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Reconceptualising patient-reported outcome measures for back pain

Submission date	Recruitment status	[ ] Prospectively registered
20/01/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/03/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/04/2022	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patient reported outcome measures (PROMs) are questionnaires used to collect information on patients' views of their health and health-related quality of life. PROMs are increasingly being used in routine clinical practice to assess patients' health, treatment and quality of healthcare. Research indicates that the use of PROMs in clinical practice might influence the process of patient care, patient experience, and outcomes. A PhD project has been set up to examine the effects of using PROMs at different frequencies in chiropractic care for low back pain. The aim of this study is to assess the effects of using PROMs and understand the process by which PROMs make these changes.

Who can participate?
Chiropractors working in musculoskeletal healthcare clinics and their patients aged over 16 with self-reported back pain

What does the study involve?
Each clinician is randomly allocated to one of three groups: routine PROM data, intensive PROM data, or a control group. Patients visiting these practitioners for chiropractic treatment for low back pain are asked to take part. At the start of the study patients complete an assessment and are asked to complete PROMs at various stages during their treatment. If their chiropractor is allocated to the routine PROM group, they are asked to complete PROMs three times. If their chiropractor is allocated to the intensive PROM group, they are asked to complete PROMs seven times. Patients in the control group do not complete PROMs. Thirty treatment sessions are audio-recorded. The audio-recordings of patient-chiropractor encounters during treatment sessions are analysed to examine the use of PROMs in clinical practice. All patients are asked to complete assessments after 90 days. Interviews are conducted individually with a sample of patients and chiropractors in order to explore the process of using PROMs, identify any unintended consequences of PROMs, and identify any mechanisms that may influence outcomes. The interviews and relevant excerpts from the treatment sessions audio recordings are analysed to identify patterns and relationships.

What are the possible benefits and risks of participating?
PROMs are increasingly being used to collect patient outcomes on a routine basis in healthcare.

This research aims to provide evidence on the use of PROMs during routine clinical interventions and the clinical and psychological effects on patients. This research could inform clinical practice on the development and improvement of PROM collection. The participants' input will help researchers to identify the role health questionnaires have in the treatment of back pain. This will help with the development of resources to support people with back pain and improve patient care in the future. Participants are not exposed to any additional risks of harm or discomfort than anticipated in routine treatment.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
January 2018 to February 2019

Who is funding the study?
1. University of Southampton (UK)
2. AECC University College (UK)
3. Southampton Complementary Medicine Research Trust (UK)
4. Royal College of Chiropractors (UK)

Who is the main contact?
Michelle Holmes

Contact information

Type(s)
Public

Contact name
Mrs Michelle Holmes

ORCID ID
https://orcid.org/0000-0002-6018-2235

Contact details
University of Southampton
Shackleton Building
University Road
Southampton
United Kingdom
SO17 1PS

Additional identifiers

Protocol serial number
20133

Study information

Scientific Title

Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for back pain

Acronym
RPROMs

Study objectives
Patient-reported outcome measures are a form of questionnaires which use patients' subjective evaluation to assess their health and wellbeing. PROMs are being increasingly utilised in routine clinical practice as an effective way to evaluate health and provision of healthcare. A recent review suggests that PROMs may affect patients through multiple processes: increasing clinicians' knowledge of patients, facilitating patient-doctor interaction, enabling patient-centered care, monitoring, informing strategies to improve care, enhancing therapeutic relationships, improving patient satisfaction, and encouraging positive patient health behaviour. From this review, a novel theoretical framework was developed: the Patient Reported Outcome Measures Pathway Theory (PROMPT), depicting the multiple components of PROMs within routine clinical practice and specifying hypothesised outcomes, mechanisms and parameters. However, there is limited empirical research examining the proposed mechanisms of action.

This study will use a cluster-randomised controlled trial and process evaluation to evaluate the use PROMs in clinical practice and to answer the following research question: what are the clinical and psychosocial consequences of using PROMs in specialist musculoskeletal care for low back pain, and through what mechanisms?

The objectives of the study are to:
1. Evaluate the clinical and psychosocial effects of implementing different levels of PROMs in routine treatment of low back pain
2. Identify any unintended consequences of PROMs
3. Assess intervention delivery and quality
4. Clarify causal mechanisms of PROMs by testing hypotheses derived from the PROMPT model of the proposed processes by which change occurs
5. Identify contextual mechanisms that might moderate outcomes

A series of hypotheses were derived from PROMPT and will be tested in this study:
1. There will be a difference in HRQoL scores at 90 days between those who complete PROMs routinely, those who complete PROMs intensively and those who do not complete PROMs
2. Those who complete PROMs will have improved scores in patient-centered communication, therapeutic relationship, patient satisfaction, self-efficacy, and self-management behaviours, compared to those who do not complete PROMs
3. Those who complete PROMs will have an increase in HRQoL mediated by improvements in communication, self-efficacy, treatment perceptions and self-management behaviours (coping appraisal pathway)
4. Those who complete PROMs will have an increase in pain-related fear mediating a change in HRQoL moderated by pain catastrophising, and self-efficacy (threat appraisal pathway)
5. Those who complete PROMs will have an increase in HRQoL mediated by improvements in communication, therapeutic relationship, self-efficacy and self-management behaviours (patient-clinician interaction pathway)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Southampton, 10/08/2017, ref: 20133

Primary study design
Interventional

Study design
Cluster randomised controlled trial (cRCT) and process evaluation

Study type(s)
Other

Health condition(s) or problem(s) studied
Back pain management by chiropractors in private settings

Interventions
The cRCT aims to evaluate the outcome of the intervention (study objective A). The process evaluation aims to understand the processes by which an intervention functions, by examining its implementation, mechanisms and context (study objectives B - E).

1. Cluster randomised controlled trial
Patients will be asked to complete PROMs at various stages during their treatment. The PROMs will be the Musculoskeletal Health Questionnaire (MSK-HQ) and the Patient Global Impression of Change Scale (PGIC). The chiropractors recruited into the study will be randomly allocated to one of the three groups using a randomisation generator. Patients booking in with these chiropractors will be asked if they would like to take part in the study and those who consent to take part to the study will be allocated to that chiropractor's group in the trial. Depending whether patients have booked in with chiropractors in the routine PROM group or the intensive PROM group, they will be asked to complete PROMs at various stages during their treatment. Patients in the routine PROM group will be asked to complete PROMs three times. Patients in the intensive PROM group will be asked to complete PROMs seven times. Those in the control group will not complete PROMs. Chiropractors in the routine and intensive PROM groups will be asked to discuss PROMs with their patients at every session after a PROM has been completed. The follow up will be 90 days.

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

2. The qualitative phase aims to understand the processes by which the intervention functions and help explain the results from the trial.

Intervention Type
Mixed

Primary outcome(s)
Back pain (physical functioning and disability) measured with the Roland-Morris Questionnaire at baseline and 90 days

Key secondary outcome(s)
Quantitative secondary outcome measures measured at 90 days:
1. Health-related quality of life (HRQoL), measured using the EQ-5D thermometer
2. Pain-related fear, measured using the fear subscale of the pain anxiety symptoms scale (PASS-

20)
3. Pain catastrophising, measured using the catastrophising subscale of the coping strategies questionnaire (CSQ-CAT)
4. Fear-avoidance behaviours, measured using the fear-avoidance beliefs questionnaire physical activity subscale (FABPA)
5. Self-efficacy for self-management, measured using the self-efficacy beliefs in patients with chronic pain subscale - self-efficacy for pain management (PSE)
6. Self-management behaviours, measured using the maintenance subscale of the pain stages of change questionnaire (PSOCQ)
7. Treatment perceptions, measured using four-item low back pain treatment beliefs questionnaire
8. Patient-centered communication, measured using patient perception of patient centeredness questionnaire
9. Therapeutic alliance, measured using working alliance inventory - short-revised (WAI_SR)
10. Patient satisfaction, measured using a one-item question: “Over the course of chiropractic treatment for your low back pain how would you rate your overall care?”, scored on a five-point scale from ‘very dissatisfied’ to ‘very satisfied’
11. Intervention fidelity, measured using a one-item question: “Did you and your chiropractor discuss the questionnaires that you filled in before, during and after your treatment?”, scored on a seven point scale from ‘never’ to ‘always'

Nested qualitative study:
1. Audio recordings - one participant per cluster will be randomly sampled to have their treatment sessions audio recorded. The audio recordings will allow researchers to explore and understand the behaviour and activities of participants in relation to discussion of PROMs within treatment sessions
2. Qualitative interviews - within one month following participants’ completion of the 90-day PROMs, qualitative semi-structured interviews will be conducted individually with a subset of participants (n = 35) and chiropractors (n = 15). Purposive sampling will be used to intentionally recruit participants from the groups who have had clinically meaningful changes in pain scores and HRQoL and participants who have no changes in pain scores and HRQoL. Using qualitative interviews allows for exploration into patients’ and practitioners’ subjective evaluations of how PROMs may have an effect when used in the treatment of low back pain

Completion date
01/09/2020

Eligibility

Key inclusion criteria
Chiropractors:
1. Be registered with the General Chiropractic Council
2. Speak and read English fluently, as the PROM used within this study has not been translated into other languages and independently assessed for validity and reliability
3. Be able to comply with all study procedures

Patients:
1. Be at least 16 years old. Due to the biological and psychological differences between children, adolescents and adults, children and adolescents have been excluded from the scope of this project
2. Speak and read English fluently. As with the chiropractors, the inclusion criteria of speaking

and reading English fluently has been set so study participants may coherently understand the questions in the PROMs used in the study
3. Be a private patient presenting to the musculoskeletal clinic
4. Present to the clinic with self-reported back pain

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Chiropractors:
1. Chiropractors who are not registered with the General Chiropractic Council
2. Chiropractors who cannot speak and read English fluently

Patients:
1. Patients who are under 16 years old
2. Patients who cannot speak and read English fluently
3. NHS patients presenting to the musculoskeletal clinic
4. Patients who do not have self-reported back pain

Date of first enrolment
31/01/2018

Date of final enrolment
20/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
University Road
Southampton
United Kingdom
SO17 1bj

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
University/education

Funder Name
University of Southampton

Alternative Name(s)
University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
AECC University College

Funder Name
Southampton Complementary Medicine Research Trust

Funder Name
Royal College of Chiropractors

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication