

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 11/09/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 11/09/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2020	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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 measure

Falls; Timepoint(s): 12 months from baseline

Secondary outcome measures

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

Overall study start date

20/10/2014

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

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 240; UK Sample Size: 240; Description: 120 intervention and 120 usual care

Key exclusion criteria

1. Unable to walk 6 metres
2. Unable to stand from a chair independently
3. Diagnosis of 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

England

United Kingdom

Study participating centre

Clinical Age Research Unit

London

United Kingdom

SE5 9RS

Sponsor information

Organisation

King College Hospital and Kings College London (UK)

Sponsor details

Child Health

Denmark Hill

London

England

United Kingdom

SE5 9RS

Sponsor type

Hospital/treatment centre

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

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?
HRA research summary			28/06/2023	No	No