Title

PHysical activity Implementation Study In Community-dwelling AduLts (PHISICAL): Study Protocol

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Word count

3217 excluding title page, abstract, references and table

Keywords: fall, community, outcome of injury

Abstract

Background: Falls in older people are a leading causes of unintentional injury. Due to an ageing population, injuries are likely to increase unless more is done to reduce older people's falls risk. In clinical trials, the Falls Management Exercise (FaME) programme has reduced the rate of falls and falls-related injuries in community-dwelling older adults. However, the commissioning of FaME is inconsistent across England, potentially due to a lack of evidence that FaME can be delivered effectively in a 'real world' setting. The PHISICAL study is designed to study the implementation of FaME in a range of different settings in England.

Methods: The PHISICAL study will use mixed-methods triangulation multi-level design to explore the implementation of FaME. Framework analysis of semi-structured interviews with up to 90 stakeholders (exercise programme users, service providers, referrers and commissioners) and observational data from locally-led communities of practice will identify the factors that influence FaME's implementation. Quantitative, anonymised, routine service data from up to 650 exercise programme users, including measures of falls and physical activity, will allow assessment of whether the benefits of FaME reported in clinical trials translate to the 'real world' setting.

Conclusion: The findings from this study will be used to develop a toolkit of resources and guidance to inform the commissioning and delivery of future FaME programmes. This study has the potential to inform public health prevention strategies, and in doing so may reduce the number of falls in the older population, whilst delivering cost savings to health and social care services.

INTRODUCTION

Falls in older people are one of the leading causes of unintentional injury and represent a major public health problem worldwide.[1] Approximately one in three community-dwelling adults aged 65 and over fall each year,[2 3] increasing to one in two for those aged 80 years and over.[4]

In England, falls admissions account for 4 million hospital bed days each year,[5] and hip fractures alone are estimated to cost the UK £2 billion.[6] The personal cost of falling includes loss of confidence, increased social isolation and severe injuries that together are a significant factor in people having to move from their own homes into high cost long term residential care.[7] With the number of people aged 65 and over predicted to increase from 10 million people in the UK in 2010 to 19 million by 2050,[8] the burden of falls on individuals, families and the health and social care system will rise.[9]

Falling risk is increased by age-related muscle weakness which impairs balance and the ability to undertake activities of daily living such as standing from a chair or walking[10]. Physical activity can play an important role in reducing this deterioration,[11] helping people retain their independence for longer[12] and reducing their risk of falls including injurious falls.[1 13] For older people at low risk of falling, activities such as tai chi, dancing, Nordic walking and yoga may be suitable,[14] but for people at a high risk of falling, a more structured approach targeting strength and balance is recommended.[7 14 15]

The Falls Management Exercise (FaME) programme[16] is a community based exercise programme that aims to improve strength and balance, and was originally recommended for older people at a high risk of falling,[13-17] but more recently has been shown to reduce falls in community dwelling older adults at lower falls risk. [13] It has also been shown to reduce injurious falls by 40%, [16] increase moderate intensity physical activity levels, with the potential to improve other aspects of health.[13 18] The programme is delivered by qualified Postural Stability Instructors (PSIs) in community venues such as village halls and leisure centres, and consists of weekly one hour group exercise classes (approximately 10 participants per class) for 24 weeks. Participants are also advised to complete two 30 minute home exercise sessions and two 30 minute walks per week.[13 18] The programme's exercise components include progressive strengthening and balance exercises targeted to the trunk, arms and legs, functional floor skills, cardiovascular conditioning, flexibility training and adapted Tai Chi. Ankle cuff weights, elastic resistance training bands and mats are also used throughout the programme. The group exercise sessions include retraining of the ability to get up from the floor and

floor exercises to improve strength, balance and coping strategies to reduce the risk of complications from a long lie.[19]

However, despite clinical trial data supporting FaME's effectiveness in reducing falls rates,[13 16] including amongst those with Parkinson's Disease,[20 21] such programmes are not consistently available to older people, or lack fidelity to the FaME programme, in the United Kingdom. For example, a national audit across England showed that 54% of falls services used the FaME programme, but the duration and dose was inadequate and referrals from rehabilitation services to continuing community based FaME programmes were lacking.[22] In particular, fidelity to strength progression, home exercise adherence and duration of programme were inconsistent. This may be due to a lack of evidence that such programmes can be delivered effectively in the complex setting of a commissioned community service. It is therefore important to explore implementation of the FaME programme in a 'real world' setting to help understand factors that influence its successful delivery.

The PHysical activity Implementation Study In Community-dwelling AduLts (PHISICAL) study is designed to examine the implementation of FaME commissioned and provided in organisationally (i.e. different local government structures), geographically, ethnically and socio-demographically distinct English localities; Derby City and Leicestershire and Rutland Counties. The PHISICAL study will use qualitative and quantitative methods to explore this implementation, with the aim of generating generalisable findings related to the factors that influence the programme's effectiveness in a community setting. The objectives of the study are multilevel as follows:

- To identify factors that influence the successful implementation of FaME within the community using the Consolidated Framework for Implementation Research (CFIR).[23] This framework includes examination of the local context, leadership and support for implementation and facilitation of the programme. We will also combine this with quantitative data collected routinely by the services on factors such as completion rates and functional outcomes, to identify characteristics of poor and well-performing providers.
- To assess the fidelity of the delivery of FaME across multiple providers and settings using the Carroll conceptual framework for implementation fidelity.[24] This framework will allow us to combine qualitative information from interviews and from observations of class delivery using a check list, with quantitative data from routinely-collected information such as class registers and questionnaires. This will include analysis of the coverage, frequency, duration and content of local programmes and factors that moderate these such as quality of delivery, facilitation strategies and participant responsiveness.

- To assess whether the clinical benefits of FaME found in previous trials, including reduced falls rates and increased physical activity[13 16 17] are realised when FaME is delivered as routine service provision in a community setting.

METHODS

Study design

This is a multi-site, mixed methods implementation study using a triangulation multi-level design as described by Tashakkori and Tedddlie 1998.[25] In this design, both qualitative and quantitative data will be collected concurrently in order to answer the three research objectives. The data will be given equal weighting when merged so that we can understand the characteristics of poor- and well-performing providers. This approach will allow us to gather the maximum amount of evidence to develop our understanding of FaME programme implementation. Given that it is a study of how the programme is implemented locally, focusing on barriers and facilitators to implementation, there is no control group, nor randomisation. The study will use qualitative interviews, observations of locally-led Community of Practice (CoP) events, observations of FaME classes and analysis of before and after anonymised quantitative data collected routinely by service providers.

Ethics approval

This study was approved by the London-Chelsea Research Ethics Committee, reference number 16/LO/0396.

Data collection methods

Qualitative interviews

Up to 90 participants will be recruited for qualitative interviews. This will consist of interviews with:

- Exercise programme users enrolled on a FaME course (up to 30) towards the end of the programme delivery period. Interview topics will include how the exercise programme users experienced participating in FaME and their plans for physical activity outside of the programme. We will use purposeful sampling to achieve a range of interviews from all of the provider sites in Derby, Leicestershire and Rutland and to achieve a range of ages and if possible a balance of male/female gender.

- Service providers (up to 30) including PSIs and their managers, interviewed at two time points: early in the implementation phase and again towards the end of the programme delivery period. Interview topics will include how they experienced providing FaME, barriers and facilitators to delivery, how they would change the programme if they were to continue delivering it and what they feel would encourage exercise programme users to maintain physical activity at the end of the programme. We will use a snowball recruitment method to identify service providers, initially asking the commissioners who to approach. We will aim to recruit as many PSIs and their managers as possible (up to 30) in the full range of provider sites.
- Referrers to FaME (up to 15), interviewed towards the end of the programme delivery period. Interview topics will include how they experienced the referral process and beliefs regarding benefits for exercise programme users. We will use a snowball recruitment method to identify referrers by asking the FaME providers who to approach. We will aim to recruit a range of referrer types (e.g. GPs, occupational therapists) from a range of provider sites.
- Commissioners of FaME (up to 15), interviewed at two time points: early in the implementation phase and again towards the end of the programme delivery period. Interview topics will include whether they felt FaME was effective and whether they would commission the programme again. As there are a small number of commissioners we will use snowball sampling methods and aim to recruit all key commissioners in Leicestershire, Rutland and Derby with a responsibility for falls prevention.

Recruitment will continue until the planned sample size is achieved. If the number of potential participants within each category is less than that stated above, recruitment will continue until all potential participants have been approached.

Interviews with exercise programme users will take place at the participants' homes or at a convenient community location. Interviews with service providers, referrers and commissioners will take place at a convenient community location or over the telephone. Written informed consent will be obtained prior to the interviews taking place. Interviews will be audio recorded and last up to 60 minutes.

See Figure 1 for a flow diagram of exercise programme user recruitment, and Figure 2 for a flow diagram of service provider, referrer and commissioner recruitment.

Observation of Community of Practice events

Communities of practice are "groups of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis".[26] They have been promoted as a way of enhancing knowledge and improving practice in the healthcare setting,[27] although the evidence supporting this is unclear.[28] The PHISICAL study will explore the degree to which CoPs assist in the successful implementation of FaME and the mechanisms involved, with the aim of creating a guide for future healthcare CoPs.

It is anticipated that up to six CoP events will take place during programme delivery in Derby City and Leicestershire and Rutland Counties and we will study each of these (up to a maximum of 6). Commissioners will invite stakeholders in each locality, including FaME exercise programme users, relevant professionals (e.g., PSIs, physiotherapists) and third sector organisations (e.g., Age UK). Invitations to attend will include a participant information sheet, stating that the event will be observed and recorded by the research team, and will include a consent form for information. Attendees will be asked to provide written informed consent upon arrival. The whole CoP event will be recorded as one data collection method and the method of recording (videotaping or note taking) will be based on the group's preference.

Observations of FaME classes

All PSIs who deliver the FaME classes will be asked if they would agree to being observed for up to two classes per instructor. The first observation will take place early in the implementation phase and the second will occur towards the end of the programme delivery period. It is anticipated that there will be up to 30 observations in total. Written informed consent will be obtained from the PSIs prior to the observations. PSIs will notify their class attendees verbally regarding the observations both the week before and on the day of the observation, with assurance that the observations are of the instructor and class delivery rather than their participation. Observations will last the duration of the class, and will be monitored using a programme fidelity checklist as a content guide to assess FaME delivery consistency and quality as provided by the PSIs.

Routinely collected quantitative data

Quantitative data will be routinely collected by the service providers from all people participating in the FaME classes; it is anticipated that this will be a maximum of 650 people. Data collected will

include attendance, functional ability, number of falls, balance confidence and physical activity. The data will be shared with the research team on an anonymised basis under information sharing agreements.

The following functional assessments will be used:

- Functional Reach[29] as a measure of balance and falls risk
- The Turn 180[30] as a measure of dynamic postural stability and falls risk
- Timed get-up and go (TUG)[31] as a measure of balance, mobility and falls risk

The following self-reported clinical outcome measures will be used:

- Falls Risk Assessment Tool (FRAT)[32] as a measure of falls risk
- ConfBal scale[33] as a measure of confidence in carrying out a range of basic activities without falling
- Short Falls Efficacy Scale-International (FES-I)[34] as a measure of concern about falling when carrying out a range of basic activities
- Phone-FITT[35] as a measure of physical activity

In addition, service providers will also collect and share the following anonymised routine data with the research team: demographic and socioeconomic information, diagnosed co-morbidities, prescription medications, falls within the last three months (number, injuries sustained and medical care received), attendance rates and exercise difficulty progression (including balance challenge, strength progression and endurance intensity).

See Table 1 for an overview of the data collected at each time point.

Table 1 – Overview of routinely collected quantitative data, collected by service providers at different time points

	Time point			
Outcome measure	**Baseline**	**Throughout 24 week programme**	**End of FaME (24 weeks)**	**12 months post FaME**
Functional Reach	x		x	
Turn 180	x		x	
Timed get-up and go	x		x	
Falls Risk Assessment Tool	x		x	x
ConfBal scale	x		x	x
Short FES-I	x		x	x
Phone-FITT	x		x	x
Demographic	x			
Socioeconomic	x			
Co-morbidities	x			
Medications	x			
Falls in last three months	x		x	x
Attendance		x		
Exercise difficulty progression*		x		

* = including balance challenge, strength progression and endurance intensity

Data analysis

Qualitative analysis

A framework analysis[36] approach will be used for all interviews and the data from the CoP events. The first five interviews will be coded to the CFIR and Carroll frameworks, which will then be amended to reflect new topics and concepts which are evident in the data. Once all interview data have been coded to the amended frameworks, each framework will be reviewed and those aspects most pertinent to the research objectives identified. This same approach will be used for analysis of the CoP events.

Transcribed interview data and CoP recorded data will be managed using the latest version of NVivo qualitative data analysis software (QSR International Pty Ltd). All qualitative data will be coded by one researcher and then a sample will be validated by a second.

For the FaME class observations, a programme fidelity checklist, based on that used in the ProAct65+ trial[13] will be used as a content guide and findings will be summarised under identified themes. We will merge quantitative data with the qualitative data in the analysis to try to identify factors that lead to poor- and well-performing providers.

Quantitative analysis

Attendance rates (including drop-out and completion rates), exercise difficulty progression, participant demographics and socioeconomic data, co-morbidities, medications, falls incidence rate over three months, functional assessments, compliance with home strength and balance exercises and clinical outcome measures will be described using frequencies, percentages, means and standard deviations (SDs), medians and interquartile ranges as appropriate. We will assess what proportion of participants comply with the programmes inclusion and exclusion criteria as set out in the service specification provided by commissioners. Outcomes will be compared between baseline, the end of the 24 week FaME programme and 12 months post FaME to allow comparison with the clinical benefits of FaME found in previous trials. The functional reach, Turn 180, TUG, FRAT, ConfBal scale and Short FES-I will be compared using paired t-tests (or non-parametric equivalent as appropriate) comparing values within participants at the end of the 24 week FaME programme with their baseline values and comparing values 12 months post FaME with baseline values. The proportions of participants reaching the recommended government target of at least 30 minutes of

moderate or vigorous activity at least five times per week[12] will be compared using McNemar's test comparing values at the end of the 24 week FaME programme and at 12 months post FaME with baseline values. The rate of falls over three months will be compared using conditional Poisson or negative binomial regression as appropriate comparing values at the end of the 24 week FaME programme and at 12 months post FaME with baseline values. In addition multi-level models will be used to analyse changes compared with baseline accounting for clustering, as participants are attending different FaME classes. The multi-level models will be linear models for continuous outcome variables, logistic models for binary outcome variables and negative binomial models for falls incidence rates. Numbers and percentages of participants with missing data will be reported for all time points. We will use multiple imputation to replace missing values at baseline or follow-up and will compare results from analyses of multiply imputed data with the results of the complete case analyses.

We will assess whether there are differential effects by age (less than 75 years/≥75 years), ethnicity, study site and sex for the outcome measures by adding interaction terms to the multi-level models, although this will be hypothesis generating as it is unlikely that we will have enough study power to detect these interactions.

All quantitative analyses will be conducted using the latest version of Stata (StataCorp, College Station, Texas, USA).

Sample size

Exercise programme users (up to 30), service providers (up to 30), referrers (up to 15) and commissioners (up to 15) will be recruited for qualitative interviews, based on the achievement of thematic saturation.[37]

Quantitative data will be routinely collected by the service providers from up to 650 people as part of programme delivery. Based on a previous FaME clinical trial[13], this number of people means the PHISICAL study will have at least 80% power (5% significance) to detect:

- An increase of 5% from 40% before the FaME programme to 45% after in the proportion of participants doing at least 150 minutes of moderate or vigorous physical activity per week, assuming the proportion of discordant pairs is 0.15.
- A reduction in the mean ConfBal score of 0.5, assuming SD of 4.0.
- A difference of 0.1 in the FRAT score, assuming SD of 0.9.

- An incidence rate ratio of 0.75 (25% reduction in rate of falls) based on a negative binomial distribution.

These are based on the null hypotheses of no difference in the outcome comparing values before and after the 24 week FaME programme.

DISCUSSION

The implementation of complex interventions such as FaME remains poorly understood. This study will use qualitative and quantitative methods to explore its implementation when commissioned routinely as a community service. This will address the gap in the literature regarding how FaME can be implemented most effectively and whether the clinical benefits found in previous trials, including reduced falls and increased physical activity [13 16 18] translate to the 'real world' setting. This could in turn provide data that will be useful in the development of return on investment tools and will inform current UK commissioning recommendations on falls prevention interventions.[9]

The findings from this study will be used to develop a toolkit of resources and guidance to inform the commissioning and delivery of FaME. The research team will ask service providers and commissioners to provide the documents used during the implementation of FaME and will update these based on the findings of the study. The toolkit will include items such as a business case, service specification, service-level agreements, promotional materials (e.g., leaflets used to recruit exercise programme users), quantitative routine data collection booklets and other forms/letters that were developed locally. Additionally, the toolkit will contain an evidence summary of the factors that influence the successful implementation of FaME in the community.

It is anticipated that the toolkit of resources and guidelines, developed from the findings of this study, will inform the commissioning of future FaME programmes in the UK and wider rollout across the health economy. This study therefore has the potential to inform public health prevention strategies, and in doing so reduce the number of falls and increase the quality of life of the older population, whilst delivering essential cost savings to health and social care services.

CONTRIBUTORS

The study was conceived by EO, DK, JG, PL and DS. HC and EO drafted this manuscript in consultation with all co-authors. All co-authors critically reviewed and approved the final version of this manuscript and response to reviewers' comments.

ACKNOWLEDGEMENTS

The study team would like to acknowledge the planned commitment from the Patient Public Representatives and Steering Group members to the oversight and interpretation of the research findings.

COMPETING INTERESTS

Dawn Skelton is a Director of Later Life Training, a not for profit training provider, delivering training to PSIs in delivery of the FaME programme. DS will not have access to any raw quantitative data to look at efficacy, and will not attend any CoP events or be able to influence the results or analysis of the study. DS will however, have access to raw data on quality assurance of the PSIs in order to provide feedback on fidelity and quality of teaching.

FUNDING

The research was funded by the NIHR Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC EM) and Leicestershire County Council. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

ETHICS APPROVAL

London-Chelsea Research Ethics Committee, reference number 16/LO/0396.

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