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Understanding barriers to increasing physical activity in chronic pain

Submission date
02/10/2020

Recruitment status
No longer recruiting

Registration date
05/10/2020

Overall study status
Completed

Last Edited
27/11/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Chronic or persistent pain is pain that carries on for longer than 12 weeks despite medication or treatment. Most people get back to normal after pain following an injury or operation. But sometimes the pain carries on for longer or comes on without any history of an injury or operation.
Evidence shows that increasing physical activity can be one of the best things to help manage chronic pain. However, people who suffer from chronic pain are often very inactive. The reasons for this may be quite different from one person to the next. We would like to find out what stops people in pain from being active and what we could do to support them to do more. Eventually, we would like to develop a plan that can be tailored to individual people who are suffering from pain, to help them stay active

Who can participate?
Adults over the age of 18 years referred by the NHS Tayside pain service. Must have experienced pain for at least 6 months

What does the study involve?
Participants are asked to join this study after being referred to the pain service and consenting to take part in the research. Participants must be assessed by the pain service as having moderate to severe pain. Participants will be asked to attend two appointments about a week apart, due to social distancing rules this is most likely to take place remotely, for example, via video call. The first appointment will include fitting an activity monitor, filling in a questionnaire and a semi-structured interview. At the 2nd appointment, participants will fill in a second questionnaire and remove the activity monitor. In between the two appointments the activity monitor will track participants' activity.

What are the possible benefits and risks of participating?
Taking part in the study may not immediately benefit those taking part. However, we hope that the results of the trial will help us manage activity in people who suffer from pain in the future. We anticipate no major disadvantages of taking part. There is a very low risk that participants

may develop a skin reaction to the waterproof dressing used to attach the activity monitor to their thigh. If this should happen we would ask participants to remove the tracker and contact the research team.

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

When is the study starting and how long is it expected to run for?
January 2020 to November 2021

Who is funding the study?
Chief Scientist Office (part of the Scottish Government Health Directorate) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271891

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 271891

Study information

Scientific Title
Understanding barriers to increasing physical activity in chronic pain: an exploratory study to develop the SUstainable Self Effective Exercise Development (SUSSED) intervention

Acronym
SUSSED

Study objectives
Using a systematic approach, to understand barriers and facilitators to physical activity in patients with moderate-severe chronic pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2020, London-Chelsea Research Ethics Committee (Research Ethics Committee London Centre, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8356; chelsea.rec@hra.nhs.uk), ref: 19/LO/2012

Study design
Mixed methods observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Quality of life

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
Increasing physical activity and exercise in chronic pain patients

Interventions
Up to 45 people referred to the Tayside pain service will be invited to take part in the study, aiming for a total of 40 completing the first study visit. They will take part in a semi-structured interview designed to assess their perceptions of the barriers and facilitators to their participation in PA. In addition, participants will be asked to complete 7 validated self-report questionnaires to collect information about their pain severity, and its impact, as well as attitudes to physical activity. Demographic and basic clinical information including age, gender, height and weight will be collected together with underlying diagnosis, other co-morbidities, and postcode to enable Scottish index of multiple deprivation to be recorded. Participants will then be provided with an activPAL4TM activity monitor (http://www.palt.com/pals/) and asked to wear this for 1 week. 20 participants who consent to wearing a Fitbit monitor will be asked to wear a Fitbit Charge 3 (https://www.fitbit.com/uk/charge3) monitor in addition to the activPAL monitor. Both the activPAL and FitBit trackers are CE marked. Participants will be contacted after 1 week and will then be asked to complete the 7 questionnaires as before as well as acceptability and feasibility questions on the activity monitors

Half the participants will receive an Activpal only and the other arm will receive an Activpal and Fitbit, all participants will wear the activity monitors for one week between appointment 1 and 2. After appointment 2 when the activity monitors are removed there is no follow up. Allocation to receive a Fitbit is based on willingness to wear one and availability (i.e. not random).

Intervention Type
Behavioural

Primary outcome measure
1. Framework analyses of semi-structured interviews with patients with moderate-severe chronic pain
2. Questionnaires at baseline and 1 week:
2.1. Fear of movement measured using the Tampa Scale for Kinesiphobia
2.2. Anxiety and stress measured using the Anxiety and Stress Scale 21
2.3. Pain measured using the Brief pain inventory
2.4. Pain catastrophising measured using the Pain Catastrophising Scale
2.5. Self-efficacy measured using the Pain Self-efficacy Questionnaire
2.6. Physical activity measured using the Physical Activity Stages of Change International Physical Activity Questionnaire (short)

3. Acceptability of activity monitors measured with questionnaire items at 1 week
4. Feasibility outcomes for activity monitors (self report at 1 week):
4.1. Number of days worn
4.2. Reported problems with wearing the monitor
4.3. Reported pain or discomfort while wearing the monitor
4.4. Reported duration and reasons for removing the monitor early (activPAL) or not wearing the monitor (FitBit)

Secondary outcome measures
1. Steps measured using ActivPal over 1 week
2. Steps measured using Fitbit (if applicable) over 1 week

Overall study start date
01/01/2020

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 02/11/2021:
Patients:
1. Referred to Tayside pain service
2. In pain for at least 6 months
3. Pain severity: moderate to severe as assessed by pain clinic questionnaires (NRS>3)
4. No clinical contraindications to wearing Fitbit
5. Consented to being contacted for research
6. Over 18

Stakeholders:
1. Member of stakeholder population, including healthcare professionals (e.g. General practitioners (GPs)/ Allied Health Professionals (AHP)s, Nurses, pharmacists); carers, 3rd sector organisations, leisure centre staff, and others identified through the Green Health Partnership
2. Over 18

Previous participant inclusion criteria:
1. Referred to Tayside pain service
2. In pain for at least 6 months
3. Pain severity: moderate to severe as assessed by pain clinic questionnaires (NRS>3)
4. No clinical contraindications to wearing Fitbit
5. Consented to being contacted for research
6. Over 18

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
40 - 45 patients and up to 16 stakeholders

Total final enrolment
57

Key exclusion criteria
1. Receiving active treatment for cancer
2. Unable to provide informed consent

Date of first enrolment
09/10/2020

Date of final enrolment
05/10/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside Pain Service
Pain Service Level 6
South Block Ninewells Hospital
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Sponsor information

Organisation
University of Dundee

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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	31/08/2020	19/08/2022	No	No
HRA research summary			28/06/2023	No	No