

A randomized controlled trial of the use of self-help materials in addition to standard general practice treatment of depression compared to standard treatment alone

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ABSTRACT

Background. The purpose of the study was to examine whether the addition of a brief individual self-help package to standard primary-care treatment of depression with antidepressants is associated with any additional improvements in clinical outcome.

Method. Individuals with major depressive disorder who were prescribed an antidepressant were recruited through their general practitioner (GP) and allocated randomly to standard treatment alone or standard treatment plus self-help. Assessments of symptoms, social adjustment, global functioning, satisfaction with treatment and knowledge about the management of the disorder were completed at three time points over 26 weeks.

Results. One hundred and twelve individuals agreed to participate and 96 met criteria for inclusion in the randomized controlled trial. Subjects in both treatment conditions improved substantially over the study period; the mean Beck Depression Inventory (BDI) score fell from 27.3 to 13.9 in the intention-to-treat analysis. There were no between group differences in outcome on any of the primary outcome measures, nor did these approach even marginal significance. Patients and GPs were highly satisfied with the self-help programme, and the intervention as compared to the control group reported significantly greater improvements in knowledge about depression and satisfaction with information received about depression.

Conclusions. An individualized self-help package improved perceived knowledge about depression but did not have identifiable effects on outcome when offered to patients treated in primary care. The study was sufficiently well powered to detect relatively small effects.

INTRODUCTION

Depression is a major public health problem (Greenberg *et al.* 1993). About 6% of the population meet the criteria for major depressive disorder (MDD) or dysthymia at any time, and 20% of those with MDD will have symptoms

that persist beyond 2 years (Keller *et al.* 1992). The disorder is highly recurrent; 30% of individuals experience a relapse within 3 months of recovery and (in the absence of continuation or maintenance treatment) 50% experience a further episode within 2 years. In the National Health Service, the cost of treating depression (£887 million) exceeds the cost of treating both hypertension (£439 million) and diabetes (£300 million) (Department of Health, 1996*a*).

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However, the direct health-care costs are dwarfed by the indirect costs (Berndt *et al.* 2000; Scott & Dickey, 2003). Days lost from work due to depression exceed all other disorders and the economic burden on family members and society is considerable (Broadhead *et al.* 1990). As the burden of depression has become clearer, the emphasis in care options has shifted in two respects. First, there has been a shift from purely biological treatments to an increased acceptance of psychological therapies or combination treatments. Second, as 90% of individuals with depression are treated in primary care, there has been an increasing awareness of the need to develop time-efficient, clinically effective strategies for clinical management that can be delivered in a sustained way in general practice settings. These views are clearly articulated in the Department of Health (1996*b*) report on psychotherapy:

Recommendation 1.7: To be cost effective, psychotherapeutic intervention should be at the least complex, costly and intrusive level consistent with effective treatment. First presentations of depression or anxiety should be treated in primary care using low cost psychological interventions in addition to physical treatment.

The efficacy of both antidepressant medication and cognitive therapy in the treatment of acute MDD is now well established (Scott, 2001). There is also evidence that their combination is better than either treatment alone (e.g. Thase *et al.* 1997). The main problem with the medication-only approach is non-adherence to treatment. This may arise as a consequence of intolerable side-effects, a misunderstanding of need to continue treatment when symptoms subside, or negative attitudes and beliefs about antidepressants (Scott *et al.* 2002). However, few studies have been carried out in primary care, and in general practice it can be difficult to access non-drug alternatives such as cognitive therapy due to a shortage of trained therapists. Recent developments in psychological treatments suggest that, for some patients, detailed self-help manuals may be a viable alternative to therapist sessions. These are being used increasingly, although the evidence base supporting their use is very limited (National Institute for Clinical Excellence, 2002). Much of the research in this field has been carried out in anxiety disorders (Bower *et al.* 2001), where a

feature of the problem is the active seeking of reassurance and other information. In depression there are usually difficulties with concentration and motivation, which mean that lengthy and detailed self-help manuals are of limited usefulness. As such, there appeared to be a role for a package of self-help material that is brief, practical and relevant to the specific needs of each individual patient.

This paper describes a randomized controlled trial of the primary-care treatment of MDD using standard antidepressant treatment alone or standard antidepressant treatment plus an individually tailored package of self-help materials (the 'CarePartners' programme) designed to improve adherence, decrease treatment drop-out and teach simple self-help strategies.

METHOD

The project received full ethical approval from the Oxford Psychiatric Research Ethics Committee (OPREC). Subjects were recruited from 46 general practices that could be regarded as broadly representative of Oxford City and county. The general practitioners (GPs) identified subjects who met the following criteria: (a) their main identified problem was depressive disorder; and (b) they had recently been prescribed antidepressant medication for that depression, (c) were able to give informed consent and (d) were aged 17–70 years. Subjects were excluded if they had (a) difficulty reading English, (b) a severe (life-threatening) medical illness, (c) current or past history of psychosis or bipolar disorder, (d) current alcohol or substance dependency, and (e) been taking antidepressants for longer than 4 weeks at the time of assessment interview. With verbal consent, the GP then gave the subject an envelope that contained an explanatory letter (information sheet), a written informed consent form, three self-rated questionnaires (see below) and a stamped addressed envelope. Both the information sheet and the consent form made it clear that participation in the study was voluntary, and that refusal to participate or later withdrawal from the study would have no influence on the patient's treatment.

Three self-report measures were used at enrolment, during acute treatment, end of treatment and follow-up. The first of these was the

depression rating scale used in the programme itself (the CarePartners Scale); this includes 17 items rated on a five-point Likert scale (from 'none of the time' to 'all of the time' with a referent of 'During the past 7 days ...'). Standardized measures were the Beck Depression Inventory (BDI; Beck *et al.* 1961) and a series of global ratings each made on a 0–8 scale. The latter included the Patient Global Improvement (PGI) rating (Guy, 1976) and ratings of the global impact of depression on the person, interference with their life, ability to work; home management; social leisure activities; private leisure activities; and relationship with their partner/spouse (Mundt *et al.* 2002).

Individuals who returned the consent form and questionnaires were contacted to arrange a meeting at their preferred venue (home or GP surgery) within 4 days. After re-establishing informed consent, a post-doctoral research fellow undertook an assessment interview using the mood disorders and substance use disorder modules of the Structured Clinical Interview for DSM-IV (SCID; First *et al.* 1997) and the subject completed the BDI. Patients meeting criteria for MDD and with a BDI score of 10 or more were then allocated randomly, using sampling without replacement, to either standard treatment (i.e. the antidepressant that they had been prescribed and any other interventions the primary-care team chose to provide) or to standard treatment plus the self-help package. Randomization was carried out independently using sealed envelopes prepared using random number tables. Groups were stratified according to gender.

Subsequent research tracking of any patients who opted into the study was by the post-doctoral research fellow so that there was no further requirement for direct involvement by the GP. GPs were sent copies of the results of the questionnaire for information. (GPs of patients in the control condition were not sent further questionnaire results; this was only done in the intervention group.) If the patient was not suitable for the study, they were sent a letter indicating that the treatment being offered would not be appropriate for their problems. A letter was also sent to the GP specifying why the patient was not being included.

At the end of the study (26 weeks), the researcher-administered SCID interview and

the patient self-report measures were repeated along with ratings of patient satisfaction with the treatment they received and benefits of treatment (e.g. gain in knowledge of depression, understanding of how to cope with symptoms or change unhelpful patterns of behaviour). These ratings were made on a questionnaire designed for this purpose, using four-point scales with a general referent. GPs also completed ratings of their views of the patient's improvement and the GPs' satisfaction with the self-help package.

The self-help programme

The self-help programme was administered by a third-party data management organization that managed the computer algorithm and patient and GP information. This organization received patient questionnaires intrinsic to the treatment package, and sent out letters, reports and booklets to patients and GPs. They administered all aspects of the self-help programme separately from the research team, who were informed of patient progress through the programme, but did not influence it in any way. Detailed safeguards relating to confidentiality and possible clinical problems were put in place; in the case of clinical issues arising, information was passed directly to the patient's GP.

The production of the programme and the day-to-day running of the algorithm were undertaken by staff employed on the CarePartners project. This was an open pilot programme offering self-help materials to patients with depression through their GP, similar to a North American programme (Beusterien *et al.* 2000) that was also sponsored by Eli Lilly. However, there was no requirement that subjects in the study or the pilot programme would be treated with any specific antidepressants and the company played no role in the selection of practices, patients or the content of the self-help material. Experts in depression, with experience of producing written materials for patients, identified key topics for inclusion and co-authored the modules that were incorporated in the booklets (P.S. and J.S.).

The brevity and personal relevance of the material sent to each subject were ensured by using a computer algorithm to design a sequence of short individually tailored workbooks on the basis of information provided in the

CarePartners Depression questionnaire completed on enrolment to the programme and at subsequent assessments. For each workbook, the algorithm generated a list of the main concerns expressed by a particular individual (high scoring items or subsets of items on the questionnaire), which triggered the selection of the relevant modules, in addition to standardized information, which was designed to inform the patient about key aspects of depression, its effects and treatment. In some instances (e.g. side-effects from medication) the workbook indicated to the patient that they should discuss the issue with their GP, and indicated that this information had been incorporated into the information sent to the GP. The written modules focused on information designed to improve patients' understanding of symptoms and problems commonly experienced by people with depression. For example, one module described current theories of depression and how these might explain symptoms experienced by the patient, another addressed common concerns about the use of medication, duration of treatment and side-effects, and another dealt with problem-solving difficulties. The other topics were low activity levels, difficulties in coping with stress, low self-esteem, relationship difficulties and hopelessness and suicidal ideation. These were each dealt with in a 3- to 6-page booklet. Each booklet had a main theme, and the format comprised a mixture of brief paragraphs of key information, simple questions to help the individual explore their own symptoms, ideas or situation, and sections where they could note down questions to ask their GP at the next visit. Most individuals received about six modules over the course of the study. In addition, each patient could request up to three additional (standardized) booklets on topics such as exercise and diet (from a total of six). The six topics were: stress and anxiety, seven steps to coping, coping with things you can control, solving problems, increasing your activity level can make you feel better and building low self-esteem.

In addition to triggering the sending of individualized self-help and educational materials, the patient-completed questionnaires were also used to produce a report for the GP, who was informed of the patient's progress (or lack of progress) and any concerns the patient had

indicated (e.g. worries about side-effects). These reports were only sent for the intervention group.

Statistical analyses

The power analysis for this study was conducted on the basis that a bare minimum difference (in terms of clinical significance) would be a two-point difference on the BDI. For an α value of 0.05 and with a power of 85%, cell sizes of 38 would be required. The main analysis used was repeated measures analysis of covariance (ANCOVA) of (i) depression measures and (ii) global impairment measures, with subsequent ANCOVAs on single variables. All variance analyses were checked for homogeneity of variances, and the Greenhouse–Geisser coefficient was used to correct for autocorrelation. Non-parametric analyses such as Pearson-corrected χ^2 , Fisher's exact and Mann–Whitney U tests were used as appropriate.

RESULTS

One hundred and twelve patients were interviewed and found suitable for the trial ($n=96$). Thirty-eight (eight male, 30 female) completed the standard treatment plus self-help arm of the study while 12 dropped out, and 39 (six male, 33 female) completed the standard treatment alone arm while seven dropped out (see Fig. 1 for CONSORT numbers).

There were no significant differences between groups in gender distribution [$\chi^2(1 \text{ df})=0.21$, $p>0.6$] or mean ages [$t(85)=0.4$, $p>0.6$]. Initial depression levels were in the moderate to severe range for both groups with mean scores on the BDI of 27.5 (s.d.=9.8) for standard treatment plus self-help and 27.1 (s.d.=10.5) for standard treatment alone.

Both groups improved significantly over time on all depression measures. The mean BDI score for the sample as a whole fell by approximately 14 points from 27 at baseline to 13 at the 26-week follow-up (see Table 1). On all key planned comparisons there were no significant group differences and no trends towards significance. Parametric analyses were carried out on the basis of analyses of covariance, with the acute (4-week), continuation (12-week) and follow-up (26-week) phases as the dependent variables,

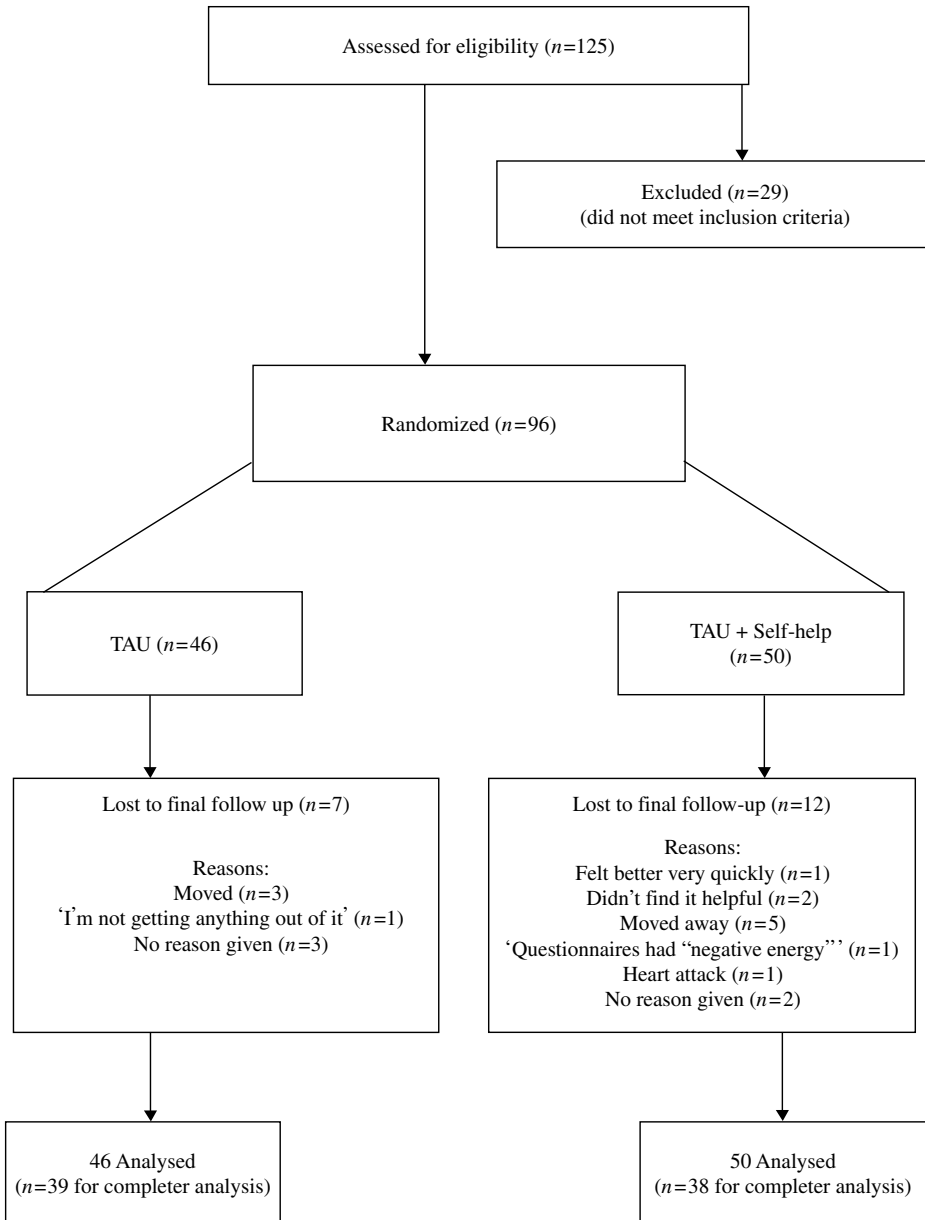


FIG. 1. CONSORT diagram for the study. TAU, Treatment as usual.

and initial scores as the covariate. With this type of analysis, a significant main effect would indicate a difference between standard treatment plus self-help and standard treatment alone. A significant interaction would indicate differential response to treatment beyond the acute stage

measure. For the BDI, there was no significant main effect ($F < 1$) or interaction [$F(2, 93) = 1.0$, $p > 0.5$]. Global ratings of depression as a problem and ratings of interference with life showed neither significant main effect of groups nor interactions (all F 's < 1). The PGI rating is

Table 1. Means and standard deviations for demographic characteristics and main outcome variables

	Intention-to-treat		Per-protocol	
	TAU	Self-help + TAU	TAU	Self-help + TAU
Gender: number and % female	41/50 (83.0%)	36/46 (78.3%)	33/39 (84.6%)	30/38 (78.9%)
Age, mean (s.d.)	40.2 (11.9)	39.2 (13.3)	40.3 (11.7)	39.8 (13.1)
Number of previous episodes of depression (data available for 30 TAU and 37 self-help + TAU)	1.5 (1.6)	1.7 (1.6)	1.5 (1.6)	1.8 (1.7)
Number with at least one previous episode of depression (where data available)	22/31 (71%)	27/37 (73%)	21/30 (70.0%)	24/33 (72.7%)
Beck Depression Inventory, mean (s.d.)				
Baseline	27.1 (10.5)	27.5 (9.8)	25.6 (9.6)	27.7 (9.9)
Four weeks	21.2 (12.5)	21.6 (12.2)	19.0 (10.4)	21.5 (11.3)
Twelve weeks	14.9 (11.0)	15.1 (10.9)	12.3 (7.6)	13.5 (9.0)
Six-month follow-up	14.3 (12.5)	12.6 (9.6)	11.6 (9.9)	11.3 (8.4)
'How much of a problem has depression been generally?'				
Baseline	5.4 (1.5)	5.1 (1.7)	5.1 (1.3)	5.0 (1.6)
Four weeks	4.4 (1.9)	3.9 (2.1)	5.2 (1.7)	3.7 (2.0)
Twelve weeks	3.0 (2.2)	2.6 (2.0)	2.4 (1.8)	2.3 (1.6)
Six-month follow-up	2.6 (2.2)	2.2 (2.0)	1.9 (1.6)	1.8 (1.7)
'How much has depression interfered with your life?'				
Baseline	5.5 (1.6)	5.2 (1.9)	5.2 (2.0)	5.2 (1.5)
Four weeks	4.7 (2.1)	4.1 (2.2)	4.4 (2.0)	4.1 (2.0)
Twelve weeks	2.8 (2.4)	2.8 (2.4)	2.4 (1.9)	2.4 (2.2)
Six-month follow-up	2.7 (2.3)	2.4 (2.1)	2.1 (1.9)	1.9 (1.8)
Patient-rated global improvement				
Acute treatment (4 weeks)	2.0 (1.1)	1.8 (1.1)	1.9 (1.2)	1.8 (1.0)
Twelve weeks	1.2 (1.0)	0.9 (0.9)	1.1 (1.0)	0.9 (0.9)
Six-month follow-up	1.0 (0.8)	1.0 (0.8)	0.9 (0.8)	0.9 (0.9)

TAU, Treatment as usual.

essentially a change score measured at the three post-treatment points, so covariance was not used. However, there was neither a significant main effect nor interaction (F 's < 1). When these analyses were repeated for only the participants who completed the study, the same pattern of results was found. Because of the possibility of type II errors (i.e. missing potential group differences by using the more stringent intention-to-treat analyses), only the per-protocol analyses were carried out for the rest of the variables.

The above were the main outcome variables in terms of psychopathology and ratings of improvement; none of the remaining variables showed a significant main effect of treatment or treatment \times time interactions. Exploratory analyses were carried out dividing patients into low- and high-severity groups but there was no

hint of any interaction of this type on the main outcome variables.

Medication adherence

There was no significant difference between groups in terms of length of time medication was taken [mean for standard treatment plus self-help was 32.3 weeks *v.* 28.8 weeks for treatment as usual; $t(57) = 1.3$, $p > 0.2$].

Patient and GP satisfaction ratings

Analysis of the patients' ratings of satisfaction with the self-help package indicated high levels of satisfaction with their treatment (68% very or extremely satisfied *v.* 62% in the treatment-as-usual group). They regarded it as easy to use and highly relevant to their problems, and also rated it as improving communication with their

GP. These data were 95% complete. Ratings by GPs were only 60% complete. However, these also indicated a high level of satisfaction with the self-help package and the majority (62%) of GPs reported finding the programme useful. None of these differences was significant.

Patient knowledge and understanding

There were significant between-group differences, favouring the intervention group, in improvement in knowledge due to treatment (Mann–Whitney U test, $p=0.004$) and in perceptions that enough information was provided about depression [34 v. 23 patients; $\chi^2(1)=10.97$, $p=0.001$], enough information was provided about making life changes [31 v. 18 patients; $\chi^2(1)=11.74$, $p=0.001$] and a similar trend for information about the effects of medication ($p=0.07$). In the intervention group, 86% reported reading all the booklets received, 22% read them several times, 50% said they discussed the contents with others and 33% reported that their partner read the booklets as well.

DISCUSSION

Our findings indicate that the individualized self-help package did not have any identifiable beneficial effects on trajectory of improvement, symptom change, medication adherence, social adjustment or self-reported global functioning in patients with MDD treated in primary care. All participants substantially improved over the study period, regardless of treatment condition. Furthermore, the study was sufficiently well powered to detect small differential effects, suggesting that this was a true negative finding at least in terms of the clinical significance of the intervention. However, significant differences were obtained in self-rated improvement in knowledge and the perception that patients had received sufficient information about both depression and making life changes.

It is possible that an atypical sample was recruited and that this accounts for the lack of an effect. Only about one in ten of the questionnaires distributed to GPs were returned to the researchers. This may have been because GPs failed to give the envelopes to patients.

However, intensive investigation of two practices suggests that the questionnaires were being distributed but were not being returned by the patients. It could be argued that including the information sheet and consent form in the recruiting material but delaying the provision of a detailed description of the self-help programme until the research interview may have resulted in a lower rate of recruitment than would otherwise have been the case. However, information from the national (non-study) project using the CarePartners programme in GP practices across the UK found a level of uptake considerably lower than predicted. Another possibility is that the introduction of the self-help package to a particular GP surgery might have resulted in changes in the doctors' behaviour. A cluster randomization procedure would deal with this issue, although it would introduce a different set of methodological problems.

Alternatively, it is possible that the lack of any between-group differences in outcome was a consequence of an above-average quality of care being offered to depressed patients by the practices participating in this research. Scott *et al.* (2002) have recently highlighted that a greater overall improvement in depression outcomes might only be achieved if we target disadvantaged practices (with lower levels of staffing, smaller multi-disciplinary mix, serving more socially deprived populations, etc.) that do not usually participate in research rather than practices that are already providing a high quality of care and/or have a greater capacity to institute good practice guidelines. In struggling practices, it can be postulated that a self-help package might have a more overt role because it might compensate for any gaps in the care provided. However, if the day-to-day clinical management of depression is of an appropriate standard, we must conclude that there is no direct clinical benefit in providing further packages of support. Verification that the intervention was ineffective would require longer-term follow-up to investigate relapse rates.

The findings reported here are consistent with the trial (in terms of both size and intent) conducted by Peveler *et al.* (1999). In that study, practice nurses were trained to offer advice to patients receiving antidepressant medication

in general practice. The advice was aimed broadly to enhance medication adherence and encourage the use of self-help techniques. No significant differences in outcome were found between the experimental and treatment-as-usual groups. It is noteworthy that our negative results are also in keeping with the current data on the effectiveness of counselling as an adjunct to other treatments for depression. Although counselling is widely available and in high demand by service users and primary-care providers, individual randomized controlled treatment trials and meta-analytic studies clearly demonstrate that there is no specific additional benefit from the use of counselling as an adjunct to standard GP treatment of depression. Compared to treatment as usual, there is only a weak effect on acute and longer-term clinical outcome (Bower *et al.* 2003). Similar considerations apply to findings in self-help and bibliotherapy for anxiety and depression (e.g. Den Boer *et al.* 2004). However, individuals who lack a confidante or other social support find counselling particularly useful and GPs feel that it is important in reducing consultation times. It can be argued that an individualized self-help programme might play a similar role, particularly as it is less costly than providing face-to-face contact with a counsellor. This intervention may be most useful where the patient is keen to acquire greater understanding and knowledge of their problems, to explore additional coping strategies and/or finds having information booklets that they and their partner or significant others can read allows for a greater dialogue about their depression.

In conclusion, this trial indicates that an interactive self-help programme directed at bolstering medication adherence, improving doctor-patient communication and fostering patients' self-help efforts is highly regarded by both GPs and patients, but makes no impact on an individuals' clinical or social outcome at 6 months, relative to standard antidepressant treatment. We also suggest that, in terms of clinical validity, the study obtained a valid negative result rather than our findings being a consequence of any methodological failings. As such, it appears that providing written information that educates individuals about depression and describes simple coping strategies

improves understanding and adjustment but is not an adequate substitute for more active treatment approaches. In the present climate of seeking new ways of disseminating psychological treatments and improving the acceptance of medication in depression, it is important to identify which strategies are ineffective as well as which are effective.

DECLARATION OF INTEREST

Eli Lilly and Company Limited funded the post-doctoral research fellow for the duration of the study (K.R.). D.S. is currently employed by Eli Lilly. P.S. and J.S. received honoraria from Eli Lilly for their work on the development of the CarePartners package.

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