Visually Impaired OLder people's Exercise programme for falls prevenTion (VIOLET): a feasibility study

Nicola Adams,[1]* Dawn Skelton,[2] Cathy Bailey,[1] Denise Howel,[3] Dorothy Coe,[1] Rosy Lampitt,[4] Jennifer Wilkinson,[4] Tony Fouweather,[3] Lex D de Jong,[2] Sheena Gawler,[1] Vincent Deary,[1] Joanne Gray,[1] Heather Waterman[5] and Steve W Parry[6]

[1]Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, UK
[2]Institute of Applied Health Research, School of Health and Life Sciences, Centre for Living, Glasgow Caledonian University, Glasgow, UK
[3]Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
[4]Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK
[5]Healthcare Sciences, Cardiff University, Cardiff, UK
[6]Institute for Ageing and Health, Newcastle University, Newcastle upon Tyne, UK

*Corresponding author nicola.adams@northumbria.ac.uk

Declared competing interests of authors: Dawn Skelton receives personal fees from Later Life Training Ltd outside the submitted work and is a Director of Later Life Training, a company that runs as a not-for-profit organisation delivering Falls Management Exercise (FaME) Postural Stability Instructor (PSI) training to health and fitness professionals across the UK.

Published February 2019
DOI: 10.3310/phr07040

Scientific summary

The VIOLET feasibility study

Public Health Research 2019; Vol. 7: No. 4
DOI: 10.3310/phr07040

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Falls prevention programmes based on the Falls Management Exercise (FaME) programme are used in mainstream falls prevention programmes with evidence of effectiveness. Fear of falling (FoF), with or without a fall, is common in visually impaired older people (VIOP) and can lead to a cycle of restricting daily activity and mobility. However, although the FaME programme has been shown to be effective, its suitability for VIOP has not hitherto been investigated. Therefore, the aim of the Visually Impaired OLder people's Exercise programme for falls prevenTion (VIOLET) study was to investigate whether or not an existing exercise programme (FaME) could be adapted for VIOP and whether or not it is feasible to conduct a definitive randomised controlled trial (RCT) of this adapted exercise intervention.

Objectives

The specific objectives were to:

1. explore VIOP's ability to act as lay partners in a study to develop a condition-appropriate intervention and the methods that enabled them to contribute to research as active partners
2. assess recruitment of participants and their willingness to be randomised
3. identify candidate outcome measures for a future RCT
4. test the trial methodology and collect outcome data to inform sample size calculations for a definitive RCT
5. explore the capacity to deliver the adapted exercise programme
6. examine delivery (fidelity) and compliance of the exercise intervention
7. explore participants' reasons for participation and acceptability of the exercise programme and trial procedures
8. develop a manualised intervention protocol and training package
9. assess the feasibility of collecting service use data for an economic evaluation of the intervention in a future RCT.

Methods

The feasibility study was carried out in several phases. There were two study sites: Newcastle upon Tyne and Glasgow. Ethics approval was obtained from the Newcastle and North Tyneside Research Ethics Committee (REC reference: 15/NE/0057).

Design

Phase I consisted of a consultation with stakeholders to adapt the exercise programme. Two focus groups were conducted, each with 10 VIOP (five from Newcastle and five from Glasgow). Adaptations for the delivery of the programme and the suitability of the outcome measures were discussed.

Phase II consisted of a two-centre randomised pilot trial of an adapted exercise programme for VIOP versus no intervention with embedded qualitative evaluation.

Phases III and IV consisted of a qualitative evaluation where nine VIOP and two exercise Postural Stability Instructors (PSIs) were interviewed regarding their views and experiences of the research process and undertaking the intervention.

Identification, screening and recruitment

Identification of potential participants was largely carried out by third sector staff or volunteers. The primary recruiting source at the Newcastle site was the Newcastle Society for Blind People. Participants from the Royal Victoria Infirmary low-vision clinic were also identified. The primary recruiting source at the Glasgow site was Visibility.

Across both sites, VIOP who expressed continued interest in participating were screened for eligibility by a researcher over the telephone or at a mutually convenient site.

Intervention

The intervention was adapted from the group-based Falls Management Exercise (FaME) programme. The exercise programme (the intervention) ran weekly over 12 weeks, with each session lasting up to 1 hour. Two exercise groups were held at the Glasgow site (one class of six and one class of nine) and three groups at the Newcastle site (one class of six, one class of five and one class of four). Participants were also asked to exercise at home for up to 2 hours per week.

Participants randomised to the usual activities group received no intervention but were offered an equivalent exercise programme after the week 24 follow-up data collection.

Semistructured interviews were conducted to explore acceptability and applicability of the intervention, the research methods and the outcome measures with nine VIOP. Structured interviews were also conducted with two exercise practitioners at two points (before training and at the end of the intervention) to explore their (changing) perspectives on the provision of the intervention over its duration.

Outcome measures

The outcome measures were completed at baseline and at follow-up at weeks 12 and 24. The primary potential outcome variable of FoF was assessed by the Short Form Falls Efficacy Scale – International (FES-I). Secondary outcome assessments were activity avoidance, current activity, balance/falls risk, physical activity, loneliness, anxiety and depression, work and social adjustment, quality of life (QoL) and economic costs. Balance/falls risk was assessed by the Timed Up and Go test and the Falls Risk Assessment Tool. Number of falls was assessed by a falls diary and weekly telephone call. Physical activity was assessed using the Phone-Frequency, Intensity, Time and Type (Phone-FITT) assessment and an incremental scale. Loneliness was assessed by the 6-Item Scale for Overall, Emotional and Social Loneliness. Anxiety and depression were assessed by the Hospital Anxiety and Depression Scale. The Work and Social Adjustment Scale was also an outcome measure and QoL was assessed using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L), and ICEpop CAPability measure for Older people (ICECAP-O). Resource use and associated costs from an NHS, social services and patient/carer perspective were assessed via a health economic self-report service receipt inventory.

Participants in the intervention group were telephoned each week to obtain consent to record any adverse events (AEs), including falls that occurred up to their week 24 follow-up.

Compliance and fidelity

Participants' compliance with the exercise programme was assessed by reviewing attendance records kept by the PSIs and the self-reported compliance with the home exercises at the end of the 12-week course. In addition, qualitative interviews, conducted by the researchers after the completion of the exercise classes, provided information on why VIOP attended/did not attend exercise classes and what barriers prevented them from attending.

Postural Stability Instructors' compliance with the course content (fidelity) was assessed by a researcher viewing a sample of exercise sessions. A standardised checklist was used and these sessions videotaped for quality assurance purposes. Following completion of the intervention, PSIs were invited to discuss their experiences of delivering the adapted intervention.

Health economics

A prospective economic evaluation was rehearsed to develop and refine methods for a subsequent definitive trial in order to identify, quantify and value accurately the additional costs of delivering the intervention and the potential resource implications versus usual 'activity' and what measurement tools are appropriate to use with VIOP. The costing approach was initially a broad analytical perspective (NHS, social services and patient/carer costs). Resources utilised in the exercise group were identified in terms of additional equipment costs (capital outlay), staff time and consumables. Resource use in terms of out-of-pocket expenses was also explored for all participants in addition to all treatment/care related to the intervention and any falls that occurred during the study period. This was assessed retrospectively at week 12 and week 24 by piloting the use of a falls resources/expenses form. Appropriate unit costs to be applied to resource use were identified and sourced from a combination of local costings and national databases. Methods to value informal carer time were also explored and defined.

Findings

Ability of visually impaired older people to act as lay partners to develop a condition-specific intervention (objective 1)

The study enabled VIOP to provide valuable input at all stages of the research regarding design, study materials, recruitment, adaptation and delivery of the intervention and dissemination via both participation in the phases of the study and membership of the project advisory group (PAG).

Adaptations to the exercise programme from the stakeholder focus groups (Phase I) consisted mainly of logistical aids to attendance rather than changes to the exercise programme content. A weekly telephone call was implemented as a result of recommendations from the stakeholder group as was the means of administering the outcome measures.

Identification, screening and recruitment for the pilot randomised controlled (objective 2)

For the Phase II pilot RCT, 82 VIOP were screened for eligibility by the researchers. Of these, 16 were eventually found to be ineligible, two declined to participate, 66 consented and 64 (78%) were randomised.

After randomisation, 33 VIOP were allocated to the intervention arm and 31 to usual activities. Two exercise groups were held at the Glasgow site (one class of six and one class of nine) and three groups at the Newcastle site (one class of six, one class of five and one class of four). Of the 33 VIOP allocated to the exercise classes, three did not attend any classes, two of whom nevertheless provided study data. During the study, one person was lost to follow-up and four people in the intervention arm withdrew completely

from the study. The remaining subjects provided data that were included in the statistical analysis. The total number of participants recruited ($n = 64$) was less than the target of 80, but 59 participants provided outcome data at 6-month follow-up, which almost met the target of 60 at this time point.

Pilot trial outcomes (objectives 3–6)

The distribution of demographic variables was similar across the trial arms; the only noticeable difference was that more participants lived alone in the usual activities arm.

The trial outcomes were collected at baseline and at weeks 12 and 24. A total of 94% of trial participants provided data at week 12 and 92% at week 24. There were very low levels of missing data.

A total of 25 (76%) out of 33 participants attended nine or more classes. Participants were encouraged to practise the exercises at home for 120 minutes per week in addition to the exercise classes, but the median achieved was 50 minutes per week.

Based on the FES-I score, the majority of participants had low or moderate concern over falling at baseline. The median change from baseline in FES-I at week 12 and week 24 was zero in both arms, although there were some large changes in both directions. Findings were similar for the other scales with the exception of typical physical activity level, which rose slightly over the follow-up period in the intervention arm and less so in the control arm.

Thus, there was little or no evidence that exercise and attitudinal outcomes differed between trial arms at follow-up, but this must be interpreted with caution given the small sample size.

Economic evaluation (objective 9)

The economic evaluation showed that, although it is possible to collect most of the data necessary for a full cost-effectiveness analysis of the exercise intervention compared with usual care, there were some practical issues in accessing information regarding participant self-reporting of resource use post intervention. The use of a more structured, previously piloted, data collection tool may have mitigated against some of these issues. The average total cost of delivering the intervention per patient across both sites was £310.

Overall, at all three data collection points, health-related quality of life was higher in the usual activities group than in the intervention group. ICECAP-O capability scores differed minimally across trial arms at each of the follow-up points. Furthermore, there was little difference between average scores in both trial arms from baseline to week 24.

Safety

A total of 180 AEs were reported; 16 were categorised as serious adverse events (SAEs) and 164 as AEs. There were nine SAEs in the intervention arm – although none of these was deemed to be caused by the intervention itself – and seven SAEs in the usual activities arm. With regard to AEs, there were 81 reported in the intervention arm and 83 in the usual activities arm. A total of 17 falls without injury (10 in the intervention arm and seven in the usual activities arm) and 28 near misses (four in the intervention arm and 24 in the usual activities arm) were also reported (see *Chapter 4* for the definition of AE).

Qualitative interviews, reasons for participation and acceptability (objective 7)

In Phases III and IV, qualitative interviews identified four main themes: reasons for participation, research process, exercise (class and home) and self-perception, which was a cross-cutting theme. Evaluative overarching issues of facilitators of and barriers to exercise included a feeling of being useful, relevance to health, well-being and lifestyle, building of relationships and social interaction. Logistical issues surrounding attendance, such as the need for physical assistance or special arrangements when attending, were also identified.

Main themes from the PSI interviews related to prior experience, benefits and potential issues. Issues surrounding the level of challenge, including floor work and backward chaining, were discussed. The main adaptation concerned session delivery and the use of a second person to assist.

Progression criteria

1. Fifty per cent or more of VIOP eligible for the study were recruited into the feasibility study.
   All but two of those VIOP found to be eligible by the researchers after screening against the inclusion/exclusion criteria were willing to be recruited into the study (66/68 = 97%), although two of these were later found to be ineligible. The exact number of potential participants approached by third sector organisations was not available, but it is known that the number screened by the researchers is much lower than the number of potential participants initially contacted. Thus, meeting this criterion does not reflect the difficulties encountered in recruiting participants to the study.
2. Seventy per cent or more of participants in the intervention arm have completed 9 to 12 group sessions in the exercise programme (compliance).
   Of the 33 participants randomised to the intervention arm, 25 (76%) attended between 9 and 12 exercise classes.
3. Data on key outcomes were collected at 24-week follow-up for ≥ 70% of those recruited.
   Overall, 92% of those recruited provided questionnaire data at the week 24 follow-up visit.
4. Fewer than 10% of SAEs were deemed to be caused by the intervention.
   There were no SAEs deemed to be caused by the intervention.

Conclusions

It was possible to adapt an extant exercise intervention for falls prevention in VIOP with participants as stakeholders and recruit and retain participants to the VIOLET study. Although adaptation, recruitment and delivery were successful, the findings (particularly from qualitative research with instructors and participants) indicated that VIOP with low to moderate falls risk could be integrated into mainstream programmes with some adaptations.

The intervention was delivered successfully at two sites and found to be both safe and acceptable to participants. Adherence to the study and participant retention were high. The high completion rates of the outcome measures suggest suitability for use in a future trial, though other outcome measures may additionally be considered.

Although the progression criteria were met, a number of suggestions are made for a definitive trial.

Providing further information on the types of exercise and the benefits of strength and balance exercises might improve recruitment and adherence to home exercises. Many participants self-presented as active and fit with low to moderate falls risk. More challenging exercises would be required for participants with this profile. Participants did not reach the recommended levels of time spent exercising, which should be addressed in future studies, perhaps by offering attendance at more group sessions.

A future definitive trial should consider the stratification of participants by degree of falls risk. Strategies to increase levels of activity/exercise at home should be developed further.

Participants reported that delivery style and the logistics of attending the venues – rather than the nature and type of the exercises – were barriers to attendance in mainstream programmes. A future definitive trial should consider graduated exercises appropriate to ability and falls risk within mainstream provision.

Trial registration

This trial is registered as ISRCTN16949845.

Funding

Funding for the study was provided by the Public Health Research Programme of the National Institute for Health Research.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PHR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/phr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Public Health Research* journal

Reports are published in *Public Health Research* (PHR) if (1) they have resulted from work for the PHR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Public Health Research* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

PHR programme

The Public Health Research (PHR) programme, part of the National Institute for Health Research (NIHR), evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad, covering a range of interventions that improve public health. The Public Health Research programme also complements the NIHR Health Technology Assessment programme which has a growing portfolio evaluating NHS public health interventions.

For more information about the PHR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/phr

This report

The research reported in this issue of the journal was funded by the PHR programme as project number 12/181/07. The contractual start date was in September 2014. The final report began editorial review in January 2017 and was accepted for publication in July 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).