Self-help materials for anxiety: a randomized controlled trial in general practice

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SUMMARY. The efficacy of a self-help package in treating chronic anxiety was evaluated in a randomized controlled trial in which the intervention group received self-help materials in the form of an audiotape and booklet, in addition to their current treatment. The intervention was successful in terms of mean depression scores (P = 0.01), anxiety scores (P = 0.04) and general health questionnaire scores (P = 0.02) which were significantly lower for the intervention group than for the controls. In addition, the depression scores fell faster for the intervention group than for the controls. The overall mean reduction in three months in adjusted depression scores was approximately two points greater for the intervention group than for the controls (P = 0.02). Clinicians welcomed the package as a valuable addition to the therapies available for managing chronic anxiety problems. Further studies should include larger sample sizes, taking into account the non-response to postal questionnaires over time.

Introduction

A SUBSTANTIAL proportion of a general practitioner's workload is concerned with the management of anxiety and depression.[1] Although it has been recognized that the use of benzodiazepines may have an adverse effect on anxiety sufferers[2] and there is evidence that the number of benzodiazepine prescriptions has been reduced,[3] the problems associated with the management of chronic anxiety still remain. For some patients drug therapy may still be of value but for others psychological therapy may be the most appropriate management. However, there are a substantial group of sufferers, particularly those who have panic attacks or anxiety resulting from a maladaptive lifestyle, for whom triadic (cognitive, behavioural and physical) anxiety management techniques would be appropriate. A number of non-drug therapies have been proposed and evaluation of these new self-help materials is necessary, especially as it has been suggested that such therapies may aggravate symptoms.[4]

Reviewing a range of self-treatment manuals, Turvey[5] expressed concern at the number of treatment packages available to the general public, which had been released without any evaluation of their effect. From this review, Turvey produced guidelines for the benefit of future authors. A multidisciplinary group of clinical psychologists and doctors in Northumberland were concerned at the lack of cheap, readily available, scientifically evaluated self-help materials which might be used as an alternative to drug therapy for anxiety. Accordingly, an anxiety management self-help package was developed using Turvey's framework, and subsequently evaluated.

Self-help package

The self-help package consisted of a cassette audiotape (total playing time 55 minutes) and a printed illustrated booklet (27 pages, approximately 4000 words) with four main sections. Section one described what it feels like to be anxious, causes and consequences of anxiety, and an outline of ways to get over anxiety. Section two dealt with stopping anxiety developing. Section three summarized ways in which anxiety can be coped with better, including understanding the problem, dealing with the causes of the anxiety where possible, using relaxation, coping with worry, planning better coping, having realistic expectations, letting other people help, and dealing with panic. Section four summarized the main points. Concise summaries highlighted key points at the end of each section. Explanations and advice were illustrated with brief quotations from anxiety sufferers and the text was broken up by drawings and diagrams. Flesch scores[6] were obtained for successive drafts of the text until the final draft had a Flesch score of 71, indicating that it was comfortably understandable by 80% of the population.

The tape repeated the material given in the booklet on side one while side two contained expanded instructions for relaxation.

Methods

The self-help package was evaluated using a randomized controlled trial. Since the subjects of the trial were suffering from chronic anxiety most of them were already using other methods of treatment. The design of the trial was thus essentially pragmatic[7] — one group of anxiety sufferers was randomly allocated to receive the self-help package in addition to their current treatment (the intervention group), while the control group received only their current treatment.

Forty general practitioners in Northumberland agreed to recruit up to six patients each, randomly selecting three for the intervention group and three for the control group. Since acute anxiety presents differently from chronic anxiety and since the latter is more common, only people suffering from chronic symptoms were admitted to the trial. Each patient received an envelope at the end of the consultation with their general practitioner, which at random contained either the self-help materials and a questionnaire or the questionnaire alone. The envelopes were similar but those containing the self-help material were heavier.

Assessment

In order to assess the effectiveness of the self-help materials both in the short and medium term the initial questionnaire was followed by postal questionnaires at six weeks and three months. Recognizing that mixed anxiety and depression are a common clinical feature study participants were assessed for both of these parameters. Thus, in addition to demographic details, the ques-

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tionnaire sought information which allowed scores on three scales to be established: the Leeds self-assessment anxiety specific scale, the Leeds self-assessment depression specific scale[8] and the general health questionnaire,[9] coded on the Likert scale. The Leeds scales provide measures of anxiety and depression in the range 0–18, where a high score is associated with a high level of anxiety or depression. Using the two Leeds scales it is possible to put patients into pure anxiety, anxiety–depression and pure depression categories. The general health questionnaire used consists of 30 items and was designed to be a self-administered screening test with the aim of detecting psychiatric disorders among respondents in community settings and primary care.

Statistical methods

Using the statistical package BMDP,[10] repeated measures analysis was carried out on the scores on the self-assessment anxiety specific scale, self-assessment depression specific scale and general health questionnaire. The covariates of age and sex and baseline scores were included in all analyses. Hence, each analysis consisted of a comparison between outcome scores at six weeks and three months, with adjustment for age and sex and more importantly, for baseline scores so that any treatment effect would not be due to initial differences between the two groups.

Repeated measures analysis makes the assumption of compound symmetry[11] and this assumption has two components. The first is that correlation among time levels is constant and the second that measurement variances are equal across time levels. A likelihood ratio test of compound symmetry was carried out for each analysis. If the assumption of compound symmetry is not valid the analysis can be carried out by specifying an unstructured covariance matrix in the BMDP programme 5V.[10]

In addition, the overall change in three months was assessed by analysis of covariance, adjusting for baseline scores, age and sex. Since it was expected that patients would gradually drop out of the study, it was necessary to analyse the characteristics of non-responders and responders in the two groups.

Results

The methods of treatment already used by the 103 patients who entered the study are shown in Table 1. The results for two patients were excluded from further analysis because these patients had purely depressive symptoms according to the Leeds self-assessment anxiety and depression specific scales. The intervention group thus comprised 51 cases, while 50 were allocated to the control group. There were no significant differences in baseline characteristics between the two groups (Table 2). A number of patients were lost to follow up but the baseline characteristics of patients with complete observations were very similar to the baseline characteristics of all patients, the main difference being that those remaining in the trial longest tended to be older (Table 2).

Patients who dropped out of the intervention group had lower baseline scores than those who dropped out of the control group but there were no statistically significant differences. The characteristics of patients prior to loss to follow up at each time period were also examined and no statistically significant differences were found between the intervention and control groups.

The means for the three outcome measures showed a clear reduction with time which was greater and faster for those given additional self-help material (Figure 1). This effect was most marked for the Leeds depression specific scale where after three months the intervention group had a mean score below seven which was consistent with scores attained by the general population.

Table 1. Treatments used by intervention and control groups at entry to the study.

Treatment at entry to study	Number (%) of patients: Intervention group ($n = 51$)	Control group ($n = 52$)
Medication only	7 *(14)*	7 *(13)*
Counselling by GP only	14 *(27)*	7 *(13)*
Referral to psychiatrist only	0 *(0)*	2 *(4)*
Mixed therapy methods	19 *(37)*	27 *(52)*
No therapy	11 *(22)*	9 *(17)*

n = total number of patients in group.

Table 2. Baseline characteristics of intervention and control groups at entry to study and after three months follow up.

	Entry to study: Intervention group ($n = 51$)	Control group ($n = 50$)	Total ($n = 101$)	Three months follow up: Intervention group ($n = 29$)	Control group ($n = 33$)	Total ($n = 62$)
Sex (no. (%) of patients)						
Male	14 *(27)*	12 *(24)*	26 *(26)*	8 *(28)*	6 *(18)*	14 *(23)*
Female	37 *(73)*	38 *(76)*	75 *(74)*	21 *(72)*	27 *(82)*	48 *(77)*
Age (years)						
Median	40	43	42	44	47	47
Range	17–77	21–72	17–77	17–77	24–72	17–77
Employment status (no. (%) of patients)						
Employed	28 *(55)*	22 *(44)*	50 *(50)*	14 *(48)*	14 *(42)*	28 *(45)*
Unemployed	23 *(45)*	28 *(56)*	51 *(50)*	15 *(52)*	19 *(58)*	34 *(55)*
Children under 5 years (no. (%) of patients)						
Yes	8 *(16)*	7 *(14)*	15 *(15)*	4 *(14)*	4 *(12)*	8 *(13)*
No	43 *(84)*	43 *(86)*	86 *(85)*	25 *(86)*	29 *(88)*	54 *(87)*
Home owners (no. (%) of patients)						
Yes	37 *(73)*	25 *(50)*	62 *(61)*	22 *(76)*	19 *(95)*	41 *(67)*
No	14 *(27)*	25 *(50)*	39 *(39)*	7 *(24)*	13[a] *(41)*	20[a] *(33)*

n = total number of patients in group. [a] Data unavailable for one patient.

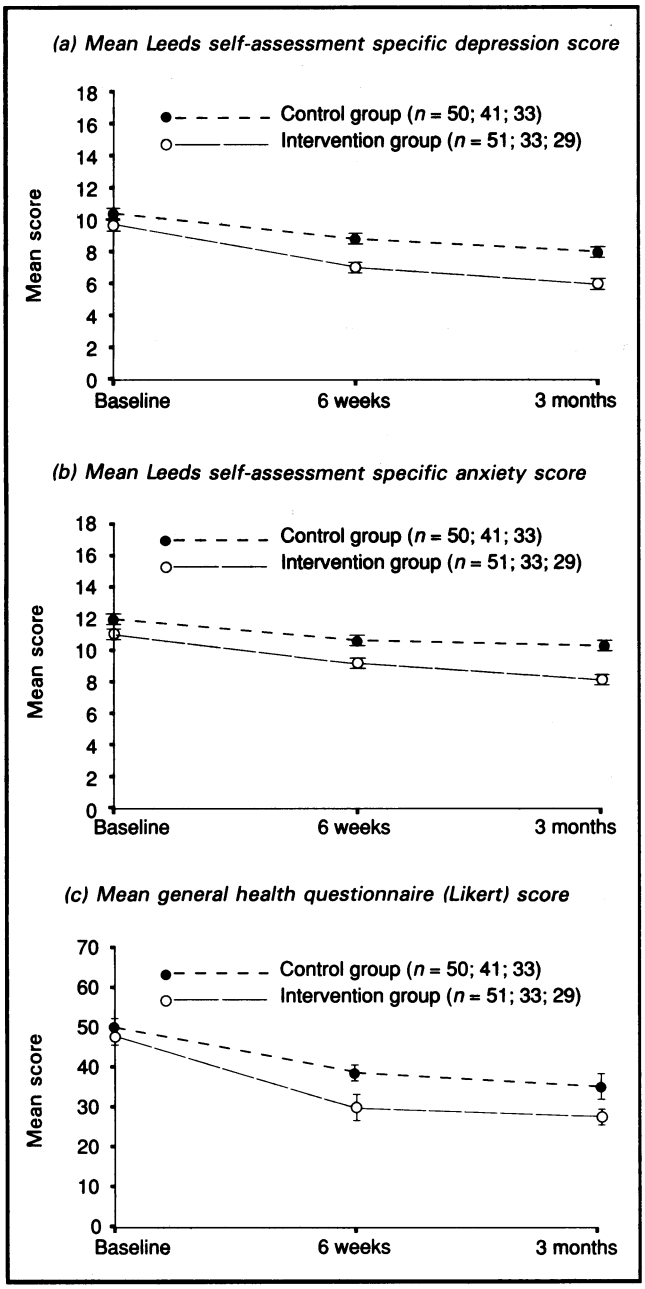

Figure 1. *Changes in mean outcome scores for the two groups on the three scales (n = number of patients in each group at each time point).*

By adjusting for initial scores repeated measures analysis compared the scores at six weeks and three months with initial scores as a covariate. This analysis showed a highly significant difference in adjusted mean scores for the intervention group compared with the controls ($P = 0.01$) for the Leeds self-assessment depression specific scale (treatment effect, Table 3). The other two outcome measures also showed significant intervention effects: Leeds self-assessment anxiety specific scale, $P = 0.04$ and general health questionnaire, $P = 0.02$. The Leeds self-assessment depression specific scores also showed a significant reduction with time. The covariates of age and sex had no significant effects on the Leeds or general health questionnaire scores, after adjusting for the initial scores. The assumption of compound symmetry was found to be reasonable for all three scales.

In assessing the overall change in three months, analysis of covariance gave a significant treatment effect for the Leeds self-assessment depression specific scale ($P = 0.02$) — the mean change in self-assessment depression specific scale scores, adjusted for covariates, was 1.7 points higher for the intervention group than for the control group (95% confidence interval 0.3, 3.1). The mean change in adjusted scores for the Leeds self-assessment anxiety specific scale was also 1.7 points higher for the self-help group than for the control group (95% confidence interval −0.2, 3.6) and although this difference did not reach statistical significance, the 95% confidence interval for this difference indicates that the difference is more likely to be positive and of the same order of magnitude as the difference in the Leeds depression scale. Since scores on the Leeds scales can only have discrete values, these results indicate that the self-help group had an approximately two points greater reduction in score over three months than the contols. The general health questionnaire scores showed a non-significant difference in mean change in adjusted scores between the two groups of 4.7 (95% confidence interval −2.6, 11.9) with the intervention group having the greater change over three months. In addition, younger patients showed a significantly greater change in general health questionnaire scores over three months than did older patients ($P = 0.04$).

Table 3. Results of repeated measures analysis of scores on the three scales after three months follow up.

	P value		
Effect	Leeds depression scale	Leeds anxiety scale	General health questionnaire
Treatment	0.01	0.04	0.02
Age	0.15	0.97	0.48
Sex	0.88	0.79	0.73
Time	0.01	0.14	0.19
Treatment time interaction	0.59	0.38	0.56
Initial scores	<0.001	<0.001	<0.001

Discussion

Although the trend may be away from the prescription of benzodiazepines for chronic anxiety the actual clinical problem still remains for patient and advisor. Alternative treatment methods do exist, although many of them, particularly counselling services, are resource intensive and often difficult to obtain. Self-help manuals have become cheaper and more accessible but have not been evaluated.[5] This is not surprising given the inherent difficulties in evaluations of this nature. Withdrawal from current treatment prior to using a self-help package may not be ethical and in the case of benzodiazepine users may precipitate a withdrawal reaction.[2] Recognizing these constraints we set out to develop an alternative to drug therapy which was readily available, cheap and easy to use and which could be evaluated in a 'real life' situation.

Although the self-help materials were designed to assist people with anxiety symptoms, the most powerful effect was on the depressive characteristics of the intervention group. From their initial scores, both experimental and control patients were essentially suffering from mixed anxiety and depression, a syndrome regularly seen in primary care, often in people who have received drug treatment for a long time without seeming benefit. Within three months of receiving the package the mean depression scores of the intervention group showed a reduction to the level of the normal population. Similarly, there was a greater reduction in scores on the Leeds anxiety scale and on the general

health questionnaire for the intervention group than for the controls. Repeated measures analysis showed that these differences were significantly greater for the intervention group than for the controls, suggesting that the intervention had succeeded on all three outcome measures of mental health.

At first sight the results might seem rather disappointing for a package which was designed to help people to manage anxiety. However, a number of factors suggest that outcome to the study has been relatively successful. From the clinical perspective it may not be unreasonable to expect depression to improve first since depression might be a secondary feature in response to a life of chronic anxiety. From a methodological viewpoint it could be argued that the low power of the test resulted in a non-significant result for the Leeds anxiety scale. A pilot study suggested that approximately 100 patients in each treatment group would be needed to demonstrate a difference of two points in mean change of scores on the Leeds anxiety scale at the 5% level of significance with a power of 95%. However, because of time constraints only 103 patients were recruited. Had more patients been recruited a statistically significant change in anxiety scores might have resulted, a conjecture supported by the 95% confidence interval of −0.2 to 3.6 for the difference between the two groups in mean change of scores on the Leeds anxiety scale. Receiving a questionnaire may have had an effect but as this Hawthorne effect should apply equally to both groups, the difference in mean scores may actually be an underestimate of the improvement in the intervention group.

Long term follow up to assess the effect of treatment was not possible because of funding constraints. Thus, we are only able to hypothesize as to whether anxiety scores would have fallen further or whether treatment effects would have diminished over a longer period of time. Even over a three month period a number of people failed to return their questionnaires, despite reminder letters and future studies of the long term effects of self-treatment packages will need to address the question of whether to use postal questionnaires or interviews to collect follow-up data. However, interviewers have a potential treatment effect on symptoms and scores and are much more costly.

No information was collected in this study on the patients' frequency of consultation because we lacked the resources to do so and, more importantly, because pragmatic trials such as this evaluate the policy as well as the treatment. Thus, if more patients in the intervention group contacted their general practitioner as a result of receiving the self-help package (whether it is used or not) it might be as a result of the policy of handing out self-help materials rather than the materials themselves. Nevertheless, since any change in consultation rate has resource implications any further study should investigate change in consultation rates and the reasons why changes occurred.

Broad guidelines on patient recruitment were given to the general practitioners, who were variously successful in recruiting patients. Only two patients were assessed as being truly depressed but in the future a method such as that suggested by Goldberg[12] for identifying cases could be valuable in choosing people who might benefit most from treatment.

Because of the methodological limitations which we have identified, some caution is needed in the interpretation of the results. Materials which were developed to help the management of anxiety might be construed as actually being more use in the management of depression. However, a more hopeful interpretation is that the picture of mixed anxiety and depression is often complex and that self-help materials which are of some proven effect, albeit in the short term, are a useful addition to the clinical repertoire. Within these limits this study has met with a measure of success and clinicians in Northumberland have expressed a desire to use the package in anxiety management. The booklet and tape will therefore be made widely available to all clinicians who regularly provide care for anxiety sufferers. Each package will outline the cases for whom the materials have been found effective and emphasize the need for follow up of patients with deteriorating symptoms and for those on benzodiazepine withdrawal programmes.

Future research should examine the effect of self-help materials over periods in excess of three months. There remains a need to evaluate many of the other alternative therapies on offer to sufferers of chronic anxiety.

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The self-help package is available from Northumberland District Health Authority for £7.00, including postage. Contact: Dr Roger Paxton, District Clinical Psychologist, St George's Hospital, East Cottingwood, Morpeth, Northumberland NE61 2NU.

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NEW EDITOR

The *Journal* wishes to announce that Dr Alastair Wright has been appointed to succeed Dr Graham Buckley as Editor of the *Journal*.

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