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Implementation fidelity of the Falls Management Exercise (FaME) Programme; a mixed methods analysis using a conceptual framework for implementation fidelity

Abstract

Objectives

Falls in older adults cause significant morbidity and mortality and incur cost to health and care services. The Falls Management Exercise (FaME) programme is a 24-week intervention for older adults that in clinical trials improves balance and functional strength and leads to fewer falls. Similar, but more modest outcomes have been found when FaME is delivered in routine practice. Understanding the degree to which the programme is delivered with fidelity is important if 'real world' delivery of FaME is to achieve the same magnitude of outcome as in clinical trials. The objective of this study was to examine the implementation fidelity of FaME when delivered in the community, to inform quality improvement strategies that maximise programme effectiveness.

Study design

A mixed-methods implementation study of FaME programme delivery.

Methods

Data from programme registers, expert observations of FaME classes and semi-structured interviews with FaME instructors were triangulated using a conceptual framework for implementation fidelity. Quantitative data were analysed using descriptive statistics. Interviews were transcribed verbatim and analysed using thematic analysis.

Results

In total 356 participants enrolled on 29 FaME programmes and 143 (40%) participants completed at least 75% of the classes within a programme. Observations showed that 72%-78% of programme content was delivered and 80%-84% quality criteria were met. Important content that was most often left out included home exercises, Tai Chi moves and floor work, whilst quality items most frequently missed out included asking about falls in the previous week, following up attendance absence and explaining the purpose of exercises. Only 24% of class participants made the expected strength training progression. Interviews with FaME instructors helped explain why elements of programme content and quality were not delivered. Strategies for improving FaME delivery were established and helped to maintain quality and fidelity.

Conclusions

FaME programmes delivered in the 'real world' can be implemented with a high degree of fidelity, although important deviations were found. Facilitation strategies could be used to further improve programme fidelity and maximise participant outcomes.

Keywords

Older adults, Implementation Fidelity, Falls, Exercise, Intervention

Introduction

Ageing is associated with declines in muscle strength and balance which impair physical function and increase disability and falls risk.^{1 2} Approximately a third of older adults aged over 65, and half of adults aged over 80, fall each year in the UK, costing the National Health Service £2.3 billion in the treatment of injurious falls.³ A recent Cochrane review reported that exercises to improve balance and functional strength reduce the rate of falls by 24%,⁴ and strength and balance exercise programmes are recommended in England for falls prevention for older people living in the community with a low to moderate falls risk.³

Understanding how well evidence-based interventions are implemented in practice i.e. the fidelity of an intervention as intended by the programme developers,⁵ is important when interpreting their outcomes. For example, if an intervention appears to be ineffective when implemented in practice, it could be because it is indeed ineffective, or it could be because it was not delivered as intended. This is particularly relevant for exercise programmes to prevent falls because to be effective they require a minimum “dose” (at least 50 hours in total) and the inclusion of highly challenging balance and progressive strength training.⁶ That said, fidelity assessment in behavioural interventions is not universally reported. A 2015 systematic review of fidelity of behavioural interventions found only 44% of studies reported the extent to which the intervention was delivered as intended.⁷ A further recent systematic review criticised the conceptualisation and measurement of fidelity of physical activity interventions as lacking attention, consistency and rigour.⁸ These reviews report assessments of intervention fidelity within the usually tightly-controlled environments of research studies. Achieving fidelity of interventions delivered in “real world” settings outside of research studies is likely to be even more challenging.

Carroll and colleagues have developed a conceptual framework for implementation fidelity.⁹ Framework elements include adherence (content, coverage, frequency and duration), moderators (intervention complexity, facilitation strategies, quality of delivery and participant responsiveness) and the identification of essential components of the intervention. Here we use this conceptual framework to assess the fidelity of a 24-week group-based strength and balance exercise programme for older people (The Falls Management Exercise (FaME) programme). In randomised trials the FaME programme increases physical activity, improves balance confidence and reduces the rate of falls amongst community dwelling older adults.¹⁰ We have previously shown that this efficacy is translated into effectiveness in practice, but with more modest outcomes.¹¹ We describe the fidelity of FaME in these same programmes using the framework described by Carroll et al.

Methods

Design

We studied 29 FaME programmes delivered in the East Midlands region of England, UK between 2016-17, using a mixed-methods triangulation study design.¹² Data were derived from *in vivo* observations of FaME classes, in-depth interviews of postural stability instructors (PSIs) who deliver the FaME programme¹³ and information from routine data collected in class registers. By combining data from different sources, we were able to build a comprehensive picture of the programme fidelity components set out by Carroll et al.^{5 14}

Study site

The programmes were in three geographically and demographically distinct localities: a rural unitary local authority, a large mixed urban/rural upper tier local authority with seven lower tier local authorities within its boundary, and an inner-city unitary local authority. In each locality FaME was commissioned (paid for) by local government organisations and delivered by local public sector leisure service providers.

Study participants

All PSIs delivering FaME were invited to participate in the study by email, telephone or face-to-face using snowball sampling and recommendations from key local government informants.

Data collection

FaME class observations

In vivo observations were carried out using a convenience sample of FaME classes, selected to fit with the observer's clinical diary commitments. They were undertaken at two time points (weeks 4-6 and weeks 18-22). Only one class per recruited PSI was observed at each time point. Informed written consent was sought from the PSIs for both observations prior to the first observation and checked again prior to the second. Observations lasted the duration of the FaME class (approximately 1 hour). Qualified and highly experienced PSI instructors (referred to as expert observers hereafter) undertook the observations.

Classes were assessed by the expert observers using a checklist based on that used previously in the ProAct65+ trial¹⁵ as a guide to assess the fidelity of intervention content and quality (see S1 supplementary material). Essential intervention content (for FaME) has been defined previously¹⁶ and is summarised in Figure 1. Intervention quality criteria included strategies to build group coherence, positive reinforcement and reminders of the

functional relevance of exercises, ensuring safety and good technique and providing motivational support to promote home exercise for an effective dose of exercise.

[Insert Figure 1 here]

Register data

Pseudonymised data from class registers included information on delivery location, PSI, frequency and duration of classes, attendance and exercise progression data (indicated by a record of the resistance band colour used in some strength exercises). Data were provided under a data sharing agreement between the local authorities and research team.

Qualitative in-depth interviews

Interviews took place at two time points: within 4 weeks of the 24-week programme starting and then towards the end of each programme. Interviews were either face-to-face or over the telephone (based on interviewee preference) and conducted by a researcher (NL). A semi-structured interview guide of questions and probes was used (see S2 supplementary material). Interviews ranged from 15 to 70 minutes in length, were audio recorded and transcribed verbatim. Informed written consent was obtained prior to the initial interview taking place and reconfirmed prior to the second interview.

Data Analysis

Semi-structured interviews

Analysis was undertaken once all interviews had been completed. Transcripts were read twice for familiarisation and then coded into themes based on the implementation fidelity framework. Themes were labelled as 1) Adherence, 2) Moderators and 3) Essential components, with subthemes within these identified to determine a secondary coding scheme. Regular meetings were held where authors NL, EO and ST reviewed the coded data and discussed the final coding for consistency and reliability. The transcripts were coded in the NVivo software package; NVivo 11 (QSR international).

FaME class observation

The checklist contained 27 criteria covering class preparation, content and quality. Criteria were scored as '*being observed*' or '*not observed*' by the expert observers. Criteria within the checklist were aggregated into two subgroups: those considered to be critical indicators of programme content adherence (8 criteria) and those considered to be indicators of quality (19 criteria, although only 18 were used in this analysis, excluding criterion 9 – “Ensured that infection control procedures are implemented and adhered to”, which, at the time, was only

appropriate for hospital settings). Scores were summarised as means and percentages observed for each item.

Register data

Quantitative process measures including attendance data and data relating to when exercise difficulty progressed for each participant was described using frequencies and percentages, mean and standard deviations.

Results

A total of 16 PSIs across all three sites were eligible to take part in class observations and 13 agreed to participate. Thirteen classes were observed at weeks 4-6 and 9 were observed at weeks 18-22. The lower number of observations in the second round was due to PSIs leaving their post during the study period or unavailability of the expert observers. All 16 PSIs were approached for interview, of which 11 agreed to be interviewed.

1) Implementation Adherence

a) Coverage, frequency and duration

Class register data were available for 356 class participants from 29 FaME courses. Of these, 261 (73%) were female, 138 (39%) lived alone and the mean age was 76.8 (standard deviation 8.27) years. English was the first language of 340 (96%) people and 333 (94%) described themselves as White British. Where postcode data were available (missing for 79 people), 115 (32%) people lived in the least deprived quintile of England using IMD2015 composite score and 17 (5%) lived in the most deprived quintile.

Each of the 29 courses ran for 24 weeks, with only 4 classes missed out of the total 696 scheduled and these were due to instructor holidays without cover. Classes ran for 1 hour in all sites. A total of 143 (40%) people attended 75% or more of the 24 weekly classes (categorised as programme completers).¹¹ The number of people referred to the programme or invited to participate was not recorded.

b) Content fidelity

Using the observation checklist, the maximum score for programme delivery content fidelity was 13 for the first observation visit and 15 for the second observation visit. Points were scored when criteria were observed in the class; 7 of the 8 criteria scored a maximum of one point and one criterion (c13) scored a maximum of 6 points for the first observation and 8 points for the second observation. This is because backward chaining (training on getting down and up from the floor) and floor work are usually introduced at around week 12 of the programme.

For visit 1 the overall content score was 72.3% (9.4/13) with only 1 criterion (C19) scoring 100% (see Table 1). Providing home exercises and cool down (C11, C13g) scored the lowest at 46.2% each. For the second visits the overall content score was 78%, (11.7/15) with including floor work (C13f - 44.4%) and cool down (C13g - 55.6%) scoring the lowest. The element of cool down least observed was the Tai Chi moves.

[Insert Table 1 here]

The interviews provided important context for the observations. For example, home exercise is essential if class participants are to reach the required dose, yet adherence varied. Attitudes ranged from not giving home exercises to prevent class participants being put off from returning, to recognising the importance of and actively encouraging them.

They were quite up for having homework actually, that was quite interesting... they asked for it a couple of weeks ago and I thought well actually I want them to be quite comfortable with what they're doing in the class before I give them anything to do at home so that is why I didn't give it to them immediately (SP_001).

I am really trying hard to encourage them to do two lots at home as well, they have all got a book and their own band and I do sort of check-up and the majority of them are telling me yes, they are doing bits at home (SP_004).

Exercise difficulty progression is essential, yet interview data showed that instructors censored the exercises in the class based on the participants' perceived abilities.

the guys there were a lot frailer and sort of 80-90 years old so I have not introduced getting down to the floor as yet because I know that most of them are unable to... (SP_006).

Despite reporting adherence to the programme, some PSIs described not including content components such as Tai Chi moves, backward chaining and floor exercises, because they lacked confidence in teaching them. Indeed, 11% of PSI sessions at visit 2 still had no backward chaining and 55% did not have Tai Chi moves in the cool down.

There were a couple of things that I didn't feel so sure about which were the backward training and the Tai Chi... (SP_001).

Backward chaining, it did scare me at the beginning, it was people's reaction because most people will say oh I can get down but you won't get me up, and that sort of you do worry that what if someone gets stuck on the ground. ... I think I have grown in the confidence with that part ... (SP_004ii).

2) Implementation Moderators

a) Quality of delivery

For the first visit the overall score for quality criteria was 80% rising to 84% for visit two (see Table 2). Across the two time points, most criteria either stayed the same or improved though one showed a reduction (18 - Reinforced the specific relevant teaching points at regular intervals).

[Insert Table 2 here]

From the interviews, PSIs felt that they delivered high-quality programmes. However, class size did emerge as an issue, with differing views on the optimal size, especially when classes have participants with a wide range of abilities.

So [...] I am by myself and yesterday there were 11 people.... I am quite nervous about being by myself with so many people if there is a problem... I think it would work better if there were two people when you start to try to attempt floor work (SP_004).

b) Complexity

FaME is a complex, multicomponent intervention that is delivered by highly trained staff over an extended period. Many of the PSIs interviewed were newly trained and often without experience of working with older, frail adults. Several PSIs felt that having varied abilities in the classes made it more complex to manage, requiring different paces and different levels of intensity.

They have both gone really well, a lot better than I expected because when I went for the course I thought it was a difficult course erm and I thought I was going to be really difficult bedding in and people getting to grips with it, but they actually really like it (SP_011)

It can be quite difficult because you have got people with varying levels of, you know, ability what you have also got to take in to account is you are getting people in there with different conditions as well so you can have quite a wide spread class, people have all different conditions to cope with, it is very hard to manage that in some ways (SP_005).

c) Facilitation Strategies

PSIs employed various facilitation strategies to deliver classes effectively. As part of the Implementation plan, structured 'Communities of Practice' (CoP) were established that brought together PSIs, managers and the funders (commissioners) of the FaME

programme.¹⁷ They served as a forum for networking, confidence-building, knowledge and skills exchange and were viewed positively.

....Just listening to the way other people are doing things, erm you know finding out what worked and what didn't work and numbers and endurance rates and it is interesting because some of the things that were said I didn't always agree....So yes I thought they were really useful (SP_004ii).

Although the observations were intended to be unintrusive, PSIs used them as an opportunity to acquire feedback and support, treating them as a form of peer review quality assurance.

And the Tai Chi... you know I did feel under confident about doing that, erm but I have done it and then [name of expert observer] who was the teacher, instructor on the course she came and observed me just before Christmas and she said that what I was doing is fine so that has given me confidence in that now (SP_001).

[name of expert observer] said oh ... you need to be getting them up more on their feet and she was right, I think she came about week six so I sort of put them up a level straight away, the next week we were doing a lot more on our feet and yes she gave me good feedback and you know some tips and it was just nice as a confidence thing to know that you were doing things right and yes I found it useful (SP_004ii).

Using class assistants/helpers was another facilitation strategy adopted. Having additional support allowed the PSIs to better manage the classes, e.g. dividing class participants into groups based on ability or exercise type. Whilst some did not have access to assistants they thought that having one would be an advantage.

... but having somebody else there, at least it means she can be doing the seated exercises, while I am standing because it is the same exercise but for them to have that visual aide for those that are seated, it makes it a lot better.(SP_006).

I have an assistant in the class with me, and I find it easy because we have only got 8 I think maximum and if I was to have more than that I think it would having different levels maybe harder, erm and then I would maybe look at trying to split a lower level and a higher level in the same classes but at the moment it is fine because I have got the assistant that will stand with the other person to help them and I can carry on with the others (SP_020).

d) Participant (PSI) responsiveness

PSIs were very positive about the progress that they had observed in their class participants. Whilst the programme was considered quite long, it was seen as necessary to cover the material and achieve outcomes.

It was interesting I thought that you know 24 weeks sounds like quite a long time, but actually with the people I have got you know you can't make too many changes I don't think too quickly. And I can see that it will take you know the 24 weeks to cover everything you know to really make sure that they are comfortable doing something before moving on to the next step (SP_001).

PSIs also recognised wider benefits of FaME as participants gained social as well as physical benefits from the programme.

You know it is the bit that if they enjoy it and they see benefit, that they will keep going, I think a lot of the enjoyment comes from the social aspect (SP_021).

I feel in the FaME sessions it is very the same because there is no music you can just have a little joke with them and afterwards they can have a talk and oh we did this and that and it really makes them want to come back and they are sad when they can't come back because they have made like a friendship group, especially some of them say they are on their own and it gets them out (SP_020).

e) Identification of essential components of FaME

Essential programme content observed by experts is described above (e.g. home exercise, backward chaining, floor work and Tai Chi moves). In addition, exercise difficulty progression is also essential. To achieve this FaME includes exercises that use resistance bands and the strength of resistance used should increase over time. Each level of resistance band has its own colour designation and is recorded in the weekly register for each participant. Only 24% of class participants were recorded as achieving sufficient resistance band progression (three or more band colours over the 24-week period) as shown in Table 3, although this rose to 43% in those completing the programme.

[Insert Table 3 here]

The interviews indicated that this was in part due to difficulties of managing people with different abilities within once class.

It is very difficult having some people that are much more capable than others so you're trying to sort of like keep the motivation of those people that are physically more capable in some aspects and whilst trying to cater for the people that are really quite unsteady, quite nervous (SP_001).

Discussion

We assessed the implementation fidelity of 29 FaME programmes in the East Midlands region of England using the conceptual framework for implementation fidelity devised by Carroll et al (2007). This was done by triangulating routinely collected class register data, observations of classes at two time points and interviews with PSIs delivering the programmes.

Adherence of the programme content was good (72%-78%) but important elements were often missed out, including allocation of home exercises, Tai Chi moves and floor work (specifically backward chaining; a technique to help people move from the floor to standing), and only 24% of people made expected difficulty progression. The programmes were well attended but only 40% of people completed at least 75% of the classes and class participants were not very socio-demographically diverse, being mostly White British in ethnicity, female and more affluent. Analysis of moderators of delivery showed that the quality of programmes was very good (80%-84%). Reported challenges included managing the range of abilities within a class, but instructors were encouraged by class participant progress and used Communities of Practice to share knowledge and build confidence.

Strengths and limitations

To our knowledge this is the first detailed description of FaME implementation fidelity outside of a clinical trial. Triangulation of qualitative and quantitative data enabled us to understand explanatory factors that lay beneath the numerical data and observations, providing important learning for future delivery. Most of the eligible PSIs participated in the interviews, meaning that the themes identified were generalisable to the programmes and very few data were missing from the registers.

Whilst the observation outcomes completed by expert observers was summarised into a composite score for content fidelity and quality, this has not been validated and was not weighted towards any particular elements of the programme that are thought to be more important than others. The scores were also inevitably subjective in terms of how the expert observers scored them. To minimise biases associated with this, only two observers were used, and they observed a sample of each other's classes early in the observation process to moderate scoring.

Whilst we described the proportion of people completing at least 75% of classes within a programme, we were not able to determine how many people completed 50 hours of strength and balance exercise or participated in elements of the programme such as floor work or Tai Chi as this information was not routinely collected as part of the programmes we studied.

Comparisons with existing research

Fidelity is poorly reported in behaviour change intervention studies⁷ and measured very heterogeneously.⁸ Consequently we found few physical activity intervention studies reporting fidelity measures with which we can compare our findings. We found 72%-78% of content fidelity criteria were observed which compares well to other behaviour change interventions. A systematic review (2015) of fidelity of behaviour change interventions reported that for 81% of all fidelity outcomes, the intervention was delivered as intended, whilst 22% of studies reported adaptations were made to intervention delivery⁷. Two exercise programmes for older people achieved higher levels of fidelity than our study; a self-efficacy based exercise programme for older women post hip fracture reported 91% adherence to intervention delivery¹⁸. The Active For Life physical activity intervention reported completion of each of 10 key steps in initial face-to-face counselling session to be “generally 98–100%”.¹⁹ Heterogeneity in fidelity assessment methods may explain differences in fidelity between these studies and our study. The first study used observations of intervention delivery, but no further details are provided¹⁸ making comparison difficult. The second study assessed fidelity using provider self-reports¹⁹, whereas our study used observations of intervention delivery. A recent systematic review reports objective measures of fidelity have shown poor convergent validity with self-reported measures in physical activity interventions⁸. Furthermore, our study measured fidelity of an intervention delivered in a “real world” setting as opposed to that delivered within a research study, and it might be reasonable to expect a lower level of fidelity outside of the strictly controlled environment of a research study.

Less than half of participants completed the FaME intervention. This was also seen in the ProAct65+ trial¹⁰ and is perhaps an indication of the multiple co-morbidities and level of frailty of some participants. Other studies have shown that participants often become unwell themselves and cannot continue to participate in exercise programme, or need to take time out to care for others.²⁰

Progressive resistance in strength training is a core component of the FaME programme. Across all the programme participants, only 24% saw the recommended 3 or more band progressions, though this was higher in those that attended more sessions. This might suggest that progression was slower than is needed for strength training gains. It is important that PSIs feel confident and competent to deliver progressive strength training within their classes and understand the necessity, for both training gains in strength and also in participants’ feeling of mastery and improvement.²¹

Long lies after a fall remain a public health challenge. One study showed that 54% of falls reports described the participant as being found on the floor and 82% of these falls occurred while the person was alone.²² Of the 60% who fell in the year follow up, 80% were unable to get up from the floor after a fall and 30% had lain on the floor an hour or more before assistance²². FaME is, to our knowledge, the only UK falls prevention programme that includes training to get up from the floor after a fall (the backward chaining technique). Fear of falling whilst getting up off the floor is also prevalent and therefore regaining this skill is important.

Another criteria not often observed, but which would improve adherence, was explaining the functional purpose of each exercise to clarify understanding of the need for each exercise and its ability to help with everyday activities and tasks, making the programme relevant. This has been shown to be a key behavioural component that aids exercise adherence in older people.²³

Implications for practice and further research

In terms of the 6 essential components of FaME, progressive strength training, encouraging home exercise, (re)training getting down and up from the floor (backward chaining) and Tai Chi moves were the least well adhered to. In-service quality assurance systems could be put in place to ensure these key elements are adhered to within the delivery of the programme for effective outcomes.

To encourage programme completion, follow up of non-attendance and encouragement to keep coming to the programme despite lapses may increase the number of participants who attend at least 75% of the group sessions, improving individual outcomes. Ensuring the exercises have relevance and are related to activities of everyday living will also improve adherence.

Conclusion

Our study has shown that the FaME programme can be delivered outside of the research setting with a high degree of fidelity. However, facilitation strategies and quality assurance systems are necessary to identify where fidelity declines and achieve high quality programmes.

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[Ethical approval:](#)

This study received a favourable opinion from London – Chelsea Research ethics committee reference 16/LO/0396.

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