Improving long-term outcome of major depression in primary care

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Chapter 3

Enhanced treatment for depression in primary care: First year results on compliance, self-efficacy, the use of antidepressants and contacts with the primary care physician

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Abstract

Objective: we describe the contents and feasibility of the Depression Recurrence Prevention (DRP)–Program, a structured psycho-educational self-management intervention based on an ongoing relationship between patient, prevention specialist and primary care physician. The DRP-Program consisted of three individual face-to-face sessions with a trained prevention specialist, followed by four telephone contacts per year.

***Methods*:** 267 primary care patients with a DSM-IV diagnosis of major depression were included and randomly assigned to care as usual (CAU; n = 72) or enhanced care (n = 195), which consisted of the DRP-Program either by itself or in combination with a psychiatric consultation or brief cognitive behavioral therapy.

***Results*:** DRP-program participation rates were high, both in the initial phase (92%) as during the first year of follow-up (95%) and patient evaluations were generally positive. Enhanced care patients were significantly more satisfied with effects of the depression care than CAU patients after three months. Perceived self-efficacy in dealing with depression was mostly similar in the four treatment groups. The use of antidepressants was lowest throughout the year in patients assigned to CBT plus DRP, who also kept less in touch with their PCP.

Conclusion: The DRP-program proved to be feasible and appreciated.

Introduction

In the Netherlands, the primary care physician (PCP) is often the first professional health care provider whom depressed patients visit. The PCP controls access to specialty mental health care, which is commonly referred to as the gatekeeper function. Several treatment strategies for the management of depressive disorders are available for the PCP. The Dutch College of General Practitioners has developed and disseminated specific Clinical Guidelines for the treatment of depression in general practice (Marwijk *et al.* 1994, 2003), based on the effectiveness of time-limited depression-targeted psychotherapies and antidepressant pharmacotherapy (e.g. Schulberg *et al.* 1998, 2002). The recommended strategy is a combination of antidepressant medication and brief, supportive counseling by the PCP.

Treatment recommendations based on a perception of depression as a potentially recurrent and chronic illness are not incorporated in these Guidelines. From such a perspective, recovery for the acute episode is not sufficient. Treatment goals should also include prevention of relapse (the return of depressive symptoms before complete recovery) and recurrence (a new episode after recovery). The rationale behind this lies in the poor long-term prognosis of depression, which is increasingly recognized as an often recurrent or even chronic disorder (Ormel *et al.* 1991, 1993; Angst 1992; Keller 1994; Judd 1997; Tiemens *et al.* 1999; Simon 2000; Brink *et al.* 2001; Spijker *et al.* 2002*).* Residual symptoms and incomplete recovery have been identified as major risk factors for this unfavourable course (Paykel *et al*. 1999). A limited number of studies suggest that psycho-education and regular patient follow-up to monitor depressive symptoms and treatment adherence are required to achieve more positive long-term outcomes (Simon 2000; Katon *et al*. 1999, 2001). Continuity of care, preferably with one primary caretaker who remains responsible for the core elements of treatment, is essential for this more active follow-up approach to depression management. However, largely due to time-constraints of PCPs and to several other organizational barriers, routine care may offer only limited possibilities for this approach. There may be a role here for other primary care providers, like (practice or psychiatric) nurses, or for mental health professionals within or outside the primary care

setting, in supporting the PCP (Simon *et al.* 2000; Hunkeler *et al.* 2000; Bower & Sibbald 2000, 2002; Mynors-Wallis *et al.* 2002; Badamgarav *et al.* 2003; Gilbody *et al.* 2003).

In this article we report the contents and feasibility of a primary care based psycho-educational self-management intervention. The Depression Recurrence Prevention (DRP) – Program is aimed at integrating acute treatment and the prevention of depression relapse and recurrences. By providing patient education, continuity of care, systematic monitoring and long-term support from a prevention specialist working in tandem with the PCP, we focus on improving patients' resilience and self-management skills. Effectiveness of the DRP-Program is currently studied in a randomized controlled trial. In the present paper we will focus on two issues. First, the question whether it is feasible to provide a DRP-Program in terms of integration into daily primary care practice, participation rates, compliance, and patient satisfaction. Secondly, a number of factors have been identified as potential mediators in the process between (delivery of) an intervention and better patient outcomes. From this perspective, we will examine whether the DRP-Program is successful with regard to improving patients' self-efficacy in managing depression, increasing compliance with antidepressant medication, and preserving the contact with the PCP.

Interventions

The Depression Recurrence Prevention (DRP) - Program is a structured psycho-educational self-management intervention based on an ongoing relationship between patient, prevention specialist and primary care physician. The primary goal is to reduce depression recurrence and chronicity, by increasing patients' self-efficacy and self-management skills, enhancing awareness of prodromal symptoms and early warning signs and extending the potential of pro-active measures and stress-management strategies available to the patient.

The DRP-Program was developed by Katon and coworkers at the Center for Health Studies of the University of Washington in Seattle, the United States (Katon *et al.* 1996; Ludman *et al.* 2000) and adapted for use in the Netherlands by Tiemens and colleagues (Tiemens *et al.* 1998).

To motivate and encourage patients we used Motivational Interviewing (Miller & Rollnick 1991). This method is characterized by an empathic, flexible and reflective counseling style, tailored to the individual patient. Motivational interviewing was used throughout the Program to enhance confidence in one's ability to succeed, support self-efficacy and to strengthen commitment to the Program over time.

Format

The DRP-Program consisted of three individual face-to-face sessions with a trained prevention specialist, followed by four telephone contacts per year for a three-year period (Figure 1). Education on self-care management of depression is an integral part of the Program. Prior to the first session, patients were handed a book and corresponding videotape containing information about depression, treatment options, relapse prevention and self-management strategies (Tiemens *et al.* 1998), and a 2-page instruction booklet to prepare for the first session.

First phase: face to face sessions with prevention specialist

In the first session the prevention specialist gave an overview of the DRP-Program, her own role and the collaboration with the patients' PCP. She collected information on current episode, past episodes, treatment history, personal situation and the use of antidepressant medication. The potential benefits of self-monitoring of depressive symptoms and various stress reduction strategies were introduced and discussed. In the second session, the personal Recurrence Prevention Plan was prepared, with special attention to self care and what could be learned from the patient's earlier episodes. Socializing and the scheduling of pleasant activities such as sports were encouraged. At the third and final session, depression specialist and patient drew up the final Prevention Plan, with the following topics: personal warning signs; stress reduction strategies; an 'Emergency-plan', with the steps that the

patient was planning to take once s/he feared a relapse or recurrence; and a medication plan for patients using antidepressants.

Figure 1: Outline of the Depression Recurrence Prevention Program

Following randomization to DRP-Program:

Patient receives the book & videotape; the first session is scheduled within 2 weeks.

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FIRST PHASE:

Session 1 (1½ hr): introduction and overview of the program → Written feedback to PCP

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2 to 4 weeks later:
Session 2 (1 hr): global draft of self care plan → Written feedback to PCP

↓

2 to 4 weeks later:
Session 3 (1½ hr): Recurrence Prevention Plan → Copy of Plan to PCP

↓

FOLLOW-UP PHASE:
(2 ½ months after session 3)

Prevention specialist mails first Progress Monitoring form, including 13-item BDI and proposes date and time for the telephone call.
Patient fills in and returns Progress Monitoring Form 1; Telephone follow-up contact 1 takes place.
After call: prevention specialist records progress and, if applicable, changes in Plan and Medication use; BDI-score is entered in graph for next FU Monitoring Form.

This procedure was repeated every three months for three years.
Recorded on the Monitoring Forms are rating of mood; checklist of early warning signs; adherence to the Prevention Program; activity rating; and compliance with antidepressant medication.

Follow-up phase: structured telephone contacts

Two weeks before the first follow-up telephone contact , patients received a 'Follow-up Patient Monitoring Form', which included a two-page copy of their Prevention Plan, a graph representing their score on the Beck Depression Inventory (BDI; Beck *et al.* 1961, 1988) at the last visit and the 13-item BDI. The Monitoring Form included:

- Current Rating of Mood

- Checklist of early warning signs (‘present in past 2 weeks?’)
- Adherence to the Prevention Program on a scale from 0 to 10
- Activity Rating
- If applicable: Compliance with pharmacotherapy.

Patients were requested to return the Monitoring Forms to the prevention specialist. This written information provided the basic material for the follow-up calls.

The main goals of the follow-up contacts were to systematically review progress and provide ongoing feedback and support. Patients were encouraged to adhere to their Depression Recurrence Prevention Plan in ‘good and in bad times’ and the prevention specialists boosted motivation and confidence in self-management skills by giving positive feedback, using motivational interviewing.

Continuous feedback to PCP

During the first phase of the DRP-Program, the PCP regularly received written feedback about patient cooperation and progress, and about medication use including side-effects. After the last session, a copy of the patients’ Prevention Plan was sent to the PCP with an accompanying letter in which specific elements of the plan were highlighted.

In the follow-up phase, contacts between prevention specialist and PCP were less regular and more on a shared ‘need to know’ base. For example, suicide threats were always reported back to the PCP. During the entire 3-year follow-up period the PCP remained in charge of treatment and was responsible for the prescription and delivery of antidepressants in adequate dosage and duration.

Prevention specialists

One experienced psychiatric nurse and two psychologists, all females, carried out the intervention. They were trained by two experts from the Seattle project, who had a background in psychology and social work (PhD). The training took four days and included

an instruction on motivational interviewing. The psychiatrist who acted as supervisor and monitored adherence of the prevention specialists to the DRP-Program in regular supervision sessions, also attended the training. A booster session was organized halfway through the follow-up phase, to reinforce (confidence in) the use of motivational interviewing with patients in various stages of the follow-up phase of the Program.

Additional treatments

The effects of the DRP-Program are evaluated not only in contrast with CAU but also in combination with two additional interventions by mental health specialists, to explore whether these treatments would strengthen the Program.

The PC+DRP group was offered one 1-hour visit with one of two available psychiatrists prior to the DRP-intervention. The PCP provided the psychiatrist with information about the patients' health and treatment status. Afterwards, the psychiatrist reported and discussed his diagnostic findings and treatment advice with the PCP. A copy of this report was also made available to the prevention specialist.

The CBT+DRP group was offered 12 individual weakly one-hour sessions of CBT treatment, tailored to primary care by Boelens (1997), a clinical psychologist / psychotherapist. The DRP-Program started after the final CBT session. The CBT-therapist informed the prevention specialist about the main themes that the CBT had addressed and the progress achieved.

Two qualified CBT therapists were employed. To reinforce concepts and CBT techniques and to monitor their adherence to the protocol, regular supervision sessions were held. Acting supervisor was the regional CBT expert who developed the adapted treatment protocol.

Care as usual

Patients randomized to the control group, CAU, received the care that the PCP seemed fit. In most cases, this will include a combination of antidepressant medication and counseling

during regular visits (Os *et al.* 1999). PCPs were free to refer patients to specialized mental health agencies including primary care psychologists, who run private practices and are popular referrals for Dutch PCPs.

Methods

Design

Evaluation of effectiveness of the DRP-Program takes place in a randomized controlled pragmatic trial (RCT). Pragmatic trials are meant to measure effectiveness, i.e. the benefit the treatment produces in routine clinical practice (Kluiter & Wiersma 1996; Roland & Torgerson 1998). Randomization took place at the patient level and was stratified for use of antidepressant medication at the baseline assessment. Patients meeting inclusion criteria were randomly assigned to one of four treatment conditions, including care as usual (control group). The experimental interventions are the DRP-Program; the DRP-Program plus a psychiatric consultation (PC+DRP); and DRP-Program with brief Cognitive Behavioral Therapy (CBT+DRP). Randomization was skewed in favor of the DRP-Program and the 'care as usual' treatment to ensure that, given the limited resources, enough patients would be available for the main comparisons. We used a computer-generated random allocation list for the treatment assignment per stratum. For the purpose of the present paper we confine ourselves to the core aspects of the study design and procedures; a more detailed description will be reported elsewhere (Smit *et al.,* in preparation).

Patient selection

Primary inclusion criterion for the study was the presence of a current DSM-IV diagnosis of major depressive disorder, according to the primary care physician and confirmed by an independent structured psychiatric interview (Composite International Diagnostic Interview version 2.0; (WHO 1997)). Primary care physicians were asked to refer any patient between the ages of 18 and 70 whom they considered to be depressed. Patients suffering from a life-

threatening medical condition, a psychotic disorder, dementia, alcohol addiction or drug-abuse, were excluded, as well as women who were pregnant or nursing, and patients already receiving mental health treatment elsewhere. Research-assistants contacted all referred patients to establish study eligibility (i.e. check of the PCP diagnosis and the presence of exclusion criteria).

Primary care physicians

The selection of PCPs was primarily guided by pragmatic principles and circumstances, such as the location of the practice, the number of physicians sharing a (group) practice and participation in earlier studies by the department. Fifty five PCPs were willing to participate and were invited to attend a 2-hour booster session about Guidelines for depression treatment (Marwijk *et al.* 1994; Jenner *et al.* 1995), including management of recurrent depression.

Outcome measures

All patients were followed up for three years with telephone interviews every three months by trained research workers. In addition, self-report questionnaires were obtained every six months. Measures included in the present paper are: DRP-Program participation, patient evaluation of the information and care received for depression, effects on perceived self-efficacy, the use of antidepressant medications, and frequency and number of contacts with the PCP in the first year.

Feasibility

Compliance with treatment data was gathered from the registration forms filled in by the prevention specialists, the psychiatrists and the CBT therapists.

Patient evaluation of treatment

At the 3 and 6 month follow-up we collected data from patients on their opinion and satisfaction regarding various aspects of the treatment received, using questions with a 4-point response format ranging from 'not at all' to 'helped a great deal'. Patients also rated their satisfaction with the PCP and the prevention specialist on a 10-point scale.

Perceived self-efficacy for managing depression

At baseline and 3- and 12-month follow-up, we assessed self-confidence in controlling depressive symptoms and preventing future episodes using the 5-item 'Depression Self-Efficacy Scale' (DSES; (Bush *et al.* 2001)). Internal consistency according to Cronbachs' alpha was .79 in the Bush et al study. The DSES contains items concerning confidence in ability to overcome or control a new episode of depression, prevent depression from returning, recognize symptoms at an early stage, take effective actions to treat depression, and seeking professional help before the depression has become too severe. Response format was a 10-point scale, with '0' indicating 'not at all confident 'and '10' indicating 'extremely confident'. The DSES summary score reflects the mean item score.

Use of antidepressants and contacts with PCP

At each 3-month FU, use of antidepressant (AD) medication and number of visits with the patients' PCP in the preceding interval were recorded.

Statistical analyses

To evaluate whether patient characteristics differed across the four study groups we used chi-square tests for dichotomous variables and analysis of variance (ANOVA) for continuous variables. If appropriate, patients from the three experimental arms were pooled and compared to patients assigned to care as usual, using t-tests. To examine change over time

and whether outcomes differed between groups we used repeated measures analyses. All analyses were conducted on an intention-to-treat base, using SPSS version 11.

Results

Participants

Out of a total of 397 referred patients, 267 (68%) met the inclusion criteria and were randomized to one of the treatment conditions. Of these, 72 (27%) were assigned to care as usual (CAU) for which they were referred back to their PCP. 112 patients (57%) were offered the DRP-Program only, 39 patients (20%) were assigned to the DRP–Program plus a psychiatric consultation (PC+DRP) and another 44 patients (23%) were assigned to the DRP-Program plus brief CBT (CBT+ DRP) .

Patients from 49 of the 55 participating PCPs were included. Enrollment differed considerably between PCPs, with 20 PCPs recruiting 90% of the patients. The mean number of patients per PCP was 5.5 (range: 1 - 35).

In Table 1, main socio-demographic and clinical characteristics of the baseline sample are summarized. Randomization proved to be successful; there were no significant differences on any of these characteristics between patients in the four treatment groups.

Response rates for the four follow-up research assessments conducted in the first year are 90 % for the three month FU, 85% for the six month FU and 84 % for the nine as well as the 12 month assessments. Response rates were similar for patients in the four groups.

Table 1. Baseline socio-demographic and clinical characteristics*

	CAU n = 72	**DRP n = 112**	**PC + DRP n = 39**	**CBT + DRP n = 44**
Female	**65 %**	**65 %**	**69 %**	**54 %**
Age *mean (sd)*	**44.2** (11.3)	**42.5** (10.6)	**41** (13.0)	**42.8** (11.6)
Marital status:				
- Married / Cohabiting	**68 %**	**69 %**	**67 %**	**48 %**
- Single	**13 %**	**18 %**	**18 %**	**34 %**
- Divorced or widowed	**19 %**	**14 %**	**15 %**	**19 %**
Primary role:				
- Employed	**56 %**	**65 %**	**59 %**	**57 %**
- Homemaker	**25 %**	**17 %**	**21 %**	**14 %**
- Student	**4 %**	**5 %**	**8 %**	**7 %**
- Unemployed	**7 %**	**6 %**	**5 %**	**14 %**
- Disabled, Retired / other	**9%**	**7 %**	**8 %**	**9 %**
Educational attainment:				
- Low	**49 %**	**42 %**	**46 %**	**39 %**
- Medium	**29 %**	**41 %**	**33 %**	**39 %**
- High	**22 %**	**17 %**	**21 %**	**23 %**
Recurrent DSM-IV MD	**74 %**	**64 %**	**64 %**	**68 %**
If recurrent: % > 3 episodes	**57 %**	**51 %**	**56 %**	**60 %**
Age at first onset *mean (sd)*	**32.4** (14.3)	**30.9** (11.8)	**30.6** (15.4)	**31.1** (13.2)

* No significant differences between randomization groups (p = 0.05)

Patient acceptance of the DRP-Program

Participation

Attendance at the face to face sessions

Overall, 92 % (179 / 195) of the enhanced care patients attended all three individual face to face sessions with a prevention specialist. Participation in this phase of the DRP-Program was highest among patients randomized to the DRP-Program only (96 %; 108/112) and in those assigned to the combination with a psychiatric evaluation (97%; 38/39). In the group where DRP followed CBT, compliance was significantly lower than in the other two DRP conditions, with 75% (33 / 44) of the patients attending all three sessions (x^2 =23.97; d.f. = 2; $p < 0.0001$).

Follow-up telephone contacts in the first year

Since 8 % (n = 16) of the enhanced care patients had either not started with the DRP-Program (n = 13) or dropped out during the first phase (n = 3), 179 patients were left for the follow-up monitoring contacts. During the first year of follow-up, prevention specialists remained in contact with the vast majority of these patients, with 95% (n = 170) of them returning their Progress registration forms and responding to the four telephone calls.

Compliance with additional treatments

All 39 patients randomized to the combination of DRP-Program with PC agreed to the visit with the psychiatrist. Of the 44 patients offered CBT, 33 (75%) completed this according to protocol, three refused to start and eight dropped out prematurely (after a mean of four sessions). Thus, patient acceptance of the CBT was significantly lower than that of PC ($p = 0.004$).

Evaluation of educational materials and prevention specialists

Patients receiving either DRP by itself or in combination with PC had obtained the educational materials in the period between treatment assignment and the first FU assessment. Results on satisfaction with these materials and the prevention specialists are shown in table 2. Since CBT plus DRP patients started later with the DRP-Program, they were asked about their opinion at the six-month FU. Compared with patients in the other DRP-Program groups, less patients indicated having used these materials (book: 56%; video: 82%) and usefulness was evaluated lower (data not shown).

Mean scores for the prevention specialists were around eight on the 10-point scale in all three intervention groups.

Table 2. Satisfaction with educational materials and prevention specialist *

	DRP N =102	**PC + DRP N = 34**
Read at least 50 % of book	79 %	77 %
Found book (very) useful **	75 %	71 %
Saw at least 50 % of tape	93 %	91 %
Found tape (very) useful	51 %	47 %
Rating of prevention specialist ***on 10-pointscale; mean (sd)***	8.28 (1.15)	8.12 (1.41)

* No significant differences between the two conditions

** Usefulness: % of patients scoring 1 (= very useful) or 2 (useful) on a 4 point scale.

Patient satisfaction

Table 3 presents three month follow-up data concerning satisfaction with the care and information received for depression for all patients. Significantly fewer CAU than enhanced care patients reported having received information about causes of depression and on different treatment methods. CAU-patients also scored significantly lower on most questions regarding more specific effects of depression care.

Results were basically the same at the six month FU. While most patients were still positive about recommending the care they (had) received, this was true for significantly less

CAU - than enhanced care patients (77% of CAU versus 87% of DRP, 97% of PC plus DRP and 97% of CBT plus DRP patients; x^2 =9.39, d.f.=3, p = 0.02).

Table 3. Satisfaction with depression care at 3 month FU

	CAU n = 64	**DRP n = 102**	**PC + DRP n = 34**	**CBT + DRP n = 40**	**Statistics**
Received information about:					
- **causes for depression**	41 %	84 %	82 %	53 %	***X^2 =40.98; df=3; p < 0.001***
- **treatment methods**	50 %	80 %	79 %	62 %	***X^2 =19.74; Df=3; p < 0.001***
Effect of information and care:					
- helped in reducing worries concerning depression	50 %	82 %	79 %	68 %	***X^2 =20.77; df=3; p < 0.001***
- increased hope in abilities to deal with depression	62 %	88 %	91 %	85 %	***X^2=21.03; Df=3; p < 0.001***
- helped in resuming normal activities	38 %	80 %	82 %	75 %	***X^2 =37.20; Df=3; p < 0.001***
- condition improved	75 %	84 %	88 %	85 %	*X^2 =5.29; df = 3 ; p= 0. 51*
Would recommend this care to depressed friends and relatives	73 %	88 %	88 %	83%	*X^2 =6.89; df=3; P= 0. 08*
Rating of satisfaction with PCP *on scale from 0 –10; mean (sd)*	6.75 (1.98)	7.29 (1.88)	7.12 (2.04)	6.75 (1.67)	*F = 1.29; df = 3 P = 0.28*

Perceived self-efficacy and confidence in managing depression

Table 4 shows mean scores of CAU and enhanced care patients on the DSES at baseline, three and twelve month FU. Perceived confidence in dealing with depression was generally low at baseline, with DSES summary scores below 6 (mean 5.65; sd 1.47) on the 10-point answer scale. Baseline levels were largely similar in the four treatment groups, with one exception: patients randomized to CBT plus DRP scored significantly lower on the item regarding confidence in ability to prevent depression from returning.

Three months later, we found higher scores on all DSES items and the mean summary score rose accordingly (mean: 6.38; sd 1.49). Perceived self-efficacy and

confidence to deal with depression had more or less improved to the same extent, regardless of treatment assignment. At the twelve month FU we again found that, although scores on most items had risen (mean summary score 6.57; sd 1.55), there were no statistically significant differences between treatment groups on any of these self-efficacy items. We checked this with additional repeated measures analysis. Despite improvement, follow-up scores on the item regarding confidence in ability to prevent depression relapse / recurrence remained the lowest (mean at 3-m FU: 5.02; sd 1.95; at 12-m FU: 5.27; sd 2.09), indicating that self-confidence in this regard was still very fragile.

Table 4. Depression self-efficacy

PERCEIVED CONFIDENCE IN: 0-10 scale, mean (sd)	***CAU***	***DRP***	***PC + DRP***	***CBT + DRP***
Ability to overcome or control a new episode of depression				
- **baseline**	5.46 (2.08)	5.39 (2.66)	5.00 (2.68)	4.77 (2.64)
- **3 m FU**	5.89 (2.11)	5.57 (1.81)	5.82 (1.77)	5.55 (1.93)
- **12 m FU**	6.66 (1.67)	6.33 (1.73)	6.43 (1.87)	6.81 (1.24)
Ability to prevent depression from returning				
- **baseline ***	3.83 (1.98)	3.71 (2.31)	3.46 (2.56)	2.70 (1.83)
- **3 m FU**	4.77 (1.85)	5.23 (1.86)	5.00 (2.03)	4.92 (2.28)
- **12 m FU**	4.85 (2.35)	5.48 (1.89)	4.86 (2.29)	5.77 (1.88)
Ability to recognize depression early on				
- **baseline**	6.47 (2.07)	6.44 (2.13)	6.82 (2.08)	6.77 (2.32)
- **3 m FU**	7.05 (1.69)	6.75 (1.74)	7.44 (1.46)	6.35 (2.07)
- **12 m FU**	7.08 (1.21)	7.32 (1.54)	7.46 (1.14)	7.41 (1.15)
Ability to take effective actions to treat depression early				
- **baseline**	6.13 (2.44)	6.61 (2.40)	6.87 (2.61)	6.14 (2.86)
- **3 m FU**	7.33 (1.99)	7.07 (1.85)	7.41 (1.60)	6.43 (2.21)
- **12m FU**	7.29 (2.03)	7.16 (2.12)	7.21 (1.71)	7.04 (1.99)
Seeking professional help early				
- **baseline**	6.18 (2.50)	6.41 (2.52)	7.38 (2.24)	6.55 (2.85)
- **3 m FU**	7.52 (2.02)	7.45 (1.82)	7.32 (1.84)	6.75 (2.39)
- **12m FU**	6.61 (2.34)	7.14 (2.22)	7.11 (1.37)	6.68 (2.09)
Self-efficacy summary score				
- **baseline**	5.59 (1.34)	5.70 (1.49)	5.91 (1.64)	5.39 (1.46)
- **3m FU**	6.47 (1.45)	6.40 (1.37)	6.60 (1.38)	6.00 (1.87)
- **12m FU**	6.46 (1.56)	6.62 (1.59)	6.61 (1.35)	6.56 (1.69)

* Ability to prevent depression from returning: baseline level significantly lower in DRP+CBT, F=2.77; d.f. = 3; p = 0.04. None of the other differences was statistically significant.

Antidepressant medication

The percentage of patients using antidepressants (AD) had decreased from 74% at baseline to 50% overall at the twelve month FU. As shown in table 5, throughout this year the percentage of patients using AD was lowest in those assigned to CBT plus DRP.

The contrast in AD use between CBT plus DRP patients and those in the other three treatment groups was statistically significant at the three month FU. Three months later, the contrast between CBT+DRP versus PC+DRP patients in AD use was still significant.

AD use in the first six months showed the least fluctuations in patients in the PC plus DRP group. Finally, there were hardly any differences in AD use between CAU and DRP only patients for most of the year, although at the 9-month FU less DRP than CAU patients used an AD (difference not significant, X^2 = 1.42; d.f.=1; p = 0.23).

Table 5. Use of antidepressants during first year

	CAU	**DRP**	**PC + DRP**	**CBT + DRP**
Baseline	76 %	74 %	72 %	73 %
3 m FU [1]	72 %	70 %	74 %	50 %
6 m FU [2]	60%	59 %	69 %	42 %
9 m FU	57 %	47 %	55 %	44 %
12 m FU	51 %	52 %	49 %	46 %

[1] CBT+DRP vs CAU: x^2 = 5.08;df=1; p = 0.02 ; CBT+DRP vs DRP: x^2=4.80; df = 1; p = 0.03; CBT+DRP vs PC+DRP: x^2 =4.27;df=1;p=0.04
[2] CBT+DRP vs PC+DRP: x^2 = 5.01; df = 1; p = 0.03

Contact with PCP

In table 6 the results on contacts with the PCP during the first year of the study are shown. In general, the majority of both CAU and enhanced care patients remained in touch with their PCP, but this proportion was lowest for the entire period in those assigned to CBT+DRP. The mean number of visits to the PCP was similar in the four treatment groups.

Table 6. Contact with PCP

	CAU	DRP	PC + DRP	CBT + DRP
Between baseline and 3 m FU :				
- **Visited PCP at least once** [1]	94 %	85 %	79 %	58 %
- **Mean number of contacts with PCP**	2.9	3.3	3.8	3.2
Between 3 and 6 month FU:				
- **Visited PCP at least once** [2]	66 %	78 %	69 %	61 %
- **Mean number of contacts with PCP**	2.4	2.2	2.5	1.8
Between 6 and 9 month FU:				
- **Visited PCP at least once** [3]	58 %	63 %	76 %	50 %
- **Mean number of contacts with PCP**	1.9	2.4	1.8	2.1
Between 9 and 12 month FU:				
- **Visited PCP at least once** [4]	60 %	65 %	76 %	46 %
- **Mean number of contacts with PCP**	2.1	1.9	1.8	2.3

[1] $x^2 = 23.24$; df=3; $p < 0.001$
[2] CBT+ DRP vs DRP: $x^2=3.89$; df=1; $p = 0.05$
[3] PC+DRP patients versus DRP+CBT patients $x^2 = 4.86$; df =1; p=0.03
[4] PC+DRP patients versus DRP+CBT patients $x^2 = 5.93$; df=1; p=0.02

Discussion

The Depression Recurrence Prevention Program described in this paper, offering a limited number of in-person visits with a professional worker followed by regular, long-term support by telephone and mailed feedback, proved to be feasible and appreciated. Patients were motivated to participate, as demonstrated by the high patient acceptance rates both in the initial phase of face to face contacts with the prevention specialists as for the first year of follow-up. Ludman and colleagues present similar findings for the Seattle project, where 93% of patients attended the (two) in-person visits with the prevention specialist and 80% completed all three follow-up telephone calls in the first year (Ludman *et al.* 2000). Patient evaluation of the DRP-Program was generally positive. Compared with CAU patients, significantly more patients in enhanced care reported having received information on

(specific aspects of) depression. Moreover, significantly more enhanced care patients stated that the information and care they received had helped them in resuming their normal daily activities, reduced their worries and increased hope in their abilities to deal with depression.

We added two treatments by mental health specialists to the basic format of the DRP-Program. Of these, the psychiatric consultation was accepted by all patients assigned to it. Findings on compliance and satisfaction with treatment were very similar between patients in the DRP and the PC+DRP groups. Compliance with CBT however was lower, with a quarter of patients assigned to this treatment either refusing or dropping out prematurely. These patients were also slightly less satisfied (n.s.) with the information and care received for depression. Our impression is that the demands of CBT, including its strong focus on recognizing and changing dysfunctional cognitions and behavior, were experienced as being too high by some of the patients. Several previous primary care studies (Scott & Freeman 1992; Teasdale *et al.* 1984) have reported comparable drop out rates for CBT, showing that this is not an uncommon finding.

In the introduction, we named perceived self-efficacy in dealing with depression, compliance with antidepressant medication and contact with the PCP as possible mediators in the process between the delivery of the interventions and improved patient outcomes. As mediators, they might strengthen or weaken the effects of the main intervention, the DRP-program.

Regarding self-efficacy, results are rather disappointing. Although perceived self-confidence in abilities to recognize and effectively manage depression increased during the first year, we found no evidence that enhanced care patients benefited more from their treatment than the patients receiving usual care. Moreover, scores on the item regarding confidence in the ability to prevent depression from returning remained the lowest overall. These findings suggest that it is difficult for patients with recurrent depression to build up trust in own capacities and skills to overcome or prevent depressive disorder, even by enhanced depression care (Ludman *et al.* 2000). The possibility that for some patients the continued focus on (recurrence of) depression may even have a negative impact on their

perceived self-efficacy, should also be considered. Not all patients may respond well to this prolonged and systematic monitoring of (residual) depressive symptoms. It is conceivable that for some this may even increase awareness of their vulnerability (Frasure-Smith *et al.* 1997; Kaasenbrood *et al.* 2004).

With respect to the use of antidepressants, we found this to be similar between care as usual and enhanced care in the first six months of the study, with the exception of patients assigned to the CBT plus DRP-Program who more often discontinued taking medication. The combination of 'talk & pills', which was generally supported by the prevention specialist, the consulting psychiatrist and the PCP, was not a focus in the CBT protocol. We also noticed that these patients were less in contact with their PCP throughout this first year, not only during the time of their CBT treatment but also after this was finished.

Contacts with the PCP were sustained in the first year of the study, with most patients in the enhanced treatment groups (although less CBT patients) visiting their PCP on a regular basis. As expected, more CAU patients visited their PCP in the first three months.

We conclude that no significant differences emerged in findings regarding the three possible mediators in the comparisons between the main treatments, CAU and DRP-Program. Regarding the two additional interventions by mental health specialists, we found patients in the PC+DRP treatment group to be more constant in the use of antidepressant medication and in staying in touch with their PCP, compared with patients in the CBT + DRP group.

Strengths and limitations

The main strength of this study is that it is a pragmatic type trial, in which different depression treatments are examined over time and under conditions that come close to real life practice. Patient inclusion criteria were relatively broad and we included depressed patients typically seen and treated in primary care. Randomization proved successful, with similar baseline characteristics of patients in all four arms. The main intervention proved to be feasible and was well received, as shown by the high participation and compliance rates in the first year.

Last but certainly not least, response rates for the follow-up research assessments reported here were good.

As to limitations, selection of the PCPs was not random. They were responsible for the initial patient selection and there were considerable differences between PCPs in the number of patient referred to the study. Finally, it was not possible to blind interviewers from treatment status of the participants.

Conclusion

Based on the experiences with the enhanced treatment program described in this paper, we conclude that it is feasible to integrate a structured follow-up and outreach program delivered (in part) by telephone and by others than the PCP in primary care depression management. Whether the DRP-Program is successful in terms of improving the (long term) course and outcome of depression, is the next question that needs to be answered. We hope to find out more about the clinical value of the DRP-program after analyzing the data from the trial and plan to report on this in the near future.