Frame Fit. A randomised controlled trial to determine the acceptability, safety and efficacy of a falls prevention exercise programme for walking frame users

Submission date	Recruitment status	[X] Prospectively registered
11/09/2014	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
11/09/2014	Completed	Results
Last Edited	Condition category	Individual participant data
24/08/2020	Injury, Occupational Diseases, Poisoning	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Julie Whitney

Contact details

Clinical Age Research Unit Denmark Hill London United Kingdom SE5 9RS

julie.whitney@nhs.net

Additional identifiers

Protocol serial number 17324

Study information

Scientific Title

Frame Fit. A randomised controlled trial to determine the acceptability, safety and efficacy of a falls prevention exercise programme for walking frame users

Acronym

Frame Fit - falls prevention for frame users

Study objectives

Falls are common among people with walking and balance difficulties, particularly those who have to use a walking frame to get around. Exercise programmes to improve balance effectively prevent falls. However, no programme has been designed to include the frame in the exercise or provided exercises to address the unique challenges to mobility and balance experienced by frame users.

This project will test a fall prevention exercise programme developed specifically for frame users. Frame users will be randomly assigned to receive either this exercise or usual care. Balance, mobility and falls will then be compared between these two groups.

A small additional exploratory study will look at mechanisms underlying balance in people who use walking frames and whether balance exercise alters these mechanisms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/LO/0556

Study design

Randomised; Interventional; Design type: Prevention, Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Primary Care, Ageing; Subtopic: Ageing, Ageing; Disease: All Diseases, All Ageing

Interventions

The participants are randomised to intervention and control group:

1. Frame fit exercise programme: Muscle strengthening and balance training exercises incorporating the walking

frame.; Follow Up Length: 12 month(s); Study Entry: Registration and One or More

Randomisations

2. Control group: Usual care

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Falls; Timepoint(s): 12 months from baseline

Key secondary outcome(s))

- 1. Fear of falling (FES-I); Timepoint(s): Baseline and 6 month follow up
- 2. Frailty index; Timepoint(s): Baseline and 6 month follow up
- 3. Gait (6 metre walk and timed up and go); Timepoint(s): Baseline and 6 month follow up
- 4. Muscle strength (grip and sit to stand); Timepoint(s): Baseline and 6 month follow up
- 5. Physical activity (IPEQ); Timepoint(s): baseline and 6 month follow up
- 6. Quality of life (EQ5D); Timepoint(s): Baseline and 6 month follow up
- 7. Standing balance; Timepoint(s): Baseline and 6 month follow up

Completion date

23/04/2019

Eligibility

Key inclusion criteria

- 1. Uses a walking frame for the majority of walking and standing tasks on a daily basis
- 2. Aged >65
- 3. Able to follow simple commands e.g. hold onto this chair with one hand and lift up your right leg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

- 1. Unable to walk 6 metres
- 2. Unable to stand from a chair independently
- 3. Diagnosis or dementia or MMSE<24 and not living with a full time carer who can commit to helping with the

exercise

- 4. Terminal illness or likely to live for <6 months
- 5. Non-weight bearing
- 6. Less than 6 weeks following an episode of delirium
- 7. Lacking in mental capacity to consent

Date of first enrolment

20/10/2014

Date of final enrolment

24/04/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Clinical Age Research Unit London

United Kingdom SE5 9RS

Sponsor information

Organisation

King College Hospital and Kings College London (UK)

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

Government

Funder Name

NIHR - Clinical Academic Training; Grant Codes: CAT CL-2013-04-007

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo