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Potential treatment mechanisms in a mindfulness-based intervention for people with progressive multiple sclerosis

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Abstract

Objectives: To explore putative mediators of a mindfulness-based intervention to decrease distress in people with multiple sclerosis (MS) and to explore the patients’ perspectives on this intervention.

Design: We used an explanatory mixed methods design incorporating quantitative data from a pilot randomised control trial and a qualitative interview study with people who completed the mindfulness intervention.

Methods: People with MS (n=40) completed standardized measures of distress (outcome), and acceptance, decentering, self-compassion and self-efficacy (potential mediators). Semi-structured interviews (n = 15) of patients’ experiences of the mindfulness intervention were analysed deductively and inductively.

Results: Decentering post-intervention explained 13% of the three-month change in distress and between 27% and 31% of concurrent changes in distress. Acceptance changed only slightly, and as a result, the indirect effect accounts for only 2% of future distress and between 3% and 11% of concurrent distress. Qualitative data showed that acceptance and self-compassion needed more time to develop whereas decentering could be implemented readily after being introduced in the sessions. Self-efficacy also had a large mediating effect. Participants in their interviews talked about group dynamics and prior expectations as essential elements that determine their engagement with the course and their level of satisfaction.
Conclusions: Mindfulness interventions for people with a chronic progressive condition may benefit from focusing on helping them to accept daily challenges and teach them to recognise their thoughts and feelings, allowing time for acceptance and self-compassion to develop. Group dynamics also play a fundamental role in the success of the mindfulness interventions.

Keywords: Multiple sclerosis, mindfulness, mediators, decentring, pilot randomised control trial

Introduction

Multiple Sclerosis (MS) is an unpredictable, chronic, degenerative disease of the Central Nervous System and causes remitting and progressive physical and cognitive dysfunction (Eeltink & Duffy, 2004). MS symptoms vary and include blurred vision, numbness and weakness, fatigue, speech problems, problems with balance, tremor, mood swings, impaired cognition, depressive symptoms, difficulty swallowing, spasticity and paralysis (Taggart, 1998).

Three different types of MS have been identified. First, the primary progressive course, which is characterised by steady increase in disability without attacks. Primary progressive is relatively rare, accounting for about 10% of MS cases. It involves a slow, but unremitting, worsening from the onset. Nevertheless, there are variations in rates of progression over time, times of stability, and occasional temporary slight improvements (Lublin & Reingold, 1996). Second, the relapsing-remitting type of MS, characterised by unpredictable attacks
can leave permanent deficits followed by periods of remission (Compston & Coles, 2008). Approximately 85-90% of individuals with MS experience relapsing-remitting symptoms (Taggart, 1998). Finally, the secondary progressive course of MS typically follows a relapsing-remitting course that suddenly declines without periods of remission. Secondary progressive MS develops in approximately 50% of those with relapsing-remitting MS, with a corresponding progression and worsening of symptoms (Compston & Coles, 2008).

A large body of literature has focused on understanding psychological factors and to a lesser extent treatments, which help or hinder adjustment to this condition (Dennison & Moss-Morris, 2010; Thomas, Thomas, Hillier, Galvin, & Baker, 2009). However, few have differentiated between people affected by relapsing remitting MS and those with a progressive (primary or secondary) form of the illness. People affected by relapsing remitting disease face unpredictable symptom flare-ups followed by periods of remission and possible residual disability. Periods of remission can last for extended periods of time during which people may feel quite well. People affected by primary progressive MS on the other hand have to live with a disease that steadily progresses from the start together with the uncertainty of how quickly this will happen. Secondary progressive MS also provides unique challenges. People have to move from accommodating to a disease, which shows some improvement during remissions and can respond in part to disease modifying medications, to accepting a condition where deterioration and increasing disability is inevitable and medications only provide some symptomatic relief. However, few have differentiated between people affected by relapsing remitting MS and those with a progressive (primary or secondary) form of the illness. Despite the particular challenges of progressive MS, most of the new MS treatments and research focuses on relapsing remitting
disease (Hind et al., 2014). This research study aims to address this issue by developing an intervention specifically for people affected by secondary progressive and primary progressive MS and assess this intervention in a pilot randomised controlled trial.

Mindfulness training is rooted in the idea that increased awareness of the present moment experiences can lead to ‘mindful’ response to challenges as opposed to reactive or habitual reaction. Responding mindfully to challenges, leads to an increased sense of control (Astin, 1997) and equips people with helpful coping strategies when difficulties arise (Kabat-Zinn, 2009). Over a typical 8-week mindfulness course participants complete daily mindfulness meditation practices and attend weekly group meetings.

Evidence shows that mindfulness courses improve psychological well-being in people with long-term conditions (Grossman, Niemann, Schmidt, & Walach, 2004). After mindfulness training, people with MS reported reduced emotional distress (Bogosian et al., 2015); improved quality of life, reduced depression and fatigue (Grossman et al., 2010), improved balance (Burschka, Keune, Oy, Oschmann, & Kuhn, 2014; Mills & Allen, 2000), and reduced pain (Tavee, Rensel, Planchon, Butler, & Stone, 2011). However, at present we know little about the specific treatment mechanisms through which mindfulness worked in these trials. Understanding mindfulness mechanisms can help clinicians optimise the intervention and determine its suitability for different patients (Simpson, Mair, & Mercer, 2015).

Theories of mindfulness cover a number of potential process mechanisms and different groups of people resonate with different mindfulness elements (Boswell, Castonguay, & Wasserman, 2010). According to a recent meta-analysis, cognitive and emotional reactivity,
mindfulness, rumination and worry are important mediators of mindfulness interventions in mental health research (Gu, Strauss, Bond, & Cavanagh, 2015). However, processes important for people with physical conditions may differ to those that are necessary for mental health populations. There is no meta-analysis of potential mindfulness mediators in physical health literature but one study showed that acceptance and self-management behaviour mediated the impact of a mindfulness intervention on changes in diabetes management (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007). Another study showed being aware of the present moment and refraining from judging inner experience were the two most important mindfulness skills for improvements of psychological functioning among cancer patients (Garland, Tamagawa, Todd, Speca, & Carlson, 2013). We explored similar mechanisms in the context of a mindfulness randomised control trial (RCT) for people with progressive MS. We used a pragmatic approach in choosing constructs that may mediate effectiveness of mindfulness in MS. Figure 1 shows the putative mediators measured in this study and how the intervention acts on these to change outcome. To reduce the number of variables measured in this study we focused on those that appear central to most theories and were most relevant to people with progressive MS.

Several theoretical reviews suggest an essential ingredient of mindfulness courses is helping people become more accepting of their experiences (Baer, 2003; Grabovac, Lau, & Willett, 2011; Kabat-Zinn, 1982; Segal, Williams, & Teasdale, 2002). Acceptance is also associated with better adjustment over time in MS (Pakenham & Fleming, 2011) and may be particularly important in the context of an unpredictable and progressive illness for which there is no cure. Many patients and health professionals believe that accepting a chronic
condition is critical for adjustment (Telford, Kralik, & Koch, 2006). Mindfulness courses may help people with MS improve their psychological well-being through increasing acceptance.

Changes in attention and acting with awareness are also constructs associated with mindfulness across a number of theoretical models (Baer & Krietemeyer, 2006; Brown, Ryan, & Creswell, 2007; Shapiro, Carlson, Astin, & Freedman, 2006; Vago & Silbersweig, 2012). Metacognitive insight is cultivated through increased attention and intention and is related to decentering (Safran & Segal, 1990). Decentering means observing thoughts and perceiving them as simply thoughts that are not a reflection of reality. Consequently, decentering helps people to acknowledge a range of responses to a challenge, allowing challenges to be addressed consciously rather than merely reacting to or avoiding them (Kumar, Lo, & Chen, 2008). In the context of MS, mindfulness may help people to become aware of recurrent thoughts about the past or worrying thoughts about the uncertain future without necessarily engaging or pursuing them.

A process discussed in most theoretical frameworks as an integral part of mindfulness courses is self-regulation (Baer, 2003; Baer & Krietemeyer, 2006; Brown et al., 2007; Grabovac et al., 2011; Holzel et al., 2011; Shapiro et al., 2006; Vago & Silbersweig, 2012). Holzel et al. (2011) in their theoretical model, draw similarities between emotion regulation and change in perspective on the self with self-compassion. Neff (2003) argues that self-compassion consists of three components: a) self-kindness in the face of suffering, b) seeing one’s experience as part of a larger human experience and c) being aware of thoughts and feelings without over-identifying with them (Neff, 2003). Self-compassion is associated with less depression and anxiety (Neff, Hsieh, & Dejitterat, 2005; Pinto-Gouveia, Castilho, Matos,
& Xavier, 2013; Van Dam, Sheppard, Forsyth, & Earleywine, 2011) and more adaptive coping skills (Allen & Leary, 2010; Leary, Tate, Adams, Allen, & Hancock, 2007). Here, we will investigate whether a mindfulness programme can cultivate self-compassion, as a facet of self-regulation, leading to reductions in psychological distress for people with MS.

Self-efficacy, although not part of any mindfulness theory, might be worth considering as a potential mechanism. Having an achievable goal may augment self-efficacy in rehabilitation, but striving for too long towards an unattainable goal is not constructive (Orbell, Johnston, Rowley, Davey, & Espley, 2001). Mindfulness encourages participants to adopt a ‘non-striving’ attitude that can lead to better decisions, since they take into account the physical illness in a reflective rather than a reactive manner. Further, during mindfulness programmes, participants learn that emotions are transitory and always changing, which yields confidence in their ability to shape their life (Nydahl, 2008). For these reasons, mindfulness might also be associated with coping self-efficacy. Indeed, many studies showed that mindfulness is linked with various forms of self-efficacy, for example, self-efficacy for managing pain (Chang et al., 2004; Cusens, Duggan, Thorne, & Burch, 2010; Morone, Rollman, Moore, Li, & Weiner, 2009) and resisting alcohol relapse (Britton et al., 2010), though not self-efficacy for managing a chronic illness. In addition, self-efficacy in MS is associated with beneficial outcomes, like increases in social activity, self-esteem (Barnwell & Kavanagh, 1997), perceived walking ability, physical and psychological impact (Riazi, Thompson, & Hobart, 2004), perceived cognitive impairment (Hughes et al., 2015) and psychological adjustment (Hughes et al., 2015; Wassem, 1992).

The aim of this study was to explore these possible treatment mechanisms in the context of
a Skype delivered mindfulness course *(ref removed for anonymous review)*. Before undertaking a fully powered efficacy RCT, we wanted to explore the possible mechanisms, which brought about this improvement to maximise treatment effects going forward. Therefore, in this secondary paper we investigated whether mindfulness mechanisms, e.g. acceptance, decentering, self-compassion and self-efficacy changed significantly across the intervention and at 3-month follow-up and if any changes in these process variables were associated with changes in treatment effects. We also explored whether changes in the mediator at the end of treatment could predict change in distress at final follow-up (i.e. change in mediator preceded change in distress) or whether change in mediators and distress occurred concurrently. We also conducted post treatment qualitative interviews to explore these mechanisms through participants’ accounts of the mindfulness course.

Methods

We used mixed methods design, which included a parallel groups pilot RCT of a mindfulness-based intervention and qualitative interviews of people who took part in the mindfulness courses. To minimise data contamination, different researchers, not involved in developing or administering the mindfulness treatment, collected and analysed the quantitative versus the qualitative data. The statistician (XX) became aware of the group assignment, after the primary analysis. The initial analysis of qualitative data was conducted by XX before knowledge of the outcome of the intervention. At a later stage, results from both data sets were brought together and integrated so that the qualitative data could enrich the findings from the quantitative analysis.
We recruited 40 participants between December 2012 and May 2013. The study was approved by XXX Research Ethics Committee (XXX) and registered at the Current Controlled Trials database (XXX). All participants completed written informed consent. A pilot trial of at least 30 participants is adequate for obtaining estimates of the standard deviation of measures used to determine sample size for an efficacy trial (Browne, 1995). We recruited potential participants through adverts on the MS Society website and from National Health Service (NHS) MS centres across the UK.

We screened potential participants over the telephone. Inclusion criteria were diagnosis of PPMS or SPMS, internet access and some level of distress determined by a score of 3 or greater, using the Likert scoring (0-1-2-3), on the General Health Questionnaire; GHQ-12 (Goldberg & Williams, 1988). This cut-off score was chosen following recommendations for MS (Lincoln et al., 2011). Exclusion criteria were severe cognitive impairment, as determined by a score of 20 or smaller on the Telephone Interview for Cognitive Status-Modified; TICS-M (Brandt et al., 1993) and high suicide risk, as assessed by a score of 20 or greater on the Clinical Outcome of Routine Evaluation; CORE-10 (Evans et al., 2002). Finally, people were excluded if they reported any serious psychological disorders (e.g. psychosis, substance abuse), severe hearing impairment, attending other psychological therapies or prior formal training in mindfulness.

Randomisation took place once a cohort of 10 patients had agreed to take part, screened and baseline data collected. An independent service XXX handled the randomisation, using fixed block sizes of two. The nature of the intervention meant it was not feasible to keep the patients or clinical supervisors blind to treatment allocation.
A registered health psychologist, experienced with working with people with MS and newly qualified mindfulness practitioner, delivered the program in 8 hour-long sessions over an 8-week period via Skype videoconferences. The mindfulness sessions were tailored to address issues specific to people with MS (see table on online supplementary material for more details on each session). Each group included 3-5 people with MS. Participants completed standardised questionnaires for the key outcomes and putative mediators, at baseline (pre-randomisation), end of the intervention and 3-month follow-up. The wait-list groups were offered the mindfulness intervention at the final follow-up. We conducted the telephone interviews as soon as possible after completion of the course (typically within two weeks).

Quantitative data

Questionnaires

*Primary outcome:* The General Health Questionnaire-12 (GHQ-12, Goldberg & Williams, 1988) measures general levels of distress in people in the community and medical settings and has been recommended for use in people with MS (Hobart, Riazi, Lamping, Fitzpatrick, & Thompson, 2005). We used the Likert scoring (0-1-2-3) and high mean scores indicate high emotional distress. Using the Health Survey for England 2004 cohort (n= 3705) showed Cronbach α for the Likert scoring was .73 (Hankins, 2008).

*Putative Mediators:* Acceptance Action Questionnaire (AAQ-II, Hayes, Luoma, Bond, Masuda, & Lillis, 2006). The 10 items on the AAQ-II are rated on a 7-point Likert scale from 1 (never true) to 7 (always
true). High mean scores on the AAQ-II reflect greater experiential avoidance and psychological inflexibility while low scores reflect greater acceptance and action. Results from 2,816 participants across six samples of students, finance workers and people who have sought treatment for drug misuse, indicate the satisfactory structure, reliability, and validity of this measure, Cronbach α is .84 (.78-.88), and the 3- and 12-month test-retest reliability is .81 and .79, respectively (Bond et al., 2011).

Experiences Questionnaire (EQ, Fresco et al., 2007) measures decentering. The 20 items on the EQ are rated on a 5-point Likert scale from 1 (never) to 5 (all the time). High mean scores indicate a high level of decentering. An initial validation study of EQ showed that levels of decentering among people with major depression were significantly and negatively correlated with concurrent self-report (r=−.46) and clinician-assessed (r=−.31) levels of depression symptoms (Fresco, Segal, Buis, & Kennedy, 2007).

Self-Compassion Scale Short Form (SCS-SF, Raes, Pommier, Neff, & Van Gucht, 2011) assesses how respondents perceive their actions towards themselves in difficult times. Self-compassion is typically evaluated using the 26-item Self-Compassion Scale (SCS; Neff, 2003). This 12-item short form is rated on a 5-point Likert scale from 1 (almost never) to 5 (almost always). In this scale, high mean scores indicate high levels of self-compassion. The SCS-SF demonstrates adequate internal consistency (Cronbach’s alpha ≥ 0.86) and a near-perfect correlation with the long form SCS (r ≥ 0.97) (Raes et al., 2011)

Self-efficacy for managing chronic disease (SEMCD, Lorig et al., 1996). We chose this scale, as it is short to administer has been used in previous psychological clinical trials (Lorig, Sobel,
Ritter, Laurent, & Hobbs, 2001) and covers several domains relevant to MS, including symptom control, role function, emotional functioning and communicating with health professionals. The 6 items are rated on a 10-point Liker scale from 1 (not at all confident) to 10 (totally confident). High mean scores indicate high self-efficacy. Secondary analyses of questionnaire data from 2,866 participants in six studies were used to assess the psychometrics of the SEMCD and showed high internal consistency (Cronbach alpha, .88-.95). The scale was also sensitive to change and significantly correlated with health outcomes (Ritter & Lorig, 2014).

In addition to these measures, participants completed a demographic questionnaire, a question about their MS type diagnosis and the self-reported Expanded Disability Status Scale (EDSS; Bowen, Gibbons, Gianas, & Kraft, 2001). EDSS measures mobility, strength, coordination, sensation, bladder, vision, speech, swallowing, and cognition. The EDSS scale ranges from 0 to 10 in 0.5 unit increments that represent higher levels of disability. EDSS steps 1.0 to 4.5 refer to people with MS who are able to walk without any aid and have some impairment in the functional systems. EDSS steps 5.0 to 9.5 are defined by the impairment to walking and severe limitation in the functional systems. EDSS has been shown to correlate well with physician-rated scores, specifically mean EDSS-physician, EDSS-self-report and intraclass correlation coefficients of agreement were: EDSS using ambulation alone (4.6, 5.1, 0.89) and EDSS using ambulation and functional scores (4.6, 5.3, 0.87) (Bowen, Gibbons, Gianas, & Kraft, 2001).

Quantitative Analysis
Mediation analysis followed the steps outlined by Baron and Kenny (1986). For an RCT this equates to i) estimate the total (intention-to-treat) effect on the primary outcome; ii) evaluate the overall (intention-to-treat) effect on the putative mediator; and iii) determine the indirect treatment effect on the primary outcome via the mediator.

Treatment effects have previously been reported (ref removed for anonymous peer review). Indirect effects were estimated using the medeff package in Stata v12 (Hicks & Tingley, 2011), based on the causal inference approach described in Imai, Keele, and Tingley (2010).

Standard errors were estimated with a nonparametric bootstrap with 1000 replications. We looked at the concurrent change in the mediator predicting change in outcome at the end of treatment and follow-up. Due to random treatment allocation, only the path from the putative mediator to the primary outcome is likely to be affected by unmeasured confounding (Emsley, Dunn, & White, 2010). Several potential confounders were included as covariates to strengthen the validity of this assumption: baseline level of the GHQ total score, age, sex, and MS type, plus the baseline levels of pain and fatigue. Since the study is an underpowered pilot study inferences are not based on a priori significance tests but on standardised effect sizes in the form of standardised group mean differences for the treatment effect estimates, and the proportion of the total treatment effect on the primary outcome that is mediated. The mediation analysis was conducted in order to explore descriptively whether the intervention works as expected. Combined with the qualitative data, this information is useful for identifying aspects of the intervention that may need to be modified to progressing to a larger trial.

Qualitative data
We used criterion sampling to collect our qualitative data, a method frequently used in mixed methods studies (Sandelowski, 2000). Everyone who completed the mindfulness intervention group were invited to an interview about their experiences. We collected the qualitative data through semi-structured interviews. As shown in Table 1, the interview schedule consisted of a series of broad, open-ended questions relating to participants’ experiences and neutral prompts to pursue material introduced by participants. The interviews lasted between 25-55 minutes.

Insert Table 1 here

Qualitative analysis

Interviews were transcribed verbatim and analysed using deductive thematic analysis, in which we categorised statements related to acceptance, decentering, self-compassion and self-efficacy. Since the mindfulness course mapped on these processes, participants talked about them without being prompted. Additional experiences of the mindfulness programme and skills learnt through the courses were analysed inductively. We conducted the analysis of the transcripts in parallel with on-going data collection. XX kept notes after each interview and throughout the analysis process. Initial codes used vocabulary as close as possible to that used by participants themselves to avoid incorporating premature preconceptions into the analysis (Glaser & Strauss, 1967). XX and XX read the transcripts and compared their initial codes to ensure fidelity; any cases of disagreement were discussed and amended as appropriate. To ensure validity during the analysis process, we paid attention to deviant cases and reviewed transcripts and initial coding with XX. In the presentation of results,
participants’ names have been changed to protect confidentiality.

Results

Participants

Forty participants were assigned to either mindfulness group (n=19) or the wait-list control group (n=21). As shown in Table 2, the two groups were well matched in terms of demographic and illness characteristics. Eighteen of the 19 participants completed the mindfulness intervention. One participant dropped out after the first session but continued to complete the study questionnaires. The remaining 18 participants continued participating in the mindfulness course until the end of the intervention and agreed to be interviewed at the end of the course. All the participants attended 4 or more of the 8 mindfulness sessions and 14 (73.7%) attended 6 or more sessions. In the wait-list group, 2 participants (9.5%) at post-intervention and 3 (14.3%) at 3-month follow-up failed to complete the questionnaire. In the mindfulness group, 2 participants (10.5%) did not complete the post-intervention questionnaires and 4 participants (21%) the 3-month follow-up questionnaires. Fifteen people were interviewed. Three participants did not respond to the invitation for this interview.

Insert Table 2 here

Change in outcomes and putative mediators

Descriptive statistics for the primary outcome and putative mediators at all-time points are reported in Table 3 (see a correlation matrix on online supplementary material). There were small to moderate treatment effects on the putative mediators (see Table 4). Effect sizes for acceptance, decentering and self-compassion all increased from post therapy to
end of treatment, with decentering showing a large effect at follow-up and acceptance and self-compassion a moderate effect. Self-efficacy showed a small effect size at both assessment points.

Insert Tables 3 and 4 here

Mediation analysis
Mediation effects are displayed in Table 5. Indirect treatment effects on GHQ total score post-intervention and at the 3-month follow-up were small, as indicated by confidence intervals including zero. People in the mindfulness group showed substantial changes in decentering. Specifically, decentering post-intervention explained 13% of the 3-month change in GHQ and between 27% and 31% of concurrent changes in GHQ (i.e. change in GHQ end of treatment). Acceptance changed only slightly and as a result the indirect effect accounts for only 2% of future GHQ and between 3% and 11% concurrent GHQ.

Insert Table 5 here

Qualitative data
Participants talked about their interpretation of the mindfulness processes that were addressed during the mindfulness course, i.e. acceptance, decentering, self-compassion and self-efficacy. They also talked about the group dynamics and how their expectations and prior experiences influenced their engagement with the course.

Acceptance and Experiential Avoidance
Quantitative data suggests that changes in acceptance were small at the end of the intervention but increase to a medium size at follow-up. This might be explained by the difficulty the participants described with the concept in their interviews. Participants found
staying with difficult thoughts and emotions demanding. Some accepted this as a necessary process whereas others were apprehensive that it may be detrimental to them in some way, and chose not to engage in this practice.

“I had a reservation that it might make me unhappy, because not understanding, very much about it, I thought I’m not really sure if I’m quite ready to accept what I’m going to learn about myself. I did think about that at the start and I do feel like I’m not scared by it anymore” (Janet, 52 years old)

Some who chose to stay with the difficulties when they aroused during the practice found it beneficial and learnt that they did not need to fear or avoid such emotions.

“Using the focusing techniques and accepting techniques for difficult problems that have been very invaluable. They are the tools that I will use. I see them as tools that you can use the same way you use a knife, a fork to eat your food, you know, use them as tools to help me manage my condition” (Julia, 67 years old)

Participants described acceptance as an on-going process. They began to accept challenges on a daily basis and slowly moved towards acceptance of more imposing difficulties in their lives. This process represents an intentional effort towards an acceptance of, and psychological adjustment to, the diagnosis of MS.
“I really truly think that I’ve moved on, quite a few steps towards acceptance of this god awful condition that we’ve all got. I can say it quite cheerfully and be quite pragmatic” (Janet, 52 years old)

Decentering

Decentering was the most likely mediator of change in distress. The increasing ability to observe their thoughts and consider multiple aspects of the situation was documented during participants’ interviews.

“I found that I was able to do the mindfulness meditation and it didn’t make my pain go away but because you are in emptying, just letting thoughts come, and they go, I found that my pain went to the back of my mind, so I found it really good like that” (Valerie, 44 years old)

Participants described separating the emotion out of the challenge and recognizing the automatic emotional response (self-criticism, blame and rumination). With this new insight, participants began to relinquish automated responses and engage in a more ‘considered response’, less emotionally charged.

“Rather than have an automatic cycle between how you feel, your emotions your body your mind, it lays it out a little bit more” (Daniel, 50 years old)

Self-compassion

As participants became more self-aware through mindfulness practice, they began to
recognise a tendency (prior to the course) to be self-critical and engage in negative self-talk. However, the interviews also showed that self-compassion is a challenging process that requires time, practice and perseverance to develop, which might explain the initial small effect size shown in the quantitative analysis. Initially, recognising and altering the automatic response was only achievable for short periods or trivial concerns.

“If I was to trip and stumble, rather than just get shouty in my head and swearing or whatever I’ll actually think about it but if I do it twice, if I trip twice I will then just go back to my old automatic angry response” (Max, 50 years old)

Gradually, participants began to respond differently towards themselves, with increased self-compassion. Participants described feeling ‘less guilty about things’ and placed more value on themselves; making time to do something for them was described as unusual and valuable.

“I’m probably spending more time on my own doing things rather than need to be with my partner, nearly all the time. I can actually do things on my own and be happy with my own company” (Teresa, 53 years old)

Self-efficacy

Through learning to be mindful participants gained freedom to choose how they wished to respond to situations. This choice was empowering as people gained control over themselves and their responses. They were relieved of the pressure and ‘struggle’ to control external situations. Consequently, participants described feeling ‘lighter’, ‘less stressed’,
‘calmer’, ‘like a better person’, ‘at peace with the world’. Their focus shifted from controlling situations to choosing their responses to situations.

“If you know you’re responding in a particular way you can steer it in another direction, if necessary. You can follow the reflex response if you want or you wish to. You have the choice.

It was interesting to think actually I can have a bigger control over my response” (Max, 50 years old)

Increased sense of control helped participants to gain an alternative, more positive, outlook. They had a deeper understanding of themselves; confidence in their ability to control their reactions and recognised what is meaningful and valuable to them.

“I came into the course, wanting to get some tools to be able to get myself under control and I am absolutely convinced that the tools that I got have enabled me to get my MS under control and how I deal with it and think about it, but also how I cope in my daily life, because now I treat others a lot better. If I bring them in one at a time, they would all say that yes, dad has changed” (Stuart, 56 years old)

Group processes

The group dynamic was an integral part of the program experience, according to participants’ interviews. Participants related to one another both as fellow mindfulness novices and as sharing a diagnosis of progressive MS. In terms of learning about mindfulness, they felt the group provided valuable alternative perspectives, challenged their
conceptions and fostered a sense of belonging. Participants shared in the discovery of solutions to common dilemmas.

“Commonality of the disease I found very helpful cause you’re all going through and can share the same difficulties and often the same fears” (Anthony, 64 years old)

Others found it uncomfortable to observe fellow participants in a more advanced stage of the disease. Some felt it was, at times, an unwelcome reminder of the reality of their situation, prophesying their health deterioration.

“It seems silly because you live with MS every day, but actually sometimes when it’s spoken in front of you makes it very real indeed, so that, I think, I found difficult at times. I like that group aspect of it, in general, just at times I felt like ‘ouch!’” (Daniel, 50 years old)

Some felt they gained most from the group sessions and discussions. This preference marked a difficulty in transitioning from the group to individual practice following the end of the course, with some wishing the group could continue indefinitely. These participants associated the end of the sessions with feelings of loss; a loss of structure, group members and guidance.

“I really, really enjoyed it and when it was finished you sort of thought, “Oh I haven't got that on a Friday now” because I enjoyed it and looked forward to it” (Valerie, 44 years old)
Participants described the facilitator as integral to their experience and to facilitating the group dynamic, which was comfortable, inclusive and put them at ease. This was highly valued by the participants, which is illustrated by the fact many contributed more to the group than they had anticipated.

“XX [facilitators name removed for blind review] brings people into things and en-encourages them in really well which is great...getting that group mentality embedded is quite important”. (Daniel, 50 years old)

Beliefs prior to the course
Participants with prior knowledge and experience of similar techniques, such as meditation, had a clear understanding of what the course could offer; whereas those with no prior experiences were unsure what to expect. One factor that influenced the degree to which participants engaged in the mindfulness processes and the course overall was how they related to the mindfulness approach. As illustrated by the contrasting quotes below, those who felt the course fitted their worldview engaged in the course effortlessly compare to those who felt it did not fit their personality.

“It’s based on Eastern philosophies and I though, I can relate a little bit to that. If you were really task driven, I think you’d struggle with it” (Daniel, 50 years old)

“I’m not really into these sorts of self-help; you know thinking about and analysing things and whatever I’m just a sort of getting on with it more pragmatic person” (Stacey, 50 years old)
Discussion

We used mixed methods to explore putative mediators of a mindfulness intervention for people with MS. The quantitative data showed small to medium mediation effects of acceptance, decentering, self-compassion, and self-efficacy for the mindfulness intervention to improve distress in people with MS. The largest change was in decentering, which also had the largest mediating effect between the mindfulness course and people’s distress scores both at the end of the intervention and at 3-month follow-up. Self-efficacy only showed a small significant change but it also appeared to be an important mediator of the mindfulness effect on distress at both follow-up points. The qualitative data allowed us to explore these four variables further and identify additional processes, like the role of the group and the role of expectations of the course.

The quantitative findings showed a very small increase in the effect of acceptance at the end of the course, which increased at the 3-month follow-up period. The qualitative results complemented these findings. Participants in their interviews talked about having difficulties grasping the concept of acceptance initially. They described a process of acceptance that stemmed from mindfulness practice, beginning with acceptance of their level of control over minor daily hustles to moving towards acceptance of the progressive course of their condition.

In line with the decentering quantitative findings, participants also talked about learning to distance themselves from their thoughts and feelings. Decentering in mindfulness aims to
reduce participants’ experiences of avoidance, allowing them to turn towards and accept distressing thoughts and feelings. Previous studies have also shown that decentering acted as a mediator of mindfulness interventions in improving psychological well-being (Josefsson, Lindwall, & Broberg, 2012), depressive symptoms (Bieling et al., 2012; Gecht et al., 2014; Hargus, Crane, Barnhofer, & Williams, 2010), and anxiety (Hayes-Skelton & Graham, 2013; Hoge et al., 2015). Here, we showed that decentering may mediate the relationship between mindfulness and emotional distress in people with MS, and it is something that might change quicker than acceptance. Chadwick, Hughes, Russell, Russell, and Dagnan (2009) and Abba, Chadwick, and Stevenson (2008) suggest that decentred awareness and metacognitive insight support acceptance of difficult experience and self-acceptance, which is described by Kabat-Zinn (1994) as one of several foundations of mindfulness. Mindfulness interventions for people with a chronic progressive condition may benefit from focusing on helping people to accept daily challenges and teach them to recognise their thoughts and feelings, observing them without getting caught up in worrying thoughts about the future or rumination about the past, allowing time for acceptance to develop through this non-judgmental and non-reactive approach to thoughts and emotions.

Self-compassion showed a small effect at the end of the course but a moderate effect at the follow-up, which can be explained by the qualitative data, where participants described initial difficulties with the concept and the need for time to be more patience with themselves. The role of self-compassion in mindfulness training is acknowledged in the literature (Van Dam et al., 2011), but a recent meta-analysis showed insufficient evidence for self-compassion as mechanisms underlining mindfulness-based interventions, as it was found to be significant mediator factor in just one high-quality study (Gu et al., 2015). Our
findings suggest that self-compassion is a process that is cultivated with practice over time, beyond the 8-week programme. Therefore, to truly assess the role of self-compassion in the mindfulness programmes, research studies may need to include extended follow-up periods.

The quantitative data showed that self-efficacy of managing one’s illness is a potential mechanism in mindfulness interventions. However, in the interviews people talked about a different kind of control, the control over their emotional reaction to MS challenges. Participants described how they learnt to be in control of their emotional world in order to better deal with stressful situations whereas the questionnaire focuses on managing symptoms such as pain, fatigue or physical discomfort from interfering with their daily activities. It seems that the questionnaire used for measuring self-efficacy did not capture the same construct described by participants. It is possible that people managed their symptoms better because they were able to control their emotional reactions to these symptoms. In future studies, it would be interesting to measure both constructs and examine the relationship between them.

People with MS valued the group dynamic and found it one of the most helpful elements of the programme. Qualitative research of mindfulness programmes illustrates the benefits the group environment in offering a sense of community and support (Allen, Bromley, Kuyken, & Sonnenberg, 2009; Finucane & Mercer, 2006; Fitzpatrick, Simpson, & Smith, 2010), opportunities for learning from others (Chambers, Foley, Galt, Ferguson, & Clutton, 2012; Griffiths, Camic, & Hutton, 2009; Mackenzie, Carlson, Munoz, & Speca, 2007), and motivation to maintain mindfulness practice (Allen et al., 2009; Griffiths et al., 2009; Langdon, Jones, Hutton, & Holtum, 2011). There is less clarity about the potential benefits
and disadvantages of homogeneous groups (Malpass et al., 2012). Our qualitative findings provide support for the positive effects of a homogeneous mindfulness group. We did not assess the group effects in a quantitative way and to the best of our knowledge there is only one large quantitative study (n=606 from 59 groups) that has looked at group processes and found a significant correlation between group-level variance and improved outcomes in participants’ levels of psychological distress (Imel, Baldwin, Bonus, & MacCoon, 2008). Future trials, should measure social support as a direct or indirect effect of mindfulness courses. The role of group processes should also be explored by introducing a non-mindfulness based control group.

These findings should be considered in the light of certain limitations. The estimates showed in the quantitative analysis are not certain. Further, the use of bootstrapping to test mediation in small samples has a tendency to inflate Type I error rate (Koopman, Howe, Hollenbeck, & Sin, 2015). The change in the distress scores (outcome variable) is large and the change in three of the four the mediators is small suggesting the possibility of multiple mediating pathways and unmeasured mediators. Finally, whereas theoretically we hypothesized the mediators to change the outcome variables, there is a possibility this relationship is in the other direction when the mediator and outcome are measured concurrently. However, the results showed a change in decentering and self-efficacy at end of treatment predicted some of the variance in change of distress at 3-moth follow-up. To test hypotheses about true mediation, we need to assess process variables at a time point that temporally precedes assessment of outcome variables with a much larger group of patients.
The present study suggests that people more easily engaged in processes like decentering, explaining some of the earlier change, whereas other mechanisms like acceptance are harder to engage with and need time to develop, therefore, they may explain later change. Group sharing is an important element of mindfulness for people with MS. Participants also talked about gaining more control over their emotions through the mindfulness course. While further work is needed, our findings suggest that we could enhance the effectiveness of mindfulness interventions for people with chronic conditions, by focusing on the idea of distancing themselves from thoughts and emotions and making sure the patients feel comfortable to share personal stories in a group session.

References


individuals with multiple sclerosis. *Archive of Physical and Medical Rehabilitation, 96*(5), 913-919. doi: 10.1016/j.apmr.2015.01.008


reporting patients’ experiences of mindfulness-based approaches. *Mindfulness, 3*(1), 60-75.


Figure 1. Diagram showing expected associations between random allocation and outcome, between putative mediators and outcome, and measured covariates. c represents the direct effect, (a, b) represents the indirect effect.
<table>
<thead>
<tr>
<th>Questions</th>
<th>Prompts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. First of all can you start by telling me what you were expecting from</td>
<td>-What did you think the programme would be like?</td>
</tr>
<tr>
<td>the mindfulness sessions?</td>
<td>-In what ways (if any) did you think it might help you?</td>
</tr>
<tr>
<td>2. How did you find the programme overall?</td>
<td>-Tell me how you found your first session</td>
</tr>
<tr>
<td></td>
<td>-Tell me about the other sessions</td>
</tr>
<tr>
<td></td>
<td>-Tell me how you found the homework tasks</td>
</tr>
<tr>
<td>3. Can you tell me what you liked about the programme?</td>
<td>-What was helpful? Why? How?</td>
</tr>
<tr>
<td></td>
<td>-Were there some sessions/ some aspects that were more helpful than</td>
</tr>
<tr>
<td></td>
<td>others?</td>
</tr>
<tr>
<td>4. Can you tell me what you disliked about the programme?</td>
<td>-What was unhelpful? Why? How?</td>
</tr>
<tr>
<td></td>
<td>-Were there some sessions/ some aspects that were less helpful than</td>
</tr>
<tr>
<td></td>
<td>others?</td>
</tr>
<tr>
<td>5. Tell me about anything that you feel has changed from having done the</td>
<td>-Can you tell me what changed? (anything different in your day-to-day</td>
</tr>
<tr>
<td>programme?</td>
<td>life, the way you are dealing with MS?)</td>
</tr>
<tr>
<td></td>
<td>-Can you tell me how you came to notice things changing?</td>
</tr>
<tr>
<td></td>
<td>-Why/how do you think things changed?</td>
</tr>
<tr>
<td>6. Do you have anything else you would like to tell me about your</td>
<td>-What would you feed back to the people who put together the programme?</td>
</tr>
<tr>
<td>experiences of this programme that haven’t already covered?</td>
<td>-What advice would you give to people thinking about taking part in</td>
</tr>
<tr>
<td></td>
<td>mindfulness based programmes?</td>
</tr>
<tr>
<td></td>
<td>Mindfulness (n=19)</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Gender, female (n, %)</td>
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</tr>
<tr>
<td>Age, in years (M, SD)</td>
<td>53.42 (8.3)</td>
</tr>
<tr>
<td>Marital status, married/cohabiting (n, %)</td>
<td>15 (78.9)</td>
</tr>
<tr>
<td>Education, College or higher (n, %)</td>
<td>13 (68.4)</td>
</tr>
<tr>
<td>Ethnicity, White British (n, %)</td>
<td>17 (89.5)</td>
</tr>
<tr>
<td>Years since diagnosis (M, SD)</td>
<td>16.24 (10.1)</td>
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<tr>
<td>Type of MS, primary progressive (n, %)</td>
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<td>EDSS (M, SD)</td>
<td>6.8 (1.6)</td>
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**Table 3.** Descriptive statistics for primary outcome and putative mediators

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<th></th>
<th>SD</th>
<th>n</th>
<th></th>
<th>SD</th>
<th>Mean diff</th>
<th>Effect size</th>
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<td>1.19</td>
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<td>5.94</td>
<td>17</td>
<td>11.43</td>
<td>3.44</td>
<td>0.62</td>
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<tr>
<td></td>
<td>3 months</td>
<td>18</td>
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<td>4.42</td>
<td>15</td>
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<td>5.23</td>
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<td>6.33</td>
<td>15</td>
<td>28.13</td>
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<td>-0.05</td>
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<tr>
<td></td>
<td>3 months</td>
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<td>7.28</td>
<td>14</td>
<td>26.44</td>
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<td></td>
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<td>10.04</td>
<td>14</td>
<td>69.57</td>
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<td>-0.66</td>
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<td>-0.03</td>
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<td>9.29</td>
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<td>37.53</td>
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<td>18</td>
<td>32.44</td>
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<td>15</td>
<td>39.99</td>
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Table 4. Estimated post-intervention differences (mindfulness course effects) for primary outcome and putative mediators

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<thead>
<tr>
<th></th>
<th>Estimate</th>
<th>SE</th>
<th>z</th>
<th>p</th>
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<th>95% UL</th>
<th>Effect size</th>
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<td><strong>Primary outcome</strong></td>
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<tr>
<td>GHQ total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Post-intervention</td>
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<td>1.76</td>
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<td>3 months</td>
<td>-5.45</td>
<td>1.66</td>
<td>3.28</td>
<td>0.005</td>
<td>-2.19</td>
<td>-8.71</td>
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<td><strong>Putative mediators</strong></td>
<td></td>
<td></td>
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<tr>
<td>Acceptance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>-1.20</td>
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<td>0.639</td>
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<td>3 months</td>
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<td>1.62</td>
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<td>1.08</td>
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<tr>
<td>Post-intervention</td>
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<td>3.32</td>
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<td>0.191</td>
<td>10.86</td>
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<td>3 months</td>
<td>10.94</td>
<td>3.41</td>
<td>4.14</td>
<td>0.000</td>
<td>17.62</td>
<td>4.27</td>
<td>1.39</td>
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<tr>
<td>Self-compassion</td>
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<td>1.92</td>
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<td>Post-intervention</td>
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<td>3.46</td>
<td>1.01</td>
<td>0.313</td>
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<td>0.32</td>
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<td>3.75</td>
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<td>10.29</td>
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Table 5 Effect size estimates of the total, direct and indirect effects of the mindfulness intervention on GHQ total score

<table>
<thead>
<tr>
<th></th>
<th>Total effect</th>
<th>Direct effect</th>
<th>Indirect effect</th>
<th>Mediated</th>
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<td></td>
<td>Beta</td>
<td>95% CI</td>
<td>Beta</td>
<td>95% CI</td>
</tr>
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<td>GHQ total, post-intervention</td>
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<td></td>
<td></td>
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<tr>
<td>Acceptance, post-intervention</td>
<td>-0.65 -1.60</td>
<td>0.31</td>
<td>-0.63 -1.50</td>
<td>0.24</td>
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<tr>
<td>Decentering, post-intervention</td>
<td>-0.59 -1.51</td>
<td>0.26</td>
<td>-0.41 -1.23</td>
<td>0.41</td>
</tr>
<tr>
<td>Self compassion, post-intervention</td>
<td>-0.59 -1.51</td>
<td>0.24</td>
<td>-0.49 -1.32</td>
<td>0.34</td>
</tr>
<tr>
<td>Self-efficacy, post-t intervention</td>
<td>-0.22 -1.11</td>
<td>0.57</td>
<td>-0.12 -0.89</td>
<td>0.65</td>
</tr>
<tr>
<td>GHQ total, 3-months</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Acceptance, post-intervention</td>
<td>-1.22 -2.26</td>
<td>-0.23</td>
<td>-1.20 -2.11</td>
<td>-0.29</td>
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<td>Decentering, post-intervention</td>
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<td>-0.24</td>
<td>-1.09 -2.07</td>
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</tr>
<tr>
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<td>-0.50</td>
<td>-1.27 -2.12</td>
<td>-0.43</td>
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<td>-0.70 -1.62</td>
<td>0.22</td>
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<td>-1.13 -1.96</td>
<td>-0.30</td>
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<td>-0.82 -1.80</td>
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<td>-0.44</td>
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<tr>
<td>Self-efficacy, 3 months</td>
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<td>-0.77 -1.63</td>
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