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#### **Compliance with Ethical Standards**

Conflict of Interest: The authors declare that they have no conflict of interest.

## Abstract

**Objectives:** The purpose of this study was to conduct the first randomised controlled trial 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 randomised controlled trial employing intent-to-treat analysis.

**Methods:** Adults with FMS received an eight-week SG-MBI known as Meditation Awareness Training (MAT;  $n = 74$ ) or an active control intervention known as Cognitive-Behaviour Therapy for Groups ( $n = 74$ ). Assessments were performed at pre-, post-, and six-month follow-up phases.

**Results:** MAT 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 (i) civic engagement partially mediated treatment effects for all outcome variables, (ii) non-attachment partially mediated treatment effects for psychological distress and sleep quality, and (iii) 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:** MAT may be a suitable treatment for adults with FMS and appears to ameliorate FMS symptomatology and pain perception by reducing attachment to self.

**Keywords:** Fibromyalgia Syndrome, Pain Disorder, Meditation Awareness Training, Mindfulness, Second-Generation Mindfulness-Based Interventions, Spirituality

## **Introduction**

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, Sherman, Mist, Carson, Bennett, & Li, 2012; Wolfe, Brähler, Hinz, & Häuser, 2013). The condition is also associated with (i) high rates of presenting at medical services (Schaefer et al., 2011), unemployment (Scott & Jones, 2014), (ii) use of incapacity for work and/or disability benefits (Sicras-Mainar et al., 2009; Wolfe et al., 1997), (iii) hypochondriasis, self-preoccupation and self-attachment (Canzonieri, Pollak, Oliveira, Costa, & Natour, 2013; Van Gordon, Shonin, & Griffiths, 2016a; Wolfe, 2009), and (iv) 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 FMS patients 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., 2016; 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, Morillo, López Montoyo, Correa, Borao, & García-Campayo, 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 healthcare 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 (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 randomised 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  $d = 0.33$ ; 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 was deemed to be “*the process of engaging a full, direct, and active awareness of experienced phenomena that is (i) spiritual in aspect and, (ii) 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 (i) a greater range of meditative techniques (generally delivered in a secular context), (ii) ethics as a key component of the taught programme, and (iii) 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, reputation, etc.; 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 wellbeing. 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 (for example) psychological distress (Van Gordon, Shonin, Sumich, Sundin, & Griffiths, 2014), self-preoccupation and maladaptive ego-constructs (Shonin, Van Gordon, & Griffiths, 2014b; Shonin & Van Gordon, 2015), 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 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 (i) is deemed by its founders to be both a psychological and spiritual intervention, (ii) 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 (iii) 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 criticised for emphasising 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: (i) being aged between 18 and 65 years, (ii) being able to read and write using the English language, (iii) not currently undergoing formal psychotherapy, (iv) no changes in psychopharmacology type or dosage one-month prior to intervention (although stable

prescription medication was permitted), and (v) not currently practicing mindfulness or meditation. Participants were also required to confirm their availability to complete an eight-week intervention and six-month follow-up assessment. Attendance at at-least seven of the eight weekly sessions is a prerequisite for course completion. In the current 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.

### ***Randomisation 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 randomisation procedure (the principal investigator was not involved in the randomisation 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). Randomisation was implemented prior to administering baseline psychometric tests in order to facilitate the blinding of researchers involved in conducting the randomisation 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 0.5, an alpha of 0.05, and 80% power. Consistent with literature reviews conducted by other authors (e.g., Glombiewski, Sawyer, Gutermann, Koenig, Rief, & Hofmann, 2010), a comprehensive literature review conducted by the present authors found that an effect size of 0.5 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***

MAT is an eight-week SG-MBI in which mindfulness is an integral component, but is not the exclusive focus (Shonin, Van Gordon, & Griffiths, 2014b; Van Gordon et al., 2014). The intervention is delivered by instructors who have undergone a three-year supervised MAT training programme. Participants attend eight weekly workshops (each lasting two hours) and receive a CD of guided meditations to facilitate daily self-practice. The weekly sessions comprise three distinct phases: (i) a taught/presentation component (approximately 45 minutes), (ii) a facilitated group-discussion component (approximately 35 minutes), and (iii) guided meditation and/or mindfulness exercises (approximately 30 minutes). A 10-minute 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-

minutes 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 the present study the intervention was slightly modified to include an additional 5-minute break that occurred 45 minutes into the session (this was achieved by reducing the duration of the facilitated group discussion component to 30 minutes). In order to directly target the key symptoms and correlates of FMS, the intervention was also modified in the present study to include an extended focus on: (i) mindfulness techniques specifically concerned with meditatively observing and objectifying somatic pain, (ii) 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 (iii) ‘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 the present 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 (i) silently observing at least 15 minutes of each weekly session (not always following the same amount of elapsed time into the 2-hour session), and (ii) engaging in discussion with the program facilitator on a weekly basis. With

the exception of the planned modifications specified above, no other deviations from the standard protocol were identified.

MAT (and the control intervention) were delivered across multiple sites in the East Midlands in separate training rooms utilised by a meditation centre and GP surgery. Other than an over-head 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 the present 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, & Griffiths (2014c). 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: (i) a taught presentation component (45 minutes), (ii) a facilitated group discussion component (30-minutes duration in the present study), (iii) guided discovery educational exercises (30 minutes), and (iv) 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 to 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-minute 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, Friend, Jones, Ward, Han, & Ross; 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 seven days and include items such as “*difficulty in sitting in a chair for 45 minutes*”, “*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 to 90) is divided by three, the summed score for overall impact domain (range 0 to 20) remains unchanged, and the summed score for the symptom domain (range 0 to 100) is divided by two. 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 (Burckhardt, Clark, & Bennett, 1991), individuals diagnosed with FMS typically score between 55-65 (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 four-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 sub-scales: (i) depression, (ii) anxiety, and (iii) stress. The scale is scored on a four-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 seven-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 four-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  $\geq 5$  indicates a poor quality of sleep (Buysse et al., 1989).

*Non-Attachment Scale (NAS; Sahdra, Shaver, & Brown, 2010; Sahdra, Ciarrochi, Parker, Marshall, & Heaven, 2015)*: 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 conceptualisations of attachment). The NAS is scored on a six-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 seven days they had spent engaging in paid work, voluntary work, participating in an event or meeting hosted by a community organisation or group, and/or mentoring another non-family member of the community.

### ***Data Analysis***

A significance level of  $p < 0.05$  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 multi-level 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; Quene & van der Berg, 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 end-point substituted using last-observation-carried-forward basis.

## **Results**

### ***Recruitment and Allocation***

Participant demographic characteristics are summarised 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 (i) currently receiving structured psychotherapy (32 individuals), (ii) unable to confirm current diagnosis of FMS (23 individuals), (iii) recent change in psychopharmacology type or dosage (13 participants), and (iv) currently attending meditation or mindfulness classes (8 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).

[Insert Table 1 and Figure 1 about here]

### ***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 ( $t(91) = -2.19, p = 0.03$ ). The main reasons for non-completion were that the participant: (i) did not attend at least seven of the eight weekly sessions (MAT = 10, CBTG = 12), (ii) found the intervention to be overly demanding (MAT = 6, CBTG = 6), or (iii) changed medicine or commenced structured psychotherapy after baseline assessment (MAT = 3, CBTG = 2). Of those participants that attended the post-intervention assessment phase, 9 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 minutes 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, 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 SDs). 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 2 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 (i) 6.24 (at post) and 7.92 (at follow-up) greater decrease in FIQ-R score, (ii) 2.01 (at post) and 3.01 (at follow-up) greater decrease in SF-MPQ score, (iii) 3.70 (at post) and 4.86 (at follow-up) greater decrease in DASS score, (iv) 1.50 (at post) and 2.28 (at follow-up) greater decrease in PSQI score, (v) 2.81 (at post) and 3.57 (at follow-up) greater increase in NAS score, and (vi) 1.69 (at post) and 2.05 (at follow-up) greater increase in Civic Engagement (see Figure 3 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.

[Insert Tables 2 and 3 and Figures 2 and 3 about here]

### ***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.

[Insert Table 4 about here]

### ***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 4) 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 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, PSAQI). 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.

[Insert Tables 5 and 6 and Figure 4 about here]

### **Discussion**

In the present study, an RCT compared MAT with a purpose-designed control intervention in individuals with FMS. MAT participants demonstrated significant 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 six-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 21-37% have been reported (e.g., Kaplan, Goldenberg, & Galvin-Nadeau, 1993; Mannerkorpi & Arndorw 2004; Weissbecker, Salmon, Studts, Floyd, Dedert, & Sephton, 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., ten 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, & Walach (2011), and given that FMS treatment studies typically report relatively high rates of drop-out (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 drop-out 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, instructor didactic style, etc.).

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, therapeutic alliance, etc.) 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 than 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) is certainly of value to the medical community. However, rather than seek to out-perform 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 conceptualisation of the technique (Van Gordon, Shonin, Lomas, & Griffiths, 2016d)

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 ten 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 conceptualisation, a practice can be deemed spiritual if it helps to transcend ‘selfhood’ (Van Gordon et al., 2016d).

The abovementioned 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 mediating the treatment effects for all outcome variables. Being more ‘other-centered’ improves life perspective and dismantles self-obsessed and self-disparaging cognitive schemas (Shonin,

Van Gordon, Compare, Zangeneh, & Griffiths, 2015a). Furthermore, a compassionate disposition and spiritual outlook has been shown to increase social-connectedness and prosocial behaviour (Hutcherson, Seppala, & Gross, 2008; Leiberg, Olga, & Tania, 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 six-month follow-up). An increased number of assessment phases would provide insights on which particular stages of the eight-week intervention have the strongest treatment effects. Furthermore, an assessment beyond the six-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, 2015b). 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 et al., 2015b). 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. The 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.

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Table 1. Baseline demographic characteristics for each allocation condition

Characteristic	MAT ( <i>n</i> = 74)	CBTG ( <i>n</i> = 74)
Age, mean ( <i>SD</i> )	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



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

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

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

	<b>value</b>	<b>CI</b>	<b>t-value</b>	<b>p-value</b>
<b>FIQ-R</b>				
(Intercept)	54.04			
Post	-6.24	-8.24:-4.25	-6.13	<0.001
Follow-up	-7.92	-13.76:-7.76	-6.14	<0.001
<b>SF-MPQ</b>				
(Intercept)	27.58			
Post	-2.01	-2.80:-1.26	-5.24	<0.001
Follow-up	-3.01	-4.09:-1.94	-5.48	<0.001
<b>DASS</b>				
(Intercept)	26.24			
Post	-3.70	-4.77:-2.63	-6.80	<0.001
Follow-up	-4.86	-6.30:-3.43	-6.63	<0.001
<b>PSQI</b>				
(Intercept)	14.09			
Post	-1.50	-2.03:-0.96	-5.53	<0.001
Follow-up	-2.28	-2.94:-1.63	-6.83	<0.001
<b>NAS</b>				
(Intercept)	18.28			
Post	2.81	1.92:3.70	6.17	<0.001
Follow-up	3.57	2.50:4.63	6.56	<0.001
<b>Civic Engagement</b>				
(Intercept)	17.78			
Post	1.69	0.53:2.84	2.86	<0.01
Follow-up	2.05	1.10:3.00	4.24	<0.001

*Note:* 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 to the control condition relative to baseline (i.e., Pre FIQ-R score).

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	<0.001
SF-MPQ	0.82	-0.16	0.03	-5.53	<0.001
DASS	3.17	-0.28	0.03	-8.28	<0.001
PSQI	0.72	-0.11	0.02	-6.71	<0.001
NAS	-2.87	0.21	0.02	9.20	<0.001
Civic Engagement	0.05	0.09	0.03	2.59	<0.05

*Note:* All outcome measure differences (baseline – follow-up) are predicted by the number of average minutes meditated per day

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
<b>Civic Engagement</b>					
FIQ-R	-2.66	-1.87	0.17	-10.80	<0.001
SF-MPQ	-1.55	-0.72	0.07	-9.44	<0.001
DASS	-1.85	-1.06	0.10	-10.35	<0.001
PSQI	-0.93	-0.42	0.05	-8.33	<0.001
<b>NAS</b>					
FIQ-R	-0.27	-2.10	0.08	-24.60	<0.001
SF-MPQ	-0.69	-0.78	0.04	-16.30	<0.001
DASS	-0.58	-1.15	0.05	-19.62	<0.001
PSQI	-0.30	-0.50	0.02	-17.11	<0.001

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)

	<b>FIQ-R</b>		<b>SF-MPQ</b>		<b>DASS</b>		<b>PSQI</b>	
	Step1	Step2	Step1	Step2	Step1	Step2	Step1	Step2
<i>Intercept</i>	-1.67	-0.77	-1.19	-0.84	-1.09	-0.59	-0.45	-0.27
<i>b</i> (IV)	<b>-7.92***</b>	<b>-4.56***</b>	<b>-3.01***</b>	<b>-1.71***</b>	<b>-4.86***</b>	<b>-3.01***</b>	<b>-2.28***</b>	<b>-1.58***</b>
<i>b</i> (Civic Eng.)		<b>-1.63***</b>		<b>-0.63***</b>		<b>-0.89***</b>		<b>-0.33***</b>
<i>F</i> change	87.84***		65.44***		79.18***		46.49***	
<i>R</i> <sup>2</sup>	0.21	0.51	0.17	0.42	0.23	0.50	0.24	0.42
<i>Intercept</i>	-1.67	-0.08	-1.18	-0.59	-1.09	-0.25	-0.45	-0.09
<i>b</i> (IV)	<b>-7.91***</b>	<b>-0.55</b>	<b>-3.01***</b>	<b>-0.27</b>	<b>-4.86***</b>	<b>-0.97*</b>	<b>-2.28***</b>	<b>-0.61*</b>
<i>b</i> (NAS)		<b>-2.06***</b>		<b>-0.76***</b>		<b>-1.08***</b>		<b>-0.46***</b>
<i>F</i> change	450.50***		195.42***		271.21***		199.3***	
<i>R</i> <sup>2</sup>	0.20	0.80	0.17	0.64	0.23	0.73	0.24	0.68

Note: Step 1 = direct effect (DV~IV), Step 2 = indirect effect (DV~IV+M) [‘~’=predicted by]

Sig. level: ‘\*\*\*’ 0.001 ‘\*\*’ 0.01 ‘\*’ 0.05

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

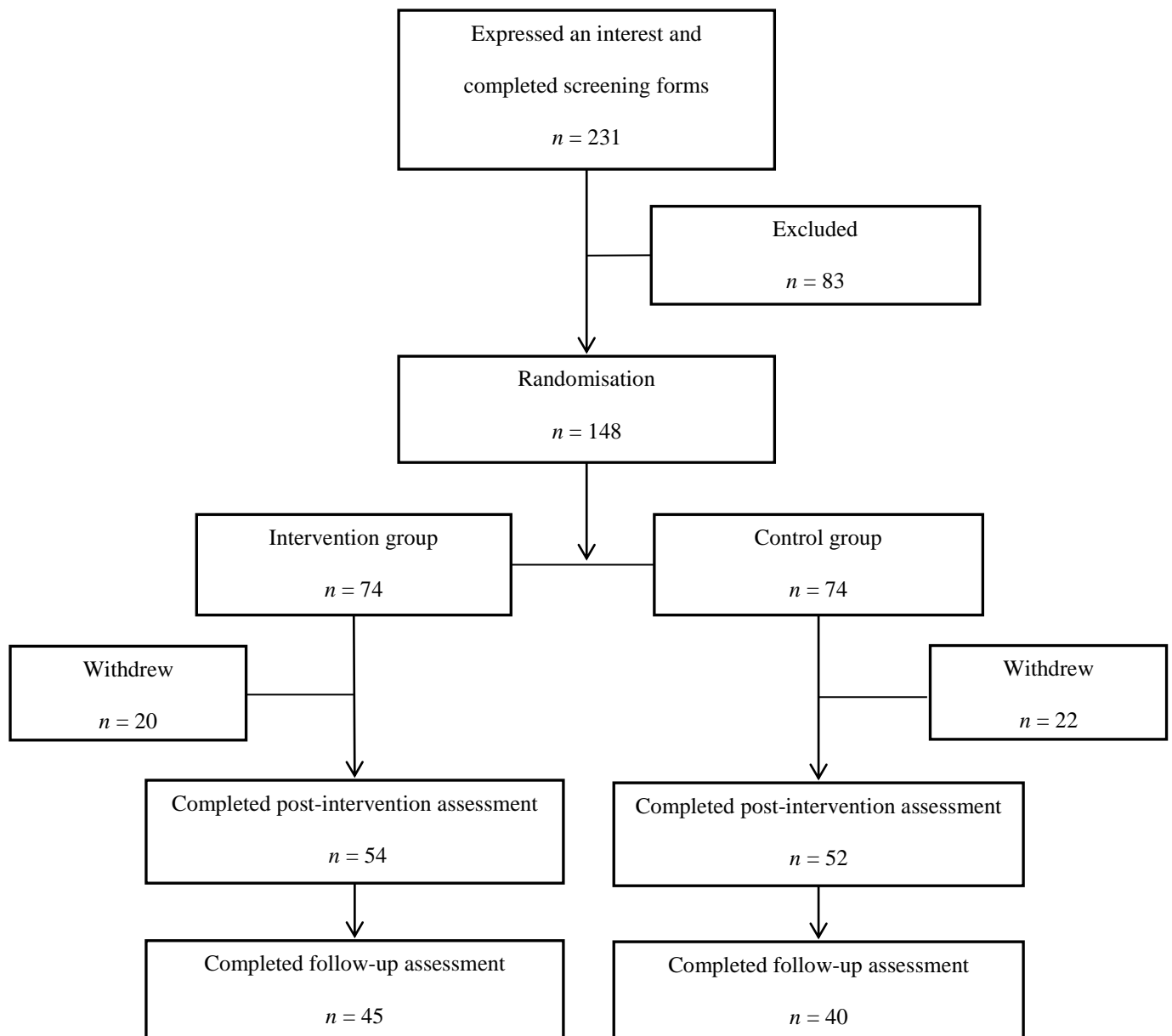
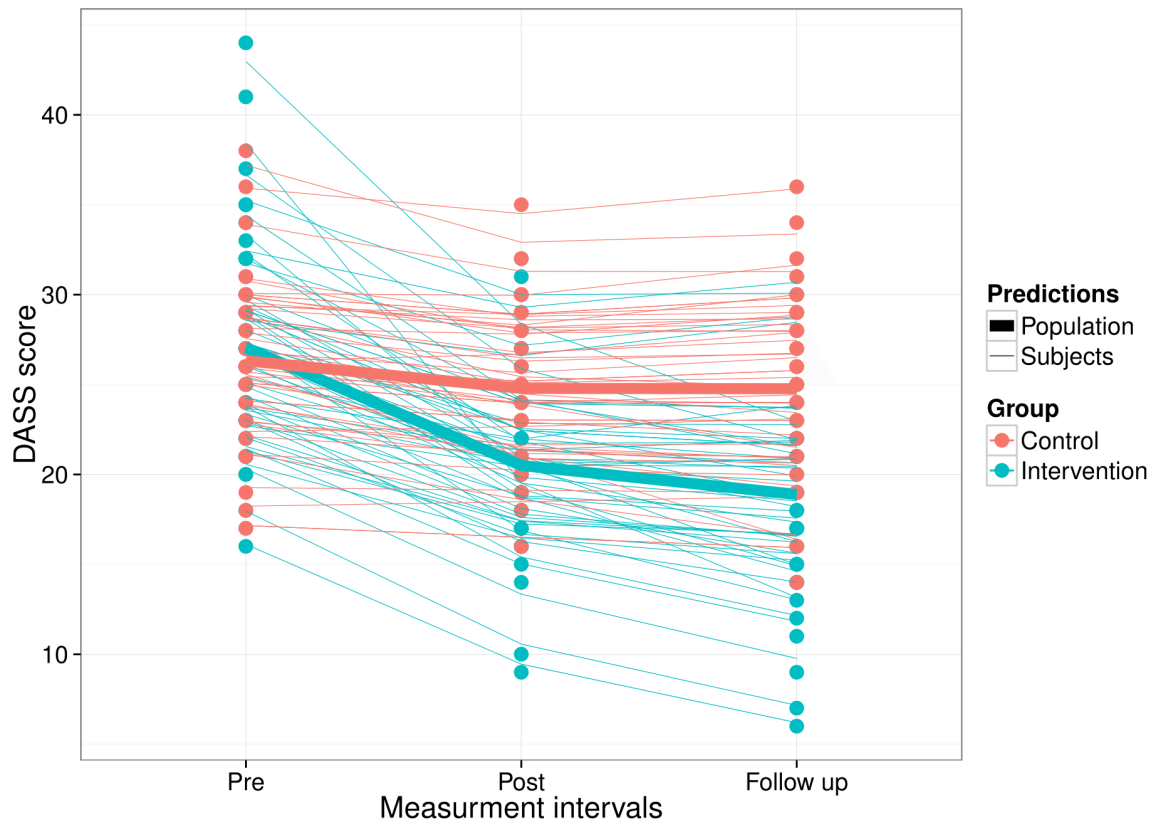
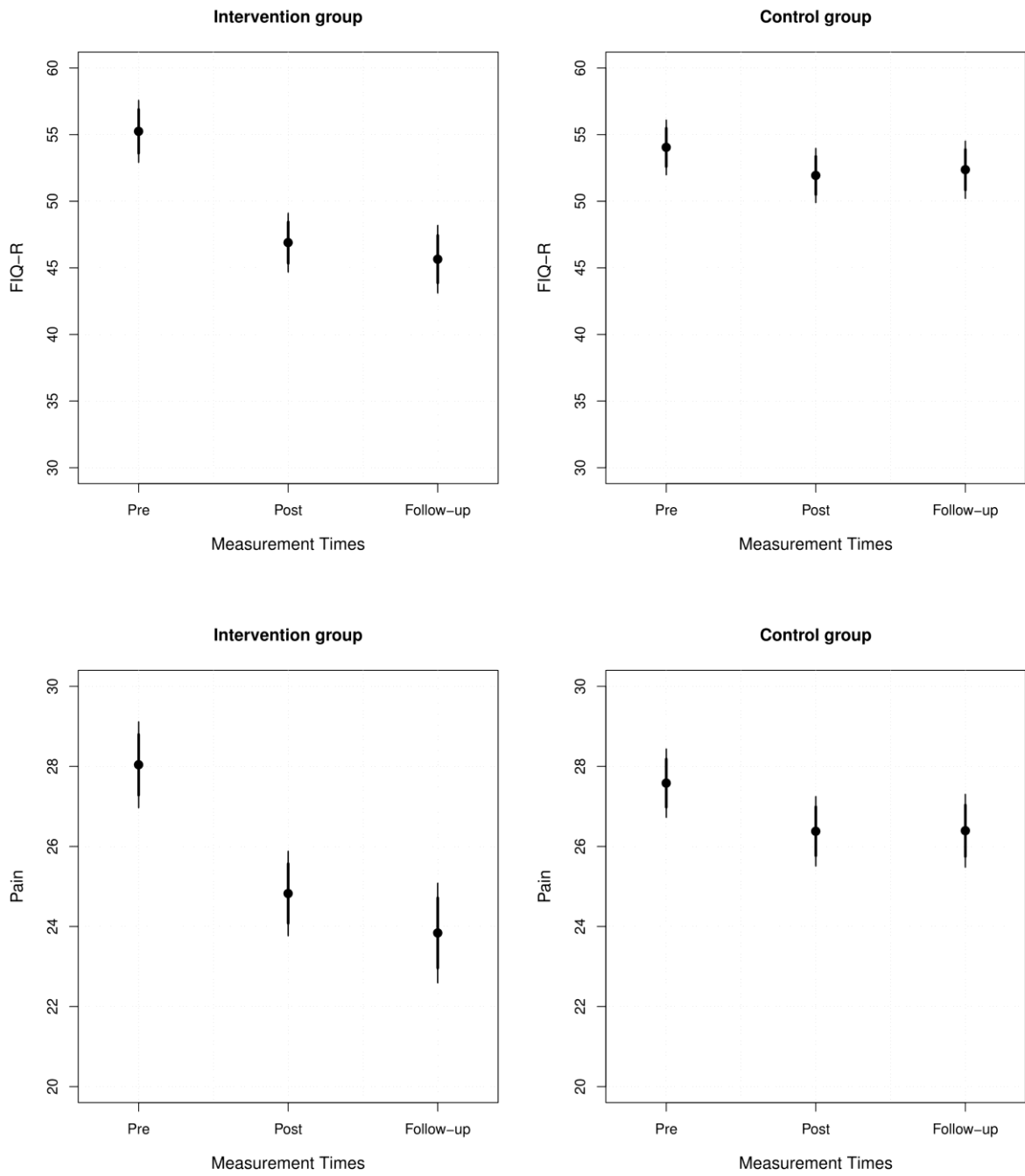


Figure 2. Mixed effect model for DASS

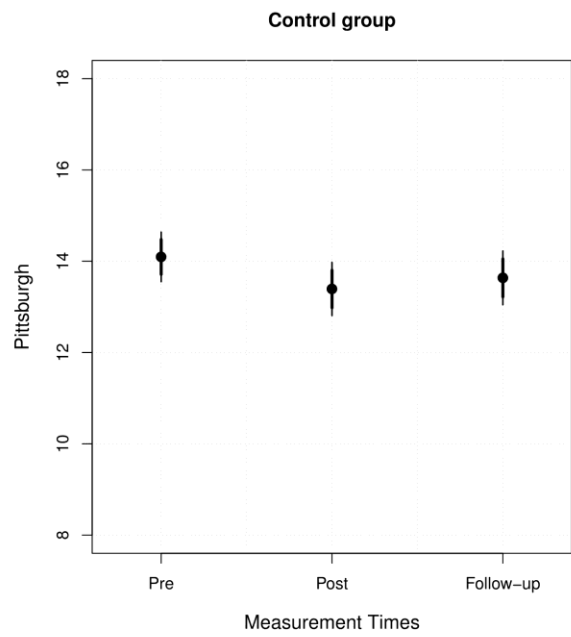
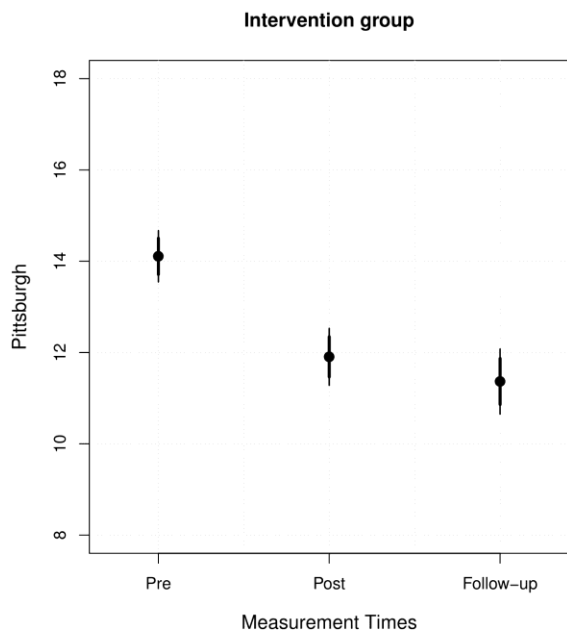
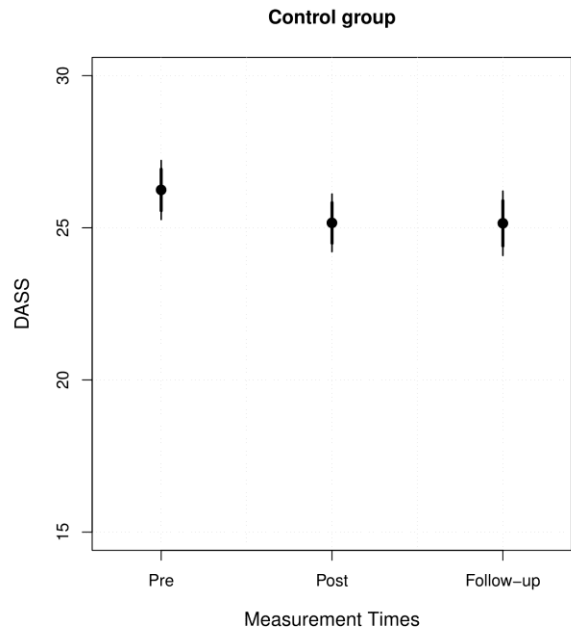
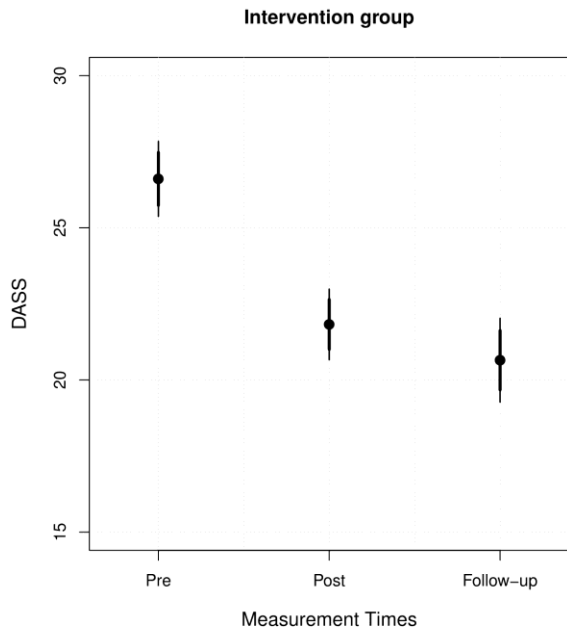


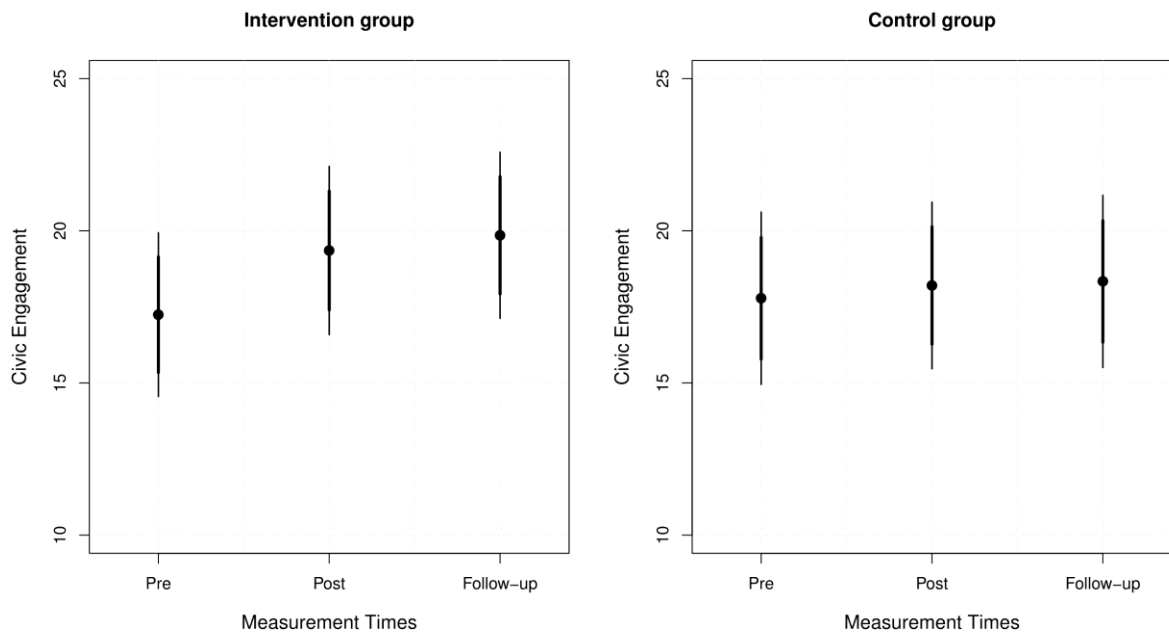
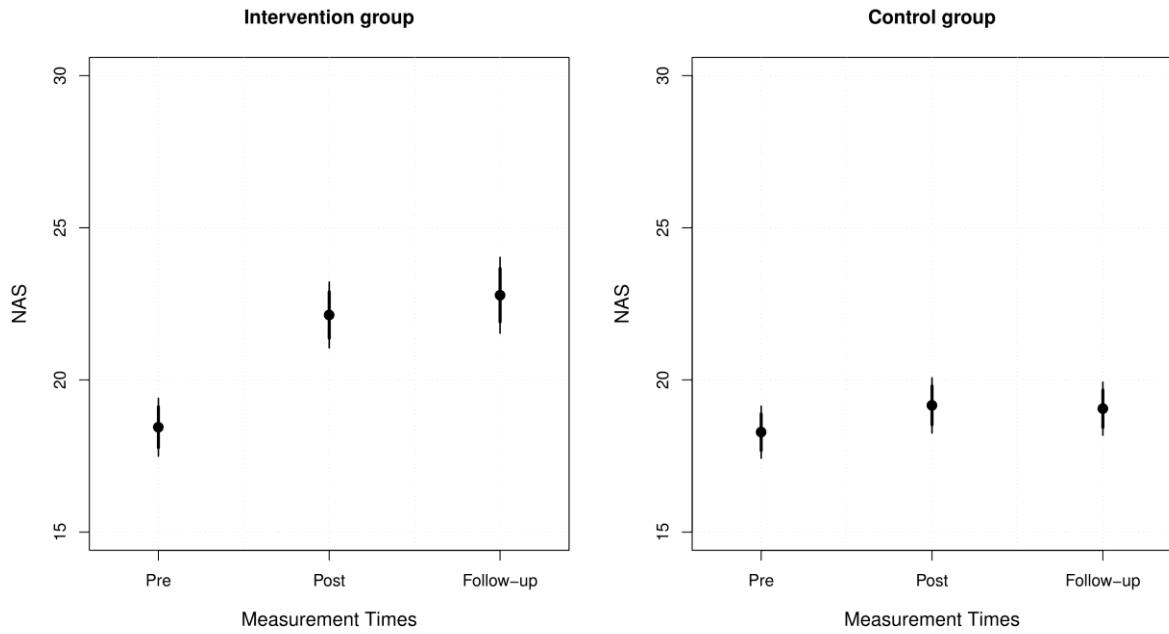
*Note:* The plot shows each participant’s DASS score trajectory across measurement intervals (pre, post, follow-up). Narrow lines illustrate trajectories at the subject-level whereas two fuller lines illustrate the predicted population estimates by group (control vs. intervention).

Figure 3. Outcome means (intervention and control) across measurement intervals with two-tier 95% CIs.









*Note:* The inner tier of a two-tiered CI represents CIs for the mean whilst the outer tier represents a difference-adjusted CI. Difference-adjusted CIs represent the individual means but calibrates the CI to indicate whether the sample means differ (using 95% confidence in the difference as a standard) (Baguley, 2012b).

Figure 4. Example of mediation model paths

