Does an outreaching stepped care program reduce depressive symptoms in community-dwelling older adults? A randomized implementation trial

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ABSTRACT

Objectives: To examine the effects of an outreaching stepped care intervention program ‘Lust for Life’ compared to usual care on depressive symptoms in older adults living in the community.

Design: Randomized clinical implementation trial.

Setting: Eighteen general practices and a home care organization in the Netherlands.

Participants: 263 community-dwelling 65+ year-olds with depressive symptoms according to the Patient Health Questionnaire-9.

Intervention: After three months of watchful waiting, participants could sequentially choose between the following evidence-based interventions: 1) guided self-help or an exercise program, 2) problem solving treatment or life review, and 3) a referral to their general practitioner.

Measurements: The outcome measure was depression severity (Patient Health Questionnaire-9), measured every three months over 2 years.

Results: After the provision of the stepped care program, a significant short-term positive effect on depressive symptoms was found in the first three months after implementation in which average PHQ-scores dropped from 9.34 (SE=0.61, 95% CI: 8.14 – 10.5) to 7.83 (SE=0.51, 95% CI: 6.84 – 8.81).

Conclusions: The ‘Lust for Life’ program has a promising potential to relieve depressive symptoms of older adults in primary care in the short term. Providing one single clinical intervention in accordance with participants’ choices instead of stepped care could be sufficient.
OBJECTIVE
Depressive symptoms are very common in later life and can have a far-reaching impact on quality of life (1-3), mortality (4), and may also lead to an excess use of health services (5,6). Depressive symptoms are the most important risk factor for developing a major depressive disorder (7), which is the second leading cause of disability worldwide. Still, despite the availability and efficacy of treatments (8), many older depressed persons receive no structured follow-up and subsequent management of their symptoms (5,9,10).

Various strategies have been proposed to improve the treatment of late life depressive symptoms (11), including mass screening, stepped care, and preference-led care. Several (large) integrated intervention studies have applied an outreaching approach by recruiting older adults with depressive symptoms by mass screening and offered them strictly supervised and structured stepped care interventions (12-18) or provided them with the choice of two interventions in order to attune to their preferences (13,18-22). Most of these studies have shown to be effective in preventing or treating major depressive disorders (12-14,16-22).

Yet it is not clear how robust these effects are when implemented in the real world of day-to-day care. Secondly, since all studies with samples consisting exclusively of older persons with depressive symptoms have applied stepped or preference-led care as a single approach, it is unknown if an evidence-based intervention program combining these approaches will be effective in reducing depressive symptoms in comparison to usual care.

The aim of this study is to determine whether implementation of an integrated stepped-care intervention program (‘Lust for Life’) is more effective compared to usual care in reducing depressive symptoms and loneliness in community-dwelling older adults.

METHODS
Study design
We conducted a pragmatic randomised controlled trial, using a stepped-wedge randomised-cluster design, a type of hybrid effectiveness/ implementation study (23). (See Figure 1). In this type of one-way crossover cluster design, all participants will receive the intervention but the time when they receive this intervention is randomly ordered (24). The program was implemented in four steps: at the onset, 3, 6, and 12 months after baseline. General practices and subjects recruited by the home care organization were randomly assigned to each of these four implementation groups (‘clusters’) after which the intervention programme was implemented (See Figure 1). Individuals enrolled were followed over two years with outcomes measured every three months. Persons served as a control group at time-points at which they had not yet received the intervention. For this study, a stepped-wedge design was chosen since it was considered advantageous compared to a conventional randomised controlled trial design for the offered clinical interventions were evidence-based and it might therefore be unethical to withhold them
from a considerable number of subjects (24). The VU University Medical Centre Ethical Review Board (No. 2010/084) approved of the study.

Figure 1: Stepped wedge randomised cluster design.

<table>
<thead>
<tr>
<th>Cluster 1</th>
<th>Cluster 2</th>
<th>Cluster 3</th>
<th>Cluster 4*</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0</td>
<td>T3</td>
<td>T6</td>
<td>T9</td>
</tr>
<tr>
<td>T12</td>
<td>T15</td>
<td>T18</td>
<td>T21</td>
</tr>
<tr>
<td>T24</td>
<td>T27</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Due to logistic reasons, the ‘Lust for Life’ program was implemented in cluster 4 with three months delay. Therefore, follow-up was extended to timepoint T27 to assure a 15-months follow-up in every cluster.

Participants

All enlisted persons of 65 and older from 18 participating general practices with 45 general practitioners and a home care facility in three areas in the Netherlands (Amsterdam, West-Friesland and Leiden) were invited to fill in a screener for depressive symptoms, the Patient Health Questionnaire-9 (PHQ-9; 25). Subjects were included when they scored above the predefined cut-off score of 6 (26) and were willing to participate in the clinical interventions. Individuals were excluded in case of severe cognitive disability (Telephone Interview Cognitive Status – Modified score <21 (TICS-m; 27) or insufficient mastery of the Dutch language.

Randomization and blinding

After baseline assessment, randomisation of the general practices to implementation groups was performed by an independent researcher, stratified by region and size of the general practice (small/large number of patients). Subjects recruited by the home care organisation were individually randomised by subject number. Subjects were informed about their randomisation status. Since outcomes were obtained by written questionnaires collected by mail, blinding of interviewers was not applicable.

Power calculation

An estimate of the minimum required sample size was computed using simulation and taking into account the multi-level structure of the data and the stepped-wedge design. The ICCs for clustering within general practices and repeated measurements within patients were set at 0.05 and 0.5, respectively. The standard deviation of PHQ-9 scores was set at 4 (28,29). A number of 10 evaluable patients with complete data recruited from each of the 18 general practices (n=180) was found to yield 80% power to detect one unit change in mean PHQ-scores after three months, approximately two units change after 12 months and three units change after 18 months with 4/5 general practices randomized to start the intervention at each step.
Outreaching stepped care program

STEP-UP RULES

The ‘Lust for Life’ program comprised the following core elements: the program 1) was outreaching (i.e. used mass screening to recruit eligible elders); 2) followed stepped-care principles; and 3) offered preference-led interventions. After a watchful waiting period of three months, subjects were invited to take part in the clinical interventions when depressive symptoms persisted (PHQ ≥ 6). Eligibility to a subsequent step was determined every three months using this same criterion. Subjects scoring below this cut-off were monitored for the next three months. The clinical interventions were offered in incremental steps according to stepped care principles, but participants could choose between two interventions in step one and two. However, given the high drop-out rates in implementation groups one and two, subjects in subsequent groups who disapproved of the step one interventions were offered to start immediately with a step two intervention. So these latter groups were given four intervention options.

CLINICAL INTERVENTIONS

Since many depressive symptoms remit spontaneously (1), all subjects entered a watchful waiting period of three months. If symptoms persisted, they were consequently invited for an intake session (Figure 2) to explain the intervention options and motivate them to choose the intervention that suited them best. The program consisted of the three following steps, each lasting approximately three months:

Step 1: Guided self-help or physical exercise program

Option 1: Guided self-help course, consisting of cognitive behavioral therapy based on the ‘Coping with Depression Course’ and tailored for use by persons of 65 years and older (30). The course comprised of several modules with exercises on relaxation, pleasant activity scheduling, changing cognitions and assertiveness that subjects could work on at their own convenience. Nurses provided guidance by means of visits (mean 4 [sd 2]) and/or telephone calls (mean 2.5 [sd 1.5]) for clarification and encouragement.

Option 2: Physical exercise. Regular physical exercise has been proven effective in reducing depressive symptoms in the elderly (31). The exercise program was delivered in groups of four to six persons and consisted of three one-hour-exercise sessions per week for a period of three months. Subjects attended two sessions a week at the gym and were requested to independently exercise at home once a week. Physiotherapists provided instructions for the home exercises and encouraged compliance.
Step 2: Problem solving treatment or Life Review

Option 1: Problem solving treatment (PST), a structured skills enhancing behavioral intervention based on the assumption that problems in daily life cause and maintain depressive symptoms. In seven one-hour sessions systematically identifying and addressing daily problems was practiced to improve problem solving skills and perceived command over daily living (32,33).

Option 2: Life Review, a structured reminiscence intervention that has been proven effective in reducing late life depressive symptoms, provided in six to eight one-hour sessions. Since the tendency to retrieve more global, negative memories from the past has been related to a worse course of depressive symptoms (34), the ‘Dear Memories’ intervention (35,36) aimed at improving the retrieving of positive, specific autobiographical memories.

Step 3: Referral to general practitioner (GP)

Elders with persistent depressive symptoms were advised to consult their GP for a referral to a mental health specialist and/or to discuss other treatment options such as a referral to a primary care psychologist or general practice nurse. Persons with severe depression at any given point during the trial, defined as PHQ > 20 (37) and a diagnosis of a vital clinical depression according to the Mini Neuropsychiatric Interview (MINI;38), were also referred to their GP to discuss treatment.

DELIVERY OF THE PROGRAM

The ‘Lust for Life’ program was provided by mental health care nurses and home care nurses. Nurses were specifically trained by a psychologist how to deliver interventions. They attended two-monthly group supervision meetings and received individual feedback on at least two tape recorded sessions of the step two interventions. Individual supervision by telephone was provided upon request. Except for the exercise program, all other interventions were individually administered at the participants’ homes or in the office of their general practitioner.

USUAL CARE

Until the interventions were offered, participants had unrestricted access to usual care for their emotional problems. Their health care use was recorded.
Subjects with a severe depression (PHQ > 20 and a clinical diagnosis of a vital depression according to the MINI diagnostic interview) were referred to specialised mental health care.

MH/HC nurse = Mental health/home care nurse
GP = General practitioner
PHQ = Patient Health Questionnaire-9, ≥6 indicative of depressive symptoms
Measures

Primary outcome measure

Depression severity was measured with the self-report Patient Health Questionnaire-9 (PHQ-9), with scores ranging from 0 to 27. Higher scores indicate greater psychological stress. PHQ-scores were collected right before the intervention program was implemented in the first implementation group (approximately one month after the baseline interview) and at 3, 6, 9, 12, 15, 18, 21 and 24 months follow-up. To assure a 12 months follow-up in each implementation group, group four was additionally measured at 27 months follow-up.

Other variables

Diagnoses of major depression and dysthymia were assessed by the MINI (38), a short structured diagnostic interview conducted by telephone by trained research staff. Cognitive functioning was measured by the TICS-m (27), with lower scores indicating worse cognitive functioning. Other background characteristics included daily functioning (Activities of Daily Living KATZ ADL; 39), self-rated quality of life (Cantril’s Ladder; 40), and the number of self-reported somatic diseases in the past 12 months.

Statistical analyses

We first checked whether randomization led to an equal distribution of variables with a potentially confounding effect on the outcome measures across the four implementation groups by means of ANOVA’s and chi2-tests. Analyses to examine the impact of the ‘Lust for Life’ program on the reduction of depressive symptoms compared to usual care were based on the intention to treat principles. All respondents randomized with at least one measurement were included in the analyses.

Data were analyzed using Generalized Estimating Equations (GEE) with an autoregressive correlation structure to take into account the correlation between repeated measurements within subjects (and adjust for baseline differences). Inference about the intervention effect was made by constructing a categorical variable that included the number of time intervals (in units of three months) since start of the intervention, which was included in all models and also served to adjust for time trend. No assumptions were made regarding the nature of the intervention effect and the effect was modeled using a categorical variable indicating the number of time intervals since the start of the implementation of the intervention for each subject. Comparisons between subsequent intervals were analyzed in post-hoc tests with Bonferroni-corrected p-values when the overall intervention effect was significant. The start of the implementation was defined for each subject as the date of their intake session. By way of sensitivity analysis, mixed models with random intercepts for general practices and participants were also performed since participants were clustered within GPs. Results did not differ from GEE-analyses (without a correction for clustering) and the variance component for general practices was very small (0.09 (SE 0.45).
explaining 0.03% of the total variance) and did not significantly differ from zero. Therefore, the use of GEE-models was justified (41). To adjust for selection bias, variables with significant baseline differences and a significant association with the outcomes (age, educational level, dwelling place and ADL) were incorporated as covariates in the analyses. Subgroup analyses were performed to determine the effectiveness of the program for participants with and without a major depression. All analyses were carried out in SPSS version 20.

RESULTS

Participant flow and recruitment
Participants were recruited between December 2010 and May 2012. All enlisted persons of 65 and older from participating general practices and a home care organization were invited to fill in the PHQ-9 (n=9,661; Figure 3). The questionnaire was returned by 5,492 persons (56.8%), of whom 758 (13.8%) scored above the predefined cut-off score of 6 for depressive symptoms (23). A total of 463 persons (60%) were unwilling to participate and 39 individuals were excluded (Figure 3). Reasons for declining participation were: perceiving no need for care (n=88), simply not being interested (n=76), perceiving no depressive symptoms (n=69), other (n=88) and reason unknown (n=135).

A total of 263 subjects of the 758 subjects with PHQ≥6-scores (35%) were included and randomized to the four implementation times. Nine subjects were excluded from the analyses since no PHQ-scores were available. Persons already on antidepressants (n=50) were admitted to the trial. Included individuals were younger (t=3.306, df=752, p=.001) and reported more depressive symptoms (t=-3.882, df=756, p=.002) compared to those who declined participation (results from independent t-test).
Figure 3: Flow diagram of the study sample

- 9,662 Screening questionnaires sent
- 4,661 Replied (and completed PHQ)
- 758 Had a PHQ-score ≥ 6
- 495 were excluded
  - 463 refused to participate
  - 18 could not be reached
  - 9 insufficient mastery of Dutch language
  - 3 moved outside research area
- 263 were randomised

Implementation group 1 (n=81):
- 46 received intervention*
  - 35 did not receive intervention
    - 3 remission (PHQ <6)
    - 32 refused

Implementation group 2 (n=56):
- 27 received intervention*
  - 29 did not receive intervention
    - 27 remission (PHQ <6)
    - 32 refused

Implementation group 3 (n=54):
- 27 received intervention*
  - 27 did not receive intervention
    - 24 remission (PHQ <6)
    - 26 refused

Implementation group 4 (n=72):
- 37 received intervention*
  - 37 did not receive intervention
    - 21 tics-m <21
    - 26 refused

- 38 completed 2-year follow-up
  - 43 loss to follow-up
    - 3 deceased
    - 7 no use
    - 12 no time/not interested
    - 3 satisfied with other care
    - 18 other/reason unknown

- 35 completed ≥1 intervention
  - 76 analysed intention-to-treat
  - 53 analysed intention-to-treat

- 3 excluded from analyses
  - (no PHQ-scores available)

- 21 loss to follow-up
  - 1 tics-m <21
  - 4 no use
  - 9 other/reason unknown

- 23 completed ≥1 intervention

- 72 analysed intention-to-treat
Baseline characteristics

Tables 1 and 2 show the socio-demographic and clinical characteristics of subjects in the four implementation groups at baseline. Participants were mainly women, had no current depressive disorder, and severe loneliness was highly prevalent. Randomisation resulted in an unequal distribution over the different implementation times for age (F=3.37, df=(3,263), p=0.019), education (F=4.49, df=(3,257), p=0.004), urban dwelling place (χ²=25.51, df=3, p<0.001) and daily functioning (F=3.10, df=(3,243) p=0.027; results from one-way ANOVA’s and chi-squared tests).

Analysis of drop-out

Two-year follow up data were available from 121/263 (46%) participants. Independent t-tests showed that subjects lost to follow-up were older at baseline (t=-2.167, df=261, p=.031), had worse cognitive functioning (t=3.313, df=260, p=0.001), received less years of education (t=2.658, df=256, p=0.008), had more problems in daily functioning (t=-3.234, df=242, p=0.001) and were more often randomised to the first two implementation groups (χ²=11.155, df=3, p=0.011). Other baseline characteristics, such as depression severity (t=-1.194, df=261, p=0.108, were not associated with drop-out. With respect to the large drop-out in our study potentially threatening the validity of the inference about effectiveness, we countered this in applying state-of-the-art intention to treat analyses.

Table 1: Baseline demographic characteristics of the participants randomized into different implementation groups.

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
<th>Total</th>
<th>Df</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, female</td>
<td>75.3 (61)</td>
<td>71.4 (40)</td>
<td>68.5 (37)</td>
<td>66.7 (48)</td>
<td>70.7 (186)</td>
<td>3</td>
<td>0.674¹</td>
</tr>
<tr>
<td>Age</td>
<td>76.5 ± 7.0</td>
<td>76.0±6.4</td>
<td>75.3±7.4</td>
<td>73.3±5.6</td>
<td>75.3±6.7</td>
<td>262</td>
<td>0.019²</td>
</tr>
<tr>
<td>Education in years</td>
<td>9.6 ± 2.2</td>
<td>9.4 ± 2.3</td>
<td>10.8 ± 3.1</td>
<td>10.6 ± 3.1</td>
<td>10.1 ± 2.7</td>
<td>257</td>
<td>0.004²</td>
</tr>
<tr>
<td>Urban dwelling place</td>
<td>59.3 (48)</td>
<td>89.3 (50)</td>
<td>90.7 (49)</td>
<td>79.2 (57)</td>
<td>77.6 (204)</td>
<td>3</td>
<td>&lt;0.001¹</td>
</tr>
<tr>
<td>Married/cohabiting</td>
<td>37.2 (29)</td>
<td>29.6 (16)</td>
<td>34.0 (18)</td>
<td>28.2 (20)</td>
<td>32.4 (83)</td>
<td>3</td>
<td>0.522¹</td>
</tr>
<tr>
<td>Household composition, alone</td>
<td>61.5 (48)</td>
<td>72.2 (39)</td>
<td>65.4 (34)</td>
<td>71.8 (51)</td>
<td>67.5 (172)</td>
<td>3</td>
<td>0.471¹</td>
</tr>
</tbody>
</table>

¹ Chi-square test ² one-way ANOVA
Table 2: Baseline clinical characteristics of the participants randomized into different implementation groups

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
<th>Total</th>
<th>Df</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD or no (%)</td>
<td>n = 81</td>
<td>n = 56</td>
<td>n = 54</td>
<td>n = 72</td>
<td>n = 263</td>
<td></td>
</tr>
<tr>
<td>PHQ-score (symptom severity)</td>
<td>8.8 ± 6.2</td>
<td>8.6 ± 5.2</td>
<td>8.2 ± 6.7</td>
<td>9.0 ± 6.2</td>
<td>8.8 ± 6.0</td>
<td>262</td>
<td>0.672²</td>
</tr>
<tr>
<td>Major depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td>0.186¹</td>
</tr>
<tr>
<td>Current diagnosis</td>
<td>27.2 (22)</td>
<td>12.5 (7)</td>
<td>14.8 (8)</td>
<td>20.8 (15)</td>
<td>19.8 (52)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past diagnosis</td>
<td>18.5 (15)</td>
<td>17.9 (10)</td>
<td>25.9 (14)</td>
<td>27.8 (20)</td>
<td>22.4 (59)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of depressive episodes</td>
<td>9.8 ± 22.3</td>
<td>7.9 ± 7.0</td>
<td>20.6 ± 29.9</td>
<td>6.9 ± 7.9</td>
<td>10.9 ± 19.9</td>
<td>102</td>
<td>0.067²</td>
</tr>
<tr>
<td>Dysthymia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
<td>0.505¹</td>
</tr>
<tr>
<td>Current dysthymia</td>
<td>8.6 (7)</td>
<td>5.4 (3)</td>
<td>11.1 (6)</td>
<td>12.9 (9)</td>
<td>9.6 (25)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past dysthymia</td>
<td>6.2 (5)</td>
<td>3.6 (2)</td>
<td>11.1 (6)</td>
<td>8.6 (6)</td>
<td>7.3 (19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive functioning (TICS-M; range 0-50)</td>
<td>32.4 ± 5.1</td>
<td>32.9 ± 4.8</td>
<td>32.1 ± 5.6</td>
<td>33.0 ±</td>
<td>32.6 ± 5.0</td>
<td>261</td>
<td>0.732²</td>
</tr>
<tr>
<td>Number of somatic diseases</td>
<td>3.3 ± 2.0</td>
<td>3.2 ± 2.2</td>
<td>3.3 ± 2.3</td>
<td>2.9 ± 1.8</td>
<td>3.2 ± 2.1</td>
<td>250</td>
<td>0.502²</td>
</tr>
<tr>
<td>Katz ADL</td>
<td>2.6 ± 2.4</td>
<td>2.4 ± 2.3</td>
<td>2.6 ± 3.0</td>
<td>1.5 ± 2.0</td>
<td>2.3 ± 2.4</td>
<td>243</td>
<td>0.027²</td>
</tr>
<tr>
<td>Quality of Life (Cantril’s Ladder)</td>
<td>6.4 ± 1.5</td>
<td>6.3 ± 1.4</td>
<td>6.0 ± 1.4</td>
<td>6.1 ± 1.5</td>
<td>6.2 ± 1.5</td>
<td>250</td>
<td>0.392²</td>
</tr>
<tr>
<td>Loneliness (range 0-11)</td>
<td>7.3 ± 3.6</td>
<td>6.8 ± 3.6</td>
<td>7.1 ± 3.4</td>
<td>7.9 ± 3.3</td>
<td>7.3 ± 3.5</td>
<td>248</td>
<td>0.396²</td>
</tr>
<tr>
<td>Severe loneliness</td>
<td>50 (39)</td>
<td>40.4 (21)</td>
<td>43.1 (22)</td>
<td>57.4 (39)</td>
<td>48.6 (121)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

² Chi-square test ¹ one-way ANOVA

Usual care

Health care use during the control period was recorded and expressed in number of consults/days per three months since the control period differed for the implementation groups. During the control period (n=182), 26 respondents (14%) consulted a psychologist or psychiatrist (mean number of consults per three months: 2.4 [sd=3.5]). Six persons (3%) were admitted to a mental health care organization (on average 7.6 days per three months [sd=3.9]). 14 persons started on antidepressants (8%) during the control period. There was no effect of use of antidepressants in intervention and controls on outcome in additional analyses (results not shown).

Compliance

Figure 4 shows the intervention choices older persons made, taking all implementation groups together. Most persons participated in a step one intervention, mostly in the guided self-help (n=95, 69%; 47 (34%) participated in the exercise program). For the step two interventions, life review (n=24, 18%) was preferred over PST (n=17, 12%). Of all randomized subjects (n=263), 88 (33.5%) completed at least one clinical intervention (data not shown).
Outcome
The ‘Lust for life’ program had a favourable impact on depression severity: the course of depressive symptoms significantly differed after the program was implemented compared to their course before implementation (Wald=19.636, df=8, p=.012; Figure 5). Post-hoc comparisons only revealed a significant decline in severity scores in the first three months after implementation (Bonferroni p=.002), with estimated means decreasing with 1.5 points on the PHQ from 9.34 [SE=0.61] pre-implementation to 7.83 [SE=0.51] at three months after implementation.
Figure 4: Older persons’ course during the intervention programme

132 Step 1 intervention
86 Self-help course
37 Exercise programme
9 Both

5 Step 2 intervention
3 PST
2 Life Review

1 Step 1 intervention
1 Exercise programme

36 Step 2 intervention
13 PST
21 Life Review
2 Both

1 Step 3 intervention
1 Mental health care

4 Step 3 intervention
4 Mental health care

randomised
N=263

Intake session
N=166

Intervention 1
N=137

Completed intervention 1
N=76

Eligible for intervention 2
N=60*

Intervention 2
N=38

Completed intervention 2
N=18

Eligible for intervention 3
N=12**

Intervention 3
N=4

78 refused
16 remission
2 deceased
1 insufficient cognitive abilities

29 refused

41 Drop-out (40 step 1, 1 step 2)
19 Untimely switch to step 2 intervention
1 Untimely switch to step 3 intervention

34 Remission***

22 refused

16 Drop-out
2 Untimely switch to step 3 intervention

7 Remission***

8 Refused
Figure 5: The impact of the ‘Lust for Life’ program on depression severity (in three months intervals after the implementation) with 95% confidence intervals and Bonferroni p-values. Results from GEE-analyses (df=8).
CONCLUSIONS

Main findings
This study was the first implementation trial to examine the impact of a preference-led stepped-care intervention program on depressive symptoms in community-dwelling older persons compared to usual care when implemented in daily practice. Data showed that the ‘Lust for Life’ program reduced the severity of depressive symptoms during the first three months, but no further improvements were seen in subsequent months. Yet, drop-out rates were considerable, and results should be interpreted with caution.

Comparison with literature
Our results support the short-term effectiveness of our program in reducing depressive symptoms in older persons. These findings are in line with the positive findings in most similar efficacy studies on the prevention and treatment of depression in older adults (12-14,16-22). Depression scores changed with 1.51 points, which would be considered as a small effect in regular RTCs (i.e. comparable to a standardised mean difference of 0.25 (SD 6.0)). Although the effects were limited, our implementation trial was a practice-based test for the robustness of this type of approach and it proved to be effective. Further, the finding that the intervention program was effective in the first three months after implementation is interesting since similar studies have demonstrated moderate to strong effectiveness at six to twenty-four months follow-up (12,17,19-21). The aforementioned studies used samples with more severe depressive symptomology, in contrast to our sample of persons with mostly mild depressive symptoms. Also, given the implementation character of our study, we allowed for a wide measure of practice variation which could explain these diverging results. Further, an analysis of elements of our first stepped care trial showed that the first guided self-help phase was not effective (42). This first step consisted of acknowledgement of symptoms, self-management or exercise. More research is needed to figure out those elements that work best for persons with different profiles.

Our finding that stepping up to a higher intensity intervention after the initial three months provided no additional value, questions the utility of such stepped care. One single intervention of their choice, followed-up by case management in primary care, could be enough for older persons with depressive symptoms.

Outreaching recruitment of participants
Routine screening yields a great potential to lower barriers to care for individuals who are reluctant to seek help, but our study showed that it required a considerable investment in time and money to detect a relatively limited number of eligible subjects willing to accept help. Of the 758 eligible persons who returned the screening questionnaire, we were able to reach 263 eligible elderly people (35%), of whom 137 (18%) took part in our interventions. We had expected a larger overall number of participants at the start of the project, but a limited perceived need may also
very well be good news for usual care. However, mass screening does not allow for the exploration of eligible respondents’ self-perceived needs for care in a personal context. Therefore, in line with the recent update of the Canadian Task Force on Preventative Health Care guidelines (43), we question the utility of screening older adults for depressive symptoms in daily practice.

Strengths and limitations
This study has several strengths. First, the implementation of the ‘Lust for Life’ program in daily practice allowed us to determine its effectiveness in a routine care situation. Second, we examined the combined approach of stepped care and preference-led interventions, which has not been studied before in a sample of older persons with depressive symptoms. Third, since the interventions were implemented in daily practice and therefore mimicked reality, results are likely to be generalizable to the target group of older persons with depressive symptoms who will take part in such a program.

Our study also has limitations. First, interpretation of the size of effects in a stepped wedge implementation trial is less straightforward than in a conventional RCT design. Second, there are more threats to validity. The design caused a substantial waiting period and frequent measurements which many participants perceived as burdensome and may have induced drop-out, but we found no association between randomisation status (i.e. duration of waiting period) and drop-out. When the alternative is to conduct no randomized trial at all, a stepped wedge design may be useful. Third, no-show and drop-out rates were substantial, which limits the generalizability of our findings, but we performed state-of-the-art intention-to-treat analyses to counter this. At baseline dropouts were older, had lower cognitive abilities, ADL functioning and education compared to completers. Perhaps our approach is less fitting for these participants. People who refused and those who accepted the interventions were comparable in gender, dwelling place and socio-economic status.

Conclusion
In conclusion, the ‘Lust for Life’ program has a promising potential to relieve depressive symptoms of older adults in primary care in the short term. Results suggest that providing only one clinical intervention of the participants’ own choice instead of a stepped care program could also be sufficient to significantly reduce depressive symptoms in older adults.
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