A Preventative Lifestyle Intervention for Older Adults (Lifestyle Matters)

Mountain, Gail; Windle, Gillian; Hind, Daniel; Walters, Stephen; Keertharuth, Anju; Chatters, Robin; Sprange, Kirsty; Craig, Claire; Cook, Sarah; Lee, Ellen; Chater, Tim; Woods, Robert; Newbould, Louise; Powell, Lauren; Shortland, Katy; Roberts, Jennifer

Age and Ageing

DOI:
10.1093/ageing/afx021

Published: 25/02/2017

Peer reviewed version

Cyswllt i'r cyhoeddiad / Link to publication

Dyfyniad o'r fersiwn a gyhoeddwyd / Citation for published version (APA):

Hawliau Cyffredinol / General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain.
- You may freely distribute the URL identifying the publication in the public portal.

Take down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.
A Preventative Lifestyle Intervention for Older Adults (Lifestyle Matters): A Randomised Controlled Trial

Objectives

To test whether an occupation based lifestyle intervention can sustain and improve the mental wellbeing of adults aged 65 years or over compared to usual care, using an individually randomised controlled trial.

Participants

288 independently living adults aged 65 years or over, with normal cognition were recruited from two UK sites between December 2011 and November 2015.

Interventions

Lifestyle Matters is a NICE recommended multi-component preventive intervention designed to improve the mental wellbeing of community living older people at risk of decline. It involves weekly group sessions over four months and one to one sessions.

Main outcome measures

The primary outcome was mental wellbeing at 6 months (mental health dimension of the SF-36). Secondary outcomes included physical health dimensions of the SF-36, extent of depression (PHQ-9), quality of life (EQ-5D) and loneliness (de Jong Gierveld Loneliness Scale), assessed at 6 and 24 months.

Results

Data on 262 (intervention =136; usual care =126) participants were analysed using intention to treat analysis. Mean SF-36 mental health scores at six months differed by 2·3 points (95 CI -1·3 to 5·9; P=0·209) after adjustments.

Conclusions

Analysis shows little evidence of clinical or cost effectiveness in the recruited population with analysis of the primary outcome revealing that the study participants were mentally well at baseline. The results pose questions regarding how preventive interventions to promote wellbeing in older adults can be effectively targeted in the absence of proactive mechanisms to identify those who at risk of decline.

Trial registration

ISRCTN67209155
Keywords

Occupational health, randomised controlled trial, mental health.

Key points

- Social participation and involvement in meaningful activities can prevent mental ill-health in older adults.
- Two US studies found that an occupation based lifestyle intervention improved the mental wellbeing of older adults.
- We adapted the US lifestyle intervention for a UK population and assessed it’s effectiveness in comparison to usual care.
- We were unable to recruit those with lowered mental wellbeing, which contributed to the intervention not showing effectiveness.
- Findings highlight the need for strategies to identify those who are on the cusp of decline.

Introduction

Current national guidance advocates the implementation of health promoting interventions for older people with the aim of compressing morbidity in the later stages of the life course and promoting quality of life and wellbeing (1,2). The guidance is informed by evidence which demonstrates the relationship between extent of social activity and morbidity and mortality in the extended lifespan (3) and the importance of participation in meaningful activities for mental wellbeing (5, 6).

An occupation based intervention designed in the US to promote continued participation and engagement (Lifestyle Redesign) was shown to be effective in improving the mental wellbeing of older adults through two randomised controlled trials (4,5). The aim of the study reported in this paper was to test whether an intervention modelled on Lifestyle Redesign and adapted for a UK population (Lifestyle Matters) could also demonstrate clinical and cost effectiveness.

Methods

Study design

A pragmatic, multicentre randomised controlled trial was conducted in two contrasting UK sites (rural North Wales and a large urban city in northern England) between December 2011 and November 2015. The study protocol was published (6). A Trial Steering Group (TSC) and independent Data Monitoring Committee (DMC) were appointed to monitor the quality and conduct of the study.

Participants

A variety of recruitment methods were used to attract community living people aged 65 years and over with reasonable cognitive ability to participate. The feasibility study had highlighted the value of using local communities to identify those who might benefit (7). Therefore considerable effort was invested in informing community health and social care practitioners...
and groups for older people through face to face meetings and media advertisements. However the time constraints of undertaking a randomised controlled trial necessitated an additional recruitment strategy via GP mail outs in the areas where intervention delivery was planned. The original intention was that mail outs would support achievement of recruitment targets within the required timeframe (8).

The intervention

Based on an occupational approach to healthy ageing, the manualised Lifestyle Matters intervention was designed to assist participants to improve their wellbeing and avoid the decline associated with social isolation and poor mental health. Participants met in a weekly group of up to twelve people over four months at a local venue. Participants were also asked to engage in monthly individual sessions with a facilitator. Session topics were either chosen from the manualised programme or new topics identified (9). The facilitators worked with the participants to explore the selected topic through discussion, activities and community enactment. The emphasis throughout was upon the identification of participants' goals, empowerment through sharing strengths and skills and providing support to enable them to practice new or neglected activities independently, particularly in the community (10,11). The facilitators were paid NHS or social care staff who were provided with training and supervised by qualified occupational therapists throughout.

Study procedures

Eligible participants were enrolled, screened for cognition and consented by a research assistant (RA) and randomised to one of two study arms (intervention or usual care) via a remote web based randomisation service. The randomisation sequence was computer generated in advance by the trial statistician and stratified by site. Random permuted blocks of variable size were used to ensure that sufficient participants were allocated in a 50:50 ratio to each arm of the trial at each study site. When a couple in the same household both consented to take part, the pair was randomised as a couple.

The principal investigator (PI), TSC, study statisticians, health economists and RAs collecting outcome data at six and 24 months were blinded to treatment allocation but the Trial Manager, clerical team and participants were not blinded. RAs who undertook follow up appointments asked participants to avoid revealing which arm they were allocated to.

All study participants were asked to participate in study data collection at baseline and follow up.

Adherence to the manualised intervention was assessed (6,9). Facilitator fidelity to the group intervention was determined by two independent researchers evaluating video recordings of four groups (two at each site) during weeks four and 10 of delivery using a checklist which rated six domains: goals and needs, resources, personal qualities, enabling, group work skills and content. “Group member performance” was also assessed using a checklist to determine a participant’s uptake of the intervention and their understanding of it. Participant attendance at group and individual sessions was monitored through registers.
Outcomes

All participants were assessed at baseline and followed up at six and 24 months post randomisation using validated questionnaires, completed either face to face or over the telephone by an RA.

The primary outcome was mental wellbeing measured by the 36 Item Short Form Health Survey (SF-36) mental health (MH) dimension score at six months (12), measured on a 0 (poor) to 100 (good health) scale. Secondary outcomes were other dimensions of the SF-36, Patient Health Questionnaire (13), EQ-5D-3L (14), de Jong Gierveld Loneliness Scale (15), General Self-Efficacy Scale (16), and Office for National Statistics wellbeing at six and 24 months post randomisation (17). Serious adverse events (SAEs) were assessed at six and 24 months; these were assessed by the PI for relatedness to the intervention. Economic evaluation involved collection of all health and social care use over the previous three months at each data collection point through application of a bespoke health and social care resource use questionnaire.

Statistical analysis

Sample size was derived from the mean SF-36 MH dimension score of a general health survey (68.3 with a standard deviation (SD) of 19.9) (18). Assuming a mean difference in SF-36 MH scores of 8 or more is of a clinical or practical importance, and a SD of 20 points, to have an 80% power of detecting this difference, significant at the 5% (two-sided) level, with cluster sizes of 10 subjects per Lifestyle Matters group, an intra cluster correlation of 0.01 and with 20% lost to follow up at six months, the study needed to recruit 268 participants (134 per arm). Primary and secondary outcomes were analysed using a linear mixed effects model with independent correlation and two levels of nested clustering. The lower level of clustering treats each couple as a cluster of size two, or each individual, if not in a couple, as a cluster of size one. The higher level of clustering regards participants in the same Lifestyle Matters intervention group as a cluster. Participants allocated to either arm who withdrew from intervention before being allocated a group were treated as a cluster of size one, or of size two if they were in a couple. An adjusted analysis was performed alongside this unadjusted analysis, which included potential baseline prognostic covariates of age, sex and baseline SF-36 mental health dimension score and whether the participant lived alone in a mixed effects model. Analysis of secondary outcomes at six and 24 months post-randomisation was performed in a similar manner.

In calculating the cost-effectiveness of the intervention, a cost perspective of the NHS and social care was adopted. Intervention costs (cost of facilitators and their supervision, venue hire and related costs of delivering the intervention), drugs, inpatient stay, general practitioner visits, outpatient appointments, visits to the emergency department and day care services were included. Costs were obtained from NHS reference costs 2013-2014 and other published sources (19,20). There was less than 5% missing data for costs and as a result no imputation was necessary. Costs and benefits had not been discounted. Utilities were calculated using SF-6D derived from SF-36 collected at baseline, six months and 24 months. Quality-Adjusted Life
Years (QALYs) were estimated using a total of 30 imputations and were calculated using the area under the curve method.

Cost-effectiveness was analysed using seemingly unrelated regression, a multivariate technique that takes into consideration potential correlation between costs and QALYs (21). An incremental analysis was conducted by dividing mean incremental QALYs to produce an incremental cost effectiveness ratio (ICER) by comparing participants in the intervention and control groups. Uncertainty in the decision is assessed from cost effectiveness acceptability curve (CEAC) which plots the probability that the intervention is cost effective for a range of thresholds that the NHS would be willing to spend per QALY.

This work was supported by the Medical Research Council [grant number G1001406], who had no input into the design, execution, analysis and interpretation of data, or writing of the study.

Results

The trial randomised 288 participants between 14th August 2012 and 19th April 2013 (18 couples and 252 individuals); 145 and 143 were allocated to the intervention and control groups respectively (figure 1). Twenty six participants either withdrew, were lost to follow up, or had missing primary outcome data at six months, leaving 262 (91%) participants in the primary analysis (136 intervention; 126 control). Baseline characteristics of the participants are displayed in table 1.

Intention to Treat (ITT) analysis found no difference in the primary outcome (SF-36 MH) between randomised groups (table 2, adjusted mean difference 2.3, 95% CI -1.3 to 5.9, p=0.209). Fifty-two percent (71/136) of participants allocated to the intervention received a therapeutic dose of group sessions in that they attended 12 or more of the 16 weekly groups before six month follow up. A sensitivity (per-protocol) analysis of the 71 participants who received a therapeutic dose of the group found similar results to the ITT analysis. Other sensitivity analyses, of the imputing missing data, gave consistent estimates of treatment difference (please see the table Appendix 1 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/). There was no evidence of difference between those the intervention and usual care groups on any secondary outcomes at six months. However at 24 months, scores on two subscales (de Jong Gierveld Emotional Loneliness and de Jong Gierveld Social Loneliness) were significantly improved in the intervention compared to the usual care group (table 2), although the relevance of this finding is questionable due to a lack of evidence to support a minimal clinically important difference (15). Assessment of fidelity to the group component was satisfactory in seven out of eight video recordings for both group member and facilitator performance, indicating that the group component had been delivered as intended. The mean number of group sessions attended per participant was 9.2 (SD = 5.8). Out of the 123 participants who attended at least one group session, 93 (75.6%) were offered four individual sessions as per protocol but only 5 (4.1%) accepted and received all four sessions. The number of participants that experienced a SAE was similar across the trial arms.
The majority of the SAEs reported persistent or significant disability/incapacity over the time scale since last assessment, which accounted for 71% of the total. All SAEs reported by intervention group participants were assessed as either unrelated or unlikely to be related to the intervention. RAs were unblinded to group allocation in 13.7% (n=109) of follow-up appointments.

The cost of Lifestyle Matters was estimated at £430 and £575 (£1 = $1.51) per person in the North England and North Wales sites respectively. From the regression analysis, the incremental cost effectiveness ratio was found to be £7621 (please see the table Appendix 2 in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/) but this lies in the third quadrant of the cost-effectiveness plane implying that the intervention is less costly but less effective. At a threshold of £20,000, commonly used within the NHS, there was a probability of 30% that Lifestyle Matters would be cost-effective. Utilities generated from EQ-5D to generate QALYs were used as sensitivity analysis. The incremental cost-effectiveness ratio was £7861 but remained less costly and less effective.

**Discussion**

This trial was undertaken to a high standard including blinding of outcome assessors, concealed randomisation techniques and recruitment to sample size. Follow-up was successful at six and 24 months post randomisation (85% retention at 24 months). Limitations were that targeted recruitment through service providers and the community (recommended from the feasibility study) was unsuccessful, despite sustained effort (7). To recruit the required numbers of participants meeting study eligibility criteria within the allocated time frame almost all were recruited through GP mail outs, resulting in a self-selecting sample.

The findings do not support the hypothesis that an intervention modelled on Lifestyle Redesign and adapted for a UK population (Lifestyle Matters) is effective at improving the wellbeing of older adults. The change in the primary outcome (mental health dimension of the SF-36) over a six month period was not significantly different between the usual care and intervention groups (12). Compared to the second US Lifestyle Redesign study, where recruited participants had a mean baseline SF36 Mental component summary (MCS) score of 41, participants in our study were mentally well with mean baseline SF36 MCS score scores of 52 (5) (MCS scores are standardised to have mean of 50 and SD of 10 the same as the reference population). Participants in the US studies were independently residing in retirement communities and private homes; those in private homes visited senior community centres. In our trial, older adults were also independently living but were recruited from the community and did not necessarily have any involvement in community centres. It can be deduced that participants recruited to Lifestyle Matters were not at a stage of their life when they would benefit most from such an intervention, nor were they activity seeking support when recruited. The US studies suggest that recruiting from an existing support group enabled recruitment of those with lowered mental wellbeing (5).

At 24 months there were significant decreases in aspects of emotional loneliness (e.g. ‘I often feel rejected’; ‘I miss having people around me’) for those who had participated in the Lifestyle
Matters intervention. This suggests that the groups could have influenced a re-appraisal of relationships and social networks, a potential area for further study. A small proportion of individuals (4.1%) took up all four offers of a one to one session with a facilitator. Fostering increased uptake of these sessions, which focussed on goal setting, may aid individuals gain quality of life in future evaluations.

Identifying older people at risk of mental decline and in particular those not known to services is challenging and has only recently been identified as a priority for UK health, social care and other agencies (2). Consensus is required as to the responsibility of clinicians – especially GPs – for identifying such individuals, and the exact methods by which isolated older adults can be identified.

Identifying older people when they are beginning to decline and taking action at that point is crucial to the success of preventive interventions. Proactive recognition and signposting strategies are required which were not in evidence during this study; the benefits of which were strongly indicated in our feasibility study (7) Unlike the feasibility study, the randomised controlled trial methodology did not provide the time required to seek those in most need. We therefore do not know if those who are experiencing mental or physical decline would actually participate in and benefit from such an intervention. Identification of those in potential need remains an elusive challenge.

Footnotes
We would like to thank participants of the Lifestyle Matters study for their important contributions.

Conflicts of interest
GM and CC are the original authors of the published Lifestyle Matters manualised programme. No other authors have any competing interests.

Authors’ contributions
GM, GW, JB, DH, SW, AK, KS, CC, SC and BW designed the study and obtained funding. AK undertook the health economic analysis with input from JB. SW designed the statistical plan and EL conducted the analyses with input from SW. LN, JR, LP and KT collected data. TC processed and cleaned the data. All authors had input into the set-up and running of the study. All authors reviewed the manuscript and gave final approval to submit to the journal. GM had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Acknowledgements
The views and opinions expressed in this paper are those of the authors and do not necessarily reflect those of the MRC. Primary Care Research Network (PCRN) funding was accessed to support recruitment activity in GP surgeries in Sheffield and NISCHR provided support in North Wales. The funder has reviewed and approved the study design including methods of data collection, analysis and interpretation of data. Dr Pip Logan, Dr Jennifer Wenborn, Dr
Linda Sheppard, Dr Fiona Goudie of the Trial Steering Committee (TSC) and Dr Mona Kanaan, Prof Avril Drummond and Dr Claire Ballinger of the Data Monitoring and Ethics Committee (DMEC) advised on and critically reviewed the trial protocol. Ms Maggie Spencer reviewed the trial protocol and supporting documents as an invaluable older person representative.

Ethical approval

Ethics approval was obtained from the South Yorkshire Research Ethics Committee (12/YH/0101).

References


Figure 1. Trial profile.

Postal candidate invitations sent via GP n=9330; also leaflets, posters

Candidate response (card/call) n=414
GP n=385 (4.1%); Leaflet or poster n=7; Friend or family n=14; Other n=7; unknown n=1

Contactable; Initial screening n=402 (97.1%)

No response n= 8945 (95.9%)

Not contactable n=12 (2.9%)

Eligibility screening n=313 (77.9%)

No eligibility appointment n=89 (22.1%)

Eligible; Consent sought n=294 (93.9%)

Not eligible n=19 (6.1%)

Not consented n=6 (2.0%)

Consented & randomised n=288 (97.9%)

Intervention n= 145 (50.3%)

6 months follow up n= 136 (93.8%)
Withdrawn n= 7 (4.8%)
Lost to follow-up n= 2 (1.4%)

ITT N= 262

Control n=143 (49.7%)

6 months follow up n= 127 (88.8%)
(complete sf-36 MH n= 126 (88.1%))
Withdrawn n= 13 (9.1%)
Lost to follow-up n= 3 (2.1%)

24 months follow up n= 125 (86.2%)
(complete sf-36 MH n= 122 (84.1%))
Withdrawn n= 3 (2.1%)
Lost to follow-up n= 5 (3.4%)
Died n= 3 (2.1%)

24 months follow up n= 120 (83.9%)
(complete sf-36 MH n= 117 (81.8%))
Withdrawn n= 1 (0.7%)
Lost to follow-up n= 2 (1.4%)
Died n=4 (2.8%)
## Table 1: Baseline characteristics by randomised group for participants in the intention to treat population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n=145)</th>
<th>Control (n=143)</th>
<th>All (n=288)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44 (30.3%)</td>
<td>48 (33.6%)</td>
<td>92 (31.9%)</td>
</tr>
<tr>
<td>Female</td>
<td>101 (69.7%)</td>
<td>95 (66.4%)</td>
<td>196 (68.1%)</td>
</tr>
<tr>
<td>Age Mean (range)</td>
<td>72.9 (65-92)</td>
<td>71.3 (65-90)</td>
<td>72.1 (65-92)</td>
</tr>
<tr>
<td>Ethnic group, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English / Welsh / Scottish / Northern Irish / British</td>
<td>142 (97.9%)</td>
<td>141 (98.6%)</td>
<td>283 (98.3%)</td>
</tr>
<tr>
<td>Irish</td>
<td>1 (0.7%)</td>
<td>1 (0.7%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>European</td>
<td>1 (0.7%)</td>
<td>1 (0.7%)</td>
<td>2 (0.7%)</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>1 (0.7%)</td>
<td>0 (0.0%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Lives alone, n (%)</td>
<td>86 (59.3%)</td>
<td>71 (49.7%)</td>
<td>157 (54.5%)</td>
</tr>
<tr>
<td>Lives with, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse/partner</td>
<td>48 (33.1%)</td>
<td>61 (42.7%)</td>
<td>109 (37.8%)</td>
</tr>
<tr>
<td>Child/children</td>
<td>3 (2.1%)</td>
<td>4 (2.8%)</td>
<td>7 (2.4%)</td>
</tr>
<tr>
<td>Both partner and children</td>
<td>5 (3.4%)</td>
<td>6 (4.2%)</td>
<td>11 (3.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (2.1%)</td>
<td>1 (0.7%)</td>
<td>4 (1.4%)</td>
</tr>
<tr>
<td>Main activity/Occupation, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed or self employed</td>
<td>6 (4.1%)</td>
<td>6 (4.2%)</td>
<td>12 (4.2%)</td>
</tr>
<tr>
<td>Retired</td>
<td>133 (91.7%)</td>
<td>134 (93.7%)</td>
<td>267 (92.7%)</td>
</tr>
<tr>
<td>Looking after home/family</td>
<td>4 (2.8%)</td>
<td>2 (1.4%)</td>
<td>6 (2.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (1.4%)</td>
<td>1 (0.7%)</td>
<td>3 (1.0%)</td>
</tr>
<tr>
<td>If employed or retired; occupation type, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>27 (18.6%)</td>
<td>20 (14.0%)</td>
<td>47 (16.3%)</td>
</tr>
<tr>
<td>Managerial/Technical</td>
<td>34 (23.4%)</td>
<td>33 (23.1%)</td>
<td>67 (23.3%)</td>
</tr>
<tr>
<td>Skilled (non-manual)</td>
<td>36 (24.8%)</td>
<td>39 (27.3%)</td>
<td>75 (26.0%)</td>
</tr>
<tr>
<td>Skilled (manual)</td>
<td>12 (8.3%)</td>
<td>24 (16.8%)</td>
<td>36 (12.5%)</td>
</tr>
<tr>
<td>Partly skilled</td>
<td>11 (7.6%)</td>
<td>10 (7.0%)</td>
<td>21 (7.3%)</td>
</tr>
<tr>
<td>Unskilled</td>
<td>18 (12.4%)</td>
<td>14 (9.8%)</td>
<td>32 (11.1%)</td>
</tr>
<tr>
<td>Age on leaving full time education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (%)</td>
<td>143 (98.6%)</td>
<td>141 (98.6%)</td>
<td>284 (98.6%)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>16.4 (2.8)</td>
<td>16.2 (2.3)</td>
<td>16.3 (2.5)</td>
</tr>
</tbody>
</table>

A level, Advanced level; AS level, Advanced Subsidiary level; CSE, Certificate of Secondary Education; GCSE, General Certificate of Secondary Education; max., maximum; min., minimum; NVQ4, National Vocational Qualification level 4; O level, Ordinary level.
Table 2. Intention to treat repeated measures analysis at baseline, 6 months and 24 months post randomisation

*Adjusted for lifestyle matters intervention group, couple, age, sex, baseline score, and if lives alone for

b-p-value for adjusted mean difference between treatment and control conditions.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Baseline</th>
<th>6 months</th>
<th>24 months</th>
<th>Adjusted</th>
<th>95% CI</th>
<th>p-valueb</th>
<th>Adjusted</th>
<th>95% CI</th>
<th>p-valueb</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
<td>Mean (SD)</td>
<td></td>
<td>n</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td>SF-36 Mental health</td>
<td>145 75.5 (18.3)</td>
<td>143 77.0 (18.2)</td>
<td>136 77.3 (18.2)</td>
<td>126 75.9 (18.7)</td>
<td>2.3</td>
<td>-1.3 to 5.9</td>
<td>0.209</td>
<td>122 78.0 (17.1)</td>
<td>117 75.4 (17.8)</td>
</tr>
<tr>
<td></td>
<td>145 67.5 (25.3)</td>
<td>143 71.7 (26.4)</td>
<td>136 66.0 (28.4)</td>
<td>126 70.7 (27.3)</td>
<td>1.0</td>
<td>-2.1 to 4.1</td>
<td>0.535</td>
<td>123 65.0 (27.8)</td>
<td>118 66.3 (29.5)</td>
</tr>
<tr>
<td>SF-36 Physical function</td>
<td>145 72.4 (17.6)</td>
<td>143 76.8 (25.5)</td>
<td>136 69.9 (29.9)</td>
<td>126 73.9 (26.4)</td>
<td>0.9</td>
<td>-4.2 to 5.9</td>
<td>0.728</td>
<td>123 69.7 (27.5)</td>
<td>117 72.5 (27.7)</td>
</tr>
<tr>
<td>SF-36 Role physical</td>
<td>145 61.2 (25.6)</td>
<td>143 64.7 (26.5)</td>
<td>136 60.5 (28.0)</td>
<td>126 61.6 (27.4)</td>
<td>1.9</td>
<td>-3.1 to 7.0</td>
<td>0.453</td>
<td>123 56.0 (25.6)</td>
<td>117 59.9 (26.1)</td>
</tr>
<tr>
<td>SF-36 Bodily pain</td>
<td>145 63.6 (20.4)</td>
<td>143 68.8 (20.4)</td>
<td>136 61.9 (22.7)</td>
<td>126 64.8 (21.1)</td>
<td>2.8</td>
<td>-0.6 to 6.2</td>
<td>0.103</td>
<td>123 64.3 (20.7)</td>
<td>117 64.0 (20.7)</td>
</tr>
<tr>
<td>SF-36 General health</td>
<td>145 58.4 (21.4)</td>
<td>143 60.3 (20.9)</td>
<td>136 56.4 (22.2)</td>
<td>126 58.0 (21.7)</td>
<td>-0.2</td>
<td>-4.0 to 3.7</td>
<td>0.929</td>
<td>122 57.1 (21.6)</td>
<td>117 57.3 (19.5)</td>
</tr>
<tr>
<td>SF-36 Vitality</td>
<td>144 82.9 (22.0)</td>
<td>142 82.0 (26.4)</td>
<td>136 77.8 (28.2)</td>
<td>126 81.3 (26.0)</td>
<td>-3.7</td>
<td>-9.4 to 2.0</td>
<td>0.205</td>
<td>122 80.7 (25.4)</td>
<td>117 79.2 (25.2)</td>
</tr>
<tr>
<td>SF-36 Social function</td>
<td>145 82.7 (23.4)</td>
<td>143 84.5 (21.5)</td>
<td>136 82.7 (23.2)</td>
<td>125 86.7 (19.4)</td>
<td>-2.4</td>
<td>-7.1 to 2.3</td>
<td>0.325</td>
<td>121 87.2 (20.2)</td>
<td>117 85.3 (22.9)</td>
</tr>
<tr>
<td>SF-36 Physical component summary</td>
<td>144 44.1 (11.0)</td>
<td>142 45.9 (10.6)</td>
<td>136 42.8 (12.0)</td>
<td>125 44.4 (11.3)</td>
<td>1.0</td>
<td>-0.6 to 2.5</td>
<td>0.21</td>
<td>121 42.1 (11.5)</td>
<td>117 43.5 (11.6)</td>
</tr>
<tr>
<td>SF-36 Mental component summary</td>
<td>144 51.3 (10.4)</td>
<td>142 51.8 (10.0)</td>
<td>136 51.5 (9.7)</td>
<td>125 51.9 (10.1)</td>
<td>-0.3</td>
<td>-2.2 to 1.6</td>
<td>0.763</td>
<td>121 53.3 (9.9)</td>
<td>117 51.6 (10.0)</td>
</tr>
<tr>
<td>EQ-5D-3L</td>
<td>142 0.73 (0.25)</td>
<td>143 0.77 (0.24)</td>
<td>133 0.71 (0.25)</td>
<td>126 0.76 (0.23)</td>
<td>-0.01</td>
<td>-0.05 to 0.03</td>
<td>0.742</td>
<td>121 0.73 (0.24)</td>
<td>116 0.71 (0.28)</td>
</tr>
<tr>
<td>EQ-5D your health state today</td>
<td>145 73.0 (19.2)</td>
<td>142 77.7 (17.6)</td>
<td>135 72.6 (18.3)</td>
<td>126 77.3 (17.0)</td>
<td>-1.6</td>
<td>-5.0 to 1.9</td>
<td>0.37</td>
<td>121 74.7 (16.9)</td>
<td>118 75.3 (16.4)</td>
</tr>
<tr>
<td>Brief Resilience Scale</td>
<td>143 3.6 (0.8)</td>
<td>140 3.6 (0.8)</td>
<td>132 3.7 (0.7)</td>
<td>123 3.7 (0.8)</td>
<td>0.1</td>
<td>-0.2 to 0.3</td>
<td>0.625</td>
<td>122 3.5 (0.8)</td>
<td>115 3.6 (0.8)</td>
</tr>
</tbody>
</table>
The Short Form (36) Health Instrument (SF-36) Dimensions are scored on a 0 (poor) to 100 (good) health scale, except for the Physical and Mental Component summary scores which are standardised to have a mean of 50 and SD of 10. The EuroQol 5-Dimension (EQ-5D) utility score is measured on a −0.56 to 1.00 (good health) scale. The EQ-5D visual analogue scale (VAS) is measured on a 0 (worst imaginable health state) to 100 (best imaginable health state).

The brief resilience scale is scored on a scale of 1 to 5 with higher scores indicating more resilience. The emotional loneliness scale of the De Jong is scored on a 0 to 6 scale with higher scores indicating more loneliness. The social loneliness scale of the De Jong is scored on a 0 to 5 scale with higher scores indicating more loneliness. The total loneliness scale of the De Jong is scored on a 0 to 11 scale with higher scores indicating more loneliness. The Patient Health Questionnaire (PHQ)-9 is measured on a 0 to 27 scale with higher scores indicating more severe depressive symptoms. General Self-Efficacy (GSE) Scale is scored on a 10 to 40 scale with higher scores indicating more perceived self-efficacy. The Office for National Statistics (ONS) instrument measures subjective well-being on a 0 to 40 scale, with higher scores indicating high subjective well-being.

For the SF-36, EQ-5D, Brief Resilience Scale, GSE, ONS a positive mean difference indicates the Invention group has the better QoL. For the de Jong Gierveld and PHQ-9 a negative mean difference indicates the Intervention group has the better QoL.

|                         | Mean 1 | SD 1 | Mean 2 | SD 2 | Mean 3 | SD 3 | Mean 4 | SD 4 | Mean 5 | SD 5 | Mean 6 | SD 6 | Mean 7 | SD 7 | Mean 8 | SD 8 | Mean 9 | SD 9 | Mean 10 | SD 10 | Mean 11 | SD 11 | Mean 12 | SD 12 | Mean 13 | SD 13 | Mean 14 | SD 14 | Mean 15 | SD 15 | Mean 16 | SD 16 | Mean 17 | SD 17 | Mean 18 | SD 18 | Mean 19 | SD 19 | Mean 20 | SD 20 | Mean 21 | SD 21 | Mean 22 | SD 22 | Mean 23 | SD 23 | Mean 24 | SD 24 | Mean 25 | SD 25 | Mean 26 | SD 26 |
|-------------------------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|--------|------|
| de Jong Gierveld        |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |        |      |
| Emotional Loneliness    | 138    | 2.3  | 138    | 2.4  | 130    | 1.9  | 122    | 2.0  | -0.2   | -0.6| 0.254  | 117  | 1.9    | 1.6  | 0.2    | 0.042|
| Loneliness              | 142    | 4.1  | 142    | 4.6  | 134    | 3.5  | 124    | 4.1  | -0.4   | -0.9| 0.201  | 121  | 3.7    | 4.8  | -0.7   | 0.026|
| Social Loneliness       | 140    | 1.8  | 141    | 2.2  | 133    | 1.6  | 123    | 2.0  | -0.1   | -0.4| 0.51   | 122  | 1.8    | 2.4  | -0.2   | 0.223|
| PHQ-9                   | 143    | 4.1  | 135    | 3.3  | 133    | 3.8  | 122    | 3.4  | -0.1   | -0.9| 0.762  | 122  | 3.8    | 4.0  | -0.7   | 0.122|
| General Self-Efficacy   | 144    | 31.7 | 143    | 31.9 | 135    | 31.9 | 124    | 31.6 | 0.5    | -0.5| 0.336  | 121  | 32.3   | 31.6 | 0.7    | 0.213|
| ONS wellbeing           | 145    | 7.3  | 141    | 7.3  | 136    | 7.2  | 124    | 7.3  | 0      | -0.4| 0.911  | 120  | 7.4    | 7.3  | 0.1    | 0.595|