PHIRST Insight

Protocol: Formative process evaluation of the Falls Management Exercise (FaME) Programme in Lincolnshire

Version 2

Funder	National Institute for Health and Care Research (NIHR) PHIRST
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Background

Falls Management Exercise (FaME) Programme

People aged 65 years and over are at risk of falls and fall-related injury. In the UK 30% of people over 65, and 50% of people over 80, fall at least once a year, bringing the risk of injury, pain, distress, loss of confidence and independence to older adults and their family and carers, as well as significant cost to the NHS. [1]. Injuries as a result of falling are often minor, but one in ten lead to bone fractures, a leading case of mortality in those over 65 [2, 3]. Falls are the most common reason for death from injury amongst the over 75s [1].

In 2018-19 there were over 220,000 emergency hospital admissions as a result of falls among adults over 65 in England, and the total annual cost of fragility fractures to the UK has been estimated at £4.4 billion which includes £1.1 billion for social care [4].

Falls and fracture risk increases with age owing to a decline in muscle strength, balance, and physical function [5, 6]. This risk can be reduced by strength and balance exercise [7]. The National Falls Prevention Coordination Group Falls and Fractures Consensus statement recommends that the optimum approach for the majority of older people living in the community with a low to moderate risk of falls should include strength and balance exercise programmes, which have been shown to be effective [8].

The Falls Management Exercise (FaME) Programme is a 24-week community-based postural stability programme. It delivers exercise classes supervised by a Postural Stability Instructor (PSI) combined with home-based exercise. FaME's components include functional floor and gait skills, with endurance, flexibility and strength and balance exercise [9]. It has been shown in clinical trials to increase physical activity and prevent falls [10, 11] and is one of only two structured exercise programmes supported by Public Health England (PHE) Cost-effective Commissioning (2018) for falls prevention [12]. A randomised controlled trial comparing FaME with usual care and the Otago Exercise Programme found it reduced the incidence of falls, and increased physical activity, at 12 months [13] and has also been shown to be effective in a 'real world' setting, although improvements in strength and balance, confidence and concern about falling seen at the end of the 24-week programme were mostly not maintained six months later, and participant attrition was high [9]. A national audit across England showed where falls services used the FaME programme, the duration and dose were often inadequate, and referrals from rehabilitation services to continuing community-based FaME programmes were lacking [14, 15]. A mixed-methods study of the implementation of FaME across 29 programmes in the East Midlands (the PHYSICAL study) found that only 40% of participants completed at least 75% of the intervention, and only 24% made the expected strength and training progression [16].

FaME in Lincolnshire

Lincolnshire is a very large, rural county, the fourth most sparsely populated county in England. Poor road and rail infrastructure and 80km of coastline lead to fundamental difficulties in the provision of services. Nearly one quarter of the population are aged 65 and over. Lincolnshire is ranked 91st out of 152 upper tier local authorities in the Index of Multiple Deprivation (IMD) in England, where 1 is the most deprived. However, Lincolnshire also hosts 29 of the most deprived lower-level super output areas (LSOA), in the 10% of all the 32,844 used in 2019 to measure overall deprivation in England [17].

Lincolnshire Clinical Commissioning Group data identified over 50,000 people recorded as frail based on Electronic Frailty index (EFI), accounting for nearly 7% of the population. In 2019/20 there were 3,305 emergency hospital admissions of Lincolnshire residents aged 65 and over because of falls and 67% of these were in people aged over 80. This generated an estimated cost of over £11.1m. There were also 7,705 ambulance callouts for people who had fallen and needed to be picked up from the floor and 69% (5,319) of these were conveyed to hospital¹. Lincolnshire's most recent Joint Strategic Needs Assessment (JSNA) identified a gap in service provision of strength and balance training [18]. As a result, Lincolnshire County Council (LCC) have commissioned One You Lincolnshire to deliver the FaME programme across the county, commencing in May 2023. The aims of the service are: a) to reduce the health impact and healthcare burden of falls and fall-related injuries in the older population and address a key indicator of frailty, b) to achieve this by delivering an evidence-based (FaME) community exercise programme to appropriate at-risk individuals, and c) to provide learning and evidence of what operational model is most suitable for Lincolnshire to inform future commissioning decisions.

While FaME is a tried and tested intervention that has been shown to reduce the rate of falls, increase physical activity levels and improve wellbeing, poor infrastructure, rural and coastal geographies, and deprivation may present particular challenges to the implementation of FaME in Lincolnshire. LCC are therefore keen to understand whether good outcomes can be achieved, and maintained, in Lincolnshire. Undertaking a process evaluation of FaME may help identify whether barriers arise in Lincolnshire which may hinder the acceptability and implementation of any wider roll out [19].

The aim of the current study is to conduct a formative process evaluation to optimise the implementation of FaME across Lincolnshire which will provide evidence of what operational model is most suitable and inform future commissioning decisions. This includes identifying what effective implementation of FaME looks like, and how it might be maintained.

The research questions to be addressed are:

- 1. How is FaME being delivered in Lincolnshire?
- 2. Is the FaME intervention accessible and acceptable to the intended target population?
- 3. What are the outcomes for those who complete the FaME intervention, and how are these achieved?

The process evaluation will use the RE-AIM framework [20] (Reach, Effectiveness, Adoption, Implementation and Maintenance) to identify lessons to inform future roll-out of FaME in Lincolnshire (which may also be applicable to other similar localities).

The known costs of running the FaME intervention in Lincolnshire, alongside the number of participants completing intervention, will also be reported at the end of the study.

¹ LCC PHE Intelligence, September 2021, cited in the service specification document for FaME in Lincolnshire

The intervention logic model

FaME is a 24-week programme aimed at the over-65s comprised of hour-long group sessions with 10-12 participants delivered by qualified Postural Stability Instructors (PSIs) in community venues. Essential intervention content has been identified in previous studies and is summarised in Figure 1 below:

1. Challenging balance (reducing support and hand hold, move from static to dynamic balance exercise as quickly as possible.

2. Progressive strength training, increasing exercise band resistance at least three times over the six-month period. Adequate repetitions/sets for strength gains.

3. Teaching safe transition (e.g. foot pedal on rising to pre-empt postural hypotension, careful turns on 180° and behind chair so participants will learn to be safer in transitions at home).

4. Having all 7 evidence-based components in place (dynamic endurance, dynamic balance, progressive strength training, getting down and up from the floor (backward chaining), floor work, flexibility, Tai Chi moves.

5. Home exercise packs provided and reminders to do home exercise given (to meet effective dose requirements).

6. Backward chaining and floor exercises delivered as soon as possible in the programme (within the first 12 weeks). These exercises help avoid long lies after falls and increase confidence and reduce fear of falling.

Figure 1. Six key elements of FaME [16, 21]

The intervention is being delivered by One You Lincolnshire (OYL), which is funded by Lincolnshire County Council to deliver a range of health and wellbeing services across the county. It is planned that each session will be followed by a half-hour informal social session (tea and chat). Participants will also be encouraged to exercise at home (an exercise booklet will be provided, alongside access to OYL's online app) with the intention that participants complete 50 hours' worth of exercise over the 24 weeks. Towards the end of the intervention, maintenance of physical activity will be encouraged by signposting towards OYL's 'Move More' pathway (six 1:1 sessions with a trainer, circuit classes, and/or 12 weeks free gym membership), and a digital gym service. OYL also plan to signpost to other physical activity opportunities and groups run by other agencies across the county.

Referrals onto the FaME programme will be made by a health professional (participants cannot selfrefer). It is planned that LCC will use their Population Health Management (PHM) dataset to identify a cohort of over-65s at risk of falls. This cohort will be shared (via the Commissioning Support Unit; LCC do not have direct access to NHS patient data) with Primary Care Networks (PCNs) in Lincolnshire and GP practices will manage referrals to the programme. This referral procedure is independent of the evaluation (usual practice) and the study researchers at the University of Bristol will not influence this process or have access to PHM data. The intervention rollout will begin in May 2023, with the intention that up to 400 participants will complete the programme by June 2024.

The PHYSICAL study [15, 16] developed a logic model for the FaME intervention [16]. The model was adapted for the current study following consultation with staff from LCC Public Health team, staff

from One You Lincolnshire delivering the programme, and two public representatives from Lincolnshire who advised on the development of the study protocol. The logic model for the FaME intervention in Lincolnshire is shown in Figure 2.

Assumptions for the model include the following:

Effectiveness

- Participants are at high risk of falling and inactive at the start of the intervention.
- Participants make expected physical and psychological improvements.
- Physical improvements lead to a reduction in falls.

Fidelity

- PSIs adhere to the FaME programme, with progressively difficult exercises.
- Participants adhere to the FaME programme (continue for 6 months, do home exercises).
- Commissioners commission programmes with adequate dose, frequency and duration.

Barriers/facilitators

- There is a pool of level 3 instructors available to train.
- The trained instructors stay local/continue to be available to public sector.
- People want to exercise.
- People want to exercise in groups.
- Referrers know about FaME.
- Referrers believe FaME is effective.
- People can get to the courses (transport, venue locations, cost).
- Suitable venues are available to deliver FaME in Lincolnshire.
- Instructors have time to talk to participants, building a good relationship.
- People get on with each other during groups/there are opportunities to bond as a group.

Figure 2: FaME in Lincolnshire Logic Model

Inputs	Activities	Outputs	Causal Mechanisms	Short Term Benefits	Long Term Benefits			
InputsFunding (Covid reserves)Infrastructure: Postural Stability Instructor (PSI) staff VenuesEquipment Digital offer - Gloji gym Printed resources. FaME commissioning toolkitDelivery co- ordination: One You Lincolnshire, Integrated Lifestyle Service	ActivitiesService Specification DevelopedRecruitment of level 3 InstructorsTraining: Postural Stability Instructors (PSI)Behaviour ChangeMake Every Contact Count (MECC)Caseload management systemIdentification of cohorts via PHMFaME delivered: Courses scheduled. Identification and	OutputsUpskilled workforcePeople have attended 6-month FaME programmes.Assessments and data collection at baseline, completion, and 3 months after the completionFollow up for people who not completed done and recorded.Participants signposted to after programme activities (including Move more)	Causal MechanismsRecruitment and training results in an increased pool of PSIsPeople receive up to full 6 month 'dose' of classes.Classes are progressive and tailored, following the FaME programme.Group sessions are social and people bond as a group.Physical activity improves physical and mental wellbeing.	Short Term Benefits Health benefits: People become more physically active. Strength and balance improve. Fear of falling decreases Confidence in daily activities improves. Carer/family Benefits. Wider benefits: People less socially isolated Increased awareness of local 'offer' - services and activities Improved mental wellbeing. Improved quality of life Improved digital skills.	Long Term Benefits Less use of healthcare: Fewer falls Fewer emergency hospital admissions Better long-term condition management Less use of social care: Continued independence. Unintended effects: Increased risk-taking.			
Service Population Health Management Dataset (PHM) Engagement with Primary care Networks (PCN)	Identification and enrolment of older people onto courses Assessments undertaken. FaME course delivery	(including Move more pathway at OYL)	Classes delivered across the county proportionally to population needs. Supportive relationship PSI/participants	System benefits: Improved understanding of barriers to participation in exercise programmes by older people. Workforce upskilled. Evidence led commissioning.				

Methods

The study is a mixed-method formative process evaluation using routine data collected by One You Lincolnshire while the intervention is being delivered, and qualitative interviews with programme commissioners, those referring participants onto FaME, delivery staff, participants and their carers, and structured observations of FaME sessions. The research questions to be addressed are:

RQ1. How is FaME being delivered in Lincolnshire?

This will include an exploration of the following:

- a. Whether the programme is delivered as described both in the programme description and in the logic model.
- b. Delivery of essential intervention content.
- c. Referral pathways.
- d. Adaptions to FaME implementation toolkit.
- e. Training and support, and retention of Postural Stability Instructors.
- f. Identification and suitability of delivery venues.
- g. Post-intervention pathways.
- h. Nature of FaME classes and interactions between participants/PSIs

RQ2. Is the FaME intervention accessible and acceptable to the intended target population?

a. Participant numbers who begin FaME, demographics, functional fitness and history/risk of falls

- b. Number of referrals and appropriateness.
- c. Completion and attrition rates.
- d. Barriers to referrals.
- e. Barriers to participation.
- f. Geographical spread (rural/coastal) and match to population need.
- g. Participant and family/carer perception of FaME.

RQ3. What are the outcomes for those who complete the FaME intervention, and how are these achieved?

- a. Change in functional measures.
- b. Change in physical activity measures.
- c. Change in falls (actual, and fear of).
- d. Quality of life measure, social isolation/loneliness.
- e. Other outcomes including use of physical activity services and activities; digital skills.
- f. Post-intervention support and maintenance of physical activity
- g. Stakeholder perceptions of the causal mechanisms of outcomes attributed to FaME.

All three research questions will be addressed with particular regard to health inequalities using the <u>Health Inequalities Assessment Toolkit</u>.

An overview of the research methods is shown in Figure 3 below.



Figure 2: Overview of research methods

Co-production activity

Lincolnshire County Council and One You Lincolnshire have been fully involved in the development of the protocol. The original logic model for FaME [22] was refined as described above. A research management group has formed, comprised of staff from the PHIRST Insight team, LCC Public Health team, One You Lincolnshire, Age UK Lincolnshire, and two public representatives who live in the county and have experience of being, and working, with older adults. The group jointly agreed the aims of the study and the research questions outlined above, and the study methodology. It will continue to meet monthly when the study begins, with oversight over study progress and outputs.

In addition, the two public representatives have commented in detail on all the research tools designed for use with FaME participants, including information and recruitment materials, and topic guides.

Routine Data Collection

One You Lincolnshire have been commissioned to collate a range of data monitoring the delivery of FaME and outcomes for participants. Anonymised data will be shared with the study mid-way through the intervention period and after the end of the intervention period.

Delivery monitoring data to be collated includes:

- Total referral numbers, and number of inappropriate referrals
- Waiting list numbers
- Number, location and start date of FaME sessions
- Number of participants starting FaME; attendance, completion and attrition rates.

Participant data collection includes:

- Demographic data: age, gender
- Functional measures (T1 pre-intervention; T2 end of intervention; T3 3 months post-intervention)
 - Timed Get Up and Go (TUG) [23]
 - Functional Reach [24]
 - The Turn 180° [25]
- Resistance band colour progression during intervention
- Self-reported clinical outcome measures: (T1 pre-intervention; T2 end of intervention; T3 3 months post-intervention)
 - Short Falls Efficacy Scale (FES-1) [26]
 - Confidence and Balance Scale [27]
- Self-reported physical activity level post-intervention
- Self-reported number of falls in previous three months
- Self-reported quality of life (T1 pre-intervention; T2 end of intervention; T3 3 months postintervention) using the EQ5D5L measure
- Number of participants entering the Move More pathway post-intervention

FaME participants will be provided with a participant information sheet (PIS) on referral to FaME (OYL will support this) and a consent form agreeing to sharing anonymised data with the study team. Participants who do not consent to the study will take part in FaME but OYL will remove their data from the dataset before sharing with the study team.

Qualitative interviews with programme commissioners and managers (N=3)

Questions about how the FaME programme is being delivered (RQ1), with reference to the logic model, intervention content, referral pathways and post-intervention support will be explored through qualitative interviews with programme commissioners in LCC Public Health, and the programme manager based within OYL (N=3). Two rounds of interviews are planned, one towards the start of the implementation period, and the second towards the end. Detailed topic guides will be developed, which in the first round of interview will include questions on the implantation of FaME with reference to the FaME implementation toolkit, the recruitment and training provided to Postural Stability Instructors, roll-out progress (and barriers), referral pathways, uptake, attrition, programme fidelity and the post-intervention pathway. The second round of interviews will review programme fidelity, rollout of the intervention, collection and review of routine monitoring data, uptake, attrition, post-intervention pathways and potential adaptions to the programme or its implementation for any future roll out.

Participants are known to the study team. They will be sent a PIS and consent form in advance of the interviews, which it is hoped will take place face-to-face at a time and venue agreed with participants.

Qualitative interviews with referrers (N=10)

Referrals onto the FaME programme will be made by a health professional based within one of Lincolnshire's 15 Primary Care Networks. To date it is unclear how the referral process will be managed within Primary Care Networks, whether GPs or other healthcare staff speak directly with potential participants or send an invitation letter for example. Although the evaluation will have no influence over this referral process, understanding it and the impact on recruitment and retention, is a key aspect of RQ1. The study will seek to interview up to 10 staff from PCNs referring to FaME, who may be GPs, nurses, occupational therapists, for example, or the GP practice manager. An email

will be sent by Lincolnshire public health team to GPs practices referring to FaME with a PIS, inviting potential participants to contact the research team if they would like to participate. It is planned that these interviews take place online (MS Teams) and last up to 30 minutes. Participants will be offered a £30 High Street voucher for taking part.

FaME Postural Stability Instructors (N=4; N=6)

OYL have plans in place to recruit and train four PSIs to deliver FaME across the county, with the potential for this number to increase. Qualitative interviews will be undertaken with PSIs towards the start of intervention roll out (N=4), and again towards the end (N=6). These interviews will inform RQs 1 and 2. Topics to be explored in the first interview will include PIS's professional background, training and support required to deliver FaME, the delivery of FaME and intervention fidelity, engagement of participants in class and with home exercise, their progression and outcomes, post-intervention pathways, and PSI's perception of the FaME intervention. The second interviews will revisit much of this but also explore aspects of attendance and attrition, implementation challenges specific to Lincolnshire, participant outcomes (and causal pathways) and potential changes to programme intervention to inform any future roll-out.

PSIs will be invited to interview through an email (with support from OYL) and invited to contact the research team and arrange a suitable time and place for face-to-face or online interview, whatever is preferred. Detailed PSIs and consent forms will be provided.

FaME participants (N=30) and family members/carers (N=10)

Participant experience and perception of FaME is particularly important to RQs 2 and 3. The study will interview a sample of 30 participants at a range of stages of involvement in the intervention. This will include within eight weeks of starting FaME classes (N=6 to capture experience of referral and starting the intervention); within three weeks of completing FaME (N=8 to explore perceptions of the intervention, outcomes, and post-intervention pathways); at least 12 weeks post-intervention (N=8 to explore outcome sustainability and post-intervention pathways) and those who drop out of the intervention before completion (N=4 to explore reasons for attrition). If possible, we would also like to interview those who are referred to FaME but decline to attend (N=4) to explore reasons why.

Recruitment will be supported by OYL and participants will be provided with a detailed PIS and an invitation to contact the research team if they would like to take part. Participants will also be recruited during observations of FaME classes, where the researcher will be available to answer further questions if necessary. For those recruited during the intervention, PSIs will be asked to distribute the PIS during classes. For those recruited post-intervention, OYL will inform the participants about the study and potential for involvement during their routine 3-month follow-up call; the PIS will be sent out to those participants if they express interest in taking part. OYL will also send the PIS and invitation to participate to those who drop out of the intervention on behalf of the study team. Interviews will take place face to face at a time and venue agreed with the participant (this may be their home) and are expected to last up to 45 minutes. Topic guides will be developed that include questions on;

- Physical activity levels, history of falls
- Referral to FaME
- Reasons for attending/not attending
- Quality of information provided about FaME
- Practicalities of attending
- Experience of FaME classes
- Perception of PSI
- Activities after class (socialising)
- Exercise outside classes

- Outcomes including functional changes, confidence, falls, other outcomes e.g. digital skills.
- How these were achieved what made the difference
- Impact on quality of life and continued independence
- Staying in touch with other participants
- Reasons for non-completion
- Post-FaME physical activity/other engagement
- Any suggested changes to FaME

Should more participants express an interest in taking part than required, we will select a purposive sample ensuring variety across gender, age, and geographical location.

Where possible, and in agreement with the participant, we would also like in up to 10 cases a family member and/or carer to be present during the interview, to understand their perspective on the FaME intervention and its impact on participants as observed by carers, and family and carers themselves.

Participants (including carers where present) will be offered a £30 High Street voucher for taking part. It is anticipated the interviews will last up to 45 minutes (and up to 60 minutes where a carer is present).

Structured observations of FaME sessions.

Structured observations of classes have been undertaken in other studies of the FaME intervention. Observation can help identify how FaME is being delivered and whether the core elements of the programme are in place. Observations can also capture details of the physical environment (accessibility and suitability) and the nature of interactions between participants and instructors. Finally, observations may also be used as another method to recruit FaME participants to qualitative interviews.

An observation checklist for this will be developed as part of the co-production work at the start of the study, and will include description of the venue (location; size; availability of natural light, area for socialising afterwards), participant and PSI interactions on arrival and throughout, including level of 1:1 interaction, interaction between participants, pre- and post-class activity, participant engagement with exercise, and clarity of instruction. Eight classes will be observed, ensuring variation across PSI instructor, venue, and point in the 24-week programme. No single group will be observed more than once.

Participants will be informed by the PSI the week before the class observation that a member of the study team will be attending during the next class. Participants will be provided with a PIS during this time. Verbal consent will be sought by the PSI, and again by the researcher before the start of the observation. Should any participant decline to be observed, the observation will not go ahead.

Analysis

All qualitative interviews will be fully transcribed, and we will work from these transcriptions during our thematic analysis. We will use the Framework method of thematic analysis [28]. Following a review of the transcripts, we will develop a draft conceptual framework that includes the key themes and sub-themes that emerge from the data for each group of stakeholders (commissioners

and managers, referrers, PSIs and FaME participants). These thematic frameworks will be used to code the data, assigning both verbatim and summarised excerpts of the transcript to one or more theme or sub-theme. The draft frameworks will be tested by members of the research team with a small number of transcripts and amended as necessary until the team are assured that the frameworks emerge from and 'fit' the data. That is to say, the thematic framework will be driven by and emerge from the data rather than the other way around. In this sense, the analysis will be 'grounded' in the data. At the same time, the framework will need to fit the study objectives and research questions (abductive approach).

Once the analytical frameworks are finalised, we will adopt a systematic approach to data management, coding the transcripts into the framework using NVivo software. Once all the transcripts have been coded, the team will have a detailed and accessible overview of the data populating each theme and sub-theme from every respondent.

Analysis of the quantitative routine data will be descriptive in nature as there is no control group with this study. Differences in outcomes (functional measures, physical activity levels, experience of falls and quality of life measures) will be compared across all three times (pre intervention; end of intervention and three months post-intervention).

Data Management

The University of Bristol will be the data controller for this study. The project will generate quantitative datasets, in the form of anonymised participant data, and qualitative datasets, in the form of interview transcripts. A data sharing agreement will be agreed between the university of Bristol and OYL before routine monitoring data is shared.

All participant data collected by OYL will be pseudonymised (names, contact details and postcodes will be removed and unique participant ID numbers assigned) by OYL team before being shared with the University of Bristol team.

Interviews will be recorded on encrypted digital audio recorders. Audio files from interviews will be uploaded to a restricted access folder on the University of Bristol server, as soon as is reasonably possible following an interview. Once uploaded, they will be securely deleted from recorders. Transcription will be undertaken by an external transcription company that has been approved to process data subject to the Data Protection Act, for which the University is the data controller. The company has entered into a formal "Personal Data Processing Agreement" drawn up by the University Secretary's Office. The University of Bristol project team, including those who may become part of the team in the future, will have access to the study data and will be able to comment on data at the analysis stage. Access to data will be restricted to these individuals. To enable anonymity, transcripts will have a unique identifier in the filename, which will be replicated on a transcript cover sheet that will also include interview location and anonymised interviewee details. No paper copies of transcripts will be made.

All data analysis will take place on password protected University laptops. No data will be stored on laptops but instead on the University's secure Research Data Storage Facility (RDSF) accessed via the University VPN.

In accordance with Research Councils UK guidance, all consent forms will be stored securely in electronic form for a period of 10 years. After 10 years, the forms will be deleted from servers. Anonymised data will not be destroyed following completion of the study but restricted access on reasonable request will be kept available for future research in 'data.bris' the University's publicly

accessible Research Data Repository. Consent for this will be explicitly sought on participant consent forms.

Sponsorship, Ethics and Regulatory Approvals

The study will be sponsored by the University of Bristol. The study will require an ethical approval from an NHS Research Ethics Committee and will also seek HRA approval. This ethics approval will ensure that issues of confidentiality, consent, anonymity, safeguarding and data management are appropriately addressed across all aspects of the research process including recruitment, data collection, analysis and dissemination.

The study received HRA approval on 7th August 2023 (ref 23/LO/0554).

Strength and balance training is not a sensitive topic, and our target populations are not particularly vulnerable groups. Discussion about experience of falls and their impact may be sensitive and we will use caution when broaching this topic. Participants will be reminded that they do not need to answer those questions if they do not want to. The University of Bristol based researcher has substantial experience in conducting health-related research interviews and of conducting interviews on sensitive topics.

In addition to scrutiny from the Sponsor and the REC and HRA we have consciously incorporated the involvement of local stakeholders as co-producers of our research tools to increase their relevance and help minimise any negative consequences for participants.

Indemnity

The University of Bristol has arranged Clinical Trials Insurance to cover the legal liability of the University as research Sponsor in the eventuality of Harm to a research participant arising from management of the research by the University. This does not in any way affect the responsibility of an NHS Trust, Local Authority or their commissioned provider(s) for any negligence on the part of their staff.

Adverse Event Reporting

One You Lincolnshire staff are responsible for managing any and all incidences of adverse events (untoward medical occurrence) that occur as a result of the FaME intervention.

Should any member of the study team become aware of an Adverse Event affecting a study participant during contact with them for qualitative interview, a record of this that includes details of the nature, seriousness, severity, causality and expectedness of the event will be reviewed by the study Chief Investigator. Any Serious Adverse Events will be recorded and reported to the Sponsor not more than 24 hours after the study team become aware of the event. Safety reporting for UoB Sponsored studies is managed on our behalf by University Hospitals Bristol and Weston, in accordance with their Safety Reporting Standard Operating Procedure (SOP).

Outputs

PHIRST Insight have developed a Dissemination, Impact, Involvement, Communication and Engagement (DIICE) template (Appendix 2), which will be completed for this study in partnership local stakeholders including from Lincolnshire County Council, One You Lincolnshire, Age UK, and our

public representatives. This will ensure that study outputs are accessible and relevant to a range of audiences. We anticipate that outputs will include:

- A short report for the local authority
- Public-facing summaries of the findings (available online, and in print)
- Online video summarising the findings
- Peer reviewed journal article of process evaluation findings
- Academic conference presentation

The <u>FaME Implementation Toolkit</u>, a resource for FaME commissioners and providers, is currently under revision and the academic lead for that process (who sits on the Advisory Group for the current study) has requested that findings from the current study inform the updated toolkit.

Timeline

	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24
Mobilisation period for FaME implementation																				
FaME Implementation																				
Ethics and submission to NHS REC			x	x	x															
Routine data collection						x	x	x	x	x	x	x	x	x	x	x	x	x		
Interviews with commissioners and managers						x	x									x	x			
Interviews with referrers									x	x	x	x								
Interviews with participants and carers							x	x	x	x	x	x	x	x	x	x	x			
Interviews with PSIs						x	x									x	x			
Observation of FaME sessions							x	x	x	x	x	x	x	x	x					
Analysis											x	x	x	x	x	x	x	x		
Reporting and outputs																			x	x

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