ISRCTN14465704 https://doi.org/10.1186/ISRCTN14465704

# 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**
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
karen.barker@ouh.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof Karen Barker

### ORCID ID
http://orcid.org/0000-0001-9363-0383

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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 hypothesis
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

### Condition
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

## Overall study end date

10/01/2024

# Eligibility

### Participant 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

### Participant 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

### Recruitment start date
01/08/2021

### Recruitment end date
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

### Sponsor details
Joint Research Office
1st Floor Boundary Brook House
Churchill Drive
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 741155
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 |