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Chapter 8

Prevention of Depression in Residents in Homes for the Elderly; do effects sustain after two years?

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Submitted

Abstract:

Objectives

To evaluate the two years effects of a stepped care programme to prevent the onset of depressive disorder in elderly people living in residential homes.

Design

A pragmatic randomised controlled trial.

Setting

14 residential homes in the Netherlands participated in the study.

Participants

A total of 185 residents with a minimum score of 8 on the Center for Epidemiologic Studies Depression Scale (CES-D), who did not meet the diagnostic criteria for a depressive disorder, and were not suffering from severe cognitive impairment, were recruited between April 2007 and December 2008.

Intervention

Participants were randomised to a stepped care programme (n=93) or to usual care (n=92). Stepped care participants sequentially underwent watchful waiting, a self-help intervention, life review, and a consultation with the general practitioner.

Measurements

The primary outcome measure was the incidence of a major depressive disorder (MDD) during a period of two years, according to the Mini International Neuropsychiatric Interview (MINI).

Results

The application of a stepped care prevention programme reduced the risk of developing a depressive order in one year (Incidence Rate Ratio (IRR) 0.26; 95% confidence interval [CI] 0.12-0.80). In two years, the IRR of MDD was 0.98; 95% CI 0.54 to 1.81. In the 76 residents who completed the two-years measurements the IRR was 0.53; 95%CI ranging from 0.32 to 0.87.

Conclusion

The effect of the stepped care intervention on prevention of depression did not sustain over two years in the intention to treat analysis. However, it did sustain in the subgroup of residents who completed all measurements.

Introduction

Mental disorders like depression and anxiety are very common in the elderly population, and they are associated with excess mortality and reduced quality of life (1-4). Given the large number of people who are affected, it is unlikely that even the most resourceful health services will be able to provide adequate treatment for them all. Therefore, preventive strategies may be a more feasible way to reduce the burden for the population, and are increasingly applied (5).

Several preventive interventions studies were successful in reducing the incidence of anxiety and depressive disorders in the elderly population (6;7). However, Cuijpers (2008) indicated a decreasing effect over time of preventive interventions in a meta-analytic review. "In fact, we found that the length of the follow-up period was inversely associated with the incidence rate ratio; although not statistically significant, this relationship can be seen as an indication of effect decay over time, which could point to a delay of incidence rather than prevention" (8). In the same time, in a study in the Netherlands carried out among people of 75 years and older living in the community, the application of a stepped care prevention programme reduced the risk of developing a depressive or anxiety disorder by 57.9% (7), and effects were retained over two years (9). Preventive interventions aim to empower persons at risk in handling the factors that contribute to the risk of the incidence of mental disorders. The risk factors themselves, like chronic illnesses, disability, and older age, are not likely to disappear. One can hypothesise that preventive activities need to be maintained to ensure ongoing effects, and therefore more studies on the longer terms effects of preventive interventions are needed.

In our study in the Netherlands carried out among people living in residential homes, the application of a stepped care prevention programme reduced the risk of developing a depressive order in one year (IRR 0.26; 95% confidence interval [CI] 0.12-0.80). The intervention was not effective in reducing the incidence of the combined outcome of depression and anxiety (IRR=0.50 and a 95% CI ranging from 0.23 to 1.12), and in reducing the incidence of anxiety disorders alone (IRR 1.32; 95% CI 0.48-3.62). Because the intervention was not effective in preventing anxiety disorders we only assessed the longer term effects of the intervention on depression. We hypothesised that the effect of the stepped care intervention on reducing incident depression might not hold, and we re-assessed the effectiveness of our intervention over two years.

Methods

Design

We tested a stepped care programme in a pragmatic randomised controlled trial with two parallel groups. In brief, 14 residential homes in Amsterdam and surroundings were willing to participate in the trial. The 14 participating homes covered several areas in and surrounding the city, including both more affluent and deprived areas of Amsterdam. The randomisation of consenting residents, stratified according to residential home, took place after the baseline measurements in blocks of four with an equal allocation ratio, carried out by an independent statistician using random number tables.

The central clinical outcome in this follow-up study was the cumulative incidence of DSM-IV depressive disorder over a period of two years, as measured with the Mini International Neuropsychiatric Interview (MINI) (10). The Medical Ethics Committee of the VU University Medical Center approved the study protocol.

Participants

Interviewers visited every address, and asked the resident(s) for permission to screen for depressive symptoms with the Center for Epidemiologic Studies Depression Scale (CES-D) (11). Respondents with a minimum score of 8, i.e. above average (12), were invited for a follow-up interview in which a diagnostic and cognitive assessment took place. Respondents who met the criteria for MINI/DSM-IV depressive disorder were excluded, as were residents with evidence of substantial cognitive impairment, measured with a cut-off score of 21 for the Mini Mental State Examination (MMSE) (11;13).

Steppe- care programme

Step-up rules

After one month of watchful waiting, assessments took place in cycles of three months. Participants were invited to step up to the next level of the intervention if the level of their symptoms had not improved by at least 5 points on the CES-D. We used this definition of improvement because a 5-point change on the CES-D is both clinically relevant and statistically reliable, and has also been used in earlier studies (14-16). If at any measurement point a participant was found to have developed a DSM-IV depressive or anxiety disorder, the preventive intervention was considered to have failed, and this failure was recorded as a clinical end-point. These residents were referred to their general practitioner for possible psychological or pharmacological treatment. Participants with a decrease in symptoms of 5 points or more were not offered the next step of the stepped care programme, but were monitored for the next three months. Two years after baseline measurement a final follow up measurement took place. The stepped care programme consisted

of four steps: watchful waiting, activity-scheduling, life review and consultation with the general practitioner, and finally, a visit to the general practitioner for additional treatment.

Usual care

Residents in the usual care group had unrestricted access to any form of health care that was considered to be appropriate. Health care utilisation of the residents in the care as usual group was recorded, including the prescription of medication.

Measures

Major depressive disorder was assessed with the MINI, which is a short, structured diagnostic interview to assess DSM-IV mental disorders. Symptoms of depression were measured with the CES-D, which consists of 20 items, with total scores ranging between 0 and 60.

Sample size

Based on the results of longitudinal studies (3;17), the (original) combined incidence rate of depression and anxiety disorders together was expected to be 35% in the usual care group and 20% in the intervention group after two years. We calculated a sample size of 67 participants per group was needed for five follow-up measurements (18;19), assuming a two-sided test at an $\alpha=0.05$ and $1-\beta=0.80$. With a drop-out of 20%, at least 168 participants were needed.

Blinding

The interviewers were not informed about the randomisation status of the participants. However, in this type of intervention it is not possible to conceal randomisation status from the participants themselves.

Analysis

We first investigated possible baseline differences in demographic and clinical characteristics across the conditions (t-tests for continuous data, and Chi-square tests for categorical data). To check for possible selective attrition, we compared the prognostically relevant characteristics of dropouts and completers in the intervention group and in the usual care group. We also compared the reasons for dropout between the groups.

The main analyses were conducted on an intention-to-treat basis. This approach implies that the analyses are based on all randomised patients, and this requires the imputation of missing end-points. We replaced missing end-points by their most likely values as those obtained with the Little and Rubin EM algorithm, as implemented in SPSS (15.0). By way of a sensitivity analysis, we also used 2

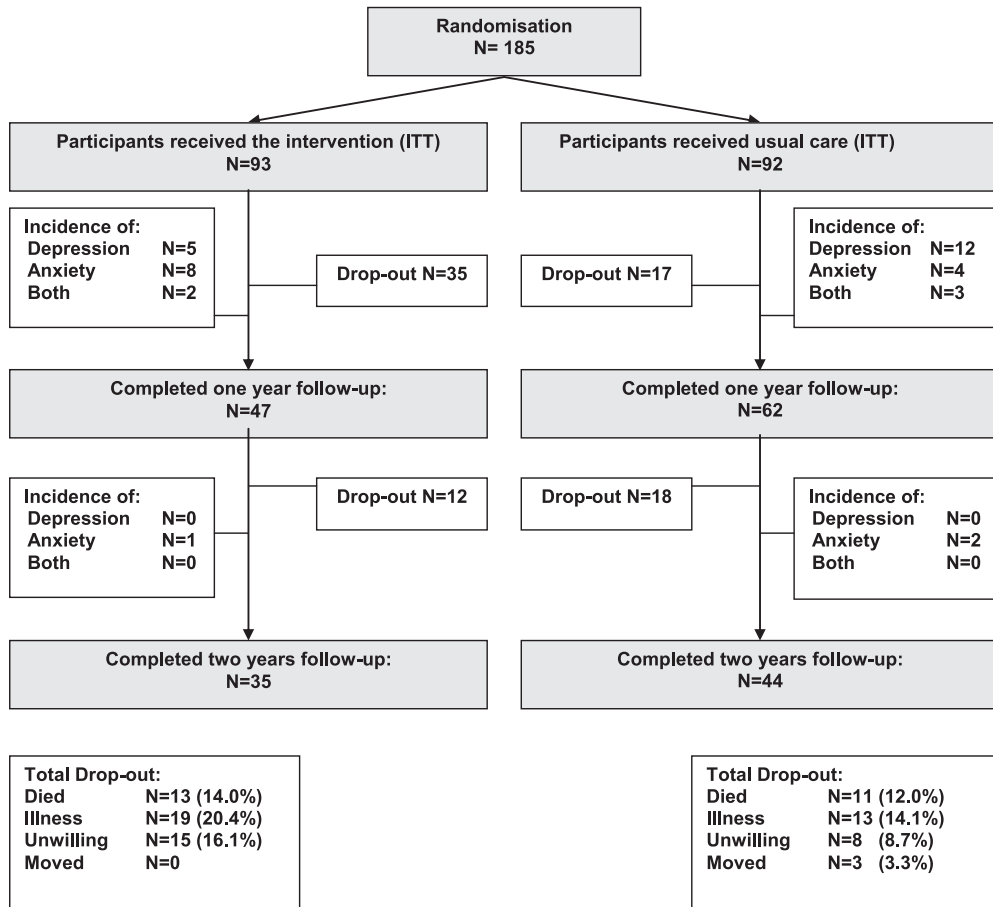


Figure 1. Flowchart of participants in the trial

other imputation strategies. First, regression imputation as implemented in SPSS 15.0, and second, multiple imputation. For this last, we used the Stata hotdeck procedure stratified for dichotomised predictors of outcome and loss to follow-up. We finally performed a “completers-only analysis”, based on the data of the participants who completed the interviews.

To estimate the extent to which the intervention reduced the risk of depressive disorder compared to usual care, we performed a Poisson regression analysis of the MINI/DSM-IV depressive cumulative incidence (1=developed a disorder and 0=remained disorder-free) on the treatment indicator (0=usual care, 1= intervention). In this way, we obtained an incidence rate ratio (IRR) which describes the difference between the incidence rate in the intervention group and in the usual care group. The superiority of the intervention would be supported if the IRR falls below 1, and would be significant at $P < 0.05$, 2-tailed.

The regression analyses were performed with Stata (version 9.1), while taking into account the clustering effect that the multi-site trial (with participants 'nested' within each of the 14 residential homes) introduced in the data. We therefore computed robust 95% CIs and test statistics by applying the first-order Taylor-series linearisation method. All regression models were specifications of the generalized linear model (GLM).

Results

Participants

Recruitment took place between April 2007 and December 2008. We randomised 185 residents to the stepped care programme (n=93) or to the usual care group (n=92) (Figure 1). Of the 185 participants, 82 (44.3 %) dropped out during the two years of the study. 27 participants developed a depressive or anxiety disorder or both, and therefore fell out of the study and were referred to their general practitioner for possible psychological or pharmacological treatment.

Baseline characteristics

The participants were mainly women (73%), with a mean age of 84.3 (SD=6.5), and most had 2 or more chronic diseases (76.3%) and poor daily functioning (51.4%). Most of the participants were living alone (83.2%), and felt lonely (70.8%). There were no significant differences between the intervention group and the usual care group at baseline, indicating that randomisation had resulted in a balanced distribution of these variables over the two groups (Table 1).

Analysis of drop-out

Dropout was associated with lower anxiety status at baseline ($t=2.69$, $df=183$, $P=0.008$), and higher MMSE score at baseline ($t=3.29$, $df=183$, $P=0.001$). No other predictors for dropout were found. In the intervention group, 13 of the 93 participants died, compared with 11 of the 92 participants in the usual care group.

Outcomes

Higher CES-D score at baseline, lower MMSE score at baseline, and the length of stay in the residential home were predictors for the incidence of a major disorder, and HADS-A and MMSE score at baseline was a predictor for drop-out. We used these significant predictors in the imputation procedures. Based on the intention-to-treat analysis with EM imputation, the incidence of depressive disorders was 15 out of 93 participants in the intervention group, and 15 out of 92 in the usual care group, resulting in an IRR of 0.98 (95% CI 0.54 to 1.81).

| Characteristics | Intervention Group (N=93) | Usual Care Group (N=92) | Total* (N=185) |
|---|---------------------------|-------------------------|----------------|
| Female gender (%) | 67 (72.0) | 68 (73.9) | 135 (73.0) |
| Age on entry in the trial (SD) | 84.5 (6.7) | 84.2 (6.4) | 84.3 (6.5) |
| Age-range | 61.8 – 100.3 | 62.1 – 94.9 | 61.8 – 100.3 |
| MMSE (SD) | 27.0 (2.1) | 27.1 (2.0) | 27.1 (2.1) |
| Married or living with a partner (%) | 18 (19.4) | 13 (14.1) | 31 (16.8) |
| Education beyond secondary school (%) | 20 (21.5) | 17 (18.5) | 37 (20.0) |
| Number of chronic diseases | | | |
| 0 (%) | 4 (4.3) | 5 (5.4) | 9 (4.9) |
| 1 (%) | 13 (14.0) | 22 (23.9) | 35 (18.9) |
| 2 (%) | 34 (36.6) | 29 (31.5) | 63 (34.1) |
| >2(%) | 42 (45.2) | 36 (39.1) | 78 (42.2) |
| CES-D score (SD) | 14.9 (5.7) | 14.4 (5.3) | 14.7 (5.5) |
| HADS-A score (SD) | 3.6 (2.8) | 3.2 (2.6) | 3.4 (2.7) |
| Loneliness score (SD) | 3.4 (0.9) | 3.4 (0.8) | 3.4 (0.8) |
| Loneliness categorical (%) | | | |
| Not lonely | 29 (31.2) | 33(35.9) | 62(33.5) |
| Lonely | 64 (68.8) | 59(64.1) | 123(66.5) |
| ADL score (SD) | 35.1 (5.7) | 34.4 (6.3) | 34.7 (6.0) |
| Major difficulties ADL (%) | 50 (53.8) | 45 (48.9) | 95 (51.4) |
| Suffering from feelings of depression/anxiety in the past (%) | 48 (51.6) | 53 (57.6) | 101 (54.6) |
| Length of stay in residential home | | | |
| <1 year (%) | 29 (31.2) | 24 (26.1) | 53 (28.6) |
| >1 year (%) | 54 (58.1) | 64 (69.6) | 118 (63.8) |
| >10 years (%) | 10 (10.8) | 4 (4.3) | 14 (7.6) |
| Hearing | | | |
| no problems | 51 (54.8) | 52 (56.5) | 103 (55.7) |
| serious problems | 43 (46.2) | 40 (43.5) | 82 (44.3) |
| Vision | | | |
| no problems | 47 (50.5) | 55 (59.8) | 102 (55.1) |
| serious problems | 46 (49.5) | 37 (40.2) | 83 (44.9) |

* There are no significant differences between groups (t-test/Chi-square test)

Table 1. Baseline demographic and clinical characteristics of the participants

Sensitivity analyses

To assess the robustness of the outcomes, we performed several sensitivity analyses, and first repeated the intention-to-treat analysis, basing it this time on regression imputation. The two-year incidence of depressive disorders then was 14 out of 93 participants in the intervention group, and 17 out of 92 in the usual care group, resulting in an IRR of 0.82 (95%CI 0.48 to 1.39). Finally, we repeated this analysis based on multiple imputations, which resulted in a similar IRR of 0.82 (95% CI 0.36 to 1.88). In a completers' analyses, however, no new cases of depression occurred in all the residents who completed the study. The incidence therefore remained the same after two years (5 out of 35 participants in the intervention group, and 12 out of 44 in the usual care group). This indicates that the results after one year did hold for the subgroup of 76 residents who completed all measurements (IRR 0.53 and a 95%CI ranging from 0.32 to 0.87 [SE=0.13 z= -2.51 P= 0.012]).

Discussion

We hypothesised that the effect of the stepped care programme on depression, based on monitoring and evidence-based interventions, after one year would not sustain after two years. The effects of the stepped care programme did, indeed, not hold in the follow-up year. Only in the "completers-only analysis", the effects remained equal to the effects in the first year. The sustained effects after two years in a similar study in a very old population the community (9) could not be confirmed.

A limitation to the study concerns the high dropout rates. Dropout of the study after two years is $n = 82$ (44.3%), which is very high, but can be expected in this very old and vulnerable population. Although the preventive effect of the intervention after one year on depression is encouraging, the two years results show that only a selected group of residents is able to benefit from the intervention on a longer term. The intention to treat analyses showed that the incidence of depression increased in the second follow up year, when no preventive activities were offered. Residents that dropped out in the second follow up year of the study are likely the residents at highest risk for developing a disorder, because of their vulnerable health status, and might have benefited when interventions would have been offered. Therefore, monitoring of symptoms and offering interventions should be ongoing in this high risk population.

Another limitation of the study concerns the sample size calculation. This was based on the combined outcome of depression and anxiety. In our study on the effects after one year, we found a significant effect only on incidence of depression. We therefore measured the follow-up effect of depression only. However, because the incidence rate of depression was lower than we had anticipated beforehand (16% vs.35%), resulting in a lack of power of our study, some caution is needed

with regard to our conclusions. Nevertheless, the point-estimate of the effect size confirms the disappearance of the effect after two years.

Strengths of the study include the fact that the study design was a pragmatic trial, with very few a priori exclusion criteria, which enhances generalisation to usual care in residential homes in the Netherlands. Other strong features include the use of structured psychiatric diagnoses to independently measure outcome and the use of a stepped care format, including evidence-based interventions. Finally, a two year period of follow up is a strength in itself, because it offers rare information on the sustained effects of a preventive intervention.

The considerable burden of common mental disorders on residents in homes for the elderly, in combination with a lack of resources for treatment, combine to make prevention an interesting option for health promotion in this setting. To our knowledge, this is the first study that evaluates the effects of a stepped care preventive programme in a residential home setting over two years. Although our programme prevented depression in the first year, effects did not hold. The frailty of the population might be the cause of a limit to longer term effects.

Participation in a preventive intervention is optional, and people in high risk groups may not acknowledge the urge to participate and modify their behaviour. This may result in some amount of self-selection of the most healthy residents in the population in which the positive effects of the intervention are sustained.

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