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Walk30X5: the development and feasibility evaluation of a physiotherapy walking programme for people with mild to moderate musculoskeletal conditions

Submission date
31/03/2014

Recruitment status
No longer recruiting

Registration date
30/07/2014

Overall study status
Completed

Last Edited
01/10/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Physical activity is a public health issue. The majority of UK adults fail to meet recommended physical activity levels. People with long-term conditions related to muscles and bones (musculoskeletal) are more likely to be inactive than their peers. Walking is an ideal, popular, exercise and guidelines insist on walking programme development. The aim of this study is to develop and refine an evidence-based, web-based physiotherapy walking programme including podcasts, blog and links. This study will also test the feasibility and acceptability of the programme.

Who can participate?
Adults with a mild/moderate long-term musculoskeletal condition and have been referred locally for physiotherapy assessment.

What does the study involve?
We will first develop the walking programme using information from previous research. Then eligible participants will be randomly allocated to either physiotherapy advice and assessment session, including goal setting, plus one follow-up session or one physiotherapy session to teach the walking programme intervention (progressing up to 3000 steps 5 days a week above what that person could do before the start of the study) and one follow-up. Qualitative interviews of participants (five in each group) and physiotherapists will be taken to understand people's views about the study, the walking programme and physical activity.

What are the possible benefits and risks of participating?
Participants cannot be guaranteed that they will benefit from taking part in the study. There are no expected risks from taking part in the study, although, as usual from taking part in exercise, people may feel slightly short of breath whilst walking and may feel some muscle aching following physical activity.

Where is the study run from?
The Physiotherapy Research Unit at Oxford University Hospitals NHS Trust, UK.

When is the study starting and how long is it expected to run for?
The study starts in July 2014 and is expected to end in June 2016. Recruitment will be between January and June 2015.

Who is funding the study?
The Physiotherapy Research Foundation, UK.

Who is the main contact?
Dr Catherine Minns Lowe
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1 18th March 2014

Study information

Scientific Title
Walk30X5: the development and feasibility evaluation of a physiotherapy walking programme for people with mild to moderate musculoskeletal conditions

Acronym
Walk30X5

Study objectives
To develop and refine an evidence-based, web-based physiotherapy walking programme intervention including podcasts, blog and links. To test the feasibility and acceptability of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 25/07/2014, REC ref: 14/SC/1018

Study design
Development of the intervention via consensus meetings. Feasibility randomised clinical trial with a nested qualitative study to obtain participant's views of the study and walking programme.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mild/moderate long-term musculoskeletal conditions affecting back, lower limbs or physical activity levels

Interventions
Participants are randomised to Group 1 or 2.

Group 1: two physiotherapy sessions. Session 1: participants are asked about their activity levels and advised how they might become more physically active. Participants will set a physical activity goal (e.g., go swimming 2-3 times per week, walk, cycle) for review at follow-up in 8 weeks' time (second session). Participants will return their pedometers, receiving them again before follow-up.

Group 2: two physiotherapy sessions. One physiotherapy session following randomisation to teach intervention (progressing up to 3000 steps 5 days a week above individual baseline) and one follow-up. During the initial session the 7-day pedometer values will be used to provide a

suitable entry point into the programme and to set step count goals for each participant (a key predictor of increased physical activity [Marshall et al, 2013]). Participants not owning an MP3 player, or concerned about downloading podcasts, will be given an MP3 player with all podcasts installed and ready to go. Participants will be shown the website and podcasts. Any person not having access to a computer will be provided with paper copies of website information. Any obvious barriers to doing the programme (e.g., coping with inclement weather) will be discussed and tips and a plan of action will be provided.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
6-minute timed walk test. Timepoints for all outcomes: baseline, 3 months (post-intervention) and 6 months.

Secondary outcome measures
1. 7-day mean step count using an Omron HJ-720ITC pedometer
2. Blood pressure
3. Peak flow
4. The British Heart Foundation's Daily Activities Questionnaire will be used to measure the amount of physical activity people have engaged in during the previous 7 days
5. Visual analogue scales will measure pain intensity, average pain and fatigue
6. The Positive and Negative Affect Schedule (PANAS) self-report measure will be used to measure positive and negative affect
7. A single question about happiness will be used from the SF-36 (short-form health survey)
8. Self-efficacy will be measured by the Generalised Self-Efficacy scale
9. A self-report exercise diary will be used to provide information about adherence to the intervention
10. Quality of life will be assessed using the EQ-5D-5L and a global health rating question will be included
11. EQ-5D-5L and resource use diaries will be used to provide data regarding health economics
12. Participants will be asked to report adverse events, including falls

Timepoints for all outcomes: baseline, 3 months (post-intervention) and 6 months.

Overall study start date
01/07/2014

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Patients referred for physiotherapy assessment and advice by GPs for any mild/moderate /none severe musculoskeletal conditions effecting physical activity (e.g., chronic back pain, fibromyalgia, lower limb arthritis) with pain (rated 4 or above on a visual analogue scale) lasting at least 3 months, and considered physically able to undertake the programme

2. Participants self-reporting < 120 mins (4 x 30 min) of moderate intensity exercise a week
3. Participants able to perform 6-minute timed walk test (own pace, no walking aid) with non-severe reports of pain (equal or less than 6/10 on the VAS scale) during screening
4. Participant is willing and able to give informed consent for participation in the study. Patient is fluent in English and able to read screens
5. Male or female, aged 18 years or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants for feasibility trial

Total final enrolment
41

Key exclusion criteria
1. Participants scoring an average pain VAS > 6 on walk test
2. Participants unable/unwilling to provide consent
3. Participants with a recent history of an illness likely to interfere with the ability to undertake the programme safely: serious cardiac or respiratory diagnoses, lower limb fractures (last 12 months), blindness, systemic illness, those reporting that a doctor had told them not to exercise
4. Pregnancy
5. Unable to participate in the intervention

Date of first enrolment
01/01/2015

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Nuffield Orthopaedic Centre
Oxford
United Kingdom
OX3 7HE

Sponsor information

Organisation
Oxford University Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Oxford University Hospitals NHS Trust
Joint Research Office
Block 60
Churchill Hospital
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OX3 7LE

Sponsor type
Hospital/treatment centre

Website
http://www.ouh.nhs.uk/

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy (CSP) Charitable Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/06/2020	01/10/2020	Yes	No
HRA research summary			28/06/2023	No	No