

# Chapter 4

**How effective is bibliotherapy for very old adults  
with subthreshold depression? Randomized  
controlled trial**

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## ABSTRACT

**Objectives:** Depressive symptoms are common among elderly primary care patients, and because they encounter considerable barriers in seeking help and they often resist referral to specialized mental health facilities, it is important to look for easily accessible interventions within the primary care setting. Bibliotherapy, which has been found to be effective among younger populations, might be an attractive option. In this study, the authors investigated the effectiveness of bibliotherapy for depressive symptomatology in very old adults.

**Design:** Randomized controlled trial. After a 3-month period of “watchful waiting,” the participants were randomly assigned to a bibliotherapy group or a usual care group.

**Setting:** Thirty-three general practices in the north-western region of the Netherlands.

**Participants:** One hundred seventy community-dwelling adults, aged 75 and older, with subthreshold depression. **Intervention:** The bibliotherapy intervention consisted of an information leaflet and a self-help manual “Coping with Depression” adapted for the elderly.

**Measurements:** Outcome measures after 3 months were a) change in depressive symptoms according to the Center for Epidemiologic Studies Depression Scale (CES-D) and b) the proportion of participants who scored a significant improvement on the CES-D.

**Results:** One hundred forty-six (85.9%) of the 170 participants completed the baseline and follow-up measurements. The authors did not find any clinically relevant and statistically significant differences between the intervention group and the control group in the severity of the depressive symptoms.

**Conclusion:** Bibliotherapy as a stand-alone intervention for the elderly (aged 75 years and older) did not reduce depressive symptoms more than usual care. This might indicate that bibliotherapy can only be effective for patients who are motivated and acknowledge their depression.

## INTRODUCTION

Depression is a common health problem among elderly people, often with a poor prognosis.<sup>1</sup> Estimates of the prevalence of depression among elderly people living in the community vary from <1% to 35%.<sup>2</sup> Subthreshold symptoms of depression are common in this population,<sup>3-5</sup> and almost one third of the elderly people living in the community with subthreshold depression will develop a full-blown depressive disorder within 3 years.<sup>6</sup>

A literature review reported that only 10% of depressed older adults receive adequate treatment,<sup>7</sup> and resistance to treatment and denial of the disease were two of the most important reasons.<sup>8</sup> The burden of depression, the considerable barriers patients experience in seeking help, and the high costs for society are important reasons why we should look for low cost, easily accessible interventions for the treatment of patients with subthreshold depression. Interventions promoting empowerment may be an attractive option. These interventions are aimed at enhancing patients' learning potentials and encouraging them to take more control over events and important situations in their lives. Bibliotherapy is a guided self-help intervention, which can address these needs and can also lead to patient empowerment. Guided self-help can be defined as psychological treatment; the patients or clients take home a standardized psychological self-help manual and work through it more or less independently.<sup>9</sup> They make use of step-by-step instructions on how to apply this generally accepted psychological treatment to themselves. The standardized psychological treatment can either be described in book form or made available through the Internet. A professional therapist or coach helps the patient to work through the course materials. This help should only be of a supportive or facilitative nature, because the contact is not aimed at developing a traditional relationship between the therapist and the patient. Interaction between the patient and the therapist can take place through face-to-face contact, telephone, e-mail, or any other method of communication.

A number of meta-analyses of the effectiveness of self-help have been conducted for various target problems, ranging from minor problems to potentially clinical disorders. In a systematic review of meta-analyses on the efficacy of self-help interventions for depression and anxiety disorders, it was found that self-help methods were effective for a range of different disorders. Most of the 13 meta-analyses that were included reported relatively large effect sizes, independent of the type of self-help, compared with control conditions. These were comparable with the effect sizes reported for face-to-face interventions.<sup>11</sup> In a recent meta-analysis, Gellatly et al. investigated the factors that moderate the effect of self-help interventions for depression.<sup>12</sup> The mean effect size was "large" (0.80).

This meta-analysis had a broader perspective than previous studies. Interventions that provided simple educational booklets and more complex self-help technologies were included. A wider variety of patients was also included (patients with depression, depressive symptoms, stress, and patients “at risk”). The fact that the self-help was guided was the only significant moderator of the treatment effect; there was no clear relationship with the background of the therapist, the content of the guidance, the mode of guidance (monitoring/supportive), or the number of sessions.

Bibliotherapy also seems to be effective in the treatment of older people with mild to moderate depression and may or may not prevent the onset of major depressive disorders. In their systematic review, McKendree et al. described three randomized controlled trials that evaluated bibliotherapy for depression in older adults, all of which found bibliotherapy to be more effective than either waiting list or placebo control conditions.<sup>13-16</sup> However, all the studies had very small sample sizes. These results support the further development and testing of bibliotherapy-based interventions.

The effectiveness of bibliotherapy in primary care has seldom been investigated. Most studies, and especially those among older adults, recruited their participants from the general public. We conducted a randomized controlled trial among general practice patients who were aged 75 years and older to evaluate the effectiveness of bibliotherapy. In this article, we address the following research question: to what extent does a bibliotherapy intervention influence the course of subthreshold symptoms of depression in older adults? We hypothesized that depressive symptoms would decrease more in older adults receiving a cognitive behavior therapy-based bibliotherapy intervention than in older adults in a usual care group.

The intervention was part of a stepped-care prevention program that halved the incidence of major depressive and anxiety disorders in the elderly.<sup>17</sup> In the stepped-care intervention, which consisted of four steps (watchful waiting, cognitive behavior therapy-based bibliotherapy, brief cognitive behavior therapy-based problem solving treatment, and referral to primary care), 11.6% developed a major disorder, compared with 23.8% in the usual care group. It is not yet clear which part of the intervention contributed most to the effectiveness of the stepped-care program. In this study, we evaluated the contribution of cognitive behavior therapy-based bibliotherapy in reducing depressive symptoms in the elderly.

## METHODS

### Design

We conducted a randomized controlled trial. After a period of watchful waiting and baseline assessment, the participants were randomized to one of two groups. The intervention group received usual care plus a cognitive behavior therapy-based bibliotherapy intervention, and the control group received usual care only. The participants were randomized with equal probability to the intervention or to usual care in blocks of four by an independent statistician, based random-number tables. The main outcome measure was a decrease in depressive symptoms, measured with the Center for Epidemiologic Studies Depression Scale (CES-D). The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

### Participants

Community-dwelling elderly people, aged 75 years and older, with subthreshold depression, able to give informed consent, and with sufficient knowledge of the Dutch language, were eligible for participation. Eligible subjects were recruited from the study sample of a larger project for frail elderly people, the "PIKO project," in which this study was embedded.<sup>18</sup> Patients in the PIKO database were recruited in general practice. The general practitioners in 33 general practices provided the names and addresses of all registered patients who were aged 75 years or older and living at home. These patients received a health survey questionnaire, including the CES-D. Patients were considered to have subthreshold depression and/or anxiety if they had a score above the cutoff of 16 on the CES-D for two subsequent measurements, which were at least 3 months apart but did not meet Diagnostic and Statistical Manual of Mental Disorders-IV criteria for major depression and/or clinical anxiety, as assessed with the Mini-International Neuropsychiatric Interview.<sup>19</sup> A CES-D score of 16 is widely accepted as an indication for clinically relevant symptoms of depression.<sup>20</sup> Patients with serious cognitive decline according to the "self-rated" Informant Questionnaire on Cognitive Decline in the Elderly<sup>21</sup> were excluded. Patients who met all the inclusion criteria were invited to participate in our study.

### Intervention

After randomization, the participants in the intervention group received a cognitive behavior therapy based bibliotherapy intervention, which consisted of an information leaflet the "Coping with Depression" (CWD) self-help manual. The CWD course includes instructions on cognitive behavior self-help with mood management skills and exercises, and it has been found to be effective in reducing depressive symptoms in

several randomized clinical trials, in group, individual and minimal-contact format.<sup>22</sup> For our study, the CWD manual was adapted for individual use in a sample of patients who were aged 75 years and older. The intervention protocol was developed in collaboration with the Netherlands Institute for Mental Health and Addiction. Participants in the intervention group were visited for a maximum of 1 hour by a specially trained home care nurse three times during a period of 12 weeks. During the first visit, the nurse gave the participant a leaflet containing information and tips on how to deal with subthreshold depression.

The aims of this first visit were a) to assess the type and level of severity of the symptoms, b) to reflect on emotional symptoms through an initial brief nondirectional investigation and discussion of everyday problems, which also helps to establish a working relationship, and c) to educate the participants about their symptoms. During the second visit from the nurse, 1 or 2 weeks later, the leaflet was briefly discussed, and the CWD self-help manual was given to the participants. They were stimulated to follow the course in their own tempo. During the last visit, 8 or 9 weeks after the first visit, the CWD course was evaluated with the participant. On average, a nurse visited the participants three times and telephoned them twice during the intervention period to discuss their progress, answer questions, and encourage them to continue with the course. However, the participants were free to decide whether they would read the information and do the exercises described in the manual.

#### **Usual care**

Participants in both groups had unrestricted access to usual care for their depression or anxiety symptoms. Their use of healthcare services and prescribed medications was recorded.

#### **Measures**

The primary outcome measure was the CES-D scale. This instrument was designed for screening and monitoring depression and consists of 20 items with a score ranging between 0 and 60. Higher scores indicate greater psychological distress, and scores of 16 and above indicate the presence of clinically significant depression.<sup>23</sup> The CES-D has been widely used in older community samples<sup>20</sup> and has good psychometric properties in elderly samples.<sup>24-26</sup> The Dutch translation had similar psychometric properties in three previously studied samples of elderly in the Netherlands.<sup>27</sup> The CES-D score was measured at baseline after the period of watchful waiting (pretest) and 3 months after baseline (posttest). Bibliotherapy was part of a stepped-care program, but all the other steps in the program were offered after the posttest measurement.

**Effectiveness**

To evaluate the effectiveness of bibliotherapy, the CES-D scores shortly before the initiation of the intervention (and at least 3 months after the assessment during the large scale data acquisition) were compared with the CES-D scores after the bibliotherapy. We analyzed the effectiveness of bibliotherapy compared with usual care in two ways. First, we compared the mean changes in CES-D scores in the bibliotherapy group and the usual care group. Second, the effectiveness of bibliotherapy was analyzed by using the CES-D as a dichotomized outcome. We compared the two groups with respect to the proportion of participants with a significant (relevant) improvement in depressive symptoms. A significant change had to be statistically and clinically relevant. The criterion we used for a statistically reliable change was the Jacobson & Truax Reliable Change Index. A change of 3.5 points in the CES-D score corresponds with the threshold for statistically reliable change,<sup>28</sup> and to be clinically relevant, a minimum change of 5 CES-D points would qualify as a medium to large effect size.<sup>29</sup> Therefore, significant improvement occurred if there was a decrease of 5 CES-D points or more between the pretest and posttest measurements. This value has also been used in earlier studies.<sup>6, 30-33</sup> Moreover, because a score of <16 on the CES-D is generally regarded to be clinically meaningful, we also calculated the number of participants with a change of 5 points or more in their score, exceeding the cutoff of 16 ("recovered").

Demographic data were also collected, including age, gender, living situation, and level of education. The presence of chronic diseases was measured with a self-report questionnaire, which included the following categories: 1) chronic nonspecific lung disease, 2) cardiac disease, 3) peripheral arterial disease, 4) diabetes mellitus, 5) cerebrovasculair accident or stroke, 6) osteoarthritis, 7) rheumatoid arthritis, and 8) cancer. These specific chronic diseases were derived from the Statistics of the Netherlands chronic disease questionnaire,<sup>34</sup> and the selection was based on high prevalence and severe functional consequences.<sup>35</sup> The participants were also asked whether they had any other chronic diseases. Adherence to the intervention program was measured 3 months after baseline by asking the participants whether they had read the leaflet and the manual (answer categories were "no," "partly," and "yes").

**Statistical analyses**

We investigated baseline similarity in the demographic and clinical characteristics and compared the baseline characteristics of dropouts and those who completed the posttest measurement by performing logistic regression analysis. The effectiveness of bibliotherapy, with the CES-D score as a continuous outcome, was analyzed with analysis of covariance.

Besides, the effectiveness was analyzed in terms of significant improvement. In this analysis, the differences in the rate of improvement between the bibliotherapy group and the usual care group were calculated with binary logistic regression and expressed as odds ratios (ORs) and their 95% confidence intervals (CIs).

With post-hoc analyses, we investigated the possible interaction effects of the intervention with demographic (age, gender, chronic diseases, and level of education) and clinical characteristics (baseline CESD). The interaction with baseline CES-D was investigated to determine whether patients with more severe depressive symptoms at baseline would benefit (more) from bibliotherapy. Patients with CES-D scores of 27 or more were considered to suffer from severe depression.<sup>36, 37</sup>

All analyses were performed according to the “intention-to-treat” principle, which means that all participants were analyzed in the group to which they were randomized. The missing values of the dropouts were handled by multiple imputation procedure (Statistical Analysis System [SAS]). Baseline demographics, treatment allocation, and data on baseline severity of the respondents and the nonrespondents were used in a regression imputation to generate 10 different datasets, with values imputed for missing posttest CES-D scores. As a result, posttest scores were based on the particular characteristics as defined by baseline characteristics (e.g., gender, age, and CESD score) and treatment allocation. The effectiveness analyses were then performed on each of the 10 resulting datasets, using analysis of covariance for the analysis with the CES-D score as a continuous outcome and logistic regression for the analysis of significant improvement. For both analyses, the multiple imputation analysis procedure was used to combine datasets into a single overall estimate with 95% CI. We also performed a per protocol analysis, comparing the outcomes of “adherers” to the intervention protocol (those who studied all the self-help materials) with the usual care group. All analyses were performed with the SPSS (version 15.0) and SAS (version 9.2) statistical packages. Statistical significance was considered as two-tailed  $p < 0.05$ .

## RESULTS

### Study sample

To evaluate the effects of the intervention versus usual care, 325 eligible elderly people were invited to participate, 170 of whom met all the inclusion criteria and gave informed consent. They were randomized to the bibliotherapy group ( $n = 86$ ) or the usual care group ( $n = 84$ ) (Figure 1).

### Baseline characteristics

The baseline characteristics are presented in Table 1. There were no significant differences in these variables between the two groups. Of the 170 participants, 24 (14.1%) dropped out during the intervention period (Figure 1). The proportion of dropouts in the intervention group (18/86) was significantly higher than in the usual care group (6/84) (OR = 3.44, 95% CI: 1.29 to 9.16, Wald  $\chi^2 = 6.12$  with 1 df,  $p = 0.013$ ). The mean CES-D scores at baseline were 21.5 and 22.5 for completers and dropouts, respectively, indicating no significant difference. Older participants (OR = 1.14, 95% CI 1.02 to 1.27, Wald  $\chi^2 = 5.57$  with 1 df,  $p = 0.018$ ) and those who were not living independently (OR = 142.86, 95% CI 0.001 to 0.058, Wald  $\chi^2 = 21.11$  with 1 df,  $p = 0.000$ ) were more likely to drop out than other participants. No other differences in baseline characteristics were found between completers and dropouts.

### Healthcare utilization

To take into account the possible influences of mental health service utilization on the outcome measures, participants were asked at baseline about their use of healthcare services during the 2-month period before baseline. During these 2 months, 71% (60/84) of the bibliotherapy group and 65% (55/84) of the usual care group had visited a general practitioner. In each group, two participants had contacted a mental healthcare specialist. None of the differences in healthcare utilization between the two groups were statistically significant.

Table 1: Baseline characteristics of the participants

	Bibliotherapy n = 86		Usual Care N = 84	
Age, mean (SD)	81.8	(3.8)	81.1	(3.5)
Female, N (%)	60	(69.8)	65	(77.4)
Living independently	76	(88.4)	81	(96.4)
Level of education, N (%)				
Lower <sup>1</sup>	60	(71.4)	62	(73.8)
Higher <sup>2</sup>	24	(28.6)	22	(26.2)
Married/cohabiting, N (%)	26	(30.2)	24	(28.6)
CES-D, mean (SD)	21.17	(4.95)	22.05	(5.24)
HADS-A, mean (SD)	5.57	(3.33)	6.05	(3.39)
Number of chronic diseases, mean (SD)	2.39	(1.52)	2.77	(1.48)

Abbreviations: HADS-A, Hospital Anxiety and Depression Scale- Anxiety subscale; CES-D, Center of Epidemiological Depression Scale

<sup>1</sup> no education, elementary and lower vocational level

<sup>2</sup> secondary, higher vocational level and university) education.

### Adherence to the intervention

Of the participants in the intervention group, 41% (35/86) had read the information leaflet and the CWD self-help manual. According to the nurses who contacted the participants during the intervention, the participants understood the materials correctly. Seven people (8.1%) dropped out immediately. The other participants did not use the course materials or completed half of the course ( $n = 44$ ; 51%). “Younger” participants and participants with more chronic diseases adhered more closely to the intervention program. No other baseline differences were found between the adherers and nonadherers.

### Effectiveness

With  $n' = 2 \times (68 \times 78) / (68 + 78) = 72$  persons per group and a one-sided test with  $\alpha = 0.05$ , we derived a power of 91% to demonstrate a moderate effect size of  $d = 0.5$ .

### Change in CES-D score

There was no significant difference in posttest CES-D score after correction for baseline scores between the bibliotherapy group and the usual care group (Table 2). The per protocol analysis, comparing only the participants who fully completed the bibliotherapy course ( $n = 35$ ) with the control group ( $n = 84$ ), revealed no other effects ( $F = 1.91$ ,  $df = 1; 372$ ,  $p = 0.168$ ). However, the decrease in CES-D score was highest for those who had fully completed the course. Their CES-D scores decreased on average with 6.38 points between the pre and posttest measurements.

Table 2: ANCOVA for bibliotherapy effects with the pre-test CES-D score as covariate

	Bibliotherapy $n=86$	Usual Care $n=84$		
CES-D pre-test, M (SD)	21.17 (4.95)	22.05 (5.24)		
CES-D post-test, M (SD)	16.60 (6.41)	17.27 (6.53)	$F_{(1,121)} = 0.12$	$p=0.734$

Abbreviations: CES-D, Center for Epidemiologic Studies Depression Scale; ANCOVA, analysis of covariance

### Significant improvement

There was no difference in significant improvement (decrease of 5 CES-D points or more) between the bibliotherapy group and the usual care group (OR = 0.86, 95% CI 0.447 to 1.657,  $t$  for beta 0 =  $-0.38$  with 81 adjusted  $df$ ,  $p = 0.704$ ). In the bibliotherapy group, 47% improved significantly, compared with 44% in the usual care group (Table 3). We also analyzed differences between the two groups in the number of participants with a change of 5 points or more, thereby exceeding the cutoff of 16 (“recovered”) (Table 3). This revealed no other effects.

The per protocol analysis (n = 119) also showed no significant effects (OR = 0.73, 95% CI 0.325 to 1.650, t for beta 0 = -0.75 with 107 adjusted *df*, p = 0.458).

**Table 3:** Participants with significant improvement, recovery and no change or deterioration in the bibliotherapy group and the usual care group

	Bibliotherapy n = 86		Usual Care n = 84	
Significant improvement <sup>1</sup> , N (%)	40	(46.9)	37	(43.6)
Significant improvement and recovery <sup>2</sup> , N (%)	31	(36.4)	25	(30.0)
No change/ deterioration, N (%)	46	(53.1)	47	(56.4)

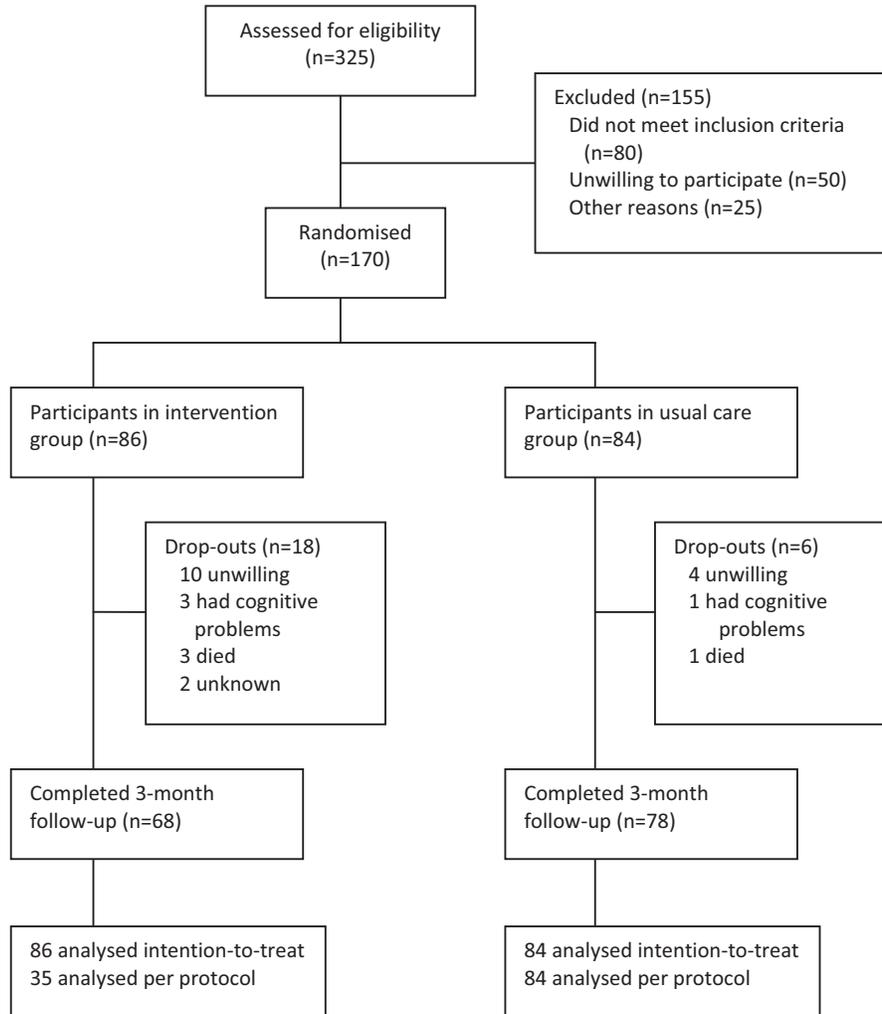
<sup>1</sup>decrease of 5 CES-D points or more

<sup>2</sup>decrease of 5 CES-D points or more and a post-test score below the cut-off of 16

### Post-hoc analyses

With post-hoc analyses, we investigated whether subgroups with specific demographic characteristics (age, gender, chronic diseases, and level of education) and clinical characteristics (severity baseline CES-D, cutoff point 27) would benefit (more) from bibliotherapy. We looked for interaction effects in the effectiveness analysis with CES-D as continuous outcome and in the analysis of significant improvement. No interaction effects were found.

Figure 1: Flow chart of drop-outs



## DISCUSSION

We could not demonstrate any clinically or statistically significant short-term effects of bibliotherapy, compared with usual care, on symptoms of depression in 170 very old adults with subthreshold depression. Previous research has shown that bibliotherapy can be effective for depression. As described in the Introduction section, several reviews and meta-analysis have been carried out in this respect, and in general, guided self-help was found to be more effective than no treatment, with mean effect sizes that ranged from 0.53 to 1.36.<sup>10, 38-42</sup> Our results are not in line with these positive findings, but there are several possible reasons for this discrepancy.

1. Case-mix differences: Most other trials have recruited patients who were seeking help for their depressive symptoms, and patients with depression were recruited by means of announcements in the media. However, the participants in our study were actively invited after screening with the CES-D in general practices and did not seek help themselves. Although they had a CES-D score of 16 or higher, many patients did not feel the need for treatment of their (mild) symptoms. Moreover, the acknowledgment of depression by the participants in our study was most likely lower than that reported in previous studies, which can also be a reason why not all participants used the course materials. Our participants were probably less motivated for bibliotherapy than the participants in other trials.
2. Adherence status: Participants who fully completed the course had a greater decrease in their CES-D scores. Although the difference, compared with the usual care group, was still not significant, it may indicate that completing the entire course enhances the effects of bibliotherapy.
3. Older age: Previous studies, in which bibliotherapy was found to be effective for older adults, had a “younger” adult population (aged 60 years and older). The aim of minimal contact interventions, such as bibliotherapy, is to empower high-risk groups to be able to solve their own problems. However, this requires certain capabilities. It is possible that not all age groups have the necessary skills for such an approach and will therefore not achieve the intended effects. Perhaps, the patients in our very old target group do not respond well to bibliotherapy in this form and need more guidance from a therapist.
4. Intensity of the guidance: Previous research has shown that self-help without guidance is not effective.<sup>12, 43</sup> The number of visits and telephone calls the nurses made in our intervention might have been inadequate, and the support provided during these contacts was perhaps not focused enough to achieve significant effects.

5. The follow-up period: This might have been too short to achieve significant effects, but the bibliotherapy may have added to the overall effect. This is possible but not very likely.
6. Publication bias: These meta-analyses may have included only studies in which relevant and significant effects were found. When sample sizes are small, which was the case for all the included studies, the chance that a study is published increases with the effect size. This can result in an overestimation of the mean effect size. The differences in depression reduction did not differ significantly between the bibliotherapy and usual care group, but the elderly in both groups improved by a considerable 5 points. A possible clarification for this improvement could be the extra attention all participants got from the interviewers who visited them to derive the measurements. Even though these interviews contained mainly structured questionnaires, the participants could have experienced the regular visits of the interviewers as supporting. Another possibility is that the improvement in both groups can be attributed to the phenomenon regression to the mean, because we only included persons with an increased CES-D score. At last, the improvement in both groups could have been attributed to spontaneous recovery.

Although we could not demonstrate that bibliotherapy was more effective in lowering symptoms than usual care, the results of our trial make a valuable contribution to the existing literature. This was the first study with a large sample size to investigate the effectiveness of bibliotherapy among very old adults. The age of our sample was also much higher than that in other trials among older adults. Moreover, we recruited in general practice patients who had subthreshold depression but did not seek help themselves.

Our study also has some limitations. Because of the stepped-care design, we were only able to study short-term effects. Another limitation is the higher drop-out rate in the intervention group. It is possible that participants dropped out because they felt better and were, therefore, not motivated to continue with the course. This introduces the possibility that those who dropped out would have shown the most improvement at the posttest measurement.

In conclusion, the hypothesis that bibliotherapy as a stand-alone intervention is more effective in lowering symptoms than usual care in a very old sample with subthreshold depression cannot be confirmed on the basis of the results of this trial. This negative outcome might indicate that bibliotherapy is only effective if patients are motivated and acknowledge their depression.

The bibliotherapy intervention in our study was part of a generic stepped-care program, and the participants had agreed to participate in a stepped-care program that included various interventions. They probably did not realize that they had to invest their time and play an active role in the treatment by reading the self-help manual and completing assignments. The stepped-care intervention, as a whole, reduced the risk of onset of depressive and anxiety disorders, and the 12-month incidence was halved, compared with usual care.<sup>17</sup> Our results question the relevance of bibliotherapy as a separate step in the program. However, bibliotherapy as an early, initial step in a stepped care intervention program has several advantages. A self-help course may lower the threshold for those who do not want or dare to ask for any kind of therapy. Moreover, it may contribute to the effectiveness of the subsequent steps (if necessary) by preparing and motivating the client for therapeutic treatment. Individual empowerment, which is one of the aims of bibliotherapy, contributes to the development of problem-solving skills and increases self-esteem and self-efficacy.

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