Developing a psychologically-informed pain management course for use in osteopathic practice: The OsteoMAP cohort study

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A B S T R A C T

Background: Multidisciplinary healthcare programmes which include psychosocial interventions for persistent musculoskeletal pain demonstrate better patient outcomes than separate physical therapies. This paper reports outcomes from the OsteoMAP study, which combined psychological and mindfulness-informed interventions from Acceptance and Commitment Therapy (ACT) with manual treatment to create a multimodal pain self-management course for delivery by osteopaths working with patients with long-term musculoskeletal conditions.
Method: A single cohort of 256 patients participated in a new persistent pain self-management course. Self-report data was collected at baseline ($n = 180$) and after six months ($n = 79$) using the European Quality of Life, Bournemouth and Revised Action and Acceptance Questionnaires and the Freiburg Mindfulness Inventory.
Results: There were significant improvements in all four outcome measures ($p < 0.001$). Changes in quality of life and coping with pain showed significant correlations with increased psychological flexibility (r = 0.69–0.71) and slightly weaker associations with mindfulness (r = 0.50–0.51).
Conclusions: This psychologically-informed self-management course was feasible for delivery in an osteopathic educational clinic and patient outcomes supported proof of concept. A pragmatic randomised controlled trial is now recommended to compare course effects with other management approaches and to continue developing multimodal care for patients with persistent pain presenting in general osteopathic practice.

1. Introduction

This paper presents patient outcomes from the OsteoMAP project, a three year cohort study that formed part of a series of research projects to develop a psychologically-informed pain self-management course, which aimed to enable osteopaths to address relevant biopsychosocial issues as part of their standard evaluation, treatment and patient management practices. Previous studies included a mixed methods pilot group study [1], a qualitative doctoral research project (unpublished), and an independent evaluation and partial fidelity assessment of OsteoMAP practitioner training and course delivery conducted by observers from the National Council for Osteopathic Research (NCOR) [2].

Long-term health conditions involve increasing costs for healthcare services [3,4], with many patients reporting symptoms in multiple sites, co-morbid health conditions [5,6] and inadequate pain management [7]. Persistent pain is often associated with psychological symptoms, including anxiety and depression, and can lead to limitations to physical activity and sleep disruption [8,9]. Non-pharmacological management, including Cognitive Behaviour Therapy (CBT), has been shown to be as effective as pharmacological treatments for pain-related depression [10], and may result in fewer side-effects [11]. Recent pain management programmes have incorporated mindfulness-based interventions [12–14] and 'third wave' models of CBT such as Acceptance and Commitment Therapy (ACT) [15,16].

Biomedical pain management programmes aim to decrease pain through more effective use of medication, psychological interventions to change maladaptive health beliefs, goal setting and teaching patients how to control pain through activity pacing [13,17]. Programmes with an emphasis on self-management focus on developing pain acceptance, rather than control, developing active coping strategies and engaging with personally valued activities to enhance wellbeing and resilience [15,16]. Interventions are either delivered to groups of patients by multidisciplinary teams [17,18] or by physical therapists with additional psychosocial training to patient groups or individuals [19–21]. The course developed for this study was designed for osteopaths with brief ACT training, working with individual patients to develop more effective self-care skills.

Patients with complex, long-term conditions, including persistent pain, who also have psychological symptoms including anxiety and depression [8], can be challenging to understand or manage using biomechanical models of osteopathic care alone [22]. Osteopathic interventions can affect pain-related psychological symptoms and a systematic review of 16 Randomised Controlled Trials (RCTs) reported encouraging outcomes in anxiety, depression, fear-avoidance, general health status and quality of life [23]. A single cohort of 58 patients with persistent pain also reported reduced pain and anxiety [24], and further research into ways of integrating psychosocial interventions into osteopathic practice has been recommended [23].

Biomedically-trained physical therapists may be the first contact for patients with musculoskeletal pain [25], but can struggle to identify and work effectively with psychosocial issues that influence pain perception and prognosis [20]. Specific musculoskeletal tissues cannot be identified as causal factors in 80–95% of low back pain [26,27] but patient management is still often based on biomechanical explanations [26], despite high levels of false positive results from diagnostic imaging [28]. A cross-sectional survey of UK osteopaths reported scope for improvement in biopsychosocial knowledge about chronic pain as some strong biomedical opinions were reported [29]. There are also concerns that therapists can unintentionally promote passive coping by using diagnostic language that promotes fear-avoidance and inappropriate advice to avoid painful activities [30,31]. Conversely, manual treatment including graded exposure techniques has been shown to increase pain tolerance and willingness to be active [32,33], and can be combined with cognitive therapy, pain education and cognitive reassurance to enhance outcomes [34,35].

CBT includes a broad range of therapeutic approaches with shared roots and has been the predominant model for addressing psychosocial aspects of pain for the last 40 years [36,37]. Effect sizes for psychological distress, disability and, to a lesser extent, pain are small to moderate for CBT [38], with similar findings for mindfulness based interventions [12–14] and 'third wave' models of CBT such as Acceptance and Commitment Therapy (ACT) [15,16]. Mindfulness has been shown to influence pain affect, rather than intensity [39], and acceptance-based interventions aim to redirect energy towards actions that promote wellbeing [40,41]. Initiatives to enable therapists to work with psychological aspects of pain management [20,21,31,35] indicate that CBT graded exposure techniques can be integrated with physiotherapy treatment [43] and brief ACT training changes physiotherapists attitudes to chronic pain [44]. This is early stage research, however, with little empirical evidence about how to train therapists, assess competence and manage challenges in learning how to apply the principles of CBT and ACT.

Psychological flexibility in the ACT model is central to resilience and wellbeing and mediates responses to pain and psychological outcomes [40]. It is described as the capacity to adapt behaviour based on personal values and awareness of opportunities for action available in the present moment [45]. It is developed through six inter-related processes: *Acceptance* - of internal experience of present moment discomfort; *Defusion* - capacity to observe thoughts and feelings without reacting to control discomfort; *Present moment awareness* - a flexible, secular form of mindfulness; *Self as context* - capacity to view one's self from multiple perspectives; clarity of personal *Values*; and willingness to engage in *Committed action* [Fig. 1; 46].

1.1. Study development

The first study was a six-week 'Living Well with Persistent Pain' group course for patients at an osteopathic educational clinic, co-facilitated by a clinical health psychologist and an osteopath [1]. Pain management groups have demonstrated positive effects, with patients reporting benefits from peer group discussion and support [19]. In the first study, ACT material was found to be relevant and acceptable to patients in this clinic but the longer-term aim was to develop an approach feasible for individual osteopaths and their patients.

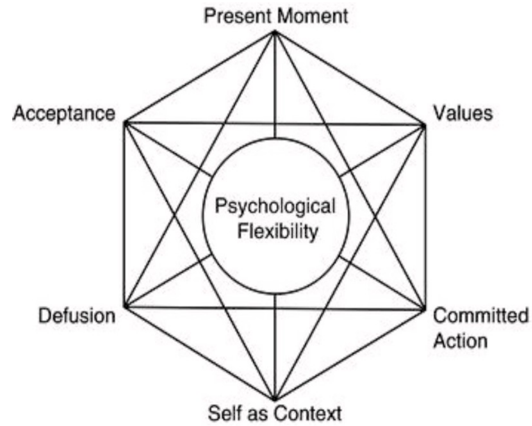

Fig. 1. The ACT Hexaflex [46].

The second study explored the processes and outcomes involved in adapting the group course for individual work. It was based on the evolutionary biology concept of exaptation, where existing structures and behaviour are adapted for new functions [47]. ACT principles were integrated into osteopathic practices to develop psychological flexibility as well as to guide collaborative treatment plans. Assessments were conducted slowly to explore interoceptive awareness and to help patients notice how they interpreted bodily sensations to initiate and control movements [48].

Four patients participated in six week courses with the osteopath, supervised by the psychologist. Audio-recorded sessions were transcribed verbatim and analysed using Linguistic Ethnography [49] to explore relationships between communication and behaviour change. Analysis illustrated how an 'expert' stance was associated with an osteopathic focus on the patient's mechanical body and practitioner-led management plans. In contrast, a 'collaborative' stance focused on the patient's experience, resulting in greater awareness, agency and flexibility. 'Choice points' were identified as moments when the osteopath shifted consciously to the collaborative stance to facilitate patient learning, and learning was used to inform the design of a following larger cohort study.

2. Method

The OsteoMAP study ran from June 2013 to May 2016 and was funded by the UK Department of Health's Innovation, Excellence and Strategic Development (IESD) Voluntary Sector Investment Programme (AIMS ref: 2527190). Approval to recruit participants in the University College of Osteopathy (UCO) clinic was obtained from the University of Bedfordshire Ethics Committee and UCO Research Ethics Committee in 2013. Approval to run courses in two local NHS surgeries was obtained in 2014 (MREC: 14/LO/0828). The study was registered on the NIHR portfolio (ISRCTN 04892266) and supported by Liaison Officers at the South London Clinical Research Network (CRN).

2.1. Recruitment

Patients were recruited using posters and study information sheets distributed in an osteopathic educational clinic and study sites in two local NHS practices. Information was also posted on the institution's website to enable applications from the wider patient community and distributed to GP practices by the CRN. Researchers ran seminars to demonstrate non-coercive ways of introducing potential participants to the study. Recruitment was based on patient choice, so direct referrals from osteopaths or GPs were not accepted and patients 'opted in' by completing application forms. Pre-course interviews were conducted to provide further information and explore patients' expectations about self-management. Eligible patients who chose to participate signed consent forms and received the first section of the Patient Workbook.

2.2. Inclusion criteria

Aged over 18, capable of giving informed consent

Musculoskeletal pain for more than six months. Duration was extended beyond three months [50] to increase the possibility of avoidant reactions that might benefit from self-management.

Willing to participate in experiential exercises and home practice.

2.3. Exclusion criteria

Contraindications to receiving osteopathic treatment.

Sufficient English to communicate without an interpreter.

Active uncontrolled psychosis or substance abuse that might influenced their ability to learn mindfulness skills.

Broad inclusion criteria were used because persistent pain is often associated with anxiety and depression [8], which may benefit from acceptance-based interventions [10]. Usual medical care was not restricted on safety and ethical grounds. Osteopathic treatment was scheduled in each session, so patients were asked not to seek additional appointments to avoid the risks of over-treatment or receiving conflicting advice. Patients attending pain management programmes or physiotherapy were not eligible to join until the course ended. Patients receiving psychological support were asked to discuss the course with their therapist. Patients were asked for consent to for the team to contact their GP, consultant or psychological therapist if it was not clear whether taking part would be appropriate. Sample size was pragmatic, based on practitioner availability, and a rolling recruitment process continued until the end of funding in May 2016 (Appendix 1: Recruitment Flowchart).

2.4. Practitioner training

Five osteopaths with more than five years' clinical and educational experience participated in four-day training led by an ACT psychologist, guided by the previous studies and activities from a core textbook 'ACT Made Simple' [46]. Training was similar in content and duration in other healthcare research. Physiotherapists in the PACT study attended a two day training, supported by a manual and two individual supervision sessions [51]. Competence was assessed from observations of role plays and monthly supervision. Fidelity to the PACT protocol was assessed using session checklists and audiotape ratings, with feedback to physiotherapists. In this study, training spread over two months allowed time for skill development and mindfulness practice. In clinic, osteopaths continued learning from individual supervision, peer group meetings, self-audit and feedback from an independent assessor [2]. The osteopaths were encouraged to apply ACT principles in experiential cycles of learning [52] and develop flexibility in their own lives before starting patient work that involved conscious shifts between therapeutic stance. Core principles were embodied in practitioners' behaviour using demonstrations and skills practice. Where possible, tutors worked with personal experiences rather than role play [53,54]. In course delivery, they were encouraged to notice when there were 'choice points' to move between providing treatment and facilitating patient learning. Practitioner Manuals and Workbooks and Patient Workbooks were developed as guidelines, but not set protocols [55].

Student osteopaths were introduced to pain neuroscience and ACT principles in 3rd year lectures and skills workshops. From September 2013, optional clinical electives for final year students involved observing tutors for six weeks and then conducting six weeks of supervised patient care. Practitioners were encouraged to develop flexible, personal approaches to working with the ACT principles, commensurate with their stage of development. Competence was not formally assessed but teams worked together to share skills and good practice and fidelity of course delivery was independently evaluated [2]. Relationships between biomechanical, psychological and social factors were discussed in pre-session meetings and debriefings to assess outcomes and note patient and practitioner issues for future attention. Clinical observations from the psychologist were used for mentoring and to amend materials after the first year of course delivery to strengthen the focus on an integrated approach.

Each session included osteopathic assessment and treatment, mindfulness practices [56] and interventions addressing core ACT principles [Table 1]. Where possible, interventions were integrated with present moment bodily experiences to create explicit links between biomechanical and psychosocial issues. Exercises were adapted from open access group protocols [57] and self-management resources [58,59]. Sessions included education about pain and stress responses [9], exercises chosen for evidence of effect and practicality [60,61], home practices and weekly workbook handouts. Sessions were divided into approximately 15 min to explore patients' experiences and learning the previous week and introduce session aims; 30 min of physical assessment and treatment [62,63] combined with mindfulness and ACT exercises to develop awareness and psychological flexibility [45]; and 15 min to explore what had been learned and its' value for daily life [56, 57]. Treatment focused on functions relevant to individual capacities and goals, activities chosen by patients and mindful movements [64]. 'The Compass' diagram (Fig. 2) was used to emphasise the role of mindfulness (vertical axis), committed action (horizontal axis) and the central stance of self-compassion.

2.5. Data collection

Data collected at baseline and six months included demographic data (sex, age, ethnicity, work status, fluency in English, living situation, pain site and duration); quality of life (European Quality of Life Questionnaire; EQ-5D-5L) [65]; pain coping (Bournemouth Back Questionnaire; BQ) [66]; psychological inflexibility (Action and Acceptance Questionnaire; AAQ-IIR) [67]; and mindfulness (Freiburg Mindfulness Inventory; FMI) [68]. Questionnaires were selected for relevance, validity and brevity to minimise participant burden. Follow-up data also included patient satisfaction, adverse reactions and self-reported changes in medication. (Qualitative data will be reported separately).

2.6. Data analysis

Questionnaire total scores were calculated according authors' instructions. BQ total scores were calculated from seven items on a scale of 0–10, where a higher score represented poorer coping with pain. Raw change scores were calculated, divided by baseline scores and multiplied by 100 to create percentage change scores [66]. Clinically significant changes have been estimated as 36% and 47% for neck and back pain respectively [69]. EQ-5D-5L scores were calculated from five items on a five point scale and translated into index scores between 0 and 1, where a higher score represented higher quality of life [65]. AAQ-IIR scores were calculated from seven items on a scale of 1–7, where a higher score represented greater psychological <u>in</u>flexibility [67]. For FMI scores, item

Table 1
Course outline.

	Session title	Focus on core ACT principles
1	'Living with pain'	Avoidance, fusion, present moment awareness,
2	'Living flexibly with pain'	Acceptance, defusion, present moment awareness
3	'Living in the present'	Present moment awareness and self-as-context
4	'Living a fulfilling life'	Values and committed action
5	'Overcoming obstacles'	Values, committed action and self-as-context
6	'Moving on'	Ways to sustain flexibility and behaviour change

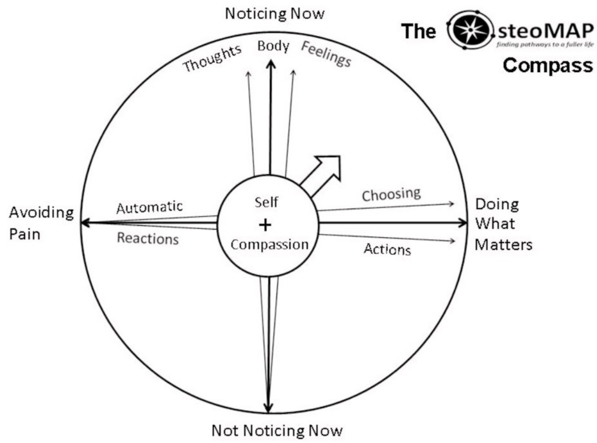

Fig. 2. The compass diagram.

13 was reversed and scores calculated from 14 items on a scale of 1–4, where a higher score indicated increased mindfulness [68]. Descriptive statistics were calculated as mean and standard deviation for normally distributed data. Significance level for hypothesis tests was set at $p <$ 0.05 and analyses were conducted using R version 3.4.1 [70].

The primary outcome measures were BQ and EQ-5D-5L scores. Predictors examined in fixed effects modelling included: age; sex; stage (baseline/follow-up); baseline AAQ and FMI scores (effect on modifying BQ and EQ-5D-5L); AAQ and FMI improvement (effect on difference in BQ and EQ-5D-5L); with subjects as random intercepts in all modelling [71]. Subgroup analyses were conducted for males and females, and age and sex were modelled as main effects and interactions with stage (Appendix 2). Missing questionnaire items were imputed by substituting the average score of items present (AAQ-IIR $n = 72$ and FMI $n = 66$). Loss to follow-up was not addressed, as only complete BQ and EQ-5D-5L data were analysed and no sensitivity analyses were used.

3. Results

3.1. Feasibility

A continuous recruitment process was used to enrol participants into their individual six-week OsteoMAP course from the start of funding in June 2013 until May 2016, with final six month follow-up data collection completed in January 2017. Five osteopaths supervised three students in each clinical elective. 78% of the 90 students attended 9 or more of their 12 sessions (Training will be reported separately). 88% of patients who applied for a course attended a 1-h screening interview and 92% were recruited. Most patients attended five or six of their six individual sessions (Appendix 1).

The study was funded as service development with optional questionnaire completion. Baseline data was obtained from 70% of the participants. Mean age was 49 and the majority were white, female, unemployed and living with others. Most participants reported low back pain (79%, $n = 142$), leg pain (57%, $n = 103$) or neck pain (53%, $n = 96$). 79% had multiple pain sites and 80% had symptoms for more than 12 months. Baseline scores for quality of life, psychological inflexibility and mindfulness were moderate (Table 2).

Of the 79 patients (44%) who provided follow-up data, 60% were unemployed and 15% had taken time off work due to pain. 42% reported using less medication at six months, although 23% reported increased medication use. 95% of these patients were 'satisfied' or 'very satisfied' with the course and 55% reported an overall improvement. No serious adverse events were reported.

There were statistically significant improvements in the primary and secondary measures (Table 3). BQ scores decreased and 47% of the patients reported changes of 36% or more, with 38% reporting changes of 47%, categorised as clinically significant for neck and back pain [69]. Increased EQ-5D-5L scores indicated improvements in quality of life. AAQ-IIR scores for psychological inflexibility decreased and FMI scores indicated increased mindfulness (see Fig. 3).

Table 2
Baseline data ($n = 180$).

Variable	Percentage (n)	Variable	Mean (SD)
Female sex	66%	Age	49.37 (15.67)
Living with others	64%	BQ (range 0–70)	42.21 (12.4)
Unemployed	54%	EQ-5D-5L (range 0–1)	0.53 (0.26)
White ethnicity	66%	AAQ-IIR (range 7–49)	29.19 (10.3)
Fluent English	89%	FMI (range 14–56)	32.94 (7.8)

3.2. Associations with psychological flexibility

A strong positive correlation between AAQ and BQ changes indicated that increased flexibility was associated with improved pain coping ($r = 0.71$, $p < 0.001$) (Fig. 4). A negative correlation between AAQ and EQ-5D-5L scores showed increased psychological flexibility was associated with improved quality of life ($r = -0.68$, $p < 0.001$). Correlations with FMI changes indicated that increased mindfulness skills were also associated with better pain coping (BQ $r = -0.51$, $p < 0.001$) and qualityof life (EQ-5D-5L $r = 0.50$, $p < 0.001$).

3.3. Demographic variables

Male participants reported better pain coping than females in baseline and follow-up data (female:male difference= 5.04 [1.45–8.62 95% C.I.]) but less improvement in psychological flexibility (female improvement = 8.46 [6.04–10.87 95% C.I.], male improvement 3.16 [-0.27 - 6.58 95% C.I.]). Older participants reported higher levels of flexibility and mindfulness in baseline and follow-up scores. Quality of life was not associated with age or gender.

4. Discussion

The aim of this study was to assess the feasibility of a new persistent pain self-management course and was the third in a series of studies to develop a multimodal intervention for osteopaths working with individual patients. The course was delivered successfully in an educational clinic [2]. Encouraging outcomes in coping with pain and quality of life supported proof of concept for integrating Osteopathy with Acceptance and Commitment Therapy (ACT). Patient courses have continued to run at the UCO since funding ended in 2016 and started recently at the European School of osteopathy (ESO) [72], suggesting that this approach has relevance for practice. The implications of study findings are discussed below in terms of patient outcomes, and potential mechanisms of effect within the context of a biopsychosocial model osteopathic practice.

4.1. Outcomes and potential mechanisms of effect

This OsteoMAP course aimed to increase flexible responses to discomfort and willingness to engage, despite pain, in valued activities [73]. The correlations observed between psychological flexibility, pain coping and quality of life were congruent with the ACT model [41,74]

Table 3
Pre and post course questionnaire changes ($n = 79$).

Mean (SD)	Change	95% CI	Statistics	p value
BQ	16.22	19.3 to 13.18	t = 10.4, df = 127.45	< 0.001
EQ-5D-5L	0.17	0.13 to 0.21	t = 7.92, df = 94.05	< 0.001
AAQ-IIR	6.92	- 8.95 to 4.96	t = 6.91, df = 96.67	< 0.001
FMI	4.45	2.51 to 6.38	t = 4.48, df = 109.04	< 0.001

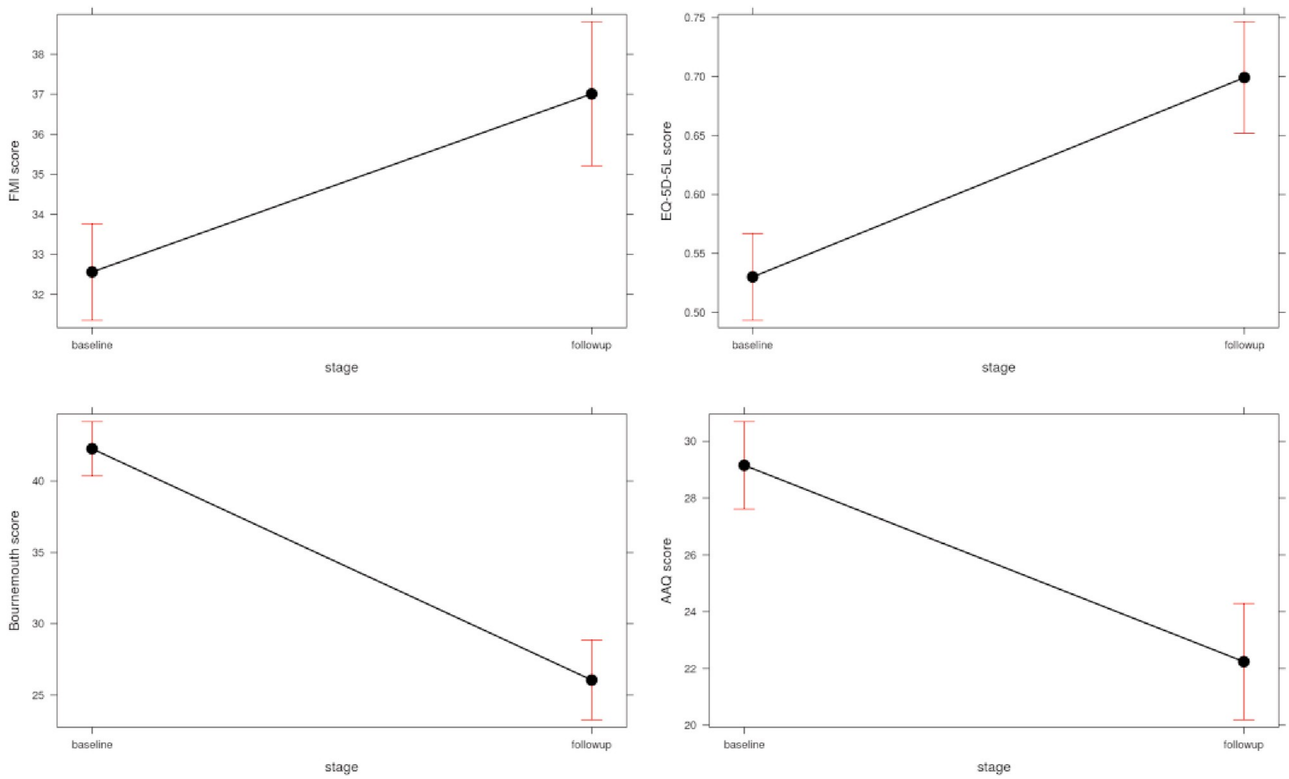

Fig. 3. Baseline and follow-up measures with 95% confidence intervals.

and supported by research showing that mindfulness influences pain responses by decoupling sensory and affective processing pain pathways [39]. Integrating physical and psychological interventions in each session enabled osteopaths to work with embodied experiences of pain, touch and movement using a flexible approach, tailored to individual capabilities, values and goals. As part of study development, challenges in combining change and acceptance-based interventions and mindfulness were identified [2], as reported elsewhere [75], and practitioner training issues will be reported in a separate paper.

Patient outcomes were consistent with results from previous CBT and ACT-based group interventions [12,15,16,19] and programmes for individuals [21,42,43,51]. Substantial evidence supports the effectiveness of CBT and MBSR compared to usual care [12], although outcomes from interventions delivered by psychologists and mindfulness teachers cannot be compared directly to physical therapists with less training or courses with less structured protocols. There is growing evidence about programmes delivered by physical therapists with brief psychological training [21,51] and limited evidence for brief mindfulness interventions, which requires further research [14].

It has been proposed that interoception is a key concept for osteopathy [76,77], and evidence from fMRI studies of parallel neurophysiological processing of sensory inputs from mindfulness practice and touch-based information [78]. Interoception involves *sensibility*, ability to notice sensations; *accuracy*, ability to interpret meaning; and *awareness* of relationships between expectations and observed sensations [79]. Changes in the central nervous system, including deficits in interoceptive processing, have been observed in patients with persistent pain, anxiety, depression and somatoform disorders [80], related to neural plasticity and sensorimotor impairment [81]. Afferent touch signals processed through affective or discriminative pathways activate adjacent areas in somatosensory and insular cortices [82]. Pain perception is influenced by preconscious interpretations of the salience of sensory inputs by the brain's predictive processes [83]. Activities in this course combined manual treatment with mindfulness, mindful movement and graded exposure to increase interoceptive awareness [32,33,84], education and cognitive reassurance to address fear-avoidance [34,35, 43].

4.2. Biopsychosocial models of osteopathic practice

Psychosocial factors are known to represent increased risks for developing persistent pain [8,10], and depression and distress are associated with poorer prognosis [85,86], but physical therapists may struggle to work effectively with psychosocial issues [20]. The course developed for this study was aligned with current healthcare initiatives to support patient self-management. In the UK government's 'Increasing Access to Psychological Therapies' (IAPT) scheme, primary care services provide mental health support for people with long-term illnesses [87], with CBT and mindfulness are offered to patients with persistent pain [88,89]. ACT principles are congruent with concepts of function and agency and access to open learning resources makes it a feasible psychological model for use by osteopaths [90].

Current neurophysiological knowledge about pain perception and the limits of body-based clinical reasoning have prompted calls to re-evaluate concepts of patient-centred care and models of practice [2, 91–93]. Pain is now being conceptualised an active, phenomenological, contextual sense-making process, and predictive processing models are being developed to explain how touch and movement influence interoception and pain perception [83,94]. This course in this study aimed to strengthen osteopaths' abilities to work with psychosocial factors using an integrated approach that was consistent with current psychological and neuroscientific beliefs that humans are whole, embodied beings [46, 83]. Osteopaths were encouraged to work with the dissonance between expectations and sensory experiences, which seemed to lead to patient learning and behaviour change. These findings support the rationale for a larger scale trial of course outcomes.

4.3. Study limitations

Practitioner training and course delivery: Osteopaths in this study

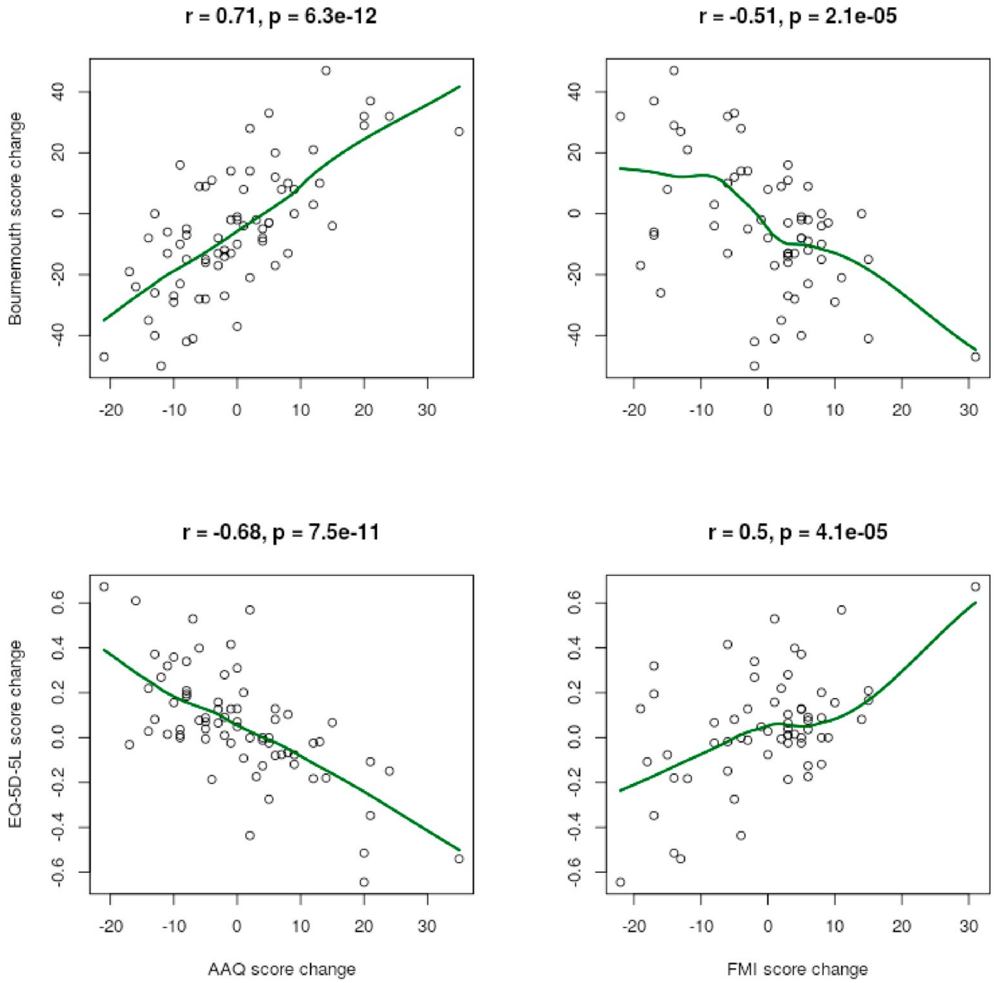

Fig. 4. Correlations between changes in outcomes.

received brief psychological training but competence in applying a principles-based ACT approach was not formally assessed and may be less effective than structured MBSR or MBCT programmes. Clinical observations by an independent assessor indicated varying competence and adherence to course aims [2]. Physical and psychosocial issues were addressed separately in some cases but course materials were rewritten to encourage a moreintegrated approach. Challenges in combining change and acceptance-based activities were observed [75]. Training processes will be reported in a separate paper.

Sample selection and patient characteristics: The study was funded as a clinical development project and the pragmatic sample size and lack of a control group limit generalisability. Broad inclusion criteria for pain conditions and psychological symptoms prevented analysis of outcomes related to specific diagnoses or confounding variables. Future research would be strengthened by using the new IASP classification, ICD-11, for chronic primary and secondary musculoskeletal pain [50]. It integrates biomedical, psychological and social factors affecting function and would enable analysis based on accurate epidemiological classification. Courses were provided free in an inner city location, so patient and practitioner characteristics are unlikely to be representative of other osteopathic settings.

Data collection: Questionnaire completion was optional. Follow-up data from 44% of the baseline participants is likely to have been positively biased. Data was not collected consistently on non-completion of course or questionnaires. Medical information recorded on clinical case notes was separated from anonymised follow-up data, so it was not possible to analyse outcomes in relation to specific patient or practitioner variables. The Bournemouth Back Questionnaire was used to measure pain coping, although patients presented with a variety of conditions. 79% reported multiple symptoms which prevented assessment of clinically important changes for single sites. Future research should use a pain interference measure for varied musculoskeletal conditions. Missing FMI follow-up scores for 13 patients suggests issues in understanding the concept of mindfulness. Self-report changes after MBSR interventions have been found to lack correlation with performance-based measures of physical function [95]. Future research should use more accessible and objective measures for both of these outcomes.

Data analysis: Only complete cases were analysed (n=79), so loss to follow-up was not addressed. No sensitivity analyses were used and there was no correction for confounding variables. Continuous variables were not dichotomised so relative and absolute risks were not calculated. More precise estimates could be obtained with a larger sample. The study had a single non-randomised sample, which further limits the generalisability of the results.

4.4. *Directions for future research*

Functional processing pathways for touch and mindfulness which converge in the interoceptive cortex support the rationale for studying interventions that combine these inputs [78]. Further research is recommended to:

- explore the effects of integrating psychological and physical interventions on interoception and pain behaviour

- identify high risk patients who may have deficits in interoceptive processing and are most likely to benefit from self-management
- identify the patient characteristics that may influence willingness to engage with acceptance and mindfulness practices

Further research is also recommended to:

- explore ways to develop practitioners' mindfulness and ability to apply the core ACT principles flexibly in work with individual patients
- develop new guidelines for mindfulness in individual physical therapy, as existing protocols are for group interventions [96,97].
- assess training and supervision needs and explore practitioners' experiences of delivering the course and effects on their practice

5. Conclusion

The psychologically-informed self-management course developed for this study combined acceptance and mindfulness interventions with osteopathic treatment for patients with persistent pain. The method was feasible for delivery by qualified and student osteopaths practising in an educational clinic setting. Recruitment and retention rates and ongoing clinical development show that the course is acceptable to patients and course outcomes are encouraging. The aim to promote active coping and self-management is aligned with neurophysiological theories of touch, mindfulness and interoception, and the integrated approach is consistent with initiatives to develop the role of physical therapists in multimodal or multidisciplinary care.

Integrating psychological, mindful and manual treatment interventions provided opportunities to expand osteopaths' current scope of care for patients with persistent pain. Significant improvements in coping and quality of life were associated with psychological flexibility and demonstrated proof of concept for combining ACT and osteopathy. Further research is needed to explore the value of this approach in other osteopathic settings and to compare course effects with existing painself-management programmes. The next stage of research would be a feasibility study for a pragmatic RCT, in line with MRC guidelines for developing complex behavioural interventions [98].

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Declaration of competing interests

The third author is the Statistical Advisor to the Editorial Board of the International Journal of Osteopathic Medicine but has not been involved in the review or any decision-making processes about this paper.

Ethical approval

London: City Road and Hampstead NRES Committee provided a favourable ethical review for the OsteoMAP study. Ref: 14/LO/0828. ISRCTN 04892266. Provenance and peer review: Not commissioned, internally peer reviewed.

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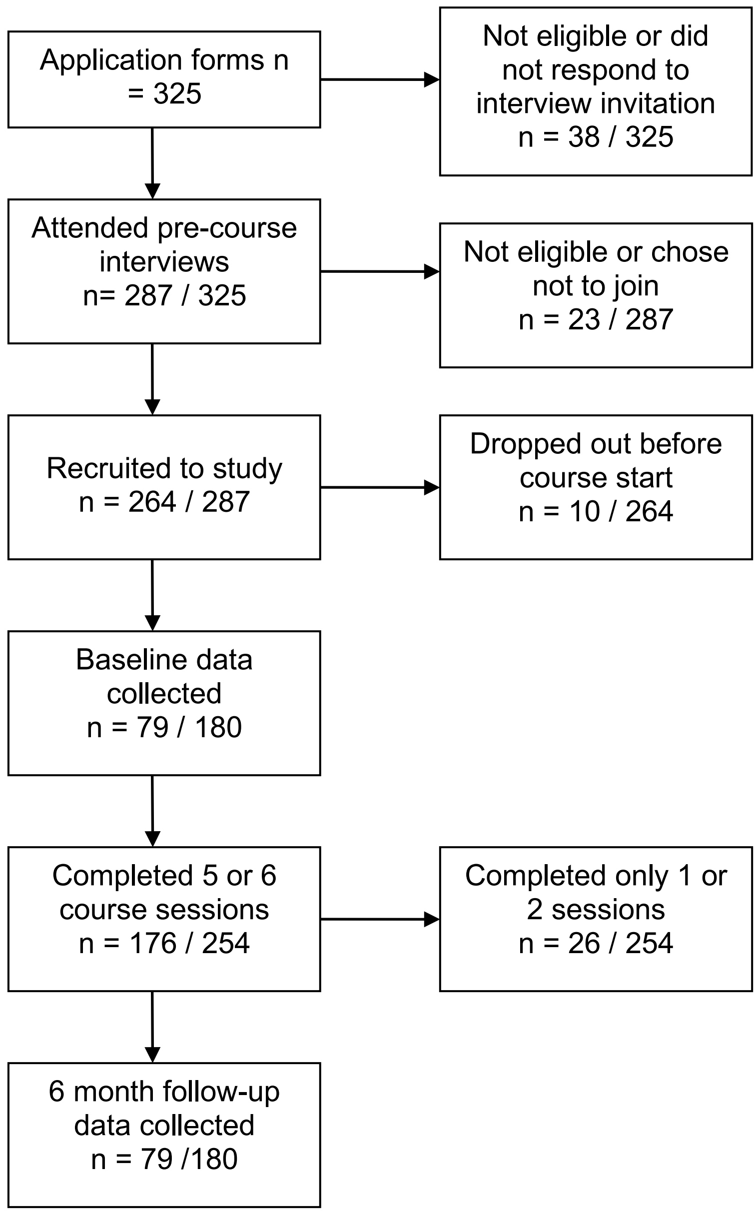
Appendix A. Supplementary data

Appendix 1 Recruitment Flowchart



Appendix 2 - Statistical Analysis Details

Statistical analyses were carried out using using R version 3.4.1 (R Core Team 2016) [1]. Sample demographic and pre-course clinical variables were tabulated (Tables 1, 2 and 3). To test if populations differed on demographic variables between baseline and follow-up, chi-squared tests were used. Fisher's exact tests were used if cell counts were too low for a chi-squared approximation. Mixed effects linear regression was carried out using R package 'lme4' version 1.1.13 [2] to assess if there was a difference in response variables: psychological inflexibility (AAQ score), Bournemouth score, mindfulness (FMI score), and quality of life (EQ-5D-5L score), before and after the course, and to the assess modifying effects of age and gender. Participants were treated as random intercepts in the mixed effects model. Wald tests were used to test the significance of model parameters using the Kenward-Roger approximation of the degrees of freedom. Nested models were compared using likelihood ratio tests. Adequacy of model assumptions were checked by examining residuals after a normalisation step [3], to account for correlations between residuals. For each of the response variables, modelling started with a full model consisting of main effects and all interactions between the fixed predictors. Automatic backward elimination was used. This starts with considerations of random effects followed by fixed effects, starting with higher order terms.

To test the hypothesis that improvement in psychological flexibility and mindfulness correlates with improvement in quality of life and reduction in pain and disability, ordinary least squares regression was used to estimate the predictive effect of change in AAQ and FMI score on change in EQ-5D-5L and Bournemouth score, with age and gender (with all interaction effects) as modifying effects.

Table 1 shows the demographic characteristics of the participants. No significant differences in the distribution of the baseline and follow-up populations were found on these variables. Table 2 indicates that most participants complained of back pain, and Table 3 shows most participants reported pain in multiple sites.

Table 1: Demographic characteristics of participants at baseline and follow up.

Demographic variable	Level	Baseline	Follow up
gender [p=0.94][a]	female	117	54
	male	60	26
living [p=1.00][a]	alone	64	30
	with others	113	51
fluency [p=0.39][b]	below average	3	0
	good	16	4
	fluent	160	77
ethnicity [p=0.78][b]	asian	7	4
	black	27	10
	mixed	11	5
	other	16	4
	white	115	56
education [p=0.91][b]	none	1	1
	<13	1	0
	13to16	36	15
	17to19	43	18
	20+	96	47
employed [p=0.65][a]	no	100	49
	yes	79	33
student [p=1.00][b]	no	169	77

Table 1: Demographic characteristics of participants at baseline and follow up.

Demographic variable	Level	Baseline	Follow up
	yes	8	4
age.group [p=0.91][a]	18-34	33	16
	35-49	58	23
	50-69	69	34
	70+	16	8

Test type: [a] Chi-squared [b] Fisher's exact

Table 2: Percentages of participants complaining of pain, per anatomical site

Back	Leg	Neck	Head	Shoulder
78.0%	56.6%	52.8%	23.6%	52.2%

Table 3: Frequency table of painful sites per participant

0	1	2	3	4	5	NA
2	39	49	39	30	21	2

Effect of Treatment, Age and Gender on Outcome Variables

Bournemouth MSK score

	Model 1	Model 2
(Intercept)	44.58 (3.79)***	44.00 (1.15)***
stagefollowup	-10.61 (5.78)	-16.99 (1.60)***
age	-0.02 (0.07)	
gendermale	6.37 (7.12)	-5.04 (1.82)**
stagefollowup:age	-0.11 (0.11)	
stagefollowup:gendermale	-16.30 (12.36)	
age:gendermale	-0.21 (0.14)	
stagefollowup:age:gendermale	0.27 (0.24)	
Num. obs.	246	249
Num. groups: subjID	171	174
Var: subjID (Intercept)	38.12	39.88
Var: Residual	121.82	121.65

***$p < 0.001$, **$p < 0.01$, *$p < 0.05$

Table 4: Modelling effect of age and gender on Bournemouth score. Initial (Model 1) and final model (Model 2)

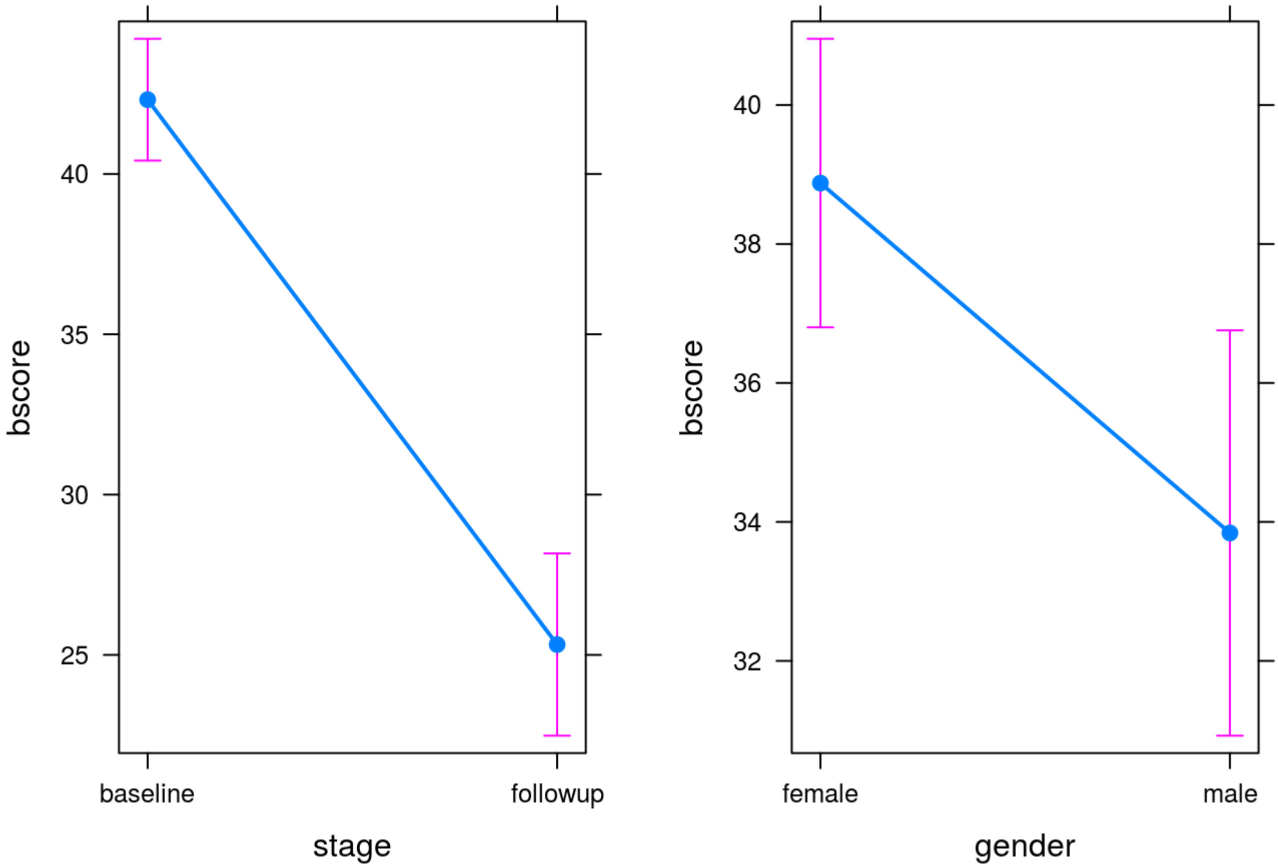


Figure 1: Effects plot for final model - Bournemouth score. Means and 95% confidence intervals.

Table 4 indicates that Bournemouth score is significantly reduced at follow-up (baseline - follow up = 16.99 [13.83 - 20.15 95% C.I.]). Gender is also significant with males reporting a lower score than females (female - male = 5.04 [1.45 - 8.62 95% C.I.]), irrespective of the stage of the study. Figure 1 shows the Bournemouth scores at baseline and follow up (left), as well as means for males and females (right), along with 95% confidence intervals.

EQ-5D-5L score

	Model 1	**Model 2**
(Intercept)	0.55 (0.07)***	0.53 (0.02)***
stagefollowup	0.07 (0.08)	0.17 (0.02)***
age	-0.00 (0.00)	
gendermale	-0.10 (0.14)	
stagefollowup:age	0.00 (0.00)	
stagefollowup:gendermale	0.15 (0.17)	
age:gendermale	0.00 (0.00)	
stagefollowup:age:gendermale	-0.00 (0.00)	
Num. obs.	245	255
Num. groups: subjID	170	178
Var: subjID (Intercept)	0.04	0.04
Var: Residual	0.02	0.02

***p < 0.001, **p < 0.01, *p < 0.05

Table 5: Modelling effect of age and gender on EQ-5D-5L score. Initial (Model 1) and final model (Model 2).

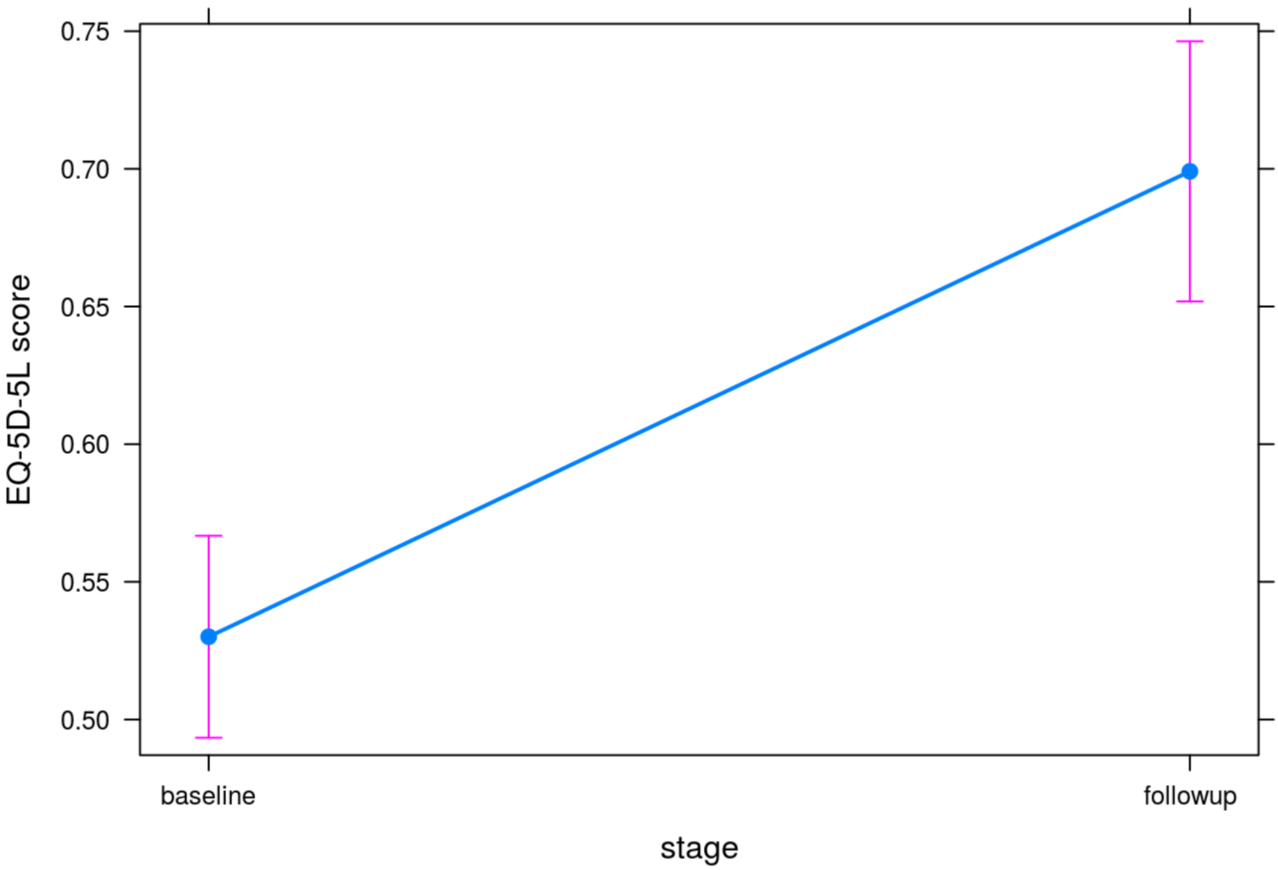


Figure 2: Effects plot for final model - EQ-5D-5L. Means and 95% confidence intervals.

Table 5 indicates that EQ-5D-5L score is significantly increased after the course (follow up - baseline = 0.17 [0.21 - 0.13 95% C.I.]). At baseline 11/180 had scores below zero. Whereas, 0/84 had scores below zero at follow up. Figure 2 shows mean scores at baseline and follow-up.

AAQ score

	Model 1	**Model 2**
(Intercept)	38.56 (2.94)***	37.77 (2.43)***
stagefollowup	-9.81 (3.64)**	-8.46 (1.22)***
age	-0.19 (0.06)**	-0.17 (0.05)***
gendermale	-4.12 (5.86)	-1.51 (1.64)
stagefollowup:age	0.03 (0.07)	
stagefollowup:gendermale	9.27 (7.75)	5.30 (2.11)*
age:gendermale	0.05 (0.11)	
stagefollowup:age:gendermale	-0.08 (0.15)	
Num. obs.	235	235
Num. groups: subjID	164	164
Var: subjID (Intercept)	55.23	55.62

Var: Residual	41.20	40.12

$^{***}p < 0.001$, $^{**}p < 0.01$, $^{*}p < 0.05$

Table 6: Modelling effect of age and gender on AAQ score. Initial (Model 1) and final model (Model 2).

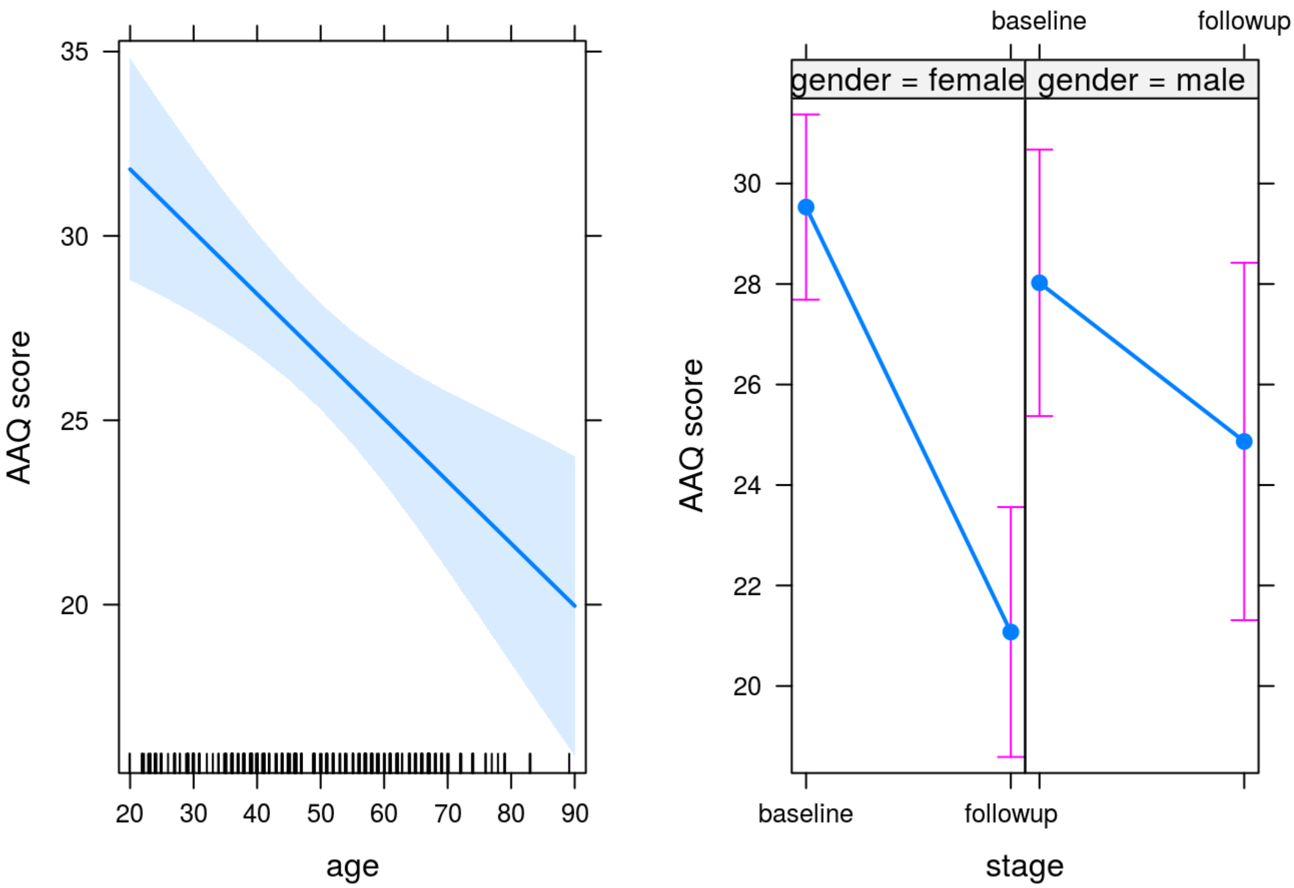


Figure 3: Effects plot for final model - AAQ. Means and 95% confidence intervals.

Table 6 indicates that AAQ score is affected by age, with older subjects reporting lower inflexibility scores, and the effect of stage is moderated by gender, with males reporting a lower improvement in flexibility than females (female improvement = 8.46 [6.04 - 10.87 95% C.I.], male improvement = 3.16 [-0.27 - 6.58 95% C.I.]). This means that improvement in flexibility is only significant in females. Figure 3 shows the relationship between age and mean AAQ score (left), and how AAQ score differs between males and females at baseline and follow-up (right), with females showing a greater effect.

FMI score

	Model 1	**Model 2**
(Intercept)	25.05 (2.28)***	25.90 (1.79)***
stagefollowup	10.20 (3.52)**	4.43 (0.98)***
age	0.16 (0.05)***	0.14 (0.03)***
gendermale	-3.09 (4.70)	
stagefollowup:age	-0.10 (0.07)	
stagefollowup:gendermale	0.11 (7.66)	
age:gendermale	0.04 (0.09)	
stagefollowup:age:gendermale	-0.05 (0.15)	

Num. obs.	218	221
Num. groups: subjID	156	158
Var: subjID (Intercept)	16.42	16.94
Var: Residual	39.42	38.93

***p < 0.001, **p < 0.01, *p < 0.05

Table 7: Modelling effect of age and gender on FMI score. Initial (Model 1) and final model (Model 2).

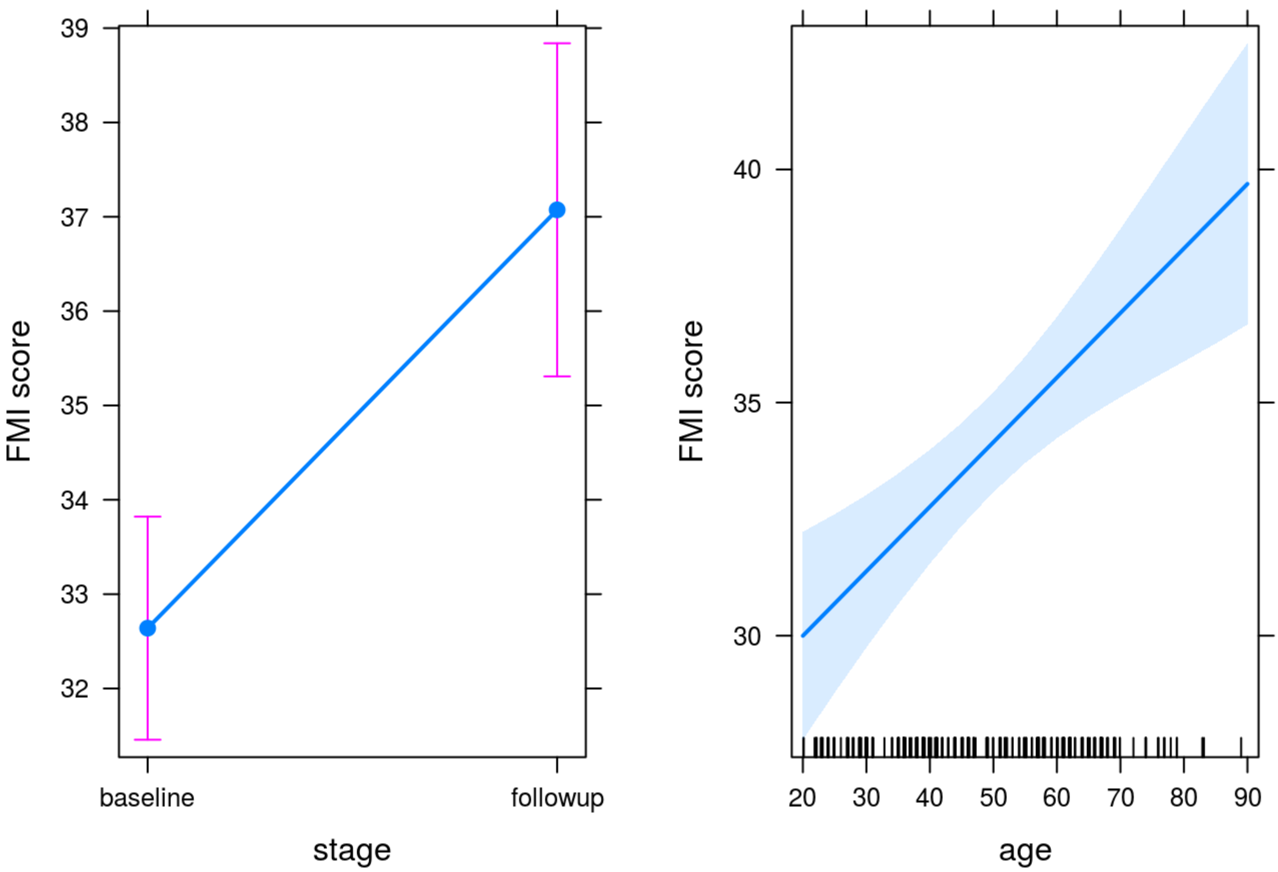


Figure 4: Effects plot for final model - FMI. Means and 95% confidence intervals.

Table 7 indicates that FMI score differs significantly between baseline and follow-up, and is effected by age, with older subjects reporting higher mindfulness scores, irrespective of stage. Figure 4 shows FMI score means at baseline and follow-up (left), and the relationship between age and mean FMI score (right).

Change in FMI & AAQ Vs. Change in EQ-5D-5L

The modelling of the effects of change in FMI and change in AAQ were carried out separately due to problems related to correlations between terms when they were both included in the same model. Table 8 shows the result of modelling the effect of change in AAQ score on change in EQ-5D-5L scores. This indicates no effect of age or gender, and a significant negative linear relationship between change in AAQ and change in EQ-5D-5L. In other words, those with improvements in psychological flexibility (reduced AAQ scores) were more likely to report improved quality of life (increased EQ-5D-5L scores).

Modelling change in FMI Vs. change in EQ-5D-5L scores and examining residuals indicated a nonlinear relationship between FMI change and EQ-5D-5L change. Therefore, a quadratic term was included (Table 9). The final model showed a significant quadratic relationship between change in EQ-5D-5L and change in FMI. This is illustrated in figure 5. This suggests that those with no change in mindfulness had the least improvement in quality of life. For most, an increase in mindfulness was associated with an increase in quality of life, but in some quality of life increased despite a decrease in mindfulness.

	Model 1	**Model 2**
(Intercept)	-0.060 (0.092)	0.103 (0.024)***
diff.aaq	-0.020 (0.008)*	-0.011 (0.002)***
age	0.003 (0.002)	
gendermale	0.201 (0.168)	
diff.aaq:age	0.000 (0.000)	
diff.aaq:gendermale	-0.003 (0.027)	
age:gendermale	-0.003 (0.003)	
diff.aaq:age:gendermale	0.000 (0.000)	
R^2	0.288	0.239
Adj. R^2	0.208	0.227
Num. obs.	70	70
RMSE	0.172	0.170

***$p < 0.001$, **$p < 0.01$, *$p < 0.05$

Table 8: Modelling effect of change in AAQ on change in EQ-5D-5L. Initial (Model 1) and final model (Model 2).

	Model 1	**Model 2**
(Intercept)	-0.013 (0.100)	0.104 (0.026)***
diff.fmi	0.001 (0.010)	
I(diff.fmi^2)	0.001 (0.000)	0.001 (0.000)***
age	0.002 (0.002)	
gendermale	0.208 (0.223)	
diff.fmi:age	0.000 (0.000)	
I(diff.fmi^2):age	0.000 (0.000)	
diff.fmi:gendermale	-0.032 (0.060)	
I(diff.fmi^2):gendermale	0.004 (0.007)	
age:gendermale	-0.003 (0.004)	
diff.fmi:age:gendermale	0.000 (0.001)	
I(diff.fmi^2):age:gendermale	-0.000 (0.000)	
R^2	0.308	0.231
Adj. R^2	0.153	0.218
Num. obs.	61	61
RMSE	0.178	0.171

***$p < 0.001$, **$p < 0.01$, *$p < 0.05$

Table 9: Modelling effect of change in FMI on change in EQ-5D-5L. Initial (Model 1) and final model (Model 2).

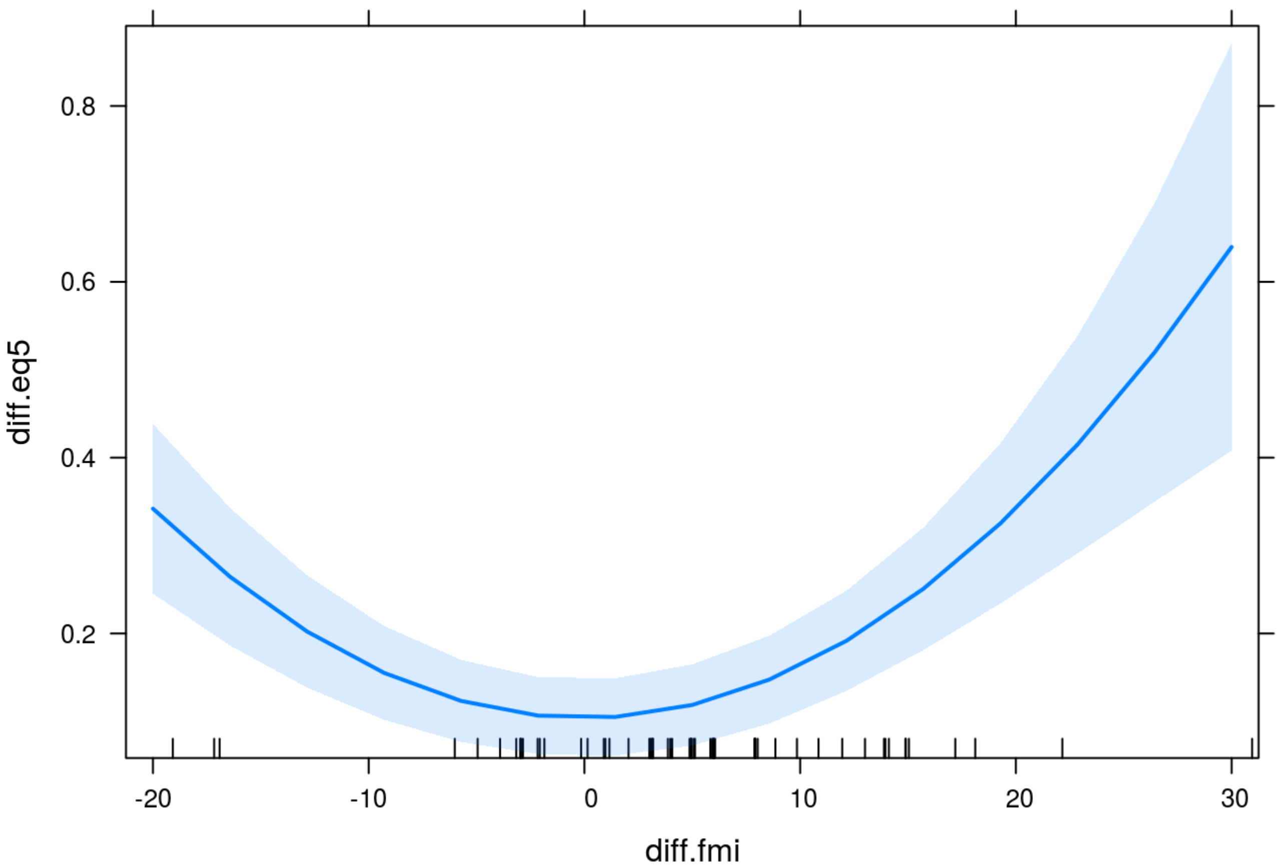


Figure 5: Model of relationship between change in FMI and EQ-5D-5L scores, with 95% confidence intervals.

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