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"STRESSPAC": THREE-YEAR FOLLOW-UP OF A CONTROLLED TRIAL OF A SELF-HELP PACKAGE FOR THE ANXIETY DISORDERS

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Abstract. In order to test the efficacy of a self-help anxiety management package, 62 anxiety disorder patients were randomly allocated to one of three conditions. "Stresspac" patients were given a self-help package, "Advice Only" patients were offered verbal advice on ways of coping. Patients in both conditions were seen on one occasion shortly after referral for assessment and management advice. They were then placed back on the waiting list for a three-month period. Patients in the "No Intervention" condition also completed measures during this time. They were formally assessed at the end of this period. All patients were then followed through therapy. Results from a previous paper clearly indicated the superiority of the Stresspac condition at all data points up to one year follow-up. This paper looks at three-year follow-up and, while finding generally good outcome across conditions, finds further evidence of the superiority of the Stresspac condition on a range of measures.

Keywords: Stresspac, self-help, cognitive-behavioural, anxiety, follow-up.

Introduction

Data from the Epidemiological Catchment Area Survey suggest that 15% of the population will suffer from an anxiety disorder at some point in their life (Brown & Barlow, 1992). Given the imbalance between therapeutic resources and the number of people who could potentially benefit from therapy, effort needs to be made to develop services to better meet the needs of individuals referred to secondary care. This remains particularly true of the National Health Service where waiting times of six months or more are not uncommon (White, 1992). As a way of alleviating this pressure and due to difficulties filling vacant posts with qualified psychologists, a recent development has been the widespread use of counsellors often trained in humanistic approaches working within clinical psychology and community mental health teams (Shillitoe & Hall, 1997). While we await controlled evidence for the efficacy of counselling, we would argue that cognitive-behavioural therapists have the expertise necessary to develop innovative approaches using their therapeutic skills and theoretical knowledge to tackle not only

"Stresspac" (revised and extended version) is available from Psychological Corporation, 24–28 Oval Road, London NW1 7DX, U.K.

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waiting list problems but also to further develop cognitive-behavioural therapies which, although often impressive, are far from offering a panacea (Chambliss & Gillis, 1993). British cognitive-behavioural researchers, aware of the log-jam at the secondary care level, have striven to develop techniques that are not only therapeutically successful but are robust enough to move from the research centre into routine clinical treatment where time considerations are of great importance. For example, Clark, Salkovskis, Hackman, Wells and Gelder (1995) report on reducing the number of sessions required for successful treatment of panic disorder with agoraphobia from between 12–15 sessions down to 6. It will be interesting to see whether American researchers, under the pressures imposed by managed care systems, will look more closely at developing techniques that U.S. clinicians can more easily use in the relatively limited number of sessions imposed by U.S. insurance companies.

One obvious approach to achieve a better compromise between the number of patients treated and the quality of the service provided is bibliotherapy self-help used in conjunction with therapist contact. Tyrer, Seivewright, Ferguson, Murphy and Johnson (1993) suggest "the personal control of therapy that is intrinsic to self-help is of major therapeutic importance" (p. 224). There is good empirical evidence to support the use of self-help with a wide range of disorders (see Gould & Clum, 1993 for a meta-analysis of self-help approaches). An important test of the robustness of self-help must relate to its ability to help the individual user to maintain therapy gains following cessation of therapist contact. This is especially important for therapists working in busy, under-resourced out-patient departments where relapse and subsequent re-referral may add to waiting list problems. The usual follow-up at six or twelve months may not be long enough to test this robustness issue as clinical experience suggests that patients often tend to be re-referred within one or two years following discharge from secondary care. This paper looks at three-year follow-up of one self-help approach to the treatment of the anxiety disorders – "Stresspac" (White, 1995).

Summary of previous study

Sixty-two patients referred by their GPs to a clinical psychology primary care service and who met DSM-III-R criteria (American Psychiatric Association, 1987) for any anxiety disorder as assessed by the Anxiety Disorder Interview Schedule-Revised (DiNardo & Barlow, 1988) were randomly allocated to one of three conditions: Stresspac–SP ($n = 21$), Advice Only–AO ($n = 20$), and No Intervention–NI ($n = 21$). Other entry criteria included a minimum SCL90–GSI T score of 63 (Derogatis & Melisaratos, 1983); a score of 11 or more on the anxiety scale of the Hospital Anxiety and Depression (HAD) Scale (Zigmond & Snaith, 1983); age between 18–65; no previous contact with clinical psychology or psychiatry; no previous experience of cognitive-behavioural treatment; no recent change in psychotropic medication and no evidence of psychotic, alcohol or drug problems.

Patients in SP and AO were seen on one occasion shortly after referral for assessment and were not then seen for three months, at which point individual therapy began. SP patients were given the self-help package at this appointment but were given no specific personal advice. They were told it was a stop-gap measure until individual therapy could be given. AO patients were given no written or audio material but were given

specific advice based on information gleaned from the ADIS assessment. NI patients completed measures during this three-month period but were not formally assessed until the end of this period, whereupon they immediately entered therapy. Patients were offered tailored individual cognitive-behavioural therapy. Treatment of SP patients was individualized and did not centre on the package. Number of sessions was dictated by the requirement of each patient. All patients completed measures, by post, at referral (baseline), at one and two months and prior to entering therapy after the three-month wait (3m/pre). Measures were also taken at discharge (post) and at three- and twelve-month follow-up. The author carried out all assessments and treatments.

"Stresspac"

"Stresspac" was written by the author for individuals suffering from anxiety. It is based on a cognitive-behavioural model of anxiety and centres on treatment for generalized anxiety. "Stresspac" contains a 79 page booklet, a four page introduction handout and a two-sided ("Deep" and "Rapid") relaxation tape. The booklet divides into Information and Treatment sections. The former contains information on the nature of anxiety, descriptions of different anxiety disorders, case histories and information relating to the causes and maintenance of anxiety. Anxiety is described using a three system analysis (Rachman, 1978). The Treatment section divides into four:

- "Controlling your body": Progressive relaxation.
- "Controlling your thoughts": Cognitive therapy based on the work of Beck and Meichenbaum.
- "Controlling your actions": Emphasizes the importance of exposure and other behavioural advice.
- "Controlling your future": Relapse prevention information ends the section.

The Flesch Reading Formula score is 73 – "fairly easy" (Flesch, 1948). Using Ley's (1977) estimate, an IQ of at least 87 is required for reasonable understanding of its contents.

Results indicated SP patients significantly improved during the three months waiting period compared to patients in the other two conditions. Almost 40% of SP patients did not require further therapy. At the end of individual therapy, SP, AO and NI patients all improved significantly but SP patients continued to improve at a greater rate. They also required fewer appointments. At one-year follow-up, patients in all three conditions maintained progress with SP patients, on average, well within the normal range on the HAD: Anxiety scale. SP patients rated the package highly throughout the trial. Results, generally, indicate the superiority of SP at all data points.

Present study

Subjects

Sixty-two patients completed treatment and one year follow-up measures (21 in SP, 20 in AO and 21 in NI). All were contacted by post three years after discharge and asked

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to complete and return enclosed questionnaires. A relatively small selection of the measures used in the original study were sent in the hope of improving response (see below). A second mail shot occurred two weeks after the first if no response was obtained. Eighteen (86%), 16 (80%) and 14 (67%) patients in SP, AO and NI responded. Of this number, 0, 3 (19%) and 2 (14%) patients respectively had received further secondary care treatment (in all cases, with either a psychologist or psychiatrist); 3 (17%), 8 (50%) and 8 (57%) had returned to their GP at some point complaining of anxiety; 1 (6%), 8 (50%) and 6 (43%) had, at some point, been given psychotropic medication and 1 (6%), 5 (31%) and 5 (36%) patients were currently taking psychotropic medication. Those patients who had received further secondary care help were excluded from the initial analyses leaving 18 (86%), 13 (65%) and 12 (57%) patients in each condition. Chi square tests, comparing return rates, further secondary care, further GP treatment and psychotropic medication between the conditions show no significant results possibly due to the small *N*s.

Measures

The following measures were completed:

1. Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983).
2. Health Locus of Control Scale (Wallston, Wallston, Kaplan, & Maides, 1976). This 11 item scale is a unidimensional measure of people's belief that health is or is not determined by their behaviour. Higher scores represent a belief in uncontrollable external factors such as luck, chance or powerful others determining health.
3. Main problem rating (scored 1–11) (White, 1995). Patients first specified the problem with which they most wanted help and then rated the severity of that problem using a 12-point analogue scale ranging from "not bad at all" (1) to "extremely bad" (12).
4. Global rating (White, 1995). Patients were asked to rate how they felt compared to when they were referred by choosing between five options ranging from "much worse" to "much better".

All patients were asked to rate how highly they would recommend their treatment to a friend or relative using a 0–100 scale. Patients in SP also rated the "Stresspac" in terms of how well it explained stress, how well it explained their own problems, how sensible the approach seemed, how easy it was to use, and how well it had worked (using 1–10 analogue scales).

Results

Overview of analyses

Results compare functioning at baseline, the end of month 3 on the waiting list/pre-therapy (3m/pre), post-therapy, one-year and three-year follow-up.[1] Means and standard deviations are shown in Table 1 and means in Figure 1. Between group comparisons were analysed using repeated measure ANCOVAs with treatment group as the

[1] No data were available at one year follow-up for HLC.

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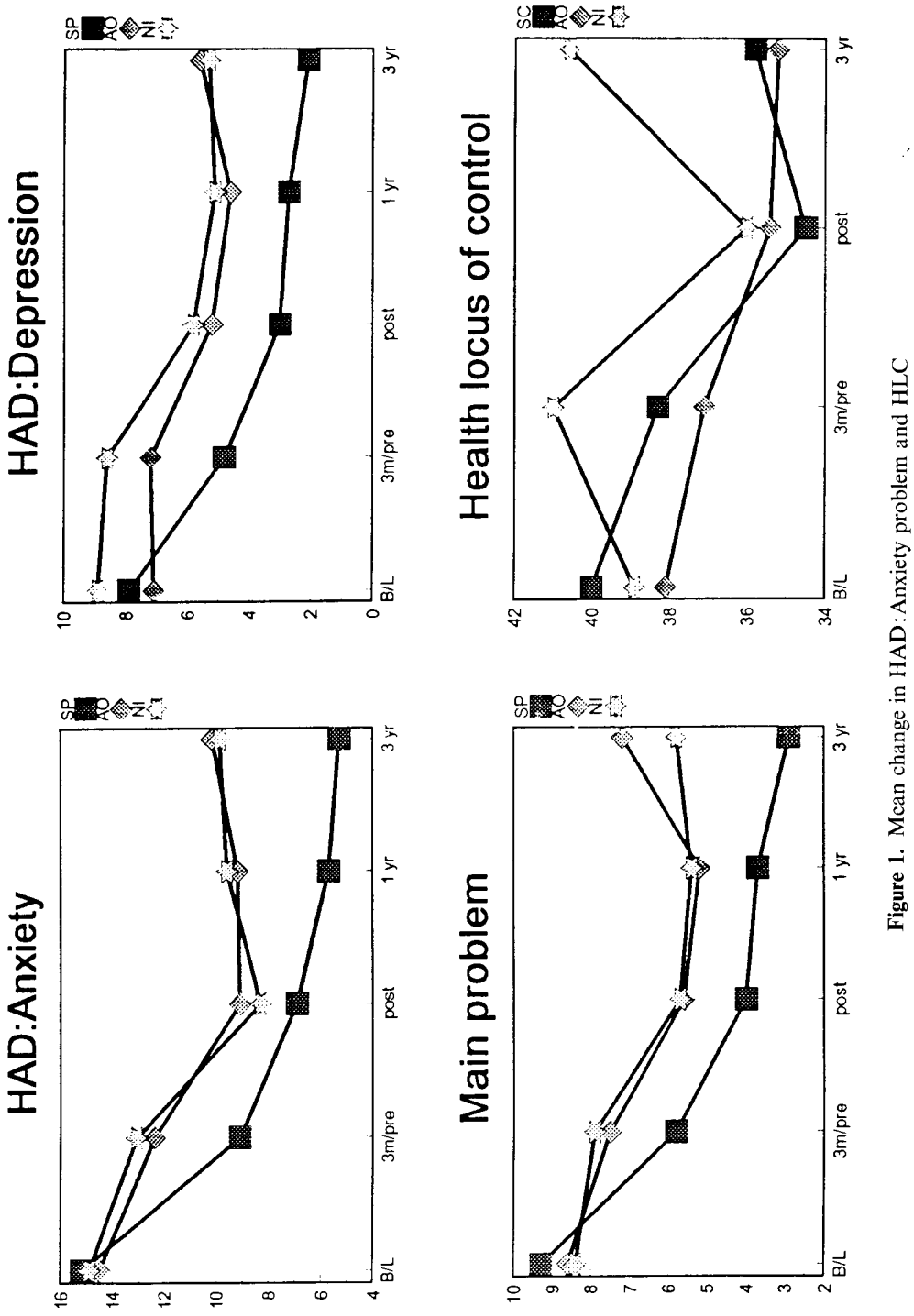

Figure 1. Mean change in HAD: Anxiety problem and HLC

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Table 1. Means and standard deviations for main outcome measures at baseline, three months wait/pre-therapy, post-therapy, one- and three year follow-up

	SP ($n = 18$)	AO ($n = 13$)	NI ($n = 12$)
HAD: Anxiety			
B/L	15.2 (2.4)	14.5 (3.3)	14.9 (3.2)
3m/Pre	9.1 (3.6)	12.4 (4)	13.1 (4.3)
Post	6.9 (1.5)	9.1 (4.6)	8.3 (3.1)
1 yr FU	5.7 (2.3)	9.2 (4.8)	9.6 (2.8)
3 yr FU	5.3 (3.1)	10.2 (4.2)	9.9 (4.1)
HAD: Depression			
B/L	7.9 (3.9)	7.1 (1.7)	8.9 (2.8)
3m/Pre	4.8 (3.9)	7.2 (2.6)	8.6 (3.3)
Post	3.0 (2.1)	5.2 (2.6)	5.8 (3)
1 yr FU	2.7 (2.8)	4.6 (3.1)	5.1 (2.4)
3 yr FU	2.1 (2.9)	5.6 (3.1)	5.3 (3.7)
Main problem (1–11)			
B/L	9.3 (1.6)	8.6 (1.2)	8.4 (2.1)
3m/Pre	5.8 (2.2)	7.5 (1.8)	7.9 (3.2)
Post	4.0 (2)	5.6 (1.6)	5.7 (2.3)
1 yr FU	3.7 (2.1)	5.2 (2.5)	5.4 (2.1)
3 yr FU	2.9 (1.9)	7.2 (5.8)	5.8 (2.5)
HLC			
B/L	40.0 (5.7)	38.1 (6.9)	38.9 (6.7)
3m/Pre	38.3 (5.8)	37.1 (5.3)	41.0 (7.4)
Post	34.5 (6.2)	35.4 (5.5)	36.0 (6.4)
3 yr FU	35.8 (10)	35.2 (7.2)	40.6 (6.9)

grouping factor and baseline score as the covariate (Frison & Pocock, 1992). Within group changes were investigated using dependent *t*-tests.

Comparison between responders and non-responders. Independent *t*-tests, comparing those, across conditions, who replied at three years and those who did not, were carried out on baseline HAD anxiety (15.05 v 14.6) and depression (8.2 v 8) scores. No differences emerged. Repeated measure ANCOVAs at one year follow-up again show no significant change. It is possible that this may be due to the relatively small sample size of the non-responders.

Within group change. T-tests showed significant change for SP, AO and NI patients between baseline and three-year follow-up on HAD: Anxiety, HAD: Depression and Main problem ratings ($ts = 3.25$ to 11.32, $ps = .016$ to $.000$). SP also showed significant change on HAD: Anxiety between post-therapy and three-years [$t = 2.19$ (df 7) $p = .04$]. NI showed significant change (relapse) on HLC (post-therapy – three-years) [$t = 2.11$ (df 12) $p = .05$]. Post-therapy – three-year FU and one-year FU – three-year FU comparisons suggest that all three conditions generally maintained post-therapy gains.

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Table 2. Between group differences using ANCOVA and Newman–Keuls (means adjusted from covariance)

		SP v AO	SP v NI	AO v NI
Variable	*F* (2939)	*p*	*p*	*p*
HAD: Anxiety	5.99	0.01	0.01	NS
HAD: Depression	2.38	NS	NS	NS
Main problem	5.91	0.01	0.008	NS
HLC	1.38	NS	NS	NS

NS = non significant.

Between group change (Table 2). Significant effects from baseline emerged on HAD: Anxiety and Main problem. In each case, SP was significantly different to both AO and NI. No differences emerged on either HAD: Depression or HLC.

Clinical significance of change. Criterion for clinical significance was defined as a score of less than 8 on the HAD: Anxiety scale i.e., in the normal range. Forty-four per cent, 15% and 8% in SP, AO and NI respectively achieved this criterion at three months/pre-therapy; 67%, 31% and 50% at post-therapy; 89%, 54% and 42% at one-year follow-up and 78%, 38% and 42% at three year follow-up. Along with Global ratings of improvement (Table 3), they provide further evidence for the superiority of the Stresspac condition.

Analyses including those in further treatment. In order to test whether the exclusion of those patients who had received further secondary care therapy biases the results, additional analyses were conducted using the above measures including those patients (3 in AO and 2 in NI). The same results emerged suggesting that the initial analyses are not artificially inflating the effectiveness of the SP intervention.

Recommendation. Asked how highly patients would recommend their therapy to a relative or friend, using a 0–100 scale, mean scores (and *SD*) for SP, AO and NI patients were 96.7 (5.7), 83.4 (18.7) and 85.4 (11.9) respectively.

SP ratings (1–10 VAS). Mean scores (and standard deviations) strongly indicate that SP patients rate the package highly in terms of how well Stresspac explained stress – 8.8 (1.1); how well it explained their own problems – 9.6 (0.5); how sensible it seemed – 9.1 (1.2); how easy it was to use – 9.4 (1) and how well it had worked – 8.9 (1.3).

Table 3. Global ratings of improvement at month 3/pre-therapy, post-therapy and three-year follow-up (%)

	Month 3/pre			Post-therapy			Three-year follow-up		
	SP	AO	NI	SP	AO	NI	SP	AO	NI
Much worse	0	0	0	0	0	0	0	0	0
Worse	0	8	17	0	0	0	0	0	0
Same	5	38	58	0	15	17	0	31	17
Better	56	54	17	39	69	33	33	31	50
Much better	39	0	8	61	31	50	67	38	33

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Discussion

The results of the present study, across conditions, provide some evidence that brief cognitive-behavioural therapies (mean number of sessions in SP, AO and NI of 3.8, 6 and 5.4 respectively), applied in routine clinical settings with a heterogeneous group of anxiety sufferers, produce reasonable improvement at post-therapy and at one- and three-year follow-up. Although many patients, particularly in AO and NI, remain anxious and require further help for their condition, most patients recommended their therapy highly (although demand factors may influence results).

The results provide further evidence supporting the value of a self-help cognitive-behavioural package used in addition to individual therapy across the anxiety disorders. Taken with the results documented in White (1995), Stresspac seems to aid patients while they remain on a long waiting list for individual therapy; appears to be, on its own, a sufficient intervention for a sizeable number of patients; enhances the effects of therapy while reducing the number of therapy sessions needed; produces a slight trend towards further improvement at long follow-up points while appearing to reduce the need for further GP consultations for anxiety, use of psychotropic medication and referral to secondary care compared to the other two treatment conditions. It would be of interest to compare this cognitive-behavioural approach with other therapies to see whether the active ingredients of the intervention are specific to CBT or are non-specific. Of particular importance may be the provision of a personally relevant, easily understood account of why they feel the way they do, combined with a straightforward therapy consistent with this account, even if that account relates to general anxiety. It may be that patients, given this general account, are able to personalize this information and extract strategies that they are able to fit around their own problems. Having the package following discharge may be helpful in dealing with the inevitable bad days and helps orientate the patient towards immediate relevant action and away from less useful coping strategies e.g., avoiding, seeking medication.

These suggestions must be regarded as speculative given the small sample, the small number of measures (some of which may be influenced by demand factors) and the lack of a face-to-face interview that was beyond the scope of this study. However, there does appear to be evidence that cognitive-behavioural techniques are flexible enough to meet the demands of routine clinical work and that, in our search for better ways to tackle the problems created by demand out-weighing supply especially at the primary care level, we should look with greater confidence at the development of innovative cognitive-behavioural practise rather than simply look outwith our area of expertise.

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