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Mechanisms in orthodox and complementary alternative medicine (CAM) management of back pain

Submission date
03/02/2015

Recruitment status
No longer recruiting

Registration date
17/02/2015

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Researchers at the University of Southampton are being funded by Arthritis Research UK to find out more about the powerful effects that practitioners attitudes, beliefs, clinic environments and communication styles have on how well people do when having back pain therapy. These effects are called the 'non-specific effects of treatment' and whilst common to all types of treatments for all sorts of conditions, are particularly powerful in complementary medicines like acupuncture. In other words, something other than the actual treatment itself can have substantial effects on pain and disability. We want to know which of these effects are the most powerful and how they compare between different treatments. We also want to develop a deeper understanding of the pathways through which these effects generate positive outcomes for people with back pain so we can help more people in the future.

Who can participate?
Adults (aged over 18) consulting physiotherapists, osteopaths and acupuncturists for back pain (about half from the NHS and half from private practice).

What does the study involve?
Participants are given a study information pack from their practitioner containing a consent form and a questionnaire. The questionnaires ask about the participants back pain and their thoughts about and experiences of treatment. We will also ask each participants practitioner to tell us about the treatment they have been given. The study has no impact on participants treatment, which will continue as normal. The practitioner will only see a participants questionnaire if they choose to show it to them. If they stop seeing their practitioner they still fill in the questionnaires. Two weeks after their first treatment (or after at least 2 treatments), participants will be sent their 2nd questionnaire so that they can tell us about how they are getting on. A third (and last) questionnaire is sent three months later. Some people are given the opportunity to have one of the consultations with their practitioner audio recorded. Our aim for this part of the study is to investigate how different practitioners and patients talk with each other during treatments for back pain. We want to understand whether particular communication styles are linked to more successful treatments. In other words, do patients find

treatments more or less effective depending on how their practitioner talks to them? The information provided in the questionnaires are used to examine, using statistical methods, which non-specific aspects of treatment influence treatment success for patients with back pain. We hope our results will help improve treatments in the future

What are the possible benefits and risks of participating?
Participants are given the chance to reflect on their thoughts about back pain, treatment, and their health in general. Some people might find this helpful. Filling in the questionnaires will take some time, but we do not foresee any other disadvantages or risks.

Where is the study run from?
Solent National Health Trust (UK)

When is the study starting and how long is it expected to run for?
January 2014 to September 2017

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Dr Susan Eardley
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
20552

Study information

Scientific Title
Mechanisms in Orthodox and Complementary Alternative Medicine (CAM) management of back pain: an observational study

Acronym
MOCAM

Study objectives
The purpose is to model the role of non-specific treatment components in orthodox and CAM management of LBP (low back pain). In doing so, we will come to understand the nature and effects of non-specific components. This is a vital next step to enable research on non-specific treatment components to contribute to developing new treatments and helping people remain active and pain-free. By addressing the aims outlined below, this project will advance our understanding of non-specific treatment components so that they can be used to enhance treatment and patient outcomes. Our research will identify the most effective non-specific treatment components in LBP and model how they produce positive patient outcomes; this will enable practitioners, policy-makers and researchers to optimise non-specific components across diverse therapies, thus enhancing treatments and maximising patient benefit. Depending on the results, we will be able to suggest how non-specific components of orthodox treatments could be enhanced by learning from CAM.
The aims are to:
1. Identify the most powerful non-specific treatment components (i.e. those that have the largest effect on patient outcomes) [longitudinal questionnaire study].
2. Compare the magnitude of non-specific effects across orthodox (physiotherapy) and CAM (osteopathy, acupuncture) therapies [longitudinal questionnaire study].
3. Test which theoretically-derived mechanistic pathways explain the effects of non-specific components [longitudinal questionnaire study].
4. Compare patient-practitioner interactions across the three therapies [nested mixed methods study of the consultation].
We will test the following hypotheses:
1. As suggested by previous research, patients will experience less back-related disability after treatment for LBP when non-specific components are more positive, i.e. when:
1.1. The therapeutic alliance is stronger and practitioner communication is more patient-centred.
1.2. The healthcare environment is experienced by patients as pleasant, accessible and convenient, and by practitioners as supportive.
1.3. Appointment duration is longer.
1.4. Patients expect their treatment to be effective, perceive it as credible and suitable for them personally, and have few concerns about it.
1.5. Practitioners have a biopsychosocial orientation to back pain and expect patients to respond well to treatment.
2. CAM therapies (acupuncture and osteopathy) will produce larger non-specific effects than orthodox therapy (physiotherapy). Differences between therapies will be more pronounced in the NHS than in the private sector.[12-14]
3. In relation to the mechanisms underpinning non-specific components, we hypothesise that non-specific components will reduce patients' back-related disability via:
3.1. Improvements in patients' pain-related beliefs, for example reduced fear of pain,
3.2. Increases in patients' self-efficacy for coping with pain, and/or
3.3. Increased implementation of theory-specific lifestyle advice.
4. CAM and orthodox consultations will differ in the extent to which they contain patient-centred communication and these differences will be associated with organisational environment and patient outcomes. We will also qualitatively compare the content and organisation of patient-practitioner interactions across physiotherapy, osteopathy, and acupuncture consultations, in order to complement the quantitative comparisons and ensure that key elements are not overlooked.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Derby, 22/08/2014, ref: 14/EM/1113

Study design
This multicentre research comprises two linked observational studies, a prospective longitudinal questionnaire study and a nested mixed methods study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Back pain management in orthodox (physiotherapy) and CAM (acupuncture & osteopathy) settings in both the NHS and private settings.

Interventions
1. Prospective Longitudinal Questionnaire Study: addresses issues that are best suited to quantitative methods, concerning effect sizes, outcome predictors and mediators. This study uses practitioner-completed and patient-completed postal and web-based questionnaires to measure key contextual components and established prognostic indicators at 3 time-points: at baseline (T1 - after the 1st consultation for a new episode of LBP), during the course of treatment (T2 – 2 weeks post-baseline and after at least 2 treatments) and at short-term outcome (T3 - 3 months post-baseline).

Some participants in the quantitative study will be invited to also take part in the nested mixed methods study.

2. The qualitative component of the nested mixed methods study is designed to explore in greater depth patient-practitioner communication and compare this across therapies.
This study will explore whether CAM and orthodox therapists use different verbal communication styles and the extent to which these are more or less effective. The questionnaire study will collect data from a large number of patients and practitioners and allow us to test the effects of non-specific factors from five domains including the patient-practitioner relationship

Intervention Type
Mixed

Primary outcome(s)
Longitudinal Questionnaire Study; the primary outcome measure will be the Roland and Morris Disability Questionnaire at T1 = baseline (after 1st treatment for new episode of LBP); T2 = during the course of treatment (2 weeks post-baseline); T3 = short-term outcome (3 months post-baseline). The main analysis will be performed by multilevel methods (e.g. REML) using appropriate statistical software (e.g. MLWin) to construct a multi-level regression model taking into account the clustering of individual patients within practitioners. This can be described as a 2-level model in which level 1 = individual patient and level 2 = practitioner. As a secondary aim,

the patient outcomes can be modelled as time-varying repeated measures while the non-specific factors remain time-invariant predictors.

Key secondary outcome(s))
1. Social Role, Disability, Work Disability, Pain, Wellbeing, Satisfaction at T1, T2 and T3
2. Therapeutic alliance (WAIS) at T2
3. Organisational appointments at T1
4. Access
5. Facilities (APS-mp, PSQ)
6. Modalities Duration
7. Treatment beliefs
8. Attitudes to back pain (ABS-mp)
9. Outcome expectations
10. Mediators/prognostic indicators
10.1. Risk complexity for recovery (STarT Back)
10.2. Self-efficacy for pain management
10.3. Adherence to lifestyle advice
10.4. Illness perceptions (Brief IPQ)
These will be measured at the same time points as the primary outcome. We will test for main effects of the predictors (whether each factor predicts outcome and determine relative effect sizes), interaction effects (interactions between non-specific factors and therapy), and mediation effects. Multilevel modelling provides an ideal framework for examining such a complex dataset and testing our hypotheses which involve not only main effects but also complex interactions between the variables.

Nested Qualitative study:
The Roter Interactional Analysis System (RAIS) will be used to generate frequency counts for different categories of utterances and we will combine frequency counts and calculate a ration of patient-centred to doctor-centred talk to produce a patient centered index for each taped consultation T2.1.
We will:
1. Quantitatively compare patient-practitioner interactions on the index of patient centeredness. Assuming scores on the patient-centeredness index are normally distributed, a 3x2 ANOVA will test for effects of therapy (osteopathy, physiotherapy, acupuncture) and healthcare sector (NHS, private) on patient-centeredness.
2. We will integrate the data from this study with the main questionnaire study and conduct regression analyses to test whether patient-centered communication predicts patient outcomes.
3. We will transcribe the consultations and conduct an inductive qualitative analysis exploring the thematic content of talk and taking a more holistic view of the consultations, thus addressing some of the limitations of relying solely on quantitative interactional analysis systems and helping us to capture any unique features of CAM consultations.

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Practitioners:
1. Registered with the relevant professional body (Osteopaths: General Osteopathic Council, GOsC; Physiotherapists: the Chartered Society of Physiotherapy, CSP; Acupuncturists: British

Acupuncture Council, BAcC)
2. Working in either the NHS or private sector
3. At least 3 years relatively recent clinical experience of musculoskeletal problems
4. Treat at least one low back pain patient per week

Patients:
1. Adult (at least 18 years)
2. Seeking treatment from a participating practitioner
3. Score at least 4 on the RMDQ (our primary outcome, described below)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Practitioners:
1. Not registered with the relevant professional body
2. Less than 3 years relevant and recent clinical experience

Patients:
1. Inability to complete questionnaires in English (waived for Welsh participants to comply with legal and research governance requirements)
2. Serious underlying pathology (inflammatory arthritis, malignancy)
3. Practitioner-identified conditions that would prevent the sought treatment being applied (e.g. pregnancy when seeking acupuncture)

Date of first enrolment
01/03/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Solent National Health Trust
St James Hospital
Locksway Road
Portsmouth
United Kingdom
PO4 8LD

Sponsor information

Organisation
The University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/05/2016	07/05/2021	Yes	No
HRA research summary			26/07/2023	No	No