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Physiotherapy exercise rehabilitation with tailored exercise adherence support for people with osteoporosis and vertebral fractures

Submission date
10/06/2021

Recruitment status
No longer recruiting

Registration date
13/09/2021

Overall study status
Completed

Last Edited
02/12/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoporosis is a condition where bones lose strength and break easily. People with osteoporosis need to keep active and exercise regularly to help manage their condition. Exercise can help to maintain an upright posture, maintain strength and balance, to continue everyday activities and prevent falls and fractures. Unfortunately, research shows sticking to exercise programmes is difficult. Techniques to encourage exercise habits may be helpful.
This study will test if adding a personalised programme of support techniques to encourage exercise adherence to a course of exercise-based physiotherapy is of more benefit to patients compared to exercise based physiotherapy alone.

Who can participate?
Patients aged 18 and over who have osteoporosis and a spinal fracture

What does the study involve?
The study will compare two groups. One group will be offered exercise-based physiotherapy (usual care). The other group will be offered this plus adherence to exercise support techniques (Intervention group). A computer programme will place patients at random into either group (similar to the toss of a coin).
Patients in the intervention group will be asked about their preferences, motivators and barriers related to exercise. The physiotherapist will prescribe exercises and at least two exercise adherence support techniques to suit the individual, selecting from a toolkit of tested support techniques.
The study will be completed in four NHS physiotherapy departments. It will test whether enhancing physiotherapy exercise rehabilitation with adherence support benefits patient wellbeing, physical function and exercise participation. Patients will be asked to complete five brief questionnaires and measures of balance, back strength, spinal shape and walking before and at 4, 8 and 12 months after treatment.
Around 15 patients and 8-12 physiotherapists who undertake the physiotherapy plus exercise support treatment will also be invited to take part in an interview about their experiences of treatment and exercise adherence.

What are the possible benefits and risks of participating?
The researchers do not believe that there are any risks. There will be no direct benefits at an individual level beyond that participants are often reported to have some benefit from the additional attention of participating in a study.

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

When is the study starting and how long is it expected to run for?
June 2021 to January 2024

Who is funding the study?
Chartered Society of Physiotherapy Charitable Trust (UK)

Who is the main contact?
Prof. Karen Burke
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Contact information

Type(s)
Scientific

Contact name
Prof Karen Barker

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
287716

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 287716, CPMS 49576

Study information

Scientific Title
OsteoPorosis Tailored exercise adherence INtervention (OPTIN): physiotherapy exercise rehabilitation with tailored exercise adherence support for people with osteoporosis and vertebral fractures: a randomised controlled trial

Acronym
OPTIN

Study objectives
Integrating an adherence intervention with the exercise intervention used in the PROVE trial, which showed short-term effects, will be beneficial for people with osteoporotic vertebral fractures treated by physiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2021, West of Scotland REC 4 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC4@ggc.scot.nhs.uk), REC ref: 21/W/0071

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Osteoporosis vertebral fracture

Interventions
Following baseline assessment and registration participants will be individually randomised (1:1) between either: Opt-In (OsteoPorosis Tailored exercise adherence INtervention) programme or usual physiotherapy exercises. A computer-generated randomisation schedule will be prepared

by the trial statistician (RK). Individual randomisation will be stratified by recruitment centre and permuted blocks of varying undisclosed sizes will be used. The randomisation schedule will be concealed in sequentially numbered, opaque, sealed envelopes for each site. A study administrator who has no interaction with blinded study staff will manage these envelopes. The administrator will open the randomisation envelope, and then communicate with the local site who will make the participant aware of their allocated group and to refer all participants for physiotherapy; making sure that participants are allocated to treating physiotherapists delivering the treatment for their allocated arm.

Due to the nature of the intervention, blinding the participant to their allocated group is not possible. Nor is it possible to blind the treating clinician to what they are delivering. Initial baseline assessment will occur prior to randomisation and the TRC undertaking assessments will not be involved in any part of the randomisation procedure to ensure that they are not able to bias the group allocation. The TRC conducting follow-up measures and the research team personnel entering data will also not be informed of the allocated group and participants will be asked and reminded not to disclose their treatment group to the TRC at follow-up appointments. As participants and treating clinicians are not blinded to their allocated treatment it is not necessary to have a code-breaking procedure.

Participants in both arms will be offered a 1-hour physiotherapy assessment and six individual outpatient physiotherapy sessions spread over 16 weeks. The physiotherapy will include a musculoskeletal assessment and treatment including balance, posture, strength training and aerobic weight-bearing exercise based on the current best practice guidance from the Royal Osteoporosis Society. Participants allocated to Opt-In will receive an additional, integrated assessment interview (30 minutes) plus 60 minutes of adherence support spread over the subsequent treatment period of 16 weeks as required by the participant. Thus overall, Opt-In will comprise 90 minutes of specific adherence support over 16 weeks. Sessions in both arms can be in-person or virtually via video-call/telephone as agreed between participant and therapist.

OsteoPorosis Tailored exercise adherence INtervention (Opt-In):
The researchers will offer participants a physiotherapy assessment and ask them to complete a questionnaire before seeing the physiotherapist. They can answer the questionnaire at home or in the waiting room prior to treatment. The Personalized Exercise Questionnaire (PEQ) was developed in Canada to support patient-centred exercise prescription for people with osteoporosis and covers topics such as; barriers to exercise, goals of treatment. The usual physiotherapy assessment will follow, extended by a collaborative discussion with the patient using a motivational interviewing approach. The discussion will draw upon PEQ responses and consider goals, motivators, facilitators, and barriers surrounding exercise. It aims to provide physiotherapists with a deeper understanding of patient motivations and circumstances, to strengthen the therapeutic alliance and the patient's own motivations for adopting exercise. Following assessment, the physiotherapist will begin to prescribe a multi-component programme of balance, posture, strength training and aerobic weight-bearing exercise. Treating therapists will receive prior training on prescription of the exercises. Using their assessment findings, the questionnaire and collaborative interview the physiotherapist will assess a participant's exercise capability (C), opportunity (O) and motivation (M) to carry out exercise behaviour and select an adherence technique from the Opt-In toolkit in response. Techniques comprise: Education about osteoporosis and exercises or fall prevention strategies, environmental enrichment/cues, Exercise Action Plans, Exercise Coping Plans, Decision balance records, Support contact call, Implementation intention statements, Self-monitoring and feedback strategies. Techniques are linked to COM-B domains to facilitate physiotherapist decision-making e.g., Education improves capability and motivation (C, M) and physiotherapists will have received further information and training by the study team about techniques and how

to use them. Subsequent sessions and adherence support opportunities will monitor and develop exercise and adherence support. Physiotherapists will prescribe at least 3 adherence techniques from the Opt-In toolkit over 16 weeks. The researchers will give participants an Opt-In folder that includes their exercises and adherence materials e.g., exercise diary, education leaflet, action plan record.

Control group participants will be offered a 1-hour physiotherapy assessment and six individual outpatient physiotherapy sessions spread over 16 weeks. A multi-component programme of balance, posture, strength training and aerobic weight-bearing exercise. rehabilitation intervention will be prescribed.

Information about relevant demographic and physical characteristics, namely: age, sex, height, weight, history of falls in the previous year, current walking ability, bone mineral density, number and site of vertebral fractures and other non-vertebral fractures, will be collected from medical records and at the baseline assessment. The TRC will also complete the weighted Functional Co-morbidities Index (w-FCI) questionnaire (18 items) to assess baseline comorbidity level. At this baseline assessment visit all outcome measures will be completed, except for the EARS scale, and the TRC will provide participants with two event diaries, one to record any falls, a second diary to record health care use. At subsequent follow-up visits at 4, 8 and 12 months the outcome measure package will be completed, including the EARS scale, and the TRC will collect and re-issue the trial diaries for the relevant time-point.

Intervention Type
Mixed

Primary outcome measure
Balance, lower limb strength and walking ability measured using the Timed Up and Go (TUG) at baseline, 4, 8 and 12 months with the main end point of 12 months

Secondary outcome measures
Measured at baseline, 4, 8 and 12 months with the main end point of 12 months:
1. Health-related quality of life (QoL) measured using QUALEFFO 41
2. Shoulder and back muscle endurance measured using Timed Loaded Standing (TLS)
3. Thoracic kyphosis angle measured non-radiographically using a flexicurve ruler
4. Back pain measured with a 10-point Numeric Pain Rating Scale (NPRS)
5. Dynamic standing balance measured using the Functional Reach (FR) test
6. Functional walking capacity and aerobic cardio-respiratory fitness measured using the six-minute walk (6MW) test
7. Fear or concern about falling during activities measured using the Falls Efficacy Scale International (FES-I)
8. Grip strength measured with an isometric hand dynamometer
9. Self-efficacy for exercise measured using the Self-Efficacy for Exercise (SEE) scale
10. Adherence measured using:
10.1. Attendance records via clinician completed treatment logs, including a checkbox to log whether adherence techniques have been prescribed (intervention group only)
10.2. Exercise adherence rating scale (EARS)

Overall study start date
04/06/2021

Completion date

10/01/2024

Eligibility

Key inclusion criteria
1. Patients who had a diagnosis of primary osteoporosis confirmed by a radiograph or dual energy X-ray absorptiometry (DEXA) scan (≥2.5 standard deviation below the norm) at the lowest lumbar level
2. Patients who had a history of at least one symptomatic osteoporotic vertebral fracture (OVF)
3. Patients aged ≥18 years
4. Patients who were postmenopausal (if female)
5. Patients able to walk ≥10 m independently with or without an aid
6. Patients able to understand and participate in the physiotherapy programme

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Patients aged <18 years
2. Patients who had osteoporosis secondary to other metabolic bone disorders or disease (e.g. rheumatoid arthritis, cancer and osteomalacia), experienced lower-limb joint surgery, or fracture, in the previous 6 months
3. Patients whose primary problem was back pain with pain radiating into the lower limb
4. Patients who had undergone vertebroplasty, facet joint injection or any physical therapy (e.g. chiropractic, osteopathic or physiotherapeutic treatment for back pain in the previous 12 weeks)
5. Patients with severe unstable cardiovascular or pulmonary disease or significant psychiatric or neurological conditions that would preclude participation in the physiotherapy treatment arms

Date of first enrolment
01/08/2021

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Oxford University Hospitals NHS Foundation Trust
Windmill Road
Oxford
United Kingdom
OX3 7LD

Study participating centre
Horton General Hospital
Oxford Rd
Banbury
United Kingdom
OX16 9AL

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Manchester Royal Infirmary
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
St George's Healthcare Nhst
Blackshaw Road
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
University of Oxford

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ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website

http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The researchers also intend to publish the protocol within the next 6 months.

Intention to publish date
10/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Barker (karen.barker@ndorms.ox.ac.uk) at 12 months after study closure in an anonymised format for the main RCT outcomes. Participants have given permission for their data to be used by the trial team only. On completion when the researchers share the results with them they will seek assent to make an anonymised dataset available for a data repository.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	11/06/2021	11/08/2021	No	Yes
Protocol article		17/09/2022	20/09/2022	Yes	No
Statistical Analysis Plan	version 1.2		09/01/2024	No	No
Other publications		11/10/2024	02/12/2024	Yes	No