

# Improving Patients' Beliefs About Antidepressants in Primary Care: A Cluster-Randomized Controlled Trial of the Effect of a Depression Care Program

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**Objective:** Many depressed patients have negative beliefs about antidepressants, leading to poor adherence, unfavorable depression outcome, and low perceived well-being, role functioning, and quality of life. Interventions to ameliorate beliefs are therefore needed.

**Method:** In a cluster-randomized controlled trial conducted from September 1999 to January 2001, 2 interventions to improve management of major depressive disorder in primary care were compared: (1) a depression care program (DCP), providing enhanced patient education, stimulation of active participation of general practitioners and patients in the treatment process, discussion of benefits and costs of taking antidepressant medication, and systematic follow-up and (2) a systematic follow-up program (SFP). Thirty general practitioners were randomly assigned, and 211 patients with current major depressive disorder (diagnosed according to DSM-IV) were included. All patients were prescribed a selective serotonin reuptake inhibitor. Beliefs were assessed at baseline, at week 10, and at week 26. Differences in change of beliefs between DCP and SFP groups were analyzed.

**Results:** Changes in patients' beliefs were more favorable in the DCP condition at week 10 and week 26, compared with SFP only (beliefs concerning appropriate medication-taking, week 10: effect size = 0.39,  $p = .012$ ; week 26: effect size = 0.55,  $p = .001$ ; beliefs concerning harmfulness, week 10: effect size = 0.45,  $p = .011$ ; week 26: effect size = 0.62,  $p = .002$ ).

**Conclusion:** The depression care program ameliorates beliefs about antidepressants in primary care patients with major depressive disorder. The study results encourage the implementation of a depression care program in order to improve beliefs about antidepressant medication in primary care patients diagnosed with major depressive disorder.

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Major depressive disorder is associated with severe personal suffering for the affected patients, great distress for their family, and major societal costs.<sup>1,2</sup> Antidepressant medication reduces depressive symptoms,<sup>3,4</sup> but negative beliefs about antidepressant medication may lead to poor adherence<sup>5,6</sup> and a consequently increased risk for chronicity<sup>7</sup> and relapse.<sup>8</sup> In addition, negative beliefs may result in low perceived well-being, role functioning, and quality of life.<sup>5,9</sup> Because negative beliefs in depressed patients are widespread,<sup>10,11</sup> interventions for reducing these beliefs are needed.

In community studies, Paykel et al.<sup>12</sup> demonstrated positive attitude changes through public education activities including leaflets, fact sheets, audio cassettes, books, newspaper and magazine articles, television and radio interviews, press conferences, and “action weeks,” and Jorm et al.<sup>13</sup> demonstrated positive results of mailing of an evidence-based consumer guide to treatment of depression, whereas Hegerl et al.<sup>14</sup> found no effects of a campaign informing the public about causes and treatment of depression using leaflets and brochures, cinema spots, posters, information events, and contests.

In depressed patients who were treated with antidepressants, coaching by community pharmacists during 3 coaching contacts, in combination with a take-home video educating patients on antidepressant medication, suggested a positive effect on beliefs about antidepressants.<sup>15</sup> Another randomized controlled trial in primary care patients at high risk for recurrent depression demonstrated positive effects of a collaborative care relapse prevention program

(including cognitive-behavioral and motivational interviewing approaches, information on depression and treatment of depression, and assistance to patients in clarifying the perceived benefits and potential risks of long-term pharmacotherapy), as compared with usual care.<sup>16</sup>

In the present primary care study, we investigated whether beliefs about antidepressant medication improve through a depression care program in which no other health care workers but general practitioners were involved.

## METHOD

Data were obtained from a cluster-randomized controlled trial performed in 30 primary care practices in the Netherlands that included patients diagnosed with major depressive disorder according to DSM-IV. The design and primary results of this study, which was conducted from September 1999 to January 2001, have been reported elsewhere.<sup>17</sup> Subjects gave written informed consent prior to participation, and the study was approved by the Medical Ethics Committee, STEGMETC, in the Netherlands. In brief, general practitioners were randomly assigned to either a depression care program (DCP) or a systematic follow-up program (SFP). In DCP, patients received a newsletter prior to every scheduled visit. These letters educated patients on depression and antidepressant medication. The effectiveness and side effects of antidepressant medication and the importance of continuing treatment for at least 6 months were addressed. The social stigma of depressive patients and the false belief that depression is a sign of weakness were challenged. The importance of social support was addressed. Patients were asked to complete the following homework assignments: (1) to fill out a questionnaire addressing the perceived costs and benefits of treatment with antidepressant medication, (2) to plan activities, and (3) to discuss their illness and treatment with significant others to enhance social support. These 2 latter components were built in to enhance self-management of patients.<sup>16</sup> The general practitioners were asked to help patients clarify the potential benefits of taking antidepressant medication and to challenge perceived costs of taking antidepressant medication. In DCP as well as SFP, 7 follow-up visits in 26 weeks were scheduled. During the visits, adherence to antidepressant medication and severity of psychopathology were assessed. The ingredients of both interventions are depicted in Table 1. The general practitioners were allowed to prescribe any of the 5 selective serotonin reuptake inhibitors that were available at the time the study was carried out (citalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline) in at least the minimum effective dose. Dose titration for those not responding was allowed. Concurrent psychological or psychotherapeutic treatment was not allowed.

From the published results of our trial, we concluded that overall adherence rates were high and treatment outcome was favorable, with no significant differences between interventions at week 10 or week 26.<sup>17</sup>

## Measurements

We used the Dutch translations of the Beck Depression Inventory<sup>18,19</sup> and the Symptom Checklist-90-Revised<sup>20,21</sup> to assess psychopathology.

We constructed a self-administered patient questionnaire based on previous reports on beliefs about antidepressants,<sup>22,23</sup> in which perceived effectiveness, harmfulness, and stigmatization seemed to be relevant beliefs. The questionnaire (Appendix 1) consisted of 12 statements, clustered a priori in 4 dimensions: (1) 2 statements (1 and 2) concerning the general effectiveness of antidepressants (Cronbach  $\alpha = .77$ ), (2) 4 statements (3 through 6) concerning appropriate medication-taking (Cronbach  $\alpha = .79$ ), (3) 3 negative statements (7 through 9) concerning harmfulness (Cronbach  $\alpha = .68$ ), and (4) 3 negative statements (10 through 12) addressing stigmatization (Cronbach  $\alpha = .90$ ). Patients responded on a 5-point Likert disagreement-agreement scale (1 = strongly disagree, 5 = strongly agree).

## Process of Care

During each visit, the process of care in the DCP group was assessed by general practitioners filling out a questionnaire on patient compliance with various components of the DCP intervention.

## Statistical Analyses

The analysis of the current study was performed on results from patients with a baseline measurement and a follow-up measurement at week 10 and week 26.

To investigate whether the a priori-identified 4 dimensions of attitude were supported by the data, we performed principal components analysis with varimax rotation using the baseline data on the 12 statement variables.

To study the effect of the DCP on each of the continuous dimensions of attitude, we first calculated the crude difference in the change of the scores during follow-up. In addition, we calculated the differences of the week 10 and week 26 attitude scores between both conditions using analyses of covariance (ANCOVA). In these analyses, the outcome scores were related to treatment group while adjusting for the baseline value. We consider these analyses the most valid, as they are unaffected by baseline differences. If, by chance, baseline scores are worse in the treatment group, the treatment effect will be overestimated by looking at change scores (because of regression to the mean). By contrast, analysis of covariance gives the same answer whether or not there is baseline imbalance.<sup>24</sup> Further, we calculated effect sizes (i.e.,  $d = M_1 - M_2/s_{\text{pooled}}$ , in which  $d$  is from ANCOVA and  $s_{\text{pooled}}$  is from the baseline

Table 1. Elements of Interventions to Improve Depression Treatment

Intervention	Evidence-Based Antidepressant Dose	Enhanced Patient Education	Discussion of Benefits and Costs of Taking Antidepressant Medication	Stimulating Active Participation of GP and Patient in the Treatment Process	Self-Management Support	Systematic Follow-Up
DCP	Yes	Yes	Yes	Yes	Yes	Yes
SFP	Yes	No	No	No	No	Yes

Abbreviations: DCP = depression care program, GP = general practitioner, SFP = systematic follow-up program.

Table 2. Baseline Demographic and Clinical Characteristics of Study Patients

Characteristic	DCP (N = 67)	SFP (N = 75)
<b>Demographic</b>		
Age, mean (SD), y	44.9 (13.2)	45.7 (13.1)
Female, %	73.1	64.0
Employed, %	63.2	61.1
Unfit for work, %	10.5	8.3
<b>Clinical</b>		
BDI baseline severity score, mean (SD)	21.5 (7.5)	21.1 (9.7)
SCL-90-R global severity index, mean (SD)	1.2 (0.5)	1.2 (0.6)
Previous depression, %	47.8	44.0
Anxiety disorder, %	36.9	48.6
Comorbid somatic illness, %	46.3	54.7

Abbreviations: BDI = Beck Depression Inventory, DCP = depression care program, SCL-90-R = Symptom Checklist-90-Revised, SFP = systematic follow-up program.

values) to express the magnitude of the treatment effect.<sup>25</sup> The 95% confidence intervals were adjusted for the cluster sampling by basing them on robust standard errors.

## RESULTS

Overall, 211 patients were randomly assigned; of these, 34 patients completely dropped out of the study. Reasons for dropout were diverse, e.g., adverse events, referral to a psychologist or psychiatrist, and no-show. Another 35 did not have follow-up ratings on the beliefs dimensions because they stopped antidepressant medication.<sup>17</sup> These patients were no longer followed up, as decided before the study started. We aimed at improving beliefs about antidepressants in patients persisting in taking these medications.<sup>26</sup> The characteristics of the patients included in the analysis are depicted in Table 2. Although there were differences between the conditions for some individual variables, the prognoses were considered similar. There were no relevant differences between DCP and SFP in proportions of patients not included in the analysis (34% vs. 32%). Patients excluded from the analysis were slightly younger (mean  $\pm$  SD age, 38.2  $\pm$  15.7 years vs. 45.3  $\pm$  13.1 years), had a somewhat higher Beck Depression Inventory score (mean  $\pm$  SD, 25.2  $\pm$  8.9 vs. 21.8  $\pm$  9.1), and had a higher score on stigmatization (mean  $\pm$  SD, 2.9  $\pm$  1.1 vs. 2.6  $\pm$  1.2).

Using the criterion of Eigen values  $>$  1, we found 4 factors, i.e., general effectiveness, appropriate medication-

taking, harmfulness, and stigmatization. This 4-factor solution explained 69.3% of the variance of the individual items. After varimax rotation, the 4 components loaded substantially ( $>$  0.5) on exactly those statement variables that were a priori representing the 4 dimensions of attitude.

A mean of 88% of patients stated that they had read the information. Questions concerning the information were asked by 22% of patients. With regard to the homework assignment, 58% of patients stated that they had completed it, and 70% discussed the homework. Of the general practitioners, 89% read the information.<sup>17</sup>

As illustrated in Table 3, changes were more favorable in the DCP group at both time points. The ANCOVA yielded statistically significant results for the dimensions of appropriate medication-taking and harmfulness, both in favor of DCP at week 10 and week 26. For stigmatization, no statistically significant differences were found, but the trend was similar with a more favorable change in the DCP group. The effect sizes were medium for appropriate medication-taking and harmfulness at both time points.<sup>25</sup>

## DISCUSSION

In this study, changes in beliefs about antidepressants were more favorable in the DCP group as compared with the SFP group, with medium effect sizes for appropriate medication-taking and harmfulness. These results suggest that a depression care program in primary care patients with major depressive disorder who start treatment with selective serotonin reuptake inhibitors can ameliorate beliefs about antidepressant medication.

Our results are in accordance with 2 randomized trials<sup>15,16</sup> demonstrating positive effects of interventions on beliefs about antidepressants. In these studies, effect sizes were 0.38 and 0.40, respectively. Our effect sizes, especially those at 26 weeks, were larger. In our study, no collaborative care was applied. Therefore, our results are relevant in situations in which collaborative care is not (yet) feasible.

Given the fact that negative beliefs about antidepressants are widespread among depressed patients,<sup>10,11,27</sup> the results give cause for cautious optimism. Adherence, depression outcome, perceived well-being, role functioning, and quality of life might be better when patients are comfortable with taking antidepressant medication.<sup>5,27</sup>

Table 3. Intervention Effects on 4 Dimensions of Beliefs About Antidepressants at Week 10 and Week 26 of the Study

Study Time Point	General Effectiveness <sup>a</sup>		Appropriate Medication Taking <sup>a</sup>		Harmfulness <sup>a</sup>		Stigmatization <sup>a</sup>	
	DCP	SFP	DCP	SFP	DCP	SFP	DCP	SFP
Baseline score, mean (SD)	3.84 (0.58)	3.90 (0.71)	2.87 (0.80)	2.99 (1.00)	3.07 (0.53)	2.55 (0.87)	2.87 (1.03)	2.28 (1.31)
Week 10 score, mean (SD)	3.94 (0.69)	3.92 (0.82)	3.33 (0.79)	3.03 (0.99)	2.07 (0.79)	2.24 (0.81)	1.92 (0.90)	1.92 (1.04)
Week 26 score, mean (SD)	3.91 (0.71)	3.92 (0.80)	3.32 (0.86)	2.87 (1.07)	1.86 (0.78)	2.13 (0.91)	1.75 (0.86)	1.76 (1.02)
Between-Group Comparisons								
Week 10								
Difference between means (95% CI)	0.08 (−0.21 to 0.36)		0.44 (0.14 to 0.74)		−0.69 (−0.99 to −0.38)		−0.58 (−0.94 to −0.22)	
p Value <sup>b</sup>	.771		.012		.011		.164	
Effect size <sup>b</sup>	0.05		0.39		0.45		0.20	
Week 26								
Difference between means (95% CI)	−0.05 (−0.23 to 0.34)		0.59 (0.27 to 0.92)		−0.77 (−1.07 to −0.47)		−0.59 (−0.98 to 0.21)	
p Value <sup>b</sup>	.948		.001		.002		.221	
Effect size <sup>b</sup>	0.01		0.55		0.62		0.18	

<sup>a</sup>Patients responded on a 5-point Likert disagreement-agreement scale ranging from strongly disagree (1) to strongly agree (5).

<sup>b</sup>p Values and effect sizes are based on the difference between the conditions from the analysis of covariance.

Abbreviations: DCP = depression care program, SFP = systematic follow-up program.

Given the results demonstrating that the changes in beliefs were more positive in DCP, one might expect better adherence rates and better depression outcome in DCP as well. This was, however, not the case, as we reported elsewhere.<sup>17</sup> In the study by Brook et al.,<sup>15</sup> this was also not the case. An explanation may be that the intensive follow-up contacts (between patient and general practitioner) in both intervention groups created a ceiling effect in adherence and outcome, obscuring any differences.<sup>17</sup>

Another explanation might be that DCP contained various ingredients, of which patient education and the repeated consideration of the costs and benefits of antidepressants addressed beliefs about antidepressants. These ingredients might have influenced adherence positively via changing beliefs in a positive direction. Possibly, other ingredients had a negative effect on adherence, counteracting the positive effect. Self-management support, consisting of enhancing social support and daily activities, might have decreased patients' attention to medication. Most depressive patients in primary care do not prefer antidepressant medication.<sup>28</sup> The net result of this combination of ingredients may also have resulted in depression outcomes that did not differ between interventions. Another possible explanation concerning adherence is that we assessed adherence using pill counts and patient reports. This method was chosen because it is feasible in primary care. This method, however, overestimates adherence and is not a sensitive measurement, possibly obscuring differences.<sup>29</sup>

In 2 observational studies<sup>27,30</sup> and 1 randomized controlled trial,<sup>16</sup> the association between beliefs and adherence was analyzed using within-patient analyses and between-patient analyses. These analyses demonstrated that beliefs about antidepressants were positively associated with adherence. However, these results are preliminary because the measurements and definitions of both beliefs and adherence were different among studies. Lacking accurate adherence data, we decided not to analyze the association

between beliefs and adherence using within-patient and between-patient data. Although this association is interesting from a clinical perspective, we consider beliefs about medication a relevant outcome in itself, in particular about medication which has to be taken during 6 months or longer. Perceived well-being, role functioning, and quality of life might be better when patients are comfortable with taking antidepressant medication.<sup>5,27</sup>

Some limitations of the study need to be addressed. The scale we used was not thoroughly validated, yet the internal consistency as well as the face validity of our scale seems reasonable. In addition, the a priori-identified dimensions of attitude were supported by the data. Second, the impact of the relatively high lost-to-follow-up rate must be considered. The proportion of lost-to-follow-up patients was similar in both treatment arms, and it seems in our view unlikely that the dropout-attitude relationship was different between the intervention arms. Thus, lost-to-follow-up is unlikely to have biased our results. Moreover, persistence and execution are different aspects of adherence,<sup>26</sup> and we aimed at improving beliefs about antidepressants in patients persisting in taking these medications. Yet, patients not included in the analyses were slightly younger, had a somewhat higher baseline Beck Depression Inventory score, and agreed more to the statements concerning stigmatization, and, therefore, generalizability to this type of patient may be limited. Given the results of the process of care assessment, compliance with some components of the DCP was lower than intended, possibly making the intervention less effective. Process of care in the SFP was not assessed. Therefore, we do not know what the general practitioners and patients in the SFP group discussed during the visits. However, it is very unlikely that the patients in the SFP group received interventions like those in the DCP group.

Given the medium effect sizes in our study and in previous studies, further research is warranted to investigate

how the effects of interventions to improve beliefs about antidepressants can be enhanced. In addition, the issue of which ingredients of interventions have the potential to improve adherence via belief change and which ingredients negatively influence this process needs further investigation. In future studies, the methods to assess adherence should meet quality criteria.<sup>29</sup>

In conclusion, our findings suggest that a depression care program in which only general practitioners and no other health care workers are involved improves beliefs concerning appropriate medication-taking and harmfulness with regard to antidepressants. The study results encourage the implementation of a depression care program in order to improve beliefs about antidepressant medication in primary care patients diagnosed with major depressive disorder.

**Drug names:** citalopram (Celexa and others), fluoxetine (Prozac and others), fluvoxamine (Luvox and others), paroxetine (Paxil, Pexeva, and others), sertraline (Zoloft and others).

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## Appendix 1. Beliefs About Antidepressants<sup>a</sup>

### Statement

- Antidepressants are effective in the treatment of depression
- Depression can be treated with medication
- Even when I feel better, I will have to continue the antidepressant medication in order to prevent a relapse
- I will have to take the antidepressant medication for a long time
- When I feel good, I have to continue the antidepressant medication
- When I feel substantially better, I have to continue the antidepressant medication
- I will suffer from bothersome side effects caused by the antidepressant medication
- Antidepressants are harmful
- Antidepressants are addictive
- I am ashamed that I need antidepressant medication
- I am afraid that others will find me weak when I take antidepressant medication
- I am afraid that others will find me crazy when I take antidepressant medication

<sup>a</sup>Patients responded on a 5-point Likert disagreement-agreement scale ranging from strongly disagree (1) to strongly agree (5).