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A mixed methods evaluation of a third wave cognitive behavioural therapy and osteopathic treatment programme for chronic pain in primary care (OsteoMAP).

Abstract

Introduction

The aim of this study was to evaluate the implementation of a 'third wave' cognitive behavioural therapy with osteopathic treatment programme (OsteoMAP) and explore its effect on patients with chronic musculoskeletal pain.

Method

This evaluation included a non-randomised before-and-after patient reported outcomes study with an embedded fidelity evaluation. Patients were seen for one hour per week for six weeks. They received a questionnaire prior to receiving treatment and six months later. A purposive sample of patients were interviewed and clinical sessions were observed to evaluate competence and adherence to the intervention manual.

Results

208 patients were enrolled and 86% attended 3 or more OsteoMAP sessions. 82 students were trained to deliver the intervention under supervision. They were >90% adherent to the manual in 8 of the 12 domains measured. At baseline (n=147), 69% of patients were female, 64% white and 77% reported pain for more than one year. At 6 months (matched pairs n=63), there were clinically important changes of 58% in a composite score for pain, function, mood and coping (Bournemouth Questionnaire) and significantly higher psychological flexibility scores (difference in means 6.98 (95% CI 4.2,9.8)) (Acceptance and Action Questionnaire)). No statistically significant change was seen in

mindfulness (Freiburg Mindfulness Inventory), 30% of patients reported temporary symptom increases during the course but 95% were satisfied or very satisfied with their overall experience and outcomes.

Conclusions

OsteoMAP was feasible, well received with some beneficial effects. Integrating psychological and osteopathic care shows promise and further research is warranted to assess effectiveness.

Key words: Chronic pain, osteopathy, mindfulness, pilot study.

Introduction

The prevalence of long term health conditions is predicted to rise as a consequence of the aging demographic and rising obesity levels¹. Chronic pain is a particularly challenging long term condition, often associated with pain in multiple sites²; disability; restricted working capacity; reduced quality of life; psychological problems including depression and high usage of health care resources^{1,3}. The effectiveness of pharmacological treatments for chronic pain is often limited, and associated with side effects⁴. Improvements in the theoretical understanding of back pain have had little impact on prevalence: the global burden of low back and neck pain, was ranked as 7th in 1990, 5th in 2005 and 3rd in 2013⁵.

Non physician-led care pathways have been recommended to promote behaviour change for healthier lifestyles and better self-management of long term conditions globally^{6,7}. Non-physician primary care health care practitioners, such as osteopaths, chiropractors and physiotherapists delivering manual therapy are ideally suited to providing additional and integrated self-management and psychological support for pain.

An important component of any manual therapy care is the psychological relationship between the patient and practitioner. An innovative care package combining osteopathy and Acceptance and Commitment Therapy (ACT)⁸, a form of third wave cognitive behavioural therapy, has been developed at the British School of Osteopathy (BSO). The Osteopathy, Mindfulness and Acceptance Programme (OsteoMAP) was designed to maximise the potential therapeutic advantages of physical and psychological interventions from osteopathy and ACT in flexibly structured six week courses for individual patients.

Mindfulness approaches have become increasingly applied to the psychological management of chronic health conditions. The construct of mindful acceptance may be transformative for those with long term conditions that are resistant to 'curative' healthcare interventions. ACT is a psychological approach that aims to facilitate psychological flexibility through the development of new self-

generated behavioural strategies and the weakening of unhelpful automatic responses based on the habitual reactions to individual experiences⁹. There are six core ACT principles, which include: the acceptance of private experiences; defusing literal interpretations of thoughts; increasing awareness of the self as an observing entity; mindfulness of present moment experiences; identifying personal values; and committed actions to live consistently with those values¹⁰.

There is evidence to show that osteopathic, ACT and mindfulness based therapies have some beneficial effects for chronic pain, but these are generally small^{11,12, 13, 14}. Combining the therapies may improve potential outcomes for people with chronic pain. The aim of this study was to evaluate the implementation of a 'third wave' cognitive behavioural therapy with osteopathic treatment (OsteoMAP) and explore its effect on patients with chronic musculoskeletal pain.

Method

OsteoMAP (the name of the intervention and the study) was a three year pilot study which was implemented and delivered from June 2013 to May 2016. The evaluation of the pilot study included a non- randomised before-and-after evaluation of OsteoMAP using patient reported outcomes and an embedded fidelity study to evaluate delivery of the intervention. The evaluation was conducted independently of the OsteoMAP team (Authors DC, TM, AP, all of whom had a background in Osteopathy). Data were collected between January 2014 and December 2015 (24 months).

Patient population

Inclusion criteria were:

- Adults over 18 years of age and able to give informed consent.
- Sufficient English to communicate without an interpreter.
- Musculoskeletal pain symptoms for more than six months.

- Suitable for osteopathic manual therapy.
- Willing to participate in the course, home practices, and pre and post questionnaire completion

Pre-course screening interviews were conducted by the clinic supervisors to assess eligibility and patients' willingness to engage in active self-management. The clinic supervisors gave potential participants information about OsteoMAP and what it involved, they then jointly explored whether the programme was suitable and appropriate for them. Potential participants were excluded if they had any uncontrolled mental health, or substance abuse issues which were beyond the scope of practice for the osteopaths and might limit the patient's ability to actively engage in OsteoMAP or if they were currently receiving psychological care from elsewhere.

Intervention setting and training

OsteoMAP patient courses were delivered in three sites; an osteopathic training clinic (BSO) and two general practices in London. Experienced registered osteopaths working as clinic tutors were trained in groups over 4 days to deliver, mentor and supervise student osteopaths to deliver OsteoMAP. Students were trained during a 12 week elective module for chronic pain management as part of a masters degree in osteopathy. The students received an OsteoMAP manual outlining key concepts, the approach and the stages of delivery. Students observed tutors treating two or three patients on individual six week courses and then treated two to three patients themselves, with tutor supervision.

The intervention

OsteoMAP: six session patient programme

Patient courses were delivered in six, weekly 60 minute sessions by: student osteopaths under the supervision of a qualified osteopath working as an OsteoMAP clinic tutor or, by the OsteoMAP clinic tutor being observed by the students as part of their training. Each patient was seen, where possible, by the same student and / or supervising osteopath.

The psychological component of the intervention was based on the therapeutic sequence outlined in 'ACT Made Simple'⁹ and adaptations of secular mindfulness approaches developed by Kabat Zinn¹⁵. Each session was divided approximately into: 15 minutes to discuss patients' home practice in the previous week and to introduce the ACT focus for the session; 30 minutes to explore body awareness and processes related to psychological flexibility using movement practices and mindful osteopathic treatment and 15 minutes for a collaborative review of patients' experiential learning and to plan values-based actions for the following weeks home practice. Practitioners carried out osteopathic treatment and guided movement practices with the intention of maintaining awareness of present moment experience and the aim of the session. For example, normal routines were often slowed down and accompanied by enquiry to enhance patient awareness of change in physical sensations, and their habitual physical, cognitive and emotional reactions to actual or anticipated discomfort.

Topics covered were:

1. 'Living with pain' (noticing autopilot reactions to avoid discomfort),
2. 'Living more flexibly with pain' (exploring acceptance of discomfort and defusion from fixed pain beliefs),
3. 'Living in the present' (developing present moment awareness and sense of self),
4. 'Living a fulfilling life' (identifying personal values and valued social roles and activities),
'Overcoming obstacles' (overcoming barriers to behaviour change) and
5. 'Moving on' (planning ways to sustain positive changes in daily life).

We collected data on the number of patients referred, number screened, number of patients starting the OsteoMAP programme, and number of sessions attended. Demographic information was collected from all patients willing to participate in the evaluation: gender, age, ethnicity, work status, language fluency, living status, pain site and duration.

Patient reported outcomes

In addition to demographic data, the pre and post intervention (6 months follow-up) self-report electronic questionnaires included:

The Bournemouth Questionnaire, a well validated (Cronbach alpha =0.9)¹⁶ seven item questionnaire which measures pain severity, pain, function, mood and coping. Patients indicate severity on a numerical rating scale from 0-10. Scores are added together and compared to the following data collection time point to create change scores (follow-up score/baseline score x 100). A clinically meaningful change score is considered to be >47%¹⁴.

The revised Acceptance and Action Questionnaire (AAQ-II) (Cronbach alpha = 0.84)¹⁷ measures psychological flexibility as acceptance and values-led action. It comprises 10 statements to which respondents complete a Likert type scale from 1-7: Never true to Always true.

The Freiburg Mindfulness Inventory (Cronbach alpha = 0.93)¹⁸ consists of 14 questions about mindfulness based thinking using a Likert type scale from 1-4: Rarely to Almost always.

At six months, patients were also asked about use of other health services and to rate experiences of, and satisfaction with, their course and whether they had any adverse events. We did not collect data about medication use.

Patient interviews

A purposive sample of patients were selected for interview on the basis of three criteria: gender; age (under or over 45), and exposure to the intervention (programme completers and partial or non-completers). Within each category patients were randomly selected to be invited for an interview.

A simple semi-structured interview schedule was designed in collaboration with the OsteoMAP team to capture data about patient experiences of, and behavioural responses to, the programme. The interviews were conducted by an independent member of the evaluation team (TM) who was not involved in the delivery of care:

- What do you remember about the course?
- Was it useful to you in any way?
- How are you now?
- Do you feel that you gained anything from participating in the course?
- What advice would you give to someone who is thinking about going on the OsteoMAP course?
- Given that we do not have a cure for chronic pain, how could we have improved the course and made it more useful to you?
- Is there anything else you would like to say before we end the interview?

Detailed notes were taken during and after the interviews and pertinent quotes were transcribed.

The data was analysed by the independent researcher using simple thematic analysis.

Fidelity assessment

Fidelity was assessed by:

- Observation of OsteoMAP training courses
- Observation and assessment of the delivery of OsteoMAP courses to patients

Fidelity assessment forms were developed as a tool for: reflective practise, experiential learning and observer assessment. We assessed adherence to the session structure and the behavioural competence of the osteopaths. We observed whether the osteopath could competently enact behaviours which were relevant to the six core ACT principles and flexibly adapt them to individual patients' needs (Table 1, first column).

As this intervention combined physical and psychological interventions, we assessed whether the osteopath used verbal and non-verbal communication competently to facilitate patient awareness and learning processes. Observations were recorded as comments on performance. Adherence was rated 0 not observed, 1 partially observed, 2 observed using the expected components to be included in each one hour OsteoMAP session (Table 1, column 2)

Table 1. Adherence

Core ACT principles	Adherence if clinician :
1. Acceptance: Did the osteopath help the patient open up to unwanted experience?	1. Introduced the general and specific purpose of the session
	2. Reviewed the patient's home practice experiences to identify barriers to action
2. Defusion: Did the osteopath help the patient notice their own thinking patterns?	3. Used barriers to guide the acceptance and osteopathic interventions in this session
	4. Took an appropriate case history or health review to assess changes from last week
3. Awareness: Did the osteopath help the patient notice 'here and now' experiences?	5. Performed relevant osteopathic physical examinations for existing/new symptoms
	6. Provided safe, effective and appropriate osteopathic manual treatment and advice
4. Resilient self: Did the osteopath help the patient put their pain experiences into a wider self-context and life history	7. Obtained relevant, on-going, informed consent for treatment and interventions
	8. Integrated ACT and mindfulness exercises with physical examinations/interventions
	9. Provided opportunities for the patient to explore home exercises in the session

<p>5. Values: Did the osteopath help the patient identify what really matters to them?</p> <p>6. Action: Did the osteopath help the patient to do what it takes to live in accordance with their personal values?</p>	10. Closed the session by eliciting what the patient learned so far/in this session
	11. Helped the patient to plan a realistic, activity linked to a personal value
	12. Gave the patient the relevant session hand-outs, during or at the session end

Results

Patient data

Five tutors were trained to mentor and supervise students to deliver OsteoMAP and 82 students were trained to deliver the OsteoMAP intervention.

Up to 31st January 2016, a total of 286 patients were invited to participate in OsteoMAP. After screening for suitability 78 chose not to participate and 208 were booked onto the programme. All patients were invited to participate in the evaluation, 147 (71%) completed baseline questionnaires prior to treatment; of these, 63 completed 6 month follow-up questionnaires (43% response rate).

One hundred and five people (50%) attended all six sessions, 74 (36%) attended three to five sessions, 20 (10%) attended one or two sessions, 8 (4%) did not attend any sessions and one person had 8 sessions.

Patients were predominantly female (69%), white (64%), living with others (62%), received education beyond age 16 (75%), were not currently in paid work (59%) and had pain for more than 12 months (77%). The most common sites of pain were back and leg pain (Table 2).

Table 2. Baseline pain characteristics of the OsteoMAP patients

Site of pain	% of cohort (N=147)	n
Back	79	115
Leg	55	80
Neck	53	77
Shoulders/arm	53	78
Headache	26	38
Other	28	45
Pain longer than year	77	116

Patient reported outcomes

Paired outcome data after 6 months, showed that patients reported significant improvements in pain mood and coping as shown by change in the Bournemouth Questionnaire (a clinically meaningful change of > 47%) and in psychological flexibility as shown by changes in the revised Acceptance and Action Questionnaire. No changes were seen in reports on general health or the Freiburg Mindfulness Inventory (Table 3).

Table 3: Patient reported outcomes, matched paired analysis (n=63)

Outcome measure	Baseline (n=63)	6 months (n=63)	Change
Bournemouth questionnaire Scale 0-70 (70 worst) (>47% change is clinically meaningful)	Mean 39.57 (range 12-64) (SD 12.3)	Mean 22.98 (range 1-55) (SD 14.2)	Change 58.1% (6 months score / baseline score x 100) Difference in means: 16.59 (CI 95% 12.61: 20.57) P<0.0001
General health Very good or good Fair Bad or very bad	Mean 2.50 (SD 0.82)	Mean 2.32 (SD 0.77)	Difference in means: 0.18 (CI95% -0.06: -0.43) P= 0.1393
Freiburg Mindfulness Inventory Scale 14 – 56 Higher scores indicate more mindfulness	Mean 31.57 (range 14-49) (SD 9.02)	Mean 34.06 (range 19-49) (SD 12.64)	Difference in means: -2.43 (CI95% -6.78: 1.92) P= 0.2681
AAQ-IIR Scale 7-50 Higher scores = less psych. flexible	Mean 25.10 (range 7-49) (SD 11.65)	Mean 18.11 (range 7-49) (SD 10.27)	Difference in means 6.98 (CI95% 4.2: 9.8) P<0.0001

We asked patients about healthcare resource use during the previous six months: one person had attended Accident and Emergency, none had any unscheduled hospital admissions. However 30 people (48%) had an MRI, CT scan or X-ray, 21 (33%) had a pain relieving injection and three (5%) people had surgery.

Temporary worsening of symptoms were reported by 19 people (30%) but nearly all respondents 60 (95%) were satisfied or very satisfied with their experience on the programme. No serious adverse events were reported.

Patient interviews

Twelve patients were interviewed, of whom 9 (75%) were female. None of the non-completers approached accepted the invitation to be interviewed and no reasons were given for declining.

Table 4. Patient profile at time of sampling and numbers interviewed

Age	>45		<45		Total
	Female	Male	Female	Male	
Completers invited (attended all 6 sessions)	23	19	12	4	58
Number interviewed	7	2	2	1	12
Non or partial completers invited (attended between 1 and 5 sessions)	4	2	6	0	12
Number interviewed	0	0	0	0	0
Total interviewed	7	2	2	1	12

Four key themes emerged from the interviews were i) the environment, ii) course delivery, iii) the therapeutic process and iv) the psychological challenges.

i) Environment

There were no issues reported with course administration, BSO clinic reception or appointment procedures. The physical environment of the BSO clinic was found to be satisfactory, although there were a few minor suggestions for improvements.

“a bit softer....less clinic like and that the rooms were rather cold” (*Patient (P) 6520*) and “a bit dark” (P6511).

ii) Course delivery

Participants commented on the personal challenges, difficulties and commitment required to complete the course. The range of responses are illustrated in the quotes below:

“Be prepared to make an effort to get the most out of it” (P6511),

“100% go.... but I found it a very emotional experience” (P6521),

“An excellent course...but it is not a self-help/support group or a pity party” (P6517),

“This is not a quick fix, not for moaners or whingers”. (P6551)

All the participants referred to the kindness, professionalism and empathy of the OsteoMAP tutors and student practitioners.

“Very compassionate and welcoming” (P6524),

“.....Well held’ and professional. It was really nice.”(P6543)

iii) The therapeutic process

Patients expressed a wide range of responses to the OsteoMAP process and its impact on them. Reported benefits included decreases in negative ‘*autopilot*’ thought processes and emotional reactions to symptoms, increased ability to cope with stressful life situations, increased confidence and social interaction and some decreases in medication usage. Positive change was attributed to being more in the present and acceptance. Mindful body scans, though challenging for some, were

used to improve sleep (P6512, P6521) and to calm anxiety and fear induced by exacerbations of symptoms (P6521, P6567). For example:

"..stopping/breathe/relax/feel/carry on.....gave me positive ways to deal effectively with physical and mental pain and stress".

"OsteoMAP taught me to slow down and think about things....." (P6512)

A patient suffering from fibromyalgia found that using the 'Notice, Breathe, Expand, Allow' exercise helped her to gain *"a totally different way of looking at pain relief Amazing to feel that you have the power to change your thoughts"*. She felt she was no longer struggling in a fight with an external entity and getting resentful and *"beating myself up"* *"The pain is part of me, it is who I am"*. (P6517)

"Pain is the messenger not the enemy". (P6527).

"an increase in confidence and ability to put myself first now less hard on myself.....I take frequent breaks where needed.....my ability to do day-to-day activities has improved....."
(P6520)

"I'm now less of a 'barking dog' with others that I used to be....., more able to 'open up' to others, by being able to 'make space for the pain'. Now not so 'defensive' or afraid that people might think that I am a 'complainer'". (P6543)

In contrast to these positive experiences, one patient commented that she *'didn't really know'* what had been gained by doing course (P6550), another found it to be *'generally enjoyable'* and a *'little bit helpful'* and because her symptoms waxed and waned it was difficult to attribute an evident improvement to OsteoMAP (P6567). One participant felt that OsteoMAP had made no difference to her day to day activities, hobbies, social interaction or medication use, and was somewhat confused by some of the mindfulness instructions, although she commented that *'reconciliation was not*

enough' and that she couldn't do the things that she wanted to, she felt that she was less embarrassed and a bit more willing to *'give things a go'* (P6524).

Another patient commented that although the course was useful in providing techniques to cope with symptom exacerbations, it had no cumulative effect and when the pain was too severe it *'overwhelmed'* efforts to be at peace with it. OsteoMAP techniques were seen as a *'sticking plaster'* to be applied when pain was troublesome rather than severe (P6551).

iv) Psychological challenges

The high levels of personal and emotional disclosure on the course were challenging for some patients:

"...all those years not expressing feelings about pain, keeping it inside me.....the opportunity to talk in safe caring environment was a massive thing". (P6550)

"Lots of emotional 'stuff' came out in a self-affirming/positive way". (P6523)

"I was upset after first session and there were some tears..... it opened a lid and it all came out..... a cathartic experience." (P6520)

The demands of the course, the personal commitment, the difficulty of understanding how mindfulness could help and establishing a regular personal mindfulness practice were all mentioned. This was the principle reason for a number of suggestions to extend the length of the course and provide increased opportunities for support afterwards.

Fidelity assessment

A partial, fidelity assessment was conducted by observing the tutor training course and nine four-hour observations of tutors and students delivering clinical interventions. We evaluated both

adherence to the intervention manual and competence. Practitioners were >90% adherent to the manual in 8 of the 12 domains. They had particular difficulty using the barriers to action identified by patients to guide new acceptance-based and osteopathic interventions (Item 3, Table 5) and integrating acceptance and mindfulness exercises with physical examination and treatment (Item 8, Table 5)

Table 5. Adherence scores

Adherence item (See items in table1)	OsteoMAP practitioner adherence scores 0= non adherent, 1 = partial and 2 = adherent										% Item score	
1	1	2	2		2	1	2		2	2	2	89%
2	2	2	2		2	1	2		2	2	2	94%
3	1	0	0		0	0	0		1	1	0	17%
4	2	2	2		2	2	2		2	2	2	100%
5	2	2	2		2	2	2		2	2	2	100%
6	2	2	2		2	2	2		2	2	2	100%
7	2	2	2		2	2	2		2	2	2	100%
8	1	1	1		1	0	1		0	0	1	33%
9	2	2	2		2	2	2		2	2	2	100%
10	1	0	2		1	0	2		2	2	2	67%
11	2	2	2		2	2	2		2	2	1	94%
12	2	2	2		2	2	2		2	2	2	100%
% Session score	83%	79%	88%		83%	67%	88%		88%	88%	83%	

We found competence difficult to rate due to the complexity and depth of the patient-practitioner interactions, but that clinical competence was grounded in the receipt of training course concepts, mentoring support and practitioner experience.

Discussion

This evaluation showed that integrating osteopathic manual therapy, mindfulness concepts and ACT was feasible, as the approaches could be combined. Practitioners could be trained to deliver principles-based interventions adherently, competently and as intended and as adapted for the healthcare needs and personal goals of individual patients. Patient reported outcome data indicated that there were positive effects for pain, function, mood and coping and that patients seemed to develop more psychological flexibility. Patients were generally satisfied with their experience of participating in an OsteoMAP course and interventions to date have not resulted in any reports of serious adverse events.

The outcome evaluation demonstrated no significant change in the Freiburg Mindfulness Inventory scores. This suggested that the brief mindfulness component of OsteoMAP tutor training was not sufficient to enable tutors to teach their students to work effectively with the mindfulness based parts of the intervention. This is consistent with the evidence from the adherence evaluation that the practitioners were weaker in two domains: using barriers to guide the intervention, and integrating ACT and mindfulness exercises with physical examinations. More intensive mindfulness training for all practitioners involved in service delivery may be beneficial, based on the principles of good practice as outlined in the current UK mindfulness teaching guidelines¹⁹.

Combination and adjunctive psychological approaches such as OsteoMAP, mindfulness based stress reduction (MBSR), mindfulness based cognitive therapy (MBCT) and self-management programmes are increasingly being explored^{13, 20, 21}. These non-pharmacological approaches to chronic pain have a number of advantages and in some cases they have been shown to be as effective as pharmacological treatments for depression^{18, 19}. They have the potential to encourage behaviour change for healthier lifestyles and consequential health gains without the side effects often experienced with pharmaceutical agents^{7, 9, 22}.

The strength of the OsteoMAP intervention is that it integrates a psychological intervention approach with manual therapy in each patient clinical encounter: it is adapted flexibly to the needs and goals of individual patients and aims to promote both mental and physical health. This study has shown that this new approach is feasible i.e. it is possible for osteopaths, and potentially other manual therapists, to deliver acceptance-based psychological interventions after brief additional training. However we do not know if the approach might be utilised and delivered differently in non-mentored or non-supervised clinical settings, further work needs to be done in this area.

This evaluation has some limitations, in particular the low follow-up response rate (43%). This was partially because most data was collected electronically via an online questionnaire with email reminders only. In the future we would also collect telephone numbers and seek ethics permission to follow-up participants with telephone calls for more core outcome data. In addition we were not able to obtain qualitative data from patients who did not complete the course so our data are limited to a sample of patients who engaged with and responded to the research. This is likely to have skewed the results favourably. This is not a major issue when assessing 'proof of concept' but it is when effectiveness or impact is considered. This was a pilot study and therefore no sample size calculations or primary outcome were stated *a priori* but the data gathered here will be important to inform future research and a randomised controlled trial protocol.

There is still much to explore, especially in the delivery of integrated biopsychosocial care for people with chronic pain, and in developing practical models for combining different components into individualised patient-centred care. Further research is needed, however, to test the effectiveness of these integrated and adjuvant therapies and to continue developing effective, feasible principle-based models for training manual therapists.

Conclusion

This evaluation of the OsteoMAP programme has shown that it is possible to integrate osteopathic, and potentially other manual therapies with ACT and mindfulness based approaches in the care of patients with chronic pain. We propose that further research should be conducted to test the effectiveness of this promising new intervention.

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