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Meditation awareness training for the treatment of fibromyalgia syndrome: A randomized controlled trial

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Objectives. The purpose of this study was to conduct the first randomized controlled trial (RCT) to evaluate the effectiveness of a second-generation mindfulness-based intervention (SG-MBI) for treating fibromyalgia syndrome (FMS). Compared to first-generation mindfulness-based interventions, SG-MBIs are more acknowledging of the spiritual aspect of mindfulness.

Design. A RCT employing intent-to-treat analysis.

Methods. Adults with FMS received an 8-week SG-MBI known as meditation awareness training (MAT; $n = 74$) or an active control intervention known as cognitive behaviour theory for groups ($n = 74$). Assessments were performed at pre-, post-, and 6-month follow-up phases.

Results. Meditation awareness training participants demonstrated significant and sustained improvements over control group participants in FMS symptomatology, pain perception, sleep quality, psychological distress, non-attachment (to self, symptoms, and environment), and civic engagement. A mediation analysis found that (1) civic engagement partially mediated treatment effects for all outcome variables, (2) non-attachment partially mediated treatment effects for psychological distress and sleep quality, and (3) non-attachment almost fully mediated treatment effects for FMS symptomatology and pain perception. Average daily time spent in meditation was found to be a significant predictor of changes in all outcome variables.

Conclusions. Meditation awareness training may be a suitable treatment for adults with FMS and appears to ameliorate FMS symptomatology and pain perception by reducing attachment to self.

Statement of contribution

What is already known on this subject?

- Designing interventions to treat fibromyalgia syndrome (FMS) continues to be a challenge.
- There is growing interest into the applications of mindfulness-based interventions for treating FMS.
- Second-generation mindfulness-based interventions (SG-MBIs) are a key new direction in mindfulness research.

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What does this study add?
- Meditation awareness training – an SG-MBI – resulted in significant reductions in FMS symptomatology.
- SG-MBIs recognize the spiritual aspect of mindfulness and may have a role in the treatment of FMS.

Fibromyalgia syndrome (FMS) is a chronic pain disorder that affects approximately 3% of adults, with higher rates of occurrence in females compared to males (Branco *et al.*, 2010). Individuals with FMS typically experience symptoms of widespread musculoskeletal pain, sleep disturbance, poor quality of life, cognitive dysfunction (particularly memory impairment), psychological distress (i.e., depression, anxiety, and stress), and fatigue (Häuser, Wolfe, Tölle, Üçeyler, & Sommer, 2012; Jones *et al.*, 2012; Wolfe, Brähler, Hinz, & Häuser, 2013). The condition is also associated with (1) high rates of presenting at medical services (Schaefer *et al.*, 2011), unemployment (Scott & Jones, 2014), (2) use of incapacity for work and/or disability benefits (Sicras-Mainar *et al.*, 2009; Wolfe *et al.*, 1997), (3) hypochondriasis, self-preoccupation, and self-attachment (Canzonieri, Pollak, Oliveira, Costa, & Natour, 2013; Van Gordon, Shonin, & Griffiths, 2016a; Wolfe, 2009), and (4) low levels of civic engagement (Van Gordon *et al.*, 2016a).

There is no reliable laboratory test for FMS, and diagnosis is often based on the exclusion of other pathologies as well as the patient's verbal responses to gentle manual pressure being applied to tender body points (Van Gordon *et al.*, 2016a). While some patients with FMS appear to respond favourably to pharmacological treatments (principally tricyclic antidepressants and serotonin–norepinephrine reuptake inhibitors), many experience limited symptom reduction as well as adverse effects (Häuser *et al.*, 2012; Luciano *et al.*, 2014; Nüesch, Häuser, Bernardy, Barth, & Jüni, 2013). Consequently, an integrative treatment approach is currently preferred whereby pharmacological treatments are combined with, for example, aerobic exercise, cognitive behavioural therapy, self-help, and/or psycho-education (Van Gordon *et al.*, 2016a).

The need for more efficacious FMS treatments – including those without the side effects of pharmacotherapy – has prompted a growth of scientific investigation into the applications of mindfulness for treating FMS (Langhorst, Klose, Dobos, Bernardy, & Häuser, 2013; Modrego *et al.*, 2016). Mindfulness derives from Buddhist practice and is concerned with focusing awareness on moment-to-moment sensory and psychological experience (Garcia-Martin *et al.*, 2016). The practice is understood to increase perceptual distance from distressing sensory and psychological stimuli, and this objectification of pain helps to regulate its impact on psychosocial functioning (Morone, Lynch, Greco, Tindle, & Weiner, 2008; Van Gordon *et al.*, 2016a).

Until recently, the health care literature has predominantly focused on what have been termed first-generation mindfulness-based interventions (FG-MBIs). The two most empirically investigated FG-MBIs are mindfulness-based stress reduction (MBSR; Kabat-Zinn, 1990) and mindfulness-based cognitive therapy (Segal, Williams, & Teasdale, 2002). Findings from FG-MBI studies indicate that they may have applications in the treatment of FMS. For example, a meta-analysis (n = 674) – incorporating six randomized controlled trials (RCTs) of MBSR – concluded that it led to short-term improvements in quality of life and pain compared to treatment-as-usual or active control groups (Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013). A more recent review study (n = 702; 10 RCTs, prospective or retrospective studies) that included a greater range of FG-MBIs (i.e., in addition to MBSR) reported mild-to-moderate treatment effects (Henke & Chur-Hansen, 2014). These findings are consistent with a meta-analysis (comprising nine RCTs with

active control groups) in which effect sizes in the mild-to-moderate range were reported for the effectiveness of FG-MBIs in the treatment of chronic pain (Cohen's d = .33; Goyal *et al.*, 2014).

Second-generation mindfulness-based interventions (SG-MBIs) reflect a new direction in mindfulness research and practice and have been formulated in order to address some of the limitations of FG-MBIs. SG-MBIs differ from FG-MBIs by adopting a broader definition of mindfulness that is more acknowledging of its spiritual roots. For example, an established FG-MBI definition of mindfulness was proposed by Kabat-Zinn who defined it as 'paying attention in a particular way: on purpose, in the present moment, and non-judgmentally' (1994, p. 4). This definition frames mindfulness as a predominantly attentional process and is therefore arguably less encompassing than a recently proposed SG-MBI definition in which mindfulness is deemed to be 'the process of engaging a full, direct, and active awareness of experienced phenomena that is (1) spiritual in aspect and, (2) maintained from one moment to the next' (Shonin & Van Gordon, 2015, p. 900).

In addition to being overtly spiritual in nature, SG-MBIs are distinct from FG-MBIs due to them employing (1) a greater range of meditative techniques (generally delivered in a secular context), (2) ethics as a key component of the taught programme, and (3) an instructor training programme that typically requires several years of supervised mindfulness practice (Van Gordon, Shonin, & Griffiths, 2015). Some SG-MBIs also introduce participants to meditative concepts such as impermanence, interconnectedness, non-self or emptiness, and non-attachment (Shonin & Van Gordon, 2015). The introduction of the non-attachment principle is based on the Buddhist view that suffering arises as a result of an individual's 'attachment' to both themselves and external phenomena (e.g., wealth, people, and reputation; Feliu-Soler *et al.*, 2016). The Buddhist notion of attachment has been defined as 'the over-allocation of cognitive and emotional resources towards a particular object, construct, or idea to the extent that the object is assigned an attractive quality that is unrealistic and that exceeds its intrinsic worth' (Shonin, Van Gordon, & Griffiths, 2014a, p. 126). Consequently, in the traditional meditation literature, reducing attachment (or augmenting non-attachment) is deemed to be an important feature of the path to psycho-spiritual well-being. Furthermore, given that self-attachment is deemed to play a role in the maintenance of FMS (Van Gordon *et al.*, 2016a), FMS interventions that specifically aim to reduce attachment (to self, symptoms, and environment) warrant empirical investigation.

A positive association has been observed between spirituality and positive affect in individuals with FMS (Moreira-Almeida & Koenig, 2008). Consistent with this finding, qualitative studies of SG-MBIs have demonstrated that participants of both healthy and clinical status attribute improvements in health outcomes to increased spiritual awareness. Although a study investigating the effectiveness of an SG-MBI for treating FMS has not been conducted to date, SG-MBIs have demonstrable applications for treating many of the individual symptoms of FMS including psychological distress (Van Gordon, Shonin, Sumich, Sundin, & Griffiths, 2014), self-preoccupation and maladaptive ego-constructs (Shonin & Van Gordon, 2015; Shonin, Van Gordon, & Griffiths, 2014b), and sleep disturbance (Van Gordon, Shonin, & Griffiths, 2016b). Using these findings as a basis, the purpose of the present RCT was to address the need for a rigorous empirical assessment of the effectiveness of an SG-MBI for treating FMS. Primary outcomes were fibromyalgia symptomatology, pain perception, sleep quality, and psychological distress. Secondary outcomes were non-attachment and civic engagement.

Method

Design

An RCT (trial no. NCT02800720) compared meditation awareness training (MAT) with a purpose-designed active control condition. Consolidated Standards of Reporting Trials (CONSORT; Boutron, Altman, Schulz, & Ravaud, 2008; Schulz, Altman, & Moher, 2010) guidelines for non-pharmacological interventions were followed where applicable. The trial was approved by the research team's University Ethics Committee. A qualitative study exploring participant's experiences and general feasibility was embedded in the RCT, and findings from the qualitative study are reported elsewhere (see Van Gordon *et al.*, 2016a).

Participants

Participants were male and female English-speaking adults with a current diagnosis of FMS (as confirmed by a letter from a general practitioner [GP], rheumatologist, or hospital pain consultant). Participation was on a voluntary basis, and individuals were recruited via talks at FMS self-help groups, posters in GP surgeries, and emails sent to members of FMS support groups. Furthermore, some East Midlands GPs were made aware of the study and were asked to informally raise awareness amongst relevant service users by suggesting that they could contact the research team for further information.

As part of the informed consent process, participants were required to acknowledge that they understood that MAT (1) is deemed by its founders to be both a psychological and spiritual intervention, (2) is not intended to be a course on Buddhism (i.e., it is secular in context) but makes extensive use of Buddhist meditative techniques and principles, and (3) was founded by two Western psychologists who are also Buddhist monks. This step was implemented for ethical and transparency reasons on account of the fact that some FG-MBIs have been criticized for emphasizing or masking their affiliation with Buddhism to suit their needs (Purser, 2015).

Eligibility criteria

In addition to a current FMS diagnosis, the eligibility criteria for participation in the study were as follows: (1) being aged between 18 and 65 years, (2) being able to read and write using the English language, (3) not currently undergoing formal psychotherapy, (4) no changes in psychopharmacology type or dosage 1-month prior to intervention (although stable prescription medication was permitted), and (5) not currently practicing mindfulness or meditation. Participants were also required to confirm their availability to complete an 8-week intervention and 6-month follow-up assessment. Attendance at at-least seven of the eight weekly sessions is a prerequisite for course completion. In this study, participants that did not attend the requisite number of sessions were classed as having dropped out and were excluded from (or where unavailable to attend) future assessment phases. Participants were informed about the attendance requirements via the informed consent procedure.

Randomization and blinding

The first author (and principal investigator) was responsible for recruitment and participant screening. Following the screening process, eligible participants were assigned five-digit pseudonyms. The document linking participant demographic data and

screening results to their pseudonyms was stored in a sealed opaque envelope in a lockable unit within the office of the principal investigator, and all other researchers were blinded as to its contents. A list of eligible participant pseudonyms, grouped by sex, was then passed to the second author who conducted the randomization procedure (the principal investigator was not involved in the randomization process). On a sex-strata basis, participant pseudonyms were placed into a bowl and then selected one at a time prior to being placed, in alternating sequence, into one of two separate envelopes corresponding to the intervention and control group (participants were grouped by sex in order to yield sex-matched intervention and control groups). Randomization was implemented prior to administering baseline psychometric tests in order to facilitate the blinding of researchers involved in conducting the randomization procedure. Participants were blinded as to allocation condition until after completion of baseline assessments and were likewise blinded as to which allocation condition featured the target intervention.

Sample size calculation

Based on an equal distribution between allocation conditions, statistical power calculations using GPOWER Software (Faul & Erdinger, 1992) indicated a total sample size of 128 participants would be required for an effect size of .5, an alpha of .05, and 80% power. Consistent with literature reviews conducted by other authors (e.g., Glombiewski *et al.*, 2010), a comprehensive literature review conducted by the present authors found that an effect size of .5 appears to be standard for efficacy studies of mindfulness-based interventions as well as FMS treatment studies. The power calculation was conducted with the primary outcome measures in mind. An over-recruitment margin of 20 participants was applied to account for drop out.

Programme description

Meditation awareness training is an 8-week SG-MBI in which mindfulness is an integral component, but is not the exclusive focus (Shonin *et al.*, 2014b; Van Gordon *et al.*, 2014). The intervention is delivered by instructors who have undergone a 3-year supervised MAT training programme. Participants attend eight weekly workshops (each lasting 2 hr) and receive a CD of guided meditations to facilitate daily self-practice. The weekly sessions comprise three distinct phases: (1) a taught/presentation component (approximately 45 min), (2) a facilitated group discussion component (approximately 35 min), and (3) guided meditation and/or mindfulness exercises (approximately 30 min). A 10-min break is scheduled prior to commencing the guided meditation exercises. In the third and eighth week of the programme, participants attend one-to-one support sessions (each of 50-min duration) with the programme instructor (for comprehensive information regarding the intervention protocol, see Van Gordon *et al.*, 2014).

Due to the fact that individuals with FMS can experience difficulties in concentrating (referred to as 'fibro fog'; Mease *et al.*, 2008), in this study the intervention was slightly modified to include an additional 5-min break that occurred 45 min into the session (this was achieved by reducing the duration of the facilitated group discussion component to 30 min). In order to directly target the key symptoms and correlates of FMS, the intervention was also modified in this study to include an extended focus on: (1) mindfulness techniques specifically concerned with meditatively observing and objectifying somatic pain, (2) compassion meditation in order to help participants become less preoccupied with their illness (i.e., by becoming more aware of the suffering of others),

and (3) 'engaged mindfulness' (a technique intended to raise participants' awareness of the benefits – to both themselves and others – of contributing to the welfare of society in a manner that does not exceed the physical and/or psychological demands of their condition).

Rather than prescribe a fixed amount of daily meditation practice time, participants are encouraged to adopt a dynamic meditation routine and are guided on an individual basis to find the optimum frequency and duration of meditation sessions. According to Van Gordon *et al.* (2014), this avoids divisions being formed between formal seated meditation sessions and meditation during everyday life activities. In this study, MAT was delivered by the second author (30 years meditation teaching experience) and the first author provided supervision in order to identify any deviations from the standard intervention delivery format. Supervision was implemented by the first author (1) silently observing at least 15 min of each weekly session (not always following the same amount of elapsed time into the 2-hr session), and (2) engaging in discussion with the programme facilitator on a weekly basis. With the exception of the planned modifications specified above, no other deviations from the standard protocol were identified.

Meditation awareness training (and the control intervention) were delivered across multiple sites in the East Midlands in separate training rooms utilized by a meditation centre and GP surgery. Other than an overhead projector, chairs and tables, a singing bowl for use during the guided meditations, and sufficient space to practice walking meditation (that requires participants to walk in single file), no special equipment or arrangements were required. In this study, the intervention was delivered using group sizes of approximately 25 participants.

Control condition

Cognitive behavioural theory for groups (CBTG) is a purpose-designed control intervention formulated by Shonin, Van Gordon, Dunn, Singh, and Griffiths (2014). CBTG is based on guidelines by MacCoon *et al.* (2012) for the development of suitable control groups for studies of mindfulness-based interventions (MBIs). CBTG involves educating participants in cognitive behavioural theory and principles. It is identical to the intervention condition on all non-specific factors such as overall course length, individual session duration, group and one-to-one discussion component, group size, and inclusion of an at-home practice element. Weekly sessions comprise: (1) a taught presentation component (45 min), (2) a facilitated group discussion component (30-min duration in this study), (3) guided discovery educational exercises (30 min), and (4) the same number and duration of breaks as the target intervention. The weekly sessions are explicitly education-focused and do not include any practice or discussion of meditation.

To control for a facilitator effect and ensure consistency of didactic style, CBTG was delivered by the same instructor who facilitated the MAT programme. To assess for differences in the instructor's levels of enthusiasm between groups, participants in both the intervention and control groups were asked to rate (on a 1–5 Likert scale) the instructor's levels of planning and motivation. As with the target intervention, the CBTG sessions were supervised to identify any deviations from the standard intervention delivery format. With the exception of an additional 5-min break that was introduced in order to match the target intervention, there were no planned or unplanned modifications to the delivery of CBTG.

Outcome measures

Study outcomes were assessed via the following well-established psychometric scales:

Revised Fibromyalgia Impact Questionnaire (FIQ-R; Bennett *et al.*, 2009): The FIQ-R assesses the impact of FMS across the three domains of function, overall impact, and symptoms. The FIQ-R includes 21 questions that are graded on a 0–10 numeric scale and higher scores correspond to higher levels of negative impact. Questions are framed in the context of the past 7 days and include items such as 'difficulty in sitting in a chair for 45 min, 'fibromyalgia prevented me from accomplishing goals for the week', and 'please rate the level of pain'. The summed score for the function domain (range 0–90) is divided by 3, the summed score for overall impact domain (range 0–20) remains unchanged, and the summed score for the symptom domain (range 0–100) is divided by 2. The total FIQ-R score is the sum of the three modified domain scores, and the maximum total score is 100. Based on over 250 studies employing either the FIQ-R or the original Fibromyalgia Impact Questionnaire individuals diagnosed with FMS typically score between 55 and 65 (Bennett *et al.*, 2009).

Short-form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987): The Pain Perception Index of the SF-MPQ comprises 15 sensory or affective pain descriptors (e.g., *throbbing*, *aching*, *heavy*, and *punishing*) that are rated on a 4-point Likert scale (0 = *none*, 3 = *severe*). Scores for each pain descriptor are combined to give a total measure of pain perception. The maximum score is 45, and a mean improvement of more than 5 points is deemed to be clinically important (Hawker, Mian, Kendzerska, & French, 2011).

Depression, Anxiety, and Stress Scale (DASS; Lovibond & Lovibond, 1995): The 21-item DASS assesses psychological distress and comprises three subscales: (1) depression, (2) anxiety, and (3) stress. The scale is scored on a 4-point Likert scale (from: 0 = *Did not apply to me at all*, to 3 = *Applied to me very much or most of the time*) and features items such as 'I found it hard to wind down' and 'I felt that life was meaningless'. The DASS is completed in respect of the foregoing 7-day period. According to the DASS manual (Lovibond & Lovibond, 1995), the percentile cut-offs and corresponding mean scores for symptom severity are as follows: 0–78 ($M \leq 13$) = normal, 78–87 (M = 14–18) = mild, 87–95 (M = 19–28) = moderate, and >95 ($M \geq 28$ = severe).

Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989): The seven-item PSQI assesses sleep quality during the past month across the domains of subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. The PSQI is scored on a 4-point Likert scale (0 = *no difficulty*, 3 = *extreme difficulty*) and features items such as 'during the past month, how would you rate your sleep quality overall?' The maximum score is 21, and a global score of ≥5 indicates a poor quality of sleep (Buysse *et al.*, 1989).

Non-Attachment Scale (NAS; Sahdra, Ciarrochi, Parker, Marshall, & Heaven, 2015; Sahdra, Shaver, & Brown, 2010): The seven-item NAS is based on a Buddhist model of mental illness and evaluates the degree to which a person becomes attached to their experiences on the psychological, social, and environmental plane. The NAS also assesses the degree to which a person is 'attached to themselves' because according to Buddhist theory, attachment to psychological or environmental phenomena arises due to a firm sense of selfhood (Van Gordon, Shonin, & Griffiths, 2016c). The NAS is constructed upon the Buddhist notion that the self does not inherently exist and that

attachment to self and environment thus constitutes a maladaptive condition (see Shonin *et al.* (2014a) for a discussion of the differences between Buddhist and Western psychological conceptualizations of attachment). The NAS is scored on a 6-point Likert scale (from 1 = *disagree strongly* to 6 = *agree strongly*) and features items such as 'When pleasant experiences end, I am fine moving on to what comes next'. The maximum score is 42, and higher scores reflect lower levels of attachment (or higher levels of non-attachment).

Civic Engagement: Participants were asked to record how many hours during the previous 7 days they had spent engaging in paid work, voluntary work, participating in an event or meeting hosted by a community organization or group, and/or mentoring another non-family member of the community.

Data analysis

A significance level of $p < .05$ and two-tailed tests were employed throughout. Independent-samples *t*-tests (for continuous variables) and chi-square tests with Yates's correction (for categorical variables) were used to identify any significant differences between groups in demographic characteristics or baseline-dependent variable mean scores.

Mixed-effects models (also known as multilevel models, random-effects model, and hierarchical models) were used to examine the effect of intervention (MAT) and control (CBTG) on all six outcome measures (i.e., FIQ-R, SF-MPQ, DASS, PSQI, NAS, and Civic Engagement). Mixed-effects modelling accounts for shared variance within-participants while modelling between-participant differences. The benefits of mixed-effects models are well-established and include reduced assumptions (i.e., homoscedasticity, sphericity, and compound symmetry) and greater statistical power over traditional methods (Baguley, 2012a; Gelman & Hill, 2007; Quené & van den Bergh, 2004; Snijders & Bosker, 1999). Furthermore, mixed-effects models adequately account for baseline differences in outcome scores by modelling (per participant) the *change* in outcome measure relative to baseline across all measurement periods (i.e., pre-, post-, and follow-up). Prior to model estimation, distributions of all outcome variables and random-effects residuals were inspected and deemed to be close approximations of normality. Using the absolute median deviation method to detect outliers (Leys, Ley, Klein, Bernard, & Licata, 2013), no data points were deemed to be extreme in the present data set. The RCT was conducted on an 'intent-to-treat' basis with missing data at endpoint substituted using last-observation-carried-forward basis.

Results

Recruitment and allocation

Participant demographic characteristics are summarized in Table 1. A total of 231 individuals completed the screening questionnaire and 83 of these were screened-out on the grounds of ineligibility. The main reasons for exclusion were (1) currently receiving structured psychotherapy (32 individuals), (2) unable to confirm current diagnosis of FMS (23 individuals), (3) recent change in psychopharmacology type or dosage (13 participants), and (4) currently attending meditation or mindfulness classes (eight participants). Of the 148 remaining participants, 74 were allocated to the intervention group and the same number to the control group (see Figure 1). MAT and the control

group interventions were each delivered in three separate tranches (i.e., approximately 25 participants per tranche).

Non-completion, attendance, and fidelity of implementation

There were no significant differences between MAT and CBTG in the number of participants that dropped out of the study prior to completing the intervention (MAT = 20, CBTG = 22). There were no significant differences between dropout and completion samples (i.e., irrespective of allocation condition) in sex, education, employment status, marital status, and ethnicity. However, there was a significant difference for age where the mean dropout and completer age were 44.4 years (SD = 8.8) and 47.9 years (SD = 9.6), respectively, $t(91) = -2.19$, $p = .03$. The main reasons for non-completion were that the participant: (1) did not attend at least seven of the eight weekly sessions (MAT = 10, CBTG = 12), (2) found the intervention to be overly demanding (MAT = 6, CBTG = 6), or (3) changed medicine or commenced structured psychotherapy after baseline assessment (MAT = 3, CBTG = 2). Of those participants that attended the post-intervention assessment phase, nine MAT and 12 CBTG participants were lost to follow-up. There were no significant differences between allocation conditions in participant ratings of the instructor's levels of planning and motivation. MAT participants practiced meditation for an average of 41.11 min per day (SD = 15.26).

Demographic and baseline characteristics

There were no significance differences between allocation conditions in baseline demographic characteristics (i.e., sex, age, education, employment status, marital status,

Table 1. Baseline demographic characteristics for each allocation condition

Characteristic	MAT (n = 74)	CBTG (n = 74)
Age, mean (SD)	46.41 (9.06)	47.34 (9.83)
Female (%)	82.4	83.8
Employed (%)	52.70	48.65
Education (%)		
School leaver	55.41	59.46
Vocational	25.68	25.68
University	18.92	14.87
Marital status (%)		
Married	56.76	63.51
Single	9.46	5.41
Divorced	27.03	24.32
Widow	6.76	6.76
Ethnicity (%)		
White (British)	77.03	71.62
White (Non-British)	9.46	9.46
Asian	8.11	9.46
Black (Caribbean)	5.3	9.46

Note. CBTG = Cognitive behavioural theory for groups; MAT = meditation awareness training.

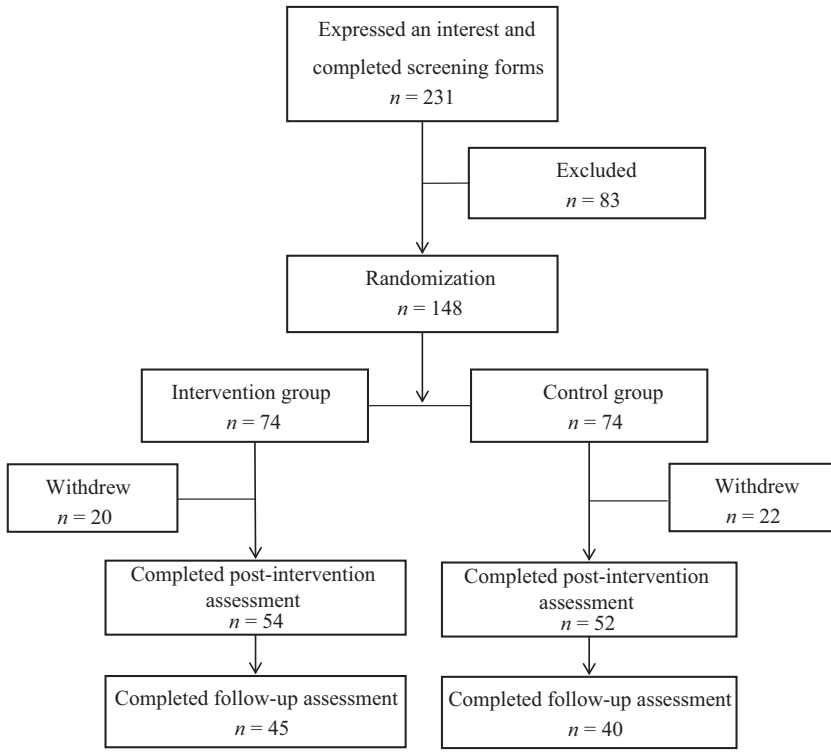

Figure 1. Flow of participants through recruitment and assessment phases.

or ethnicity). Likewise, there were no significant differences between MAT and the CBTG group in baseline scores on each of the six outcome measures.

Analysis of outcome measures

A separate mixed-effects model was estimated for each outcome measure (see Table 2 for means and *SD*s). Each model included Group (control, intervention) and measurement Interval (pre-, post-, follow-up) as fixed effects (i.e., in the form of an interaction predictor [Group*Interval]) and Participant (within measurement Interval) as a random effect. This allowed a unique regression model (i.e., intercept and slope) to be specified for every participant across measurement intervals (see Figure S1 for an exemplar modelling DASS scores across measurement intervals). Results from the six estimated mixed-effects models show an overall strong effect of intervention compared to control for all outcome measures (see Table 3 for summaries of each model). More specifically, relative to baseline and compared to control, intervention resulted in a (1) 6.24 (at post) and 7.92 (at follow-up) greater decrease in FIQ-R score, (2) 2.01 (at post) and 3.01 (at follow-up) greater decrease in SF-MPQ score, (3) 3.70 (at post) and 4.86 (at follow-up) greater decrease in DASS score, (4) 1.50 (at post) and 2.28 (at follow-up) greater decrease in PSQI score, (5) 2.81 (at post) and 3.57 (at follow-up) greater increase in NAS score, and (6) 1.69 (at post) and 2.05 (at follow-up) greater increase in Civic Engagement (see Figure S2 for a breakdown of intervention and control group outcome means across measurement intervals). Overall, results demonstrate that MAT significantly outperformed CBTG at both post- and follow-up assessment phases for all six outcome measures.

Table 2. Means and standard deviations of outcome variable scores for group and time

		FIQ-R		SF-MPQ		DASS		PSQI		NAS		Civic engagement	
	Group	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*	Mean	*SD*
Pre	Intervention	55.24	10.06	28.04	4.64	26.61	5.33	14.11	2.43	18.45	4.11	17.24	11.62
	Control	54.04	8.86	27.58	3.69	26.24	4.19	14.09	2.35	18.28	3.70	17.78	12.23
Post	Intervention	46.89	9.55	24.82	4.56	21.82	5.02	11.91	2.71	22.14	4.68	19.35	11.95
	Control	51.93	8.80	26.38	3.75	25.16	4.11	13.39	2.53	19.16	3.92	18.20	11.83
Follow-up	Intervention	45.65	10.95	23.84	5.38	20.65	5.96	11.36	3.09	22.78	5.39	19.85	11.80
	Control	52.36	9.29	26.39	3.93	25.15	4.58	13.64	2.55	19.05	3.78	18.34	12.23

Note. DASS = Depression, Anxiety, and Stress Scale; FIQ-R = Revised Fibromyalgia Impact Questionnaire; NAS = Non-Attachment Scale; PSQI = Pittsburgh Sleep Quality Index; SF-MPQ = Short-form McGill Pain Questionnaire.

Table 3. Fixed-effects estimates (at post- and follow-up assessment phases) with 95% CIs for all six outcome measures

	Value	CIs	*t*-Value	*p*-Value
FIQ-R				
(Intercept)	54.04			
Post	−6.24	−8.24 to −4.25	−6.13	<.001
Follow-up	−7.92	−13.76 to −7.76	−6.14	<.001
SF-MPQ				
(Intercept)	27.58			
Post	−2.01	−2.80 to −1.26	−5.24	<.001
Follow-up	−3.01	−4.09 to −1.94	−5.48	<.001
DASS				
(Intercept)	26.24			
Post	−3.70	−4.77 to −2.63	−6.80	<.001
Follow-up	−4.86	−6.30 to −3.43	−6.63	<.001
PSQI				
(Intercept)	14.09			
Post	−1.50	−2.03 to −0.96	−5.53	<.001
Follow-up	−2.28	−2.94 to −1.63	−6.83	<.001
NAS				
(Intercept)	18.28			
Post	2.81	1.92 to 3.70	6.17	<.001
Follow-up	3.57	2.50 to 4.63	6.56	<.001
Civic engagement				
(Intercept)	17.78			
Post	1.69	0.53 to 2.84	2.86	<.01
Follow-up	2.05	1.10 to 3.00	4.24	<.001

Note. DASS = Depression, Anxiety, and Stress Scale; FIQ-R = Revised Fibromyalgia Impact Questionnaire; NAS = Non-Attachment Scale; PSQI = Pittsburgh Sleep Quality Index; SF-MPQ = Short-form McGill Pain Questionnaire.
The reference category in all cases is the control group. This means a Post-FIQ-R score of −6.24 can be interpreted as a −6.24 change in FIQ-R score in comparison with the control condition relative to baseline (i.e., Pre-FIQ-R score).

Intervention engagement effects

A linear model was estimated, regressing the number of minutes meditated per day onto the difference between baseline and follow-up for each outcome measure. Results showed significant linear relationships between the number of minutes meditated and all outcome differences (see Table 4). This suggests that the level of engagement with meditation is a good indicator of its effect, as captured by six different outcome measures.

Mediation analysis

Several models were estimated to test the mediating effects of the two secondary outcome variables (Civic Engagement, NAS) on all primary outcome variables (FIQ-R, SF-MPQ, DASS, PSQI). Given the established relationships between IV-DV and IV-M (i.e., paths *a* and *c* of Figure S3) via the mixed-effects models (see Table 3), only path *b* was inspected for a correlation between mediator and DV (Baron & Kenny, 1986). Analysis demonstrated significant relationships between each mediator and respective outcome measure (see

Table 4. Parameter estimates of linear models for minutes meditated and outcome measures

Outcome measures	Intercept	Estimate	*SE*	*t*-Value	*p*-Value
FIQ-R	7.59	−0.50	0.06	−8.05	<.001
SF-MPQ	0.82	−0.16	0.03	−5.53	<.001
DASS	3.17	−0.28	0.03	−8.28	<.001
PSQI	0.72	−0.11	0.02	−6.71	<.001
NAS	−2.87	0.21	0.02	9.20	<.001
Civic engagement	0.05	0.09	0.03	2.59	<.05

Note. DASS = Depression, Anxiety, and Stress Scale; FIQ-R = Revised Fibromyalgia Impact Questionnaire; NAS = Non-Attachment Scale; PSQI = Pittsburgh Sleep Quality Index; SF-MPQ = Short-form McGill Pain Questionnaire.
All outcome measure differences (baseline – follow-up) are predicted by the number of average minutes meditated per day.

Table 5). Having established that all variables were correlated, a comparison between the direct (path *c*) and indirect effects (paths $c + b$) was undertaken to determine whether the relationship between the IV and DV was attenuated by the inclusion of a mediator (M).

The results showed that Civic Engagement was a partial mediator of treatment effects across all outcome measures (FIQ-R, SF-MPQ, DASS, PSQI). This can be seen in Table 6 where each IV-DV regression coefficient is reduced (but remains statistically significant) when Civic Engagement is introduced into the model. Treating NAS as a mediator resulted in partial mediation of treatment effects for DASS and PSQI but close to full mediation (i.e., IV-DV paths became non-significant with the inclusion of M) for FIQ-R and SF-MPQ (see Table 6). This suggests that non-attachment to the self and environment is an important mediating mechanism in reducing fibromyalgia symptoms.

Discussion

In the present study, an RCT compared MAT with a purpose-designed control intervention in individuals with FMS. MAT participants demonstrated significant

Table 5. Parameter estimates of path b treating the potential mediator as a predictor of each outcome measure

	Intercept	Estimate	*SE*	*t*-Value	*p*-Value
Civic engagement					
FIQ-R	−2.66	−1.87	0.17	−10.80	<.001
SF-MPQ	−1.55	−0.72	0.07	−9.44	<.001
DASS	−1.85	−1.06	0.10	−10.35	<.001
PSQI	−0.93	−0.42	0.05	−8.33	<.001
NAS					
FIQ-R	−0.27	−2.10	0.08	−24.60	<.001
SF-MPQ	−0.69	−0.78	0.04	−16.30	<.001
DASS	−0.58	−1.15	0.05	−19.62	<.001
PSQI	−0.30	−0.50	0.02	−17.11	<.001

Note. DASS = Depression, Anxiety, and Stress Scale; FIQ-R = Revised Fibromyalgia Impact Questionnaire; NAS = Non-Attachment Scale; PSQI = Pittsburgh Sleep Quality Index; SF-MPQ = Short-form McGill Pain Questionnaire.

Table 6. Parameter estimates for mediation models with civic engagement and NAS as separate mediators of all primary outcome variables (FIQ-R, SF-MPQ, DASS, PSQI)

	FIQ-R		SF-MPQ		DASS		PSQI	
	Step 1	Step 2	Step 1	Step 2	Step 1	Step 2	Step 1	Step 2
Intercept	−1.67	−0.77	−1.19	−0.84	−1.09	−0.59	−0.45	−0.27
b (IV)	−7.92***	−4.56***	−3.01***	−1.71***	−4.86***	−3.01***	−2.28***	−1.58***
b (civic eng.)		−1.63***		−0.63***		−0.89***		−0.33***
F change	87.84***		65.44***		79.18***		46.49***	
R^2	.21	.51	.17	.42	.23	.50	.24	.42
Intercept	−1.67	−0.08	−1.18	−0.59	−1.09	−0.25	−0.45	−0.09
b (IV)	−7.91***	−0.55	−3.01***	−0.27	−4.86***	−0.97*	−2.28***	−0.61*
b (NAS)		−2.06***		−0.76***		−1.08***		−0.46***
F change	450.50***		195.42***		271.21***		199.3***	
R^2	.20	.80	.17	.64	.23	.73	.24	.68

Note. DASS = Depression, Anxiety, and Stress Scale; FIQ-R = Revised Fibromyalgia Impact Questionnaire; NAS = Non-Attachment Scale; PSQI = Pittsburgh Sleep Quality Index; SF-MPQ = Short-form McGill Pain Questionnaire.
Step 1 = direct effect (DV~IV), Step 2 = indirect effect (DV~IV + M) ['~'=predicted by].
Sig. level: ***.001, *.05.

improvements over control group participants in levels of FMS symptomatology, pain perception, sleep quality, psychological distress, non-attachment, and civic engagement. The therapeutic gains attributed to MAT were maintained (and in some cases slightly augmented) at 6-month follow-up.

Approximately one in four MAT participants did not complete the intervention. This level of non-completion is consistent with other studies administering meditation-based interventions to individuals with FMS where non-completion rates between 21% and 37% have been reported (e.g., Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Mannerkorpi & Arndorw, 2004; Weissbecker *et al.*, 2004). However, in the present study, only six participants reported that they dropped out because the intervention was over-demanding. A more common reason for non-completion was failure to attend at least seven of the eight weekly MAT sessions (i.e., 10 participants reported that they were unable to attend one or more sessions due to unforeseen circumstances). Given that some studies investigating the applications of mindfulness for treating FMS have set the requisite attendance rate as low as 50% (e.g., Grossman, Schwarzer, Jena, Naumann, and Walach (2011), and given that FMS treatment studies typically report relatively high rates of dropout (i.e., when compared to other patient groups), the present authors deem that the non-completion levels observed here support the acceptability of MAT for the target population (i.e., an equivalent level of dropout observed in an intervention with higher attendance requirements suggests that it is relatively more acceptable). Additional support for the acceptability of the intervention is derived from the fact that no significant differences in drop out were observed across allocation conditions.

With the exception of meditative practices and principles, the CBTG control condition was designed to replicate MAT on all other intervention design factors (e.g., duration, facilitator–participant contact time, group discussion, and instructor didactic style). Compared to a wait list control, treatment-as-usual, or 'convenience' comparison intervention, the use of a 'matched' active control condition allows therapeutic gains due to non-specific factors (e.g., group interaction and therapeutic alliance) to be filtered out. Consequently, findings from the present study provide a reliable indicator of the treatment effects that can be attributed to the 'active ingredient' of MAT (i.e., meditation). The fact that therapeutic improvements were due to meditation is further supported by findings from the regression analysis that showed average daily time spend meditating was a significant predictor of changes in all outcome variables. Designing studies that permit such inferences to be made is particularly important for MBIs because such interventions typically employ a variety of therapeutic and relaxation techniques.

Irrespective of allocation condition, a slight but statistically significant age difference was observed in the present study between completers and non-completers. The fact that non-completers were slightly older that completers (mean age of 47.9 and 44.4 years, respectively) could suggest that the acceptability of both MAT and CBTG is reduced in slightly older FMS populations. However, both the age difference and non-completion sample size are too small to draw reliable conclusions in this respect. Furthermore, this finding has not been observed in other studies of MAT or – to the best of the present authors' knowledge – in other MBI studies involving individuals with FMS. Nevertheless, future FMS treatment studies using MBIs could seek to investigate this finding further.

The improvements experienced by participants across all primary outcome measures (i.e., fibromyalgia symptomatology, pain perception, psychological distress, and sleep quality) are largely consistent with FG-MBI studies involving individuals with FMS (e.g., Davis & Zautra, 2013; Henke & Chur-Hansen, 2014; Lauche *et al.*, 2013). However, based on a single SG-MBI study, it is difficult to draw reliable conclusions as to the comparative

effectiveness of SG-MBIs and FG-MBIs for individuals with FMS. Reliably formulating such conclusions would require further controlled large-sample FMS treatment studies using SG-MBIs and/or several purpose designed head-to-head studies. Data on which particular MBI is most effective for FMS (or a given medical illness) are certainly of value to the medical community. However, rather than seek to outperform or replace FG-MBIs, the primary intent underlying the SG-MBI initiative appears to be that of providing service users with a greater choice of evidence-based mindfulness intervention – including that of practicing mindfulness in a manner that is more consistent with the traditional spiritual conceptualization of the technique (Van Gordon, Shonin, Lomas, & Griffiths, 2016).

Notwithstanding the consistency between findings from primary outcome measures in the present study and those from FMS treatment studies using FG-MBIs, a qualitative feasibility study that was embedded within the present RCT (i.e., Van Gordon *et al.*, 2016a) reported outcomes that are not typically associated with FG-MBIs. More specifically, analysis of interview transcripts from 10 MAT participants that were randomly allocated to a qualitative arm yielded a master theme of *spiritual growth*. This theme is consistent with outcomes from the mediation analysis which showed that non-attachment to self almost fully mediated the treatment effects for FMS symptomatology and pain perception. In Buddhism, 'spiritual growth' and 'reductions in attachment' are arguably synonymous terms because according to the Buddhist conceptualization, a practice can be deemed spiritual if it helps to transcend 'selfhood' (Van Gordon, Shonin, Lomas, *et al.*, 2016).

The above-mentioned qualitative study also reported a theme of increased willingness to civically engage that participants attributed to greater spiritual awareness as well as a reduced emphasis on their own suffering and life problems (Van Gordon *et al.*, 2016a). This is consistent with the finding in the current study of civic engagement partially meditating the treatment effects for all outcome variables. Being more 'other-centred' improves life perspective and dismantles self-obsessed and self-disparaging cognitive schemas (Shonin, Van Gordon, Compare, Zangeneh, & Griffiths, 2015). Furthermore, a compassionate disposition and spiritual outlook has been shown to increase social-connectedness and prosocial behaviour (Hutcherson, Seppala, & Gross, 2008; Leiberg, Klimecki, & Singer, 2011). Thus, viewing the findings of this and the embedded qualitative study as a collective, it seems reasonable to conclude that a meditation-induced growth in spirituality played an important mechanistic role in improving both primary and secondary outcomes.

Key limitations of the study were reliance on self-report measures and the fact that outcomes were only assessed at three time points (i.e., pre-, post-, and 6-month follow-up). A greater number of assessment phases would provide insights on which particular stages of the 8-week intervention have the strongest treatment effects. Furthermore, an assessment beyond the 6-month stage would provide a better indication of maintenance effects as well as the need for booster sessions. A further factor that may limit findings is a phenomenon that has been termed the 'popularity effect' (Shonin, Van Gordon, & Griffiths, 2015). Mindfulness and meditation are experiencing growing popularity amongst both the scientific community and general public. Consequently, outcomes of both FG-MBI and SG-MBI studies could be influenced by participants' belief that they are receiving a 'fashionable' and/or 'proven' psychotherapeutic technique (Shonin, Van Gordon, & Griffiths, 2015). This is a difficult confounding factor to control for because it is almost impossible to blind participants from the fact they are undergoing mindfulness training. Finally, although GPs and other health professionals assisted in raising awareness of the study, interested participants were required to contact the research team directly in

order to be considered for recruitment. Thus, participants in the present study were effectively 'self-referring' and it is difficult to gauge whether outcomes would be as favourable for individuals directly referred by their GP or another health professional.

The present study suggests that MAT is an effective FMS treatment and contributes further evidence supporting the applications of SG-MBIs in clinical and other applied settings. A considerable focus on the 'self' by some individuals with FMS means that SG-MBIs (that place emphasis on reducing attachment to self) may be particularly suitable treatments for this population group. Further controlled empirical studies using large sample sizes are therefore warranted.

Author contributions

We confirm that all authors of this article had access to the study data, are responsible for all contents of the article, and had authority over manuscript preparation and the decision to submit the manuscript for publication.

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Ethical compliance

The study received ethical approval from the ethics committee of Nottingham Trent University College of Business Law and Social Sciences.

Conflict of interest

All authors declare no conflict of interest.

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Supporting Information

The following supporting information may be found in the online edition of the article:

Figure S1. Mixed effect model for DASS.
Figure S2. Outcome means (intervention and control) across measurement intervals with two-tier 95% CIs.
Figure S3. Example of mediation model paths.