



visually impaired older adults exercise programme for falls prevention

Manualised Intervention Protocol

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Introduction

This manual details the first health promotion falls prevention exercise intervention protocol developed collaboratively with visually impaired older people (VIOP), specifically for community living VIOP. This intervention has been tested in a pilot study [1] and this manual will allow accurate replication of the pilot study intervention in a larger multi-site study in the future, or it can be used to ensure adaptations to the original Falls Management Exercise (FaME) intervention [2, 3] for VIOP can be replicated in practice in falls prevention programmes.

The rationale for basing the VIOLET intervention on FaME was the following:

- a) Nine months of FaME has been shown to reduce falls in frequently falling (≥ 3 times previous year) women aged 65 years or older when delivered as a once a week group class supplemented with twice a week home exercise [2].
- b) Six months of FaME (1xpw class, 2xpw home) has been shown to increase habitual physical activity (moderate to vigorous activity) and reduce falls in lower risk (inactive and ≤ 2 falls in previous year) men and women aged 65 and older recruited through GP practices [3, 4].

This manual details the FaME intervention¹ and training to become a Postural Stability Instructor (PSI); the additional training of PSIs to work with VIOP (based on views and preferences of VIOP); the progressions and adaptations used to deliver safe and effective falls prevention exercise to VIOP; and the quality assurance needed to ensure intervention fidelity throughout the programme.

Initial Assessment

The initial assessment takes approximately **one hour**. Screening is performed in the participant's home, so that an unfamiliar location and environment will not be a barrier to involvement. With consent from the participant, their GP is contacted to ensure no medical exclusions to exercise. The GP clearance letter is provided in Appendix 1.

A brief check with the participant to identify health issues that might influence participation or require adaptation to exercise delivery is performed. A health checklist is provided in Appendix 2.

¹ Background Intellectual Property (IP) of FaME is owned by Later Life Training. The Foreground IP lies with the VIOLET Team and the new learning about adaptations for OPVI is freely available.

Training of PSIs delivering intervention

Training will be provided for qualified PSIs² on working with VIOP and checks will be made to ensure that exercise instructors comply with the course content (fidelity).

Local qualified FaME exercise instructors working on each site will be trained by a research team member on adapting the exercises for people with visual impairment based on the key learning from discussions with VIOP prior to the pilot study [1] and key learning during the delivery of the pilot intervention.

A full description of the original FaME programming and progression has been published [7].

Training includes:

- Brief reminder of the evidence base behind FaME (already covered in depth during initial PSI training).
- Explanation of the different forms of visual impairment and the potential functional difficulties associated (e.g. Depth perception, contrast and lighting, reduced peripheral vision or visual neglect).
- Sighted guide training and understanding vision impairment, including the wearing of sight impairment glasses (replicating common forms of sight impairment) for them to fully understand the adaptations that may be needed for different individuals.
- Practical sessions on adaptations to PSI for VIOP, including placement of participants in sessions, verbal descriptions of exercises and verbal instructions for transitions between exercises and between components within a session.
- Trial administration procedures for PSIs (register, progression, quality assurance etc.).

The training slides are presented in Appendix 3

Standard Operating Procedure (SOP) - Staff Training

The SOP used for the training of staff within the pilot study is appropriate to be adapted for use in a larger study and can be found in Appendix 4.

² PSIs have to have a successful completion and qualification from Later Life Training. This qualification is endorsed by Skills Active and the Register of Exercise Professionals and sits at Level 4 – exercise training for specialist populations. See <http://www.laterlifetraining.co.uk/courses/postural-stability-instructor/about-postural-stability-instructor/>

Intervention Delivery

It is essential the PSIs are qualified to deliver the adapted FaME exercise programme and have a current Disclosure and Barring Service certificate in place. They must be willing to undertake study specific and visual impairment specific training, work to the study protocol, be willing to be observed at fidelity visits and follow standard operating procedures, including risk assessing the venue and participants within the group. The SOP regarding intervention delivery can be found in Appendix 5.

Adaptations for VIOP

Some of the adaptations for delivery of PSI to VIOP are led by discussions with the OPVI stakeholder group and from interviews with VIOP following the pilot intervention. Others are informed by feedback from the PSIs who delivered the pilot intervention.

Adaptations from a VIOP perspective

Some key points for adapting the normal 'running' of a PSI session were verbalised in the Stakeholder Panel of VIOP. These included:

- Fully accessible familiar venue or ability to get to know unfamiliar venue (potential for pre session visit)
- Taxi to venue/aid getting to and from venue if required
- Group size: Maximum 8
- No music
- Individual adaptation regarding lighting and glare
- Choice to bring another person with them
- Social element (tea and chat) post the exercise session
- Potentially run more than one class (flexibility of time) at the beginning for group bonding
- Home exercise: reduce length of home exercise session to 10-20 minutes. Give a variety of exercises. Provide prompts (large print format, DVD, audio). Integrate into activities of daily living.
- PSI: training on impact of visual impairment and adaptations (aids) that could be used for specific visual impairment. Training on communication (verbal clarity)
- Potentially more than one instructor or additional person to help VIOP.
- Information regarding the individual VIOP to be passed to PSI, time to fully understand the nature of the impairment and how this may affect the individual and how that may vary across timeframes.
- Tailoring of content to individual (floorwork)

Indeed, recent work suggests that ‘barriers’ to uptake of exercise in older people related to identity, choice/control, cost, and venue, and ‘solutions’ included providing choice/control, relating exercise to identity, a personal touch, and social support [8]. Barriers to adherence included unrealistic expectations and social influences, and solutions identified were encouraging commitment, creating social cohesion, and an emphasis on achieving outcomes [8].

Discussions with VIOP in the pilot study after completion of the pilot interventions suggested we must be mindful of the following:

- Some people with VIOP within the pilot study spoke of difficulty finding space or time to do the home exercise programme. The home exercise sheets therefore mention places in the home that individual exercises should be able to be performed with enough space (e.g. Kitchen) and ideas on integrating exercises into their daily life activities.
- It is important for the PSI not to be overprotective, they get about with their daily life without a PSIs help most of the time, ask them what help they want/need and to ask if they want help, do not assume they always want it. They have often built up their own coping strategies and resilience and the PSI must complement that not undermine it. This was reinforced by most OPVI suggesting the exercise prescription should/could be harder and more challenging.

Adaptations from a PSI perspective

Discussions with the PSIs delivering the pilot intervention revealed some pertinent issues:

- Descriptive commentary required, include wider description of what is going on inside the exercise room, who enters, who leaves.
- Use communication strategies to enable the recognition of voices, use first names so that the individual is aware when a comment is directed at them.
- The exercises can be quickly visually demonstrated for those with some sight, but for others there is a need for a detailed verbal description of the exercises (paint a picture). Use big gestures in demonstrations and wear clothing that contrasts with the ‘wall’ colour – avoid using venues that have a mirror behind the instructor.
- Room layout of participants should take into account particular visual impairments (eg. how intact is peripheral vision for those with macular degeneration, do they need to be to the side of the PSI to see them?).
- Within the pilot study, less exercises could be delivered in the one hour session than a class for older adults without visual impairment. To ensure that as much of the session is focused on strength and balance work, the warm up was shortened to between 5-10 minutes.

- Progression of strength work (repetitions/sets and theraband resistance) required no adaptations for VIOP. The aim is to progress each participant up at least 2 band resistances in the 12 weeks.
- Often the PSI must take a more 'hands on' approach than in mainstream PSI class. The placing of people into the correct positions, hands on the therabands enables the pace of the session to be maintained.
- Balance work required adaptation, some of the dynamic balance exercises required even more care and emphasis on group organisation and control to avoid collisions between participants (eg. Heel walks). Safety: all participants need to start dynamic exercise at the same time. This avoids people walking into the back of each other. In just the same as in a non-adapted PSI class, some participants required additional balance challenges to maintain progression (such as catching a ball in toe raises) if deemed safe by the PSI.
- Use of an 'anchor point'. All participants whether they need a balance aid or not (chair) should have an anchor point in the room. Each person should sit on/stand behind a chair that becomes their individual anchor point. Somewhere for the VIOP to go from and return to (aids spatial awareness).
- Retraining getting down to and up from the floor is to be offered to all participants. It was possible to get participants onto the floor and competent and confident to get up again within the 12 week timeframe of the VIOLET pilot study. Once the basic skill of getting down to and up from the floor is mastered, floorwork aimed at improving strength and balance can be instigated but for time management purposes it is best to alternate sessions so that one week most of the class is on the floor (except for those who have seated or standing adaptations) and the following week theraband work for strength and standing balance is done. A second person (spotter/helper) is necessary during any sessions including floorwork but this is because of other co-morbidities and general class management safety issues, not because of sight impairment.

As seen in a study looking at increasing adherence to home exercise (the Otago programme) [9] many VIOP are not fully adherent to home exercise prescription. They will also often compensate and do less habitual physical activity as they perceive they are doing enough by doing the exercise programme for the study [9], therefore it is important to reiterate the importance of the home exercise programme (perhaps with prompts and support from family or carer) and the importance of keeping up other activities and indeed, increasing these.

Group Exercise Programme

Classes will be timetabled between Monday and Friday between 10.30am and 3pm. This will minimise the impact on the family/domestic duties of the VIOP and their accompanying family member or friend.

The intervention runs once a week over 12 weeks, with each session lasting up to one hour. Participants will be provided with transport by taxi to the classes and back. For those participants who do not wish to take up this offer it is important that the exercise venue is accessible by public transport and has adequate parking facilities. All travel expenses will be reimbursed.

Cultural issues such as family support will be encouraged and facilitated. The participants will be informed that they can if they wish bring with them a family member or friend. If the family member or friend feels able they can assist the OPVI with the exercise programme. If they require a guide dog to get to the venue, provision should be made by the participant for someone to look after the guide dog during the group session. As well as this, guide dogs must not compromise the safety of other participants (trip hazard) and it is therefore suggested that they sit at the side of the session, rather than sitting next to their owner.

The programme includes leg muscle strengthening and balance retraining that progress in difficulty. Progressive trunk and arm muscle strengthening, bone loading endurance (including walking and flexibility training, functional floor skills and adapted Tai Chi) complete the evidence based programme. Therabands and mats are also used throughout the programme. The group exercises include retraining of the ability to get up from the floor (backward chaining) and floor exercises to improve strength, balance and coping strategies to reduce the risk of complications resulting from a long-lie.

Risk Assessment

A risk assessment of the venue must be completed and any concerns highlighted to the venue and the study team, and acted upon before group sessions start. A copy of the risk assessment paperwork for a venue is included in Appendix 5.

Participant numbers

A range of 8-10 VIOP per class, with one PSI and one 'spotter/helper' to aid with those with multiple sensory impairments (eg. Profoundly deaf) or those whose sight means they are unable to position themselves safely with regards to others in the class.

Welcome and Group Register

The PSI is to follow up (apart from week 1) on whether people have done their home exercise programme and any problems in adherence or difficulties with particular exercises. This will inform the tailored home exercise prescription each week for each participant. They document relevant information on the register. The PSI also asks about any falls, losses of balance (and corrections – i.e. near falls) and any changes in

health that might either impact on their ability to exercise in the session and relevant information is documented on the register. This documentation on the register allows for any PSIs covering (due to illness) to be informed quickly and easily of historical information of relevance for the group they are leading.

The PSI will also keep registers of attendance and monitor and record any adaptations to the programme and any feedback from participants. A copy of the register is available in Appendix 6.

Home Exercise Programme

Participants are encouraged to exercise at home at least six times per week (aiming at a total of 2 hours home exercise per week), on all the days they are not at the group class. The PSI explains each prescribed exercise and observes the participant performing them (within the group class), to ensure that they are confident to undertake them independently at home. In Weeks 1-4 of the programme, they are encouraged to perform home exercise in 'chunks' of 10 minutes, to increase compliance and avoid compensation due to fatigue, building to a total duration of 2 hours in between group sessions. In Weeks 5-8, they are encouraged progress to 'chunks' of 15 minutes at a time, and in Weeks 9-12 to 'chunks' of 20 minutes. Participants are given therabands to take home for use at home, and these are replaced with stronger resistance bands as the programme progresses. The home exercise prescription is supported by a variety of options that best fit the needs of the OPVI.

Each participant to be provided with a choice of:

- a) Personalised A4 exercise folder that includes pictures of and large font instructions for each exercise.
- b) Otago DVD for those that can see well enough to 'follow' exercises on their TV (the one used was the one that showed efficacy in a feasibility study [10]).
- c) Audio clips of exercises that can be played on CD player or through computer.

The home exercise sheets are chosen by the PSI to ensure they are tailored to meet the needs of individuals in terms of safety at doing that exercise unsupervised at home and on specific components of fitness they need to work on. Each exercise sheet reminds the individual why the particular exercise will help them functionally, for example with an every day living task, and also where at home they could do the exercise to fit in with everyday activities (eg. One leg stand while waiting for kettle to boil). Examples of the home exercise sheets are provided in Appendix 7.

For those that prefer the DVD, exercise numbers on the DVD (which has each exercise listed and can be watched rather than having to watch all exercises) allows tailoring of exercises by the PSI. The same tailoring can be applied to the audio clips of exercises.

These personalised resources mean that a preferred mode of delivery of home exercise instruction that best fits that persons visual impairment and preference is given.

Progression

PSIs modify the exercise prescription, re-assessing and using participant feedback to ensure progression where appropriate i.e. increasing repetitions, sets or adding new balance exercises to provide an on-going moderately intense strength and balance challenge and providing additional behavioural support to encourage compliance and motivation.

In the first two weeks of the programme, the PSI chooses exercises that will start a balance challenge and start strength training but the aim is to ensure compliance and the learning of good exercise technique rather than on training gains. Weeks 3-12 will progress the balance challenge and strengthening work to ensure training gains. Appendix 8 gives the basic principles of Weeks 1-2 prescription and of Weeks 3-12 prescription. Appendix 9 gives examples of session plans over the 12 weeks to show the progression of exercises.

Support Strategies for increasing adherence

Feedback from the VIOP in the pilot study was that many felt fatalistic about the prevention of falls and that falls were inevitable. This has been seen in previous research with VIOP [11] and so concentrate on the other benefits of strength and balance exercise to remaining independent and coping with falls (getting back up again).

Some also felt that they were not at risk of falls (too fit!) and did other exercise. Although notably this was often walking and cardiovascular exercise, and their balance was not good. We suggest concentrating on challenging balance and the theraband work and floorwork and highlight these different components of fitness to stamina exercise.

It is important to follow up with a phone call if someone does not attend and encourage them to come back the following week. The VIOP appreciated the 'interest' of the PSI and felt it helped compliance to return if they missed a week through illness or another appointment (e.g. Hospital). It was also important to the VIOP that the PSI fully understood their particular visual impairment and the effects on them functionally and within the sessions.

For those with a family member or carer who comes to the group session, discussion about supporting their home exercise programme (especially if there are memory or stability concerns) is appropriate.

The social time after the session was deemed important for VIOP in the pilot study. They found it useful to share experiences but felt a more structured and informative session might also be useful some times (covering discussion on other topics of health or falls prevention). A half hour social time could be increased to one hour to add a half hour structured discussion on other health topics of interest to them.

Adverse Events

Adverse events (i.e. events that occurred because of treatment and were unexpected, unintended or unanticipated) will be noted and recorded by PSIs on the register if mentioned during discussion in the group sessions on a one to one basis, or indeed occur during the group session (e.g. a fall). The Chief Investigator will determine whether any AE was serious and directly attributable to the intervention and requires reporting to the sponsor and TOC.

Standard Operating Procedure (SOP) - Intervention Delivery

The SOP used for the Intervention Delivery within the pilot study is appropriate to be adapted for use in a larger study and can be found in Appendix 10.

Intervention Fidelity / Quality Assurance

A standardised checklist will be used to check effective and safe delivery of the programme including progression, adherence to the protocol (i.e. providing home exercise programme and checking on adherence to home exercise and recording any falls mentioned) and completion of all paperwork.

The PSIs compliance with the course content (fidelity) will be assessed by videoing 2 sessions (at weeks 3/4 and week 9/10) for PSI.

These videos will be examined by a research team member to check that the main components of fitness are covered and progressed sufficiently. PSIs will be given a flexible framework of lesson plans for the 12 weeks programme prior to the start of the intervention. Their delivery will be signed off by checking against the videos provided.

Each PSI will receive a written grading (satisfactory, minor concerns or serious concerns) and follow up visits were arranged if necessary. A copy of the Quality Assurance (QA) checklist is provided in Appendix 11.

Standard Operating Procedure (SOP) - Quality Assurance

The SOP used for the quality assurance within the pilot study is appropriate to be adapted for use in a larger study and can be found in Appendix 12.

References

1. Skelton DA, Bailey C, Howel D, Cattan M, Deary V, Coe D, de Jong L, Gawler S, Gray J, Lampitt R, Wilkinson J, Adams N. Visually Impaired OLder people's Exercise programme for falls prevenTion (VIOLET): a feasibility study protocol. *BMJ Open* 2016 Aug 2;6(8):e011996. doi: 10.1136/bmjopen-2016-011996.
2. Skelton DA, Dinan SM, Campbell MG, Rutherford OM. Tailored Group Exercise (Falls Management Exercise - FaME) reduces falls in community-dwelling older frequent fallers (an RCT). *Age Ageing*. 2005; 34: 636-639.
3. Iliffe S, Kendrick D, Morris R, Griffin M, Haworth D, Carpenter H, Masud T, Skelton DA, Dinan-Young S, Bowling A, Gage H. The effects of exercise interventions delivered through primary care on physical activity in older people: The ProAct65+ cluster randomised controlled trial. *Br J Gen Pract*. 2015 Nov;65(640):e731-8. doi: 10.3399/bjgp15X687361.
4. Gawler S, Skelton DA, Dinan-Young S, Masud T, Morris RW, Griffin M, Kendrick D, Iliffe S for the ProAct65+ team. Reducing Falls among older people in general practice: the ProAct65+ exercise intervention trial. *Arch Gerontol Geriatr* 2016; 67: 46-54. doi: 10.1016/j.archger.2016.06.019.
5. Stevens Z, Carpenter H, Gawler S, Belcher C, Haworth D, Kendrick D, Morris R, Masud T, Skelton DA, Iliffe S. Lessons learnt during a complex, multi-centre cluster randomised controlled trial: the ProAct65+ study. *Trials*, 2013. Jul 1;14(1):192. doi:10.1186/1745-6215-14-192.
6. Perry L, Kendrick D, Morris R, Dinan S, Masud T, Skelton DA, ILIFFE S. Completion and Return of Fall Diaries Varies With Participants' Level of Education, First Language, and Baseline Fall Risk. *J Gerontol A Biol Sci Med Sci*. 2012; 67A(2): 210-214.
7. Skelton DA, Dinan SM. Exercise for falls management: Rationale for an exercise programme to reduce postural instability. *Physiotherapy: Theory and Practice* 1999; 15: 105-20.
8. Hawley-Hague H, Horne M, Skelton DA, Todd C. Older adults' uptake and adherence to exercise classes: Instructors' perspectives. *J Aging Phys Act*. 2016 Jan;24(1):119-28. doi: 10.1123/japa.2014-0108.
9. Waterman H, Ballinger C, Brundle C, Chastin S, Gage H, Harper R, Henson D, Laventure B, McEvoy L, Pilling M, Olleveant N, Skelton DA, Stanford P, Todd C. A feasibility study to prevent falls in older people who are sight impaired: the VIP2UK randomised controlled trial. *Trials*. 2016 Sep 26;17(1):464. doi: 10.1186/s13063-016-1565-0.
10. Davis JC, Liang Hsu C, Robertson C, Cheung W, Brasher P, Li LC, Khan K, Sykes J, Skelton DA, Liu-Ambrose T. Can the Otago Falls Prevention Program be Delivered by Video? A Feasibility Study. *BMJ Open Sport Exerc Med* 2016;2:1 e000059 doi:10.1136/bmjsem-2015-000059.
11. Brundle C, Waterman HA, Ballinger C, Olleveant N, Skelton DA, Stanford P, Todd C. The causes of falls: views of older people with visual impairment. *Health Expect*. 2015 Dec;18(6):2021-31. doi: 10.1111/hex.12355.

Appendix 1: GP clearance letter



(please print on relevant headed paper)

[Date]

Dr

Address.....

Dear Dr

Re: *[Insert Participant's name]*

Study Title: Visually Impaired Older people's Exercise programme for falls prevention: a feasibility study (Violet Study)

PI: *[insert PI name]*

We are writing to inform you that your patient has volunteered to take part in a National Institute for Health Research funded research study led by Northumbria University (CI Prof Nicola Adams), titled as above, at [site name] . It will randomise participants to either an adapted exercise programme group or a usual activity group.

The exercises are adapted from the FaME (Falls Management Exercise) programme. This is an evidence-based structured exercise programme designed for older people and used in the community setting. It incorporates stretch, balance and endurance exercises. FaME has been evaluated in people aged 65-95 and has been shown to reduce the number of falls, prevent injuries resulting from falls and prevent further falls. The exercise programme in the study is planned to last 12 weeks, with a once a week exercise class lasting one hour for participants in the intervention arm. The 12 week exercise programme has been adapted for the visually impaired population by a stakeholder panel and is tailored to the individual by experienced exercise instructors. The exercise itself can be chair based and progressed at each individual's pace. It is a safe, standardised exercise programme commonly used in the UK for falls prevention and delivered by specifically trained postural stability instructors.

Your patient has given informed consent to participate in the study. However, before we randomise your patient, we would like to ask you if you feel that your patient is well enough to take part in a low impact exercise class, if randomised to this arm of the study. The inclusion and exclusion criteria for the study are set out overleaf. Please could you or a Practice Nurse complete the attached eligibility form and return in the stamped addressed envelope enclosed. We would be extremely grateful if the completed eligibility form could be returned within 10 days of the date of this letter, to enable us to meet our funder's milestone for study recruitment. If you prefer, you may return the

eligibility form to the research team via fax to the number supplied at the bottom of the eligibility form. In addition, we have a small budget and are happy to reimburse you up to £25 for your time. If you would like to take up this offer, then please enclose an invoice with your reply.

If participants are randomised to the intervention arm they will undergo a brief health screening prior to commencing the exercise class. If the researcher or exercise instructor has any concerns following the health screening, or at any point during the exercise sessions, the participant will be advised to make an appointment with their GP.

For your information we have enclosed the participant information sheet. Should you wish to access the full protocol please follow the link to the VIOLET study website [website address – to be advised].

Inclusion criteria

- Aged ≥60 years
- Attend a low vision clinic and/or are members of organisations for the visually impaired such as NSBP in Newcastle or Visibility in Glasgow
- Live in their own home
- Can walk indoors without the help of another person but may use a walking aid such as a stick
- Can walk outdoors but may need the help of another and/or walking aid
- Physically able to take part in a group exercise class
- Participant has given informed consent (as appropriate to each older person with visual impairment) to participate in the study prior to any study-specific procedures

Exclusion criteria

- Unable to comprehend or follow simple movement instructions in English (to an extent of being unable to follow simple movement instructions)
- Acute or uncontrolled medical problems which the participant's General Practitioner considers would exclude them from undertaking the exercise programme (*e.g.* uncontrolled heart disease, poorly controlled diabetes, acute systemic illness, neurological problems, severe COPD) in addition to visual impairment
- Conditions requiring a specialist exercise programme *e.g.* uncontrolled epilepsy, severe neurological disease or impairment, unable to maintain a seated upright position or unable to move independently indoors
- Current involvement in other falls prevention exercise programmes (but not excluding walking programmes), investigational studies or trials

Yours sincerely,

[Research staff name & contact details]

Encl. Participant Information Sheet

Stamped Addressed Envelope

Eligibility Form

Patient's name :.....(to be pre-filled by research team)

Based on a review of the above inclusion and exclusion criteria, please indicate below if you feel your patient is well enough to take part in the VIOLET study:

I confirm that (patient's name) is able to take part in the VIOLET study.	Sign: Print name:..... Designation (GP/Nurse):..... Date:.....
I confirm that (patient's name) is NOT able to take part in the VIOLET study. Please add your reason:	Sign: Print name:..... Designation (GP/Nurse):..... Date:.....

Thank you for your time. Please return this form in the stamped addressed envelope provided.

Or, if you prefer, please fax to:

[Research staff name & secure fax number]

Please include an invoice of up to £25 if you wish to claim payment.

Invoices to be addressed to:

Finance Officer,
Northumbria University,
Faculty of Health and Life Sciences, Coach Lane Campus West,
Newcastle upon Tyne, NE7 7XA

Appendix 2: Health checklist

Violet Health Questionnaire

Strictly confidential

Name:	Date of Birth:
Address:	GP name:
Postcode:	Surgery:
Telephone number:	Emergency contact name:
Mobile number:	Emergency contact number:
Any known allergies:	

Has a doctor ever told you that you have, or have had, any of the following conditions? If the answer is YES to any questions please give some details, including dates where possible.

High blood pressure?	Yes / No
Any heart conditions? Angina / MI	Yes / No
Stroke / Blood clots / TIA's / PVD?	Yes / No
Asthma?	Yes / No
COPD / any other breathing disorder?	Yes / No
Diabetes? Type I / Type II	Yes / No
Have any joint, back or neck pain?	Yes / No

Have you any known arthritis? RA / OA / Other	Yes / No
Have you had a recent injury within last 6 months?	Yes / No
Have you had surgery within last 6 months?	Yes / No
Have you any other medical condition not listed? e.g. cancer, thyroid, epilepsy, hernias etc.	Yes / No
Do you feel pain in your chest at rest or during physical activity?	Yes / No
Do you have unexplained breathlessness?	Yes / No
Do you ever have dizzy spells or faint?	Yes / No
Are you currently taking any tablets prescribed by your GP? list:	Yes / No Please
Do you require any special considerations due to a physical disability?	Yes / No
Do you smoke?	Yes / No
Within the last 5 years?	Yes / No
Have you fallen in the past year? How many times (approximately)?	Yes / No
Do you have any problems with your bones? e.g.osteoporosis	Yes / No
Can you get down onto the floor and up again unaided?	Yes / No

Appendix 3: Training slides

Visual Impairment Awareness

Shelagh Palmer



Vision and Falls?



Stability and Balance

Inputs to balance

- Visual information
- Vestibular information
- Proprioceptive information



All decline with age.

All components of postural sway

Postural sway increases by
20 -70% with impaired vision.



Eye conditions and Falls

- Age matched older women with AMD have slower reaction times and increased risk of falls (Sazbo et al 2008)
- Reduced contrast sensitivity associated with postural instability and gait changes (Wood et al 2009)
- Timmis (2012) found those with central field loss adopted cautious gait to reduce risk of falling
- People with sight loss adopted different or unsafe gaits such as stepping too high (Buckley 2010)
- Glaucoma and field defects to be x3 more likely to have fallen. Field loss decreases postural stability, increases chance of bumping into things (Haymes 2007)
- Not much evidence about Diabetic retinopathy but poor balance, foot problems must increase risk.



Common Eye Conditions

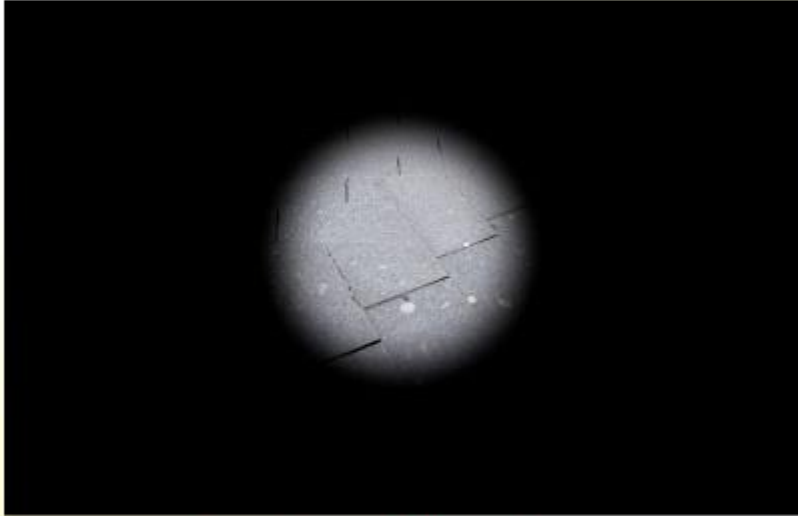
- Loss of central vision
- Loss of peripheral vision
- Blurry or patchy vision





Central Vision Loss





Peripheral Vision Loss



Poor contrast and depth perception





Patchy vision





Haemianopia



What can help?

- Understanding family and friends
- Good V.I. role model
- Knowledgeable professionals
- Equipment
- Make things big, bold and bright
- Good verbal communication
- Sighted guiding



Registration

- Need to be certified by a consultant ophthalmologist
- BP1 form completed as Blind or Partially Sighted
- Register is kept by Local Authority
- Triggers provision of specialist services in local area
- Can be a “passport” to other services
- Registration is voluntary
- Can be long waiting times for point of registration to assessment



Communication

- Listen
- Acknowledge the negatives
- Deliver a positive
- Encourage alternatives
- Reward effort
- Support new skills
- Signpost to support





Visibility Knitting Group



Be descriptive !

- It's a black and white photo of a group of fifteen women, a formal posed assembly with five seated in front and the rest standing behind.
- The photograph was taken outdoors in bright light but it must have been a cool day as most of the women are wearing coats and jackets and even a tartan rug is in evidence. They range in age from probably 30 to 80 but are mostly older women. It is a very soberly dressed and formal, almost intimidating group; the woman in the centre front is sitting with her feet planted, her hat and overcoat on and a Maggie Thatcher style handbag squarely placed in her lap.



Communication Tips

- Identify yourself
- Offer assistance positively - "Are you managing ok or would you like some help?"
- Talk directly to the person – not their companion
- Speak clearly
- Be specific and be descriptive
- Say when you are leaving a room

Relax. Ask if you are unsure of what to



Improve lighting and glare



Multiple, good lighting sources



Lighting and glare



Equipment



- Basic daily living aids
- Advanced electronic equipment
- Catalogues



How we can make things easier?

Make things big

Make things **bright**

Make things **BOLD**



Large Print

<p>Please contact London Travel Information on 020 7222 1234 to pick up a copy of the Fares and the booklet at your local Underground station.</p>	<p>Printed text in 'Times' at 10 point size, as seen by a person with macular degeneration.</p>
<p>Please contact London Travel Information on 020 7222 1234 to pick up a copy of the Fares and the booklet at your local Underground station.</p>	<p>Printed text in 'LPfont' at 16 point size, as seen by a person with macular degeneration.</p>



Colour and contrast



Colour Contrast



 visibility

Signage



www.findsignage.co.uk/signage/

 visibility

New skills, new interests



 visibility

Tips for Guiding

- Ask whether a person would like assistance
- Where does the person want to go and how they would like to be guided?
- Give the person time to grip and walk off.
- Give the person adequate room for obstacles
- Look for hazards – ground, ahead and above
- Explain any loud noises which may alarm
- Explain changes in surfaces e.g. grass, puddles
- Try to walk at other person's pace

 visibility

Visibility services

- Information Line
- Resources Room
- Hospital Support
- Peer Support Groups
- Technology Project
- Eccentric Reading
- Scanning Training
- Falls Prevention
- Toddler Groups
- Working Age Project
- Mobility Training
- Older people (OPALs)
- Positive Outlook Courses
- Home Support (SW contract)
- Social/ Recreational Activities
- Children and Families





2 Queens Crescent
Glasgow G4 9BW
www.visibility.org.uk

Email: info@visibility.org.uk
0141 332 4632



Visually Impaired Older people's Exercise
programme for falls prevention: a feasibility
study

Where are we now: Recommendations
from the stakeholder panels

Background

- What is VIOLET?
 - Two centre pilot study lasting 6 months
 - Adaptation of an existing (FaME) group based intervention versus usual activity
 - 80 older people with a visual impairment (OPVI)
 - Quantitative (questionnaires) and Qualitative (interviews) methods

Outcomes

- Can an existing programme be adapted and is it feasible?
 - Develop a manual
 - Assess recruitment and willingness to be randomised
 - Explore reason to take part/not take part
 - Explore partnerships with OPVI
 - Identify outcome measures for full trial/methods
 - Explore delivery, fidelity, compliance and economic evaluation.
- Primary outcome is a reduction in the fear of falling

Work package 1

- Stakeholder panels completed in November 2014
- Two at each site
 - Adaptability of the FaME programme
 - Outcome measures
- 14 participants (8) (5) with VI plus facilitators/partners and research staff

- Experience of falls
 - Fear of falling, invisibility, near miss, visual impairment
- The intervention
 - Taster session, falling better, floor exercises
 - Group size and structure
 - Music and lighting
 - Significant other
 - Social element
 - Venue
 - Home exercise
 - Transport
 - Instructors

- Outcome measures: forms
 - Self completed, face to face, phone, email
- Content
 - Tools being used, falls diary, timed up and go
- Additional outcome measures
 - Visual impairment, impact on daily life, participant led outcomes, individual requirements

Recommendations

- The overall recommendation from the stakeholders is that personal choice and individual adaptation should be paramount across the study.

Recommendations

- Venue
 - Accessibility/taxi
- Group
 - Size, music, lighting, glare, significant other
- Social element post exercise
- Flexibility in class time/place
- Home exercise
 - Reduce length, prompts
- PSI
 - training on VI, adaptation and communication, additional person

Recommendations

Outcome measures

- Weekly telephone call
- Define slip, trip and fall (near miss)
- Personal outcomes
- Impact of visual impairment.

- From the VIOLET team thank you very much for listening.....



Adverse Events and Significant Adverse Events

- All clinical research collects information on what are termed 'adverse events'.
- They are:
 - 'Any untoward medical occurrence in a subject to whom a study intervention or procedure has been administered, including occurrences which are not necessarily caused by or related to that intervention'

- Fall, slip, trip (not near miss unless it results in injury)
 - Consequence of fall: cuts, abrasions, soft tissue injury, fracture, pain
 - Worsening of an existing condition
 - Angina, COPD (chest), Infections
 - Minor illness with or without medical intervention
 - Hospitalisation
 - Death
-
- NB: changes in medication.

- The process in VIOLET:
 - All participants will receive a weekly telephone call from the research staff.
 - If a participant reports an adverse event (not just a fall) the research staff will collect information about this.
 - If a participant reports an adverse event to the PSI at one of the exercises sessions they should be advised to report that to the research staff.
 - The PSI also needs to inform the research staff as soon as possible.

- It is the responsibility of the research staff to follow up all adverse events to assess their:
 - Relatedness
 - Causality
 - Seriousness
 - Severity
- It is also their responsibility to inform the trial management team.

- If a participant suffers an adverse event during an exercise session the PSI should first deal with the incident and then report it to the research staff **as soon as possible after the event.**
- The PSI needs to follow the accident/incident policies of the hosting organisation i.e. Trinity Church Centre (Newcastle), Visibility (Glasgow).
- It is the PSI's responsibility to make themselves aware of these and to follow them.
- If the research staff are not present please collect as much information as possible on the form supplied.

Serious Adverse Event

- Results in death
- Is life threatening (an event in which the subject was at risk of death at the time)
- Requires hospitalisation
- Results in persistent or significant disability/incapacity
- Considered medically significant by the PI/CI

If you suspect the event is SERIOUS please inform a member of the research staff as a matter of urgency

- Fall:
'an unexpected event in which the participant comes to rest on the ground, floor, or lower level'.
- Near miss:
'an occasion where you felt you were about to fall but did not actually fall'.

Source: Prevention of Falls Network Europe (PRoFaNE)

Thank you very much

Questions?

Appendix 4: Staff training SOP

Staff Training

SOP Reference: NUVI/SOP/001

Associated Documents:

Recruitment of participants

Baseline Visit

12 Week Visit

24 Week Visit

Adverse events and Serious adverse events

Northumbria University/Glasgow Caledonian University lone-worker policy

Scope:

This SOP describes the processes for the training of the research site staff.

The Principal Investigator at each site will be responsible for the delegation of duties to the research staff. It is their responsibility to ensure the site staff comply with the study protocol and conduct themselves inline with the standard operating procedures for the study and the principles of Good Clinical Practice (GCP). All researchers will be required to reach acceptable levels of competence and reliability before commencing assessment of study participants. In addition, all members of the research team will be expected to provide evidence of training in those aspects of Good Clinical Practice that are relevant to their role in the study. In line with Sponsor policy, evidence of initial or GCP update training every three years will be required.

Procedure:

1. Training Research Staff

1.1. Prior to recruitment all study specific research staff will receive training.

1.1.1. Training will include latest revisions to the protocol, standard operating procedures, eCRF.

1.2. Once training and the site initiation visit has been completed, the principal investigators will complete a study specific delegation log.

1.3. Training will be offered to new members of the research staff and refresher training will be given if required.

2. Training Postural Stability Instructors (PSI)

The suitability of the exercise instructors will be assessed by their current employers who are stakeholders in the project. It is essential the PSI are qualified to deliver the adapted FaME exercise programme and have a current Disclosure and Barring Service (DBS) certificate in place. They must be willing to undertake training, work to the study protocol and standard operating procedures.

- 1.1. Research specific training will be offered to the exercise instructors by the research staff.
 - 1.1.1. This will include training on the protocol, the adapted FaME programme and relevant standard operating procedures.
 - 1.1.2. It will also include information about visual impairment and the potential impact of that on the participant and any adaptations (aids) which may be required.
- 1.2. It is essential that the health and safety procedures of the hosting organisation are followed by the exercise instructors.
 - 1.1.1. The employer will ensure that the exercise instructors are aware of this and that policy and procedures are followed.
- 1.3. Quality assurance of the intervention is covered in NUVI/SOP/012: Quality Assurance of the PSI.

Appendix 5: Venue risk assessment

Health and Safety Venue Assessment for L4 PSI SPECIALIST SESSION (Exercise for the Prevention of Falls and Injuries in Frailer, older People)					
Venue Information and contacts					
Venue Name		Date of Assessment / Review date			
Contact Person / Details for Venue		Person(s) writing assessment			
Address of Venue					
Client/Patient Information					
Maximum number within class		Any known special requirements of client group i.e. Medical/Overall Risk Stratification/Behavioural	NO	YES	
Are support Staff required			(if yes please indicate action below)		
First Aid and Fire					
Location of First Aid Kit		Fire Exits			
First Aider on call during class		Fire Fighting equipment locations			
Location of Telephone		Fire Assembly point			
Venue specific procedure for 1 st Aid		Venue Specific procedure for Fire			
Site Information					
Location / Distance of toilets		Wheelchair access			
Car Parking Information		Hearing aid loop?			
Equipment Used: Safety Points.					
Equipment Name	Hazards or Risks Associated (i.e. perished resistance-bands)	Controls in place (instructor actions) to reduce risk	Likelihood (L) x Severity (S) = Risk (R)	Risk Rate	
			L S =R	H/M/L	
			L S =R	H/M/L	
			L S =R	H/M/L	
			L S =R	H/M/L	
			L S =R	H/M/L	

PSI Environmental/Exercise/Client Based Risk Assessment					
Potential Risk	Hazards or Risks Associated (i.e. uneven floor surfaces)	Controls in place (instructor actions) to reduce risk	Likelihood (L) x Severity (S) = Risk (R)	Risk Rate	
Ceiling Height			L S =R	H/M/L	
Floor			L S =R	H/M/L	
Obstacles			L S =R	H/M/L	
Temperature / Ventilation			L S =R	H/M/L	
Equipment			L S =R	H/M/L	
Access to venue (i.e. car loading etc)			L S =R	H/M/L	
Privacy / Protection issues			L S =R	H/M/L	
Exercise / Skill Choices			L S =R	H/M/L	
Health/ Suitability of Clients			L S =R	H/M/L	
Lighting/Distractions			L S =R	H/M/L	
Other			L S =R	H/M/L	

Appendix 6: Attendance register

	PSI name:	Venue:	Day & time:											
Participant name	Medical con code(s)	Patient ID number	/	/	/	/	/	/	/	/	/	/	/	Attendance notes
		Total attendance												

Appendix 7: Home Exercise Programmes



VIOLET Study

10 Minute Strength & Balance Home Exercise Programme

Warm up exercises

Always begin with a warm up to prepare your body for the main exercises.

There are 3 warm up exercises.

Complete them all:

Aim to do these home exercises **every day of the week** except the day you go to your exercise class.

Safety

Ensure that the chair you use is sturdy and stable. Wear comfortable clothes and supportive footwear.

Prepare a space and have your exercise band ready before you start.

While exercising, if you experience chest pain, dizziness or severe shortness of breath, **stop immediately** and contact your GP (or call an ambulance if you feel very unwell and your symptoms do not go away when you stop exercising).

If you experience pain in your joints or muscles, stop, check your position and try again. If the pain persists, stop doing that exercise and speak to your exercise instructor when you next see them.

1. March

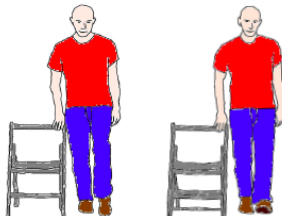
- Stand (or sit) tall
- Hold the back of the chair (or sides of the chair, if you are seated)
- March with control
- Build to a rhythm that is comfortable for you
- Continue for **1-2** minutes



2. Ankle loosener

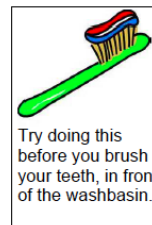
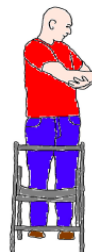
- Stand tall (or sit tall at the front of the chair)
- Hold the back (or sides) of the chair
- Place the heel of one foot on the floor then lift it and put the toes down on the same spot
- Repeat **5** times on each leg

Try doing this while waiting for some food to cook, holding the kitchen worktop.



3. Spine twists

- Stand (or sit) very tall with your feet hip width apart
- Fold your arms across your chest
- Twist your upper body and head to the side keeping your hips forwards
- Twist to the other side
- Repeat **5** times



Main exercises

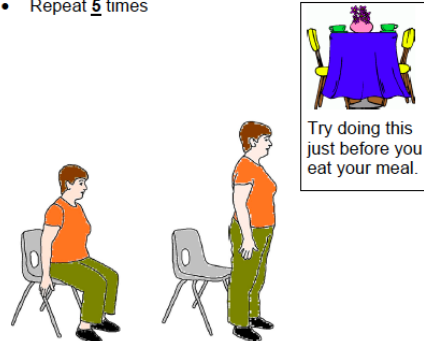
There are 5 exercises in this section.

Complete them all.

The first 2 exercises are to help improve your bone and muscle strength.

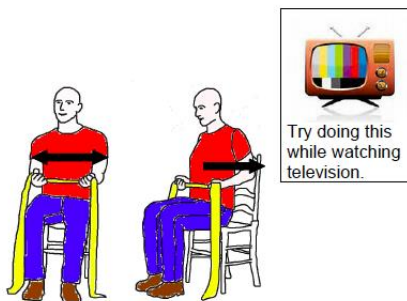
1. Sit to stand

- Sit tall near the front of a sturdy chair
- Place your feet slightly back
- Lean forwards slightly
- Stand up (using your hands on the chair if needed)
- Step back until your legs touch the chair then slowly lower your bottom back into the chair
- Repeat **5** times



2. Upper back strengthener

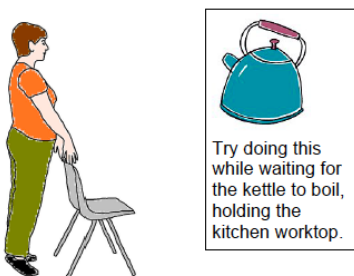
- Hold the band with your palms facing upwards and your wrists straight
- Pull your hands apart then draw the band towards your hips and squeeze your shoulder blades together
- Hold for a slow count of 5 whilst breathing normally
- Release, then repeat **7** more times



The following 3 exercises are to help improve your balance.

1. Heel raises

- Stand tall holding a sturdy chair, table or the sink
- Raise your heels taking your weight over your big toe
- Hold for a second
- Lower your heels with control
- Repeat **10** times



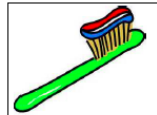
2. Toe raises

- Stand tall holding your support
- Raise your toes taking your weight back into your heels without sticking your bottom out
- Hold for a second
- Lower your toes with control
- Repeat **10** times



3. Tandem Stand

- Stand tall holding the support
- Place one foot directly in front of the other so that your feet are in a straight line
- Ensure your weight is shared between both feet and your knees are soft
- Hold the position for **10 seconds**
- Repeat with the other foot in front



Try doing this before you brush your teeth, holding the washbasin.

1. Calf stretch

- Stand behind the chair holding on with both hands
- Step back with one leg and press the heel down
- Check that both feet face directly forwards
- Feel the stretch in your calf
- Hold for **10-20** seconds
- Repeat on the other leg



Try doing this just before clearing the table, holding the dining chair.

Ending the session

Finish by performing the following stretches:

2. Chest stretch

- Sit tall away from the back of the chair
- Reach behind with both arms and grasp the chair back
- Press your chest upwards and forwards until you feel the stretch across your chest
- Hold for **10-20** seconds



Try doing this while watching television.

Well done! You have finished your exercises for today.

Try to do these exercises **every day of the week** except the day you go to your exercise class.

If you have any queries or concerns regarding this home exercise programme please speak to your exercise instructor.

Thank you for your continued participation in the study.

VIOLET Study

15 Minute Strength & Balance Home Exercise Programme

Warm up exercises

Always begin with a warm up to prepare your body for the main exercises.

There are 3 warm up exercises.

Complete them all:

Aim to do these home exercises **every day of the week** except the day you go to your exercise class.

Safety

Ensure that the chair you use is sturdy and stable. Wear comfortable clothes and supportive footwear.

Prepare a space and have your exercise band ready before you start.

While exercising, if you experience chest pain, dizziness or severe shortness of breath, **stop immediately** and contact your GP (or call an ambulance if you feel very unwell and your symptoms do not go away when you stop exercising).

If you experience pain in your joints or muscles, **stop**, check your position and try again. If the pain persists, **stop doing that exercise** and speak to your exercise instructor when you next see them.

1. March

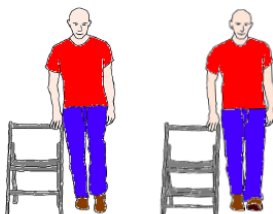
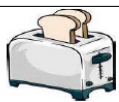
- Stand tall
- Hold the back of the chair
- March with control
- Build to a rhythm that is comfortable for you
- Continue for **1-2** minutes



2. Ankle loosener

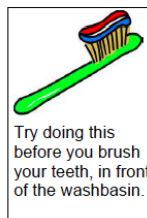
- Stand tall (or sit tall at the front of the chair)
- Hold the back (or sides) of the chair
- Place the heel of one foot on the floor then lift it and put the toes down on the same spot
- Repeat **5** times on each leg

Try doing this while waiting for some food to cook, holding the kitchen worktop.



3. Spine twists

- Stand very tall with your feet hip width apart
- Fold your arms across your chest
- Twist your upper body and head to one side, keeping your hips facing forwards
- Do this on the opposite side
- Repeat **5** times



Main exercises

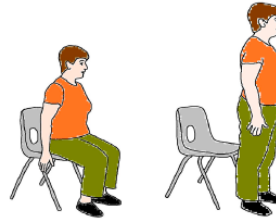
There are 5 exercises in this section.

Complete them all.

The first 2 exercises are to help improve your bone and muscle strength.

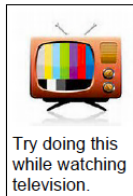
1. Sit to stand

- Sit tall near the front of the chair
- Place your feet slightly back
- Lean forwards slightly
- Stand up (using your hands on the chair if needed)
- Step back until your legs touch the chair, then slowly lower your bottom back into the chair
- Repeat **10** times

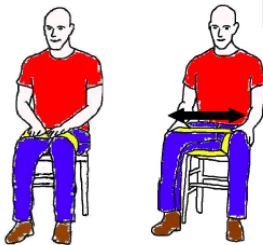


2. Outer thigh strengthener

- Sit tall near the front of the chair with your feet and knees touching then wrap the band around your legs (keeping the band as flat as possible)
- Take your feet and knees back to hip width apart
- Push your knees outwards and hold for a slow count of 5
- Release, then repeat **7** more times

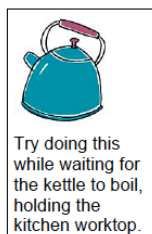


Try doing this while watching television.



1. Toe walk holding support

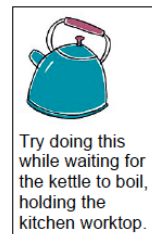
- Stand side on to your support & hold on
- Raise your heels (weight over big toe) then take **10** small steps forwards
- Bring your feet together then lower your heels with control
- Repeat in the other direction



Try doing this while waiting for the kettle to boil, holding the kitchen worktop.

2. Heel walk holding support

- Stand side on to your support & hold on
- Raise your toes without sticking your bottom out, then take **10** small steps forwards
- Lower your toes with control
- Repeat in the other direction



Try doing this while waiting for the kettle to boil, holding the kitchen worktop.

3. Flamingo swings

- Stand side on to your support & hold on
- Swing the leg furthest from the chair forwards and back with control
- Perform **10** swings
- Repeat on the other leg



Try doing this while waiting for some food to cook, holding the kitchen worktop.

1. Calf stretch

- Stand behind the chair holding on with both hands
- Step back with one leg and press the heel down
- Check that both feet face directly forwards
- Feel the stretch in your calf
- Hold for **10-20** seconds
- Repeat on the other leg



Try doing this just before clearing the table, holding the dining chair.

Ending the session

Finish by performing the following stretches:

2. Back of thigh stretch

- Make sure you are right at the front of the chair
- Straighten one leg placing the heel on the floor
- Place both hands on the other leg then sit really tall
- Lean forwards with a straight back until you feel the stretch in the back of your thigh
- Hold for **10-20** seconds
- Repeat on the other leg



Try doing this while watching television.

Well done! You have finished your exercises for today.

Try to do these exercises **every day of the week** except the day you go to your exercise class.

If you have any queries or concerns regarding this home exercise programme please speak to your exercise instructor.

Thank you for your continued participation in the study.

VIOLET Study

20 Minute Strength & Balance Home Exercise Programme

Warm up exercises

Always begin with a warm up to prepare your body for the main exercises.

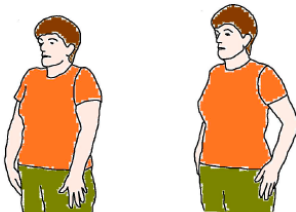
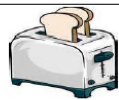
There are 3 warm up exercises.

Complete them all:

2. Shoulder circles

- Stand tall with your arms at your sides
- Lift both shoulders up to your ears, draw them back then press them down
- Repeat slowly **4** times

Try doing this while waiting for some food to cook.



Aim to do these home exercises **every day of the week** except the day you go to your exercise class.

Safety

Ensure that the chair you use is sturdy and stable. Wear comfortable clothes and supportive footwear.

Prepare a space and have your exercise band ready before you start.

While exercising, if you experience chest pain, dizziness or severe shortness of breath, **stop immediately** and contact your GP (or call an ambulance if you feel very unwell and your symptoms do not go away when you stop exercising).

If you experience pain in your joints or muscles, stop, check your position and try again. If the pain persists, stop doing that exercise and speak to your exercise instructor when you next see them.

1. March

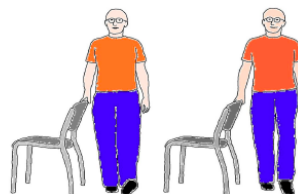
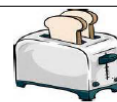
- Stand tall
- Hold the back of the chair
- March with control
- Build to a rhythm that is comfortable for you
- Continue for **2-3** minutes



3. Ankle loosener

- Stand tall
- Hold the back of the chair
- Place the heel of one foot on the floor then lift it and put the toes down on the same spot
- Repeat **4** times on each leg

Try doing this while waiting for some food to cook, holding the kitchen worktop.



Main exercises

There are 7 exercises in this section.

Complete them all.

The first 4 exercises are to help improve your bone and muscle strength.

1. Thigh Strengthener

- Sit tall towards the front of your chair
- Place the band under the ball of one foot and grasp it with both hands at knee level (picture 1)
- Lift your foot just off the floor then pull your hands to your hips (picture 2)
- Press your heel away from you until your leg is straight and your heel is just off the floor (picture 3)
- Hold for a **slow count of 5** then return to the start position
- Repeat **6-8** times on each leg



Try doing this while watching television.

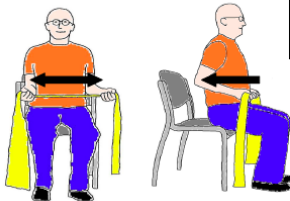


2. Upper back strengthener

- Hold the band with your palms facing upwards and your wrists straight
- Pull your hands apart then draw the band towards your hips and squeeze your shoulder blades together
- Hold for a **slow count of 5** whilst breathing normally
- Release, then repeat **7** more times



Try doing this while watching television.



3. Knee bends

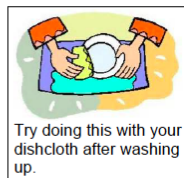
- Stand with your feet hip width apart and hold the support
- Bend your knees and push your bottom backwards as though you were going to sit down
- Try not to lift your heels
- Ensure your knees do not roll inwards
- Come back up to the start position
- Repeat **10** times
- If you feel steady perform without holding on



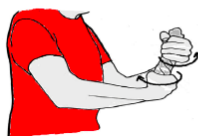
Try doing this while waiting for the kettle to boil.

4. Wrist strengthener

- Fold or roll your band into a tube shape
- Sit or stand tall
- Squeeze and twist your band, hold for a slow count of 5, then release
- Repeat this exercise **6-8** times



Try doing this with your dishcloth after washing up.



The following 3 exercises are to help improve your balance.

1. Toe walk no support

- Stand tall
- Raise your heels (weight over big toe) then take **10** small steps forwards
- Bring your feet together then lower your heels with control
- Repeat in the other direction



Try doing this while waiting for the kettle to boil.

2. Heel walk no support

- Stand tall
- Raise your toes without sticking your bottom out, then take **10** small steps forwards
- Lower your toes with control
- Repeat in the other direction



Try doing this while waiting for the kettle to boil.

3. Tandem walk

- Stand tall, side on to the wall or kitchen worktop.
- Walk **10** steps forwards placing one foot directly in front of the other (like walking on a tightrope)
- Look ahead and aim for a steady walking action
- Take the feet back to hip width apart before turning towards the support, then repeat the steps in the other direction



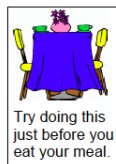
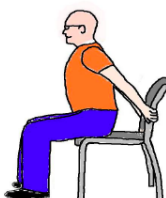
Try doing this while waiting for some food to cook.

Ending the session

Finish by performing all the following stretches:

1. Chest stretch

- Sit tall away from the back of the chair
- Reach behind with both arms and grasp the chair back
- Press your chest upwards and forwards until you feel the stretch across your chest
- Hold for **10-20** seconds



Try doing this just before you eat your meal.

2. Back of thigh stretch

- Make sure you are right at the front of the chair
- Straighten one leg placing the heel on the floor
- Place both hands on the other leg then sit really tall
- Lean forwards with a straight back until you feel the stretch in the back of your thigh
- Hold for **10-20** seconds
- Repeat on the other leg



Try doing this while watching television.

3. Calf stretch

- Stand behind the chair holding on with both hands
- Step back with one leg and press the heel down
- Check that both feet face directly forwards
- Feel the stretch in your calf
- Hold for **10-20** seconds
- Repeat on the other leg



Try doing this just before clearing the table, holding the dining chair.

Well done! You have finished your exercises for today.

Try to do these exercises **every day of the week** except the day you go to your exercise class.

If you have any queries or concerns regarding this home exercise programme please speak to your exercise instructor.

Thank you for your continued participation in the study.

Appendix 8: PSI Phases 1 & 2 - intervention planners

PSI Phase 1, Weeks 1- 2

Warm up (15 mins):

Seated or standing circ boost (2-3 mins): arm swings, toe lifts, slap & clap, gentle march

Seated or standing mobility (8-10 mins): shoulder lifts, shoulder circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between

Seated stretches (5-6 mins): hamstring, chest, calf & triceps (8-10 secs hold per stretch)

Endurance (5 mins):

Standing: marching , side taps & single side steps (with or without support)

Seated resistance work (15 mins):

Upper back, front of thigh, wrist, hip abduction (with light therabands) & sit to stand (5-8 reps each)

Standing dynamic balance (5 to 10 mins):

Heel raises with support (x5), one leg stand or flamingo swing with support (10-15 secs per leg), toe raises with support (x5), tandem stand (10 seconds per leg), toe walks (x5)

Cool down (10-15 mins):

Seated circ lowerer (2-3 mins): arm swings, gentle march, slap & clap, toe lifts

Seated stretches (6-8 mins): as warm up but longer hold (12-20 secs per stretch)

Seated or standing tai chi (2-3 mins): painting the fence

PSI Phase 2, Weeks 3-12

Warm up (10 mins):

Standing circ boost (2-3 mins): marching, arm swings, marching with arm swings

Standing mobility (5 mins): shoulder lifts, shoulder circles, side bends, trunk twists, heel & toe (4 reps each) with marching in between

Standing stretches (3 mins): calf, chest, & upward side stretch plus seated hamstring stretch (8-10 secs hold per stretch)

Endurance (10 mins):

Side taps, side steps, double side steps, interval conditioning (fartlek) marches (work hard 4, ease off 4), wide base sway, turning, light lunging, offer arm lines, ensure aerobic curve ie build intensity to peak effort (fartlek) then cool down, ensure nil stopping (possible blood pooling)

Balance(10 mins):

Heel raise, toe walk, toe raise, heel walk – 3 steps & combinations of toe and heel walks e.g. toe walk 3 steps, rest, turn, heel walk 3 steps back to support, tandem walk, flamingo swing and step swings, compensatory stepping – front, side, back diagonal, across, single & double step

Seated (& standing) resistance (10 mins):

3 or 4 of the following: sit to stand, seated upper back, bicep curls, backward press, seated outer thigh strengthener, leg press, wrist strengthener, wall press, ankle strengthener, static lunge (6-8 reps of all resistance work with peak strain holds of up to 5 secs)

Floorwork (10-12 mins):

3 or 4 of the following: Box balance, prone balance, box bone load, side lying leg lift, prone back extension, prone transversus, prone hip extension (6-8 reps of all resistance work with peak strain holds of up to 5 secs), bum walking and/or crawling forwards

Cool down (8-10 mins):

Seated circ lowerer (1-2 mins): arm swings, gentle march

Seated stretches (4 mins): hamstrings, chest, upward side stretch and standing calf (10+ secs per stretch)

Standing tai chi (2-3 mins): working the oar

Appendix 9: Session plans

<u>Session Plan Week 1</u>
<u>Introduction (15mins)</u> Take the register Introductions - Instructor and clients Explain and demo the fire procedures Show around the building toilet and exits Check health status, medications and medical conditions – Any changes? Any Latex allergies? Explain the outcomes of the programme and what to expect in the coming weeks including the importance of home exercise
<u>Warm up (12 mins)</u> Seated circulation booster (2-3 mins) toe taps, gentle march, arm swings Seated mobility (6 mins) shoulder circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between Seated stretches (2-3 mins) Back of thigh and back of arm (8-10 secs hold per stretch)
<u>Targeted Resistance(10 mins) 6 reps</u> ➤ Easy Bands – Yellow Sit to Stand Upper Back Strengtheners
<u>Cool Down Hold for 12-20 seconds</u> back of arm, chest, side, calf, back of thigh Home Exercise programme handouts and reminder Tai Chi – If time permits – Rowing the Oar

Session Plan Week 4

Introduction (5mins)

Take the register
Client welcomes- each client to say their name
Ask if clients need a refresher of the environment. Fire procedures, exits and toilets etc.
Check health status, medications and medical conditions – Any changes?
A reminder of the importance of home exercise

Warm up (15mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Seated or standing mobility (6 mins) shoulder raises, circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between
Seated stretches (2-3 mins) back of arm, side, chest, back of thigh and calf (8-10 secs hold per stretch)

Dynamic Endurance (6mins)

Standing - marching, side taps, wide base sway and single side steps (with or without support).
Interval conditioning (fartlek) marches (work hard 4, ease off 4) ensure aerobic curve then cool down. No stopping (possible blood pooling)

Dynamic Balance (8 mins)

Heel raises with support 8-10 reps
Toe raises with support 8-10 reps
Flamingo Stand/ Flamingo Swing
Toe walks Heel Walks
Tandem Walk

Targeted Resistance (8 mins)

- Easy Bands – Yellow

Upper Back Strengtheners, wrist strengthener 10 reps for both

Backward Chaining (10mins)

Back Leg Lifts 6-8 reps each leg

Cool Down (10 mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Back of arm, chest, side, calf, back of thigh. 12-20secs hold per stretch
Tai Chi – Clouds
Home Exercise programme reminder

Session Plan Week 6

Introduction (3mins)

Take the register
Check health status, medications and medical conditions – Any changes?
A reminder of the importance of home exercise

Warm up (15mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Seated or standing mobility (6 mins) shoulder raises, circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between
Stretches (2-3 mins) back of arm, side, chest, calf and back of thigh (seated) (8-10 secs hold per stretch) with gentle marching in between.

Dynamic Endurance (5mins) Shorten recovery to help fitness and to give more time to prioritise dynamic balance

Standing - marching, side taps, wide base sway and single side steps (with or without support).
Interval conditioning (fartlek) marches (work hard 10, ease off 10) x 3 ensure aerobic curve then cool down. No stopping (possible blood pooling)

Dynamic Balance (8 mins)

Knee Bend and Toe raises 8-10 reps
Flamingo Swing
Walk Forward, Walk Backwards
Tandem walk backwards

Targeted Resistance (8 mins)

Outer Thigh, Wrist strengthener 10 reps

Backward Chaining (10mins)

Back Strength 6 reps, Wrist, Bridge, 6 - 10 reps

Cool Down (10 mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Back of arm, chest, side, calf (Always Standing), back of thigh. 12-20secs hold per stretch
Tai Chi – Clouds
Home Exercise programme reminder 15 mins

Session Plan Week 8

Introduction (3mins)

Take the register
Check health status, medications and medical conditions – Any changes?
A reminder of the importance of home exercise

Warm up (15mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Seated or standing mobility (6 mins) shoulder raises, circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between
Stretches (2-3 mins) back of arm, side, chest, calf and back of thigh (seated) (8-10 secs hold per stretch) with gentle marching in between.

Dynamic Endurance (6mins)

Standing - marching, side taps, wide base sway and single side steps (with or without support).
Interval conditioning (fartlek) marches (work hard 10, ease off 10) x 3 ensure aerobic curve then cool down. No stopping (possible blood pooling)

Dynamic Balance (8 mins)

Sit to Stand (second set is harder version - hover) 8-10 reps x 2
Tandem walk forwards and backwards. (For those able. lift knee up then put in place - only forwards)
Side Steps harder version with knee bend in between
Flamingo stand

Targeted Resistance (8 mins)

Front and back of arm with the pause on second set 10 reps x 2
Wrist Strengtheners and chest strength seated

Backward Chaining

None today

Cool Down (10 mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings
Back of arm, chest, side, calf, back of thigh. 12-20secs hold per stretch
Tai Chi – Clouds
Home Exercise programme reminder 15 mins

Session Plan Week 10

Introduction (3mins)

Take the register

Check health status, medications and medical conditions – Any changes?

A reminder of the importance of home exercise

Warm up (10mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings

Seated or standing mobility (6 mins) shoulder circles, head movements (Otago), side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between

Stretches (2-3 mins) back of arm, side, chest, calf and back of thigh (seated) (8-10 secs hold per stretch) with gentle marching in between.

Dynamic Endurance (6mins)

Standing - marching, side taps, light lunging, wide base sway, high knees, single side steps (all with or without support). Interval conditioning (fartlek) marches (work hard 1 min ease off 20 secs) x 1 ensure aerobic curve then cool down. No stopping (possible blood pooling)

Dynamic Balance (8 mins)

Knee Bends x 10 x 1 however with the hover

Flamingo Stand x 1 each side 20 secs each side

Tandem Walking, Backwards tandem Walking back (or backwards walking if too difficult 8 steps x 2 reps. (2nd set with raised knee lift but not backwards)

Targeted Resistance (8 mins)

Front of arm, back of arm 10 reps each side x 1 set

Outer thigh x 10

If time allows Upper back strengthener followed by chest. (10 easy version then 5 harder version for both these exercises)

Backward Chaining

None this week as prioritising band work

Cool Down (10 mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings

Back of arm, chest, side, calf, back of thigh. 12-20secs hold per stretch

Tai Chi – Rowing the Oar

Home Exercise programme reminder 20 mins

Session Plan Week 12

Introduction (3mins)

Take the register

Check health status, medications and medical conditions – Any changes?

A reminder of the importance of home exercise

Warm up (10mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings

Seated or standing mobility (6 mins) shoulder raises, circles, side bends, trunk twists, heel & toe (4 reps each) with gentle marching in between

Stretches (2-3 mins) back of arm, side, chest, calf and back of thigh (seated) (8-10 secs hold per stretch) with gentle marching in between.

Dynamic Endurance (6mins)

Standing - marching, side taps, wide base sway and single side steps (with or without support).

Interval conditioning (fartlek) marches (work hard 20, ease off 20) x 2 ensure aerobic curve then cool down. No stopping (possible blood pooling)

Dynamic Balance (8 mins)

Toe Raises x 10 for 5 secs

Heels raises x 10 for 5 secs

Knee Bends with heel raise x 8 each side

Tandem walk then backwards

Targeted Resistance (8 mins)

Front and back of knee strengthener 10 reps each side

Backward Chaining (10mins)

Back Strength

Wrist Bone load

Box Balance

All 10 reps

Cool Down (10 mins)

Seated or standing circulation booster (2-3 mins) toe taps, gentle march, arm swings

Back of arm, chest, side, calf, back of thigh. 12-20secs hold per stretch

Tai Chi – Rowing the Oar

Home Exercise programme reminder 20 mins

Appendix 10: Intervention delivery SOP

Adapted FaME Exercise Programme Procedures

SOP Reference: NUVI/SOP/005

Associated Documents:

Informed consent
Baseline Assessment
Recruitment of participants

Scope:

The exercises are adapted from the FaME (Falls Management Exercise) programme. This is an evidence-based structured exercise programme designed for older people and used in the community setting. It incorporates stretch, balance and endurance exercises. FaME has been evaluated in people aged 65-95 and has been shown to reduce the number of falls, prevent injuries resulting from falls and prevent further falls. Exercises are tailored for the individual's ability and health need. The FaME programme concentrates on endurance, strength and balance training. Strength training is important for older adults because of the wider benefits that are seen to immune and endocrine function, mobility and activities of daily living (Skelton 2003).

FaME is a group exercise programme which was developed and tested in a controlled trial in the UK (Skelton 2005). It includes part of the Otago Exercise Programme (OEP) and aims to reduce asymmetry as well as improve balance. It was designed to be delivered by qualified postural stability instructors.

FaME has not been evaluated in the visually impaired population. VIOLET aims to explore the feasibility of adapting the existing FaME programme for OPVI and to collect information from the stakeholders involved. In addition VIOLET aims to capture data regarding concordance, fear of falling, activity avoidance, number of falls, quality of life, (including loneliness, depression and perceived health status) and cost implications. VIOLET is an randomised control trial with 2 arms, one arm will contain those OPVI's who will attend the 12 week modified FaME programme, the other will contain those OPVI's randomised to the normal daily activity arm. Data will be collected on all study participants at baseline, 12 weeks post baseline (post the FaME programme to those randomised to that arm) and at 24 weeks.

Definitions:

Procedure:

1. Exercise Programme.

- 1.1. The adapted FaME includes and extends the OEP. It will comprise one hour-long postural stability instructor (PSI) delivered group exercise class at a local venue for a maximum of 10 participants for 12 weeks. Participants will be advised to exercise at home for up to 2 hours using an adapted standardised home exercise programme.

- 1.2. The programme includes leg muscle strengthening and balance retraining that progress in difficulty. Progressive trunk and arm muscle strengthening, bone loading endurance (including walking and flexibility training, functional floor skills and adapted Tai Chi) complete the evidence based programme. Ankle and wrist cuff weights, therabands and mats are also used throughout the programme.
- 1.3. The group exercises include retraining of the ability to get up from the floor (backward chaining) and floor exercises to improve strength, balance and coping strategies to reduce the risk of complications resulting from a long-lie.
- 1.4. The PSI will also keep registers of attendance and monitor and record any adaptations to the programme and any feedback from participants. They will notify the research team of any non-attenders and the reason for non-attendance or drop out. It is the PSI's responsibility to contact non-attenders.
- 1.5. All participants will be given information in their preferred format (large print, audio or DVD) regarding their home exercises

2. FaME group classes

- 1.1. The adapted FaME group exercise participants will be informed of their exercise venue and timetable
- 1.2. The venue ideally will be close to the participant's local community. The travelling distance between a participant's home and the class venue should be as minimal as possible to reduce the burden on participants.
- 1.3. Where possible exercise venues will provide separate female and male changing areas and/or privacy for changing for those who prefer not to change in the company of others. The appropriate attire would be able to be worn to and from the class as an alternative arrangement.
- 1.4. The exercise room will be screened for the duration of the class as appropriate.
- 1.5. Cultural issues such as family support will be encouraged and facilitated. The participants will be informed that they can if they wish bring with them a family member or friend. If the family member or friend feels able they can assist the OPVI with exercise programme.

3. Transport

- 1.1. All participants in the adapted FaME exercise programme will be offered a taxi service to and from the exercise venue. For those participants who do not wish to take up this offer it is important that the exercise venue is accessible by public transport and has adequate parking facilities. All travel expenses will be reimbursed.

4. Day and Time

- 1.1. Classes will be timetabled between Monday and Friday between 10.30am and 3pm. This will minimise the impact on the family/domestic duties of the OPVI and their accompanying family member or friend.

5. Concordance/compliance

- 1.1. Concordance will be recorded by means of an attendance register. A participant is deemed as fully concordant if they attend 9 out of 12 exercise classes

Appendix 11: Quality Assurance checklist

VIOLET

PSI QUALITY ASSURANCE CHECKLIST

					Warm-up	Dynamic Endurance	Dynamic Balance	Seated / Standing Resistance	Backward Chaining	Floor work	Cool-down Flexibility	Cool-down Adapted Tai Chi
Preparing					Teaching							
Took register of attendance					Engaged participants in order to motivate and promote confidence							
Verbally screened participants for falls, previously reported injuries and new or known medical conditions					Selected safe and effective exercises appropriate to the component.							
Appropriately followed up returners after period of absence					Selected safe and effective exercises appropriate to the stage in the intervention							
Reminded attenders to keep up with and submit diaries					Selected the appropriate speed for the exercises							
Ensure that infection control procedures are implemented and adhered to					Gave effective visual and verbal instructions							
Ensure that confidentiality of personal and medical data is respected					Provided specific relevant teaching points to enhance technique, effectiveness and postural stability							
					Reinforced the specific relevant teaching points at regular intervals							
					Provided safe transitions between exercises and session components							
					Demonstrated and performed exercises accurately and with good posture							
					Changed teaching position to improve observation and enhance communication							
					Demonstrated the use of observation and effective correction							
					Explained the purpose of the exercises, relating them to postural stability and daily life							
					Encouraged interactive communication, to check or clarify understanding, with group and one to one.							
					Spoke clearly, audibly and at an appropriate pace							
					Adapted exercises to meet the needs of participants with postural stability challenges							
					Offered alternatives to allow for different levels of ability / tailored exercises to individuals							

Appendix 12: Quality Assurance SOP

Quality Assurance of Exercise Intervention

SOP Reference: NUVI/SOP/012

ASSOCIATED DOCUMENTS:

PSI Quality Assurance Checklist

SCOPE:

The Violet study exercise intervention (an adapted version of FaME) needs to be standardised across research sites (Newcastle and Glasgow). Standardisation of the exercise intervention will be achieved by delivery of trial specific training to the PSIs including dissemination of stakeholder interview outcomes, submission (by PSIs) and signing off (by RA) of FaME session plans, QA of FaME delivery via observing and videoing of selected FaME classes and by the completion and analysis of QA paperwork.

This standard operating procedure describes how to train and monitor PSIs in the Violet study.

DEFINITIONS:

- QA: Quality Assurance
- PSIs: Postural Stability Instructors
- RA: Research Assistant
- FaME: Falls Management Exercise
- OPVI: Older People with visual impairment

PROCEDURE:

1. Trial training

1.1 To achieve standardisation of PSI sessions, PSIs are required to attend PSI Trial Training, which is no more than one day of training. .

1.2 The training will additionally include dissemination of information gathered at stakeholder interviews regarding adaptation to the standard FaME intervention needed for OPVI.

1.3 Trial training will also inform PSIs about the QA process, including familiarisation with the QA Checklist, QA visits, videoing and session plan submission.

1.4 Following training and before the intervention start date, PSIs will be required to submit basic lesson plans for the 12 week programme to ensure fidelity. These should be based on the standard FaME intervention and adhere to the principles of FaME and progression as well as incorporating adaptation requested by stakeholders. The plans will be checked and signed off by trial staff at each trial site.

2. Quality Assurance Visits

2.1 In order to standardise the delivery of the FaME classes and capture the adaptations used by Violet PSIs for VIOP, visits will be made to two of the taught exercise classes in weeks 3/4 and 9/10 of the 12 week intervention.

2.2 At each QA visit the RA will monitor the PSI session using the PSI QA Checklist. The QA Checklist and QA process will be familiar to the PSI. Copies of completed QA checklists will be supplied to the PSI.

2.3 The RA will video the visited sessions to capture adaptations used by Violet PSIs for OPVI.

2.4 The RA will compare the video to the relevant session plan supplied by the PSI to ensure the PSI is adhering to the plan and to capture adaptations used by Violet PSIs for OPVI.

3. Paperwork

3.1 PSIs will be required to complete an attendance register for each week of the intervention. Registers should not display patient ID codes nor personal information e.g. medical conditions.

3.2 Attendance registers will be photocopied on site by the RA at each week of the intervention.