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A study exploring a new walking frame for older people living in their own homes.

Submission date
18/09/2024

Recruitment status
Recruiting

Registration date
20/09/2024

Overall study status
Ongoing

Last Edited
10/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The study is focused on evaluating a new indoor walking frame designed for older adults. Walking frames have been used for many years to help people who are unsteady or have difficulty walking, but the traditional frame has some limitations. This new frame aims to address common issues, such as difficulty moving on carpets or navigating small spaces in homes. The primary goal of the study is to explore whether this new walking frame is feasible for use in a larger trial, and to gather feedback from users about its acceptability and potential benefits. The study will also look at whether using the frame increases the activity levels of participants.

Who can participate?
The study is open to adults aged 65 or older who have been using a traditional walking frame for over a year and live in their own homes. Participants must be able to provide informed consent and be physically capable of safely using the new walking frame. People who live in care homes, are non-weight-bearing, or have vision problems that cannot be corrected with glasses are excluded from the study.

What does the study involve?
Participants will use the new walking frame for an 8-week period. Physiotherapists will provide training on how to use the frame safely. Participants' activity levels will be tracked both before and after using the frame using simple devices such as accelerometers. Throughout the study, feedback will be collected through interviews and follow-up phone calls. Physiotherapists involved in the study will also provide their feedback through focus groups. The study will not only look at the physical impact of using the new frame but also participants' overall experience and its usability in a home setting.

What are the possible benefits and risks of participating?
The possible benefits include improved mobility, greater independence, and potentially a reduction in falls due to better use of the walking frame. However, as with any walking aid, there are risks involved, such as the chance of falls or injury while using the frame at home without immediate medical assistance. Participants will be fully informed of the risks before joining the study.

Where is the study run from?
The study is being conducted by the University of Exeter, primarily in participants' own homes. Physiotherapists will deliver the intervention, and the study's management is based at the University of Exeter.

When is the study starting and how long is it expected to run for?
August 2024 to October 2026

Who is funding the study?
The study is funded by the Chartered Society of Physiotherapy Charitable Trust (CSPCT), which supports research that can improve physiotherapy care and outcomes.

Who is the main contact?
The Chief Investigator for the study is Dr. Abi Hall, a Senior Research Fellow at the University of Exeter. You can contact her via email at a.hall4@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Abi Hall

Contact details
University of Exeter, Heavitree Road
Exeter
United Kingdom
EX1 2LU
-
a.hall4@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333393

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
The Chartered Society of Physiotherapy Charitable Trust Grant Codes: PRF-23A-POD11; CPMS 58368

Study information

Scientific Title
A new, novel walking frame for older adults in community settings – a single-arm feasibility study with embedded process evaluation and health economic analysis

Acronym
FORWARD

Study objectives
The primary objectives of this feasibility study will be to explore feasibility of trial processes (e. g., recruitment, data collection) and assess the acceptability of the walking frame which would be used in a subsequent large multi-centre randomised controlled trial (RCT). We will also estimate the potential effectiveness of using the novel walking frame.
The aim of the future RCT would be to determine the effect of the intervention on activity levels, mobility and the cost effectiveness compared to standard care.
Thus, for this feasibility study the objectives will be as follows:

Primary objectives will be to:
- determine the feasibility of data collection
- explore adherence to using the new walking frame
- determine recruitment rates and time to recruit participants
- explore the eligibility of potential recruits
- explore any adverse advents of using the frame

Secondary objectives:
- Explore the acceptability and feasibility of using the new walking frame;
-- from the perspective of the patient
-- the experiences of the carer (if present)
- Explore the thoughts and beliefs of the physiotherapist
- Estimate the standard deviation of continuous outcomes to help inform the sample size calculation for a subsequent definitive RCT of intervention effectiveness
- Estimate the follow-up rate
- Explore changes in activity levels using the new walking frame
- Explore whether the frame results in any change in health and social care service utilisation

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/09/2024, Frenchay REC (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 207 1048106; frenchay.rec@hra.nhs.uk), ref: 24/SW/0103

Study design
Single-arm non-randomized feasibility study with embedded process evaluation and health economic analysis

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Exploring a new walking frame for older people living in their own homes

Interventions
We will train physiotherapists in how to use the frame and teach older people to use it. We will then ask them to provide the walking frame to the older person and ensure they are safe to use it. We will collect data such as how active the person is before using the frame and then whether they are more active using this new frame. We will also collect data about how their activity levels affect their quality of life and the social and health care costs.
We will talk to the older people and physiotherapists to explore what they think about the frame - what is good and what could be improved.
We will give the older person 8 weeks to use the frame, after which they are able to keep the frame if they would like to.

Intervention Type
Behavioural

Primary outcome measure
Feasibility measured using ... at ...

Secondary outcome measures
1. Demographic data collected will include age, sex, ethnicity, highest education level, marital status, Index of Multiple Deprivation (from postcode), Clinical Frailty Scale, Health and social care service utilization
2. Clinical outcome measures will be taken at baseline and 8 weeks after being given the frame
2.1. Short Physical Performance Battery (SPPB)
2.2. EQ-5D-5L
2.3. Timed up and Go
2.4. Goal Attainment Scale
2.5. General self-efficacy framework
3. The Zarit Burden Interview will be undertaken with carers (if present) at baseline and 8 weeks
4. Activity tracking will be undertaken for 1 week prior to the provision of the new walking frame. This will include activity tracking of the person and of the walking frame. We will use simple accelerometers to measure the activity in terms of distance moved, time moving as well as speed of movement. We will also collect data about any other walking aids that they use. A further 1 week of activity tracking will be undertaken at the end of the intervention period

Overall study start date
01/08/2024

Completion date
01/10/2026

Eligibility

Key inclusion criteria
Patient participants who:
1. Live at home in a suitable environment to use a frame
2. Have the capacity to provide informed consent to take part in the study and use the frame safely
3. Understand and converse in English
4. Use a traditional frame for >1 year
5. Are over the age of 65 years old

Therapist participants who:
1. Have at least a year of experience working as a physiotherapist in the community
2. Have delivered the intervention to at least 1 participant, for the qualitative data collection

Participant type(s)
Patient, Health professional

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
Patient participants who are:
1. Living in care homes
2. Non-weight bearing
3. Experiencing visual disorders not correctable by glasses

Therapist participants who have:
1. No experience working in community settings

Date of first enrolment
01/11/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
-
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University of Exeter

Sponsor details
Stocker Road
Exeter
England
United Kingdom
EX4 4PY
+44 1392726621
res-sponsor@exeter.ac.uk

Sponsor type
University/education

Website
https://www.exeter.ac.uk/

ROR
https://ror.org/03yghzc09

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
The study results are planned to be published in a high-impact, peer-reviewed journal, following the completion of the study. The research team will disseminate the findings widely through academic journals, conferences, and other platforms. Additionally, results will be shared on the University of Exeter's open access repository, Open Research Exeter (ORE). This will ensure that the study data is available for further research and public access. The final study report, anonymised participant-level dataset, and statistical code for generating the results will be prepared after data analysis is complete.

Intention to publish date
31/12/2026

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	10/09/2024	20/09/2024	No	Yes