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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

Registration date
11/09/2014

Overall study status
Completed

Last Edited
24/08/2020

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 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
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