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Process and Outcome of a Non-Guided Self-Help Manual for Anxiety and Depression in Primary Care: A Pilot Study

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Abstract. Self-help interventions in mental health are increasingly seen as one way of overcoming problems with access to psychological therapy, but there is insufficient evidence of effectiveness in routine care settings. This paper investigates the process and outcome of a non-guided self-help manual for anxiety and depression compared to a waiting list control in a primary care setting. Patients with mild to moderate mental health problems were recruited from routine GP referrals to the local Primary Care Mental Health Team. Thirty patients were randomly assigned to either non-guided self-help or a waiting list control group. Patients completed outcome measures at baseline, 6 weeks and 12 weeks. Intention to treat analysis found no significant differences between the two groups on measures of anxiety or depression at 12 weeks. Between 40% to 50% of patients in both groups were no longer clinical cases at the end of the trial. However, there was a high level of satisfaction with the self-help manual. Within the limitations of the small sample size, the study does not support the hypothesis that non-guided self-help is superior to waiting list control in the treatment of anxiety and/or depression in primary care.

Keywords: Self-help, anxiety, depression, primary care, non-guided.

Introduction

Common mental health problems, such as anxiety and depression, are prevalent in primary care and account for up to one-quarter of all General Practitioner (GP) consultations (Goldberg and Bridges, 1987; Department of Health, 2000). Since only 10% of those presenting to the GP are referred onto specialist mental health services, most are treated in primary care (NICE, 2002). Although medication is accessible and effective, many patients want psychological treatments (Priest, Vize, Roberts, Roberts and Tylee, 1996).

Cognitive Behaviour Therapy (CBT) is a psychological therapy, which has robust evidence of effectiveness and is recommended as the treatment of choice in the treatment of common mental health problems (Department of Health, 2001). However, access to CBT is limited

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due to a lack of appropriately trained therapists and the adoption of traditional outpatient models of service provision, i.e. six to twelve one-hour appointments delivered between the hours of 9.00 am to 5.00 pm (Lovell and Richards, 2000). Current Government policy on mental health in primary care is exemplified by standards two and three of the NSF for mental health (Department of Health, 1999), which focus specifically on improving access to evidence-based psychological treatment in primary care. In order to meet these standards, service providers will need to consider alternative delivery systems. Self-help manuals based on the CBT approach offer one potential solution to bridging the gap between demand and supply (Lovell and Richards, 2000), but their wider adoption depends on rigorous evidence of effectiveness in routine settings.

A recent report identified seven meta-analyses or systematic reviews of self-help interventions for mental health problems (Lewis et al., 2003). Although broadly supportive of self-help, many of these reviews (and the trials on which they are based) are methodologically flawed and many of the studies have been carried out in other settings, which makes it unclear whether the results will generalize to the UK setting. Furthermore, there is significant variation in the nature of self-help treatments that have been evaluated, and it is important for the manuals that are actually being used in clinical practice to be evaluated. Many of the manuals used in research trials are produced for the research only and are not the same as the ones more readily available to the general population (Scogin, Bynum, Stephens and Calhoon, 1990; Lewis et al., 2003).

Aims and hypotheses

The main hypothesis of this study was that patients on a waiting list for psychological therapy services who were given a self-help manual would demonstrate superior outcomes in depression and anxiety compared to patients who remained on the waiting list without the manual. The study also examined the process of self-help, in terms of whether patients read the material, which elements they found most useful, and their overall satisfaction. Finally, the study aimed to generate data to be used to conduct a power calculation should a definitive trial be indicated.

Methods

Research design

The study was a pilot randomized controlled trial. The two conditions were non-guided self-help and waiting list control. Outcome measures were taken at baseline and repeated at 6 weeks and 12 weeks.

Sample size

A target sample of 30 was set, which was feasible within the resources available to the current project and sufficient to provide adequate quantitative data to compare outcomes in the groups and obtain an indication of possible effect size estimates for a definitive trial.

Ethical approval

Ethical approval for the study was obtained from the Local Research Ethics Committee and the local NHS Trust.

Table 1. Trial inclusion and exclusion criteria

Inclusion criteria:
Meet referral criteria of PCMHT (age 16+, mild to moderate problems, not actively suicidal, not primary diagnosis of substance misuse)
Mild to moderate anxiety and/or depression, as assessed by a score of between 8 and 14 on either anxiety or depression sub-scale of HADS
Exclusion criteria:
Unable to complete questionnaires owing to language difficulties, illiteracy or learning disability

Recruitment

Patients were recruited from routine GP referrals to Warrington Primary Care Mental Health Team (PCMHT). As per routine practice, all referrals to the PCMHT were sent a Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983) and a stamped addressed envelope to return as part of an opt-in procedure. The opt-in procedure establishes that the patient requests further contact from the service and if patients do not return the opt-in information they are discharged back to the care of the GP.

The principle investigator scored all HADS, and patients who met the criteria for mild to moderate anxiety and/or depression (Snaith and Zigmond, 1994) were sent information on the study and asked to contact the PCMHT if they were interested in participating. Patients who did respond received a 60-minute face-to-face assessment by the principle investigator to ensure they met the rest of the inclusion criteria for the study (see Table 1). Six hundred and six patients were referred to the service during the 4-month trial period (July to October 2002) of which 362 (60%) did opt in. Of those patients who opted-in, 130 (36%) met the inclusion criteria, of which 32 (25%) agreed to participate and were subsequently assessed. Thirty patients (5% of total number referred) were eventually recruited to the study (see Figure 1 for patient flow through study).

Randomization

The 30 patients were randomly allocated to one of two groups, self-help intervention ($n = 15$) or waiting list control ($n = 15$). Randomization was conducted using sealed plain opaque envelopes inside 15 of which was a slip of paper stating "control group", whilst the other 15 contained a slip stating "experimental group". All the envelopes were equal in terms of size, design and weight.

The 30 envelopes were then mixed up and given to the administrator of the Primary Care Mental Health Team, who randomly slotted an envelope into each of the 30 consecutively numbered study packs. The packs were then allocated by the principle investigator to patients in the order in which patients could attend for assessment.

Assessment

The assessment was conducted by the principle investigator and was either conducted in the patient's own home or GP surgery. The assessment lasted no more than one-hour and involved an assessment of current problems and treatment, a risk assessment, and second HADS questionnaire. The second HADS was completed at this stage to confirm the patient

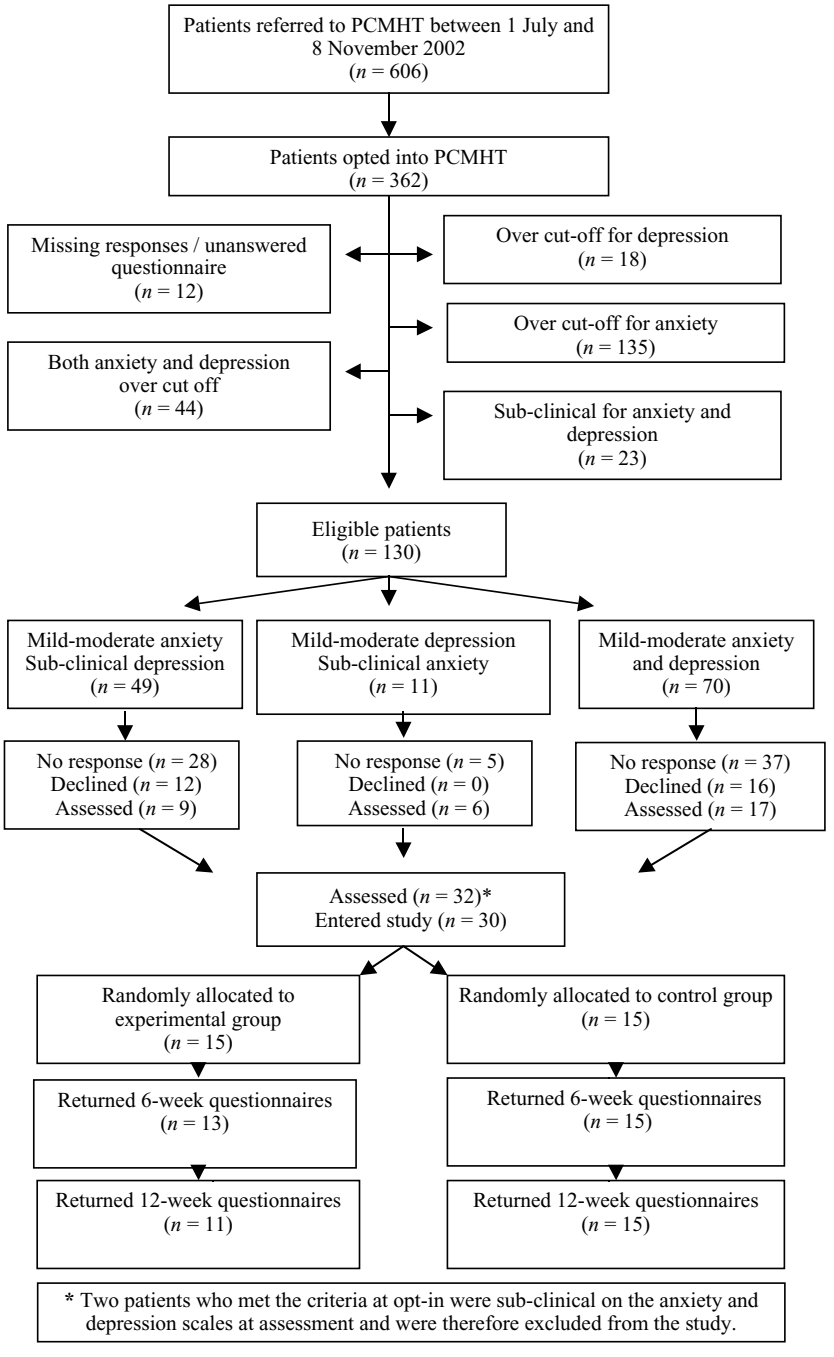

Figure 1. Progression of patients through the study

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still met the inclusion criteria for the study. This was necessary as several weeks may have passed between the patient completing and returning the initial HADS with the opt-in and the date on which the patient could attend for assessment. At the end of the assessment, patients were informed as to whether they still met the inclusion criteria. If the patients did still meet the criteria, they were given an explanation of the study, any questions were answered and they were asked to complete the consent form and a questionnaire detailing patient demographic details, including previous mental health problems and treatment. Whilst the patient was completing the forms, the principle investigator opened the sealed envelope and once the forms were completed, the patient was informed of which study group they were assigned to. Two patients did not meet the inclusion criteria and were offered treatment as usual with the local psychological therapy service.

Treatment conditions

Those patients assigned to the treatment group were then given the self-help manual, *A Handy Guide to Managing Depression and Anxiety: what should I do?* (Kennedy and Lovell, 2002). The manual is pocket sized and has two distinct parts. Part one gives general advice about lifestyle, professional help and treatments available for anxiety and depression. Part two uses cognitive behavioural techniques to help the reader identify and change the thoughts and behaviours that lead to negative emotional states. This second part helps the reader to recognize thoughts, physical symptoms and behaviour and also to identify problems and set goals. The second part also teaches self-help interventions such as behavioural activation, relaxation, problem solving, exposure and cognitive therapy. The self-help manual was developed by clinicians and researchers from the University of Manchester, in consultation with service users, and has been piloted in an uncontrolled evaluation of a self-help clinic (Lovell, Richards and Bower, 2003) and is currently also being tested in a larger randomized trial.

The patients were given a brief description of the book and advised to read it at their own pace. The control group were informed that on receipt of their final questionnaires they would be sent a copy of the manual.

Outcome measures

Outcome measures were completed at baseline (week 0), week 6 and week 12. The outcome measures used were:

a) Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983). The HADS was used as the primary outcome measure and is a 14-item self-completion questionnaire, combining two sub-sections, designed to detect the presence and severity of anxiety and depression independently. Each sub-section scores 0–21 and provides an overall severity score, which characterizes patients as follows: non-cases (0–7); mild cases (8–10); moderate cases (11–14), or severe cases (15–21). The tool is intended both as a screening tool and to chart progress over time and, although originally designed for non-psychiatric hospital outpatient settings, it has been widely used in community and primary care settings (Wilkin, Hallam and Doggett, 1992).

b) Clinical Outcomes in Routine Evaluation (CORE) (CORE System Group, 1998). A 34-item self-completion questionnaire designed to assess the clinical domains of subjective

well-being, symptoms (including anxiety, depression, trauma and physical symptoms), functioning (including close relations, social relations, and life functioning) and risk. Although scores can be reported for each domain, the total score was used in the present study. This is a relatively new tool, which is frequently used in primary care psychotherapy services (Mellor-Clark, Connell, Barkham and Cummins, 2001).

Patients in the intervention group also completed a process/satisfaction questionnaire (available from the author) at week 6 and week 12.

Analysis methods

Conventional statistical analyses were conducted, although the small sample size meant that they would have sufficient power to detect only very large effects. Therefore, a standardized effect size was also calculated, in order to allow the results in the present study to be compared with previous studies and meta-analyses.

All data were entered into the computer software package, SPSS Release 11.5. The main analysis used an independent samples *t*-test to detect significant differences between the intervention group and the control group on week 12 scores using intention-to-treat analysis, with missing data replaced by last observation carried forward (LOCF). Therefore, data collected at weeks 0 or 6 were used in the analyses when data at week 12 were not available.

Reliable and Clinically Significant Change (RCSC) analysis was also conducted as it is clinically relevant and is easier for both patients and clinicians to understand. RCSC concerns the evaluation of change between two time points for each person, taking into account the relationship of the individual change scores to pre-treatment sample scores and the psychometric reliability of the outcome measure (Evans et al., 2000). To determine RCSC, mean scores at pre and post were entered into the computer package CORE-PC, which then reported RCSC results for each patient for which pre and post data were available. These categorical data were then entered into SPSS, and significant differences between groups were then checked using the Fisher's exact test. The Fisher's exact test was used as there were numbers less than 5 in one or more of the cells on the chi-squared test and this test always give an exact rather than an approximate *P* value.

Finally, the process of and satisfaction with the self-help intervention were measured by calculating the percentage of patients who read each part of the manual and the level of satisfaction with each part.

Results

Baseline characteristics

There were no large differences in baseline characteristics between patients in the two groups (Table 2).

Loss-to-follow-up

At the end of the trial, four patients in the intervention group were considered lost-to-follow-up. The two significant differences found between completers and those lost-to-follow-up were (1) age, which was higher in the latter group (t, -3.62; df, 28; $p = .001$), and (2) CORE total score, which was also higher (t, 2.74; df, 28, $p = .011$). Baseline depression scores on the

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Table 2. Baseline characteristics

Characteristic	Control $n = 15$ Mean (*SD*)	Experimental $n = 15$ Mean (*SD*)	Overall sample $n = 30$ Mean (*SD*)
Age in years	37.7 (10.1)	39.5 (13.28)	39 (11.6)
Range	16–61	21–70	16–70
Pre HADS			
Anxiety	10.3 (2.19)	9.9 (2.25)	10.1 (2.41)
Depression	7.9 (3.00)	8.9 (2.19)	8.4 (2.63)
Pre CORE			
Total score	50.8 (17.27)	52.3 (16.84)	51.57 (16.78)
Well-being	9.1 (3.17)	9.1 (3.49)	9.07 (3.28)
Problems	21.5 (6.90)	22.8 (8.08)	22.10 (7.41)
Functioning	18.9 (6.96)	19.3 (6.17)	19.10 (6.47)
Risk	1.5 (2.10)	1.1 (1.92)	1.30 (1.99)
	n (%)	*n* (%)	*n* (%)
Gender			
Male	4 (27%)	3 (20%)	7 (23%)
Female	11 (73%)	12 (80%)	23 (77%)
Marital status:			
Single	2 (13%)	3 (20%)	5 (17%)
Married	10 (67%)	7 (47%)	17 (57%)
Separated/divorced/widowed	3 (20%)	5 (33%)	8 (27%)
Ethnicity			
White	15 (100%)	15 (100%)	30 (100%)
Education			
No qualifications	1 (7%)	1 (7%)	2 (7%)
Less than degree	12 (80%)	12 (80%)	24 (80%)
Degree or higher	2 (13%)	2 (13%)	4 (13%)
Employment status			
Employed	12 (80%)	12 (80%)	24 (80%)
Unemployed	3 (20%)	3 (20%)	6 (20%)
In receipt of benefits			
No	12 (80%)	13 (87%)	25 (83%)
Yes	3 (20%)	2 (13%)	5 (17%)
Accommodation style			
Rented	4 (27%)	5 (33%)	9 (30%)
Home owner	11 (73%)	10 (67%)	21 (70%)
Previous mental health contact			
No	10 (67%)	13 (87%)	23 (77%)
Yes	5 (33%)	2 (13%)	7 (23%)

HADS almost reached significance (t, -2.02; df, 28; $p = .054$), the scores again being higher in those lost-to-follow-up.

Main analyses

Table 3 shows the results of the independent t-test analyses used to test for significant differences on the end of trial outcome measures between the intervention and control

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Table 3. Statistical analyses comparing the outcome measure scores of the two groups

Outcome Measure	Control group Mean (*SD*)	Experimental group Mean (*SD*)	95% confidence interval of the difference	*T*	*df*	*p* value	Cohen's *d*
Post HADS Anxiety*	8.47 (3.34)	8.13 (3.11)	−2.75 to 2.08	−.28	28	.779	0.12
Post HADS depression*	6.27 (2.99)	7.47 (3.85)	−1.38 to 3.78	.95	28	.349	−0.35
Post CORE** Total	35.53 (19.70)	37.47 (18.36)	−12.31 to 16.18	.28	28	.783	N/A

* Range, 0–21 (high scores indicate dysfunction).
** Range 0–136 (high scores indicate dysfunction).
N/A = Not applicable in this study.

Table 4. Reliable and clinically significant change data based on CORE outcome measure scores

Change	Control $n = 15$	Experimental $n = 13$[a]
Reliable and clinically significant change*	6 (40%)	6 (46%)
Reliable change only**	2 (13%)	0 (0%)
Clinical change only***	1 (7%)	2 (15%)
No reliable change****	6 (40%)	5 (39%)

[a] Does not include the two patients lost-to-follow-up who did not return the CORE at week 6 or at week 12.
* Change that is both reliable (statistically significant) and clinically significant (changed from a clinical to a non-clinical population).
** Change that is statistically significant (i.e. unlikely to be due to measurement error).
*** Change that is clinically significant but not statistically significant.
**** Change that is either non-reliable improvement or non-reliable deterioration.

groups. No statistically significant differences were found between the two groups at end of treatment on any of the outcome measures. As it was not clear whether the data met all the requirements for a parametric test, a Mann Whitney test was also conducted, which also showed no statistically significant differences.

Reliable and clinically significant change (RCSC)

Table 4 summarizes the RCSC data for the intervention and control group based on the CORE outcome measure scores. No significant differences between the two groups were found.

Effect size

The computer program Meta 5.3 was used to calculate the unbiased effect size *d*, which is based on the difference in the means of the two groups divided by their pooled standard deviation. The effect size on the HADS was −0.35 for depression (favouring the control group) and 0.12 for anxiety (favouring the intervention group). Cohen (1988) described effect sizes of 0.2 as a "small" effect, 0.5 as a "medium" effect and 0.8 as a "large" effect.

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Process/satisfaction

Process/satisfaction data were collected from the experimental group. There was a high level of satisfaction with the self-help, with all parts of the book being rated as useful or highly useful by over 50% of the patients (except for "evaluating your progress" for which several patients gave feedback that 12 weeks was too soon to evaluate progress). Patients recorded particularly high levels of satisfaction with the "recognizing problems and coping strategies", "helping yourself" and "help from other people" (89%, 78% and 78% respectively) sections in part one of the book. In the second part of the book, which contained more CBT specific interventions, high levels of satisfaction were found for "recognizing thoughts, symptoms and behaviour", "identifying problems and goals", and "relaxation" (89%, 78% and 78% respectively). Most patients reported that they had read most parts of the book, with only one person not reading seven sections of the book and two not reading one section.

Discussion

The results suggested that there was no benefit for patients in receiving the self-help manual in terms of reducing severity of anxiety and/or depression. Little difference between the self-help intervention group and the control group is observed for RCSC. The effect size for anxiety was very modest, and that for depression favoured the control group. However, there is a risk of a Type II error given the small sample size as this makes the confidence interval wider and much more likely to overlap zero. In addition, the risk of this error occurring is magnified given that only 5% of the total number of referrals to the Primary Care Mental Health Team actually took part in the trial. Despite this, the study did find that the self-help intervention was acceptable to patients, who reported adhering to the intervention and being satisfied with it especially in terms of identification of problems and setting goals.

The negative outcome of the study is not consistent with other trials of non-facilitated self-help. In fact, the effect sizes are different from the overall effect size of 0.41, which was found in a systematic review that included a number of non-facilitated self-help interventions (Bower, Richards and Lovell, 2001). Such lack of effectiveness does not reflect low compliance, however, as patients reported that they used the manual and were satisfied with it. The interpretation of this finding raises a number of issues that are discussed below.

Patient population

The study looked at a very small number of patients with very mild symptoms of anxiety and/or depression. Interestingly, 40% of patients in the control group, despite not receiving the self-help manual, had made reliable and clinically significant change. A similar improvement was also observed in the group mean where pre anxiety was 10.3 and post was 8.47 and the pre depression of 7.9 reduced to 6.27 post study. This finding supports previous literature, which suggests that many common mental problems are self-limiting (Goldberg and Huxley, 1992).

Use of antidepressant medication was not an exclusion criterion, but data gathered about patient use of antidepressants was incomplete, mainly due to patient recall issues. Future studies should report medication use. Similarly no detailed information was gathered on the nature of the contact that seven of the patients had had previously with mental health services;

this would be an important issue in any future larger trials where sub-analyses would be possible.

Aspects of the intervention

The lack of effectiveness may relate to the design and execution of the intervention. Users were involved in the production of the self-help manual, but it may be that the format of the manual might not have been appropriate and might require alterations, taking into account the issues raised by Holdsworth and colleagues (Holdsworth, Paxton, Seidel, Thomson and Shrubb, 1996). Several patients commented on the size of the book, having expected something more substantial. However, patients did report a high level of satisfaction with self-help as an intervention, especially for the parts of the manual that involved identifying problems and setting goals. Patients in the current study also reported having read a greater percentage of the self-help manual than in previous studies (Glasgow and Rosen, 1978; Heather, Robertson, MacPherson, Allsop and Fulton, 1987). However, self-report may overestimate compliance with self-help material.

Patients did report a lower rate of usefulness for the elements of the book that dealt specifically with cognitive and/or behavioural interventions. This may be because the manual is not aimed towards anxiety or depression specifically and some of the interventions in the manual would not be beneficial to patients with depression and similarly with patients with anxiety. Patients may also have experienced difficulties implementing the interventions, and the use of case vignettes to aid patient understanding with some of the more complicated aspects of therapy may have improved the patient's use of these interventions. Therefore, either the manual may need to be re-written with more of a specific disorder focus or with more guidance for patients on when to use particular interventions, dependent on whether their problem is with depression or anxiety. Alternatively, this may be where guided self-help would give additional benefits.

Given more time and resources, a longer follow-up period would have been useful, as there is some evidence that cognitive treatments continue to demonstrate benefits for many months after treatment has ceased (Butler and Beck, 2000). Also of interest would have been any effect of the intervention on later uptake of psychological therapy.

Finally, the present study was conducted using patients on a waiting list who knew that conventional CBT was available. This may have negatively affected patients' motivation to use the self-help interventions.

Methodological issues

The following sections will consider key issues in the internal and external validity of the study findings. The external validity of the study is limited because a high proportion of referrals to the service were ineligible for the study and many of those patients who were eligible chose not to participate. Patients who choose to participate in trials may differ from the general therapy population in terms of issues such as motivation (Bradley, 1993). However, it would generally be assumed that patients who volunteer for such studies would be most motivated to use self-help, and thus it would generally not be expected that patients with lower motivation would gain more than those who decided to enter the study. However, this is an empirical question, as some patients who do not wish to enter research trials for other reasons may still potentially benefit from self-help materials.

In terms of internal validity, the comparison of outcome was based on a randomized controlled trial, which is generally the most rigorous approach available, but the analyses are limited because of the small sample size and consequent lack of power, a problem that has plagued psychotherapy trials (Churchill et al., 2002). Small trials such as this are also more vulnerable to the effects of outliers and the possibility that randomization might fail to balance groups successfully, and thus the negative results must still be treated with some caution.

In addition, some might argue that this study is not "unguided" self-help in its purest form, given that patients received a one-hour assessment appointment with a trained psychotherapist. This assessment may well have acted as an intervention in itself; however as patients in both arms of the study received the same, the effect on the study outcomes will be negligible.

Recommendations for further study

Despite the lack of clinical improvement observed in patients receiving non-guided self-help in this study, there is some evidence for the effectiveness of self-help interventions that are guided (or facilitated) by a health professional (Kupshik and Fisher, 1999; Keeley, Williams and Shapiro, 2002). However, many questions about facilitation remain unanswered, such as the optimal amount of therapist contact time, and the type of professional who provides such contact. The new graduate workers in primary care (Department of Health, 2000) have been suggested as potential providers of guided self-help (Bower, 2002). Computerized systems of delivery might allow more interactive presentation of material and thus increase effectiveness compared with books alone (Lewis et al., 2003), although the current evidence does not support this (Kaltenthaler et al., 2002).

Future studies might also benefit from qualitative research conducted alongside trials to better understand patient responses to self-help and the place of such technologies in current mental health services. Many patients who met the criteria for this study chose to remain on a waiting list rather than receive self-help; therefore it is important to consider patient choice, motivation and satisfaction with self-help and how these issues affect the process and outcome of self-help. Studies concerned with the process of self-help should also consider when, how and where patients read or use self-help.

One interesting aspect about this type of low intensity intervention which does warrant further investigation concerns whether self-help has a priming effect where patients who have received the manual and do go on to further therapy actually achieve better outcomes in individual therapy and/or require fewer sessions than patients who have not been introduced to the treatment concepts in this way. In addition previous research has rarely considered the cost-effectiveness of self-help interventions and therefore it is recommended that any future studies include economic analyses.

Conclusion

Although the results are not definitive, this pilot study would not suggest that an un-guided self-help manual is an effective intervention. However, in this study this maybe due to the transient nature of the problems studied and due to the every small sample size included. A definitive trial, including patients with more significant levels of anxiety and/or depression i.e. HADS score of 11 or more, would still be useful to confirm or reject the outcome and future research should examine how self-help interventions can be made more effective through professional

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input (e.g. facilitation). From a public health perspective, the high level of satisfaction in this study could indicate that the use of a cheap, readily accessible self-help manual may be useful for patients while they are waiting for evidence-based therapy.

The present study has increased the literature examining the use of self-help interventions in the treatment of anxiety and depression and has influenced the re-design of local primary care mental health services.

Conflict of interest

Dr Karina Lovell is co-author of the self-help manual used in this study but receives no financial recompense from it.

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