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Evaluation of the early adoption of the Falls Management Exercise Programme in Ireland

Submission date
29/08/2024

Recruitment status
No longer recruiting

Registration date
09/09/2024

Overall study status
Completed

Last Edited
18/10/2024

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

Background and study aims
Falls are common, with over a third of those aged 65 years and older falling each year. Falls can lead to injuries and admission to hospital or care homes. Many falls are preventable. Research shows that exercise, including strength and balance training, is key to reducing falls. For maximum results, people need to exercise three times per week and train balance and strength progressively and safely. FaME is a community-based falls management exercise programme. It is 6 months long, led by specialist trained physiotherapists and exercise instructors. It has been shown to reduce falls and improve physical activity levels and wellbeing. FaME was first introduced in Ireland in 2021, and there will be over 100 specialist instructors trained to deliver FaME by the end of this year. This study aims to find the best way to get FaME up and running well in Ireland, linked to the Irish healthcare system. Specifically, the aims are to explore access, acceptability, efficiency and cost of the programme through interviews, and observations with the service providers and users.

Who can participate?
Those who are attending a FaME programme in Ireland at any of the three early adopter sites can participate in the study. People who live in the community, are aged 65 years and over and have fallen, or fear falling are eligible to join the FaME programme. Those delivering the programme at those three sites will also participate in the study.

What does the study involve?
The study will involve interviewing the FaME service users about halfway through the programme, at the end of the programme, and completing a brief survey about three months after the programme. The service providers will also be interviewed mid-way and at the end of the programme.

What are the possible benefits and risks of participating?
There are no real benefits or risks to the participants taking part in this study. However, the information will help future scaling up of the programme in Ireland.

Where is the study run from?
Three early adopter sites in Ireland: Health Service Executive Community Organisations at Leitrim, Kerry and Dublin. All are community-based centres.

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

Who is funding the study?
The Health Research Board, with co-funding from the Health Service Executive (Ireland)

Who is the main contact?
Dr Ruth McCullagh, r.mccullagh@ucc.ie

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Falls Management Exercise Programme: Improving Reach, Effectiveness, VaLue and SustAiNability in IrelanD. Case studies for learning (FaME Ireland)

Acronym
FaME Ireland

Study objectives
Establishing the Falls Management Exercise Programme is complex, involving many key agencies and stakeholders, and must be adapted to the local needs and availability while remaining effective. We aim to examine the early adoption of FaME to learn lessons about delivering FaME in the Irish Healthcare landscape, to learn lessons about its future scaling.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/10/2024, Clinical Research Ethics Committee of the Cork Teaching Hospitals (6, Lancaster Hall, Little Hanover St, Cork, T12 W778, Ireland; +353 (0)21 4901901; crec@ucc.ie), ref: ECM 3 (aaaa) 02/07/2024

2. approved 13/09/2024, Sligo Research Ethics Committee (Research & Education Foundation CLG, ETC Building, Sligo University Hospital, Sligo, F91H684, Ireland; +353 (0) 7191 80305; office@ref-sligo.ie), ref: 1019

Study design
Multicentre observational evaluation study

Primary study design
Observational

Study type(s)
Other, Treatment

Health condition(s) or problem(s) studied
Older adult falls prevention

Interventions
Observational data of the falls prevention programme will include interviews and observational data. data will help identify key local issues. These issues will be addressed at a co-design workshop, and local practical solutions will be agreed by key stakeholders. The programme will be observed again to identify the impact of the changes. An implementation toolkit will be drawn up for the Irish context.

Intervention Type
Mixed

Primary outcome(s)
Participants will be interviewed twice and will complete two surveys:

Interview 1: Participants experience and perception of the exercise programme early in the programme (within the first 13 weeks)
Interview 2: Participants experience and perception of the exercise programme later in the programme (within 6 weeks of the end of the programme)

Survey 1: Participants preferences in exercises beyond the programme (midway through the programme [weeks 10-16])
Survey 2: Exercise practice after the FaME programme (follow-up, at 6-12 weeks)

Trained Instructors will be interviewed once about their perception and experience of delivering the programme midway through the programme (week 10-16)

Referrers to the exercise programme will be interviewed once about their experience and perception of falls prevention exercise programmes (before week 24).

All the qualitative data will be analysed using thematic analysis.

Routinely collected outcome data will be analysed to determine effects from baseline. Data will be analysed to determine its distribution, and the appropriate tests will be used to determine differences from baseline. Percentage or average mean differences will be compared to the minimal clinically important difference, or indicators of independent community ambulation, when appropriate. Results will be compared to previous implementation studies for indicators of effectiveness.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
03/03/2026

Eligibility

Key inclusion criteria
Health professional:
All health professionals providing the falls prevention programme at the early adopter sites

Service users:
All service users at the early adopter sites are eligible to participate. People who are eligible to use the FaME programme are:
1. Aged 65 years and over who are at risk of falling
2. Currently living at home (i.e. not in residential care)
3. Medically stable
4. Capable of walking independently indoors and outdoors (with or without walking aids or help from another person)
5. Physically able to take part in a group exercise class as assessed by the referrer.

Other (service commissioner):
All commissioners of the service at the three early adopter sites

Participant type(s)
Health professional, Service user, Other

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
Service users:
1. Uncontrolled high blood pressure or tachycardia
2. Experienced a significant drop in BP during exercise
3. Psychiatric conditions which would prevent participation in an exercise class
4. Uncontrolled medical problems, which the GP considered would exclude patients from
5. Undertaking the exercise programme (e.g. acute systemic illness such as rheumatoid arthritis) conditions requiring one-to-one or therapy-led exercise programme (e.g. unable to maintain a

seated upright position)
6. Not living independently (e.g. living in residential or nursing homes)
7. Cognitive impairment preventing the ability to follow simple instructions

Date of first enrolment
10/09/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
Ireland

Study participating centre
Cork Kerry Community Healthcare, Health Service Executive
Rathass, Tralee, Co. Kerry
Tralee, Co Kerry
Ireland
V92 YA25

Study participating centre
Community Healthcare Organisation CDLMS (Area 1), Health Services Executive
The Bungalow, St John's Hospital Campus, Sligo, Co. Sligo
Sligo
Ireland
F91 Y992

Study participating centre
Community Healthcare Organisation North Dublin (CHO 9), Health Services Executive
Health Services Executive, CHO 9
161-171 Vernon Ave Health Centre
Dublin
Ireland
D03 WT26

Sponsor information

Organisation
University College Cork

ROR
https://ror.org/03265fv13

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Funder Name
Health Service Executive

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes