Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a randomised feasibility study

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1 **Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults: a**

2 **randomised feasibility study**

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Background: Low quality social relationships in older adults are strongly associated with feelings of loneliness. Physical activity interventions could reduce loneliness and improve psychological well-being, among other health benefits. The aim of this study was to examine the feasibility of a Physical Activity Intervention for Loneliness (PAIL) in community-dwelling older adults at risk of loneliness.

Methods: The PAIL feasibility study was a 12-week randomized controlled feasibility trial (RCT) conducted in Birmingham, United Kingdom, from February 2018 to August 2018 and ran in two waves of data collection. Eligible participants were community-dwelling adults aged 60 years and older, sedentary (less than 20 min of moderate-to-vigorous PA (MVPA) a week), and at risk of loneliness. The intervention included: once weekly group walk and health education workshop up to 90 minutes per session in total, with a wait-listed (WL) control group. The primary feasibility outcomes were to estimate recruitment, retention rates and adherence to the intervention. Secondary outcome measures (not blinded assessment) were body mass index, blood pressure, physical activity, and psychosocial variables. Process and outcome evaluations were conducted using focus groups interviews. The recruitment and retention progression criteria for the definitive large-scale RCT was set *a-priory.*

Results: Forty-eight participants were recruited over 4 months with a recruitment rate of 25% (48/195); 52% (25/48) met the inclusion criteria and 100% (25/25) were randomised into the intervention (N=12) and WL control groups (N=13). Participants were 25 older adults (mean (SD) 68.5(8.05) years), 14 (56%) female, and 18 (72%) white. At 12 weeks, 10/12 (83.3%) intervention and 10/13 (76.9%) control participants completed the final assessments. The average attendance rate was 58.3% for the intervention group (range 33.0%-75.0%) and 42.3% (range 23.1%–69.2%) among controls. The *a priori* recruitment and retention criteria for progression were not met. No serious adverse events occurred. The focus group results identified three themes which showed overall positive experiences of participation in PAIL in terms of: 1) study design and intervention; 2) walking sessions; and 3) health education workshops.

43   **Conclusions:** The findings suggest that community-dwelling older adults at risk of loneliness found

44   the intervention and measures acceptable and could safely participate. However, a more extensive

45   and robust strategy would be needed to support adequate recruitment of lonely older adults and

46   adherence into a definitive RCT.

47

48   **Trial registration:** Clinicaltrials.gov Identifier: NCT03458793.

49   **Keywords:** Feasibility study, Physical activity, Loneliness, Older adults, Randomised Controlled

50   Trial.

51

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Background

Maintenance of social connectedness throughout the lifespan is an important aspect of successful ageing [1]. The disruption of established social patterns or poor quality of social relationships is strongly associated with loneliness especially in older adults [2]. Defined as a discrepancy between a person's desired and actual social relationships [3], loneliness and a lack of social relations are considered to be high risk factors for morbidity and mortality, and the negative impact of loneliness can be as harmful as smoking fifteen cigarettes a day [4]. Due to deteriorating health condition of older adults and less abilities to engage in social connections, the early prevention of loneliness in community programmes seems prudent.

Due to deteriorating health conditions associated with ageing, older adults are highly predisposed to declines in cognitive and physical function [5]. However, regular exercise in older adults at the recommended minimum of 150 min of moderate PA per week performed in any length of bouts [6] can contribute to the maintenance of physical health. Additional benefits are associated with muscle strengthening and balance exercises performed in 10 min bouts for the risk of falls prevention [7]. Moreover, active older adults retain cognitive function at a high level throughout their older years, which is a very important aspect of social life and wellbeing [8, 9]. It is a health behaviour that can increase peripheral social networking and the acquisition of new social contacts due to engagement in a variety of physical and leisure activities by older adults outside the home. In turn, this can replace or compensate lost social connections for older adults with feelings of loneliness, and turn these feelings into meaningful social connections based on the social compensation model [10]. PA improves psychological and emotional wellbeing leading to direct health benefits based on the so-called "feel-good effect" of exercise identified in the literature [11], which is associated with increases in serotonin, monoamine and neurotrophin production and reductions in the stress hormone cortisol [12].

79   Mechanisms of action of PA interventions are suggested to relate to loneliness reduction models,

80   stress reduction, and increased social support during activities. The social compensation model [13]

81   suggests that PA can work via compensation for lost meaningful social connections due to increased

82   peripheral social networking during friendly conversations between participants [14]. The hypothesis

83   of the broaden-and-build theory of positive emotions [15] posits that enjoyable forms of PA generate

84   happiness and bring positive emotions, which in turn could be associated with loneliness reduction

85   [16]. Based on the stress/social support model [17], social networks promote well-being that is

86   associated with loneliness reduction in older adults. Finally, the tripartite model of group

87   identification has been shown to be effective in group-based PA settings among specific population

88   groups, such as lonely seniors, due to a sense of social identification [18, 19]. This model considers

89   three aspects, such as cognitive (social categorisation, i.e., the degree by which an individual

90   categorises him/herself as similar to other group members), affective (i.e., the degree to which an

91   individual feels affectively attracted to the other group members), and behavioural (interdependence,

92   i.e., the degree to which an individual evaluates his/her group as important for teaching objectives)

93   [18, 19]. Through shared interests and goals during engagement in physical activities it boosts social

94   activity and leads to group identification through the feeling of social attraction to other group

95   members.

96

97   A previous review found that few PA interventions for loneliness reduction have been conducted in

98   community settings [20]. This is also consistent with previous systematic reviews and meta-analyses

99   [2, 18, 21, 22]. Results of meta-analysis performed for social functioning (as a sub-domain of health-

100   related quality of life) in this review showed, that specific aspects of PA interventions can

101   successfully influence social health [20] with the strongest effects being obtained for group setting

102   exercise interventions, with delivery by a health/medical professional, and in a diseased rather than

103   healthy population [20]. In addition, the majority of studies used a cross-sectional or longitudinal

104   design, which does not allow determination of causality and limits the rigour of the research evidence

105 [18]. Others assess loneliness as a secondary outcome within a number of other psychosocial

106 outcomes, which limits the ability to fully examine the effectiveness of these interventions for

107 reducing loneliness [23].

108

109 Further, a number of moderating, such as global [23, 24] and domain-specific self-efficacy [25] and

110 mediating (driving the influence of PA on loneliness) factors, such as social support [26] between

111 loneliness and PA may help to determine additional pathways of any PA intervention effects.

112 Bearing in mind the limitations of the current literature, understanding the mechanisms through which

113 PA may reduce loneliness may bring new insights to the design of novel and effective PA

114 interventions [18]. Further research is needed to explore the association between loneliness, self-

115 efficacy and social support in the context of PA interventions for older adults. However, before the

116 mechanisms can be fully understood, the practicalities and feasibility of implementation of such

117 interventions with older adults should be tested in a feasibility trial [27] before proceeding to a

118 definitive RCT. In order to assess participant experiences of such interventions, the present study

119 utilised a mixed-methods research design, defined as the class of research where the researcher mixes

120 or combines quantitative and qualitative research techniques, methods, approaches, concepts or

121 language into a single study [28]. This research design can add valuable knowledge into a feasibility

122 study. The aim of the study was to examine the feasibility of the Physical Activity Intervention for

123 Loneliness (PAIL) intervention in community-dwelling older adults at risk for loneliness. For the

124 planned future large-scale RCT, the primary hypothesis was that, compared with the inactive control

125 group, participants in the intervention group would report a greater decrease in loneliness. The

126 secondary hypothesis was that participants in the intervention group would significantly increase their

127 amount of physical activity engagement per week, and this would be associated with greater positive

128 changes in other psychosocial and health outcomes compared with the control group participants. The

129 following specific aims of this feasibility study were to estimate:

130   1. Recruitment rate, attendance and retention rates (number of participants completing the study as

131   a proportion of those randomised).

132   2. The acceptability of the intervention by participants, and willingness to participate.

133   3. The appropriateness of the statistical methods of data analysis used.

134   4. The required sample size for a future large-scale RCT derived from a power calculation.

135   5. The acceptability of measures, and the most suitable primary outcome measure for a future large-

136   scale RCT.

137

138 In addition, to reflect the aims of a future large-scale RCT that this feasibility study was seeking to

139 inform, the effect sizes between the intervention and control groups were examined, however the

140 analysis was exploratory due to feasibility studies not being adequately powered to test the

141 effectiveness of the intervention [29].

142

Methods/design

143

144 The full description of methods in available elsewhere [30]. A brief description is presented here.

145 PAIL was a two-arm, 12-week randomised feasibility trial with a wait-listed control group delivered

146 in Birmingham, United Kingdom, from February 2018 to August 2018 and ran in two waves of data

147 collection. The trial was approved by the Science, Technology, Engineering and Mathematics

148 (STEM) Research Ethics Committee of the University of Birmingham, UK (ERN_16-1419A). This

149 feasibility study was guided by a populated CONSORT Extension to Pilot and Feasibility Trials

150 (Additional file 1) and template for intervention description and replication (TIDieR) checklist [31]

151 (Additional file 2). Written informed consent was obtained from all participants prior to entry into

152 the study.

153

Participants

154

155 *Recruitment*

156   Participants were recruited in two waves from September 2017 to April 2018 from the local

157   neighbourhood (households) and communities in Birmingham via leaflets. Additional recruitment

158   was facilitated during the eligibility screening [32]. Recruitment was aimed to be at a rate of 10

159   participants a month (to a minimum of 40 participants) for estimation of the critical parameters of the

160   feasibility study [33].

161

162   Initial eligibility was the phone-based with the further eligibility screening conducted at the university

163   centre. After providing informed consent, participants were invited to a presentation meeting about

164   the study. This was delivered at the University by the main researcher (AS), and included a detailed

165   description of the project aims, methods and procedures, and a Question and Answer session.

166   Attendees were invited for further eligibility screening at the university. Potentially eligible

167   participants identified after baseline screening were randomised into the intervention or a WL control

168   group using a computer-generated random sequence performed by an external researcher not involved

169   in the delivery of the intervention or outcome assessment. Participants were informed about the group

170   allocation by e-mail or a phone call by a person not involved in assessments or delivery of the

171   intervention. At the outcome assessment level, participants who were assessors of their own

172   psychosocial outcomes using questionnaires, were blinded to their group allocation at the time of

173   completing the initial questionnaires. Intervention providers who were responsible for outcome

174   assessments were not blinded to the intervention delivery as this would not be possible, given that the

175   PhD student researcher (AS) conducted the study and walks.

176

177   *Eligibility*

178   Participants were eligible if they were: 1) community-dwelling older adults aged 60 years and older;

179   2) previously sedentary (i.e. less than 20 minutes of moderate-to-vigorous PA (MVPA) per week over

180   the past month) [34]; 3) at risk of loneliness and having ≥ 6 out of 9 points on the 3-item loneliness

181   scale during the phone screening [35]; 4) physically mobile as measured using the Short Physical

182 Performance Battery (SPPB) [36] with a score ≥ 9 out of 12 [37]; 5) having chronic diseases but

183 ambulatory; 6) able to give written informed consent; and 7) English speaking and able to complete

184 paper and pencil questionnaires. Exclusion criteria were: <60 years old, regularly physically active

185 or already engaged in another PA intervention, socially active, having a disease that seriously

186 precluded participation in PA, having a cognitive impairment as assessed by the Montreal Cognitive

187 Assessment (MOCA) [38] with a score ≥ 22 out of 30 [39] and not English literate.

188

189 **Intervention development and delivery**

190 The development of the PAIL intervention was a results of collaborative work of research group

191 based on the characteristics of effective interventions obtained our previously published systematic

192 review [20]. The theory of active engagement [40] influenced the choice of moderators such as social

193 support and a self-esteem through acquired sense of purpose and confidence during enjoyable forms

194 of PA. The walking group leader attended a training course focused on exercise for older adults

195 "Move it or lose it" [41] and was a certified group exercise instructor. The intervention was a group

196 walking intervention with an education workshop on healthy ageing topics alongside each walking

197 session once per week. After the pilot of the entire intervention with five people and feedback

198 obtained at focus group interview conducted in March 2018, minor changes were needed to modify

199 the delivery approach of the intervention. Firstly, it was suggested to facilitate the recruitment of

200 participants by contacting the 1000 Elders group [42] and the BVSC consortium [43] to advertise the

201 intervention for the summer period. Due to a small number of participants per group, the intervention

202 was lacking the necessary social interactions between participants. Therefore, it was suggested to add

203 new participants who were eligible to join the current groups, and identify the start date of their 12-

204 week intervention from the day they joined (e.g. on a rolling basis). Participants received a weekly

205 e-mail with information about the walking route and a topic of the workshops to set appropriate

206 expectations and help them prepare for the discussion. Weekly information about social events was

207 added to support local engagement with activities and facilitate within group social support.

208 Additionally, free access was gained to Winterbourne House and Gardens (add in website link to

209 Winterbourne here) to deliver a healthy workshop, which included free beverages".

210

211 **Interventions**

212 The PAIL feasibility study was a 12-week intervention consisting of group walks and health

213 educational/social interaction workshops performed once weekly for a duration of up to 90 minutes

214 per session. The design and features of the PAIL intervention were derived from the findings from a

215 systematic review of PA interventions for loneliness by Shvedko et al. [20]. The theory of active

216 engagement [40] influenced the choice of moderators such as social support and a self-esteem through

217 acquired sense of purpose and a confidence during enjoyable forms of PA. The PAIL was a face-to-

218 face intervention delivered in small groups (up to 8-9 people per group) by a trained walk leader

219 certified in group exercise to older adults and run in various locations and parks in Birmingham, UK.

220 Prior to the first walking session, participants received a copy of a General Practitioner (GP) letter to

221 inform their doctor of participation. Walking sessions were based on the principles of gradual

222 progression and adaptation to PA [44]. The intensity of the walks was light-to-moderate and was

223 monitored objectively by heart rate monitors using the age-predicted heart rate maximum (HR_{max})

224 method [45] and subjectively using the talk test [46] and the 0-10 Borg Ratings of Perceived Exertion

225 scale (RPE) [47]. Participants had to talk back comfortably during exercises using the talk test [46],

226 and rate their RPE from 2 to 4 [47]. Participants followed a trained walking leader via a specific route

227 (Additional file 3). A warm-up preceded each session followed by an end of session cool-down and

228 breathing exercises. Group walking sessions were followed by health education/social interactions

229 workshops on a variety of healthy ageing topics such as eye hygiene, mental health and well-being,

230 preventing falls, social support, nutritional guidelines, and PA recommendations for older adults

231 where participants shared their knowledge and experiences about the topics discussed.

232

233 *Intervention group*

234   After randomisation, participants in the intervention group started the 12-week intervention.

235

236   ***Wait-listed Control group***

237   Participants in the WL control (delayed intervention) group started the intervention after their follow-

238   up measures were completed, approximately 12 weeks post-randomisation.

239

240   **Measures**

241   All measures were conducted at the host academic institution at baseline and immediately post the

242   intervention period. Participants provided socio-demographic information about their age, gender,

243   ethnicity, marital status, living arrangements, level of education, any children, employment status and

244   any medical conditions. *Cognitive function* was assessed using a Montreal Cognitive Assessment

245   scale (MOCA) designed to test mild cognitive impairment [38]. *Physical functioning* was assessed

246   using the Short Physical Performance Battery (SPPB) [36]. *Height* was measured to the nearest 0.1

247   cm using a stadiometer (Seca AG, Reinach, Switzerland) and recorded in metres. *Weight* was

248   assessed using weighing scales (Tanita UK Ltd., Middlesex, UK) to the nearest 0.1 kg. *Resting blood*

249   *pressure* (BP rest, mm Hg) was measured using a portable semi-automatic OMRON

250   sphygmomanometer (OMRON HEM705CP sphygmomanometer; Omron Matsusaka Co Ltd, Japan).

251   *Physical activity* was measured using ActivPAL accelerometers (PAL Technologies Ltd. Glasgow,

252   UK) at baseline and immediately post intervention over a continuous 7-day period of awake and

253   sleeping (24 hours a day) except when bathing or swimming [48].

254

255   ***Questionnaires***

256   *Loneliness* was assessed using the 8-item UCLA Loneliness Scale (UCLA-8) [49]. *Social support*

257   was assessed using the 20-item Medical Outcomes Study Social Support Survey (MOSSSS) [50].

258   *Social networks* were categorised using the 6-item Lubben's Social Network Scale (LSNS-6) [51].

259   *Depression and anxiety* were assessed using the 14-item Hospital Anxiety and Depression Scale

260 (HADS) [52]. *Self-efficacy for exercise* was measured using the revised 9-item Self-Efficacy for

261 Walking/Exercise Scale (SEE), using a paper-and-pencil format [53]. *Satisfaction with level of social*

262 *contacts* (SSC) was measured with the question "How satisfied are you with your social contacts?"

263 [54]. *Expected outcomes and barriers for exercise* were measured using the Expected Outcomes and

264 Barriers for Habitual Exercise scale [55] adapted for the older adult population. Four questions related

265 to sport competence were deleted from the expected outcomes sub-scale due to irrelevance for this

266 population group [55]. The expected outcomes and barriers for exercise scale has demonstrated good

267 internal consistency from 0.66 to 0.85, and a high test-retest reliability of 0.78 in previous research

268 [55].

269

270 *Qualitative assessments*

271 To understand participants' experiences of taking part in the PAIL feasibility trial, focus groups were

272 conducted at mid-point (between week 4 and 5) and at the end of the 12-week intervention using

273 semi-structured discussions in groups of 4-9 people per group of mixed gender (Additional files 4,5)

274 on the following topics: reasons for participation, progress on intervention delivery and possible

275 barriers to attending. The research team iteratively analysed the mid-point data to identify if any

276 alterations in the intervention were required based on the participants' feedback. Focus groups were

277 audio recorded using a digital recorder and transcribed verbatim. An independent trained focus group

278 leader acted as moderator and facilitator of the focus groups [56].

279

280 *Feasibility outcomes*

281 The following specific aims of this feasibility study were assessed:

282 1) Attendance was calculated as the total number of attended sessions divided by the total number of

283 sessions of the intervention and recorded as a percentage;

284 2) Recruitment rate was calculated as the number of individuals responding to advertisements and

285 friends' referrals out of a total number of formal invitations given/advertisements placed (including

286   web-based advertisements, advertisements placed in the local cohort groups and poster and leaflet

287   material disseminated in the community). Recruitment rate was recorded as a percentage, e.g. 25%

288   (48/195). It is acknowledged that advertisements may reach a large number of individuals, but it

289   was impossible to quantify this;

290   3) Retention rate was calculated as number of participants completing the study as a proportion of

291   those randomised;

292   4) The assessment rate of questionnaires was evaluated as the total number of completed

293   questionnaires divided by the total number of questionnaires and recorded as a percentage;

294   5) The suitability of the statistical methods of data analysis was investigated using reliability analyses.

295   Internal consistency reliability (Cohen's alpha) was calculated at each time point (pre and post) and

296   averaged to give overall reliability. The expected outcomes and barriers for exercise questionnaire

297   was completed twice at baseline, with a week between measures, to allow for test-retest reliability

298   analysis.

299   6) The acceptability of the intervention by participants, and willingness to participate was assessed

300   using focus group interviews. The focus group transcripts were analysed using a phenomenological

301   inductive approach [57], and these data were used to guide the research team in improving the quality

302   of the delivered intervention by informing positive changes in the methodology and design of the

303   intervention for the future implementation in a consequent study;

304   7) Statistical power and sample size estimation was calculated for meaningful potential future primary

305   outcomes (e.g. loneliness or social support) using a method based on the differences in means between

306   the intervention and control groups, using G-power software [58];

307   8) An effect size (ES) was calculated for loneliness, social support, social networks, anxiety and

308   depression, self-efficacy for exercise, satisfaction with level of social contacts, and the expected

309   outcomes and barriers for exercise. Means (M) and standard deviations (SD) were used to investigate

310   the effect size for change in loneliness using mixed between (intervention group vs. control group)

311   and within (over time) repeated-measures analysis of variance (ANOVAs) with post-hoc

312   comparisons.

313

314   **Data monitoring**

315   The data monitoring committee for this project was the supervisory research team (three academic

316   supervisors). They were responsible for checking accuracy of quantitative data upon assembly of the

317   final database following completion of data collection prior to data analysis. The qualitative data were

318   analysed iteratively by AS with independent analysis and oversight by a member of the supervisory

319   team with expertise in qualitative and mixed methods research (JT). AS was responsible for

320   monitoring and reporting spontaneous adverse events or any unintended trial effects to the

321   supervisory team, and the primary supervisor (AW). The trial was also subject to independent audit

322   request by the sponsor, the University of Birmingham, by a team independent of the

323   supervisory/research team.

324

325   **Data collection**

326   Data were collected at the university facility at screening, baseline and post-intervention period (12

327   weeks after the start of the intervention). After providing baseline eligibility screening, potential

328   participants were offered a total of five visits for health assessments at the university facility.

329   Participants in the intervention group had an additional sixth visit for attending the mid-point focus

330   group.

331

332   **Sample size**

333   As this was a feasibility study to inform the design of the future large-scale RCT, a total targeted

334   sample of 40 older adult participants was considered necessary to be recruited for estimation of the

335   critical parameters [33] with 20 in the intervention group and 20 in the WL control group.

336

337 **Progression criteria**

338 The progression criteria to a definitive large-scale RCT were: 1) no any serious adverse events, such

339 as hospitalisation, life-threatening condition, death and any adverse events associated with the

340 intervention experienced by less than 5% of participants per group; 2) recruitment rate of no less than

341 75% by the end of the four months recruitment period; and 3) retention rate of no less than 75% in

342 each group at 12 weeks (end-point). If all three criteria were not met, there would be insufficient

343 evidence to justify proceeding to the definitive RCT. No targets were set for other feasibility

344 outcomes, e.g., questionnaire completion rates or attendance at the intervention sessions.

345

346 **Data analysis**

347 Quantitative data were analysed using SPSS version 22.0 for Windows (SPSS Inc., Chicago, IL)

348 employing an intention-to-treat analysis (based on their treatment allocation and irrespective of

349 participants' adherence or withdrawal) [59]. The level of significance was set at p <.05, however any

350 hypothesis testing was preliminary, and any results were interpreted with caution as this feasibility

351 study is underpowered and the analyses based on small numbers. Baseline differences between groups

352 for continuous data (e.g. age, BMI, resting blood pressure, number of comorbidities, cognitive and

353 physical functioning, and outcomes of questionnaires) were analysed using one-way analysis of

354 variance (ANOVA). Chi-squared tests were applied for nominal data (e.g. gender, ethnicity, marital

355 status, living arrangements, level of education, children, and employment status). For descriptive

356 statistics, data were presented as means (M) and standard deviations (SD). Nominal data were

357 presented as number (N) and percentage. Mixed between (group) and within (time) repeated-

358 measures ANOVAs with post-hoc comparisons were applied to investigate the effect of the

359 intervention versus control on psychosocial outcomes (loneliness, social support, support networks,

360 depression, anxiety, self-efficacy for exercise, satisfaction with level of social contacts), expected

361 outcomes and barriers for exercise, and accelerometer data. The accelerometer data were analysed

362 using the ActivPAL software V7.1.18 (PAL technologies, Scotland, UK). Recorded data were

363 downloaded to a computer, and data for average daily amount of stepping (step counts), average time

364 lying and sitting (h) in increments of 15 s, average time standing (h), and energy expenditure (EE,

365 MET/h) were analysed using mixed between (intervention group) and within (time) ANOVAs. For

366 the Expected Outcomes and Barriers for Habitual Exercise scale [55], additional test-retest reliability

367 was calculated via correlation. In order to explore which outcome measures are likely to be most

368 important for the main trial, Pearson's correlations were performed between calculated change scores

369 over time in the experimental group for all psychosocial outcomes (Lubben's social networks,

370 loneliness and self-efficacy for exercise) and change scores for averaged daily physical activity (time

371 lying/sitting (h), time standing (h), time stepping (h), step counts, sit to stand transitions (n) and

372 energy equivalent (METs/h)). Statistical power and sample size estimation for a future large-scale

373 RCT were calculated for meaningful outcomes (e.g. loneliness or social support) using the method

374 based on the differences in means between the intervention and control group using the G-power

375 software Version 3.1 [58].

376

Qualitative study

377

378 Qualitative data were thematically analysed by two research team members independently using a

379 phenomenological inductive approach [57]. Transcripts were returned to participants for

380 comments/correction to ensure transparency and trustworthiness of the data (member checking) [60].

381 Validated transcripts were read several times by the two independent researchers to obtain an overall

382 meaning. Then, themes and subthemes with important meanings common across all participants were

383 derived from the obtained data. Results were compared through discussion between reviewers [61].

384 Data were pseudo-anonymised with a unique identification number (ID) and stored confidentially in

385 locked filing cabinets/on password protected university computers accessible only to the research

386 team. Audio recordings were destroyed after the recordings were transcribed verbatim.

387

Results

388

Participant characteristics

Participants were 25 (mean (SD) 68.5(8.05) years, range 60-92 years) healthy, inactive, community-dwelling older adults, 14 (56%) female, and 18 (72%) white. Baseline descriptive statistics of participants are shown in Table 1.

Feasibility and safety

Recruitment and retention

The flow of participants through the study is shown in Figure 1. The intervention was advertised using 192 advertisements (145 leaflets and 47 advertisement posters), which yielded a total of 48 potential participants (45 expressing the initial interest and three recruited through friends' referrals). The recruitment rate was 25% (48/195). Two declined to participate before completing the phone-based screening. Forty-six potential participants were assessed for eligibility using the phone-based screening with 21 excluded due to not meeting the eligibility
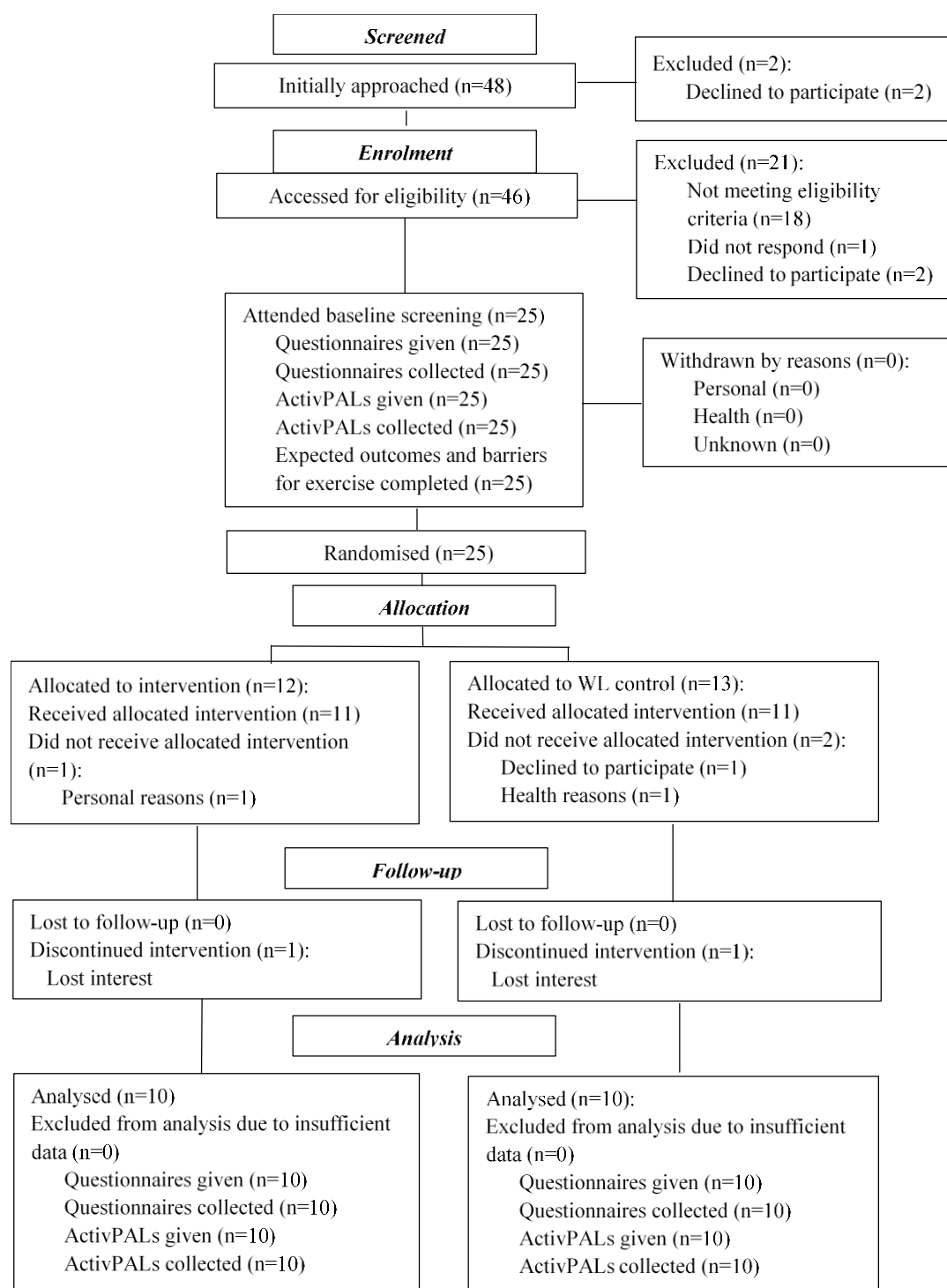
```
                    ┌─────────────────┐
                    │    Screened     │
              ┌─────┴─────────────────┴─────┐       ┌──────────────────────────┐
              │ Initially approached (n=48) ├───────┤ Excluded (n=2):          │
              └──────────────┬──────────────┘       │   Declined to participate│
                             │                       │   (n=2)                  │
                    ┌────────┴────────┐              └──────────────────────────┘
                    │    Enrolment    │
              ┌─────┴─────────────────┴─────┐       ┌──────────────────────────┐
              │ Accessed for eligibility    ├───────┤ Excluded (n=21):         │
              │ (n=46)                      │       │   Not meeting eligibility│
              └──────────────┬──────────────┘       │   criteria (n=18)        │
                             │                       │   Did not respond (n=1)  │
                             │                       │   Declined to participate│
                             │                       │   (n=2)                  │
                             │                       └──────────────────────────┘
```

Attended baseline screening (n=25)
Questionnaires given (n=25)
Questionnaires collected (n=25)
ActivPALs given (n=25)
ActivPALs collected (n=25)
Expected outcomes and barriers
for exercise completed (n=25)

Withdrawn by reasons (n=0):
   Personal (n=0)
   Health (n=0)
   Unknown (n=0)

Randomised (n=25)

Allocation

Allocated to intervention (n=12):
Received allocated intervention (n=11)
Did not receive allocated intervention
(n=1):
   Personal reasons (n=1)

Allocated to WL control (n=13):
Received allocated intervention (n=11)
Did not receive allocated intervention (n=2):
   Declined to participate (n=1)
   Health reasons (n=1)

Follow-up

Lost to follow-up (n=0)
Discontinued intervention (n=1):
   Lost interest

Lost to follow-up (n=0)
Discontinued intervention (n=1):
   Lost interest

Analysis

Analysed (n=10)
Excluded from analysis due to insufficient
data (n=0)
   Questionnaires given (n=10)
   Questionnaires collected (n=10)
   ActivPALs given (n=10)
   ActivPALs collected (n=10)

Analysed (n=10):
Excluded from analysis due to insufficient
data (n=0)
   Questionnaires given (n=10)
   Questionnaires collected (n=10)
   ActivPALs given (n=10)
   ActivPALs collected (n=10)

402

403 **Fig. 1.** CONSORT flow diagram of Physical Activity Intervention for Loneliness (PAIL)
404 intervention.

405

406 criteria (N=18), declined to participate (N=4) and no response (N=1). Reasons for not being eligible

407 were already physically active or taking part in another intervention (N=11), or not at risk of

408 loneliness (as assessed using the phone-screening tool) (N=7). Reasons for declining to participate

409 were pressures of work/lack of time and health reasons. A total of 31 participants (31/46, 67.4%)

410   attended the further eligibility screening at Visit 1, and 25 were eligible to proceed with baseline

411   assessment (Visit 2). Using Wilson's 95% confidence interval [62], at 12 weeks, 10/12 (83.3%;

412   95% CI 55.20 to 95.30) intervention and 10/13 (76.9%; 95% CI 49.74 to 91.82) control participants

413   completed final assessments. The retention rate satisfied the criteria of the study, e.g. > 75% of

414   participants at 12 weeks (end-point period), although the recruitment rate of 25% by the end of the

415   four months was somewhat lower than was initially proposed at 75%. There were no serious

416   adverse events, or any adverse events observed related to study participation.

417

418   *Attendance*

419   The average attendance rate for the total of 12 sessions of the walking intervention was 58.3% for the

420   intervention group, with attendance ranging from 33.0% to 75.0% (Additional file 6). The average

421   attendance rate for the WL control group was 42.3%, with attendance ranging from 23.1% to 69.2 %.

422   The mean (SD) number of attended sessions per person was 8.6(2.8) and 6.6(2.6) in the intervention

423   and wait-list control group, respectively. After completing the 12-week intervention, 7/10 participants

424   from the intervention group and 6/10 participants from the wait-list control group continued walking.

425   The follow-up attendance rate assessed during the 12-week post-intervention period was 48% for the

426   intervention and 52% for the WL control group.

427

428   *The assessment rate of questionnaires*

429   Baseline questionnaires and accelerometer data were provided by 100% (25/25) of participants

430   recruited into the study. Post-intervention questionnaires and end-point accelerometer data were

431   provided by 100% (10/10) of the intervention and 100% (10/10) WL control group participants.

432

433   *The appropriateness of the assessment tools*

434   The average reliability was high for all psychosocial outcomes: loneliness (Cronbach's alpha 0.857),

435   social support (Cronbach's alpha 0.975), Lubben's social networks (Cronbach's alpha 0.721),

436 depression (Cronbach's alpha 0.744), anxiety (Cronbach's alpha 0.693) and self-efficacy for exercise

437 (Cronbach's alpha 0.925). The expected outcomes for the exercise sub-scale of the Expected

438 Outcomes and Barriers for Exercise questionnaire showed high internal consistency reliability at

439 baseline, with Cronbach's alpha equalling 0.926 (a week before) and 0.938 (a week after); at post-

440 intervention the value was 0.976. Barriers for the exercise sub-scale of the Expected Outcomes and

441 Barriers for Exercise questionnaire showed high internal consistency reliability at baseline, with

442 Cronbach's alpha equalling 0.888 (a week before) and 0.924 (a week after); at the post-intervention

443 period the value was 0.943.

444

445 **Findings from the qualitative study**

446 *The appropriateness, practicality and acceptability of the intervention by participants*

447 A total of 5/12 (42%) participants in the intervention group attended two focus group interviews, at

448 the mid-point and end-point intervention periods. The focus group attendees were representative of

449 the overall intervention group characteristics. The responses of participants during the focus groups

450 were summarised in the main themes for mid-point and end-point intervention periods and presented

451 below.

452

453 **1. Mid-point focus groups**

454 Participants ranged in age from 62-76 years, 60% (3/5) female, 80% white, with 60% (3/5) living

455 alone, having a university degree, having children, being retired and having one medical condition.

456 The main themes were: study design and recruitment (3 subthemes), healthy workshops (3

457 subthemes) and walking sessions (3 subthemes) (Additional file 4).

458

459 Mid-point focus group results showed that in terms of the appropriateness and practicality, the spring-

460 summer seasons were a better to start the intervention than winter time. Overall, participants had very

461   positive views of the walking intervention, particularly the benefits of walking, its cost-effectiveness

462   in terms of the economic benefits for older adults and direct positive health effects:

463   *"And because I am on a fixed income now, you know I can't just go out and earn a bit more money*

464   *to do something, it does limit you a little bit in what you can do and you have got all this time, but*

465   *you haven't got the money. Err, you know, and I brought up a child on my own so she took quite a lot*

466   *of my salary when I was working [Kate laughs], you know I have never got a lot of money (all* laugh*)*

467   *to do what I would really like to do. So, you have to work within that (.)"* (Alison, 75, female).

468

469   For others, it was a chance to meet new people and get access to local community groups:

470   *"I mean walking is good because it loosens everybody up a bit, gets people to know each other (.)"*

471   (Andrew, 68, male).

472

473   The content of the healthy workshops was relevant and allowed them to share feelings and

474   knowledge. However, the main barriers to attend walks were: 1) personal, such as lack of time

475   associated with family and community celebrations, holiday, home refurbishments, and carer

476   responsibilities; and 2) environmental barriers, such as transportation and the weather (Additional file

477   3). Participants found it difficult to get to the location by public transport, or to find the nearest parking

478   area if the meeting point was on campus:

479

480   *"And some of the walks, like [the place of the walk], although it wasn't that particularly early, it's*

481   *getting there (.) [an issue] on public transport"* (Sarah, 76, female).

482

483   **2. End-point focus groups**

484   Participants ranged in age from 65-76 years, 20% (1/5) female, 80% white, 60% (3/5) living alone,

485   40% (2/5) with university degree, 60% having children, retired and having one or more medical

486   condition. The main themes were: study design and recruitment (3 subthemes), healthy workshops

487 (3 subthemes), and walking sessions (2 subthemes) (Additional file 5). Participants felt that

488 participation in the intervention helped them to become more physically active, which was their

489 initial aim:

490 *"You have to just try and keep motivating [yourself], just keep going I suppose, rather than just*

491 *sitting at home. I don't know how (.) for me like, I am working four days a week at the moment, so I*

492 *don't know how I would feel when I retire, which is going to happen next year so (.)"* (Ben, male,

493 65).

494

495 *"I enjoyed the exercise thing. It is quite, you know (.) it is just (.) She (referring to the exercise leader)*

496 *sort of said, you know, made us aware of sort, of what sort of exercise is good for, what parts of your*

497 *body and so forth. So, I mean it is important, isn't it to keep moving, keep active and this is what part*

498 *of the programme is about, isn't it?"* (Ben, male, 65).

499

500 Common interests raised during the walks allowed first friendship gains that started from as early as

501 the second or third walk and continued after the programme's end at 12 weeks. Walking was seen to

502 promote the bonding of participants and improved their aspirations for friendship-based relationships:

503 *"I have definitely made new friends, enjoyed meeting new people and you gel with some people*

504 *which is a human nature, so (.)"* (Sarah, female, 76).

505

506 Future recommendations included more group leaders per group and classification of walks by ability

507 level (e.g. beginner, improver):

508 *"(.) and it was only (the Researcher). But if (the Researcher) had two other people on our walk (.).*

509 *You can do a slow one slightly less (distance), a medium one slightly further and a faster one even*

510 *further. I don't know how you would organise that, but that would take care of the pacing (.) The*

511 *Researcher will need help. You can't do that with one person because you got to lead, so she actually*

512 *does need somebody to lead a group"* (Alison, 75, female).

513

514 Another suggestion was to conduct healthy workshops during a separate session/time:

515 *"-You suggest a separate session for loneliness? (*Focus group lead).

516 *-A separate [Kate: a separate session yeah (.)] without so many leaflets* (Alison, 75, female).

517 *-Yeah, so that will be a little bit (.) it will be a good focus for each of us to learn, to share (.)"* (Kate,

518 62, female).

519

520 **Changes in outcome measures**

521 There were no significant differences between the intervention and control groups at baseline in all

522 measures except for number (n) of sit-to-stand transitions, which were 14.4 points lower in the

523 intervention group (mean 43.3(11.3)) compared with controls (mean 57.6(15.8); 95% CI 2.91, 25.81).

524 Table 2 shows the between group differences for secondary outcomes. In general, a pattern of

525 improvement was seen across all psychosocial and physical activity outcomes in the intervention

526 group. All correlations performed for psychosocial outcomes are shown in Table 3. Correlation

527 analysis performed for calculated change scores over time in the experimental group for all

528 psychosocial outcomes showed no significant correlations between any other psychosocial outcomes

529 except for a moderate negative correlation between self-efficacy for exercise and loneliness, and a

530 moderate negative correlation between self-efficacy for exercise and the family sub-scale of Lubben's

531 social networks. A moderate positive correlation emerged between self-efficacy for exercise and the

532 friendship sub-scale of Lubben's social networks, such that an increase in self-efficacy for exercise

533 was associated with a larger family and friends social network size.

534

535 **Power Calculation**

536 The potential sample size for a future large-scale trial was calculated for each psychosocial outcome

537 using *post-hoc* analyses first to estimate the observed power based on the effect sizes from the

538 repeated measures between-within ANOVAs on the 25 participants using the partial eta-squared from

539   the interaction effect (η^2). Following this, a sample size was calculated *a priori* for a future trial using

540    $\alpha = 0.05$ and power at 80% for each measure: loneliness (N=72, η^2=0.014), social support (N=48,

541   η^2=0.030), Lubben's social network (N=48, η^2= 0.026), depression (N=378, η^2=0.008), anxiety

542   (N=68, η^2=0.032), SEE (N=12, η^2=0.122), expected outcomes (N=60, η^2=0.033), and barriers for

543   exercise (N=172, η^2=0.011) (Additional file 7). The calculation of estimated sample size for SSC

544   was not possible as η^2=0.000 (insufficient power).

545

Discussion

547   This study assessed the feasibility of the Physical Activity Intervention for Loneliness (PAIL)

548   intervention in community-dwelling older adults at risk for loneliness. Based on the progression

549   criteria, the retention rate was satisfactory, e.g. >75% of participants at 12 weeks (end-point period),

550   as well as no adverse events during the intervention. The recruitment rate of 25% by the end of the

551   four months was somewhat lower than initially proposed at 75%. Therefore, only two out of three

552   criteria of progression to the definitive RCT were satisfied, meaning that the study was not feasible

553   to deliver in its present form. However, these findings were not surprising based on the inability to

554   accurately estimate recruitment rates in the present study, as well as the fact that it is difficult to access

555   socially isolated older adults who may be less interested in joining an intervention than those who are

556   more socially engaged. Therefore, recruitment from GPs may be more advantageous than

557   advertisement via mass media resources such as leaflets or advertisement posters in a future large-

558   scale trial to recruit older adults at high risk of loneliness or social isolation [20, 63, 64].

559   The low attendance rate (58.3% for the intervention group, 42.3% in the WL control group) in this

560   study is not surprising given that the PA intervention is considered to be a behaviour change strategy

561   that is not easily initiated or consistently maintained in older adult populations [65]. Based on

562   participant responses, providing transport to and from walking session locations may significantly

563   improve adherence and provide easier access to various locations of walks to maintain interest of

564   older adults.

565 No significant changes in outcome measures were found after 12 weeks of the PAIL intervention. As

566 reported in the literature, the acute exercise effect is brief [66] and a longer duration intervention as

567 well as an adequate follow-up period of the future intervention may be needed to allow participants

568 to build upon transforming new contacts into meaningful relationships based on trust, which previous

569 studies suggest may be up to 5 months [67, 68].

570 Given that the initial aim of the intervention was to see if loneliness could be impacted, and the

571 observed power and estimated sample size for this seems achievable, this could be recommended as

572 a future primary outcome. However, a feasibility study, by its very nature, may be under powered to

573 achieve statistical significance at α=0.05 [69]. Therefore, any interpretation based on significance

574 levels should be treated with caution. Post-hoc sample size calculations were possible, however are

575 not advisable for feasibility studies [70]. Therefore, additional feasibility is recommended using the

576 minimum clinically important difference (MCID) [69], which was performed for depression and

577 anxiety as they had a set cut-off point of 4 scores. The mean between group difference at 12 weeks

578 was non-significant and less than the a priori determined MCID of 4 points with 95% CI crossing

579 zero (MD=1.0, 95% CI: -1.8 to 3.9, p=0.457), suggesting that the results are equivocal. Similar results

580 were obtained for anxiety (MD=-0.5, 95% CI: -3.4 to 2.5, p=0.744). Given the small effect sizes for

581 SCC, a sample size calculation was not possible, thus future feasibility testing of this measure is

582 advised. The efficacy outcomes of the current feasibility study may be used in exploratory analyses,

583 but further changes in the intervention design and methods are required before proceeding to a

584 definitive trial. For example, a larger sample and more rigorous recruitment strategy, as well as easier

585 access to walking locations may significantly improve the quality of future research. A future

586 intervention would also be advised to: 1) classify walking groups by ability level; 2) add more group

587 leaders per group; 3) conduct healthy workshops during a separate session/time; 4) provide transport

588 to walking locations in order to maintain high adherence and diversity of routes; and 5) conduct focus

589 group discussions for control participants to understand their experience of the research processes,

590 questionnaires and other elements.

591

Strengths and limitations

This study had a robust design and highlighted the importance of PA interventions for loneliness in older adults based on the lack of existing research [20]. Walking was chosen as it has been shown to be the most feasible and cost-effective method of physical activity for older adults [71, 72]. Other strengths of this study include objective measurement of PA, use of reliable methods of assessment of psychosocial outcomes in older adults, and the mixed methods research design that allowed for collecting feedback from participants during and at the end of the intervention.

Study limitations include selection bias associated with the recruitment of physically mobile participants as assessed during the eligibility screening. Therefore, any treatment effect of this feasibility study may be blunted by this selection bias [14, 21] and inclusion of higher functioning older adults. The identification of sedentary individuals in this study was done using the modified short form of the CHAMPS physical activity questionnaire adopted for use in an older adult population [73]. For future studies it is advisable that instead of using this general normative definition of a sedentary individual, this exclusion criterion could be exclusive to walking. Future studies should consider using objective methods of assessment of PA (e.g., pedometers or accelerometers) in older adults in addition to the phone-based screening for a rigorous eligibility process. The optimum dose was not a feasibility outcome in the present study. However, the low attendance suggested that more frequent sessions would not be feasible. In terms of PA, the ideal dose would be a total of 150min per week, but the present study suggests this is unlikely. Appropriate blinding of the researcher was not possible in the present study due to a lack of resources available to pay an independent person to deliver the intervention and collect all of the data. As such, it is recommended that future studies are resourced to allow for the recruitment of a trained walking leader to deliver the intervention and an independent assessor of outcomes to allow for adequate blinding and reduce detection bias. The mixed design of the intervention allowed for the enrichment of the quantitative data of the intervention by including the opinion of participants about the study.

617   However, the low attendance of focus groups was a limitation. Out of 12 people in the intervention

618   group, only 58.3% attended the 12-week intervention with a mean (SD) number of attended sessions

619   per person 8.6(2.8). The reasons for not attending focus groups were work/lack of time, health reasons

620   and other (e.g. transport difficulties, lack of motivation, family reasons). In addition, older adults with

621   loneliness may have barriers for open discussions due to the "stigmatising nature of loneliness," [14,

622   74-76]. Therefore, a future study may consider using one-to-one interviews instead. In addition, WL

623   control group participants may have experienced a significant nocebo effect (a worsening symptom

624   or disappointment) [77]. Compared to control group designs with no treatment, participants with WL

625   control group designs have a hope for the intervention delivered later, however, this may also induce

626   frustration [78]. This may be especially true for lonely older adults with high levels of depression or

627   anxiety, and the likelihood of worsening their psychological well-being is high which, in turn, may

628   influence questionnaire responses. Future research should attempt to address these issues by changing

629   the control group design to a no treatment control, but this brings its own ethical issues surrounding

630   not offering an intervention to individuals who have the potential to benefit from it. It should be

631   acknowledged that even with the use of the loneliness screening measure, individuals with highest

632   loneliness risk may be those least likely to respond to an invitation to eligibility screening due to low

633   confidence and motivation.

634

635   **Conclusions**

636   The present study suggests that community-dwelling older adults at risk for loneliness can

637   successfully complete a 12-week walking intervention programme, reporting enjoyment and benefits,

638   and they were keen to share their knowledge and experiences during the healthy/social workshops.

639   The efficacy outcomes of the current feasibility study may be used in exploratory analyses, but the

640   changes suggested above to the intervention design and methods would be necessary before

641   proceeding to a definitive trial. Further feasibility testing based on the different CIs with a MCID set

642   a priori would be advisable.

643

Abbreviations

ANOVA: the repeated-measures analysis of variance; B: the standardised regression coefficient;
BMI: Body Mass Index; BP rest: Resting blood pressure; CHAMPS: Community Healthy Activities
Model Programme for Seniors; CI: Confidence Intervals; EE: energy expenditure; ES: the effect size;
GP: General Practitioner; HADS: Hospital Anxiety and Depression Scale; LSNS-6: 6-item Lubben's
Social Network Scale; M: means; MCID: minimal clinically important difference; MET: the
metabolic equivalent; MOSSSS: the Medical Outcomes Study Social Support Survey; MOCA: the
Montreal Cognitive Assessment; MVPA: Moderate-to-vigorous physical activity; N: number; NHS:
National Health Services; PA: physical activity; PAIL: Physical Activity Intervention for Loneliness;
R: correlation coefficient; RCT: Randomised Controlled Trial; RPE: SD: standard deviations; SEE:
Self-efficacy for exercise scale; SSC: Satisfaction with level of social contacts; SPPB: the Short
Physical Performance Battery; STEM Ethical Review Committee: the Science, Technology,
Engineering and Mathematics Ethical Review Committee; TIDieR: template for intervention
description and replication checklist; UCLA-8: the 8-item The University of California, Los Angeles
Loneliness Scale; UK: The United Kingdom; WL: wait-listed control group.

659

672

Availability of data and materials

674 Not applicable.

675

Authors' contributions

677 AW, JT and CG advised regarding development of trial design and study protocol, assisted obtaining

678 ethics approval and amendments, helped in facilitating patient recruitment, register study protocol,

679 structure the research stages and oversee all study procedures. JT also helped to design and analyse

680 focus group interviews. FN helped to conduct and analyse focus group interviews. The doctoral

681 research student (AS) obtained funding and was involved in the design of the study protocol,

682 participant recruitment, health assessments and implementation of the intervention.

683

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685 AW is Professor in Behavioural Medicine, JT is a Professor of Public Health Nutrition and Exercise,

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688

Competing interests

690 The authors of this review declare that they have no competing interests.

691

Consent for publication

693 Not applicable.

694

Disclosure statement

696   The authors of this review declare that they have no known conflicts of interest.

697

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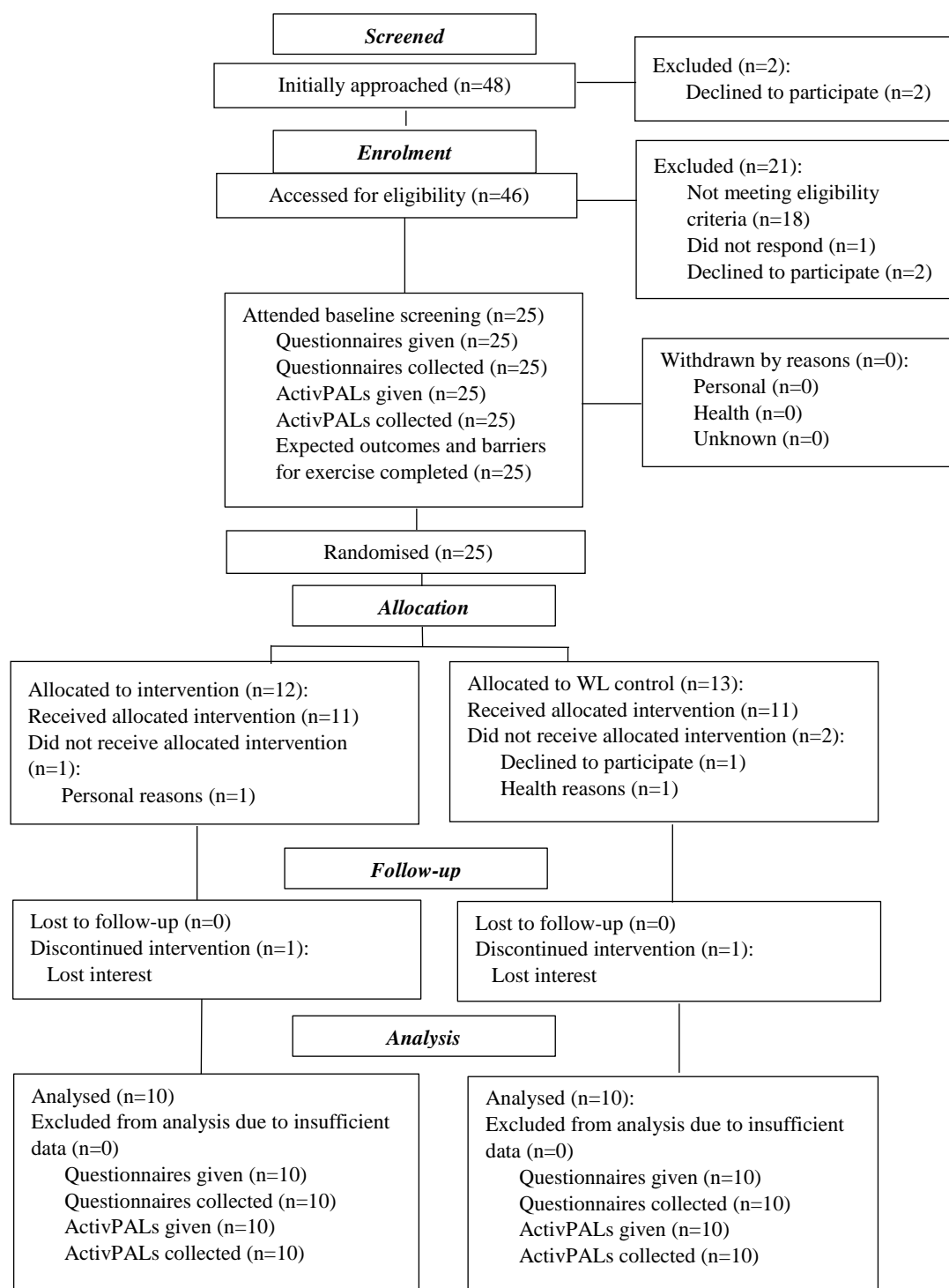887   32.

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Fig. 1. CONSORT flow diagram of Physical Activity Intervention for Loneliness (PAIL) intervention.

919　Table 1. Baseline socio-demographic, anthropometric and health-related characteristics of study

920　participants by group (n=25).

Variable	Intervention (n=12)	Control (n=13)
Age, years	68.4(5.9)	67.3(11.5)
Male, n (%)	5(41.7)	6(46.2)
Ethnicity, n (%)		
White	7(58.3)	11(84.6)
Black	2(16.66)	0(0)
Asian	1(8.33)	1(7.69)
Other	2(16.66)	1(7.69)
Marital status, n (%)		
Married	4(33.3)	2(15.4)
Single/never been married	4(33.3)	4(30.8)
Divorced/separated	2(16.7)	5(38.5)
Widowed	2(16.7)	2(15.3)
Living alone, n (%)	8(66.7)	9(69.2)
Education, n (%)		
No qualification	2(16.7)	1(7.7)
Secondary education	2(16.7)	4(30.8)
College degree	3(25)	2(15.4)
University degree or higher	5(41.7)	6(46.2)
Having children, n (%)	7(58.3)	10(76.9)
Not employed /retired, n (%)	10(83.3)	8(61.5)
Comorbidities, n (%)		
0	3(25)	3(23.1)

1	5(41.7)	2(15.4)
≥2	4(33.3)	8(61.5)
Physical function	10.3(1.2)	10.8(1.0)
(SPPB score ≥ 9 points)		
Cognitive function	28.3(1.9)	27.5(2.4)
(MOCA score ≥ 22 points)		
Height, m	1.7(0.1)	1.7(0.1)
Weight, kg	68.2(12.8)	68.8(14.2)
Body mass index, kg/m^2	24.7(3.0)	24.7(3.4)
Systolic blood pressure, mmHg	128.9(7.9)	133.1(16.6)
Diastolic blood pressure, mmHg	75.7(8.9)	77.9(11.9)

921   Values are the mean (SD) unless indicated otherwise.

922   Abbreviations: n- number; SPPB – Short Physical Performance Battery, MOCA – Montreal

923   Cognitive Assessment scale.

924

925 Table 2. 12-week group differences between intervention and control groups in anthropometric,

926 health-related, physical activity and psychosocial outcomes from baseline.

	Mean (SD)		
Variables	**Intervention** (n=12)	**Control** (n=13)	**Difference (95% CI)**
Height, m	1.7 (0.1)	1.7 (0.1)	-0.0 (-0.1 to 0.1)
Weight, kg	67.9 (12.6)	68.4 (14.2)	-0.5 (-11.6 to 10.7)
BMI, kg.m^{-2}	24.3 (2.8)	24.5 (3.5)	-0.2 (-2.9 to 2.4)
SBP, mmHg	123.3 (8.3)	129.9 (13.8)	-6.6 (-16.1 to 2.9)
DBP, mmHg	74.1 (8.9)	74.5 (9.6)	-0.4 (-8.1 to 7.3)
Loneliness	18.1 (5.2)	18.6 (5.2)	-0.5 (-4.8 to 3.8)
Social support	63.9 (19.8)	59.8 (20.7)	4.1 (-12.7 to 20.9)
LSN (Total)	15.4 (5.0)	12.0 (6.3)	3.4 (-1.3 to 8.2)
LSN (Family)	6.9 (4.4)	5.9 (3.8)	1.0 (-2.4 to 4.4)
LSN (Friends)	8.5 (2.5)	6.1 (4.9)	2.4 (-0.9 to 5.7)
Depression	6.5 (3.0)	5.5 (3.8)	1.0 (-1.8 to 3.9)
Anxiety	6.9 (3.3)	7.4 (3.7)	-0.5 (-3.4 to 2.5)
SEE	7.1 (1.7)	5.2 (2.2)	1.9 (0.3 to 3.6)
SSC	6.5 (3.1)	5.3 (3.6)	1.2 (-1.7 to 4.1)
Expected outcomes	3.8 (1.1)	3.9 (0.8)	-0.1 (-0.9 to 0.7)
Barriers for exercise	2.6 (0.9)	2.9 (1.0)	-0.3 (-1.0 to 0.5)
Time lying/sitting (h)	16.8 (1.9)	17.1 (1.8)	-0.3 (-1.8 to 1.2)
Time standing (h)	5.5 (1.5)	5.1 (1.6)	0.5 (-0.9 to 1.7)
Time stepping (h)	1.9 (0.7)	1.8 (0.7)	0.1 (-0.6 to 0.7)
Step counts	9067.5 (4355.7)	8575.6 (4117.5)	491.9 (-3013.6 to 3997.5)

Sit to stand transitions (n)	45.3 (10.6)	60.3 (14.6)	-15.0 (-25.7 to -4.4)
Energy Equivalent (METs/h)	34.4 (1.7)	34.1 (1.6)	0.3 (-1.1 to 1.7)

927   Abbreviations: BMI - body mass index, DBP – diastolic blood pressure, n- number, SBP – systolic

928   blood pressure, SEE – self-efficacy for exercise; SSC – satisfaction with social contacts, LSN –

929   Lubben's social networks.

930 Table 3. Pearson product-moment correlations between change scores of psychosocial outcomes in the Intervention group (n=12).

Scale	1	2	3	4	5	6	7	8	9	10
1. UCLA -8	-									
2. MOSSSS	0.046	-								
3. LSN (Total)	-0.140	0.107	-							
4. LSN (Family)	0.278	0.044	0.593*	-						
5. LSN (Friends)	-0.470	0.057	0.313	-0.579*	-					
6. Depression	0.411	-0.506	0.315	0.126	0.171	-				
7. Anxiety	0.183	-0.503	-0.161	-0.238	0.117	0.530	-			
8. SEE	-0.707*	-0.148	-0.108	-0.648*	0.655*	-0.197	0.131	-		
9. SSC	-0.597	0.381	0.261	0.050	0.216	-0.320	-0.741**	0.425	-	
10. Expected outcomes	-0.043	0.209	0.332	0.223	0.073	-0.106	-0.722**	-0.240	0.563	-
11. Barriers for exercise	-0.229	-0.208	-0.205	-0.437	0.309	0.133	-0.033	0.414	0.422	-0.102

931 Abbreviations: UCLA- 8 – 8-item University of California at Los Angeles loneliness scale; MOSSSS – Medical outcomes study social support survey, LSN

932 –Lubben's social networks, SEE – Self-efficacy for exercise, SSC – Satisfaction with level of social contacts.

933 Notes: *Significant correlation at $p<0.05$ (two-tailed), ** Significant correlation at $p<0.01$ (two-tailed).

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