Psychological Medicine, 2005, **35**, 1633–1643. © 2005 Cambridge University Press
doi:10.1017/S003329170500560X Printed in the United Kingdom

The clinical effectiveness of guided self-help *versus* waiting-list control in the management of anxiety and depression: a randomized controlled trial

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ABSTRACT

Background. There are significant barriers to accessing effective psychological therapy in primary care resulting from a lack of suitably trained therapists to meet current demand. More efficient service delivery using minimal interventions (such as bibliotherapy) provided by paraprofessional therapists may be one method of overcoming these problems, and is the subject of attention in the UK and elsewhere. A randomized trial was conducted to test the clinical effectiveness of this model. Assistant psychologists delivered a guided self-help intervention to patients with anxiety and depression who were currently waiting for psychological therapy.

Method. A total of 114 patients were randomized either to guided self-help or a waiting-list control group. All patients were followed up 3 months later, prior to starting conventional psychological therapy. Measures included self-reported adherence to the intervention, anxiety and depressive symptoms, social functioning and patient satisfaction.

Results. Adherence to the guided self-help intervention was acceptable and patients reported satisfaction with the intervention. However, there were no statistically significant differences between groups in anxiety and depression symptoms at 3 months.

Conclusions. The results demonstrate that this model of guided self-help did not provide additional benefit to patients on a waiting list for psychological therapy. The results are considered in the context of possible internal and external validity threats, and compared with previous trials of minimal interventions. The implications of the results for the design of future minimal interventions are considered.

INTRODUCTION

A lack of trained therapists means that psychological therapy services cannot currently meet demand, resulting in long waiting lists and dissatisfaction among patients and clinicians (Lovell & Richards, 2000). Services faced with the need to bridge the gap between demand and supply have a number of potential solutions, including use of 'minimal interventions' and the employment of paraprofessional therapists.

Minimal interventions

'Minimal interventions' are designed to provide effective care while reducing the need for input from specialist therapists (e.g. self-help books, or 'bibliotherapy'). Treatments without therapist contact ('pure self-help') could have the biggest impact on access, but may not be effective with depressed patients lacking motivation

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https://doi.org/10.1017/S003329170500560X Published online by Cambridge University Press

and confidence. 'Predominantly self-help' interventions involve a small amount of therapist contact beyond an initial assessment (e.g. supplying an initial therapeutic rationale), while 'minimal contact' is defined as 'active involvement of the therapist, including any treatment in which the therapist helps with initial hierarchy construction' (Newman *et al.* 2003). A recent review suggested that minimal interventions with greater amounts of therapist contact were effective for a wider range of anxiety problems than self-administered treatments (Newman *et al.* 2003), and direct comparisons have indicated that interventions with some therapist contact may be more effective than 'pure self-help' (Kupshik & Fisher, 1999; Sharp *et al.* 2000). The 'guided self-help' (GSH) model is an example of 'minimal contact', where the focus is on bibliotherapy, but the therapist teaches effective use of the bibliotherapy as a 'health technology' (Richards *et al.* 2003*b*).

Paraprofessional therapists

Based on previous reviews (Durlak, 1979; Stein & Lambert, 1984; Berman & Norton, 1985), it has been suggested that paraprofessional therapists (defined as those without post-baccalaureate clinical training) may achieve equivalent outcomes to professionals (Christensen & Jacobson, 1994). Although these conclusions have been criticized (Roth & Fonagy, 1996), interest in the use of paraprofessionals remains. A relevant new role has been introduced in the UK: the 'primary care graduate mental health worker' (PCGMHW) (Secretary of State for Health, 2000). PCGMHWs are psychology graduates with a year's training in delivering 'brief therapy' (Bower, 2002).

The recent National Institute of Clinical Excellence (NICE) guidelines for managing depression (National Collaborating Centre for Mental Health, 2005) include GSH delivered by PCGMHWs as an intervention in a stepped care model. Evidence exists on the effectiveness of both minimal contact interventions and paraprofessionals, but these data are often based on non-clinical populations recruited outside primary-care settings and are hampered by significant methodological limitations (Den Boer *et al.* 2004). The present study reports on a randomized controlled trial (the Self-Help in Anxiety and Depression, or SHADE, trial), which aimed to provide a rigorous test of the effectiveness of GSH delivered by assistant psychologists (APs) compared with waiting-list control (WLC) for patients with anxiety and depression symptoms referred from primary care. The trial was designed as a 'pragmatic' study to inform policy and practice (Roland & Torgerson, 1998), seeking high levels of internal validity without compromising external validity. The results have important implications for the implementation of new models of depression care in the UK and beyond.

METHOD

Design

The study was conducted in three psychological therapy services in the North West of the UK. Participants were recruited from waiting lists of referrals from primary care, prior to patient contact with specialist therapists (i.e. at the interface between primary care and specialist services). Those who agreed and met the eligibility criteria were randomly allocated to either GSH or to WLC. All patients were followed up 3 months later, prior to entering the psychological therapy for which they were originally referred (Fig. 1). The trial has been registered (ISRCTN33308608).

Participants

In this pragmatic trial inclusion was not restricted to particular diagnoses; rather, external validity was maximized by including the heterogeneous mix of patients with symptoms of depression and anxiety who are routinely referred from primary care for psychological therapy (Friedli *et al.* 1997; Ward *et al.* 2000; Simpson *et al.* 2003). Patients were required to be aged 18+ years and to have been referred to the participating psychological therapy service from primary care with significant anxiety or depressive symptoms [defined as 14+ on the Beck Depression Inventory (BDI) or 11+ on the anxiety scale of the Hospital Anxiety and Depression scale (HADS)]. These criteria were based on previous studies (White, 1995; Ward *et al.* 2000) and were used to avoid very mild, transient cases entering the trial. Patients were also required to have at least 3 months remaining on the waiting list for therapy so that outcomes were not confounded. Exclusion criteria

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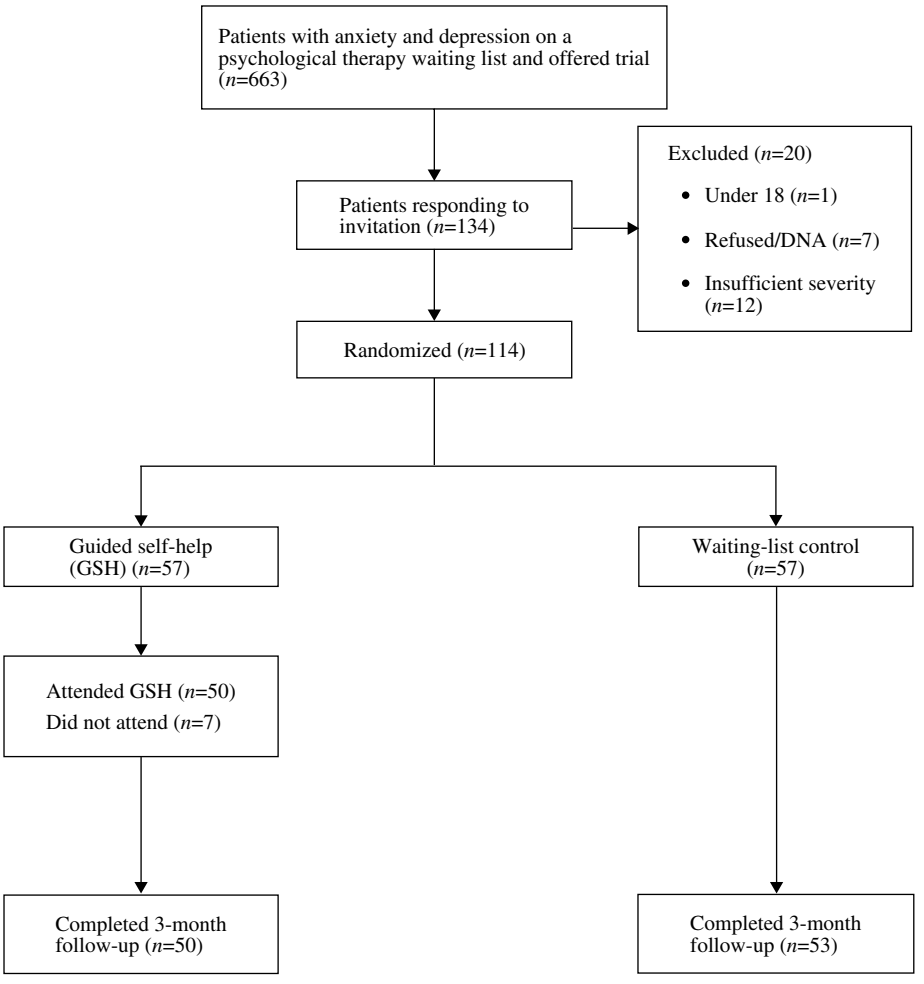

FIG. 1. CONSORT diagram showing participant flow through the SHADE trial.

were active suicidal thoughts and plans, current involvement with other statutory specialist mental health services (e.g. substance abuse), and inability to complete the questionnaires or read the self-help manual.

Treatment conditions

The WLC group involved routine care from primary-care professionals, which may involve general support, antidepressant medication or referral to community agencies.

The GSH intervention involved two components: (*a*) a written self-help manual (designed for the trial), and (*b*) one-to-one sessions with an AP. The written manual was in two parts. Part one included information about anxiety and depression and available interventions. This section was augmented throughout by descriptions of patients' experiences, derived from focus groups with service users, who were also involved in evaluating the draft manual. Part two was a therapeutic section based on cognitive-behavioural principles and containing specific exercises: behavioural activation, exposure, problem solving, cognitive restructuring and lifestyle strategies, with case vignettes and details of how to apply the interventions. Two of the authors (D.R. and K.L.)

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have previous experience in developing self-help materials.

APs were selected to deliver the intervention because they were existing paraprofessionals similar to the proposed PCGMHWs in terms of background, experience and role (Bayliss, 2002). Ten APs were involved. Training took 3 days (conducted by the authors), and included supervised observation of practice. The APs were taught therapeutic skills (i.e. engagement, problem identification, empathy, alliance building, risk review and interview problem solving), knowledge of the interventions and how to guide patients using a 'health technology' rationale (Richards *et al*. 2003*b*). Some of the APs' regular clinical supervisors attended the training. To enhance external validity, supervision of GSH was the responsibility of these supervisors, although the authors provided further assistance when requested, based on reviews of audiotaped sessions with trial participants. The GSH sessions were planned to be brief, with a maximum of four per patient (usually delivered weekly) lasting 15–30 minutes each.

Measures

All outcomes were self-report, measured at baseline and at 3 months. The primary outcome measure was the 14-item HADS (Zigmond & Snaith, 1983), comprising seven items relating to anxiety and depressive symptoms respectively. The two symptom dimensions correlate highly (Goldberg *et al*. 1987) and this was replicated in the current sample ($r = 0{\cdot}63$). Thus, scores on these two scales were combined to create an overall measure of common mental health symptoms, a procedure adopted in previous primary-care trials (Sorby *et al*. 1991; Atherton-Naji *et al*. 2001).

The 21-item BDI (Beck & Steer, 1987) was included as an additional measure of depressive symptoms, and the 34-item Clinical Outcomes in Routine Evaluation outcome measure (CORE-OM; Evans *et al*. 2000) was included as a measure of subjective well-being, symptoms, functioning and risk/harm. Both were used to facilitate comparisons with published psychological therapy studies.

The 45-item Social Adjustment Scale (SAS; Cooper *et al*. 1982) has subscales measuring respondents' functioning in relation to paid work, housework, social and leisure activities, and relationships with close and extended family. Respondents completed all relevant subscales, and a total score was calculated based on the average across these.

Measures of the treatment process included patient self-reported use of the self-help manual and an 8-item questionnaire concerning aspects of their relationship with the AP (e.g. feeling understood and supported). This scale has been used in previous psychological therapy studies in the same context (Friedli *et al*. 1997; King *et al*. 2000) and was included to enable comparison between patients' satisfaction with the APs and satisfaction with professional therapists (such as counsellors and clinical psychologists) from previous trials.

Patients' preference for the intervention (King *et al*. 2005) was measured on a single 10-point scale.

Procedure

Eligible patients were identified by staff at each psychological therapy service from information in referral letters. Patients were invited into the trial by post, with respondents assessed for eligibility (usually in their own homes) by researchers, after obtaining informed consent. Complete baseline data were collected from those patients who met the eligibility criteria prior to their allocation to treatment, which was undertaken using a dynamic form of random allocation called minimization (Treasure & MacRae, 1998) conducted by an external specialist clinical trials unit. Allocation was thus effectively concealed from the researchers making judgements of eligibility (Altman & Bland, 1999). Allocation between trial arms was 1 : 1 and minimized by BDI score (0–22, or 23+), estimated time remaining to first formal therapy appointment (3–5 months, 6–8 months, or 9 months or over) and type of therapy for which patients had been referred (CBT/psychodynamic therapy or counselling). The study received ethical approval from the relevant NHS local research ethics committees.

Analysis

Analyses and presentation were conducted in line with CONSORT guidelines (Moher *et al*. 2001). Primary analysis was by intention-to-treat, with patients analysed in the group to which they were randomized irrespective of treatment

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compliance. Data missing because of loss to follow-up were not imputed, but stepwise logistic regression (with backward selection) was used initially to investigate predictors of loss to follow-up. The main analysis used multiple regression, adjusting for baseline values of the relevant outcome, the minimization variables, and those variables identified as predictors of loss to follow-up. Regression diagnostics were used to check the assumptions underlying the main analyses. Standardized effect sizes (Cohen's *d*) were calculated in order to facilitate comparison with published studies. Analyses were conducted using STATA, version 8 (Stata Corporation, College Station, TX, USA) and SPSS, version 10.1 (SPSS Inc., Chicago, IL, USA).

RESULTS

Sample size and power

Participant flow is shown in Fig. 1. Recruitment occurred from February 2002 until March 2004. The pre-trial power calculation, based on detecting differences in health-care *costs* rather than clinical outcomes, required 300 patients in total. However, problems with recruitment meant that this sample could not be attained. Instead, recruitment continued until the trial had 80% power to detect a medium effect size of 0·5 ($\alpha = 0{\cdot}05$) in *clinical* outcomes (assuming a pre-post correlation of $r = 0{\cdot}4$ in the primary outcome). In total, 114 patients were recruited.

Twenty per cent of patients invited to participate responded, of whom 85% were eligible. Based on available data, respondents (mean = 41·1 years, S.D. = 11·6, $n = 114$) were slightly older than non-respondents (mean = 37·4 years, S.D. = 11·4, $n = 524$; difference 3·72, 95% CI for difference 1·53–5·90), but did not differ by sex (32·8% male *versus* 38·9% respectively; difference 6·1%, 95% CI 15·1–2·87).

Reasons for referral reported by participants' general practitioners were categorized as 'depression' ($n = 30$), 'anxiety' ($n = 22$), 'panic, with or without agoraphobia' ($n = 21$), 'depression and panic' ($n = 8$), 'anxiety and panic' ($n = 5$), 'mixed anxiety and depression' ($n = 13$), specific phobia ($n = 3$), social anxiety ($n = 7$), other ($n = 2$) and missing ($n = 3$). Baseline characteristics of the two trial groups are presented in Table 1; differences were not tested for statistical significance, in line with current guidelines (Roberts & Torgerson, 2000).

Treatment uptake and attrition

Of the 57 patients offered the GSH intervention, 50 (88%) attended at least one session, and 31 (54%) attended all four. The mean number of sessions attended was 3·16 (S.D. = 1·94)† and the mean session length was 32 minutes (S.D. = 6·3).

Three quarters of patients provided adherence data: 88% reported reading 'at least half the manual', although only 52% reported conducting self-help exercises 'at least weekly'. The self-help activities undertaken were (in order of frequency): (*a*) 'trying to look at thoughts in a different way' (100%), (*b*) 'keeping a diary of thoughts and feelings' (71%), (*c*) 'confronting my fears' (62%), (*d*) 'doing more enjoyable activities' (57%), (*e*) 'doing more regular exercise' (50%), (*f*) 'keeping a diary of how I spend my time' (45%). Over 90% indicated they would continue to use the manual.

Aside from GSH, no significant differences were found in other aspects of health-care utilization over the 3-month follow-up period. Intervention group patients reported a mean 1·79 GP contacts (S.D. = 1·52, $n = 47$) compared with 1·65 contacts for control patients (S.D. = 1·59, $n = 49$; difference 0·14, 95% CI −0·491 to 0·771). Twenty-six intervention group patients (53·1%) and 28 control patients (57·1%) were taking prescribed psychotropic medication at 3-month follow-up (difference −4·0%, 95% CI −23·8 to 15·6). Fifteen intervention patients (31·3%) and 23 control patients (46·0%) reported one or more 'psychosocial contacts' over the 3-month period (difference −14·8%, 95% CI −33·8 to 4·30). 'Psychosocial contacts' was defined broadly, and included contacts with NHS and private psychological therapy providers, community psychiatric nurses, social workers, workplace counselling services, voluntary support groups (e.g. Samaritans) and self-help groups other than trial GSH sessions.

† One patient was a protocol violator who, due to a crisis event occurring during the intervention period and subsequent assessment of significant risk, received ongoing support from the AP while more specialist assistance was arranged. In total, this patient received 13 sessions. The mean number of sessions with this patient excluded was 2·98 (S.D. = 1·4).

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Table 1. *Baseline demographic characteristics, clinical characteristics and preferences of patients assigned to the guided self-help (GSH) and waiting-list control (WLC) groups*

Characteristic	GSH ($n=57$)	WLC ($n=57$)
Mean age (S.D.)	38·7 years (10·70)	40·8 years (11·75)
Sex		
Female	41 (71·9%)	36 (63·2%)
Ethnicity		
White	57 (100%)	57 (100%)
Marital status		
Single	16 (28·1%)	16 (28·0%)
Married/co-habiting	33 (57·9%)	27 (47·4%)
Separated/divorced/widowed	8 (14·0%)	14 (24·6%)
Educational qualifications		
Degree/higher degree or equivalent	12 (21·1%)	10 (17·5%)
Post-16 years non-degree level	14 (24·6%)	14 (24·6%)
Secondary-school level	19 (33·3%)	25 (43·9%)
None/other	12 (21·0%)	8 (14·0%)
Accommodation		
Owner-occupied	37 (64·9%)	31 (54·4%)
Rented from council	8 (14·0%)	14 (24·6%)
Privately rented	12 (21·1%)	12 (21·0%)
Socioeconomic class[a]		
Managerial and professional occupations	19 (33·3%)	16 (28·1%)
Intermediate occupations	16 (28·1%)	13 (22·8%)
Routine and manual occupations	12 (21·1%)	19 (33·3%)
Unemployed/long-term sick	10 (17·5%)	9 (15·8%)
Mean number of primary-care contacts in previous 6 months (S.D.)	4·5 (3·2)	4·6 (2·8)
% Currently prescribed psychotropic medication	65%	68%
% Having had contact with a mental health professional in previous 6 months	25%	23%
Mean HADS score (S.D.)	25·26 (6·66)	24·95 (5·40)
Mean BDI score (S.D.)	25·71 (10·93)	25·73 (9·30)
Mean CORE-OM score (S.D.)	1·98 (0·64)	1·87 (0·55)[b]
Mean SAS score (S.D.)	2·68 (0·59)	2·57(0·51)[b]
Preference score (S.D.)[c]	8·66 (2·28)[d]	8·64 (2·01)[e]

HADS, Hospital Anxiety and Depression Scale; BDI, Beck Depression Inventory; CORE-OM, Clinical Outcomes in Routine Evaluation outcome measure; SAS, Social Adjustment Scale.

[a] Based on National Statistics Socio-economic Classification of occupations (NS-SEC).

[b] $n=55$ (data missing for two patients).

[c] 10-point scale, high scores represent stronger preference for GSH group.

[d] $n=56$.

[e] $n=53$.

Eleven patients (9·6%) were lost to follow-up at 3 months (defined as failure to collect primary outcome data). Key predictors were study site, baseline combined HADS score and waiting time for conventional therapy. In addition, a small number of patients did not provide data on some secondary outcomes at follow-up.

Clinical outcomes and satisfaction

Table 2 shows descriptive statistics for the main outcome measures at 3 months, the results of the main regression analysis, and the effect sizes. The effect size estimates on three outcomes showed some benefit for GSH, but these were 'small' according to current conventions (Cohen, 1988; Lipsey, 1990) and only the effect on the social functioning scale approached statistical significance ($p=0·054$).

Data on patient satisfaction with the APs were compared with data (using the same 8-item scale) from a previous trial of CBT and non-directive counselling (delivered by more experienced therapists working in the same setting). Satisfaction in the current study was significantly higher (mean = 4·15, S.D. = 0·52, $n=42$) than in the previous trial (mean = 3·89, S.D. = 0·81, $n=297$; difference 0·26, 95% CI 0·007–0·513).

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Table 2. *Clinical outcomes at 3 months*

Outcome	GSH (mean, S.D., *n*)[a]	WLC (mean, S.D., *n*)[a]	Adjusted mean difference (95% CI)[b]	*p* value for group effect	Effect size[c]	Adjusted effect size[d]
HADS	20·08 (7·56) (50)	21·48 (7·90) (53)	1·18 (−1·46 to 3·81)	0·38	0·18	0·18
BDI	17·78 (10·66) (50)	19·98 (11·96) (53)	1·46 (−2·19 to 5·11)	0·43	0·19	0·16
CORE-OM	1·54 (0·76) (49)	1·58 (0·89) (51)	0·13 (−0·14 to 0·39)	0·35	0·05	0·19
SAS	2·33 (0·54) (48)	2·46 (0·72) (51)	0·19 (0·0 to 0·38)	0·054	0·20	0·40

GSH, Guided self-help; WLC, waiting-list control; HADS, Hospital Anxiety and Depression Scale; BDI, Beck Depression Inventory; CORE-OM, Clinical Outcomes in Routine Evaluation outcome measure; SAS, Social Adjustment Scale.

[a] The variable n reflects the fact that patients completed some but not all of the outcome assessments.

[b] Adjusted mean difference and 95% confidence intervals based on output from analysis of covariance, adjusting for baseline values of the relevant outcome, the minimization variables, and those variables identified as predictors of loss to follow-up.

[c] Effect size based on difference in raw means divided by pooled post test standard deviation.

[d] Effect size based on difference in adjusted means divided by root mean squared error from the regression equation.

DISCUSSION

The main analysis showed no significant benefit on the primary outcome associated with the intervention. There was some evidence of significant benefit in social functioning but this is difficult to interpret. The 'phase' theoretical model of change (Howard *et al.* 1999) hypothesizes that psychological treatments work through a sequential influence on *remoralization* (support and optimism), *remediation* (symptom reduction) and *rehabilitation* (improvement of functioning in life roles). The effect on social functioning does not accord with this model since it does not appear to be mediated through significant symptom reduction. Patients did report high levels of satisfaction concerning their relationship with the APs.

Internal validity

Several design features heighten internal validity. Concealment of allocation is a key quality criterion for randomized trials (Schulz *et al.* 1995), but a recent systematic review found that this is rarely reported in studies of minimal interventions (Den Boer *et al.* 2004). Effective concealment of allocation, combined with relatively low levels of attrition, ensure that the comparison of outcomes in the present study is likely to be unbiased. The outcome measures in the trial were all validated, although it should be noted that all were self-report measures, and there was no observer-rated measure. Despite randomization, there were more females, homeowners and non-manual workers in the intervention group (Table 1). However, evidence concerning the relationship of patient characteristics and outcomes in minimal interventions is limited (McKendree-Smith *et al.* 2003), and there is no *a priori* reason to assume that these differences would have substantive importance.

Although the original sample size was not achieved, that was based on *cost* estimates where sample sizes are traditionally higher (Briggs, 2000). The study did have acceptable power to detect the conventional 'medium' effect size of 0·5 (Cohen, 1988), which is also the minimum effect size considered 'clinically significant' for treatment guidelines developed by NICE (National Collaborating Centre for Mental Health, 2005). Recruitment to trials of psychological therapy in primary care is notoriously difficult (Fairhurst & Dowrick, 1996; Hetherton *et al.* 2004) and the sample size is relatively high compared to studies of minimal interventions included in recent reviews (Den Boer *et al.* 2004; National Collaborating Centre for Mental Health, 2005; Anderson *et al.* 2005).

Integrity and adherence checks are a key aspect of 'explanatory' studies but are not generally considered critical for 'pragmatic' designs. Tapes of sessions were reviewed, although there was no formal evaluation of integrity. However, there was some evidence that APs had experienced some difficulties in keeping sessions within time limits, with the overall mean just exceeding the maximum length originally proposed (30 minutes). This has been noted in other studies of GSH in this group (Lucock *et al.* 2004), but is unlikely to be a significant threat to internal validity.

There was evidence that patients were exposed to the planned intervention. The proportion

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attending more than one session (81%) was almost exactly the same as in a previous trial of conventional CBT treatment in the same setting (King *et al.* 2000). Whilst there are obvious limits to the validity of self-reported adherence, a significant proportion of patients reported undertaking therapeutic activities from the manual. Although limited, the available data do not provide strong evidence that problems with adherence account for the null findings.

Patients in both groups accessed 'psychosocial' services outside the trial. This was more frequent in the control group (although the difference did not reach statistical significance). It is possible that the lack of effect of GSH partly reflects greater help-seeking in controls. Pragmatic trials conducted in routine care settings are unable to restrict patient access to other services, but the frequency of such help-seeking has important implications for the cost effectiveness of stepped care systems (Bower & Gilbody, 2005).

External validity

There are obvious concerns about external validity, given the relatively small percentage of potential patients who responded to the invitation. The reason for poor uptake is unclear, but may reflect low acceptability of minimal interventions to patients, patient reluctance to participate in research, or the ineffectiveness of postal recruitment within a depressed population. It should be noted that many psychological therapy trials in the UK that recruit via primary-care clinicians are simply unable to report numbers of eligible patients who are initially approached to participate (Ward *et al.* 2000; Chilvers *et al.* 2001). It is, therefore, unclear how the proportion recruited in the present study compares to the wider literature.

Clearly the results cannot be generalized to *all* patients waiting for psychological therapy. However, it is likely that patients who agreed to participate were those who were most motivated to receive the GSH intervention. Given that no significant effect was found in this group, it seems unlikely that positive effects would be found in the wider population of those referred for treatment who did *not* opt to participate. Second, although use of GSH within a stepped care system is predicated on at least a proportion of patients agreeing to use it, it is not necessarily the case that it is to be used with *all* patients. Therefore, although the results of the present study cannot be generalized to the wider population waiting for treatment, the population of interest may in fact be those who would actively agree to such treatment.

The results in the context of the wider literature

Relating these results to the wider literature is complex due to problems of comparability between different settings, samples and interventions. Previous meta-analyses examining minimal contact CBT bibliotherapy in depression and anxiety have reported 'large' effect sizes of around 0·8 (Cuijpers, 1997; Gregory *et al.* 2004; Den Boer *et al.* 2004). However, many of the included studies used volunteers recruited from advertisements rather than clinical populations, and there is evidence that this factor is a key moderator of effects in psychological therapies (Churchill *et al.* 2002).

Greater comparability is found in studies of patients treated in primary care. A meta-analysis of six trials of 'pure self-help' found a more modest overall effect size of 0·41 (Bower *et al.* 2001), although most of the trials involved anxiety. The quality of the included studies was relatively low, however, which may account for the larger estimate of effect. Recent similar trials of GSH in primary care have reported even smaller effects, similar to those in the present study (Richards *et al.* 2003*a*; Willemse *et al.* 2004). However, a high-quality trial of computerized CBT for depression reported a larger effect size of 0·47 (Proudfoot *et al.* 2004). Thus, some minimal interventions appear capable of achieving substantial effects in clinical populations.

Clearly, the present results may not relate to all minimal interventions, and specific aspects of this particular GSH intervention may be responsible for the null findings. A concurrent study, utilizing the same self-help manual developed for the present trial but in a 'pure self-help' model, also reported no benefit (Fletcher *et al.* 2005). This suggests the manual itself may have been ineffective, although it was evaluated favourably by users before and during the trial, and included relatively well-tested cognitive-behavioural techniques. However, the range of techniques incorporated may have failed to include some of relevance to certain patients

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in what was a highly heterogeneous sample. This could have been overcome using more specific trial inclusion criteria, or greater matching of patient problems to particular minimal interventions (e.g. using a range of therapy manuals). Whilst potentially more effective, such procedures would be a poor reflection of current practice, highlighting the tension that exists between explanatory and pragmatic trials (Roland & Torgerson, 1998).

As noted in the Introduction, there is evidence that self-help treatments with more therapist contact demonstrate more robust effects across a range of anxiety diagnoses (Newman *et al.* 2003). This was one of the reasons for adopting the GSH model in the present study, as it was hypothesized that contact with a professional (even a relatively inexperienced one) would maximize impact and provide critical 'common factors' (Roth & Fonagy, 1996). However, it is possible that use of relatively inexperienced staff with only brief training made the intervention *less* effective. Some of the contact between APs and trial participants may have been insufficiently focused on the key cognitive-behavioural mechanisms, so diluting delivery of the effective mechanisms of change, and there may be a degree of tension between encouraging self-help and empowerment in patients, and having access to a trained professional and expectations of traditional psychological therapy. There was evidence from taped sessions that patients were sometimes able to engage APs in broader discussions about issues not in line with the 'health technology' model. This might account for the advantages of computerized therapy, which may provide a more standardized intervention and thus maximize effectiveness. Clearly, this is an important empirical and theoretical issue.

The intervention may have been aimed at the wrong group of patients. It is possible that the patients were too mildly ill to demonstrate additional benefit over and above the general tendency to remit. However, baseline BDI scores were similar to those from previous studies in similar contexts (Friedli *et al.* 1997; Ward *et al.* 2000), and it may be that the current sample may represent a population more relevant for *higher* levels of the stepped care system involving brief psychological therapy. A recent study of minimal contact psychotherapy for sub-threshold depression (i.e. symptoms not meeting DSM-IV criteria for depressive disorder) did find a significant effect on the incidence of major depression (Willemse *et al.* 2004) which suggests a role for minimal interventions in a different patient population to that studied here.

Finally, patients included in this study had already been referred for conventional psychological therapy, which would have generated particular expectancies as to the content and outcome of psychological treatment. Such expectancies may influence outcome (Marks *et al.* 2003).

Untangling these potential explanations is a complex task. The authors have adopted the Medical Research Council's 'complex interventions' framework (MRC, 2000), and are taking a staged approach to develop a clearer understanding of the important factors and mechanisms of change in these types of interventions.

ACKNOWLEDGEMENTS

The study was funded by the National Primary Care Research and Development Centre, University of Manchester, which is funded by the Department of Health. The views expressed in the paper are those of the authors and do not represent the views of the funding body. We are grateful to Dr Anne Kennedy, who co-wrote the self-help manual, and to the assistant psychologists and patients who participated in the trial. We also thank Professor William B. Stiles for helpful comments on an earlier version of this manuscript.

DECLARATION OF INTEREST

The written self-help manual used in this study is part of a series. Other titles in the series have been published commercially. The University of Manchester receives some funds from those sales, but there is no benefit to individuals. No decision has been made on the commercial sale of the manual used in the present study.

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