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A feasibility study of a digital self-management physiotherapy intervention for individuals with musculoskeletal pain

Submission date
10/05/2022

Recruitment status
No longer recruiting

Registration date
15/07/2022

Overall study status
Completed

Last Edited
11/05/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Pain in the muscles, joints, bones and soft tissues (musculoskeletal [MSK] pain) affects 18.8 million people in the UK. In Wales about 1 in 3 people have an MSK condition, with back pain and knee osteoarthritis being the most common conditions. Conservative treatments such as exercise and physiotherapy are recommended but they appear to have limited benefit in helping people manage their condition at home, as they often struggle to keep going with regular exercise. Technology like TRAK-MSK has the potential to make a difference. TRAK-MSK is a new digital physiotherapy intervention for people with MSK pain, that helps people to manage their exercise and pain at home. In this intervention individuals can have up to five online consultations with a specially physiotherapist trained in self-management. The timing and number of appointments will be decided by the participant. Individuals will have immediate access to the TRAK-MSK website throughout, which provides information, personalised video-based exercise plans, progress tracker, individual set challenges and remote access to a physiotherapist. The combination of online consultations with a specially trained physiotherapist and access to the TRAK-MSK website will support individuals to practice and gain the skills to manage their condition themselves at home.
The aim of this study is to find out if the TRAK-MSK intervention can be delivered and if people find it acceptable. This study will ask whether people with MSK pain can be recruited and retained in clinical studies of TRAK-MSK and what it costs to deliver the TRAK-MSK intervention. The researchers will see if TRAK-MSK increases people's confidence to independently manage their pain and help them remain physically active.

Who can participate?
Patients over the age of 18 years with activity-related MSK pain originating from their back, legs or arms

What does the study involve?
Participants will be asked to fill out a screening questionnaire online to check if they are eligible to take part. If eligible, they will be asked to complete an informed consent form on the TRAK-MSK website. Following that, they will be asked to complete a number of questions on the TRAK-

MSK website asking about joint pains and how they are coping with them. Participants will then be randomly allocated to receive either the TRAK-MSK intervention for 4 months or they will continue with their usual NHS care that is available in the area they live for 4 months.
If offered the TRAK-MSK intervention, they will receive up to five one-to-one sessions with a clinical practitioner through video call. These sessions will take place over a 4-month period to help self-management of joint pain. After 6 months, regardless of which treatment they received, they will be asked to fill out the same questionnaires as at baseline. At the end of the trial, we may ask some participants about their experiences of being in the trial.

What are the possible benefits and risks of participating?
At this stage of the research, the direct health benefits for participants are unknown, but participantswill help the researchers to gather evidence about the effectiveness of using an online intervention to aid patients in self-managing their joint pain. There is a chance that participants might find some topics sensitive or upsetting while taking part in the one-to-one support sessions, or whilst taking part in the interview.

Where is the study run from?
Cardiff and Vale University Health Board with support from the Centre for Trials Research at Cardiff University (UK)

When is the study starting and how long is it expected to run for?
December 2021 to June 2023

Who is funding the study?
The study is funded by the Welsh Government through the Health and Care Research Wales (Research for Patient and Public Benefit (RfPPB) scheme (UK)

Who is the main contact?
Andrew Dean-Young
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Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/trak-msk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310033

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 310033, CPMS 52142

Study information

Scientific Title
TRAK-MSK: a randomised controlled feasibility study of TRAK musculoskeletal digital self-management physiotherapy intervention for individuals with musculoskeletal pain

Acronym
TRAK-MSK feasibility

Study objectives
To evaluate whether the TRAK musculoskeletal digital self-management intervention (TRAK-MSK), for people with soft tissue or joint pain (MSK pain), can be delivered within physiotherapy outpatient services and whether people can be recruited and retained for this study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/04/2022, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd Floor, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048225, +44 (0)2071048109; queensquare.rec@hra.nhs.uk), ref: 22/LO/0141

Study design
Two-arm individually randomised feasibility study with embedded process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal pain

Interventions
This is a two-arm individually randomised feasibility study with embedded process evaluation comparing the TRAK-MSK intervention to usual care (UC) for patients over the age of 18 years with activity-related MSK pain, who are referred for physiotherapy outpatients. The TRAK-MSK intervention will be delivered over a 4-month period by self-management trained physiotherapists. Core intervention activities involve:
1. Online consultations delivered by trained physiotherapists
2. Use of the TRAK-MSK website

Participants will be asked to fill out a screening questionnaire online to check if they are eligible to take part. If eligible, they will be asked to complete an informed consent form on the TRAK-MSK website. Following that, they will be asked to complete a number of questions on the TRAK-MSK website asking about joint pains and how they are coping with them. Participants will then be randomly allocated to receive either the TRAK-MSK intervention for 4 months or they will continue with their usual NHS care that is available in the area they live for 4 months. The randomisation will have an allocation ratio of 1:1 within each stratum and across the study. Participants will be stratified by site. Randomisation will be completed via secure web access to the remote randomisation site.

If offered the TRAK-MSK intervention, they will receive up to five one-to-one sessions with a clinical practitioner through video call. These sessions will take place over a 4-month period to help self-management of joint pain. After 6 months, regardless of which treatment they received, they will be asked to fill out the same questionnaires as at baseline. At the end of the trial, we may ask some participants about their experiences of being in the trial.

Intervention Type
Other

Primary outcome measure
The feasibility of a future definitive trial, assessed using:
1. The feasibility of recruitment in three trial sites (Cardiff and Vale, Powys and Cwm Taf)
2. Participants' willingness to be randomised after consenting, recorded as the number of eligible participants who consent to participate in the study by 12 months
3. The acceptability to participants of completing outcome measures (completion rates and perceived burden)
4. The feasibility of obtaining follow-up data by analysing follow up rates (proportion of participants completing 6-month follow-up assessment)
5. Participants’ engagement with the intervention (the number of online consultation and logins, pages visited, number of visits to goals and activity plans, number of activity logs and frequency of email correspondence)

6. The safety of the intervention (self-reported issues such as increased pain symptoms or muscle soreness)
7. The acceptability of the intervention through interviews with participants about their confidence to self-manage, digital literacy, technology acceptance and barriers and facilitators to participating
All of the primary outcome measures will be assessed as part of the final analysis which will be completed at months 16 and 17.

The researchers will also evaluate whether the following continuation criteria have been met, prior to planning a future definitive trial: progression criteria are based on a traffic light system (green, amber, red) for the TRAK intervention. Recruitment and randomisation rates, along with outcome measures completion will be monitored at the monthly project management meeting. If at the end of the study all feasibility progression criteria are achieved (green), then the recommendation would be to move to a full RCT. Remediable modifications in the study processes or the intervention may be required if progression criteria are not fully achieved (amber). If there is no identifiable reason or remediable action that can be taken (red), then progression to a full trial would not be recommended. Intervention adherence and fidelity are not formal progression criteria but will be closely monitored and considered in any final recommendations.
1. Recruited participants per month per site (Cardiff and Vale/Powys/Cwm Taf). Number of participants at each site: 10/5/5 = Green; 8/3/3 = Amber; 6/2/2 = Red
2. Participants willingness to be randomised: 70% or higher = Green; 50-70% = Amber; 49% or lower = Red
3. The completeness of PROMS's outcome data at 6-month follow-up: 70% or higher = Green; 60-70% = Amber; 59% or lower = Red

Secondary outcome measures
1. Symptoms of musculoskeletal conditions measured using the Musculoskeletal Health Questionnaire (MSK-HQ) at baseline and 6 months
2. Pain measured using the Numeric Pain Scale (NRS) at baseline and 6 months
3. Depression measured using the Patient Health Questionnaire for depression (PHQ-9) at baseline and 6 months
4. Symptom severity of four common anxiety disorders measured using the General Anxiety Disorder Scale (GAD-7) at baseline and 6 months
5. Health-related quality of life measured using the EQ-5D 5L at baseline and 6 months
6. Participants' confidence in performing activities while in pain measured using the Pain Self-Efficacy Scale (PSEQ) at baseline and 6 months
7. Capability and well-being measured using the ICEcap Capability measure for Adults (ICECAP-A) at baseline and 6 months as part of an economic evaluation
8. Comorbid conditions assessed using the Self-reported Comorbidity Questionnaire at baseline

Overall study start date
01/12/2021

Completion date
30/06/2023

Eligibility

Key inclusion criteria

1. Adults aged over 18 years
2. Referred or self-referring for physiotherapy
3. Activity-related joint pain
4. Have either no self-reported morning joint stiffness or morning stiffness that lasts no longer than 30 minutes
5. Have self-reported pain for more than 3 months and on most days of the previous month

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
Musculoskeletal pain participants will be excluded if:
1. There is a contraindication to exercise
2. They have pain caused by malignancy
3. They have fractures or inflammatory arthritis
4. They have received surgery for their MSK pain in the last 12 months
5. They are unable to give written informed consent

Date of first enrolment
01/07/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff and Vale NHS Trust
Cardigan House
University Hospital of Wales
Heath Park

Cardiff
United Kingdom
CF14 4XW

Study participating centre
Cwm Taf NHS Trust
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Powys Health Care NHS Trust
Bronllys Hospital
Bronllys
Brecon
United Kingdom
LD3 0LY

Sponsor information

Organisation
Cardiff and Vale University Health Board

Sponsor details
2nd Floor Lakeside Building
Heath Park
Cardiff
Wales
United Kingdom
CF14 4XW
+44 (0)2920 747747
CAV_research.development@wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cardiffandvaleuhb.wales.nhs.uk/home

ROR
https://ror.org/0489f6q08

Funder(s)

Funder type
Government

Funder Name
Llywodraeth Cymru

Alternative Name(s)
Welsh Government, The Welsh Government

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings will be circulated to a variety of audiences and tailored accordingly. We will hold a feedback event for key stakeholders. Findings will be distributed publicly via NHS and university websites, social media accounts and press releases in collaboration with Cardiff and Vale and Cardiff University press offices. Our findings will be presented to the academic community via publication in open access peer reviewed academic journals and at an international conference.

Intention to publish date
31/05/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No