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Telephone-supported acceptance and commitment bibliotherapy for people with multiple sclerosis and psychological distress: A pilot randomised controlled trial

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ABSTRACT

A few randomised controlled trials (RCTs) show that Acceptance and Commitment Therapy (ACT) is beneficial for people with Multiple Sclerosis (MS), but the effectiveness of telephone-supported self-help ACT for people with MS with low mood has not been evaluated. We assessed the feasibility of conducting an RCT of an intervention (8 weekly telephone-calls plus a self-help ACT book) compared to treatment-as-usual. Participants' mood, quality of life, and impact of MS were assessed at baseline and 12 weeks post-randomisation. Some were interviewed to assess feasibility and acceptability. Twenty-seven participants were randomised. Most participants found the trial procedures acceptable. We found a large and significant effect at follow-up, favouring the intervention in reducing anxiety ($d = 0.84$, 95% CI = 0.02–1.66). However, the high attrition rate (33% overall) meant that the trial in its current format was not feasible. The intervention needs to be revised following user-testing and feedback before it can be put to a full trial.

1. Introduction

Multiple Sclerosis (MS) is a central nervous system disease, wherein brain-areas are inflamed or destroyed by the immune system. More than 100,000 people in the UK are currently diagnosed with MS (MS Trust, 2017): most have a relapsing-remitting form; some stay as relapsing-remitting and a minority remain benign, however, for most, symptoms become permanent and degenerative (termed progressive MS).

MS can have diverse and unpredictable effects on psychological wellbeing (Wilkinson & das Nair, 2013) reflected in high prevalence-estimates for depression (30%) and anxiety (22%) (Boeschoten et al., 2017). Psychological and psychosocial problems frequently arise in relation to physical functioning, fatigue, pain, cognition, and relationships with others (Khan, Turner-Stokes, Ng, Kilpatrick, & Amatya, 2007).

1.1. Acceptance and Commitment Therapy (ACT)

ACT is a third-wave of Cognitive-Behavioural Therapy (CBT) underpinned by the theory of psychological flexibility, and is efficacious

across a broad range of physical and psychological symptoms (A-tjak et al., 2015; Hacker, Stone, & MacBeth, 2016; Ruiz, 2010). ACT is designed to improve functioning and quality of life (QoL) by enabling individuals to live in accordance with personally-held values (Hayes, Strosahl, & Wilson, 1999). The model views experiential avoidance as a core pathogenic process, and attempts to increase acceptance of aversive experiences: as a means of promoting engagement with valued, and previously avoided, activities (Dahl, Wilson, & Nilsson, 2004).

ACT may be particularly suited to those with chronic physical health conditions, as traditional CBT thought-challenging of illness-beliefs may be limited when such cognitions could be accurate (Dennison, Moss-Morris, & Chalder, 2009). Furthermore, there is evidence that, in MS, avoidant coping strategies predict poor outcomes (Pakenham, 1999), and acceptance is the strongest predictor of adjustment (Pakenham, 2006). There is some preliminary research to suggest that group-based face-to-face ACT can be effective in reducing experiential avoidance and psychological distress in people with MS (Nordin & Rorsman, 2012; Pakenham, Mawdsley, Brown, & Burton, 2017).

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1.2. Teletherapy

ACT is typically delivered face-to-face, but other delivery-formats warrant evaluation due to the costs of providing face-to-face therapy and because of a lack of services, particularly for those living in remote areas. Furthermore, people with MS may not be able to access face-to-face therapies due to MS-related fatigue and reduced mobility. Telephone-psychotherapy (teletherapy) facilitates delivery to people in their own home: a recent review found that the teletherapy format could be efficacious for improving psychological outcomes (including depression, fatigue, and quality of life) in people with MS (Proctor, Moghaddam, Vogt, & das Nair, 2018); however, many of the studies were of poor methodological quality, so findings should be interpreted with caution.

1.3. Bibliotherapy

Bibliotherapy (self-help texts) is another common alternative or adjunct to face-to-face therapy, which can be supplemented with teletherapy. Meta-analyses have shown that bibliotherapies – including ACT-based bibliotherapies – can improve psychological outcomes, as compared to control conditions (den Boer, Wiersma, & van den Bosch, 2004; French, Golijani-Moghaddam, & Schröder, 2017). A previous trial of an eight-week telephone-supported CBT bibliotherapy for people with MS found significant reductions in depression (Mohr et al., 2000). However, the trial was specific to those with depression diagnoses and did not consider the multitude of other psychological difficulties experienced by people with MS.

A telephone-supported ACT bibliotherapy may therefore provide an appropriate, accessible, and effective way of delivering psychotherapy to people with MS and psychological distress. To date, no studies have examined whether this format of ACT intervention is feasible within this population.

1.4. Aims

The primary aim of this study was to explore the feasibility of conducting an RCT of telephone-supported ACT bibliotherapy plus treatment-as-usual (TAU), compared with a TAU control group, for people with MS and psychological distress. Secondary to this, we explored between- and within-group differences to generate parameters for designing a full trial.

2. Methods

2.1. Participants

This study was approved by Institutional and NHS Research Ethics Committees (14/EM/1228). The trial was registered on ClinicalTrials.gov (ID: NCT02596633). Participants did not receive any financial incentive for participation.

We aimed to recruit 25–30 participants: to generate data enabling parameter-estimation for designing a full trial (Julious, 2005). Participants were recruited through a neurology outpatient clinic at an acute National Health Service (NHS) hospital in Nottingham, UK, and through an advertisement placed in a regional MS Society (charity) publication. Participants were adults with MS, diagnosed at least 12 months prior to trial-enrolment. Participants were screened for psychological distress using the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). They were eligible if they met ‘caseness’ criteria on the HADS (scoring > 7 for anxiety/depression), which is recommended in MS populations (Honarmand & Feinstein, 2009). Completion of the screening measure occurred in-clinic for those recruited through the NHS-service and via postal-return for those recruited through the MS Society. Participants unable to read and write English, and those receiving other psychotherapy, were excluded.

Informed consent was obtained.

2.2. Assessment

Basic demographic details, time since MS diagnosis, time since last relapse, most recent Expanded Disability Status Scale (EDSS; Kurtzke, 1983) score, and current medication were noted from clinical records. Participants also self-reported current medications and contacts with health services on a bespoke healthcare-utilisation questionnaire. This is not a validated questionnaire but based on the resources available in the Database of Instruments for Resource Use Measurement (dirum.org; Ridyard & Hughes, 2012), which includes the number and types of primary and secondary care NHS resources used, and changes to employment status.

Baseline assessments were administered to all participants pre-randomisation, and these assessments were repeated at follow-up, 12 weeks post-randomisation. Co-primary outcome measures were the Generalised Anxiety Disorder 7-item (GAD-7) scale (Spitzer, Kroenke, Williams, & Löwe, 2006) and the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams), which captured anxiety and depression, respectively. Secondary outcomes were the Multiple Sclerosis Impact Scale (MSIS-29; Hobart, Lamping, Fitzpatrick, Riazi, & Thompson, 2001) which splits into physical and psychological subscales (Ramp, Khan, Misajon, & Pallant, 2009). The EQ-5D-5L (Herdman et al., 2011) was administered to assess QoL. The Acceptance and Action Questionnaire (AAQ-II; Bond et al., 2011) was included as a process measure, to gauge variability in ACT-targeted processes of experiential avoidance and psychological inflexibility. Measures were administered securely online using www.esurv.org; except the EQ-5D-5L, which was administered and collected via post.

2.3. Design

The study was a pilot RCT – as defined by Eldridge et al. (2016). Participants were randomly allocated to intervention or control (1:1 ratio). The randomisation sequence was computer-generated by one researcher (NM), concealed from other researchers, and entered into a standalone web-based system (Cunningham, 2006). The recruiting researcher (BP) used this system to request individual time-stamped allocations at the point of consent, before informing the participant of their allocation.

Feasibility and acceptability feedback was obtained via telephone-interviews, conducted by an independent researcher with a sub-sample of participants, 12-weeks post-randomisation. We followed guidance for maximising the impact of qualitative methods within a pilot trial (O’Cathain et al., 2015) and used maximum variation purposive sampling to select five participants from each arm to capture a diverse range of perspectives within our sample, sufficient to provide elaborative nuance to this primarily quantitative design.

2.4. Intervention

The intervention arm consisted of TAU plus the self-help book “Get out of your mind and into your life” (Hayes, 2005) – with guidance on which chapters to read each week. This coincided with eight weekly support-calls, theoretically orientated to the ACT model, from a trainee clinical psychologist (BP), who supported participants in understanding the text and engaging with the model. BP received supervision from an experienced ACT practitioner-researcher (NM). The book covers all components of the ACT model and prompts self-application through multiple semi-structured exercises per chapter – enabling the reader to tailor material to their own idiosyncratic needs. Participants in this arm received no other psychological therapies.

The control arm consisted solely of TAU, conforming to UK National Institute for Health and Care Excellence guidance for MS symptoms (NICE, 2014), which typically involves referral to psychological

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