoidance (i.e. trying to avoid thoughts and feelings, even when harmful in the longer term) and psychological inflexibility (i.e. rigid attempts to control psychological reactions) (Hayes et al., 2012). Where the CBT model attempts to reappraise thoughts, the ACT model instead advocates accepting them as they are, whilst instead taking action in ways which follow values (directions which give a person meaning) to live a rich, fulfilling and meaningful life (Hayes et al., 2012). This focus on acceptance over reappraisal seems promising when considering the benefits of this style of coping in MS adjustment literature (Meek et al., 2020), and the difficulty with emotion-focussed coping strategies (i.e. styles of coping which focus on reducing emotional distress; such as through avoidance of painful feelings or thoughts) (Dennison et al., 2009).

Meta-analyses have found ACT had greater efficacy than treatment as usual or placebo on anxiety disorders, depression, addiction and somatic health problems (A-tjak et al., 2015). However, one meta-analysis raised concern around the poor methodological quality of ACT randomised controlled trials, and recommended that in some client groups ACT should still be considered a 'probably efficacious' or 'experimental' treatment (Ito & Muto, 2020; Öst, 2014). The literature seems to suggest that ACT shows greater effectiveness in conditions which are chronic, long term, and which share symptoms with SPMS. The use of ACT in chronic conditions may outperform CBT when the clients are older (Wetherell et al., 2016); the average age of onset for SPMS is around 54 (Koch et al., 2010).

ACT proponents consider psychological flexibility as a key ingredient to living a rich, full and meaningful life (Harris, 2009), with increased psychological flexibility correlating to reduced distress. However, it was unknown whether this applied to those with SPMS. A questionnaire precursor to this study showed that in a sample of 688 people with SPMS, psychological flexibility was negatively correlated with distress[2]. This suggests, as has been done in chronic pain (Wicksell et al., 2010), that psychological flexibility may play a moderating role on measures of wellbeing in SPMS (e.g. distress, quality of life), and thus provides a greater justification for use of the model.

Providing psychological therapy to those with MS has challenges. Psychological support provision is often unavailable from National Health Service (NHS) neurology services, as already stretched staff (Rolewicz et al., 2019) lack the skills, time and resources to deliver it (Davies et al., 2016). Any trial of psychological therapy in this population would need to have the potential for future application, and this suggests that an effective lower resource intervention may be more suitable. One option could involve running ACT groups (e.g. Brassington et al., 2016; Nordin & Rorsman, 2012), where a number of patients could be seen at once, thus reducing appointment pressures. However, this has challenges of its own: several ACT trained staff would be required to run the group, and patients would need to regularly attend the clinic, which may discourage those with SPMS without transport, who have difficulty balancing and walking (88.6%), or with incontinence (67.6%) (Gross & Watson, 2017).

An alternative would be to use telephone appointments, delivered previously in combination with an ACT bibliotherapy resource (i.e. self-help text). A recent review recommended the use of ACT self-help as an intervention, especially when combined with clinician guidance. However, they cautioned that methodical and reporting flaws may be "overselling" ACT bibliotherapy (French et al., 2017). There has been further evidence of efficacy in a case study of those with multiple sclerosis (Harrison et al., 2017) and a larger, more robust trial in chronic pain (Veillette et al., 2019). A review examining the efficacy of psychotherapy delivered over the telephone in multiple sclerosis showed moderate benefits in physical and mental health domains, with the authors recommending further studies of better quality are needed (Proctor, Moghaddam, Vogt, et al., 2018).

The potential of an ACT-based telephone supported bibliotherapy is recognised in chronic conditions, and trials have been conducted in multiple sclerosis which show preliminary evidence that ACT can reduce anxiety in MS (Proctor, Moghaddam, Evangelou, et al., 2018). However, this trial has limitations due to its small sample and poor adherence, and therefore the evidence base for ACT-based telephone supported bibliotherapy is limited. Some authors have created their own workbooks and materials (Brassington et al., 2016; Ford, 2017), whereas others have used existing ACT specific texts (Hayes, 2005). A benefit of ACT is it is presented as a 'transdiagnostic' model (Hofmann & Hayes, 2018); in theory the guiding principles can be applied to a range of conditions. However, this has not translated into bibliotherapy resources, and there is some evidence that these non-specific resources, especially if deemed confusing or complex, can lead to higher attrition rates and lower compliance (Proctor, Moghaddam, Evangelou, et al., 2018). The level of input from the therapist is also important, with bibliotherapy and support calls combined, found more effective than bibliotherapy on its own (French et al., 2017; Potter et al., 2020).

The overall aim of this project was to assess the feasibility of conducting a randomised controlled trial (RCT) of a ACT-based telephone supported bibliotherapy intervention. The intervention was focussed on supporting those with SPMS who experienced difficulties following their transition from

[2] See Extended Results 3.5.3 for further details on psychological flexibility and distress in SPMS

RRMS. The specific, primary aims (1-4) of the trial were to determine the feasibility of the following, with a secondary aim (5) to determine participant response and whether there is a signal of efficacy:

1: recruitment capability and resulting sample characteristics
2: data collection procedures and measures
3: acceptability and suitability of intervention and study procedures
4: ability to manage and implement the study and intervention
5: participant responses to intervention and signal of efficacy

Method

We followed the CONSORT checklist[3] for reporting trials (Schulz et al., 2010).

Design

A single centre, mixed methods feasibility RCT. The trial had two-arms, with participants split on a 1:1 ratio to: (1) Acceptance Based Support + Usual Care (ABS+UC) and (2) Usual Care only (UC). Participants were assessed at baseline, and then again at 8- and 12-weeks post-randomisation. A selection of participants were invited to complete feedback interviews; seeking participant feedback was a recommendation from a previous comparable trial (Proctor, Moghaddam, Evangelou, et al., 2018)[4].

Participants

We aimed to recruit 20 participants per arm (40 total) to allow for expected attrition and produce an estimate sample size for a future trial (Whitehead et al., 2016). Four from each group (eight total) were invited to participate in feedback interviews[5]. Participants were recruited from an outpatient MS clinic at an NHS Trust in the UK, or through self-referral in response to an advert placed on an SPMS specific Facebook group[6].

Inclusion Criteria.

We included those who:

- had received a diagnosis of SPMS according to the McDonald criteria (Thompson et al., 2018) in the last 12 months[7]
- were able and willing to consent to the trial
- were 18 years or older
- had a score greater than seven on either component of the Hospital Anxiety and Depression Scale (HADS)
- were able to communicate in English

Exclusion Criteria.

We excluded those who:

- were currently receiving any psychological or cognitive or mental health intervention, or had done in the previous six months
- had a serious co-morbid physical health diagnosis at screening (e.g. dementia, cancer)

[3] See Appendix A for a completed CONSORT checklist
[4] See Appendix B for a schematic diagram showing the flow of participants through the study
[5] See Extended Methods 2.3 and 2.4.2 for further detail about sample size and sampling respectively
[6] See Extended Methods 2.2 for further details about the avenues of recruitment
[7] Ethical amendment: This was initially 6 months and was changed to be consistent with the McDonald criteria suggesting yearly review of SPMS patients by neurology services

- were participating in another intervention study.

Measures

The measures used in the study can be seen in Table 1[8]. We used the Hospital Anxiety and Depression Scale (HADS) as a measure of anxiety and depression (Zigmond & Snaith, 1983), as it has been validated for use in MS and both subscales have high sensitivity and specificity (Honarmand & Feinstein, 2009). The Comprehensive Assessment of Acceptance and Commitment Therapy processes (CompACT) was used to measure psychological flexibility, as it has excellent internal consistency and test-retest reliability (Bayliss, 2018). To measure impact on MS specific symptoms, we used the Hobart et al. (2001) Multiple Sclerosis Impact Scale (MSIS-29), as its reliability has been demonstrated across community and hospital settings and it has excellent internal consistency (Jones et al., 2013). Self-efficacy, an important predictor of health in MS, was measured using the Multiple Sclerosis Self-Efficacy scale (MSSE) which has good internal consistency and test-retest reliability (Rigby et al., 2003). Quality of life was measured through the EuroQol Quality of Life (EQ-5D-5L) which is a widely used and reliable measure for use in MS (Kuspinar & Mayo, 2014).

Table 1

Self-report measures used to measure change across timepoints (T^0, T^1, T^2) in the trial

Name	Concept(s) Measured	Scale Type	Response options	Min/Max score	Higher scores meaning
HADS	Anxiety, Depression	Likert	4	0/42	Greater distress
MSIS-29	Perceived impact of MS	Likert	5	29/145	Greater impact of MS
MSSE	Self-efficacy	Likert	6	14/84	Greater self-efficacy
EQ-5D-5L	Perceived health status	Visual analogue	N/A	0/100	Greater perceived health
CompACT	Psychological flexibility	Likert	7	0/138	Greater psychological flexibility

Note. HADS: Hospital Anxiety and Depression Scale, MSIS-29: Multiple Sclerosis Impact Scale, MSSE: Multiple Sclerosis Self Efficacy Scale, EQ-5D-5L: EuroQol Quality of Life, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy processes

Procedure

Eligible participants from the MS clinic were informed about the study by their regular neurologist or MS Nurse Specialist. The contact details of interested parties were passed to the Trial Manager by consent to contact form[9], who telephoned them to confirm their willingness to participate. Eligible participants from the SPMS specific Facebook Group advert route self-referred to the Trial Manager by telephone. Potential participants from both routes were screened initially for eligibility over the telephone based on the inclusion and exclusion criteria. If eligible, a participant information sheet[10] and a consent form[11] were posted to the participant.

[8] See Extended Methods 2.5.2 for further information on the measures
[9] See Appendix C for the consent to contact form
[10] See Appendix D for the participant information sheet
[11] See Appendix E for the participant consent form

Demographic and illness data were collected from the MS service[12]. Baseline self-report measures were taken using standardised assessment questionnaires to assess depression and anxiety, impact of MS, self-efficacy, quality of life, and psychological flexibility. All participants were sent the same measures at baseline (T^0), eight weeks (T^1) and 12-weeks (T^2) post randomisation. Measures were completed by post or using online survey software (dependent on participant preference). If participants had difficulty, they could request help by telephone from the Trial Manager. No changes were made to measures during the trial.

Randomisation was then completed by the Trial Manager using an online randomisation service and randomly sized permeated blocks to each arm, at a ratio of 1:1[13]. Following randomisation, a face-to-face session was arranged for all participants individually with the Trial Manager at their home. This was used to inform participants of their randomisation condition, to collect consent forms, and distribute workbooks to those in the ABS+UC group. Once a participant had completed the trial, a sample were invited to consent to a recorded semi-structured feedback interview about their experience[14] [15]. These interviews were delivered by a trainee clinical psychologist independent from the research team using an interview schedule[16]. Text messages were used in a systematic way to improve response rates (Weston et al., 2017). A text message was sent the day measures were posted to participants, as well as when they had been received back by the researcher (and a prompt after 7 working days if they had not been received) as part of the mailing process (Sarathy et al., 2020)[17].

Intervention

Acceptance Based Support (ABS)[18] was a weekly six-session individually delivered ACT-based telephone supported bibliotherapy intervention with a Trainee Clinical Psychologist (the Trial Manager) for those transitioning to SPMS. The Trial Manager had two years of experience delivering ACT in face to face settings. The first session was face-to-face, with the subsequent five sessions completed via telephone whilst the participant was at home. All sessions were 30 minutes in length. In the first session, participants were given a 49-page SPMS specific workbook[19] adapted for this study[20], and they used this during and between sessions. During the telephone sessions, participants would receive psychological support which followed an ACT approach, with the workbook also consistent with the ACT model. The purpose of the support and the workbook was to increase psychological flexibility and wellbeing.

The workbook contained three ordered sections: familiarisation, mindfulness, and valued action[21] – and homework's were set every week. Through the telephone sessions the Trial Manager assisted the participant apply the ACT model to their own lives and helped them navigate the workbook; the pace of the progression through the workbook was adapted to each participant needs. The fidelity of

[12] See Extended Methods 2.5 for further detail about demographic data collected
[13] See Extended Methods 2.6 for further detail about randomisation
[14] See Appendix F for participant interviews information sheet
[15] See Appendix G for participant interviews consent form
[16] See Appendix H for the interview schedule
[17] See Extended Methods 2.8 for further detail about the use of the study mobile phone
[18] See Extended Methods 2.7 for further detail about the intervention including a TIDieR checklist
[19] See Appendix I for a sample of the workbook used in the study. Full workbook available on request.
[20] See Extended Methods 2.7 for further details on the creation of the workbook from existing materials
[21] See Extended Methods 2.6 for a further detail of the intervention and ACT processes

the intervention was assessment by a clinical psychologist supervisor (NM) with several years of ACT experience against published criteria (O'Neill et al., 2019)[22].

The UC arm of this study consisted of a 1:1 face to face appointment but no telephone calls. In both arms, UC referred to the typical contact made to those recently diagnosed with SPMS by the neurology service which followed standard NICE guidelines for management of MS (NICE, 2014).

Analysis

The analysis of this feasibility study was structured and numbered using the Orsmond and Cohn (2015) framework (Table 2)[23]. We defined this study as feasibility study, within which Eldridge et al. (2016) asks the question: "Can this study be done?" but recognise it could also be described as a *pilot* study "a future study conducted on a smaller scale" (Eldridge et al., 2016). There is debate about the difference between these terms, and are often interpreted as synonymous (Whitehead et al., 2014).

The primary aim of this feasibility study was to assess aspects related to feasibility, not statistical significance or power (Tickle-Degnen, 2013). However, statistical analyses were used to describe effect sizes and explore confidence intervals to calculate the sample size for a future study and to determine a signal of efficacy.

Framework Analysis (Ritchie et al., 2003) was used to analyse interviews of those who have completed the study, following the stages of Gale et al. (2013) to build the framework. Care was taken to mitigate for bias through double-coding and oversight of the analysis, addressing pitfalls around reliability and validity in qualitative research (Noble & Smith, 2015). Transcription, familiarisation and coding (stages 1-3) were completed by a second researcher along with the Trial Manager, with each transcript double-coded and then combined through mutual agreement into one master set of codes. Developing and applying the Framework (stages 4-5) onwards were completed solely by the Trial Manager. Pre-defined categories were used to create the framework matrix (stage 6) based on the Orsmond and Cohn (2015) framework. The codes placed into these categories emerged inductively from the interview data. Relevant codes were assigned to these categories to build the framework, and irrelevant codes which did not fit into the framework were discarded.

Table 2

Analysis plan for the feasibility trial

Title	How this is measured
1: Recruitment Capability and Resulting Sample Characteristics	Descriptive statistics: The number of suitable participants who were referred, the proportion of those who were eligible, source of referral, number of participants who were excluded along with the reasons for exclusion, total number of participants recruited, recruitment rate. Framework analysis: The appeal of this intervention to the population.
2: Data Collection Procedures and Measures	Descriptive statistics: The percentage of missing online and postal data returned, number of prompt text reminders required to complete the questionnaires, and percentages of incomplete or incorrectly completed scales. Framework analysis: Acceptability of completing the measures.

[22] See Appendix L for a description and the scoring of the ACT-FM fidelity measure

[23] See Appendix J for the Orsmond and Cohn framework

3: Acceptability and Suitability of Intervention and Study Procedures	Descriptive statistics: The rate of attrition, percentage of missed face-to-face and telephone contacts and the reasons for this, average length of contacts with participants recorded in minutes, length of time participants remained in the study in weeks, number of participants asked to complete feedback interviews and percentage who agreed, and length of feedback interviews in minutes. Analysis of workbook text: Readability analysis, and reading age calculation using www.readibilityformulas.com. Framework analysis: Acceptability and suitability of the study procedures.
4: Ability to Manage and Implement Study and Intervention	Descriptive statistics: Time required for the Trial Manager to conduct recruitment, deliver therapy and manage the administrative recorded in number of days and hours, adverse events were recorded as a brief description of (i) what the event was and (ii) the effect it had.
5: Participant Responses to Intervention	Quantitative Group level analysis: Mixed model ANOVAs was used to measure differences between the two study arms over time (T^0, T^1, T^2) from measures of anxiety, depression, MS impact, self-efficacy, quality of life and psychological flexibility. Within group effect sizes and confidence intervals for each group were calculated across timepoints. Standard deviation and clinically meaningful difference scores from the literature were used with the HADS and CompACT to predict a full sample for a future RCT. Individual level analysis: RCI and CSC used to measure individual change over time (T^0, T^1, T^2) for anxiety, depression (RCI: +/- 5, CSC clinical cut-off: 7.5) and Psychological Flexibility (RCI: +/- 16, CSC clinical cut-off: 84.5)[24]. Framework analysis: Participant response to intervention.

Note. ANOVA: Analysis of Variance, T^0: baseline, T^1: eight-week follow up, T^2: 12-week follow up, HADS: Hospital Anxiety and Depression Scale, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy, RCI: Reliable Change Index, CSC: Clinically Significant Change

Ethics

The study was approved by University of Nottingham (ID: 19019) and NHS (ID: 19/NW/0261) Research Ethics Committees[25]. The trial protocol was also registered on ClinicalTrials.gov (ID: NCT04239664). Participants did not receive any financial compensation for their participation.

Results

1: Recruitment Capability and Resulting Sample Characteristics

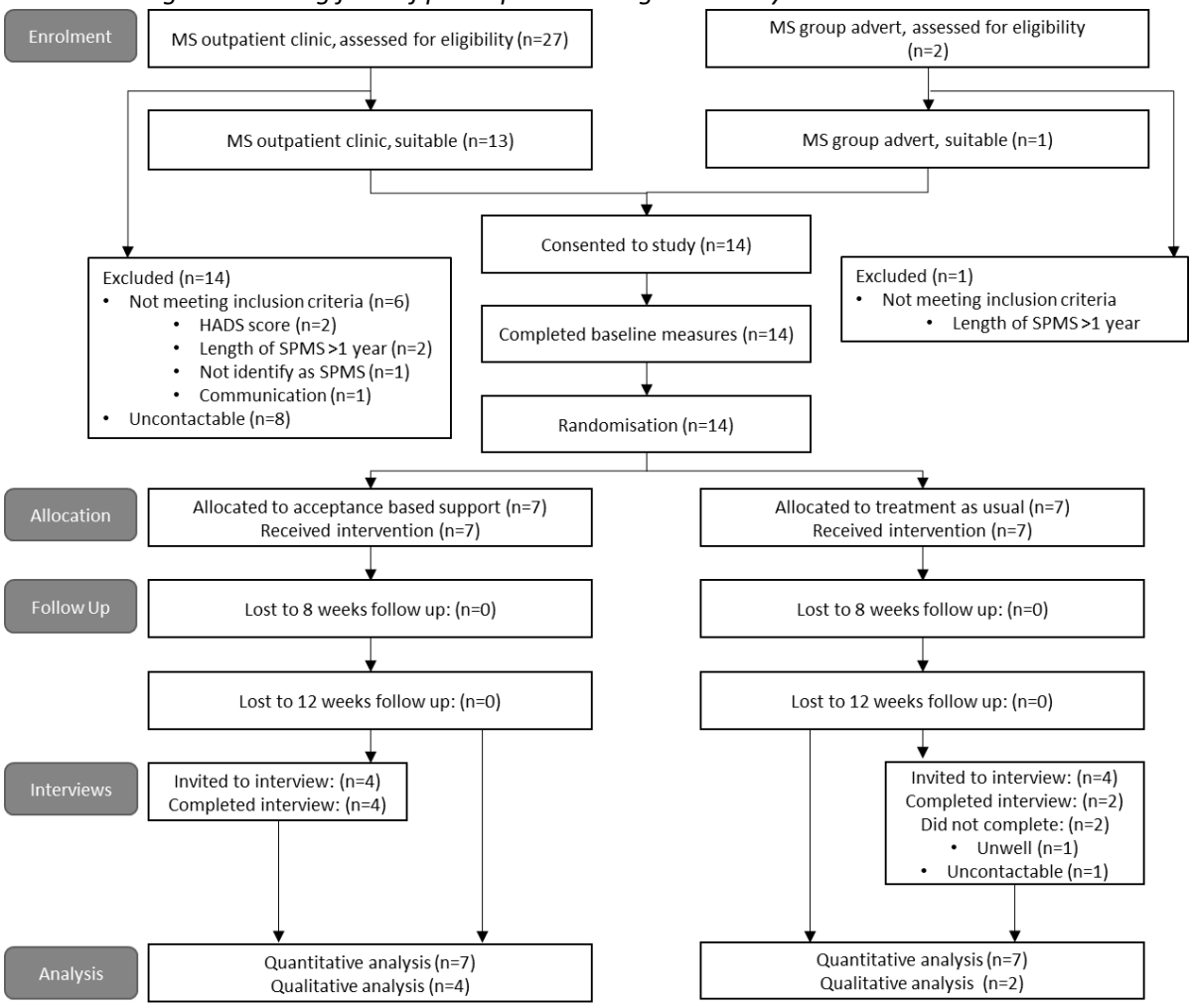
Sample.

From the outpatient clinic, consultants referred 28 patients, of whom 13 consented between September and December 2019. An amendment was requested to allow the recruitment of patients through MS specific networks through Facebook. Three MS charities were contacted but unable to assist with the recruitment. Two participants responded to a Facebook advert placed in September 2019, and one consented, bringing the total number enrolled to 14 (Figure 1). Baseline demographic (Table 3) and clinical characteristics (Table 4) are recorded. Independent samples t-tests were conducted (as assumptions for parametric tests were met) which showed no significant differences between groups.

[24] See Extended Methods 2.10 for further detail on individual change analysis
[25] See Extended Methods 2.11 for further detail on ethical approval

Figure 1

CONSORT diagram showing flow of participants through the study



Note. MS: Multiple Sclerosis, SPMS: Secondary Progressive Multiple Sclerosis, HADS: Hospital Anxiety and Depression Scale

Table 3

Baseline Demographic and Illness Characteristics

Characteristic	UC *M (SD)*	ABS+UC *M (SD)*	*p* value
Age, years	51.60 (8.39)	54.40 (6.58)	0.86
Male/Female [a]	2/5	2/5	
White British/Other Ethnicity [a]	7/0	7/0	
Deprivation score	5.57 (3.11)	5.57 (2.42)	1.00
Months since SPMS diagnosis	5.4 (4.50)	6.4 (2.61)	0.62
EDSS Score	6.07 (1.01)	6.50 (0.50)	0.34
Employment status [b]			
Educational achievement [b]			

Note. [a]: t-tests were not performed as they are not continuous data, [b] : This data was not able to be accessed through clinical records, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care, EDSS: Extended Disability Status Scale

Table 4

Baseline Clinical Characteristics

Characteristic	UC *M (SD)*	ABS+UC *M (SD)*	*p* value
HADS-A	13.00 (5.77)	8.57 (5.80)	0.18
HADS-D	10.00 (3.65)	8.86 (5.18)	0.64
MSIS	102.29 (21.24)	107.85 (17.70)	0.60
MSSE	38.67 (11.45)	43.00 (12.51)	0.56
EQ-5D-5L (VAS)	51.00 (25.99)	52.86 (26.44)	0.90
CompACT			
OE	24.57 (8.56)	27.71 (10.21)	0.54
BA	9.43 (4.43)	10.00 (4.55)	0.82
VA	31.42 (6.78)	34.14 (5.90)	0.44
Total	65.43 (15.63)	72.00 (12.38)	0.40

Note. HADS-A: Hospital Anxiety and Depression Scale Anxiety, HADS-D: Hospital Anxiety and Depression Scale Depression, MSIS: Multiple Sclerosis Impact Scale, MSSE: Multiple Sclerosis Self Efficacy Scale, EQ-5D-5L (VAS): EuroQol Quality of Life – Visual Analogue Scale, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy, OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care

Recruitment.

All participants contacted who were eligible consented to take part. However, there were a proportion whose eligibility could not be determined (8 of 28, 28.57%) who did not respond to a first (2 of 8, 25%) or subsequent (6 of 8, 75%) attempt (phone call, email, or text) to enrol in the study. Through attendance at clinics and liaison with some members of the neurology team, we were able to recruit participants at a relatively stable rate of 3.5 participants per month over four months.

Relevance of Study to the Population.

Framework analysis (Table 5) highlighted the relevance of the study to those with SPMS. Social support in this population is often self-limiting to avoid burdening others and because of perceived societal lack of understanding of MS. Healthcare support, such as General Practitioner (GP) or consultant contact, can also be difficult to access and time limited. Those with SPMS subsequently often value having an outlet to be able to talk to a professional and appreciated the opportunity to help and provide value (others with MS, research, the community). In general, the study was perceived as an attractive outlet to meet these needs.

Table 5

The relevance of Acceptance Based Support to the Secondary Progressive MS population

	Themes			
Participant	Social Barriers	Healthcare Support	Talking Therapy	Motivation to Help
Intervention 1	Guilt about seeking partners support: "Well, you keep your feelings to yourself anyway, you don't like to bother your partner" (137)	Feeling guilty and being dismissed: "It feels like you're wasting your GP's time" (74) "[Neurology staff] tell you 'Go away, that's it, we can't do anything else for you'" (150)	Felt comfortable: "It's nice to talk about it to be honest with you" (137) "to somebody who's not talking down to you" (155)	Benefiting others with MS: "Hopefully some good comes out of [the study]" (46)

Intervention 2	Lack of societal understanding restricts openness: "People don't seem to have any understanding about MS … so I've only told my very close family that now it is only going to be deterioration" (444)	Availability: "There's nothing available" (22) "Anything would be better to help people when they have this diagnosis given to them" (165)	Impartiality and avoiding medication: "Talking to [a therapist] that's impartial and knows exactly what you're talking about it just helps people. If it stops you from taking more medication it's got to be better hasn't it?" (184)	Freeing up the GP: "You're leaving appointments open for really poorly people" (193) Benefiting others with MS: "Hopefully … other people will benefit from having a few sessions with a professional" (362)
Intervention 3	Protecting family: "I realised that I hadn't talked to people about the whole issue of MS [transition] … I was trying not to let it affect my family and friends" (82)	-	-	Purpose and being valued: "I like helping people, and I felt like I was involved in something again … I've enjoyed being able to do something that I felt has a value and that I was valued." (192)
Intervention 4	Protecting family: "With family and friends you put on a brave face, … you're really struggling but because you don't want to upset them" (54)	Time with professionals and being dismissed: "I eventually got to see my consultant, and you don't have a lot of time to talk [about transition]" (28) "Just getting shoved out of the door like 'There you are now go and get on with it'" (228)	Impartiality and reliability: "It's nice to talk to somebody who isn't in the situation … you can just say things to that you wouldn't normally" (48) "Nice knowing that once a week for half an hour you've got someone's ear to bend" (76)	-
Control 1	Support available: "I've got some good friends who if I wanted to talk to them about any problems that I was feeling of facing then I could talk to them" (81)	Frustration and feeling selfish: "I understand how busy the NHS is … but from a selfish point of view leaving a message when you really need to speak to somebody is a little frustrating" (64)	Not needed: "I have got access to … counselling and mentoring if I need it. I never use it, ever" (133)	Benefiting others selflessly: "I just wanted to help … so it's no skin off my nose to do that" (74) "Somebody would benefit from my profile and disease journey" (139)
Control 2	-	-	-	[Interviewer: You took part to help?] "That's right, yeah" (34)

Note. Dashes represent no appropriate quotation. Parentheses represent line numbers.

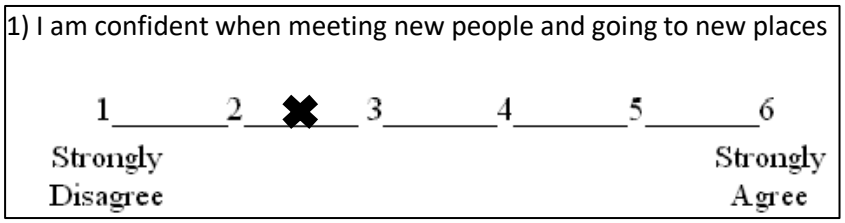
2: Data Collection Procedures and Outcome Measures

Completion Rates and Errors.

At baseline (T^0), eight-week (T^1) and 12-week (T^2) follow-up, all 13 participants returned their postal measures and one returned their online measures; a 100% assessment completion rate. The questionnaires were generally well tolerated, with 100% of HADS, MSIS and EQ-5D-5L questionnaires completed and 41 of 42 (98%) CompACT questionnaires completed (with one pack returned by a participant with the CompACT unfilled). However, the MSSE was frequently completed incorrectly, due to the questionnaire having an unclear layout, which meant that only 31 of 42 (74%) were interpretable (See Figure 2). At eight-week and 12-week follow up, one of 14 (7.14%) and six of 14 participants (42.86%) received a prompt reminding them to complete their questionnaires, respectively. All measures were completed between September 2019 and February 2020.

Figure 2

Common error on the MSSE due to its layout resulting in uninterpretable result (i.e. 2.5)



Acceptability of Questionnaires and Letter-based Outcome Measures.

Five of six participants found the postal system acceptable, and the questionnaires straightforward to complete. However, one participant felt his concerns regarding text size of the questionnaires were ignored (Table 6).

Table 6

The acceptability of the processes in completing the measures in the trial

	Themes	
Participant	Questionnaires	Postal System
Intervention 1	Easy to complete after practice: "Well I found them quite easy. You just got used to doing them in the end … It weren't confusing, it was just me, it just took me a few sessions to get it right kind of thing" (121)	-
Intervention 2	Honest reflection of experience after therapy, but missed measuring during therapy: "He sent me the questionnaires when I was starting to feel quite down about things again, and I thought no I've got to be honest and say no I'm not feeling good" (275). This was due to timing: "It would have been nice to be more positive. To say how much I benefitted from it at the time" (405) … "I could have done a questionnaire right at the end or after session 5 and then I could have said how much better I was feeling and then he would have known" (414)	"Like I say, it wasn't a problem at all" (309)
Intervention 3	Found advice on using first instinct helpful: "Well it did advise don't think about it too much, just put down what you first think, so I did that! I thought that was very good guidance" (155)	"Absolutely fine, yep" (159)
Intervention 4	Of the questionnaires; "they're straightforward" (166)	-
Control 1	Unspecified questionnaires were frustrating: "It's very frustrating to answer because it just doesn't make sense" (29). Typeface size and responsiveness to needs: "Reading very small type is really quite difficult for me. I put it on the first sheet that I sent, I said "please could	-

	you increase the font size of the type face for me?", and it wasn't done and I got all of the questionnaires in exactly the same size … that was annoying (36)" … "I've asked for it to be made larger so I can read it and they've just completely ignored me" (50)	
Control 2	"Well it was alright. I just filled in or spoke when I needed to …" The questionnaires were: "Easy enough. … it was simple (19)".	"It was simple" (25)

Note. Dashes represent no appropriate quotation. Parentheses represent line numbers.

3: Acceptability and Suitability of Intervention and Study Procedures

Attrition.

All participants completed the study.

Face-to-face Meetings and Support Calls.

Overall, all participants received one face-to-face meeting, and all in the intervention group received five support calls. Of the 14 face-to-face meetings, none were rearranged. Of the 30 support calls, four were rearranged (13%) for the following reasons: participant too busy (3), hospital appointment (1). All three participants asked agreed to have one of their support calls recorded to assess fidelity. Face-to-face meetings were scheduled for 30 minutes each. All meetings followed this time approximately. The average length of support call was 32 minutes (*SD* = 5 minutes). The average length of time a participant took to complete the six-week intervention was 6.65 weeks (range = 5.29-8.14 weeks) (*SD* = 0.96 weeks). All sessions happened between September 2019 and February 2020.

Qualitative Outcomes.

The first eight participants (four from each group) who completed the study were asked to participate in feedback interviews. Of these, six participants accepted (four in intervention group, two in control group), with an average length of 23.62 minutes (*SD* = 15.15). The intervention group interviews (*M* = 29.85, *SD* = 11.12) were longer than the control group interviews (*M* = 11.12, *SD* = 9.03).

Workbook Readability.

A sample (6.25%, 3 pages [Page 2, 22, 42]), of the 48-page workbook was assessed for readability. A *Readability Consensus* was generated which combines seven readability formulae[26]. This judged the text to be 'fairly easy to read', requiring a reading age of 12-14 years.

Accessibility.

Participants found the telephone calls and completing measures convenient, and some preferred being able to receive support over the telephone rather than needing to attend a clinic (Table 7).

Table 7

The accessibility of the trial for participants

	Theme
Participant	Accessibility
Intervention 1	"[Therapy] was quite easy because it was over the telephone" (35) "no trouble whatsoever" (43)
Intervention 2	"Instead of me having to go to a clinic or a hospital or whatever, that it was just half an hour on the phone. It wasn't an hour out of the day … it was easier" (63) "[Telephone calls are] less tiring and more convenient" (72)
Intervention 3	-
Intervention 4	-

[26] See Appendix J for the readability consensus

Control 1	Abundance of time: "I've got lots of time on my hands because I'm unable to work, so I'm very happy to help out and spend some of my time filling out forms … it's no problem" (92)
Control 2	"[The trial was] easy. I didn't have to do anything" (13) "All I've had to do is fill out the questionnaires" (45)

Note. Dashes represent no appropriate quotation. Parentheses represent line numbers.

Randomisation.

Randomisation was easy to perform and resulted in even groupings. Participants understood the randomisation process and found it acceptable (Table 8).

Table 8

The experiences of randomisation from those in the control condition

	Theme
Participant	Randomisation
Control 1	"It was fine, I understood [why I was in the control]… I'm quite a strong-minded kind of chap" (55) "I was told that some would and some wouldn't [be in the therapy group]" (72)
Control 2	"I don't really mind [being put into the control], I know you're only here to help" (31)

Note. Parentheses represent line numbers.

Telephone Sessions and the Workbook.

Telephone sessions were found to be generally acceptable in their structure, but two of four participants mentioned they would have preferred longer sessions. The workbook was acceptable and used by all participants, however one participant struggled to engage in homework (Table 9).

Table 9

Participant experience of the ABS telephone sessions and workbook

	Themes	
Participant	Telephone Sessions	The Workbook
Intervention 1	"It was nice that [support calls] had got a set time, I made myself sit down" (59) "[Session duration] was fine" (82) "[Session frequency] was alright" (67)	"In MS your attention span is crap. So sometimes I had to put [the workbook] aside, leave it a few days and then come back to it" (88) "I did [the workbook] in my own time which I did like" (91) "I always kept [the workbook] at my side somewhere I could easily reach it" (102)
Intervention 2	"[Support calls] were mentally tiring" (78) "[Support calls] were just right; I just wish that they'd been a bit longer. Say a 12-week course. I just think 6 is a bit too short" (141) "An hour a week for 6 weeks, that would be better. Half an hour seems quite short" (153) "Maybe you could run the [support] as a group session … to spread the money a bit further" (161)	"Well it was absolutely fine for me … I said "I'm very sorry [researcher] but I've actually read the whole booklet because I was interested" (202) "Filling in things that we were going to talk about … then it's in front of you for the next time" (204) "I felt that the topics that were in the booklet were very relevant" (229)
Intervention 3	"[Length of support calls] is actually the right amount. Any shorter might of felt rushed, and any longer isn't really practical" (117) "[Session frequency] is about right" (110)	"I can say I wasn't entirely happy with [the coping strategies section], it was worded as if someone was newly diagnosed" (26) "It was good to work through the workbook … I did find some of it very very helpful" (31) "I sort of mentally refer to [the workbook] and think about the exercises" (90)

Intervention 4	"Possibly a little bit longer might have been nice … you're watching the clock thinking 'My time's nearly up'" (113) "You can sometimes feel more free [over the telephone] to be a bit more honest because you're not actually face to face" (132)	"It was alright. I sometimes struggled to do [workbook homework] to be honest. With [acute unrelated physical health problem] it was a bit hard to find time to do it and to be in the right head space to do it" (141) "It's a bit like being back at school, like you feel guilty that you haven't done [homework]" (152)

Note. Parentheses represent line numbers.

4: Ability to Manage and Implement the Study and Intervention

The research team was kept abreast of study developments via newsletter by the Trial Manager[27]. No adverse events were reported. The study carried a recruitment, therapeutic and administrative burden, and this was managed primarily by the Trial Manager. One full day per week was dedicated for seven months, from the beginning of recruitment to the final measure collected (approximately 28 eight-hour days).

5: Participant Responses to Intervention

Fidelity.

A sample (7.14%, three telephone calls) of the 42 telephone calls were assessed. All sample calls were judged to be ACT consistent[28].

Signal of Efficacy.

Quantitative Outcomes.

None of the pairwise comparisons between groups were statistically significant in this small sample (Table 10). Within groups, a significant improvement was found in anxiety in the control group between T^0 and T^2, and no other significant effects were found (Table 11).

Table 10

Mixed ANOVA with interaction effects (T^0 is baseline, T^1 is 8-week follow-up, T^2 is 12-week follow-up)

Measure	T^0		T^1		T^2		F value (*p*)
	UC	ABS+UC	UC	ABS+UC	UC	ABS+UC	
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	
HADS-A	13 (5.77)	8.6 (5.80)	12.29 (5.65)	8.57 (4.69)	10.00 (5.51)	9.43 (4.79)	3.21 (0.10)
HADS-D	10 (3.65)	8.86 (5.12)	10.29 (4.46)	8.86 (3.80)	9.00 (5.54)	8.43 (3.78)	0.12 (0.89)
MSIS	102.29 (21.24)	107.85 (17.70)	104.43 (20.46)	107.29 (19.20)	100.43 (16.98)	105.00 (17.25)	0.41 (0.54)
MSSE[a]	35.67 (16.26)	36.33 (9.87)	34.00 (15.52)	35.00 (6.00)	36.00 (15.87)	37.33 (5.51)	0.01 (0.93)
EQ-5D-5L	51.00 (25.99)	52.86 (26.43)	36.43 (26.41)	41.43 (19.73)	43.71 (23.31)	43.86 (22.45)	0.10 (0.75)
CompACT OE	24.57 (8.56)	27.71 (10.21)	24.86 (6.07)	28.14 (8.36)	30.83 (15.84)	29.00 (10.38)	0.31 (0.59)

[27] See Appendix K for an example monthly newsletter

[28] See Appendix L for the evaluation of the telephone calls against fidelity criteria

BA	9.43 (4.43)	10.00 (4.55)	10.29 (4.96)	8.00 (3.70)	14.50 (8.12)	13.14 (6.69)	0.49 (0.50)
VA	31.42 (6.78)	34.14 (5.90)	30.14 (8.59)	33.00 (7.53)	31.17 (8.50)	31.43 (6.90)	0.78 (0.40)
Total	65.43 (15.63)	72.00 (12.38)	65.29 (69.14)	69.14 (13.72)	76.50 (28.63)	73.57 (10.32)	0.36 (0.56)

Note. HADS-A: Hospital Anxiety and Depression Scale Anxiety, HADS-D: Hospital Anxiety and Depression Scale Depression, MSIS: Multiple Sclerosis Impact Scale, MSSE: Multiple Sclerosis Self Efficacy Scale, EQ-5D-5L: EuroQol Quality of Life – Visual Analogue Scale, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy, OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care, [a]: *n* = 3.

Table 11

Effect sizes with p values for the two groups

Measure	ABS+UC				UC			
	$T^0 - T^1$		$T^0 - T^2$		$T^0 - T^1$		$T^0 - T^2$	
	Effect size (95% CI)	*p*	Effect size (95% CI)	*p*	Effect size (95% CI)	*p*	Effect size (95% CI)	*p*
HADS-A	0.00 (-1.60, 1.60)	1.000	-0.54 (-2.17, 1.09)	0.518	0.47 (-1.15, 2.10)	0.573	1.91 (-0.03, 3.83)	**0.038**
HADS-D	0.00 (-1.60, 1.60)	1.000	0.24 (-1.37, 1.84)	0.514	-0.18 (-1.80, 1.42)	0.823	0.55 (-1.08, 2.18)	0.514
MSIS	0.11 (-1.49, 1.71)	0.894	0.46 (-1.17, 2.08)	0.587	-0.41 (-2.03, 1.20)	0.619	0.30 (-1.31, 1.91)	0.723
MSSE[a]	0.41 (-2.39-3.21)	0.785	-0.66 (-3.51, 2.18)	0.664	0.52 (-2.30, 3.33)	0.734	-0.33 (-4.53, 3.87)	0.883
EQ-5D-5L	1.07 (-0.64, 2.78)	0.215	0.96 (-0.73, 2.66)	0.260	1.36 (-0.42, 3.14)	0.121	0.78 (-0.88, 2.44)	0.358
CompACT								
OE	-0.10 (-1.70, 1.51)	0.909	-0.18 (-1.79, 1.42)	0.826	0.10 (-1.50, 1.71)	0.902	-0.70 (-2.36, 0.94)	0.406
BA	1.08 (-0.63, 2.80)	0.212	-1.02 (-2.72, 0.68)	0.238	-0.67 (-2.31, 0.98)	0.431	-1.45 (-3.25, 0.35)	0.103
VA	0.40 (-1.21, 2.02)	0.631	1.01 (-0.69, 2.71)	0.240	0.71 (-0.94, 2.36)	0.404	0.06 (-1.54, 1.66)	0.945
Total	0.42 (-1.20, 2.04)	0.615	0.14 (-1.46, 1.74)	0.867	0.18 (-1.42, 1.79)	0.827	-0.82 (-2.49, 0.84)	0.335

Note. T^0: baseline, T^1: 8-week follow-up, T^2: 12-week follow-up. Effect sizes with a negative (-) sign are in the direction of deterioration. p values in bold denote significance at $p < 0.05$. HADS-A: Hospital Anxiety and Depression Scale Anxiety, HADS-D: Hospital Anxiety and Depression Scale Depression, MSIS: Multiple Sclerosis Impact Scale, MSSE: Multiple Sclerosis Self Efficacy Scale, EQ-5D-5L: EuroQol Quality of Life – Visual Analogue Scale, CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy, OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care, [a]: *n* = 3.

Clinically significant individual level changes in anxiety, depression and psychological flexibility were uncommon; a minority of participants demonstrated reliable change across the clinical threshold in both groups, however the majority made no reliable and clinical change at eight and 12 weeks (Table 12).

Table 12

Number of participants showing reliable improvement or deterioration compared to Baseline (T^0)

Measure	T^1						T^2					
	UC			ABS+UC			UC			ABS+UC		
	↑	↓	↔	↑	↓	↔	↑	↓	↔	↑	↓	↔
HADS-A	1	0	6	0	0	7	1	0	6	0	1	6
HADS-D	0	1	6	0	0	7	2 *(1)*	1	4	1 *(1)*	1	5
CompACT^T	0	2	5	1 *(1)*	2	4	3 *(2)*	1	3	1 *(1)*	0	6

Note. HADS-A: Hospital Anxiety and Depression Scale Anxiety, HADS-D: Hospital Anxiety and Depression Scale Depression, CompACT^T: Comprehensive Assessment of Acceptance and Commitment Therapy Total, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care, ↑: Improvement, ↓: Deterioration, ↔ : No change, Parentheses: number crossing clinical threshold

Sample Size Estimation.

Fifty-four participants (*n* = 53.76) would be required to have a 95% confidence of detecting, as significant at the 5% level, a decrease of 5 points on the HADS (*SD* = 9.54, *SE* = 2.55), and a decrease of 16 points on the CompACT (*n* = 54.10, *SD* = 14.00, *SE* = 3.73). Therefore, in a two-armed RCT, the sample size would need to be 108. This assumes attrition levels will be the same as in this trial (i.e. 0%).

Qualitative Outcomes.

The control group reported no changes in mood or quality of life. In the intervention group, the mood of two of the participants had improved, one had remained the same, and one felt better initially but got worse later. In terms of quality of life, two participants reported feeling much better, one slightly better, and one initially better, but now worse (Table 13).

Table 13

Participant feedback on mood and quality of life

	Themes	
Participant	Mood	Quality of Life
Intervention 1	"[Mood is] About the same" (145)	"[Quality of life is] About the same, going on to better" (135)
Intervention 2	"I did feel so much better during those six weeks … My mood was better, I felt less depressed" (108) "I had started to feel so much better and so much more positive, and I suddenly found myself sliding back" (279)	"Well I suppose, to be honest, it's [quality of life] worse … but while I was doing it it was so much better. So it's a disappointment" (316)
Intervention 3	"I'm actually in a better place than I was before, feeling happier and coping better" (20) "I would say my day-to-day moods are much better" (179)	"A lot better. A lot better. It really has had a very beneficial effect on me" (162)
Intervention 4	"I'm a little bit happier in myself, so that's always a good sign" (171) "I used to sometimes get a bit upset if I was telling someone I'm secondary progressive – I don't anymore" (195)	"It's better, definitely" (169)
Control 1	"[Mood is] About the same" (88)	"[Quality of life is] About the same" (85)
Control 2	"[Mood is] About the same" (76)	"[Quality of life is] About the same" (73)

Note. Parentheses represent line numbers.

Three of four intervention group participants mentioned the process of becoming more mindful or present, with two mentioning following their values and an increase in focus on things that are important. Two specifically mentioned a values-focussed metaphor from the workbook[29]. Three of four intervention group participants reported change in their coping strategies and mindset. Two spoke about having a more positive and values-based mindset. One spoke of the difficulty of changing entrenched ways of coping, but that moving towards acceptance has been a helpful change. All participants described the intervention in positive terms as beneficial, with one participant describing it as a lifeline, and another stating that the work should be replicated (Table 14).

Table 14

Participant feedback on psychological flexibility, mindset and coping, and experience of the intervention

	Themes		
Participant	Psychological Flexibility and ACT Processes	Mindset and Coping	Intervention Experience
Intervention 1	-	-	"[Therapy] was beneficial for myself, it really was" (176) "I did enjoy [therapy]" (148)
Intervention 2	"You … have your moment of panic and then you go 'No, let's think about this rationally, let's think about what [therapist] said'" (260) "That's another of my values that I'm letting go … thinking 'Gosh, I hadn't realised that's what I'd done'" (86) "I loved the [ACT metaphor] with the boat, like I said to you, and I thought 'God I've thrown everyone off me boat!'" (225)	"I felt as if a weight had been lifted off my mind actually. And I felt more positive about the future" (130)	"Well I hope you do do this work again in the future because I know what a benefit it did for me" (21) "I really enjoyed it actually … I found it a very positive experience" (33)
Intervention 3	"[I learnt to] focus on being in the moment a lot more and I now use it a lot more for my day-to-day life" (50) "The mindfulness made me realise that I could actually build that into my day" (59) "I was so busy managing my health that I wasn't actually looking to the future, I wasn't sailing my boat [ACT metaphor], I was bailing" (40) "It made me realise what I really want to do, which is to help my family and friends and be there for them" (111)	"It's really moved me forward … in terms of acceptance (60) "I thought I was quite good at letting things go … [the] process helped me to let go more effectively" (79) "I've developed my coping strategies" (179) "It made me look towards the future and what I wanted, and what my values were, and where I wanted to head" (108)	"Everything has been beneficial" (180)

[29] See Appendix M for the boat metaphor in the workbook

Intervention 4	"It made you stop and think … [not] just sort of going with the flow" (36) "I do try to be little bit more mindful … taking a step back" (88)	"It really helped me come to terms with it, and to get some ways in which to manage how I was feeling" (22) "I think it made things a bit easier to manage. I wouldn't say cope, but manage how you're feeling" (40) "[Change is] not easy because it's breaking long instilled habits" (95) "It's just a case of being a kick-ass MS warrior really and getting on with it" (199)	"I found [therapy] incredibly helpful" (48) "[Therapy was a] little lifeline in amongst all the other rubbish that's going off" (85)

Note. Dashes represent no appropriate quotation. Parentheses represent line numbers.

Discussion

This is the first study to assess the feasibility of delivering an ACT-based telephone support intervention to those transitioning to SPMS. We have used the Avery et al. (2017) traffic light system for pilot trials to structure this discussion, and applied this method to the Orsmond and Cohn (2015) feasibility framework: green (go), amber (i.e. yellow; amend), and red (stop). Based on these criteria, we conclude that significant changes to the recruitment strategy and the intervention are required and that currently this is not a feasible trial. Based on the results of efficacy, and the small sample, it would be premature to conclude that the use of the ACT-based telephone supported bibliotherapy is not effective based solely on these self-report outcomes, but the intervention was not supported here. The data collection procedures, acceptability of the intervention (workbook, telephone calls) and the ability of the Trial Manager to manage the trial all worked well and we recommend that these elements are retained in future trials with SPMS patients.

ACT-based interventions primarily aim to target psychological flexibility, and the intervention group failed to demonstrate a significant improvement in psychological flexibility in this trial. However, participants in the intervention group spoke positively about the intervention and the process in broad terms. It may be that the intervention was beneficial in a social sense and gave a feeling of being supported during the trial but did not demonstrate efficacy on impacting clinical change. It may be tempting to conclude that an ACT based intervention is not suitable in SPMS, but we would argue that the results would refute the ACT model more if psychological flexibility did change in the absence of corresponding change on other measurements of wellbeing (such as distress, or quality of life). What we can say is that this novel intervention will need to be re-evaluated to ensure that psychological flexibility is successfully targeted, as it has demonstrated no effect which does not fit with the majority of the evidence base for ACT-based bibliotherapy interventions (French et al., 2017) or teletherapy in MS (Proctor, Moghaddam, Vogt, et al., 2018).

Feasibility

1: Recruitment Capability and Resulting Sample Characteristics.

Rating: Amber.

This intervention was attractive to those with SPMS. Around half of those deemed eligible enrolled in the study, but the recruitment strategy was not feasible and should be reconsidered for any future trial. The neurology service ran several MS clinics each week, but attending a clinic took four hours and proved to be an inefficient way of meeting participants as the vast majority (>95%) were unsuitable for the study. The Trial Manager needed to attend the service, as despite prompting,

neurologists rarely made referrals when the Trial Manager was not on the premises. This may have been due to the busy nature of the service. Several alternative research studies were also running concurrently, and neurologists may have been unable to hold each study in mind. Unclear computer records and letters on when patients were transitioning to SPMS made targeting suitable participants difficult. Only 27 potentially eligible participants were identified, far below the 40 needed. As 48% of those eligible were recruited, 82 eligible participants will need to be identified in a future study to achieve the 40-participant sample.

In terms of age, gender and clinical data, the two groups in the sample were well matched and representative of the wider client group. As all participants were White British, they may not be representative of Black and Minority Ethnic (BAME) populations. The sample for the feedback interviews may not have been representative in the control group, as those who provided feedback were both male and showed the least distress on baseline measures[30].

A future study, using the same methodology in a single neurology clinic would achieve an estimated recruitment rate of three-to-four participants a month. To increase the rate of recruitment, the one year criterion of time since transition could be relaxed instead to three years to allow for the inherent uncertainty around transition, which lasts an average of three years (Katz Sand et al., 2014).[31]

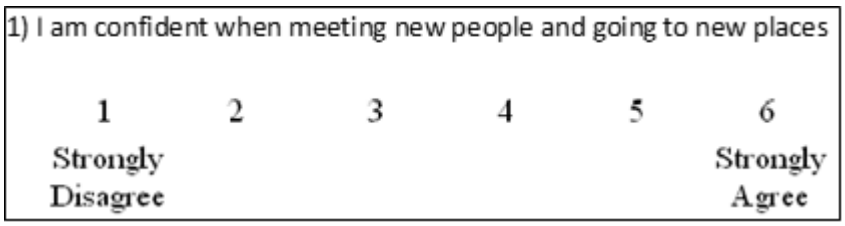
2: Data Collection Procedures and Measures.

Rating: Green.

Data collection procedures were very successful[32]. However, the measure of self-efficacy needs to be displayed more clearly to avoid uninterpretable data. Rigby et al. (2003) did not include a formatted participant-ready questionnaire, and a flawed version was used during this trial. A future trial should remove the lines on the Likert scale, and ask participants to '… please circle a number to indicate your level of agreement or disagreement …' rather than 'tick' (Figure 3). Ensuring that all measures are of an appropriate text size and being responsive to visual needs are additional areas for improvement.

Figure 3

Improved version of the Multiple Sclerosis Self Efficacy scale



3: Acceptability and Suitability of Intervention and Study Procedures.

Rating: Green.

The suitability of the intervention and procedures were a success, with all participants completing the intervention and the providing positive feedback. Participants understood the workbook contents, and preferred the sessions being over the telephone to attending a clinic. Randomisation procedures were acceptable, although the small male sample with low baseline distress may not

[30] See Extended Discussion 4.1.1 for addition discussion on the sample
[31] See Extended Discussion 4.2 for additional detail about recruitment and recommendations
[32] See Extended Discussion 4.3 for additional detail about data collection procedures

have been completely representative of the control group. Changes could be made to the length or number of sessions, as some participants wanted a higher intensity of therapy. This would have disadvantages however, as it would mean a greater time burden for the trial and may impact on the ability to manage the study[33].

4: Ability to Manage and Implement the Study and Intervention.

Rating: Green.

The study carried a recruitment, therapeutic and administrative burden, managed successfully by the Trial Manager working one full day a week with no reported adverse events. Recruiting at a higher rate would require an equivalent increase in time resource to avoid the study becoming unmanageable[34].

5: Participant Responses to Intervention.

Rating: Red.

A lack of difference in pairwise comparisons between and within groups on measures means that the efficacy of the intervention has not been demonstrated in this small sample, with the only significant effect being a reduction in anxiety in the control group. In addition, on individual level analyses, few participants showed reliable clinical improvements from baseline, with only one participant showing reliable clinical improvement in the intervention group at both T^1 and T^2, compared with zero (T^1) and two (T^2) in the control group.

The intervention group participants, although only a small sample of four, spoke positively about their experience at interview, with specific mentions of improvements in ACT-specific concepts of mindfulness, acceptance, and values. This should have been captured on the CompACT measure but was not. As the interview feedback was not corroborated by improvements in measures, we hypothesised this may have been related to demand characteristics. However, participants did mention some benefits not captured on the selected measures, such as being able to talk to someone impartial and reliable, or changes in outlook and coping. A future trial could measure changes in loneliness or coping in self-report measures validated for use in MS populations (e.g. Pakenham, 2001; Russell et al., 1980). Changes to the intervention are needed to ensure psychological flexibility is targeted before progression to a future trial.[35]

Strengths and Limitations

Strengths.

Our use of a mixed methodology to allow us to conduct both statistical and framework analysis was a strength. The framework analysis component was rigorous, as an individual independent from the study team, but trained in semi-structured interviewing was used to conduct the interviews. The early stages of framework analysis were completed jointly to mitigate for any researchers' personal biases, and the latter stages reviewed by two other members of the team (NM, RdN). This resulted in rich feedback and reduced the likelihood of three types of bias: social desirability bias on the part of the participant, confirmation bias and leading questions bias on the part of the researcher. This structure generated criticism on some aspects of the study, which adds credibility to the positive feedback for some other elements.

Further strengths included ensuring there was an assessment for fidelity to the intervention using recorded sessions analysed by a different member of the study team, and analysis of the readability

[33] See Extended Discussion 4.4 for further discussion of the trial procedures
[34] See Extended Discussion 4.5 for further discussion on management of the study
[35] See Extended Discussion 4.6 for further discussion on participant response to intervention

of the self-help material as confusing language has been a criticism of similar ACT workbooks in previous studies. No attrition is also a strength.[36]

Limitations.

The main limitation of this study was the failure of the recruitment strategy which led to a far smaller sample than we expected to achieve. An assumption was made early in the research that we would be able to recruit quickly based on clinic size and number of SPMS patients being seen by the clinic. However, locating suitable participants quickly presented a challenge, due to the use of strict recruitment criteria and an inefficient recruitment strategy. A second limitation is that the intervention failed to demonstrate efficacy, and revisions to the delivery of the intervention will need to be made. Lastly, as the quantitative and descriptive data was collected and analysed by the Trial Manager (with supervision and oversight), this may have lent itself to positive researcher bias.[37]

Conclusions

A future trial with those transitioning to SPMS using a similar ACT-based telephone support bibliotherapy intervention and this methodology is not feasible, due to an unsuccessful recruitment strategy and low signal of efficacy. Data collection and trial procedures were successful. A more efficient recruitment strategy, or longer recruitment period is needed to recruit a large enough sample. Adapting the intervention is also needed to ensure that it targets ACT-processes, and this could include changing the workbook or delivery of sessions.

Disclosures

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[36] See Extended Discussion 4.8 for further discussion around strengths

[37] See Extended Discussion 4.9 for further discussion around limitations

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Extended Paper

1. Extended Introduction

In the extended introduction the disease course of MS and Secondary Progressive MS are discussed, along with the transition between RRMS and SPMS. An examination of the difficulties associated with this transition is considered, including an overview of different strategies of coping with the transition. The use of psychological therapy in MS is reviewed, and an overview of Acceptance and Commitment Therapy, Teletherapy, Bibliotherapy, and feasibility Randomised Controlled Trials are provided. Finally, a questionnaire study completed in tandem to the feasibility trial which may provide additional justification for use of ACT in SPMS is introduced.

1.1 What is Multiple Sclerosis

Multiple sclerosis is an inflammatory disease of the central nervous system and is characterised by demyelination and axonal degeneration. It typically first presents in young adults and occurs around twice as often in women. The short paper lists some of the most common symptoms, and additional symptoms not referenced are heat sensitivity and Lhermitte's sign (electrical sensation down the spine). Some early signs may include tremors, decreased perceptions of pain or vibration, decreased strength and impaired coordination. Many common symptoms of MS are invisible. A lack of public and clinical awareness of MS can contribute to people feeling misunderstood and invalidated by others if symptoms are not obvious and visible (Parker et al., 2020).

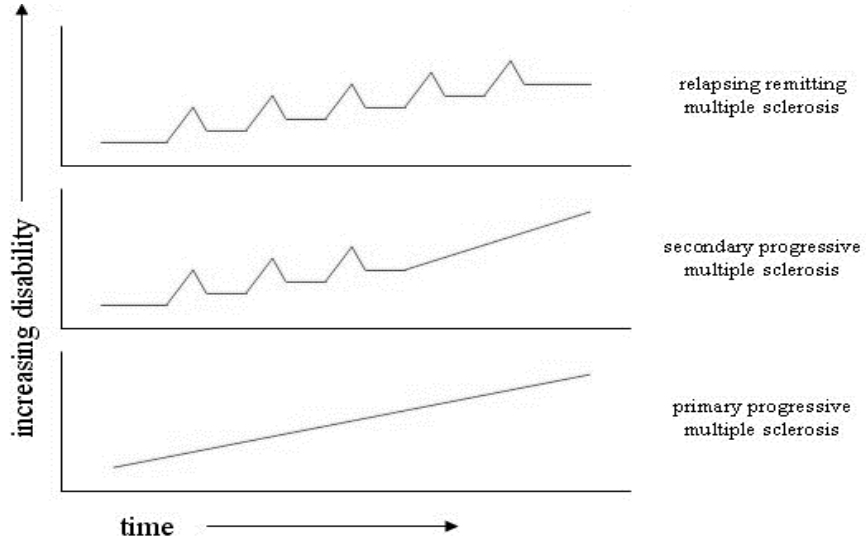
MS is frequently overlooked in the early stages as symptoms often appear and then resolve, with sometimes long gaps between symptoms. Once patients do present to services, they are diagnosed through the identification of lesions on the central nervous system (more than once, which occur at least 3 months apart) (Calabresi, 2004).

1.1.2 Disease Course and Subtypes of Multiple Sclerosis

When a patient shows characteristics of inflammatory demyelination for the first time, they are referred as having a clinically isolated syndrome (CIS), as MS criteria stipulate the dissemination of demyelination over time. If there are further clinical relapses followed by periods of remission, then a diagnosis of Relapsing Remitting MS (RRMS) is given, and if disease progression happens gradually without a relapsing remitting course, then a diagnosis of primary progressive MS (PPMS) is given. The diagnosis of SPMS is usually made retrospectively following a gradual worsening of symptoms after an initial relapsing course and signifies the start of a progressive disease course. There is no clear clinical or biological criteria which determines the point of transition to SPMS, and this transition is usually gradual (Lublin et al., 2014). Figure 4 shows the disease trajectory for MS subtypes.

Figure 4

MS disease courses and their degree of disability over time



1.1.3 Transitioning from RRMS to SPMS.

Difficulties transitioning from RRMS to SPMS have become better understood in recent years (Bogosian et al., 2017; Davies et al., 2015; O'Loughlin et al., 2017). The short paper describes some of the distress and uncertainty which can surround this experience. The diagnosis for some can come as a shock, but this is not the same for everyone. Bogosian et al. (2019) found that for most of those with SPMS transition was expected, but that it was also a difficult time which elicited feelings of helplessness.

Patients' experiences of transition are variable but common themes emerge from the literature. One of these is the role of services in supporting the transition. Currently, neurology services are not as available as patients want them to be, with patients and their care providers wanting greater support around new developments for treatment and education in MS (Falet et al., 2019). Patients also have concerns around the transparency of services, not helping them to understand what the transition to SPMS would mean for them (Davies et al., 2015), with diagnoses often given in a way which can have a negative psychological impact without accompanying wellbeing support available (O'Loughlin et al., 2017).

1.1.4 Coping Styles During Transition.

The individual coping strategies employed during transition to SPMS varies widely (Davies et al., 2015), and the importance of maintaining healthy coping strategies is key to successful adjustment (Bassi et al., 2019). This large-sample questionnaire study found that patients' beliefs about their illness and the strategies they used were directly related to positive and negative psychological adjustment. They recommended that future psychological interventions should target not only individual health or illness related issues (e.g. depression), but instead look more broadly at bringing people's awareness to their beliefs and associated strategies, especially if these involve restricting their social support systems. This mirrors the findings of a metasynthesis of the SPMS transition literature, which recommended proactively supporting positive coping strategies and supporting social relationships as these are the key determinants of successful adjustment. Coping strategies which were identified as related to better adjustment were those which emphasised *acceptance* of the situation, and making appropriate *adaptations* to continue to keep active (Meek et al., 2020).

1.2 Psychological Therapy in MS

NICE guidelines do not currently recommend any one specific psychological therapy for use in MS, however they do recommend the use of a coordinated multidisciplinary response, including psychological input (NICE, 2014). Thomas et al. (2006) reviewed the use of psychological interventions in MS, and found at this time that evidence was too weak to recommend a specific approach, but the strongest evidence was for use of CBT to target depression in MS (Mohr et al., 2001).

1.3 Acceptance and Commitment Therapy

This section provides an overview of the theoretical underpinnings of Acceptance and Commitment Therapy (ACT) and why it may be a suitable intervention for this population.

1.3.1 ACT Explained.

To summarise, ACT is a mindfulness based behavioural therapy in the "third wave" of behavioural therapies. It differs from the "second wave" therapies (i.e. CBT), through its focus on aspiring towards living a rich, full and meaningful life, rather than achieving a reduction in distress. It differs from alternative "third wave" approaches such as dialectical behaviour therapy (DBT) and mindfulness based cognitive therapy (MBCT) as it is neither designed for specific populations nor a manualised treatment protocol. It focusses on accepting or making room for thoughts (positive, neutral or negative) without trying to change them, whilst always trying to take actions which move a person towards the things they value. ACT emphasises the role of experiential avoidance (the struggle to avoid distressing thoughts and feelings) in the maintenance of distress (Hayes, 2016).

1.3.2 ACT Theory.

ACT has been described as sitting at the top of a three-story mansion, with relational frame theory (RFT), applied behavioural analysis and functional contextualism as the foundations holding it up on each descending floor underneath. Exploring these concepts fully is beyond the scope of this piece, but RFT and functional contextualism will be briefly summarised below.

ACT is a behavioural therapy, and it has its underpinnings in RFT, a behavioural account of human cognition and language (Hayes et al., 2001). RFT argues that the foundations of higher cognition and language among humans is relating, and the ability to create bi-directional links between stimuli. It posits that natural human language allows us to specify the strength of links between stimuli, the type of relationship and the dimension along which the relation is made. These relations are referred to as relational frames and can refer to a myriad of abstract comparisons that can be learned, independently of direct experience, based on arbitrary contextual cues. Together, these relational frames form cognitive networks, and account for how humans derive complex explanations for the features of the world and how it works. It can explain how humans connect things which can have no physical relation to one another, and never appear together in time and place. It therefore helps to account for why a given thought may trigger a thought about something else unrelated (for example, a thought about how sweet your spouse is may remind you of a past relationship which ended in a deep betrayal, connecting your spousal relationships through an "is opposite to" relational frame and leading to distressing thoughts about your current partners trustworthiness). Hayes argues that this has implications for therapy.

Traditional cognitive ideas (used in CBT) strive to unravel and reconstruct these dense networks of relationships in the brain, but RFT would interpret this as like trying to rearrange a vast spiders web, a futile task. RFT, and its therapeutic consequence in ACT, posit that attempts to change and control these relationships essentially leaves the person with an internal struggle, which keeps them stuck fighting their thoughts, and distracts them from living a rich, full and meaningful life (Hayes, 2019).

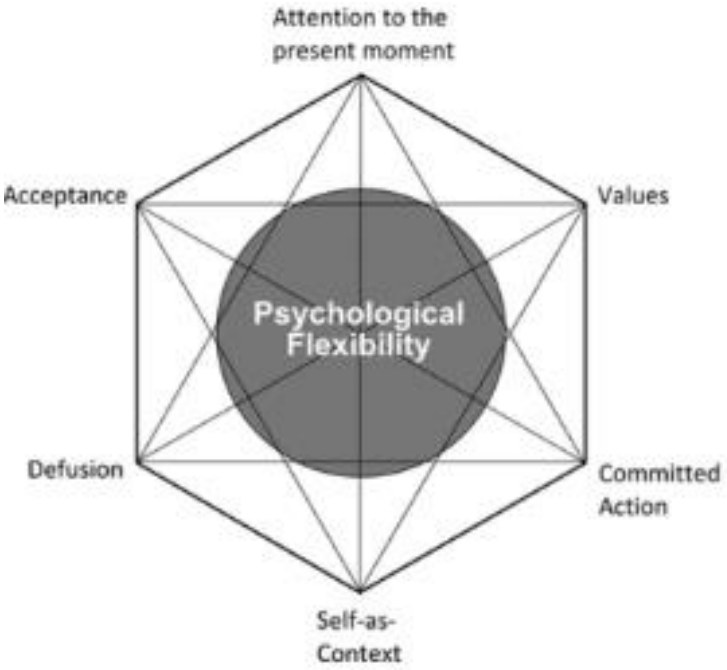
In a philosophical sense, functional contextualism is the idea that everything is context dependent, and that therefore no object, thought, or feeling is inherently problematic or dysfunctional. An example is a chair with three legs – it may be described as "faulty" or "broken", but this is only because of the context. In a comedy sketch or a practical joke, a three-legged chair might entirely serve its purpose (Harris, 2009). In applying this in therapeutic terms, thoughts and feelings may appear but elicit great discomfort in a context only where the person struggles with and attempts to avoid feeling them. In a separate context (e.g. a context of acceptance in ACT), these thoughts and feelings may function very differently.

1.3.3 ACT Processes.

The ACT model aims to target six core processes; attention to the present moment, values, committed action, self-as-context, defusion, and acceptance. In ACT terms, these processes form the Hexaflex (See Figure 5) and together are the key to improving psychological flexibility; the ability to engage in the present moment, avoid being swept along by thoughts, and make decisions which are in line with the person's values.

Figure 5

The Hexaflex model as used in ACT (Harris, 2009)



1.3.4 ACT Evidence Base.

ACT therapy research is still in its infancy compared to many other psychotherapies. Although the early stages of development began in the 1970s (Zettle, 2011), it is only since the turn of the millennium that books detailing the approach (e.g. Hayes et al., 2001; Hayes et al., 1999) have subsequently led to an increased clinical and research interest. Trials have been carried out to aim to determine its usefulness in numerous mental and physical health contexts.

Treatment with ACT is best evidenced in chronic pain, with a recent meta-analysis finding ACT to be effective treatment for improving patients experience of pain (g = -0.40), reducing depression (*g* = -0.52) anxiety (*g* = -0.47) , and improving quality of life (*g* = 1.14) (Kang et al., 2019). A subsequent study has found similarly positive clinically meaningful change in chronic pain intensity (*d* = 0.50) and pain interference in daily life (*d* = 1.08), and fatigue levels (*d* = 0.37) (Yu et al., 2020). An interesting

nuance in chronic pain treatment was that age seems to have a moderating effect on whether ACT is the preferred treatment of choice. Wetherell et al. (2016) found older adults responding favourably to ACT in comparison to CBT, a trend reversed in younger adults.

The current evidence base for ACT in physical health and chronic conditions other than chronic pain is in its infancy. A recent meta-analysis found that study quality and the state of the evidence is low, and ACT was not yet a well-established intervention for chronic disease or long term conditions (Graham et al., 2016). The authors concluded that there was promising data from higher quality studies to support claims of increased psychological flexibility (*d* = 0.57-0.72) and improvements in disease self-management (*d* = 0.23-0.68).

Several reviews have been conducted into the efficacy of ACT on psychiatric disorders including most commonly anxiety and depression, and generally have found ACT to be a promising and favourable approach, but not evidenced above and beyond other established psychotherapeutic approaches or active controls (A-tjak et al., 2015; Hacker et al., 2016; Swain et al., 2013; Twohig & Levin, 2017). This seems like the general state of the evidence now for common mental health conditions, when considering that there have been reviews which have been both more favourable, and critical of the ACT approach.

A favourable review (Ruiz, 2012) stated that acceptance-based protocols are usually more effective than control based protocols, and that in a review of ACT versus CBT, mean effect sizes favoured ACT (*g* = 0.40). A more critical review by Öst (2014) concluded that current studies were prone to methodological issues, and that due to a small effect size (0.42), ACT is not well established for use in any disorder. The Öst (2014) review was however the subject of criticism that the review contained numerous errors, and that it should be set aside when considering the evidence for ACT (Atkins et al., 2017), a suggestion the original author strenuously disagreed with (Öst, 2017).

Some proponents of ACT have been criticised by others in the academic community for exaggerating efficacy and denigrating other strands of cognitive therapy in the absence of empirical support. ACT has been praised as an important therapy with interesting and novel ideas, but one which has at times been excessively promoted, despite its currently modest evidence (Kanter, 2013). In the case of the Öst (2014) review, there is a conflict between proponents of ACT and CBT. These possible vested interests distract from independent scientific rigour.

1.3.5 ACT in MS Evidence Base.

The ACT in MS evidence base is still in its infancy, and there is little evidence specifically for use of ACT in SPMS. A study which measured the efficacy of a single ACT-based workshop session found that over a three month follow up period significant improvements in areas such as depression (η_p^2 = 0.29), impact of pain on behaviour (η_p^2 = 0.37) and quality of life (η_p^2 = 0.34) were found (but not in physical symptoms or mindfulness). This study had limitations however with a small sample (*n* = 15) and no control condition (Sheppard et al., 2010). In another study which compared ACT to an active control condition (relaxation training), differences were found which reflected the processes of each model (i.e. the relaxation group reduced in anxiety, the ACT group improved in acceptance) (Nordin & Rorsman, 2012).

Further small sample and single case design studies have been conducted since. In one of these studies in Azerbaijan, 30 MS patients were recruited and assigned to either an ACT or control group, and after 10 sessions of individual therapist delivered ACT, showed improvement in acceptance and psychological flexibility (Pak & Abdi, 2017). In another, an ACT based resilience programme consisting of 8 group sessions without a control group found significant improvements in resilience

(g = .47), physical health quality of life (g = -.76) and mental health quality of life (g = -.46), depression (g = .38), stress (g = .33) and ACT processes such as defusion (g =-.54) (Pakenham et al., 2018). Finally, a case study using ACT with a woman with SPMS reported a reduction in distress to non-clinical levels and an improvement in acceptance of her MS (Gillanders & Gillanders, 2014). There is a growing evidence for the usefulness of ACT in MS, but this is less than in other conditions which share similarities (such as chronic pain), and therefore larger and more powered studies need to be conducted.

1.3.6 ACT Bibliotherapy in MS Evidence Base.

A recent meta-analysis examined the efficacy of ACT bibliotherapy across mental and physical health conditions in randomised controlled trials, finding a significant and small effect size favouring ACT bibliotherapy for depression (g = .34), anxiety (g = .35) and psychological flexibility (g = .42) and concluded that bibliotherapy, especially if combined with higher levels of clinician guidance could be suitable in a number of conditions (French et al., 2017). In MS specifically, a small sample 8-week support intervention which contained elements of CBT and ACT based bibliotherapy found that the majority (5/7) showed significant positive change in psychological processes. The authors concluded, consistent with the French et al. (2017) review, that further research into bibliotherapy interventions with accompanied telephone support in MS is needed (Harrison et al., 2017).

1.3.7 Rationale for use of ACT Telephone Bibliotherapy in SPMS.

In recognition of the increasing evidence for the usefulness of both ACT and bibliotherapy in MS, a small sample telephone supported bibliotherapy ACT intervention was conducted with a control condition. The authors found that despite methodological issues around recruitment and attrition, that a large and significant effect was found favouring the ACT bibliotherapy intervention in reducing anxiety (*d* = 0.84), with smaller positive effects for psychological flexibility (*d* = 0.23). However, participants found the bibliotherapy text difficult to engage with and in conclusion the author suggested further studies with a greater focus on using service user involvement to inform intervention content, format and ease of understanding to maximise engagement with self-help materials (Proctor, Moghaddam, Evangelou, et al., 2018). If such an effect can be found in an MS sample, perhaps this can also help those during the transition period to SPMS as found in the Gillanders and Gillanders (2014) case study.

Bibliotherapy can be delivered using CBT in some conditions such as depression (Bilich et al., 2008), however some have suggested that CBT is less suited to an SPMS population because it is distinct from ACT as it employs an “antecedent orientated” approach, in contrast to ACT “response oriented” approach (Hofmann & Asmundson, 2008). CBT employs strategies such as cognitive reappraisal (i.e. assessing the truth of thoughts). In some conditions this is appropriate (e.g. overestimation of threat in anxiety disorders), but in a chronic condition such as MS, the illness beliefs and distress may be entirely logical and appropriate as a response, and therefore CBT may be of limited use (Dennison et al., 2009). In contrast, the “response oriented” approach taken by ACT does not rely on cognitive reappraisal, and instead focusses on increasing acceptance. Acceptance has long been recognised as a strong predictor of adjustment in MS (Pakenham, 2006), and more recently in SPMS specifically (Meek et al., 2020).

Bibliotherapy has the advantage of being low resource, as services do not have the skills, time and resources to deliver face-to-face individual work. Any trial of psychological therapy in this population would need to have the potential for future application, and this suggests that an effective lower resource intervention may be more suitable. One option could involve running ACT groups (e.g. Brassington et al., 2016; Nordin & Rorsman, 2012), where a number of patients could be seen at once, thus reducing appointment pressures. However, this has challenges of its own: several ACT

trained staff would be required to run the group, and patients would need to regularly attend the clinic, which may discourage those with SPMS without transport, who have difficulty balancing and walking (88.6%), or with incontinence (67.6%) (Gross & Watson, 2017). One way to deliver the intervention would be to combine bibliotherapy with *teletherapy* (Proctor, Moghaddam, Evangelou, et al., 2018). Teletherapy is defined as providing therapy at a distance, and its effectiveness has been found across physical health (Hailey et al., 2011) and mental health conditions (Leach & Christensen, 2006), with a preliminary review of studies conducted into teletherapy in MS showing promise (Proctor, Moghaddam, Vogt, et al., 2018). Teletherapy has been found to have similar therapeutic effects to face-to-face therapies, and client satisfaction of the teletherapy has been found to be high. In a contemporary review, teletherapy was found to be clinically effective, and that despite an ongoing *perception* that the therapeutic alliance will be impacted negatively when sessions are delivered by phone, actually the empirical evidence does not provide support for these attitudes (Irvine et al., 2020; Rushton et al., 2020). Therefore, an ACT based bibliotherapy support programme, delivered over the telephone, would be defendable and appropriate for use in this population based on the existing literature supporting each aspect.

1.4 Feasibility Randomised Controlled Trials

Those transitioning to SPMS currently find their transition difficult, with a lack of emotional support from services. Therefore, this study will assess the feasibility of conducting a larger trial to evaluate the effectiveness of a low resource ACT-based telephone supported bibliotherapy intervention with clinician support to address this panacea. This intervention would meet the Medical Research Council's criteria for a complex intervention (Craig et al., 2008), and therefore a feasibility and piloting phase is indicated (Moore et al., 2015). Feasibility trials are warranted to assess whether a (more costly and taxing) trial of effectiveness can feasibly be conducted, and to identify and ameliorate potential barriers and pitfalls (Tickle-Degnen, 2013).

1.5 Primary Aims

The primary aims of the trial were to assess the feasibility of progressing to a future effectiveness trial. The feasibility trial will aim to:

1: Assess recruitment capacity and sampling characteristics through identifying aspects such as the size of the population available, the appropriateness of the eligibility criteria for recruiting that population, and whether recruitment was successful.

2: Assess the data collection processes and outcome measures and their appropriateness for the SPMS population, in order to evaluate and then refine the process.

3: Assess the perceptions of participants towards the acceptability and suitability of the self-help book alongside the other trial procedures, and any barriers to engagement.

4: Assess whether the resources needed to run the trial (in terms of staff and time) are available and whether the study is manageable.

5: Gather some preliminary feedback from the participants on their response to the self-help intervention and whether they found it helpful or efficacious.

1.5.1 Secondary Aims.

Our secondary aims were to obtain an estimate of efficacy, and this will be done through group level exploratory analyses to obtain effect size estimates, and individual change analyses to identify how individuals improved or deteriorated from baseline. Individual analysis gives extra depth to the data

and is achievable in a feasibility sample. These secondary aims will allow for preliminary, but underpowered, analysis of the intervention efficacy.

1.6 Epistemological Position

This work has been completed from a post-positive metatheoretical stance, which differs from positivism which argues that the researcher and the researched object are independent of one another. Postpositivists argue that bias will have an inevitable impact on research through the researchers own "conjectures" (theories, hypotheses and judgements). Using ACT terminology, researchers will view the world through their respective value systems, however by recognising the effect these conjectures can have, postpositivists can work to alleviate this and still seek and recognise an objective truth. The flexibility of postpositivism and its allowance of biases and differing perspectives also lends itself to the use of qualitative methodology used in mixed methods research (Adam, 2014).

1.7 Psychological Flexibility and Distress in SPMS Questionnaire

In previous studies, lower psychological flexibility has been found to be related to greater anxiety and depression (e.g. Graham et al., 2016; Kashdan & Rottenberg, 2010; Wersebe et al., 2018). This is an important consideration in our trial because it suggests that psychological flexibility may have a moderating effect on anxiety and depression. If this is the case, then it provides additional justification for an ACT-based therapy which targets psychological flexibility as it may also reduce distress. Alternatively, if psychological flexibility, anxiety and depression are not found to be linked – or that higher psychological flexibility is associated with more severe anxiety and depression, then it provides less justification for use of ACT-based therapy for reducing distress. It is key to remember however, that the aim of ACT is not to reduce distress, but instead to facilitate living a rich, full and meaningful life. Distress reduction is not a target but may change naturally in the process of ACT-based therapy.

No such relationship between psychological flexibility, anxiety and depression has previously been researched before in those with SPMS. Gathering an understanding of this relationship will help to inform whether those with SPMS could achieve an additional unintended benefit from a trial of ACT-based telephone support, and therefore as an adjunct to the main trial, we aimed to explore this relationship through use of questionnaires on the UK MS Register platform. To determine whether this relationship existed, we sought to compare existing collated anxiety and depression data already stored on the UK MS Register, with a psychological flexibility measure collected for the purpose of this trial. The measures compared are the same as in the short paper; the HADS and the CompACT.[38]

The UK MS Register can anonymously link patient data at the individual level, whilst maintaining privacy. It collects data in three ways: using a purpose-built web portal to collect data directly from those with MS, through collecting routine administrative data, and through patient-management systems in NHS neurology clinics. The web portal route has been routinely collecting data since its launch in May 2011. The register has robust information governance arrangements and uses secure technological processes; it makes use of a Secure Anonymised Information Linkage (SAIL) system, which was developed by the Health Information Research Unit (HIRU).

The web portal of the MS Register functions as a questionnaire platform for those with an MS diagnosis. Individuals can provide information on their MS experiences using several validated

[38] This questionnaire will be described in brief in this extended paper with some preliminary findings only. It was intended as an adjunct, for future publication as a standalone piece of work. Preliminary data is included to complement the trial and demonstrate additional research undertaken. A short Introduction, Methods, Results and Discussion is included.

scales, which the register asks people to routinely complete. This includes the HADS, but also the MSIS-29 and the EQ-5D-5L, also used in the short paper. Baseline demographic data is also collected as part of the MS Register registration process, such as age, gender, date and type of diagnosis, and this method of data collection has been found feasible for use in characterising a cohort of people with MS (Ford et al., 2012).

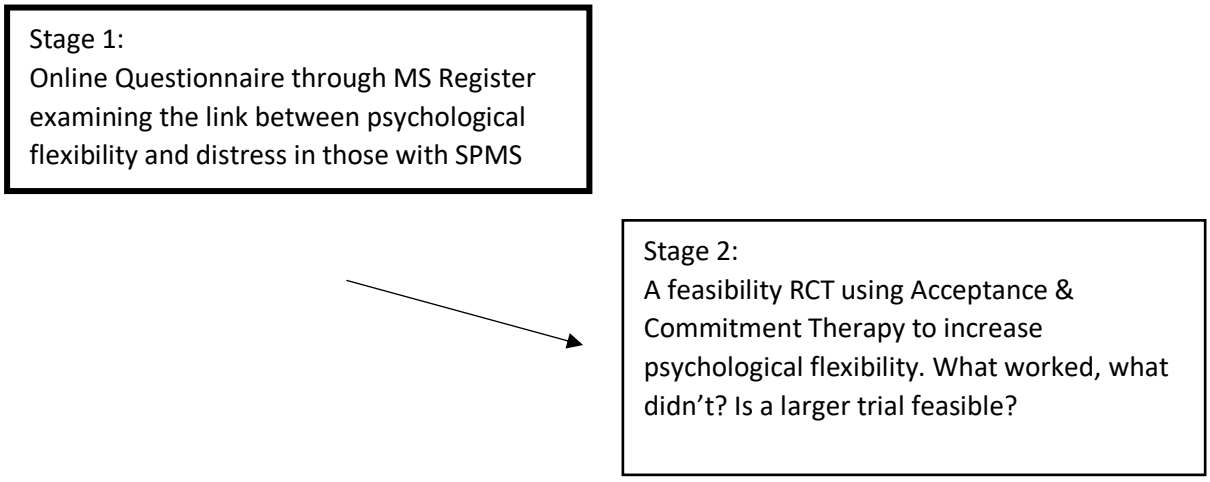
1.7.1 Questionnaire Aims

The purpose of this adjunct questionnaire is to inform the suitability of an ACT-based psychological support intervention for those with SPMS (See Figure 6). Its primary aims are to:

- Describe the level of anxiety, depression and psychological flexibility in this population
- Identify the strength and direction of any correlation
- Separate the component parts of psychological flexibility, and measure the strength and direction of correlation to anxiety and depression for each
- Determine whether a therapy targeting psychological therapy could be of use in this population

Figure 6

Stages of the project into psychological support in SPMS



2. Extended Method

The extended methods section will discuss in more detail elements relating to participant recruitment, and then the demographic and outcome measures. Following this, study procedures such as randomisation and the study procedure not explained in the short paper will be elaborated on. The type of analysis will then be explained, and any ethical considerations discussed. Finally, the methodology for the questionnaire study will be described.

2.1 Patient and Public Involvement in Design

Consultation with a Patient and Public Involvement (PPI) group was obtained when designing the research. An MS specific meeting was conducted on 27/07/18 where this project was presented by the Trial Manager to MS patients with a range of subtypes, carers, and MS clinicians. There was an opportunity for those present to question the Trial Manager about the project and raise any concerns.

Anonymised feedback from 5 people with MS and 4 carers was obtained through use of questionnaires. These questionnaires asked about the purpose, recruitment, methodology, outcomes and service user involvement of this research. Overall this feedback was very positive,

with an average (rounded) score on a 5 point Likert scale (where 1 is very poor and 5 is very good) of 4 for each area (purpose: 4.4, recruitment: 3.7, methodology: 4.2, outcomes: 4.3, service user involvement: 4.1).

2.2 Recruitment

Participants were recruited from two separate sources. Primarily, participants were recruited from a neurology department based in a city in the UK, but a secondary source of recruitment was through use of MS charities and Facebook community groups. The decision to open a secondary source of recruitment was made in September 2019, following a slower than expected uptake through the primary source.

2.2.1 MS Clinic.

The TM spent two months prior to the study attending the Neurology department on a weekly basis to build up relationships with clinicians and presented the study at the weekly team meeting. Participants were seen for their appointments at the Neurology clinic as part of their usual MS care. If they had recently been diagnosed with SPMS and appeared interested in extra support, a Consent to Contact form was given to them or verbal consent was obtained by their clinician. The Consent to Contact form, or verbal contact information, was passed to the TM by the clinician. Participants were then contacted by telephone and their interest and eligibility confirmed through (i) delivering the HADS over the telephone and (ii) asking questions to ensure they did not meet exclusion criteria; participants were informed during the telephone call whether they were eligible for the study. An Information Sheet and Consent Form was then sent to those who met the screening criteria.

2.2.2 Facebook.

The study was advertised on the "UK Secondary Progressive Multiple Sclerosis" Facebook Group with consent from the group administrator, and an email sent to three MS charities in the UK (See Appendix N). Individuals were asked to contact the study specific mobile telephone if interested in taking part, and eligibility for the study was ensured in the same way, but as there was no clinician input, the participants self-report of their MS status was used.

2.3 Sample Size

A recent systematic review found that ACT bibliotherapy interventions have a small to medium effect size for depression, anxiety and psychological flexibility of between 0.34 and 0.42 (French et al., 2017), which mirrors the findings of small effect sizes in non-self-help ACT systematic reviews (Öst, 2014). As the effect size of this specific type of self-help acceptance-based support is unknown and has not been used previously in this population, we estimated the required effect size as between small and medium, and therefore aimed to recruit 20 participants per arm (40 total), which should give more power and allowance for attrition than the 12 per arm suitable as a rule of thumb for feasibility studies (Julious, 2005).

Four participants from each group (eight total) were planned to take part in feedback interviews, as this was considered a pragmatic and achievable number large enough to provide enough insight, whilst also being representative of each arm of the sample. We felt this was the correct number with its specific feasibility focus, rather than using a decontextualized rule of thumb, a current criticism of samples used in qualitative and mixed research (Vasileiou et al., 2018).

2.4 Inclusion Criteria

Participants needed to have received a diagnosis of SPMS in the previous 12 months, confirmed by the Neurology service (although self-report was accepted for those recruited through Facebook). This criterion was originally six months, but due to patients typically have 12-monthly follow ups this

was changed to be consistent with the McDonald criteria (Thompson et al., 2018). These explicitly state that one should review the clinical course of diagnosis over the *past year* to determine the progression between Relapsing Remitting MS and Secondary Progressive MS.

Scoring above the clinical cut-off on the HADS questionnaire (Zigmond & Snaith, 1983) was to ensure that the study was only available to those who had a clinical need for support; and those more likely to benefit from psychotherapy. The published cut-off for the measure is eight and above for mild distress and has been used previously in several other studies when screening for MS distress (Forman & Lincoln, 2009; Proctor, Moghaddam, Evangelou, et al., 2018), and this is the criteria we applied for study inclusion. The HADS was chosen as it a commonly used quick measure of depression and anxiety, validated in MS populations (Honarmand & Feinstein, 2009).

Participants needed to be over 18, a criterion met comfortably by all participants as SPMS primarily effects older people. They also need to understand English and consent to take part, both of which were assessed through telephone conversation during screening.

2.4.1 Exclusion Criteria.

Participants needed to not be receiving another psychological or cognitive mental health intervention (or in the previous six months), and this was stipulated to reduce the risk of confounding variables from alternative therapies. Thought was given with what constituted an intervention, and we took the view that if it was delivered by a trained therapist or mental health professional then this would result in exclusion, whereas informal health promoting behaviours (e.g. exercise, yoga) would not result in exclusion.

2.4.2 Sampling.

Purposive sampling was used to recruit participants for the feasibility study, with each person who met the criteria and who had consented to contact from clinicians contacted by the Trial Manager. Opportunity sampling was then also used for the feedback interviews; with participants asked following study completion until four participants had been invited from each study arm. This method of sampling can be prone of bias and lower levels of generalisability, however it was the only appropriate method of sampling when recruiting from such a small sample population of people for a study with this size and resource (Palinkas et al., 2015).

2.5 Demographic Measures

Basic demographic details including age, gender, ethnicity, employment status, and educational achievement were collected for all participants through clinical records, and illness data (time since diagnosis, EDSS score). Social Economic Status (SES) data was collected through postcode estimates as described in Danesh et al. (1999), using the most recent Indices of Deprivation data (Noble et al., 2019, September 26).

2.5.1 Primary Outcome Measures.

As this was a feasibility study and was not sufficiently powered to find significant effects, there were no primary outcome measures as such. Instead, five areas of study design were assessed for feasibility using the Orsmond and Cohn (2015) framework (Appendix F) and reported through descriptive statistics (e.g. percentages) and framework analysis.

2.5.2 Secondary Outcome Measures.

Secondary outcomes were the self-report outcome measures of effectiveness used in the study. These were used for both group level and individual level analyses. The HADS was used as the distress (anxiety, depression) measurement (Zigmond & Snaith, 1983). It has been used previously to

identify elevated levels of distress in MS populations (Jones et al., 2012), and it has been validated for use in MS (Honarmand & Feinstein, 2009; Watson et al., 2014).

The CompACT (Francis et al., 2016) was used to detect changes in psychological flexibility and the constituent components of ACT, which include openness to experience, behavioural awareness and valued action. Previous extant commonly used ACT process measures, such as the AAQ-II (Bond et al., 2011) are circumscribed in their focus, and have been criticised for conflation of process and outcomes measurements, lack of consistency between items, and being a measure of distress rather than psychological flexibility (Ong et al., 2019; Wolgast, 2014). The CompACT has been described as providing a more nuanced and clinically meaningful understanding of psychological flexibility than the AAQ-II and was selected for this study on this basis (Rogge et al., 2019). As a therapy, ACT specifically aims to target psychological flexibility, which is strongly correlated with distress in SPMS[39]. The CompACT has been shown to have good internal consistency (α = .92), and test-retest reliability (*r* = .88) (Bayliss, 2018).

To measure the impact of the intervention specifically on MS, the Multiple Sclerosis Impact Scale (MSIS) was used (Hobart et al., 2001). This 29-item measure measures two domains – the psychological, and physical impacts of MS on an individual. Reliability has been demonstrated across community and hospital settings (McGuigan & Hutchinson, 2004), with excellent (a = .97) internal consistency (Jones et al., 2013). The physical and psychological scales were measured separately, to avoid masking otherwise differential effects on well-being (Jones et al., 2013; Ramp et al., 2009).

Self-efficacy, a sense of being able to manage, has been shown to be important in predicting health status in MS (Riazi et al., 2004), more so than the physical manifestations of the disease alone (Mitchell et al., 2005). It was measured through use of the MSSE (Rigby et al., 2003). The MSSE has good internal consistency (α = .81) and test-retest reliability (*r* = .81) in MS.

To measure quality of life, the EQ-5D-5L was used (Herdman et al., 2011). The EQ-5D-5L defines quality of life using measures of participation (social, physical) and functioning. This measurement has been shown to be highly correlated with disability progression in mild to moderate MS, but its discriminatory capacity lessens in those with the most severe disability (Fogarty et al., 2013). Test-retest reliability has been demonstrated to be good (*r* = .81) (Kuspinar & Mayo, 2014).

2.6 Randomisation

Participants were randomised after completing and returning their baseline outcome measures on a 1:1 ratio between the two arms. This was done using Sealed Envelope (www.sealedenvelope.com), an online randomisation company by the Trial Manager. Random permuted blocks were used by the service to balance the numbers of participants allocated to each arm. As this was conducted by the Trial Manager, they were not blind to which condition each participant was in. Participants were notified of their group allocation during the face-to-face session with the Trial Manager. Two researchers (NM, RdN) were blind to group allocation and oversaw and verified the statistical analysis completed by the Trial Manager.

2.7 Intervention

In the intervention condition participants were given a 49-page SPMS specific workbook created for use in the study during the face-to-face appointment, which they kept during and after the study. This was intended to be shorter, more targeted, easier to understand and less Americanised than the *Get Out of Your Mind and Into Your Life* workbook (Hayes, 2005), which were common complaints from previous attempts to use it in a Self-Help format (Potter et al., 2020; Proctor,

[39] See Extended Results 3.5.3 for the relationship between psychological flexibility and distress.

Moghaddam, Evangelou, et al., 2018). The workbook was split into three sections (See Table 15), with the first section focussed on building rapport and familiarising the participant to the model (See Chapters 5 & 6 in Harris, 2009), and the next two sections focussing on areas of the "Hexaflex" (Harris, 2009, p. 10). Regarding pacing, the Trial Manager focussed on each section for approximately two sessions but prioritised the needs of the individuals above completing the full workbook. The Trial Manager set homework each week which corresponded to activities in the workbook. A TIDieR checklist (Hoffmann et al., 2014) further describing the intervention can be seen in Table 16.

Table 15

Sections of the workbook used in the trial

Section	Pages	Heading	Subheadings	ACT Processes Targeted
1	1-11	Introduction	Living with a diagnosis of SPMS SPMS-related distress and how we respond to it Moving forward with SPMS: 'Sailing our Boat'	Introducing ACT Creative Hopelessness
2	12-35	Dealing with unhelpful thoughts, feelings, and physical sensations	Acceptance Mindfulness	Acceptance Contact with Present Self as Context Defusion
3	36-49	Doing what matters	Values Moving Forward	Values Committed Action

Note. SPMS: Secondary Progressive Multiple Sclerosis, ACT: Acceptance and Commitment Therapy

Table 16

Description of the Acceptance Based Support intervention

Checklist Item		Description of Intervention
1	Name	Acceptance Based Support (ABS)
2	Why	ABS is based on ACT, a therapy which has been used successfully in similar populations to increase psychological flexibility and wellbeing
3	Materials	The support included a 49-page SPMS specific ACT-based workbook, adapted from previous materials, and created specifically for the study. This was used as a supplement to ACT-based psychological telephone therapy. It contained three sections, with the first section focussed on building rapport and familiarisation to the model, and the next two sections addressing ACT processes.
4	Procedures	The participant was given the workbook in the first session and allowed to keep it during and after the study. During each subsequent session, the therapist and the participant would have physical copies of the workbook and would follow it together. Pacing was determined by individual response to the workbook, completing the full workbook was not an expectation. Homework's were set every week and anchored to suggested activities in the workbook.
5	Who	A third-year trainee clinical psychologist (male, 27) delivered the intervention. The trainee had approximately 2 years of experience delivering ACT in NHS outpatient mental health settings. The trainee was also the Trial Manager.

6	How	Face to face and telephone calls delivered individually.
7	Where	Whilst the participants were at home.
8	When	One initial face-to-face session and five subsequent telephone sessions, each approximately 30 minutes in length, were delivered on a weekly basis over six weeks.
9	Tailoring	Participants and the therapist followed the exercises in the ACT workbook. Activities selected and processes targeted were always workbook-based and ACT-consistent but tailored to individual needs.
10	Modifications	None
11	Fidelity	The fidelity of the intervention was assessed by a clinical psychologist supervisor (NM) with several years of ACT experience. A sample (approximately 10%) of the intervention telephone calls were recorded and assessed against published criteria (ACT FM) (O'Neill et al., 2019).

Note. ACT: Acceptance and Commitment Therapy, SPMS: Secondary Progressive Multiple Sclerosis, NHS: National Health Service, ACT-FM: Acceptance and Commitment Therapy Fidelity Measure

The workbook was developed from previously designed self-help formats for ACT (Brassington et al., 2016; Ford, 2017) with the permission of the corresponding author[40] for use in this study. This was adapted for MS populations (das Nair & Topcu, 2018), and the Trial Manager for use in SPMS. ACT is a "process" model rather than a technique model; which allows others to adapt resources so long as the same six core processes of ACT are being targeted. The use of previous iterations of this workbook have their roots in previous Self-Help ACT texts by Hayes (Hayes, 2005, 2016) and Harris (Harris, 2008, 2009).

The progress of participants through the workbook has been measured in previous studies, however we purposely did not measure it here as rigid compliance to pre-determined sections of the workbook has contributed to previous high levels of disengagement (Proctor, Moghaddam, Evangelou, et al., 2018).

2.8 Procedure: Text Messages

When posting a questionnaire, a text message was sent in parallel using the following structure: "Hi [participant name], I am sending you through some questionnaires to complete and return, if possible. Thank you." When in receipt of a returned questionnaire, a text message was sent saying the following: "Questionnaires received, thank you". A standardised prompt was given for questionnaires which had not been received after 7 days through text using the following structure: "Hi [participant name]. I sent some questionnaires through to you in the post – I wonder if you have received them or been able to fill them in?". All participants were thanked after responding to prompts: "Thank you, [participant name]". At the end of the study, the participants were sent a text message saying the following: "Hi X. Thank you for taking part in the study looking at supporting people during transition to SPMS. I wanted to give you a quick courtesy update. The study is now finished, thanks to you and other time and efforts along the way. I will now write up what I found and offer feedback to everyone in [Month] by letter. I am happy to answer any questions over the telephone and by text as normal at that point. I would like to take this opportunity to wish you well for the future. Chris."

[40] D. Gillanders (personal communication, October 26, 2018).

2.9 Exploratory Group Analysis

Correlational analysis was used on the baseline data to investigate correlations between anxiety, depression (HADS) and psychological flexibility (CompACT).

A mixed ANOVA was used, as this is a method which can be used to look for mean differences between two groups which have been split on two independent variables where one variable is a between subjects (in this case *Group Condition* [Control, Intervention]), and one variable is within subjects (in this case *Time* [T^0, T^1, T^2]). Assumptions of the mixed ANOVA are that variables are continuous, there are no significant outliers, there is a normality of distribution, a homogeneity of variances and sphericity (the variances are qual between all combinations of related groups). This was done through checking Box's Test of Equality of Covariance Matrices, Levene's Test of Equality of Error Variances, and Mauchly's Test of Sphericity

An alternative type of analysis which would have been suitable was a linear mixed model, and this would have been more helpful if there were missing data points or groups of varying sizes.

2.9.1 Sample Size Estimates.

The sample size used in feasibility and pilot trials is not needed to detect the effectiveness of an intervention, and instead the purpose of these types of studies is to highlight whether a larger and more powered study would be feasible to run, and warranted (Eldridge et al., 2016). Therefore, these studies can still fulfil their aims with small samples. We aimed to recruit 20 participants per arm. This would allow for attrition rates of up to 42%, as seen in a similar chronic pain self-help intervention (Johnston et al., 2010), but still meet the Julious (2005) requirement of 12 participants per arm as acceptable for feasibility studies.

When estimating the sample for use in fully powered study, we used the standard deviations of the HADS and CompACT at post-intervention across all participants. We calculated the number needed to detect a change of five points (HADS) and 16 points (CompACT), at the 5% significance level. These figures reflect a clinically significant change for each measure.

2.10 Individual Change Analysis

Like many health interventions across disciplines, people vary in their response to psychological therapy. Large sample RCTs are therefore used to mitigate the effect of individual differences between groups and can measure significant differences between groups by comparing their central tendencies. This is important for demonstrating significant difference between groups, but this does not mean that those involved in the study achieved any *clinically significant* change. Through individual change analysis, we can estimate the reliability and clinical significance of the effect of the trial on each individual (either improvement, deterioration or no change). As measuring efficacy was only a secondary aim of this trial, we decided to report this type of analysis on only the HADS and CompACT measurements in the short paper. The MSSE, MSIS and EQ-5D-5L measures were not assessed for individual change as this was also beyond the scope of the project.

The Leeds Reliable Index Change Index calculator (Agostinis et al., 2008) method was used to conduct analysis using the Reliable Change Index (RCI) and Clinically Significant Change (CSC) of all participants, with eight- and 12-week follow-ups compared to baseline. Through use of existing literature on the reliability and standard deviation of our measures, we were able to calculate whether individual participants showed any reliable improvement or deterioration over these timepoints.

Using published reliability (.83) and standard deviation (*SD* = 13.96) scores for the CompACT, we calculated its Reliable Change Criterion at 15.95. This means that we recorded a participant as

having achieved Reliable Change on the CompACT if their scores deteriorated or improved by 16 points or greater. The clinical cut-off scores for the CompACT in the literature are 84-85, and therefore we recorded any participant who achieved Reliable Change *and* crossed this a cut-off of 84.5 as having also achieved Clinically Significant Change (Bayliss, 2018; Francis et al., 2016). For the HADS, we identified the psychometric data of its anxiety (Reliability = .83, *SD* = 4.44) and depression (Reliability = .83, *SD* = 4.05) subscales, and calculated the Reliable Change Criterion at 5.07 and 4.63 respectively. We considered reliable change to be a deterioration or improvement of five points or greater on either scale, with a Clinically Significant Change cut-off of 7.5 (Honarmand & Feinstein, 2009; Marrie et al., 2018).

2.11 Ethical Approval

To recruit patients through MS specific networks on Facebook and through MS charities, ethical permission was granted by the University of Nottingham (Appendix O). To recruit participants from the outpatient neurology clinic, ethical approval was granted by the NHS Preston Research Ethics Committee and Nottingham University Hospitals Research and Development (Appendix P). For the additional adjunct questionnaire data gathered through the MS Register, approval was granted by the ethics committee of the register itself (Appendix Q).

2.11.1 Informed Consent.

We followed Good Clinical Practice (GCP) and REC guidance for the provision of informed consent, an important foundation in clinical research (Vijayananthan & Nawawi, 2008). In this study, participants were first approached by their clinician (i.e. neurologist, MS nurse) who suggested the study, before forwarding on interested parties contact details to the Trial Manager using the Consent to Contact form. Those recruited through the Special interest Facebook/MS Charity route responded to a single posted advert to contact the Trial Manager.

Once the Trial Manager had received participant telephone details they were telephoned and had the study explained verbally. If interested, they were then sent a consent form through the post and given one week to read through it. They were again telephoned again by the Trial Manager a week later, to ensure they understood the study and agreed to take part. This enabled the research team to ensure the participant had received and understood the Participant Information Sheet (PIS) and to answer any questions they may have. Participants were informed there was no requirement to complete the study and that they could withdraw themselves, without explanation, at any time and assured it would not affect their treatment as usual.

2.11.2 Confidentiality and Data Protection.

All data was stored securely as specified by ethics committees. Hard-copy questionnaire data was kept at the University of Nottingham in a locked cabinet in a locked office. Participant consent forms (which included names) were kept in a separate locked cabinet in a different office. All electronic data was kept securely on University of Nottingham servers, with participant contact details secured on a single password-protected excel spreadsheet. Each participant was assigned a unique identifier (X01-X14) and these identifiers were linked only through the password-protected excel spreadsheet and were used on all documentation and questionnaires so that no data was identifiable.

2.11.3 Safeguarding.

We did not foresee any serious risk to participants taking part in this research, especially as the content was tailored to the individual and delivered by a therapist with several years of experience. However, psychological therapy can cause emotional discomfort, and we ensured therefore that the information sheet included numbers for people if they felt they were struggling (which included the Trial Manager's work-phone, charities, and crisis contact information).

2.12 Psychological Flexibility and Distress in SPMS Questionnaire, Method

Participants were recruited through the MS Register. The MS Register is a large database of those with MS in the United Kingdom, created in 2011, and contains >10,600 consented patients across 48 sites who complete regular online questionnaires. The MS Register therefore has an existing demographic and clinical dataset, which it allows for use by researchers. The MS register have their own ethical review procedures and provided approval (See Appendix Q for confirmation) for the authors to obtain and use the requested demographic (Age, Gender, Type of MS) and clinical data (HADS, CompACT).The MS Register placed a version of the CompACT questionnaire (Francis et al., 2016) online for one month available for those with SPMS to complete. This was compared to previously completed[41] HADS questionnaires (Zigmond & Snaith, 1983).

2.12.1 Analysis.

Descriptive statistics were used on demographics of the questionnaire sample to describe the age (*M*, range, *SD*, *SE*) and gender (percentages, ratios). Those who completed the CompACT but were excluded from the analysis were reported (n, percentage) along with the reasons for exclusion. Clinical characteristics were reported including anxiety, depression and total distress scores (*M*, *SD*, *SE*). Psychological flexibility, along with its subcomponents of openness to experience, behavioural awareness and valued action were reported (*M*, *SD*, *SE*) and all clinical scores were compared to a UK general population reference group.

Internal consistency of all measures was determined through use of the alpha coefficient ($\alpha > 0.9$ = excellent, $\alpha > 0.8$ good, $\alpha > 0.7$ acceptable) to determine the reliability of the measure result (Henson, 2001; Tavakol & Dennick, 2011). Correlational analysis using Spearman's rank coefficient was used. We measured the correlation between psychological flexibility and anxiety, depression, and total distress. The correlations between the subscales of psychological flexibility on the CompACT (openness to experience, behavioural awareness and valued action) and anxiety/depression were also measured. We used the Dancey and Reidy (2004) categorisation to report the strength of the correlation relationship (0.1-0.3 = weak, 0.4-0.6 = moderate, 0.7-0.9 = strong).

3. Extended Results

The short paper has a comprehensive results section and therefore this section will contain little additional data. It will look at baseline correlations between measures, then normality and variance testing. Additional exploratory group level data and additional framework analysis results data will be presented and the results of the adjunct questionnaire study.

3.1 Baseline Correlation Results

Pearson's correlation coefficient was used to assess relationships between Anxiety, Depression and Psychological Flexibility. A moderate negative relationship was found between psychological flexibility and both anxiety ($r = -0.55$, $n = 14$, $p = 0.41$) and depression ($r = -0.57$, $n = 14$, $p = 0.33$). Anxiety and depression scores had a strong positive relationship ($r = 0.69$, $n = 14$, $p < 0.01$).

3.2 Normality and Variance Testing

The short paper contains the baseline clinical characteristics and shows no significant differences between the control and intervention groups. However, for these independent t-tests to be valid, they need to be normally distributed. They are assumed to be normally distributed if the Shapiro-Wilk p value is over .05 and the kurtosis and skewness z values are between -1.96 and +1.96. Table

[41] Date these questionnaires were completed is not yet analysed but the majority completed within 12 months (Feb 2019-Feb 2020).

17 shows that none of the data differ significantly from normality as all Shapiro-Wilk test values are above .05, and no z values fall outside of the -1.96-1.96 range. We can therefore assume that our data is normally distributed.

Table 17

Normality testing of the baseline data

Measure	UC			ABS+UC		
	Kurtosis	Skewness	Shapiro-W	Kurtosis	Skewness	Shapiro-W
HADS-A	0.14	0.66	0.83	0.71	0.79	0.47
HADS-D	-0.88	-0.58	0.27	0.02	0.35	0.99
MSIS	-0.44	-0.0	0.98	0.64	-1.33	0.42
MSSE	1.25	-1.55	0.31	0.81	-0.21	0.78
EQ-5D-5L	0.25	-1.04	0.37	-0.43	0.44	0.60
CompACT^{T}	-0.73	-0.88	0.36	0.54	1.46	0.22
OE	-0.93	0.98	0.08	1.66	1.91	0.10
BA	-0.01	0.55	0.42	0.82	1.06	0.58
VA	-0.60	1.14	0.12	-1.34	0.01	0.41

Note. HADS-A: Hospital Anxiety and Depression Scale Anxiety, HADS-D: Hospital Anxiety and Depression Scale Depression, MSIS: Multiple Sclerosis Impact Scale, MSSE: Multiple Sclerosis Self Efficacy Scale, EQ-5D-5L: EuroQol Quality of Life – Visual Analogue Scale, CompACT^{T}: Comprehensive Assessment of Acceptance and Commitment Therapy Total, OE: Openness to Experience, BA: Behavioural Awareness, VA: Valued Action, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care

3.3 Exploratory Group Level Changes

Most group level analyses can be seen in the short paper results section (Tables 11, 12), and all assumptions for the use of a mixed ANOVA were met. However, the EQ-5D-5L was simplified to only contain the visual analogue scale data. Table 18 show the Likert scales of the EQ-5D-5L. As in the short paper, no pairwise comparisons for the EQ-5D-5L were found to be statistically significant in this sample.

Table 18

Mixed ANOVA with interaction effects for items on the EQ-5D-5L (T^0 is baseline, T^1 is 8-week follow-up, T^2 is 12-week follow-up)

Measure	T^0		T^1		T^2		F value (*p*)
	UC	ABS+UC	UC	ABS+UC	UC	ABS+UC	
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	
Mobility	3.29 (0.95)	3.43 (1.27)	3.57 (0.98)	3.57 (0.79)	3.57 (0.79)	3.29 (1.25)	1.00 (0.83)
Self-Care	2.43 (1.27)	2.57 (0.79)	2.86 (1.21)	2.86 (0.53)	2.71 (1.11)	2.71 (1.25)	0.81 (0.78)
Usual Act	3.29 (0.76)	3.00 (1.00)	3.57 (0.98)	3.43 (0.53)	3.43 (1.27)	3.43 (1.07)	0.28 (0.61)
Pain	3.00 (0.82)	2.71 (0.76)	3.43 (0.98)	2.57 (0.79)	3.29 (0.95)	3.14 (1.06)	1.37 (0.27)
Anx Dep	2.86 (1.07)	2.00 (0.82)	3.14 (0.90)	2.29 (1.22)	2.71 (1.25)	2.14 (1.07)	0.30 (0.60)

Note. EQ-5D-5L: EuroQol Quality of Life, Usual Act: Usual Activities, Anx Dep: Anxiety and Depression, UC: Usual Care, ABS+UC: Acceptance Based Support + Usual Care

3.4 Framework Analysis

In Stage 3 (Coding) the researchers (Trial Manager, MSc student researcher) identified an initial set of 49 codes, which were condensed down into 40 codes as similar codes were grouped together. During the Stage 4 (Developing the framework) phase, 19 codes were assigned to the pre-determined (Orsmond & Cohn, 2015) framework categories and the other 21 codes were deemed to not fit the framework. These 19 codes were then transformed during Stages 5-6 into the final 15 codes (Table 19). The final codes and themes used in the framework match the results in the short paper.

Table 19

The framework at each stage using the (Gale et al., 2013) method of Framework Analysis

Codes				
Stage 3 Coding the Framework		Stage 4 Developing the Framework	Stage 5-6 Charting the Framework (Theme)	
Accessible	Impact of involvement	Burdening Others	Social Barriers	(1)
After diagnosis	Impact of therapist	Feeling Heard	Healthcare Support	(1)
Availability	Isolation	Healthcare Sup.	Talking Therapy	(1)
Beneficial	Medication	Hoping to benefit	Motivation to Help	(1)
Burdening others	Mental Health	Timing	Questionnaires	(2)
Change	Metaphor	Questionnaires	Postal system	(2)
Cognitive	Mindfulness	Accessible	Accessibility	(3)
Communication	Mood	Homework	Telephone Sessions	(3)
Comorbidity	Quality of life	Randomisation	The Workbook	(3)
Coping	Questionnaires	Session Structure	Randomisation	(3)
Correspondence	Randomisation	Workbook	PF + ACT Processes	(4)
Difficulty	Session duration	Beneficial	Mood	(4)
Enjoyment	Session frequency	Coping	Mindset + Coping	(4)
Existing support	Session Structure	Mindfulness	Intervention Exp.	(4)
Fatigue	Social support	Mood	Quality of Life	(4)
Feeling Heard	The future	Quality of Life		
Frustration	Therapy	The future		
Healthcare support	Timing	Therapy		
Homework	Values	Values		
Hoping to benefit	Workbook			

Note. Themes: (1) Recruitment Capability and Sample Characteristics, (2) Data Collection Procedures and Outcome Measures, (3) Acceptability and Suitability of Intervention and Study Procedures (4) Participant Responses to the Intervention, PF + ACT: Psychological Flexibility and Acceptance and Commitment Therapy, Sup.: Support, Exp.: Experience

3.5 Psychological Flexibility and Distress in SPMS Questionnaire

3.5.1 Description of Respondents.

Participants (*n* = 776) completed the CompACT questionnaire over a one-month period between February and March 2020. The completed CompACT questionnaires were compared to the most recently completed HADS questionnaire on the system (with the vast majority having been completed in the preceding 12 months). Of these, a sample (*n* = 50) were removed from the analysis

as they had completed the questionnaire, but their demographic data showed they were not listed as having SPMS. An additional group (*n* = 38) were removed as they did not have a completed HADS questionnaire, totalling an 11% exclusion rate (*n* = 88). Of participants included in the analysis (*n* = 688), 72.1% were women and 27.9% were men (2.58 women: 1 man). The mean age of the respondents was 60.65 years (Range = 33-86, *SE* = 0.30, *SD* = 7.99).

The mean total HADS score was 15.53 (*SE* = 0.30, *SD* = 7.88), anxiety score was 7.21 (*SE* = 0.17, *SD* = 4.57), and depression score was 8.32 (*SE* = 0.16, *SD* = 4.18). In the UK population reference group the mean values for anxiety and depression were 6.14 (*SD* = 3.8) and 3.68 (*SD* = 3.1), respectively (Crawford et al., 2001).

On the CompACT, the mean total psychological flexibility score was 81.94 (*SE* = 0.86, *SD* = 22.60). The mean openness to experience subscale score was 31.33 (*SE* = 0.44, *SD* = 11.67), behavioural awareness score was 16.53 (*SE* = 0.29, *SD* = 7.49) and valued action score was 34.08 (*SE* = 0.32, *SD* = 8.40). This compares to a UK population reference group (*n* = 313) for total psychological flexibility of 85.07 (*SD* = 20.62), openness to experience of 31.85 (*SD* = 11.79), behavioural awareness of 16.05 (*SD* = 6.73) and valued action of 37.17 (*SD* = 6.59) (Bayliss, 2018).

3.5.2 Internal Consistency.

The CompACT was found to be internally consistent (α = 0.90), along with its subscales of openness to experience (*a* = 0.84), behavioural awareness (α = 0.85) and valued action (α = 0.83). The HADS anxiety (α = 0.89) and depression (α = 0.84) scales were also found to be internally consistent.

3.5.3 Relationship between Psychological Flexibility and Distress.

Spearman's rank correlation coefficient was used to assess relationships between anxiety, depression and psychological flexibility. A moderate negative relationship was found between Psychological Flexibility and Distress scores (r = -0.65, n = 688, p < .001), Anxiety scores (r = −0.58, n = 688, p < .001), and Depression scores (r = 0.56, n = 688, p < .001). Openness to Experience had a moderate negative relationship with Anxiety (r = -0.55, n = 688, p < .001) and Depression (r = -0.42, n = 688, p < .001). Behavioural Awareness had a moderate negative relationship with Anxiety (r = -0.49, n = 688, p < .001) and Depression (r = -0.46, n = 688, p < .001). Valued Action had a weak negative relationship with Anxiety (r = -0.37, n =688, p < .001) and a moderate negative relationship with Depression (r = 0.51, n =688, p < .001). Depression and anxiety scores had a moderately positive relationship (r = 0.61, p < .001), like the general population reference group (r = 0.53, p < .001).

4. Extended Discussion

This extended discussion will look in more detail at our primary aim of exploring study feasibility, and then our secondary aim of demonstrating efficacy reflecting on both the group level and individual level analysis. It will discuss some of the theoretical implications of our findings, some additional strengths and limitations, and finally suggest some directions for future research.

4.1 Recruitment Capability and Resulting Sample Characteristics

4.1.1 Sample.

The sample was majority female (72.43%) which closely mirrors the prevalence of MS in the wider population[42], and both groups contained the same number of males and females. The average age was around 53 which matches the estimated time of transition to SPMS in the literature (Koch et al., 2010). Both groups had an identical "deprivation score". This is helpful as although employment status and educational achievement are currently unobtainable, they are direct components of the

[42] See Extended Results 3.5.1 for gender breakdown of adjunct questionnaire study

deprivation score measure. Ethnicity variation may be an issue, despite BAME being underrepresented compared to Caucasians in MS, they are still affected and all participants were White-British. Ethnicity aside, the other demographic data give us confidence that although small, our sample is well balanced and in terms of age and gender, representative of the newly diagnosed SPMS population.

The level of anxiety and depression in our sample was higher than in the wider SPMS population, which may reflect that those less distressed were excluded from participating, and our use of purposive sampling. Our sample also had lower psychological flexibility than those in the wider SPMS population. This was also expected, as our questionnaire study found that psychological flexibility is negatively correlated with distress in SPMS[43].

The sample used in feedback interviews was less well balanced, which was compounded in part to two in the control group not completing interviews. The four intervention group interviewees seemed more representative of their condition overall; although there were no men interviewees, most of the group were women, and their baseline anxiety and depression scores were varied, mild to severe distress was represented. However, the two control group interviewees were less representative. They were both men, and this is less representative of their group (every other member was a woman), and in addition to this, they also had the mildest baseline anxiety and depression in their group. This is important, because it means we may have missed something about the experience of being in the control group (i) as a woman, and (ii) with severe distress.

4.2 Recruitment

The original recruitment strategy of recruiting 40 participants was not feasible in the four months we had available. In fact, it would have taken around a year to recruit this sample using the same recruitment methodology. The issue was not that those with SPMS were not interested in participating. On the contrary, there was real concern among participants about the lack of available social and healthcare support resources they had available, which fits with the previous literature around the key importance of social relationships during SPMS transition (Henry et al., 2019; Meek et al., 2020). Participants spoke during interviews of the attraction to having an independent, reliable source of social support. The issue with the recruitment strategy was a combination of difficulty identifying suitable participants, and inclusion criteria being too narrow.

To demonstrate the first and most important point, even if we recruited every potentially eligible participant, we would still only have 27 recruits, far below our 40-recruit target. For a future study with the same inclusion criteria, the pool of potentially suitable participants would need to be approximately three-times larger (27*3 = 81 participants) as this study recruited 48% of those who were potentially eligible (81*0.48 = 39 participants [82 required for 40 participants]). A clear indication of a larger pool of potentially suitable participants, along with the methods of identifying these patients (either through clinics, or through computer records) and buy-in from clinical staff is needed to improve efficiency and drive up recruitment.

To demonstrate the second point, changes to the inclusion criteria could also increase the recruitment rate (albeit slightly). Four participants were excluded because of their anxiety and depression scores on the HADS were too low or they did not meet the < 1-year cut-off for transition to SPMS. For a future study, we would recommend removing the requirement for a minimum HADS score altogether. As this is an ACT-based intervention and the target is not on reducing distress, even someone who is not clinically depressed or anxious can still benefit from learning to live a more rich,

[43] See Extended Results 3.5.3 for more details on the relationship between psychological flexibility and distress

full and meaningful life. This is evidenced through empirically evaluated ACT self-help, targeted at the general public and not just those with clinical level distress (e.g. Hayes, 2005). The transition cut-off criteria could also be loosened to three years as suggested in the short paper, and this may better reflect the fact that transition takes a long time (Katz Sand et al., 2014). The degenerative nature of SPMS means people are not just adjusting to one point in time, but to every increase in disability and subsequent restriction of their liberty associated with SPMS transition (Meek et al., 2020). This could increase the proportion of those eligible for the study from 13/27 (48%) to 17/27 (63%) and mean that the sample of available potential participants can be lower, with just 63 potentially eligible participants required (63*0.63 = 40 participants).

4.3 Data collection Procedures and Measures

Data collection measures were very successful as every pack of measures were returned. We attributed this success to a combination of the postal system procedure (using large, pre-stamped, addressed envelopes), text messaging procedure[44], and the high quality of the questionnaire packs with personalised (named) cover sheets (Appendix R). Missing data was very uncommon across measures, but uninterpretable data did occur at a higher rate on the MSSE, which is addressed in the equivalent discussion point in the short paper. This was a surprise, as it was an assumption of the research team that online questionnaires would have higher return rates and postal questionnaires would not be completed; however, in making this assumption we importantly did not factor in the *age* of participants. Older people are more likely to respond to postal questionnaires than web-based questionnaires (Mickael & Morten Bo, 2009). It should be noted that postal questionnaires are a more expensive method and the materials involved costed around £110 for 14 participants (£7.80 each). We estimate that a future RCT with 40 participants would cost approximately £314 in materials. Participant feedback was that in general both the questionnaires and postal system were easy to complete and navigate, with one instance of an important and unacceptable exception addressed below.

Responsiveness of the research team to questionnaire feedback was poor, and this led to one member of the control group expressing how angry they were at not being listened to when they wanted the font size increased at feedback. This occurred when the participant gave feedback on the questionnaire itself and wrote “text too small!”. This was noticed by the team, but no record was made, leading to the same pack of small-text questionnaires being sent again. A system for responding to participant feedback (e.g. recording participant requests highlighted on the database next to where their address is stored) must be used to help avoid frustrating participants like this in future studies. This change of text size should have no impact on the validity of the questionnaire.

4.4 Acceptability and Suitability of Intervention and Study Procedures

The study procedures were a success and acceptable to participants as there was no attrition from the trial. Support calls were rarely rearranged, and when they were done so, this was the participants choice. I considered this important; one of the reasons given for the attractiveness of the intervention was a *reliable* person to talk to. This can be different to how people are usually sent appointments on dates without their input, and sometimes subject to cancellations and rearranging.

4.4.1 Support Calls.

Participants in the intervention group gave positive feedback about how beneficial they found the support calls. The style of the support calls were changed to be more flexible and tailored in response to previous recommendations that the intervention should be created to be delivered over a certain number of weeks but adapting to the participants pace and needs (Potter et al., 2020;

[44] See Extended Methods 2.7 for text messaging procedure

Proctor, Moghaddam, Evangelou, et al., 2018). Not having to attend clinics was listed as a bonus by two participants, perceiving having to navigate public transport as a barrier of doing therapy face-to-face. On recommendation from a previous thesis (Proctor, 2016); we employed a one session face-to-face session for both groups, which may have increased the rapport and relationship with the Trial Manager. These processes seemed to have been successful in improving the patient experience and lowering attrition rates.

4.4.2 Feedback Interviews. Feedback interviews were completed by all invited participants in the intervention group, but only two of four in the control condition, and this may have been because those in the control group had less contact with the Trial Manager, and perhaps felt more detached from the study. One invited participant was also having an acutely difficult time, and therefore it was agreed they would not do the call.

4.4.3 Randomisation.

Randomisation was described as acceptable by both participants in the control group. One added that they were told this would happen, suggesting that they had understood the study procedures before consenting. This is encouraging, but the sample asked about randomisation was very small, heterogenous, and as described above only contained those with *mild* baseline distress[45]. In addition, the intervention group were not asked about their experiences of randomisation. Seeking a wider range of participant views would have increased our understanding of the acceptability of randomisation.

4.4.4 The Workbook.

The workbook was well-received in general, with one of the intervention group participants saying that they read through it very quickly, and several others mentioned about how it was good to have the materials within arm's reach to refer back to, with one adding that their memory was affected by the SPMS. There was some mixed feedback about the topics and tasks in the workbook. For example, a section on coping strategies was viewed as targeting a newly diagnosed MS client group. This is understandable as the workbook was developed from a similar workbook on newly adjusting to an initial MS diagnosis. Completing the workbook was sometimes difficult for participants to find the time to do with life getting in the way. As the therapist I anecdotally felt that the homework completion rates were low, and many participants instead just made use of the support calls.

4.5 Ability to Manage and Implement the Study and Intervention

The study was successfully managed by the Trial Manager, but they were working at full capacity as mentioned in the short paper. This is important because although capacity was not an issue due to the difficulty in attaining a large sample, if the recruitment rate is increased then the trial will not be able to be managed successfully. Appointments and administrative burden increased as the number of participants increased, which reduced the time available for the difficult element of this trial; recruitment. At this sample size, I did not feel that being more available for recruitment would have had a large impact on recruitment rate, as the difficulty in identifying enough numbers of potentially eligible participants was a neurology service issue and I was able to contact all that were available. However, in an increased sample, the burden of support telephone calls and administrative duties (i.e. sending letters, entering SPSS data) would lead to the trial becoming unmanageable and this could have unforeseen consequences. The therapist could become overwhelmed and support call quality reduced (Dinger et al., 2008), or trial processes missed, which may lead to an increase in missing data or attrition.

[45] See Extended Discussion 4.1.1 for further detail about control group feedback sample

4.6 Participant Responses to Intervention and Theoretical Implications

4.6.1 Quantitative Outcomes.

Group Level Change.

On all measures, neither the intervention or the control group showed significant change and were not significantly different to each other after between group analysis. Within group analysis of the control group showed significant change in anxiety scores between baseline and 12-week follow up. We conducted multivariate analysis, despite the small underpowered sample, to be fully transparent with the data. However, caution is therefore recommended during interpretation of the pairwise comparisons.

The lack of change across groups was unexpected; prior to the study we expected the intervention group to outperform the control group in increasing psychological flexibility and decreasing distress. This was based on the previous literature showing ACT improving psychological flexibility in similar bibliotherapy and teletherapy studies, and the negative correlation between psychological flexibility and distress shown in the adjunct questionnaire study. The effect sizes in the intervention group across timepoints are concerning; across measures of distress and flexibility the effect was practically non-existent or confusing (i.e. an improvement in behavioural awareness at eight-weeks, which by 12- weeks demonstrate a similar strength deterioration). These findings suggest that the intervention was inert, and not targeting the ACT processes as it is expected to.

The significant improvement in the control group anxiety scores was also very unexpected; considering that the eight-week follow up showed an improvement but not to near the level of significance. As there was no intervention given to the control condition above one face-to-face meeting at week one, and no contact for the following 11 weeks apart from questionnaires and reminder text messages, we are perplexed as to how the study would have influenced a significant improvement in this way. We therefore considered that based on group-level analysis the finding is probably a Type 1 error, based on the low sample size and the possibility of outlier(s) (who have had significant improvements in mood from external factors) skewing the data.

Individual Level Change.

Individual change analysis highlights a peculiarity in the data, as we see that despite a significant group level change detected in anxiety in the control condition between T^0 and T^2, on individual change only one individual made a clinically significant improvement in their anxiety, with the other six showing no clinically significant change[46]. When this individual case was explored further, they had moved from severe anxiety at baseline (HADS-A = 19) to mild anxiety 12-weeks later (HADS-A = 10) without any intervention provided. As this participant was one of the last to finish the study, they were not invited to participate in feedback interviews and therefore we do not have an explanation for their rapid improvement. We also observed that the same participant also showed a significant improvement on their levels of depression from T^0 (HADS-D: 13) to T^2 (HADS-D: 7) and psychological flexibility from T^0 (CompACT = 34) to T^2 (CompACT = 71). This suggests that psychological flexibility unexpectedly increased for this participant whilst distress decreased, a relationship we may expect to have seen in the intervention condition. This adds evidence to the conclusion about the significant change in anxiety in the control condition; only one participant changed significantly whilst the other six remained broadly the same, but this change skewed the data to look like significant change but was likely a Type 1 error.

[46] See Journal Paper Table 13 for individual change

Across the intervention group, individual level changes were rare with most participants showing no positive or negative change. This mirrors the findings of the group-level analysis and adds to the evidence that the intervention was inert and did not affect significant change in anxiety, depression or psychological flexibility.

4.6.2 Qualitative Outcomes.

The interview feedback from the two participants in the control condition was that they felt *about the same* in terms of both mood and quality of life, which was to be expected as they had not received any intervention above their usual care.

The intervention condition generally described improvement in mood, feeling more mindful or present or experiencing a change of mindset (75%) with all participants describing their experience of the intervention as "beneficial" or "helpful" as described in the short paper. This again was the hypothesised impact expected from an ACT-based therapy on this client group.

4.6.3 Unclear Picture.

The measures and interview data paint an unclear picture of intervention efficacy, with the measures suggesting the intervention is inert. This is in stark contrast to the interviews which suggest it is *helpful*, and most participants make reference to changes in elements of psychological flexibility and mindset, which we would expect to see translated onto outcome measures such as those targeting quality of life (EQ-5D-5L), self-efficacy (MSSE) and psychological flexibility (CompACT). It is useful to have both sources of data in this instance, to try and triangulate and offer some explanations for this discrepancy.

To try and create a clearer picture, one possible explanation may be that the outcome measures were completed whilst the participants were sitting on their own. They may be a more accurate representation as participants felt less influenced or would be less susceptible to demand characteristics (i.e. saying what the experimenter would want you to hear). Although the interviewer was separate from the study team, participants may have still felt uncomfortable at being critical about elements of the intervention whilst being recorded (especially if they enjoyed the effort placed into offering support, and felt guilty they found it ineffective). This could be the case, but then there were several instances where negative or constructive feedback was provided, and this would be unusual if demand characteristics made it difficult to be honest. An alternative explanation may be that as participants were not observed, the questionnaires were completed quickly and without much thought, making them more prone to inaccurate results than the interview where the participant is engaged fully in a discussion about the intervention. We feel this explanation is probably unlikely however, at a glance most questionnaires correlated quite closely with each other between timepoints, and this suggests that participants know what they were thinking about their scores for each of the items. In addition, the questionnaires follow the expected relationship cross-sectionally at baseline (i.e. HADS negatively correlated with CompACT), which if they were rushed you would not expect to be the case and would expect a more random response.

A final explanation is that both the questionnaires and the qualitative outcomes are accurate forms of feedback but demonstrate that these methods are assessing different things. The questionnaires are looking at markers of clinical change, which have not changed because the intervention has been unsuccessful in changing psychological flexibility (the ACT *mechanism* of change). In contrast, the interviews may have mainly assessed the participants *enjoyment* of the intervention and that statements like "beneficial/helpful/positive" are broadly saying that the intervention was welcomed but that the target was not measured by the questionnaires. If we were to speculate, we could refer to the important characteristics of therapeutic or social relationships. People might feel better

understood, more heard, more supported, enjoyed a boat metaphor, built a relationship with someone, and may have enjoyed the sessions – none of which we would expect to have captured on our measures but all of which have been alluded to at interview.

Why the intervention did not improve psychological flexibility could be due to the type of intervention. In previous studies (Proctor, Moghaddam, Evangelou, et al., 2018), ACT based materials have been followed more closely and the completion of these materials has been monitored as an element of feasibility. However, based on feedback following high attrition rates, the style of intervention changed (to a novel teletherapy and bibliotherapy combination, with a tailored focus). This style of therapy maybe did not ensure that participants had enough ACT processes targeted during the 6-weeks intervention (for example, a participant who preferred to focus on mindfulness for all of their sessions would miss important elements scored on the CompACT scale (such as valued action, behavioural awareness subscales). I therefore feel that this is the most likely explanation for the unclear picture of intervention efficacy.

4.7 Theoretical Implications

As we did not observe change in the intervention group on psychological flexibility in response to the ACT-based intervention, we could assume that ACT does not lead to increases in psychological flexibility when transitioning to SPMS. However, this contrasts with the ACT evidence base of similar chronic conditions (Kang et al., 2019), even if evidence in the field is still in its infancy (Graham et al., 2016). Even the most critical meta-analyses found that ACT interventions outperformed control conditions on increasing psychological flexibility, despite concluding that ACT efficacy is premature (Öst, 2014). We could then alternatively conclude that it is the bibliotherapy or teletherapy in particular which is the ineffective part, but again this contrasts with the findings of reviews within which ACT bibliotherapy and teletherapy outperforms control groups in both arenas, especially when clinician guidance is greater as it was in this study (French et al., 2017; Proctor, Moghaddam, Vogt, et al., 2018). In summary, these findings do not fit well into the existing literature base.

It may be that it is the SPMS client group does not lend itself to ACT in some way, and therefore evidence in other comparable chronic disorders is not replicated here. A hypothesis may be that chronic pain itself, which currently has the best evidence of efficacy, contains a psychological aspect; i.e. people may feel less pain in response to better mental wellbeing. This may contrast with the disability itself that comes with SPMS that will never change through psychological intervention (although stress may exacerbate symptom severity). Perhaps the chronic pain literature is benefiting from an additional bonus of symptom reduction, where SPMS does not. However, this is not an entirely convincing argument, as several other conditions (even those which could be considered more psychological in nature) have demonstrated efficacy using the ACT approach (A-tjak et al., 2015).

This specific intervention has been ineffective at reducing psychological flexibility, but this does not refute the proof of principle of the ACT model. As happened here, we would expect other measures of outcome such as distress, quality of life and self-efficacy which correlate with psychological flexibility to also not change. For example, if psychological flexibility changed but quality of life did not, we could conclude that psychological flexibility has a weak relationship with quality of life. ACT theorists would refute this, as they would assume that being able to be more accepting of difficulties but continuing to take valued action (psychological flexibility) should positively correlate with increased quality of life.

The negative relationship between greater distress and greater psychological flexibility at baseline are consistent with previous findings that those with SPMS cope better when they are more

psychologically flexible and more able to accept and adapt to their diagnosis (Meek et al., 2020), and this finding fits well with the existing literature and adjunct questionnaire study.

4.8 Extended Strengths

In addition to the use of a range of methodologies applied (framework analysis, group level, and individual level analysis) and data collected (measures, interview) mentioned in the short paper, an additional strength is of course that this trial was a randomised controlled trial (RCT), the gold standard when assessing the effectiveness of an intervention (Sibbald & Roland, 1998). This method allows us to account and mitigate for placebo effects and external factors which may give us false positive or negative effects associated with trial participation.

A secondary strength of this study referenced in the short paper but not elaborated upon here is the excellent rates of measure response and lack of attrition, which stands out as excellent amongst other feasibility trials where you would expect a significant rate of attrition and missing data (Whitehead et al., 2016). This success is attributed to the relationship built with participants in the trial, even those in the control conditions, by the initial face-to-face meeting. There seems to be something inherently powerful about meeting someone face-to-face, and additionally taking the time to drive to their house; even if it is a long distance away. It may demonstrate the effort shown to include the client which they may not receive from other services, and understanding the sacrifice made by the researcher may increase their loyalty and determination to see the study through. This effort was also shown with individually addressing and posting the questionnaires and providing a stamped envelope to reduce the participant burden as much as possible.

4.9 Extended Limitations

The two main limitations of the study have been covered in the short paper; these are the failure of the recruitment strategy to achieve the expected sample and the failure of the intervention to demonstrate efficacy. With the first limitation, it is simpler to identify how to remedy this (we know that recruitment rate is too low, and we have identified options for increasing the recruitment rate). The second one however is a more damning limitation as the intervention has been shown to be ineffective on the measures, but we have no definitive understanding of why this is. The problem could conceivably be the teletherapy, bibliotherapy, or ACT model (although there is refutational evidence for efficacy of all of these in the literature), the therapist delivery (although a fidelity measure found this consistent with the model, the clinical psychologist fidelity checker was a supervisor on the project and therefore may have been positively biased), individual differences among our small sample or a combination of each of the above. Therefore, it is very difficult, unlike the first weakness, to know exactly what to target for change.

Sample limitations such as having a lack of BAME participants in the trial, which is not representative of the UK MS population (Alsaeed et al., 2018), and also having an unrepresentative control group in the feedback interviews are weaknesses of the study. In addition, a lack of service user involvement in the design of the intervention (i.e. building the workbook) and the recruitment process which was a recommendation of Proctor, Moghaddam, Evangelou, et al. (2018) may have impacted on the difficulties with the recruitment process and is a further limitation. A further limitation also related to recruitment was the difficulty in engaging clinicians at the Neurology service in this process (and them providing referrals), despite efforts to do so. Further explanation and advertising of the study to clinicians may have been a necessary missed step to improve recruitment.

A final limitation is the Trial Manager was acting in several roles during this study. As the recruiter, therapist, data collector, analyst and author, the data collected is prone to bias which is a study limitation. This bias may come from the participants themselves (i.e. at interview, they may feel

more connected to the Trial Manager, and less willing to criticise), or the Trial Manager (i.e. interpretation of qualitative interview data being influenced by knowledge of the participant from the therapy sessions, write-up being skewed by the experiences in the trial). Steps were taken to try and reduce this bias (such as joint analysis, and a colleague completing feedback interviews), but this remains a limitation of the study. It is difficult to rectify without the resource of paid assistance, but further steps could be taken (i.e. two trainees could analyse each other's qualitative feedback interviews completely independently, reducing bias).

4.10 Directions for Future Research

In brief, a future trial using this methodology is not recommended or feasible. Certain aspects, such as the trial recruitment need changing, and there are some methods suggested to address this. However, the key finding is that the ACT-Based intervention did not demonstrate the ability to change psychological flexibility (and as this was the target of change, other measures did not change either). There were very promising elements of the intervention and methodology such as no attrition or missing data. These methods can be applied to future research to achieve similar findings.

It is premature to abandon ACT-based interventions in SPMS, however. They have shown promise in similar conditions and the intervention group participants in this study reported their experience as *beneficial* – it just did not lead to change on measures. Future ACT-based interventions in SPMS should ensure that they are evidenced in targeting psychological flexibility. One way of doing this would be to use previously evidenced methods of using ACT or developing an alternative SPMS specific ACT text. It may also include being more prescriptive to ensure that the ACT model is covered – striking more of a balance between the very flexible approach to ACT used in this study (which meant that some aspects of the model may have been missed) and the very manualised approaches used in others. The fidelity checking for a future study could be improved if it was completed by an independent party, rather than a project supervisor.

4.11 Ethical Reflection

An element of the procedure for the screening of participants would not be suitable to use in future studies. In this trial, the participant gave consent to be contacted to their Neurologist in clinic, which was passed to the Trial Manager. At this point, the Trial Manager then telephoned the participant and asked some screening questions to see whether they were interested and would be suitable (before sending out the pack of forms, including the consent form). This included a brief screening of distress (i.e. asking how they were coping, or some of the HADS questions informally).

This was to avoid the participant filling in a pack of several forms before screening them and then having to tell them they were ineligible, and that they had wasted their time. However, this procedural element was problematic as the participant had not yet consented to the study and was giving personal information related to distress. Although this did not lead to difficulties in this study, this could conceivably lead to myriad of difficulties (i.e. the participant disclosing risk information). A solution to this would be to telephone the participants to simply inform them that the information sheet and consent form had been sent through (either by letter or giving them an online link). Once this had been returned, the Trial Manager could talk to the participants more fully and send the pack of questionnaires separately.

4.12 Psychological Flexibility and Distress in SPMS Questionnaire

This questionnaire achieved some important significant novel findings. Most importantly, it demonstrated that in SPMS specifically, psychological flexibility was negatively correlated with distress (r = -0.65) anxiety (r = -0.55) and depression (r = -0.56). This means that it can be considered

logical to aim to increase psychological flexibility in this population and expect this to reduce distress. Interventions and therapies to increase psychological flexibility are justified, however they should be modified from the intervention used in the trial.

The questionnaire also demonstrated that when compared to a reference group of a non-clinical sample (Masuda & Tully, 2011), the relationship between psychological flexibility and distress is considerably more strongly correlated in the SPMS sample (SPMS: r = -0.65, non-clinical: r = -0.46). This might be because the questionnaire also found that psychological flexibility is lower, and that anxiety and depression are more severe in the SPMS sample than in a reference group non-clinical sample. This suggests that ACT may be a more important target in an SPMS population, than a non-clinical population as increasing psychological flexibility will have an increased effect in reduction of distress.

The biggest strength of this study is the large sample, which allows the measurement of separate subcomponents of psychological flexibility against the components of distress to identify and compare the strength of the relationships. However, this questionnaire study has some key limitations. Firstly, it is only completed at one timepoint, and therefore we are unable to measure the strength of the relationship between psychological flexibility and distress as they each change. Secondly, the measures were not always completed at the same timepoint. The CompACT measures were all completed very recently, as were *most* of the HADS, but some of the HADS comparisons are 1+ years old. This discrepancy may reduce confidence in the conclusions drawn as distress may have changed over time. These limitations should be addressed with a second timepoint planned soon.

5. Reflective Section

This reflective piece will comment on the author's response to the findings of the project, the scope of the project, and the writing of the manuscript in the current conditions.

5.1 The findings

As a clinical psychology trainee, I am trained to be a scientist-practitioner as well as a reflective-practitioner. In practice, this means keeping a neutral view when reporting the scientific evidence, whilst also reflecting on and acknowledging the emotional impact of the process on myself as a human being. In this thesis, I reflect below on my feelings of disappointment at the results.

Not only did the (lack of intervention efficacy) results make for a difficult write up fraught with confusion, as I concluded that the intervention had not worked, but that I didn't know why – it also led to other uncomfortable feelings. Firstly, I have been doing this project for three years, and dedicated hundreds upon thousands of hours of my life towards its completion. It seems deeply unsatisfying to therefore conclude "it didn't work, not sure why". I am of course aware that the purpose of the project was fulfilled; we know it isn't feasible, there are some messy recommendations, and I think I have demonstrated doctoral research skills to let everyone know, but it does feel somewhat unfulfilling on a personal level. I reflected on Plato's account of a quotation from Socrates; 'I know that I know nothing'; despite many lonely pages, questions remain unanswered and this is saddening.

I tried to save myself and explain away the null results using the qualitative feedback; "the measures weren't sensitive enough – we should go on the great interviews" (without evidence on measure sensitivity, of course). I was quickly reigned in by my supervisors wearing their more neutral hat forcing me to face my null results of doom. I felt frustrated by the post-positivist epistemological position I had taken, as this position assumes there is one truth to be found, and therefore concluding with ongoing uncertainty feels like I did not attain it.

Not only unfulfilled, I knew that also these results directly reflected on me as the therapist delivering the intervention, and that was tough. I had dedicated 6 weeks of therapy to each participant, and it was difficult to separate null results from null therapeutic skill. It felt like not only was it a test of ACT, the workbook and the structure of the sessions, but also of my therapeutic and clinical acumen. Thankfully, I am aware of these thoughts, and as Joe Oliver would say in his Unwanted Party Guest metaphor, I will invite them in and let them stay for drinks.

5.2 The scope of the project

I always seem to make more work for myself than I need to. If I'm writing an essay, I always seem to land on choosing a psychological model I barely know and must rush to learn it whilst under my breath rueing the missed opportunity of another CBT formulation. Naturally, the thesis was no different. Without necessity, I pressed on with recruiting and supervising a MSc student and arranging a 700-odd person questionnaire on the side, keeping myself on my toes. This is a difficult element of my make up; it helps to reduce my anxiety that I won't have done enough, whilst taking me away from important things like spending time with those I care about. Reigning myself in and pulling away from work can be hard, and often takes support and reminders from those around me ("your eyes look bloodshot"). Future me plans to share this tendency with supervisors and leave work before 5. Not at 8, whilst squeezing in a PhD at the weekend.

5.3 Writing the manuscript

'This coronavirus pandemic has come at a handy time' was my first thought, however I quickly realised that there was a downside to writing a thesis but being unable to leave the house. My usual strategies for de-stressing; playing tennis, going to the gym - that's about it - went out the window. I have decided in the last few weeks to take part in a weekly 2-hour mindfulness intervention with the NHS trust I work for (see first line, 5.1.2.), but nothing helps de-stress me like exercise. As I write the final lines of this thesis, I very much look forward to taking my new rolls and emaciated legs on a few more runs round the block.

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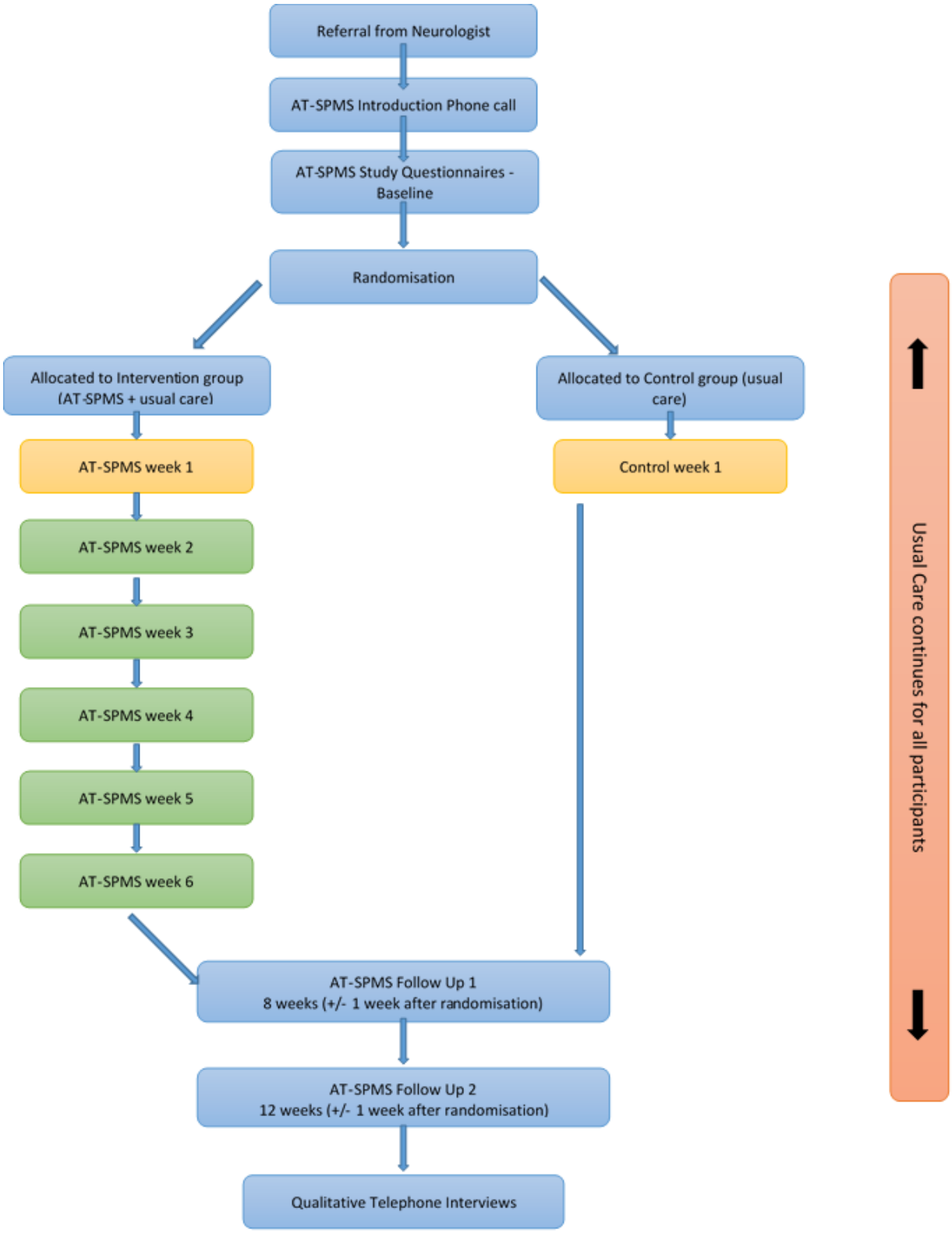
Appendices

Appendix A: CONSORT Checklist

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	6-7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	7
Sample size	7a	How sample size was determined	7 (+EP)
	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	8 (+EP)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8 (+EP)
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	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	15, 16
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	12, 13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	19
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	18
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	22-25
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22-2
Other information			
Registration	23	Registration number and name of trial registry	11
Protocol	24	Where the full trial protocol can be accessed, if available	11
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also

Appendix B: Schematic Diagram + Study Flowchart



CONSENT TO CONTACT FORM
(Final Version 2.0: 17.05.19)

Title of Study: Acceptance Based Telephone Support when Transitioning to SPMS

IRAS Project ID: 257248

Name of Researcher: Christopher Meek

Please initial box

1. I consent for the above researcher to contact me by telephone to tell me about a research study at the University of Nottingham I may be interested in. It does not mean I have to take part. ☐

2. I understand that my participation in any research is voluntary and I am free to withdraw at any time. ☐

3. I understand that my telephone number will be stored at the hospital on this form, and the above researcher will come in person to collect it and phone me whilst at the hospital. If I choose to take part, the sheet will be transported and stored securely at the University of Nottingham for 12 months. If I do not want to take part, this sheet will be not be transported from the hospital, and disposed of securely as a confidential document. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Telephone Number(s) to contact on:

Home: _____

Mobile: _____

Preferred days to contact (tick)		Preferred times to contact (tick)	
Any	☐	Any	☐
Monday	☐	AM	☐
Tuesday	☐		
Wednesday	☐	PM	☐
Thursday	☐		
Friday	☐		

Appendix D: Participant Information Sheet

Participant Information Sheet

(Final Version 2.0: 17.05.19)

IRAS Project ID: 257248

Title of Study: Acceptance Based Telephone Support when Transitioning to SPMS

Name of Chief Investigator: Roshan das Nair

Local Researcher(s): Christopher Meek, Nima Moghaddam, Gogem Topcu, 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?

People with Multiple Sclerosis often tell us that they feel less support is available after they are diagnosed with Secondary Progressive Multiple Sclerosis, compared to before they received this diagnosis. People sometimes experience a lessening of support, despite their physical symptoms becoming more severe from both professionals and those in their personal lives. The purpose of this study is to see whether providing some telephone support to those who have recently received a diagnosis of Secondary Progressive Multiple Sclerosis is experienced as helpful and is possible to do practically. This study will help us understand which type of support may be helpful for patients like you in the future and may pave the way for larger studies and changes to NHS provision.

Why have I been invited?
You are being invited to take part because you have recently transitioned to Secondary Progressive Multiple Sclerosis. We are inviting 40 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 be given this information sheet to keep and be asked to sign a consent form. 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?
You will have already been asked by your Neurologist or MS Nurse to take part in the study and have provided written consent to be contacted, which will be stored by the research team. Your details were passed to the study team at the University of Nottingham, who telephoned you within a week to tell you a bit more about the study and ensured you were suitable for the study by asking you some questions. You have received this information sheet because you are interested and suitable

for the study. We will now send you some paper or online questionnaires to complete and return. After this, the researcher will come and visit you face to face to introduce themselves and tell you more about the study. They will also tell you what "group" you have been randomly put into. There are two groups. We would ask those in the first group to commit to receiving a 30 minute support phonecall each week for five weeks in addition to any usual care, and the second group will receive their usual NHS care. The support phonecalls will draw from techniques used in a type of psychological therapy (acceptance and commitment therapy). All the phonecalls can be done whilst you are at home or in a quiet place of your choosing. After this, both groups will fill in some more paper questionnaires eight and twelve weeks after the start of the study. We expect that you will be involved in the study for around 4 months, and a flow chart of a participants journey in the study can be found at the end of this information sheet.

Expenses and payments
You will not be paid to participate in the study. Travel expenses will however be offered for any visits incurred as a result of participation.

What are the possible disadvantages and risks of taking part?
We do not foresee any serious risks to taking part in this research. However, discussing your problems may evoke some emotional discomfort in some people. A disadvantage may be the time necessary to take part in the study and answer the phonecalls.

If you feel like you are struggling, you may like to consider the following support:

Trial manager	Contact details on the last page (may need to leave a message)
Samaritans	Call: 116 123 (Free, 24/7), Email: jo@samaritans.org
MS Society Helpline	Call: 0808 800 8000 (Free, Mon-Fri, 9-7), Email: helpline@mssociety.org.uk
NHS Non-Emergency	Call: 111 (24/7)
Your GP	

What are the possible benefits of taking part?
You may find receiving the telephone intervention helpful. We cannot promise the study will help you but the information we get from this study may help us to improve the intervention offered to better help others with Secondary Progressive Multiple Sclerosis in the future.

What happens when the research study stops?
Once the research study stops, we will start to analyse the data of the study at the University. If you would like to know the results of the study, we will need to hold on to your contact details until they are ready, and we will ask for your consent for us to do this. We will hold on to your details for 12 months, and after we have told you what we found, your details will be deleted.

We will also conduct some feedback interviews. You may be asked whether you would like to tell us how you found the study over the telephone to a researcher independent from the project for up to 30 minutes. A separate consent form and information sheet will be provided at this point specifically for this.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the Trial Manager who will do their best to answer your questions. The Trial Managers 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 Queens Medical Centre Patient Advice and Liaison Service on: 0800 183 0204

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs.

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, we will use information collected from you during the course of the research. This could include your completed questionnaires, and relevant questions about your medical history for example. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally identifiable information possible. Your GP will be informed that you are taking part in the study.

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

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

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

Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the study findings (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. 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 given permission by the data custodian will have access to your personal data, and a unique identifier will be used in place of your name, to ensure you cannot be identified by any materials used in the study.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we will have to report this as appropriate. We will always inform you if we plan to do this.

The Trial Manager may request to record a telephone session to ensure that the programme is being delivered as intended, or to record your consent. This will always be with your permission, and you can refuse without it affecting your participation in any way. If your session is recorded, the recording will be taken and stored securely at the University of Nottingham and be immediately transferred from the Dictaphone to a secure, encrypted protected server within 24 hours. It will be stored for a maximum of 3 months, until it is it transcribed anonymously. The recording will then be permanently deleted, and the transcription will be kept with the research data for 7 years.

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. You can withdraw immediately by contacting the trial manager. Alternatively, we will automatically withdraw you if we are unable to contact you by telephone on three consecutive occasions without a response, as we will assume you are no longer interested in participating. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?
The results of this research will be submitted to the University of Nottingham by the trial manager (Christopher Meek) as part of an educational requirement for his studies. As we store your contact details for 12 months following the study, you will be contacted on the number held by telephone to ask whether you would like to receive a summary of the findings. You can also request a summary of the findings from the team using the contact details below. You will not be identified in any report or publication.

Who is organising and funding the research?
This research is being organised by the University of Nottingham and is being funded by Health Education East Midlands.

Who has reviewed the study?
All research in healthcare 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 the Preston Research Ethics Committee.

Further information and contact details

Trial Manager: Christopher Meek

Email: christopher.meek@nottingham.ac.uk

Phone (Best): 07895 080021

(if no answer, please feel free to leave a message or send a text and I will respond as soon as possible)

Chief Investigator: Roshan das Nair

Email: roshan.dasnair@nottingham.ac.uk

Phone: +44(0)115 8230589

CONSENT FORM
(Final Version 2.0: 17.05.19)

Title of Study: Acceptance Based Telephone Support when Transitioning to SPMS

IRAS Project ID: 257248

Name of Researcher: Christopher Meek

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.0 dated 17.05.19 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 medical care or 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. ☐
3. I understand that relevant sections of my 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 understand that any details I share with the study team will be kept confidential, unless it presents a risk to myself or others. In this case, the study team reserve the right to share the minimum relevant information to maintain my safety or the safety of others. ☐
5. I agree to my GP being informed of my participation in this study. ☐
6. I understand that the results of this research study will be submitted by the Trial Manager as part of an educational requirement for his studies, but I will not be identified in any submission, report or publication ☐
7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes

Appendix F: Patient Information Sheet: Interviews

Participant Information Sheet: Interviews

(Final Version 2.1: 07.06.19)

IRAS Project ID: 257248

Title of Study: Acceptance Based Telephone Support when Transitioning to SPMS

Name of Chief Investigator: Roshan das Nair

Local Researcher(s): Christopher Meek, Nima Moghaddam, Gogem Topcu, Nikos Evangelou

We would like to invite you to take part in our feedback interviews in relation to the study. Before you decide we would like you to understand why the interviews are 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 interviews?
The purpose of the interviews is to give you an opportunity to feedback how you experienced being a participant in the study. Your responses will help the researchers understand your experience, and help them use this to think about how to adapt similar studies in the future.

Why have I been invited?
You are being invited to take part because you have taken part in the *Acceptance Based Telephone Support when Transitioning to SPMS* study. We are inviting 12 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 be given this information sheet to keep and be asked to sign a consent form. 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 choose to take part, we will first ask you to sign a consent form. Then, we will arrange a time with you where you would be available for a researcher to contact you for up to 30 minutes over the telephone. You can therefore take part in the interviews without leaving home.

When the researcher telephones, they will confirm that you remember reading this information sheet and signing the consent form, and offer you a chance to ask any questions. They will then explain that the interview will last for a maximum of 30 minutes, and that this will be recorded. They will explain that the recording will be kept safely on a secure dedicated web server, and be password protected, and the recordings will be destroyed as soon as they are transcribed (written down).

The researcher will then begin the interview and tell you that he will start the recording. He will ask you about your experience of being in the study, for example: *How did you find taking part in the study?, Were the telephone calls too frequent, not frequent enough, or just right?*. The researcher may ask you follow up questions, for example: *Could you tell me a little bit more about that?*

Once you have answered the questions the interview will end and the recording stopped. You will be thanked for your time.

Expenses and payments
Participants will not be paid to participate in the interviews.

What are the possible disadvantages and risks of taking part?
There should be few disadvantages or risks of taking part in the feedback interviews. However, a disadvantage may be that you need to dedicate 30 minutes of your time. In addition, some people may find talking about their experiences upsetting.

If you feel like you are struggling, you may like to consider the following support:

Trial manager	Contact details on the last page (may need to leave a message)
Samaritans	Call: 116 123 (Free, 24/7), Email: jo@samaritans.org
MS Society Helpline	Call: 0808 800 8000 (Free, Mon-Fri, 9-7), Email: helpline@mssociety.org.uk
NHS Non-Emergency	Call: 111 (24/7)
Your GP	

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 design better ways of helping people similar to you in the future following the SPMS diagnosis. In addition, by participating a charitable donation will be made to the MS Society.

What happens when the research study stops?
After the completion of the interviews, the recordings taken will then be transcribed (written down) by a transcription service, and the recordings destroyed. The transcriptions will be anonymised and analysed by the researchers.

If you would like to know the results of the study and the interviews, we will need to hold on to your contact details until they are ready, and we will ask for your consent for us to do this. We will hold on to your details for 12 months, and after we have told you what we found, your details will be deleted.

What if there is a problem?
If you have a concern about any aspect of these interviews, 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 Queens Medical Centre Patient Advice and Liaison Service on: 0800 183 0204

In the event that something does go wrong and you are harmed during the interviews and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs.

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 participate in the interviews, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a secure server at the University of Nottingham. All interview recordings will be **taken and stored** securely at the University of Nottingham and be immediately transferred from the Dictaphone to a secure, encrypted protected server within 24 hours. It will be stored for a maximum of 3 months, until it is it transcribed anonymously (with names and personally identifiable information removed). The recording will then be permanently deleted, and the transcription will be kept with the research data for 7 years.

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

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

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

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

After you participate in the interviews, you will be assigned a unique identifier (code) which will ensure you cannot be identified by any of the materials used in the study.

Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the findings of the (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. 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 given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we will have to report this as appropriate. We will always inform you if we plan to do this.

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 we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. Anonymised quotes may be used from your interview in the final study reports, however you can refuse use of any quotes by informing the Trial Manager within 3 months of your interview taking place. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What will happen to the results of the research study?
The results of this research will be submitted to the University of Nottingham by the trial manager (Christopher Meek) as part of an educational requirement for his studies. The research team will also seek to publish the study in an academic journal in 2020/2021, and you will be contacted by telephone to ask whether you would like to receive a summary of the findings. You will not be identified in any report or publication.

Who is organising and funding the research?
This research is being organised by the University of Nottingham and is being funded by Health Education East Midlands.

Who has reviewed the study?
All research in healthcare 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 Preston Research Ethics Committee

Further information and contact details
Trial Manager: Christopher Meek

Email: christopher.meek@nottingham.ac.uk

Chief Investigator: Roshan das Nair

Email: roshan.dasnair@nottingham.ac.uk

Phone: +44(0)115 8230589

CONSENT FORM
(Final Version 2.1 07.06.19)

Title of Study: Acceptance Based Telephone Support when Transitioning to SPMS: Feedback Interviews

IRAS Project ID: 257248

Name of Researcher: Christopher Meek

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 2.1 dated 07.06.19 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 medical care or 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. ☐

3. I understand that the feedback interview will be recorded and that anonymous direct quotes from the interview may be looked at by authorised individuals from the University of Nottingham research group and may be used in the study reports. I give permission for these individuals to have access to this transcript 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 understand that any details I share with the study team will be kept confidential, unless it presents a risk to myself or others. In this case, the study team reserve the right to share the minimum relevant information to maintain my safety or the safety of others. ☐

5. I agree to take part in the above feedback interviews. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Interview Schedule Questions
(Final 2.1, 10.01.20)

Hi, my name is _____, is this _____? I understand you took part in the research study recently with Chris? (*if yes: continue*)
Thank you for taking part. My name is _____ and I have been asked to gather some independent feedback from you about the study following you giving written consent on xx/xx/xx.

Have you had a chance to read the information sheet? Do you have any questions about this? Please be aware that for the purposes of the research, we will need to record the interview today, but we will keep this recording safe and delete the recording as soon as we have written it down.
(if not read information sheet, ask if they would take a few minutes to read through it. If they do not have it, read the information sheet verbally over the telephone)

Do you still consent, and are you happy to continue?
(if yes, continue, if no, attempt to address any concerns the participant may have. Thank them for their time and abandon interview if they still refuse)

In this telephone call I would like to ask you about your experience of the study, and it may take up to 30 minutes. Is now a good time; will you be available for the next 30 minutes? (*if yes, continue*).

Both groups:

1. How did you find taking part in the study?

2. What was it like being in the telephone support/control condition?

If in telephone support group:

3. What was helpful/unhelpful about the telephone support, if anything? (Prompts: best, worst parts, things valued, things not valued)

4. What changes have you noticed in yourself since therapy started?

5. Were telephone calls too frequent, not frequent enough, or just right?

6. Were telephone calls too long, too short, or just right?

7. How did you find completing the homework tasks set between sessions? (Prompts: did you complete them/too difficult/easy/motivation/forgetting?)

8. Did you receive other support outside the study other than the study phone calls?

    a. If so, what kind of support? (i.e., family, friends, professionals) (physical, emotional)
    b. If so, how frequent?

If in control group:

9. How did you find the usual care you received?

10. How did you feel when you were told you would not receive the telephone calls? (Prompts: disappointed, unphased)

11. Did you receive any other support outside of the study whilst taking part?

    a. If so, what kind of support? (i.e., family, friends, professionals) (physical, emotional)
    b. If so, how frequent?

Both groups:

12. How did you find completing the questionnaires? (Prompts: simple, difficult, posting letters, completing online questionnaires)

13. If you were to compare your quality of life now to before you began the study, would you say it is better, worse, or about the same?

14. If you were to compare your general mood this week to before you began the study, would you say it is a better, worse, or about the same?

15. What has it been like for you being involved in the research?

Appendix I: Workbook Sample, Booklet Introduction (Pages 1-4)

University of Nottingham
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AT-SPMS
Acceptance Based Telephone Support when Transitioning to SPMS

Better living after transitioning to SPMS

Patient Workbook

This workbook was developed by the AT-SPMS Research team members at the University of Nottingham in collaboration with the University of Lincoln. November 2018.

Contents

Preface

This workbook is part of the AT-SPMS Emotional Support Programme which aims to support people during the transition to SPMS. This workbook was developed based on the research evidence, consultations with stakeholders, Patient and Public Involvement input and our clinical experiences. The workbook uses Acceptance and Commitment Therapy (ACT)[1] as the basis and includes exercises which are based on materials from previously designed guided self-help formats for ACT[2-4].

[1]Hayes, et al. (1999). Acceptance and commitment therapy: an experienced approach to behaviour change. New York: Guildford Press.
[2]Brassington, et al. (2016). Better living with illness: a transdiagnostic acceptance and commitment therapy group

Section 1 Introduction

Living with a diagnosis of SPMS

We'd like to understand more about your experiences living with SPMS. If it helps, you can use this space to write a bit about how having SPMS is impacting on your life right now:

Appendix J: Readability Consensus

Readability Consensus

Based on (7) readability formulas, we have scored your text:

Grade Level: 8
Reading Level: fairly easy to read.
Reader's Age: 12-14 yrs. old (Seventh and Eighth graders)

Analysed Text

Page 2:

Most people with SPMS have tried different things to cope with their symptoms and come to terms with their change in diagnosis. Take some time to think about what you have tried. Use the worksheet on the next page to list the treatments and strategies that you have tried. Next, think about how these treatments and strategies have benefitted you over the short and long term. You may want to write about benefits in the form of pain relief, improved mood, reduction in symptoms, greater ability to function, relationships, etc. Also, think about any difficulties associated with these strategies and treatments. What have the strategies cost you over both the short and long term? It may be money, time, energy, additional health problems, or loneliness, to name but a few. While you are doing this, try to focus on why these strategies or treatments worked or did not work. Was it that they didn't change your health, or improved or worsened it? Side effects? Did any of them help you do more of the things you wanted to do?

Page 22:

5 senses of mindfulness. Here's a simple way of getting present. We have five senses: seeing, hearing, smelling, touching, and tasting. Day to day you can use all your senses to bring your attention to what is going on around you; from taking a shower to preparing a meal. In the next hour or so, pick three situations to be 'mindful' with. This shouldn't require much effort because you would have been doing the tasks anyway. It's just that this time we want you to practice doing it mindfully. Below we have given an example of how to mindfully wash your clothes. It's a task that is so routine that we would normally allow our mind to wander. See if you can become more mindful the next time you wash your clothes.

Page 42:

Clarifying values. See if you can take a few minutes each day to focus on one of the values that you've noted above and choose something that you could do, perhaps something very small that would take you towards living your values. There is a worksheet on the next page that you can use to keep a note of the steps you take over the next week in your valued direction.

Appendix K: Example Monthly Newsletter

University of Nottingham
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AT-SPMS Monthly Newsletter, February

NHS
Nottingham University Hospitals
NHS Trust

Hi Roshan, Nikos, Nima, Rod, Gogem, Chris, and Sophie,

This is the fourth monthly update *[no January update]* of the AT-SPMS (Acceptance Based Telephone Support in Secondary Progressive MS) project.

As a recap, we currently see this project as having three related parts, each with ethical approval.

1:	2:	3:
Online Questionnaire examining the link between psychological flexibility and distress in those with SPMS	A feasibility RCT using a psychological therapy (Acceptance & Commitment Therapy), to increase psychological flexibility	Qualitative interviews with participants in the trial What worked, what didn't?

Target deadlines: Finish recruitment (feasibility study): Jan, 2020, Submit for publication: June, 2020

Updates

1:

The Online Questionnaire is live and is currently being completed by those with SPMS! Excellent, thanks Rod! Katie at the MS Register will be providing regular updates with numbers completed.

2:

The feasibility RCT is closed to recruitment. We ended up recruiting 14 participants (7 therapy, 7 control). Although we did not hit the numbers we'd hoped; we have information now about the potential rate of recruitment from one site.

Every participant therapy session has now been completed. Promisingly, there was no drop out OR missed therapy sessions (42/42 phonecalls completed [3 rearranged]). Post- outcome measures have been collected for 11/14 participants so far (the remaining three have only recently had their outcomes sent to them, so I'm hopeful for a 100% return rate). The fidelity of the telephone sessions has been assessed by Nima and judged to be ACT-compliant.

3:

The interviews are underway! We have completed three interviews so far – and we hope to complete at least another three, however it has been slightly harder to engage completers in this. Sophie has worked hard to transcribe the three interviews we have, and we have some promising feedback as the therapy seemed to be well received. In addition, Nikos sent a lovely text this week saying how someone went into the clinic and mentioned their positive experience to him!

Thanks everyone for your continuing support. Besides our overestimating the recruitment rate, the study seems to have worked well. Full results should be available in a few months.

Key contacts in the AT-SPMS Team

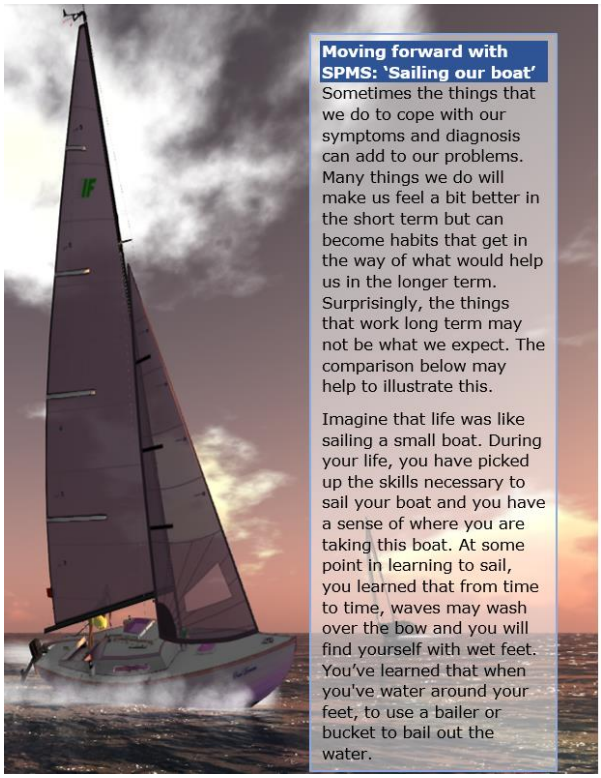
Christopher Meek (Trial Manager), Nikos Evangelou, Roshan das Nair, Nima Moghaddam, Christopher Allen, Gogem Topcu, Rod Middleton, Sophie Harrison

Appendix L: Fidelity Criteria

ACT-FM Criterion	Description
Psychologist Stance	The stance taken by the psychologist is equal, compassionate and non-judgemental. The psychologist should show empathy and warmth and be guided by what the patient brings. The psychologist does not try to change the patient's mind, but to guide noticing of their own experience. The psychologist encourages responsibility, focuses on context, and models psychological flexibility in their responses and behaviour.
Aware Response Style	This is the ability to flexibly contact the present moment. The psychologist may encourage the patient to take an observer perspective on their psychological experiences, when doing so helps increase the effectiveness of patient behaviour.
Open Response Style	This is the ability to open-up to experiences, and to observe and describe these without becoming entangled in them or trying to diminish them. The psychologist might promote patient willingness to sit with difficult thoughts, emotions, or sensations, when in the service of their values and goals. They might help patients to notice or distance themselves from their thoughts (not allowing thoughts to become a barrier to effective action).
Engaged Response Style	This is the ability to identify, clarify and act according to one's values on an ongoing basis. The psychologist might give the patient opportunities to identify their values. They may help the patient to define goals and actions that support their values, and to plan and do these actions.

AT-SPMS fidelity assessment

Criteria	Call	Response			
Did the psychologist 'check in' with the participant?	1	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	2	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	3	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
Did the psychologist refer to and support use of the patient workbook?	1	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	2	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	3	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
Were psychologist contributions consistent with our ACT-based approach to emotional support?*	1	☐ No (0)	☐ Somewhat (1)	☐ Mostly (2)	☑ Yes (3)
	2	☐ No (0)	☐ Somewhat (1)	☐ Mostly (2)	☑ Yes (3)
	3	☐ No (0)	☐ Somewhat (1)	☐ Mostly (2)	☑ Yes (3)
Was any support inconsistent with this model?* [Reverse-scored]	1	☑ No (2)	☐ Somewhat (1)	☐ Yes (0)	
	2	☑ No (2)	☐ Somewhat (1)	☐ Yes (0)	
	3	☑ No (2)	☐ Somewhat (1)	☐ Yes (0)	
Was the psychologist suitably flexible and responsive to issues raised by the participant?	1	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	2	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	
	3	☐ No (0)	☐ Somewhat (1)	☑ Yes (2)	



Moving forward with SPMS: 'Sailing our boat'

Sometimes the things that we do to cope with our symptoms and diagnosis can add to our problems. Many things we do will make us feel a bit better in the short term but can become habits that get in the way of what would help us in the longer term. Surprisingly, the things that work long term may not be what we expect. The comparison below may help to illustrate this.

Imagine that life was like sailing a small boat. During your life, you have picked up the skills necessary to sail your boat and you have a sense of where you are taking this boat. At some point in learning to sail, you learned that from time to time, waves may wash over the bow and you will find yourself with wet feet. You've learned that when you've water around your feet, to use a bailer or bucket to bail out the water.

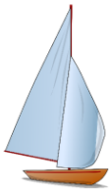
So, you've learned about the bailer, but when it's not needed it has been put away in a locker. At some point along your journey waves have come over your boat and there is now water in the bottom of your boat. So, you have started to do the thing that is sensible and logical to do: get rid of the water.

You have been using that bailer a lot, sometimes bailing quickly, sometimes bailing carefully, sometimes bailing wildly, sometimes bailing desperately. In your experience, have you managed to get rid of the water yet? All this time that you have been bailing, what has been happening to the direction and progress your boat has been making? Is it fair to say that you have been bailing more than you have been sailing this boat? The promise of bailing is this: once you get rid of the water, then you'll get this boat back on track and start sailing it where you want it to go.

What if you were able to let go of needing to get rid of the water, and begin to look up from the bailing and look out in front of the boat and actually choose a direction that you want to take this boat? What if this workbook could be about helping you to put both hands back on the wheel and to choose to pull in the sails and get the boat moving in whatever direction you choose? This could be very slowly at first, there is no speedometer in this work. Once you get the boat moving, then you might be able to investigate some other ways of bailing; if they prove to be useful strategies in helping you to take this boat where you want it to go.

The question to ask yourself is this; would you rather have a boat with only a little water in the bottom – but it is drifting and you are not choosing the direction you sail – or would you want a boat which has water in the bottom, maybe sometimes so much water that you wonder how it is still afloat, but you are taking this boat, however slowly, in the direction that you would most want to take it? Being willing to be wet while we journey where we want to go is a bit like doing what's important to us even though we have MS.

We will look at what 'direction' means in Section 3. This involves living towards your values – the things that are important to you and setting achievable goals along the way.



Appendix N: Advert for MS Charities

Email Invitation – Feasibility Trial

[Organisation Name]

Dear [Sir/Madam/Named Contact]

My name is Christopher Meek, and I am a final year Trainee Clinical Psychologist at the University of Nottingham under the supervision of Professor Roshan das Nair. I am currently running a research study for those with Secondary Progressive Multiple Sclerosis. Receiving this diagnosis for many means the loss of disease modifying treatments, less contact with services, and greater psychological distress. The purpose of the study is to determine whether providing some brief psychological support shortly after the point of transition (from RRMS, to SPMS) would be feasible and helpful. If so, this could pave the way for further, larger research studies.

To do this, I will invite 40 people with SPMS, within 1 year of receiving this diagnosis, to take part. These people will then be randomised to one of two study groups. Both groups will be asked to fill in some questionnaires and have an initial meeting either in person, or over Skype. Group 1 will then receive five telephone psychological support phonecalls (each of 30 minutes each), and Group 2 will receive usual care. It is hoped that the psychological support phonecalls may be found to be helpful. I have attached an information sheet with more information for your convenience. This study has received ethical approval from the University of Nottingham Ethics Committee [25/09/19]

I therefore wondered whether you could recommend ways of distributing information about this study to your members (e.g. newsletter, email, social media)? Recruitment is open immediately but will close early next year. An example advert is included below.

Best wishes,
Christopher Meek
Trainee Clinical Psychologist
Room B16, Yang Fuijia Building, Jubilee Campus
DClinPsy - Division of Psychiatry and Applied Psychology (School of Medicine)
The University of Nottingham

Study Advert

Have you recently been diagnosed with Secondary Progressive Multiple Sclerosis?
A University of Nottingham research team are hoping to speak to those who have been diagnosed with SPMS in the last year to see whether brief psychological support would be helpful. If you think you might be interested, please text Chris (Researcher) the word "Interested" on Study Mobile Number: 07453786033 and he will contact you to tell you more and give you the opportunity to answer any questions you may have.

Appendix O: Ethical Approval, University of Nottingham

University of Nottingham
UK CHINA MALAYSIA

DPAP Committee

25/09/2019

Supervisor: Roshan das Nair

Applicant : Christopher Meek

Project: Project Id Acceptance Based Telephone Support when Transitioning to SPMS

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

If it is proposed that if an approved project is subsequently subject to any significant change (for example to the date or place of data collection, or measures used), an Amendment Form should be submitted. This can be done in 'Create Sub Form' in the Actions Menu on the left hand side of the page on the on-line system: Select 'Amendment Form'.

yours

David Daley

Professor David Daley

Co-Chair of DPAP Ethics Subcommittee

Amanda Griffiths

Professor Amanda Griffiths

Co-Chair of DPAP Ethics Subcommittee

Page 1 of 1

Appendix P: Ethical Approval, National Health Service

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Roshan das Nair
B19, Institute of Mental Health
Innovation Park, Triumph Road
University of Nottingham
NG72TU

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

10 June 2019

Dear Professor das Nair

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Acceptance Based Telephone Support around the time of Transition to Secondary Progressive Multiple Sclerosis: A Feasibility Randomised Controlled Trial**
IRAS project ID:	**257248**
Protocol number:	**19019**
REC reference:	**19/NW/0261**
Sponsor	**University of Nottingham**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Appendix Q: Ethical Approval, The MS Register

United Kingdom Multiple Sclerosis Secure e-Research Platform

DATA ACCESS AGREEMENT

Version	1.1
Effective from	10/10/17
Review by	10/10/18
Approved by	Mr R. M. Middleton
Approval date	10/10/17

Revision chronology		
Version no.	Effective date	Reason for change
1.1	14/12/2007	Modified SAIL data access agreement for MS Register SeRP

UK MS Regsiter Secure e-Reseaarch Platform

DATA ACCESS AGREEMENT

I have read the terms and conditions set out in the UKMSR Data Access Agreement version 1.1 and agree to be bound by them. I declare that I am not currently being investigated under the Data Protection Act and have not been found to be in breach of the Act.

Name: Christopher Meek

Job Title: Trainee Clinical Psychologist

Organisation: The University of Nottingham

Signature: Chris Meek

Date: 20/03/20

Appendix R: Questionnaire Cover Sheet

University of Nottingham
UK | CHINA | MALAYSIA

NHS
Nottingham University Hospitals
NHS Trust

Dear

It was good talking to you over the telephone and I am pleased you would like to hear more about the study.

Please find enclosed the following:

-Participant Information Sheet

-Consent Form

-Questionnaires

-Pre-paid Envelope

1. Please first read through the **Participant Information Sheet** to help you understand the study. I will arrange a time with you over the telephone to give you the opportunity to ask any questions you may have.
2. If after the telephone call the study does sound like something you are still interested in, then please complete the **Consent Form** and **Questionnaires**.
3. Please place the **Questionnaires** in the pre-paid envelope provided and put it in the postbox. **Please keep the Consent Form at home.**
4. Once I receive the letter, I will arrange by telephone to come and visit you.

Yours Sincerely,

Christopher Meek (Trial Manager)

Appendix S: Framework Analysis, Coding Framework

CODE	DESCRIPTION
Recruitment Capability and Sample Characteristics	
Social Support	*The social support systems available to all participants*
Healthcare Support	*The experiences of healthcare support of all participants*
An Ear to Bend	*All participants ability to converse, talk, and share experiences*
Motivation to Help	*Reasons given of motivations to take part in the study by all participants*
Evaluation and Refinement of Data Collection Procedures and Outcome Measures	
Questionnaires	*All participants perceptions of completing the questionnaires*
Postal system	*All participants perceptions of using the postal system to receive, complete, and return questionnaires*
Evaluation of Acceptability and Suitability of Intervention and Study Procedures	
Accessibility	*How taxing or accessible all participants found general study procedures*
Telephone Sessions	*How those in the intervention condition experienced the telephone intervention structure*
Using the Workbook	*How those in the intervention condition viewed the workbook, both in and between sessions*
Randomisation	*How those in the control condition felt about the process of randomisation*
Preliminary Evaluation of Participant Responses to Intervention	
Psychological Flexibility and ACT Processes	*Reported changes of those in the intervention condition in psychological flexibility*
Mood and Quality of Life	*How all participants felt their mood and quality of life had changed*
Mindset and Coping	*Changes in coping strategies or world outlook of those in the intervention condition*
Intervention Experience	*How those in the intervention condition found taking part more generally.*

Appendix T: Medical Research Council GDPR Certificate (Required for access to MS Register)

This is to certify that:

Christopher Meek

Passed

Research, GDPR and confidentiality Quiz

Date / Time	Student Score	Passing Score	Result
March 20, 2020 3:56 pm	77.77	70	Pass

(Click here to print this page)

Appendix U: Contextual Behavioural Science, Guidelines for Authors

Written for publication in the Journal of Contextual Behavioural Science (6000 word limit).

Journal Paper Wordcount: 5,826 (excluding tables, figures, references, appendices)

Style: APA style (7th Edition)

Guidelines for Authors (Pages 4-13):
https://www.elsevier.com/journals/journal-of-contextual-behavioral-science/2212-1447/guide-for-authors

ACT for Secondary Progressive Multiple Sclerosis: A feasibility RCT

Christopher Meek, Nima Moghaddam, Nikos Evangelou, Roshan das Nair

Trent Doctorate in Clinical Psychology, Nottingham University Hospitals NHS FT

Introduction

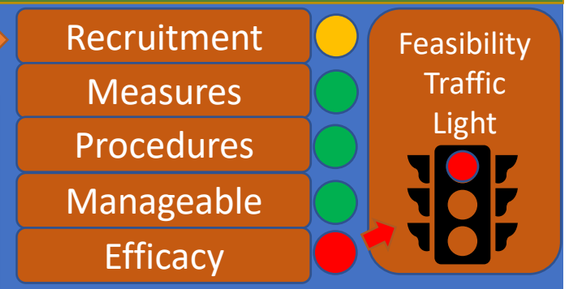
- Multiple sclerosis (MS) is a neurological condition and Secondary Progressive MS (SPMS) is the chronic stage
- Transitioning to SPMS described as a "fear point" of the disease
- Drug treatments are withdrawn and people see less of their Neurologist
- Increased disability means it is harder to see family and friends
- General social support lessens and people feel abandoned; we know supportive relationships are key to successful transition
- Could we provide brief emotionally supportive therapy, easy for services to deliver and valued by patients?
- Acceptance and Commitment therapy (ACT) can help with flexible coping. This beats avoidant coping.
- Similar chronic conditions have shown ACT as an effective therapy option

Aims

To see if its feasible to do a trial of an ACT-Based telephone support and workbook therapy to help patients transitioning to SPMS

Results

- Ten women, four men (n=14) mean age of 53 were recruited from a NHS UK neurology service
- Therapist telephone support needed as participants expressed a lack of social and healthcare support
- Recruitment strategy not feasible; 3.5 participants recruited a month, would take 12 months to reach 40 participants
- Trial procedures were acceptable and sensible: no attrition or missing data
- ACT-based therapy did not show efficacy Anx: d = .00, Dep: d =.00, PF d = .42
- Positive interview feedback, participants enjoyed intervention but no change on measures



Quotations

"It's nice to talk to somebody who isn't in the situation, you can say things you wouldn't normally"

"I learnt to focus on being in the moment a lot more and I now use it for my day-to-day life"

Methods

Single centre, mixed methods, two-arm RCT

Discussion

- Many need social support after SPMS diagnosis
- ACT-based telephone support RCT was conducted and procedures were acceptable
- Recruitment was not feasible and would require a longer recruitment window
- Intervention failed to demonstrate efficacy on measures and a future trial is not indicated
- Future telephone support trials could learn from the successful procedural elements to avoid attrition and missing data

References

- Meek C, Topcu G, Moghaddam N, das Nair R. Experiences of adjustment to secondary progressive multiple sclerosis: a meta-ethnographic systematic review. Disability and Rehabilitation. 2020 Mar 13:1-2.
- Hayes SC, Strosahl K. D. and Wilson, KG (1999) Acceptance and commitment therapy: An experiential approach to behavior change. Guilford, New York.
- Davies F, Edwards A, Brain KA, Edwards M, Jones R, Wallbank R, Robertson NP, Wood F. '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. 2015 Jul 1;5(7):e007674.