Northumbria Research Link

Feasibility of Trial Procedures for a Randomised Controlled Trial of a Community Based Group Exercise Intervention for Falls Prevention for Visually Impaired Older People: The VIOLET Study.

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42

Abstract

Background

Visually impaired older people (VIOP) have a higher risk of falling than their sighted peers, and are likely to avoid physical activity. The aim was to adapt the existing Falls Management Exercise (FaME) programme for VIOP, delivered in the community, and to investigate the feasibility of conducting a definitive randomised controlled trial (RCT) of this adapted intervention.

Methods

Two-centre randomised mixed methods pilot trial and economic evaluation of the adapted group-based FaME programme for VIOP versus usual care. A one hour exercise programme ran weekly over 12 weeks at the study sites (Newcastle and Glasgow), delivered by (voluntary and community organisations). Participants were advised to exercise at home for an additional two hours over the week. Those randomised to the usual activities group received no intervention.

Outcome measures were completed at baseline, 12 and 24 weeks. The potential primary outcome was the Short Form Falls Efficacy Scale – International (SFES-I).

Participants' adherence was assessed by reviewing attendance records and self-reported compliance to the home exercises. Adherence with the course content (fidelity) by instructors was assessed by a researcher. Adverse events were collected in a weekly phone call.

Results

64 82 participants, drawn from community-living VIOP were screened; 68 met the inclusion

65 criteria; 64 participants were randomised with 33 allocated to the intervention and 31 to the

66 usual activities arm.

67 94% of participants provided data at the 12 week visit and 92% at 24 weeks. Adherence was

68 high. The intervention was found to be safe with 76% attending nine or more classes.

69 Median time for home exercise was 50 minutes per week.

70 There was little or no evidence that fear of falling, balance and falls risk, physical activity,

71 emotional, attitudinal or quality of life outcomes differed between trial arms at follow-up.

72 **Conclusions**

73 The intervention, FaME, was implemented successfully for VIOP and all progression criteria

74 for a main trial were met.   The lack of difference between groups on fear of falling was

75 unsurprising given it was a pilot study but there may have been other contributory factors

76 including suboptimal exercise dose and apparent low risk of falls in participants. These

77 issues need addressing for a future trial.

78 **Trial Registration**

79

80 Current Controlled Trials ISRCTN ID: 16949845 Registered: 21 May 2015

81

82 **Keywords**

83 Falls management, exercise, visual impairment, older people, feasibility clinical trial

84

Background

Falls in older people are common [1, 2] and are associated with considerable morbidity and mortality [3], with approximately 10% of falls resulting in fractures [4]. Costs account for 0.85–1.5% Western economies' total health-care expenditure [5]. In the UK, in 2015, falls in the over 65s were estimated to cost £4.6 million a day [6] and thus represent a high cost to health and social care budgets [7, 8].

The incidence and prevalence of older people with significant sight loss is increasing[9]. Older people with visual impairment have a 1.7 times higher risk of falling than the general population, requiring more hospital and nursing home admissions. More contact with their general practitioner (GP) than sighted peers is also reported. [10]. Eight per cent of falls-related hospital admissions are likely to occur in people who are visually impaired [8], which accounts for approximately 21% of the total cost of treating falls. Visual impairment thus acts as an independent risk factor for falls [11-13] with falls risk factors including poor visual acuity and contrast sensitivity, decreased depth perception and reduced visual field [14-18], in addition to more general factors such as muscle weakness and balance.

Fear of falling (FoF), an umbrella term for the psychosocial consequences of falls, is common and a significant predictor of a future fall alongside a cycle of restricting daily activity and mobility with loss of confidence, reduced social participation, increased frailty and reduced quality of life [19-22]. A vision charity found that older people are highly likely to avoid activity because of their visual impairment [23]. Anxiety and depression are also common in those with visual impairment with concomitant reduced activity [3].

A Cochrane review found that exercise can reduce fear of falling in the short term, with insufficient evidence for longer term efficacy [24, 25]. A high risk of bias was noted in most

109 included trials. There are also limited health economic data about fear of falling interventions

110 [26-27]. Multifactorial falls intervention programmes are effective in reducing falls among

111 older people [28-31]. A Cochrane systematic review reported that home safety assessment

112 and multi-component group and home-based exercise programmes reduce the rate of falls and

113 the risk of falling in community dwelling older people [30]. For example, a New Zealand

114 based randomised controlled trial (RCT), [32], showed no benefit from a multicomponent

115 home-based exercise programme in visually impaired participants, though those with stricter

116 adherence to the exercise programme had fewer falls. Adherence to the home based exercise

117 programme in VIOP was poor with only 18% of VIOP completing all home exercise sessions

118 over a year period. In a subsequent 3-armed UK based feasibility trial (VIP2 UK), all

119 participants who completed the trial reported partially or completely adhering to home safety

120 recommendations, but evidence for adherence to home exercise was equivocal [33].

121 Older people with visual impairment are therefore at higher risk of falls and fear of falling

122 and its associated adverse psychosocial effects. Evidence of the effectiveness of exercise

123 programmes and adherence to them in such individuals is lacking, though there is some

124 evidence to suggest that group based exercise may be of more benefit than individual

125 programmes. In addition, there is an issue with case ascertainment in those with falls and

126 visual impairment, with only half of falls clinics in the UK assessing routinely for visual

127 impairment [34].

128 The current study used a known effective community-based exercise intervention, routinely

129 used in falls services in the UK [35]. The aims of the study were to conduct a feasibility study

130 to inform the design and conduct of a future definitive multicentre randomised controlled trial

131 (RCT) and economic evaluation of an adapted group-based exercise programme to prevent

132 falls and reduce fear of falling among VIOP. Specific aims of the feasibility study were to

133 assess recruitment and retention to the study, willingness to be randomised and to test the trial

134 methodology, including the identification of candidate outcome measures and rehearse the

135 methodology for cost effectiveness analysis. Participants' adherence to the exercise

136 programme was also examined. The acceptability of the intervention was examined

137 qualitatively, and will be reported in a separate paper.

138

Methods

Study Design

141 The study adheres to CONSORT guidelines for the design and reporting of clinical trials.

142 This study adapted an existing effective group-based health promotion intervention (FaME)

143 for VIOP. Because of the lack of relevant information for a full RCT on this topic, a

144 randomised mixed methods feasibility study was designed to inform the design and conduct

145 of a future definitive multi-centre RCT on an adapted version of a community-based exercise

146 intervention for falls management, the FaME programme.

147 The design was a two-centre (Newcastle and Glasgow) randomised pilot trial and economic

148 evaluation of an adapted exercise programme for older visually impaired people versus no

149 intervention with embedded qualitative evaluation. Interviews were conducted to explore

150 acceptability and applicability of the intervention, the research methods and the outcome

151 measures. The results of these interviews are being reported in a separate paper.

152 Visually impaired community-dwelling older people were recruited from the 2 study sites

153 and were randomised into one of two groups. Group One was a 12-week exercise programme

154 (one-hour session per week), and Group Two was usual activities.

Inclusion and Exclusion criteria

156 The inclusion and exclusion criteria have been published in a previous protocol paper [36]. In

157 brief these were: aged 60 years and over, community dwelling and attending a low vision

158 clinic and/or were members of organisations for the visually impaired. Exclusion criteria

159 were acute or uncontrolled medical conditions and inability to comprehend simple movement

160 instructions.

161

Ethical Approval and Consent to Participate

163 Favourable ethical opinion from the Newcastle and North Tyneside Research Ethics

164 Committee and R&D approval was obtained prior to commencement of the intervention.

165 Glasgow Caledonian University was approved as a non-NHS site with local ethics approval.

166 Information sheets were provided to all eligible participants and written informed consent

167 obtained prior to any study procedures. Signed or verbal consent was sought and if

168 participants were unable to sign, consent was sought by a third party who signed the witness

169 section of the consent form.

170

Identification, Screening, and Recruitment

172 Previous studies have identified that recruitment and adherence in frail older people can be

173 difficult, although data for recruitment and retention rates in VIOP was relatively unknown.

174 Within the VIP2UK study [33], only 10% of those initially screened and 51% of eligible

175 participants agreed to take part. Recruitment in the current study was from both National

176 Health Service (NHS) and non NHS sources, in order to maximise recruitment as this has

177 been found to be difficult in previous trials

178 The Ophthalmology Department in Newcastle, Newcastle Society for Blind People (NSBP),

179 and Visibility in Glasgow identified potential participants and passed on the expressions of

180 interest to the research team. VIOP who expressed an interest in participating in the study

181 received further detailed information (in English only).

182 Following initial low referrals from the Newcastle Low Vision Clinic, and with appropriate

183 ethical approval, Eye Clinic Liaison Officers (ECLOs) were empowered to identify and

184 approach potential participants. With permission, expressions of interest were forwarded to

185 the research team who assessed for eligibility in the same way as the participants identified

186 through the low vision clinic and NSBP.

187

188 Participants gave permission for the study team to contact their General Practitioner (GP), via

189 letter, to ensure medical fitness of the participant to take part in the study, and once eligibility

190 confirmed, the participant was randomised.

191

192 **Randomisation**

193

194 Randomisation has been previously described [36], was stratified by centre and was

195 administered centrally via Newcastle Clinical Trials Unit using a secure web based system

196 using a blocked allocation system to allocate participants to the two groups. Participants were

197 informed of their allocated treatment group following randomisation.

198

199 **Study Intervention**

200

201 The logistical delivery of the group-based Falls Management Exercise (FaME) programme

202 was adapted for VIOP by stakeholders and is reported in a separate paper. The exercise

203 component and progression content of FaME remained as the original. The exercise

204 programme (the intervention) consisted of one hour weekly sessions over 12 weeks and these

205 were held in community venues with a maximum capacity of ten participants per group. Two

206 exercise groups were held at each site, with a third in Newcastle added to maximise

207 recruitment. Participants were offered taxi transport and also brought a companion or support

208 if they wished.

209

210 All participants completed a health screening tool, normally administered by the exercise

211 instructors prior to delivery of the FaME programme. The exercises consisted of balance

212 specific, individually-tailored and targeted training for dynamic balance, strength, endurance,

213 flexibility, gait and functional skills, training to improve 'righting' or 'correcting' skills to

214 avoid a fall and backward-chaining i.e. retraining of the ability to get down to and up from

215 the floor. Functional floor exercises and adapted Tai Chi exercises were also carried out with

216 progressively more challenging content over the 12 weeks. Resistance bands and mats were

217 used [37].

218

219 Participants were also advised to exercise at home for up to two hours per week. The

220 exercises were to be performed if possible daily, on the days the participant was not

221 attending the exercise class. All home programmes contained 'prompts' that linked exercises

222 to daily tasks e.g. performing heel raises whilst waiting for the kettle to boil, in order to

223 improve adherence. Exercises were provided in a large text booklet, DVD or audio format.

224 Exercises were designed to be completed in 10 to 20 minute blocks, becoming more

225 challenging and graduating into longer periods. Thus the intervention comprised up to 36

226 hours over the 12 week period (with full adherence), concordant with current evidence [38].

227

228 **Control Group**

229

230 Those participants who were randomised to the usual activities group received no

231 intervention and continued with their usual activities. They were offered an equivalent

232 exercise programme after the 24-week follow-up data collection at both sites.

233

234

Outcomes

236

237 The progression criteria to judge the feasibility of progressing to a full trial were that

238 following the six-month follow-up data collection [36]:

239   1) ≥50% of eligible participants recruited into the feasibility study;

240   2) ≥70% of the participants in the intervention arm completed nine to twelve sessions in

241   the exercise programme.

242   3) ≥70% of participants had data collected on main outcomes at six-month follow-up;

243   4) <10% of serious adverse events deemed due to the intervention.

244

Outcome Measures

246

247 Following consent, a researcher assessed all participants, either on site or in their own home,

248 depending on the participants' preferences. Information on demographics, co-morbidities,

249 current medication, socio-economic information and the main study outcome measures were

250 collected at the baseline visit.

251

252 The selected outcome measures were standardised assessment instruments that have been

253 used in falls research. These were assessed at baseline, 12 weeks and 24 weeks (Table 1,

254 Figure 1). Fear of falling (FoF) was selected as the primary outcome variable. The Short Falls

255 Efficacy Scale – International (SFES-I), captures the participants' concerns about doing

256 everyday activities without falling[39].

257

258 Secondary outcome measures included: Activity avoidance [40]; Timed Up & Go test (TUG),

259 [41] Falls Risk (FRAT) [42]; Physical Activity (Phone-FITT) [43]; Loneliness (Six-Item

260 Scale for Overall, Emotional, and Social Loneliness)[44]; Hospital Anxiety and Depression

261 Scale (14 item) [45]; Work and Social Adjustment Scale (WSAS) [46]; Health related quality

262 of life (EQ-5D-5L) [47] and quality of life (ICECAP-O) [48]. Currently performed physical

263 activities/exercise were also assessed using a short bespoke self-report inventory. Because of

264 their visual impairment, assistance was often required to fill in the questionnaires, either by

265 the researcher reading out the questions and filling out the forms, or by providing the

266 questionnaires in a format accessible to the participant. Where no more than 20% of

267 questions were missing or uninterpretable on specific scales, the score was calculated by

268 using the mean or median value (as appropriate) of the respondent-specific completed

269 responses on the rest of the scale to replace the missing items [49].

270

271

272 Each participant completed a falls diary each week, with assistance from a Researcher, during

273 a weekly telephone call. Details of any adverse events and near misses were also recorded at

274 this time and are described in the safety analysis. When a fall did occur, the researcher

275 completed the falls resource/expenses form on behalf of the participant retrospectively during

276 the weekly telephone at 12 and 24 weeks follow up.

277

278 **Sample Size**

279 As this was a feasibility study, a formal power calculation was not appropriate. We aimed to

280 obtain a minimum of 30 responses in each trial arm at 6 month follow-up to estimate critical

281 parameters to the necessary degree of precision [50]. To provide feasibility data, we aimed to

282 recruit a total of 80 community-living VIOP to allow for loss to follow-up.

283

284

285 POSITION **FIGURE 1**

286

287 **TABLE 1 Trial Procedures**

	Intervention	**Control**
Weeks 1-12	Daily completion of falls diary 1 hour weekly exercise session Advice to carry out up to two hours of additional home exercise per week Weekly telephone call to/from researcher to record any adverse events Completion of falls resource/expenses form with the researcher (if required).	Daily completion of falls diary Weekly telephone call to/from researcher to record any adverse events. Completion of falls resource/expenses form with the researcher (if required).
Week 12 ((+/- 2 weeks)	Following information collected: Co-morbidities, current medication, any changes in socioeconomic information, and incidental costs (intervention group only) and the outcome measures were completed.	Information collected as per intervention group
Weeks 12-24	Daily completion of falls diary Weekly telephone call to/from researcher to record any adverse events. Completion of falls resource/expenses forms with researcher if required	Information collected as per intervention group.
Week 24 (+/- 2 weeks)	Assessed on all measures	Assessed on all measures

288

289

Adherence

Adherence to the group exercise programme (register) and home exercise programme (self-report) was assessed. Participants were classed as adherent to group exercise if they attended nine out of 12 of the group sessions [36].

Economic Evaluation

Cost effectiveness analysis was rehearsed from an NHS and personal social services perspective using the EQ-5D-5L and ICECAP-O as outcome measures and via a health economic self-report service receipt inventory. Costs of the intervention were micro-costed using the Violet feasibility study records. For each trial participant, all components of treatment costs stratified by category of resource use were computed by multiplying units of resource use by their unit costs. These were then summed over all resource use categories to obtain a total cost for each participant. This was then used to generate the average cost per patient in each arm of the trial. All unit costs were expressed in GBP (£) and valued at 2015-16 prices. The mean cost of the intervention across the two sites was estimated. Utilities were estimated and reported for each trial arm using means, standard deviations, the median and the range.

Fidelity of the Intervention

Instructors submitted basic lesson plans for the 12-week programme prior to the start of the intervention. Their adherence with the course content (fidelity) was assessed by a researcher

315 (SG) attending 20% sample of exercise sessions. A standardised checklist was used, similar

316 to that used in a previously published trial [35], and these sessions were videotaped for

317 quality assurance purposes.

318

Safety

320

321 All adverse events judged as having a reasonable suspected causal relationship to a study

322 procedure (i.e. definitely, probably or possibly related) were considered to be related adverse

323 events. The opinion of a physician was sought if required. Severity of all AEs was graded on

324 a three-point scale of intensity (mild, moderate, and severe). Expected adverse events

325 included: Fall/trip/slip and its consequences: cuts and abrasions, soft tissue injury, fracture;

326 muscular/joint pain associated with the above or with increased physical activity; minor

327 illness not requiring GP intervention (cold, flu etc.); minor illness requiring GP intervention

328 (chest infection, urinary tract infection etc.)

329

330 Any serious adverse events were recorded until a participant reached their 24-week follow-up

331 visit and included injurious falls, serious falls and/or hospitalisation due to falls.

332

333

Statistical Analysis

335

336 Since this was a feasibility trial, the main analyses were descriptive, in order to inform the

337 design, choice of primary outcome, sample size and approach to analysis for a future

338 definitive study. The main outcomes were feasibility outcomes; the numbers of eligible

339 participants seen over the recruitment period, and the resulting rates of recruitment,

340 compliance with randomisation, and data completion were presented. Data completeness of

341 the instruments and any potential bias in the completion of follow-up data to inform the

342 choice of instruments in a future trial was ascertained. The majority of the outcome data is

343 presented in simple descriptive tables, presenting percentages, means and standard deviations

344 or 5-number summary (as appropriate), for each arm of the study.

345

346 There was potential for clustering effects, particularly class-based clustering in the

347 intervention group and this study aimed to investigate and estimate the size of any such

348 effects.

349

350

351 **RESULTS**

352

353 **Identification of potential participants**

354

355 In Newcastle, a dedicated member of NSBP telephoned members aged over 60 years to gain

356 permission to forward their contact details to the research team. It is not known precisely how

357 many potential participants were approached by NSBP, but anecdotal information suggests

358 that over two hundred calls were made. From these, thirty-five expressions of interest were

359 passed to the researchers. The primary source of potential participants at the Glasgow site

360 was Visibility. Anecdotally, over one hundred direct contacts were made by Visibility staff,

361 and the research team received forty-eight expressions of interest. The process of identifying

362 potential participants was time consuming and incumbent upon the resources of the third

363 sector organisations.

364

365 Identification of participants from the RVI Low Vision Clinic in Newcastle initially proved

366 problematic: very few of the staff referred potential participants to the researchers, only seven

367 were initially identified. After the involvement of ECLOs, fifteen further potential

368 participants were identified, and their expressions of interest were forwarded to the research

369 team. No screening or recruitment took place from the Low Vision Clinic in Glasgow as it

370 was closed over the period of recruitment.

371

372 All participants who had expressed an interest in the pilot trial were contacted by the research

373 team and assessed for eligibility in a consistent manner.

374

375 **Participant flow**

376 Participant flow is illustrated in the CONSORT diagram in Figure 2.

377

378 **FIGURE 2**

379

380 After assessment for eligibility, 68 people were asked if they would be willing to be

381 randomised and 66 agreed to do so (97%). This consent rate was much higher than the target of

382 50%, but will be biased upwards as a number implicitly declined to enter trial at an earlier

383 stage when they failed to send back an expression of interest.

384

385 Recruitment to the trial took place between June and November 2015. Recruitment was closed

386 when 64 participants had been randomised, which was below the target of 80.

387

388 After randomisation, 33 VIOP were allocated to the intervention arm, and 31 to usual

389 activities. Of the 33 VIOP allocated to the intervention arm, 3 did not attend any classes: 2 of

390 those who didn't attend any classes nevertheless provided study data. During the study, 1

391 person was lost to follow-up and 4 people in the intervention arm withdrew completely from

392 the study. The remaining 59 subjects provided data that was included in the statistical analysis:

393 this was only slightly below the target of follow-up data on 60 participants.

394

Baseline Participant Characteristics

396 Demographic and baseline characteristics at randomisation were compared across treatment

397 groups (Tables 2 and 3). The distributions of demographic variables were similar across the

398 trial arms: the only noticeable difference was that there were more who lived alone in the

399 usual activities arm.

400

401

402 **Table 2: Baseline demographic characteristics, by treatment arm**

Variable		Intervention Arm (n=33)	Usual activities Arm (n=31)
Gender	Male	14 (42%)	11 (35%)
	Female	19 (58%)	20 (65%)
Age (years)			
	Median (IQR)	80 (75, 87)	78 (68, 83)
Mean (SD)		79.3 (8.7)	76.5 (9.7)
	Range	61-95	62- 95
Participants' first language:			
	English	32 (97%)	28 (90%)
	Other	1 (3%)	3 (10%)
Ethnicity			
	White	33 (100%)	29 (94%)
	Asian or Asian British	0 (0%)	2 (6%)
Marital status:			
	Married/living as married	16 (48%)	8 (26%)
	Living with other family members	0 (0%)	2 (6%)
	Living alone	11 (33%)	16 (52%)
	Widowed	6 (18%)	5 (16%)
Employment status			
	Full time employment	0 (0%)	1 (3%)
	Retired	29 (88%)	28 (90%)
	Other	4 (12%)	2 (6%)

403

404 Table 3: Baseline numbers of self-reported co-morbidities, by treatment arm

Comorbidities		Intervention Arm (N=33)	Usual activities Arm (N=31)	Total (N=64)
Any comorbidities reported	Yes	25 (76%)	20 (65%)	45 (70%)
	No	8 (24%)	11 (35%)	19 (30%)
Numbers of comorbidities per participant	Min	0	0	0
	LQ	1	0	0
	Median	2	2	2
	UQ	5	6	5
	Max	9	13	13

405

406 **Delivery of intervention and intervention adherence**

407 A staggered start was used to facilitate the running of the first set of classes in both

408 Newcastle and Glasgow. This enabled those for whom the GP confirmation of eligibility had

409 not been returned promptly to start at any time within the first three weeks and continue to

410 complete the twelve sessions. In Newcastle, a third set of classes was provided for those who

411 had been recruited later, or whose eligibility checks took a long time to complete. In

412 Glasgow, the class sizes were six and nine respectively and, in Newcastle, class sizes were

413 six, five and four respectively.

414

415 Four withdrew completely from the study and attended 0, 2, 3 and 11 classes prior to

416 withdrawing. One participant died while in the trial, after attending 6 exercise classes. One

417 participant withdrew from the intervention after 3 classes but continued to provide trial data.

418 Two additional participants randomised to the intervention arm did not attend any classes as

419 their GP consent was not received in time, but continued to provide follow-up. Despite this,

420 76% attended 9 or more classes, which was one of the feasibility criteria for a future trial.

421

422 Table 4 summarises the number of sessions attended by participants randomised to the

423 intervention arm on the basis of class registers, and how often they exercised at home (self-

424 report) with its frequency and duration. It can be seen that on average they spent 50 minutes

425 per week, though there was a large variation in the amount of time spent exercising. This was

426 much less than the 2 hours per week that they were encouraged to so.

427 **Table 4: Summary statistics for the exercise classes attended and home exercise**

	min	LQ	Median	UQ	max
Number classes attended	0	9	10	12	12
Weeks when exercised at home during intervention*	0	5	9	11	14
Average weekly exercise frequency^	0	1.8	3.4	4.6	6.7
Average exercise duration per week (min)^	0	17.3	50.4	75.7	122

428 *'during intervention' is any calls made in the period between 1st exercise class and last class + 7*

429 *days*

430 *^ is the average frequency or duration for all weeks when participant reported exercising at home in*

431 *the valid timeframe * (note that these include zeros for weeks where no exercise at home was done)*

Data Completeness

Sixty out of 64 (94%) provided data at 12-week visit (four had withdrawn completely from the study at this point). Fifty nine out of 64 (92%) participants completed the 24-week visit (four had withdrawn completely and one was lost to follow up from the study at this point). In two cases, assessments were completed outside the two-week limit, due to other commitments or extenuating circumstances.

All those participants in the intervention arm remaining in the trial at each time point completed each of the questionnaires. There were two occasions when participants in the usual activity arm only partially completed a questionnaire (but this was still usable using missing data rules), and two occasions on which whole questionnaires were not completed. The elements of the phone-FITT questionnaire were completed for all those remaining in the trial at each time point. This suggests that all the chosen scales were suitable for use in a future trial, though the need to have researchers help participants, proved time consuming.

Questionnaire data throughout the trial

Table 5 summarises numeric outcome measures by trial arm and data collection point, for the SFES-I, WSAS, FRAT and phone-FITT. It can be seen that, based on the SFES-I score, the majority of participants had low or moderate concern over falling at baseline. The change from baseline in SFES-I at 12 and 24 weeks was minimal in both arms. There was a very wide range of WSAS impact scores at baseline, but the median changes over time were small.

456 For FRAT, the scores were generally low at baseline and showed little change over time.

457 Using the Phone-FITT summary, it can be seen that typical physical activity levels rose

458 slightly over the follow-up period in the intervention arm, and less so in the control arm,

459 though no formal comparison was made. These illustrate that concern over falling (the

460 proposed primary outcome for a definitive trial), and assessment of falls risk was low in the

461 participants recruited, so there was little progress to be made by any intervention.

462 **POSITION TABLE 5**

463 **Safety Analysis**

464

465 A total of 180 Adverse Events (AEs) were reported; these were categorised as 16 Serious

466 Adverse Events (SAEs) and 164 AEs. The majority of AEs reported were due to minor illness

467 and unrelated to the intervention.

468 There were 81 reported AEs in the intervention arm and 83 in the usual activities arm. No

469 AEs or SAEs occurred during the exercise classes. There were 9 SAEs in the intervention

470 arm and 7 SAEs in the usual activities arm. Of the 9 SAEs in the intervention arm, 4 were

471 fractures due to falls. There were no fractures due to falls in the usual activities arm.

472 However, of the 4 participants who sustained fractures due to falls in the intervention arm, 2

473 of these participants did not actually begin the intervention and had a self- reported history of

474 repeated previous falls. With regard to the other two participants in the intervention arm who

475 sustained fractures: one had taken part in 7 exercise classes when they tripped and fell in

476 their own home, whilst the other had taken part in 10 exercise classes when they tripped and

477 fell outside. There appears to be no evidence of a link between taking part in the intervention

478 and being at greater risk of a fracture due to a fall. One intervention participant died during

479   the study, but the death was unrelated to the intervention. This highlights that these VIOP had

480   multiple medical conditions and syndromes of ageing that affected their participation.

481

Economic Evaluation

483

Data regarding the intervention itself and the associated costs were fully recorded.

Though 31 falls were reported (in 20 participants), only six participants utilised

health and social care interventions post-fall, with none of these being quantifiable

in terms of costs, due to missing data regarding the type of intervention utilised.

The average total cost of the intervention per patient across both sites was £310 and

is shown in Table 6

490

Table 6: Costing of intervention

492

Resource use	Cost (£)	Unit	Source
Costs of Consumables			
Yoga Mats and exercise bands	420	Total cost	VIOLET study files
DVDs and CDs	65	Total cost	VIOLET study files
Costs of Staff Time			
Newcastle PSI (12 sessions x 3 cycles)	66.66	Per hour	HealthWorks
Glasgow PSI (12 sessions X 2 cycles)	61.50	Per hour	LLT
Glasgow PSI set up time (0.5 hours per session for 24 sessions)	30.75	Per 30 mins	LLT
Glasgow PSI travel and parking costs (per session)	7.24	Per session	LLT
Costs of Room Hire and Refreshments			
Newcastle (3 x 12 week cycles)	1925	Total Cost	HealthWorks
Glasgow (2 x 12 week cycles)	1476	Total Cost	Visibility

493

494 KEY: PSI= postural stability instructor, LLT =Later Life Training

495

496 Table 7 shows the EQ-5D-5L utilities for both trial arms at baseline and each of the

497 two follow up periods. Results show that for both treatment groups at baseline, EQ-

498 5D scores were poor, indicating 'a state worse than death' with the health state

499 being worse in the intervention group.

500

501

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503

504 **Table 7: EQ-5D-5L utility scores and ICECAP-O for health-related quality of**
505 **life by trial arm**

EQ-5D-5L Utility Scores	Intervention Arm				Usual Activities Arm			
	N	Mean (SD)	Median (IQR)	Range	N	Mean (SD)	Median (IQR)	Range
Baseline	28	-0.23 (0.25)	-0.25 (0.39)	0.83	31	-0.15 (0.24)	-0.19 (0.18)	1.15
12 weeks	28	-0.2 (0.22)	-0.2 (0.29)	0.78	31	-0.12 (0.27)	-0.15 (0.35)	0.95
24 weeks	28	-0.21 (0.27)	-0.26 (0.47)	0.9	31	-0.06 (0.28)	-0.09 (0.43)	1.14
ICECAP-O Capability Scores	Intervention Arm				Usual Activities Arm			
	N	Mean (SD)	Median (IQR)	Range	N	Mean (SD)	Median (IQR)	Range
Baseline	27	0.79 (0.14)	0.84 (0.22)	0.46	31	0.77 (0.12)	0.77 (0.2)	0.43
12 weeks	27	0.8 (0.11)	0.82 (0.13)	0.46	31	0.8 (0.13)	0.83 (0.19)	0.48
24 weeks	27	0.8 (0.14)	0.83 (0.14)	0.67	31	0.78 (0.15)	0.82 (0.24)	0.54

506

509 Compared to baseline the utility, scores at both follow up periods were improved

510 for both groups but still showing average health related quality of life scores being

511 poor. The range of utility scores were much larger in the usual activities arm

512 compared to the intervention arm with more observations showing positive health

513 related quality of life.

514

515 The capability score in the intervention arm was slightly higher compared to the

516 usual activities arm at baseline. At 12 weeks, capability was slightly higher with

517 both groups having on average 80% capability.

518 At 24 weeks, capability was maintained at an average of 80% capability in the

519 intervention arm, with a slight reduction in the usual activities arm (78%

520 capability).

521

522 Table 8 identifies the main issues raised and implications for a future trial.

523 **Table 8 : Summary of issues raised and implications for a future definitive trial**

Issues	Findings	Implications for future trial
Identifying potential participants	a) Via third sector organisations Not clear how many had been contacted Very time consuming Impractical to use research staff b) Via low vision clinic Only few expressed interest when Eye Clinic Liaison Officers involved	Would need to support third sector staff more Debatable whether Eye Clinic is worthwhile route First contact may be better via GP
Did eligible participants	66/68 (97%) of those eligible consented	Unreliable estimate from this

| consent? | to enter trial: exceeded target of 50%

Estimate biased upwards since some declined before being screened | pilot trial |
|---|---|---|
| Met recruitment target? | Randomised 64 participants to trial: below target of 80 | Recruitment was more difficult than anticipated: need to improve procedures |
| Compliance with intervention | 25/33 (76%) completed at least 9/12 group sessions : exceeded target of 70% | Compliance with exercise class regime is possible |
| Home exercise duration per week | Median duration 50min : encouraged to exercise for 120min | Need to find ways of encouraging participants to exercise at home for longer |
| Intervention | FaME intervention successfully adapted for VIOP | Need exercises appropriate to ability of individual, providing sufficient challenge |
| Retention throughout study | 59 participants retained to end of study: narrowly missed target of 60 | Retention was better than anticipated |
| Outcome assessments completed | 60/64 (94%) provided data at 12 week visit

59/64 (92%) provided data at 24 week visit : exceeded target of 70%

Very few items of missing data on any scale | Once recruited, retention and data collection was very good. No problem with completion if researchers can help, but this is time-consuming |
Suitability of candidate outcome measures	Suitable, howeverelements of standard assessments were occasionally inappropriate for VIOP	Other outcome assessments may additionally be included.
Safety issues?	16 serious adverse events, but none deemed due to intervention: less than target of <10%	No safety issues
Sample size calculation for definitive trial	Calculation very imprecise because of lack of estimates of parameters for SFES-1	Better estimates necessary
Data collection for health	Data often missing from resources form	Data collection form needs to be more structured

economic analysis		

524

525

526 **DISCUSSION**

527 The study has shown that it is feasible to conduct a RCT of a modified FaME

528 exercise intervention in visually impaired older people. Recruitment of eligible

529 participants to the randomised feasibility study exceeded the pre-planned

530 progression criteria, as did the adherence of participants to the intervention and data

531 collection from the participants. In addition, as planned, less than 10% of serious

532 adverse events were due to the intervention itself.

533 **Improving Recruitment**

534 Variation in the way participants were identified across the two study sites led to

535 some discrepancies in the recording of eligibility for the study. We are aware that

536 over 300 direct contacts (phone or letter) were made to potential participants, which

537 converted to 105 expressions of interest. An accurate count of contacts would be

538 required for future studies.

539 Overall, recruiting from third-sector (voluntary and community)organisations was

540 successful, though organisational feedback suggested that the conversion rate from

541 initial contact to expression of interest was poor. Also, one of these organisations

542 was able to provide a dedicated member of staff for recruitment, but the other was

543 not. Thus, identification of potential participants was more burdensome to the

544 voluntary and community organisations than expected. In future multi-site studies,

545 a recruitment strategy should be discussed and agreed across recruiting

546 organisations with provision of additional resource and support. Further stakeholder

547 involvement may improve recruitment and should be considered for a future

548 definitive study.

549 It proved difficult to recruit from the NHS Low Vision clinic. Since this was a

550 regional centre, many patients lived too far away from the exercise classes

551 provided. On the other hand, the NHS ECLOs dedicated a member of staff to

552 identify potential participants and pass on expressions of interest. This recruitment

553 strategy met the progression criteria with near to 50% conversion rate, though low

554 overall numbers. Only two of those originally found eligible for the study declined

555 to take part.

556 Given the difficulties experienced in recruiting via third-sector organisations and an

557 NHS low vision clinic, in a future study it may be advisable to use the primary care

558 setting with the dual purpose of GP-led assessment of health exclusions and

559 recruitment. Previous research suggests that a 'personal' invite by a health care

560 professional increases uptake of community exercise classes [51].

561

562 **Delivery of the Intervention**

563 A key component of the VIOLET study was the successful delivery of the adapted

564 FaME programme in which instructors adapted their delivery style to the needs of

565 participants.

566 For each cohort, quality assurance checks were performed, ensuring fidelity of the

567 programmes at both sites. We recommend that for future studies, participating

568 instructors should have an opportunity to attend two workshops, to share and

569 discuss findings regarding successful delivery of the intervention.

570 Within the exercise classes, a wide range of participant ability led to some

571 participants reporting not being physically challenged nor understanding the

572 relevance of specific exercises. There is a need for falls prevention programmes to

573 emphasise facilitating independence as well as other positive benefits, such as

574 socialising and receiving useful health education, in addition to an exercise

575 component. However, it is possible that the dose and duration of exercise classes

576 were insufficient for many of these participants to notice tangible benefits, as many

577 exhibited low FoF and low to moderate falls risk scores.

578 Guidelines recommend at least 36 hours of exercise per falls prevention exercise

579 programme, over the 12 weeks of participation, equating to a total of three hours

580 per week [2,29,38]. However, VIOLET study participants spent an average of 50

581 minutes on home exercise, which only provided 1 hour 50 minutes in total when the

582 weekly group exercise intervention was included. Home exercising was hard to

583 sustain, particularly once the 12 weekly group classes were completed: this

584 concords with other research [32, 33, 35]. The VIP and VIP2UK studies [32, 33]

585 and ProAct65+ [35], reported poor adherence to the home exercise component,

586 although the studies suggested that stricter adherence was associated with fewer

587 falls. Access to home exercise information could be enhanced technologically by

588 providing audio material that can be easily paused, revisited and generally modified

589 to individual preference, such as DAISY (Digital Accessible Information System),

590 screen reader, voice synthesiser, MP3, talking book and Braille. Continued

591 development of strategies to increase adherence to home exercise, or an alternative

592 may be to offer more group sessions in a week, is recommended, rather than

593 reliance upon home exercise. Classes may also provide a platform for an informal

594 sharing and exchanging of broad health information. Because reduction in falls risk

595 does require sustained engagement with exercise to maintain strength and balance

596 as we age, irrespective of VIOP, it is important that future studies attempt to

597 incorporate strategies to encourage behaviour change beyond the intervention.

598 Many falls interventions attempt to do this by encouraging self management and

599 self-efficacy with engagement in home exercise, but as engagement with home

600 exercise in VIOP appears so challenging, other strategies may need to be adopted.

601 **Methodological Issues**

602 The completion rates of the outcome measures were very high. Ninety-four percent

603 of trial participants provided data at 12 weeks and 92% at 24 weeks, although as

604 researchers often were needed to aid completion, the time allocated to this task

605 requires consideration. In general, these participants took longer to perform the

606 TUG time/functional ability assessment than that reported for healthy community

607 dwelling subjects 65-84 years [52]. Additional outcome measures, such as frailty,

608 may be included in future, in order to indicate whether exercise is maintaining the

609 level of resilience, even if it does not lead to an improvement. This may be more

610 appropriate and realistic for an older population with many co-morbidities. Further,

611 a longer follow-up period of 12 to 18 months would also be recommended in future

612 studies to explore effects of discontinuation and longer term effects (30).

613

614 Within the VIOLET feasibility study there was no assessment of visual impairment.

615 This was largely a pragmatic decision; however, this is recommended for future

616 studies as it would allow an assessment of whether a VIOP might be able to join a

617 mainstream class, or whether they might require one to one intervention, or more

618 intensive supervision. The inclusion criteria did not allow screening out for

619 'deafness'. People who are profoundly deaf and have a VI are difficult to

620 accommodate in a group setting. The assessment of whether potential participants

621 were 'physically able to take part in a group exercise class' category was, on the

622 whole, carried out when face to face, and thus open to individual interpretation.

623 This was also the case when assessing the participant's ability to walk indoors and

624 outdoors with or without aid. Mixing together able and less able participants,

625 impacts on the challenge and potential effectiveness of the programme.

626 Stratification by functional ability, as well as falls risk, is recommended for a

627 definitive trial.

628 There were a number of potential participants who 'self-reported' an uncontrolled

629 medical condition as reason for exclusion, however the degree of concordance with

630 a GP was not assessed. If recruitment were to be carried out in primary care in a

631 future study, the assessment would be carried out by a GP, rather than by a

632 participant or a researcher, who may not be medically trained, although our method

633 replicates current practice in falls services.

634 Although the progression criteria to judge the feasibility of progressing to a full

635 trial were all met, suggesting that this intervention could be taken to a full study,

636 recommendations from the research team and participants suggested that most

637 VIOP in the pilot trial could have been integrated into a mainstream class. Training

638 (CPD) of instructors to accommodate a range of VIOP in their mainstream sessions

639 is minimal and easy to facilitate through online training so would be affordable and

640 have sustainable reach. Only those with multiple co-morbidities (such as extreme

641 deafness or extreme frailty) required significantly more supervision. Mainstream

642 classes can be much larger, so if VIOPs were to join, extra supervisors may be

643 necessary.

644

Economic Evaluation

646 The current feasibility study has shown that whilst it is possible to collect most of

647 the data necessary for a full cost-effectiveness analysis of the exercise intervention

648 compared with usual care (cost of intervention per se, utility values and capability

649 values), there were some practical issues in accessing information regarding

650 participant self-reporting of resource use post intervention. It is unclear whether

651 this was due to their visual impairment. Participant inputs on use of health and

652 social care services and broader service use were often missing, despite telephone

653 calls by researchers. The data collection instrument for this was the participant self-

654 reported Falls Resources / Expenses Form (including informal care givers time).

655 This was based on a series of open ended questions as it was initially thought by

656 study team that carers filling out the form would find these types of questions easier

657 to respond to. However, from this data capture form, it was unclear whether an

658 absence of recorded data signified missing or whether participants had not actually

659 received any formal care. Furthermore, detail of the type of care was also lacking,

660 rendering any estimation of costs of the use of health and personal social care

661 resources difficult. The use of a more structured previously piloted data collection

662 tool may have mitigated against some of these issues though it is well documented

663 that reliance on patients/carers as a data collection method is limited by biases in

664 recall, nonresponse, and evasiveness [53]. Missing data is a common problem for

665 economic evaluations that run alongside clinical trials [54].

666 The HRQoL scores showed that participants in both arms of the trial at all time

667 points were poor. However, capability scores were towards the high end of being

668 capable. The ICECAP measures potentially offer a broader assessment of quality of

669 life and well-being, in comparison to measures routinely used in economic

670 evaluation, such as the EQ-5D-3L [55]. This broader assessment may allow

671 measurement of the full effects of an intervention or treatment. Previous research

672 has indicated that the ICECAP-O (for older people) and EQ-5D-3L measures

673 provide complementary information and are not substitutes [56]. The same may be

674 true for the EQ-5D-5L however, this is currently not addressed in the literature.

675

676 **Limitations**

677 The main limitations were that the sample recruited typically exhibited low to

678 moderate falls risk and relatively low fear of falling. The intervention may have

679 benefited higher risk fallers and these should be targeted for recruitment in future

680 studies. Recruitment proved difficult and we did not recruit the originally planned

681 sample of 80 participants, though retention was better than anticipated.

682 It is possible that there was potential bias by having the weekly telephone call,

683 which may have acted like an intervention in itself. There was no assessment of

684 visual impairment and we only recruited English speaking participants. These

685 findings limit the generalisability of the findings to a wider, more ethnically diverse

686 population. There was a lack of appropriate estimates upon which to calculate

687 sample size for a definitive trial.

CONCLUSIONS

It was possible to adapt successfully an existing, widely used exercise intervention for falls prevention (FaME) for people with visual impairment. Adherence to the intervention was high with very low attrition rates. It was to be expected that there would be no difference between the two groups in the main outcome measure, fear of falling, but a further two reasons may have contributed to the finding: there was possible a sub-optimal dose of exercise and the majority of participants were found to be of low risk. Although the progression criteria were met, a future definitive trial should consider the development of strategies to increase physical activity and structured exercise at home, in order to reach recommended levels of activity. Stratification of those with low, moderate and high falls risk should also be explored and that should include an assessment of visual impairment and functional ability as those with better functional vision may be able to be integrated into mainstream programmes. A recruitment strategy should be discussed and agreed across recruiting organisations which should also could include primary care practices and involve the multidisciplinary team.

LIST OF ABBREVIATIONS

Abbreviation	*Definition*
PHR	*Public Health Research*
TMG	*Trial Management Group*
NIHR	*National Institute of Health Research*
VIOLET	*Visually Impaired Older Adults Exercise Programme for Falls Prevention.*

GCP	*Good Clinical Practice*
PI	*Principal Investigator*
FaME	*Falls Management Exercise*
VIOP	*Visually Impaired Older Person*
RCT	*Randomised Controlled Trial*
SFES-I	*Short Falls Efficacy Scale - International*
R&D	*Research and Development*
VI	*Visual Impairment*
GP	*General Practitioner*
NHS	*National Health Service*
TUG	*Timed Up and Go*
FoF	*Fear of Falling*
DAISY	*Digital Accessible Information System*
NSBP	*Newcastle Society for Blind People*
PAG	*Project Advisory Group*
ECLO	*Eye Clinic Liaison Officer*
FRAT	*Falls Risk Assessment Tool*
HADS	*Hospital Anxiety and Depression Scale*
WSAS	*Work and Social Adjustment Scale*
PSI	*Postural Stability Instructor*
AE	*Adverse Event*
SAE	*Serious Adverse Event*
TOC	*Trial Oversight Committee*
PIS	*Patient Information Sheet*
QoL	*Quality of Life*

ICC	Intra-class correlation coefficient
NuTH	The Newcastle upon Tyne Hospitals NHS Foundation Trust
REC	Research Ethics Committee
NRES	National Research Ethics Service
ICE-CAP-O	ICEpop Capability Measure for Older People

707

DECLARATIONS

Ethical Approval and Consent to Participate

Favourable ethical opinion from the Newcastle and North Tyneside Research

Ethics Committee and R&D approval was obtained prior to commencement of the

intervention. Glasgow Caledonian University was approved as a non-NHS site with

local ethics approval.

Information sheets were provided to all eligible subjects and written informed

consent obtained prior to any study procedures.

Consent for Publication

Not Applicable

Availability of Data and Material

The dataset is held at an institutional repository. To access the dataset, please

contact the lead author (NA), who was Chief Investigator and representative for the

Sponsor of the study. The full protocol has been previously published [36].

Competing Interests

Dawn Skelton (DS) is a Director of Later Life Training Ltd, a company that runs

as a not for profit organisation, delivering FaME (PSI) training to health and fitness

professionals across the UK.

Authors' Contribtuions

NA took overall responsibility for the study and the writing of the manuscript. DS contributed to the design of the study, led on the production of the adaptation of the FaME exercise intervention manual and contributed to the drafting of the manuscript. CB contributed to its design and the writing of the manuscript. DH and TF, contributed to the design of the study, conduct of the trial, managed the

analysis and interpretation of the quantitative and statistical results and co-drafted

relevant sections of the manuscript. RL and JW to the design of the study, managed

the conduct of the trial. DC managed the Newcastle site data and LD de Jong

managed the Glasgow site. SG managed quality assurance and the production of

the FaME exercise intervention manual. JG conducted the health-economic

analysis. VD contributed to the design of the study. MC, was PI for the study NHS

site, NHS low vision clinic recruitment and clinical overseeing of the study's

serious adverse events. HW and SP, provided expertise and guidance throughout

on all aspects of design. All authors contributed to drafting the manuscript.

REFERENCES

1. Painter J, Elliott S, Hudson S. Falls in community-dwelling adults aged 50 years and older: prevalence and contributing facotrs. Journal of Allied Health. 2009;38:201-7.

2. Panel on Prevention of Falls in Older Persons, American Geriatrics Society, British Geriatrics Society. Summary of the Updated American Geriatircs Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. Journal of American Geriatric Society. 2011;59:148-57.

3. Parry S, Bamford C, Deary V, Finch T, Gray J, MacDonald C, et al. Cognitive-behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial - the Strategies for Increasing

775 Independence, Confidence and Energy (STRIDE) study. Health Technology

776 Assessment. 2016;56.

777 4. American Geriatrics Society, British Geriatrics Society, American Academy of

778 Orthopadic Surgeons Panel on Falls Prevention. Guideline for the Prevention of

779 Falls in Older Persons. Journal of American Geriatric Society. 2001;49:664-72.

780 5. Heinrich S, Rapp K, Rissman U, Becker C, Konig H. Cost of falls in old age: a

781 systematic review. . Osteoporosis International. 2010;21:891-902

782 6. Age UK. Falls in the over 65s cost £4.6 million a day. In: Age UK, editor. 2015.

783 7. Tian Y, Thompson J, Buck D, Sonola L. Exploring the system-wide costs of falls

784 in older people in Torbay. London.2013.

785 8. Boyce T. Falls—costs, numbers and links with visual impairment RNIB,

786 Evidence and Service   Impact. London: RNIB, 2011.

787 9. Evans J, Fletcher A, Wormald R, Ng E, Stirling S, Smeeth L, et al. Prevalence of

788 visual imparment in people aged 75 years older in Britian: results from the MRC

789 trial of assessment and management of older people in the community. British

790 Journal Opthalmology. 2002;86:795-800.

791 10. Steinman B, Nguyen A, Pynoos J, Leland N. Falls-prevention interventions for

792 persons who are blind or visually impaired. Research and Practice in Visual

793 Impairment Blindness. 2011;4:83-91.

794 11. Lamoureux E, Gadgil S, Pesudovs K, Keeffe J, Fenwick E, Dirani M, et al. The

795 relationship between visual function, duration and main causes of vision loss and

796 falls in older people with low vision. Graefe's Archive of Clinical Experimental

797 Opthalmology 2010;248:527-33.

798 12. de Boer M, Pluijm S, Lips P, Moll A, Volker-Dieben H, Deeg D, et al.

799 Different aspects of visual impairment as risk factors for falls and fractures in older

800 men and women. Journal of Bone and Mineral Research. 2004;19:1539-47.

801 13. Klein B, Moss S, Klein R, Lee K, Cruickshanks K. Associations of visual

802 function with physical outcomes and limitations 5 years in an older opoulation: the

803 Beaver Dam eye study. Opthalmology. 2003;110:644-50.

804 14. Lamoreux E, Chong E, Wang J, Saw S, Aung T, Mitchell P, et al. Visual

805 impairment, causes of vision loss, and falls: The Singapore Malay eye study.

806 Investigative Ophthalmology and Visual Science. 2008;49:528-33.

807 15. Lord S, Smith S, Menant J. Vision and Falls in Older People: Risk Factors and

808 Intervention Strategies Clinical Geriatric Medicine. 2010;26:569-81.

809 16. Rubenstein L. Falls in older people: epidemiology, risk factors and strategies

810 for prevention. Age Ageing. 2006;35(S2):ii37-41.

811 17. Dhital A, Pey T, Stanford M, R. Visual loss and falls: a review. Eye.

812 2010;24:1437-46.

813 18. Brundle C, Waterman H, Ballinger C, Olleveant N, Skelton D, Stanford P, et al.

814 The causes of falls: views of older people with sight impairment. Health Expect.

815 2015;42:2021-31.

816   19. Scheffer A, Schuurmans M, van Dijk N, van der Hooft T, SE. dR. Fear of

817   falling: measurment strategy, prevalence, risk factors and onsequences amoung

818   older persons. Age Ageing. 2008;37:19-24.

819   20. Yardley L, Smith H. A prospective study of the relationship between feared

820   consequences of falling and avoidance of activity in community-living older

821   people. Gerontologist. 2002;42:17-23.

822   21. Zijlstra GA, van Haastregt J, van Eiijk J, van Rossum E, Stalenhoef P, Kempen

823   G. Prevalence and correlates of fear of falling, and assoicated avoidance of activity

824   in the general population of community-living older people. . Age Ageing.

825   2007;36:304-9.

826   22. Grue E, Finne-Soveri H, Stolee P, Poss J, Wergeland Sorbye L, Noro A,

827   Hirdes J, Hylen Ranhoff A. Recent visual decline-a health hazard with

828   consequences for social life: a study of home care clients in 12 countries. . *Current*

829   *Gerontology and Geriatric Research.* 2010., Article ID 503817, 9 pages.

830   http://dx.doi.org/10.1155/2010/503817

831   23. Campbell S. Deteriorating vision, falls and older people: the links. In:

832   Visibility, editor. Glasgow, 2005.

833   24. Kendrick D, Kumar A, Carpenter H, Zijlstra G, Skelton D, Cook J, et al.

834   Exercise for reducing the fear of falling in older people living in the community.

835   Cochrane Database Syst Rev. 2014 Nov 28;(11):CD009848. doi:

836   10.1002/14651858.CD009848.pub2.

837   25. Kumar, A, Delbaere K, Zijstra G, Carpenter H, Illifie S, Masud T, Skelton D,

838   Morris R, Kendrick D. Exercise for reducing fear of falling in older people living in

839   the community: Cochrane Systematic Review and Meta-Analysis. Age and Ageing

840   2016; 45(3) 345-352

841   26. Hadjistavropoulos T, Delbaere K, Fitzgerald T. Reconceptualizing the role of

842   fear of falling and balance confidence in fall risk. Journal of Aging Health.

843   2011;23:3-23.

844   27. Parry S, Finch T, Deary V. How should we manage fear of falling in older

845   adults living in the community? British Medical Journal. 2013;346:f2933.

846   28. Cameron, Ian D. and Gillespie, Lesley D. and Robertson, M. Clare and Murray,

847   Geoff R. and Hill, Keith D. and Cumming, Robert G. and Kerse, Ngaire. 2012.

848   Interventions for preventing falls in older people in care facilities and hospitals.

849   Cochrane Database of Systematic Reviews. 12: pp. CD005465-1-CD005465-63.

850   29. NICE 21 Falls Guideline. Falls: assessment and prevention of falls in older

851   people. National Institute of Clinical Evidence 2010.

852   30. Gillespie LD, Robertson M, Gillespie WJ, Sherrington C, Gates S, Clemson

853   LM, Lamb SE. Interventions for preventing falls in older people living in the

854   community. Cochrane Database of Systematic Reviews 2012, Issue 9. Art. No.:

855   CD007146. DOI: 10.1002/14651858.CD007146.pub3

856   31. Lamb S, Gates S, Fisher J, et al. Scoping exercise on fallers' clinics, report.

857   London: National Co-ordinating Centre for NHS Service Delivery and Organisation

858   R & D, 2007.

859   32. Campbell AJ, Robertson MC, Grow SJL, Kerse NM, Sanderson GF, Jacobs RJ,

860   Sharp DM, Hale LA. Randomised controlled trial of prevention of falls in people

861 aged > or =75 with severe visual impairment: the VIP trial. BMJ. 2005;331:817–23.

862 doi: 10.1136/bmj.38601.447731.55.

863 33. Waterman H, Ballinger C, Brundle C, et al. A feasibility study to prevent falls

864 in older people who are sight impaired: the VIP2UK randomised controlled trial.

865 *Trials*. 2016;17:464. doi:10.1186/s13063-016-1565-0.

866 34. Royal College of Physicians. Older people's experience of therapeutic exercise

867 as part of a falls prevention service. London: R Coll P, 2012.

868 http://www.laterlifetraining.co.uk/wp-content/uploads/ 2012/03/patient-and-public-

869 involvement-report-march-2012.pdf

870 35. Iliffe S, Kendrick D, Morris R, Masud T, Gage H, Skelton D, Dinan S, Bowling

871 A, Griffin M, Haworth D, Swanwick G, Carpenter H, Kumar A, Stevens Z, Gawler

872 S, Barlow C, Cook J, Belcher C Multicentre cluster randomised trial comparing a

873 community group exercise programme and homebased exercise with usual care for

874 people aged 65 years and over in primary care. *Health technol Assess*. 2014.

875 Aug;18(49):vii-xxvii, 1-105.

876 36. Skelton DA, Bailey C, Howel D*, et al*. Visually Impaired OLder people's

877 Exercise programme for falls prevenTion (VIOLET): a feasibility study protocol

878 BMJ Open 2016;6:e011996. doi: 10.1136/bmjopen-2016-011996

879 37. Skelton DA and Dinan SM. Exercise for falls management: rationale for an

880 exercise programme to reduce postural instability. Physiotherapy: Theory and

881 Practice 1999; 15:105-120

882 38. Power V, Clifford A. Charateristics of optimum falls prevention exercise

883 programmes for community-dwelling older adults using the FITT principle.

884 European review of Aging and Physical Activity. 2013;10(2):95-106.

885 39. Kempen GI, Yardley L, van Haastregt JC, et al. The Short FES-I: ashortened

886 version of the falls efficacy scale-international to assess fear of falling. Age Ageing

887 2008;37:45–50.

888 40. Zijlstra GA, van Haastregt JC, van Eijk JT, et al. Prevalence and correlates of

889 fear of falling, and associated avoidance of activity in the general population of

890 community-living older people. Age Ageing 2007;36:304–9.

891 41. Podsiadlo D, Richardson S. The timed 'Up & Go': a test of basic functional

892 mobility for frail elderly persons. J Am Geriatr Soc 1991;39:142–8.

893 42. Nandy S, Parsons S, Cryer C, et al, on behalf of the Falls Prevention Pilot

894 Steering Group. Development and preliminary examination of the predictive

895 validity of the Falls Risk Assessment Tool (FRAT) for use in primary care. J Public

896 Health 2004;26:138–43.

897 43. Gill DP, Jones GR, Zou GY, et al. The phone-FITT: a brief physical activity

898 interview for older adults. J Aging Phys Act 2008;16:292–315.

899 44. De Jong Gierveld J, Van Tilburg T. A 6-item scale for overall, emotional, and

900 social loneliness: confirmatory test on survey data. Res Ageing 2006;28:582–98.

901

902 45. Zigmund AS, Snaith RP. The hospital anxiety and depression scale. Acta

903 Psychiatr Scand 1983;67:361–70.

904 46. Mundt JC, Marks LM, Shear MK, et al. The Work and Social Adjustment

905 Scale: a simple measure of impairment in functioning. Br J Psychiatry

906 2002;180:461–4.

907 47. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of

908 the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011;20:1727–36

909 .

910 48. Davis JC, Liu-Ambrose T, Richardson CG, et al. A comparison of the ICECAP-

911 O with EQ-5D in a falls prevention clinical setting: are they complements or

912 substitutes? Qual Life Res 2013;22: 969–77.

913 49. Peyre H, Leplege A, Coste J. Missing data methods for dealing with missing

914 items in quality of life questionnaires. Quality of Life Research 2011; 20:287-300

915 50. Lancaster G. Design and analysis if pilot studies: recommendations for good

916 practice. J Eval Clin Pract 2004; 10(2): 307-12

917 51. Bunn F, Barnet-Page E, McInnes E, Dickenson A, Horton K. A systematic

918 review of older people's perceptions of facilitators and barriers to participation in

919 falls-prevention interventions. Ageing and Society 2008;4:449-72.

920 52. Medley A, Thompson M. The effect of assistive devices on the performance of

921 community dwelling elderly on the timed up and go test. Issues Aging

922 1997;20(3):7.44.53.Bowling A. Mode of questionnaire administration can have

923 serious effects on data quality. Journal of Public Health. 2005;27:281-91.

924 54. Petrou S, Gray A. Economic evaluation alongside randomised controlled trials:

925 design, conduct, analysis, and reporting. British Medical Journal. 2011 342:d1548.

926 55. Keely T, Coast J, Nicholls N, Foster S, Jowett S, Al-Janabi H. An analysis of

927 the complementarity of ICECAP-A and EQ-5D-3L in an adult population of

928 patients with knee pain. Health and Quality of Life Outcomes. 2016;14:36.

929 56. Davis J, Liu-Ambrose T, Richardson C, Bryan S. A comparison of the

930 ICECAP-O with EQ-5D in falls prevention clinical setting: are they complements

931 or substitutes? Quality of Life Research. 2012;22(5):969-77.

932

933

FIGURE LEGENDS

FIGURE 1 Schematic Representation of the Randomised Controlled Trial

FIGURE 2 CONSORT Diagram of the VIOLET Study

Table 5: Numeric outcome measures by trial arm and data collection point (weeks 0, 12 & 24)

	Week	Intervention arm						Usual activities arm					
		n	min	LQ	Med	UQ	max	n	min	LQ	Med	UQ	max
SFES-I (concerns over falling) *Scores 7-28*: *Higher scores=>more concern*	**0**	32	7	8	9	10	15	31	7	7	9	11	23
	12	29	7	8	9	11	14	30	7	7	8	10	20
	24	28	7	7	8	10	21	31	7	7	8	11	17
Impact of visual impairment (WSAS) *Scoring (0-40)*: *Higher scores => more impact*	**0**	32	0	5.6	11.9	18.1	27.5	30	0	5.0	12.5	23.8	38.8
	12	29	0	10	15	20	35	31	0	3.8	11.3	17.5	37.5
	24	28	0	12.5	20	25.6	40	31	0	5	15	26.3	33.8
Falls risk assessment tool (FRAT) Scoring (0-5): *Higher scores => more risk*	**0**	33	0	0	1	3	5	31	0	1	1	3	4
	12	29	0	1	1	3	4	31	0	1	2	3	4
	24	28	0	1	1	3	4	31	0	1	2	3	4
Phone-FITT Total Frequency and Duration (FD)	**0**	33	0	34	49	89.5	296	31	1	16	42.5	66	222
	12	29	0	41	55	96	209	31	0	25	47	67	377
	24	28	9	30.8	52.1	100.5	410	31	0	18	43	66	1506
Functional test (TUG) Time in seconds to complete the test	**0**	33	8.8	9.8	13.3	16.8	35.6	31	7.4	10.7	13.3	20	120
	12	28	8.9	11	13.5	18.4	30.2	31	6	11.1	17	19.2	975
	24	28	8.2	10.3	13.8	16.3	28.5	31	6.6	10.4	15.1	18.2	100

Figure 2

Enrolment

Expressions of interest passed to researchers (n=105)

Excluded (n=23)

- Declined to participate prior to screening (n=21)
- Expression of interest form returned too late (n=2)

Screened by researcher for eligibility (n=82)

Excluded (n=16)

- Not meeting inclusion criteria (n=14)

Informed consent (n=66)

Excluded (n= 1)

- Not meeting inclusion criteria (n=1)

GP confirmation of eligibility (n=65)

Excluded (n= 1)

- Did not meet inclusion criteria (n=1)

Randomized (n=64)

Allocation

Allocated to Intervention (n=33)

- Received allocated intervention (n=30)
- Did not receive allocated intervention (n=3)

Allocated to Usual activities (n=31)

- Received allocated intervention (n=31)
- Did not receive allocated

- Lost to follow-up/died (n=1)
- Withdrew from study (n=4)

- Lost to follow-up (n=0)
- Discontinued intervention (n=0)

Figure 1