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A pragmatic randomized controlled trial of a guided self-help intervention versus a waiting list control in a routine primary care mental health service.

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ABSTRACT

Objectives: To evaluate the effectiveness of a two session guided self-help (GSH) intervention provided by primary care graduate mental health workers (PCGMHWs) in a primary care mental health service.

Design: Pragmatic randomised trial, with a wait list control design.

Method: Patients presenting with significant anxiety and depression problems were given one or more self-help booklets at screening and randomly allocated to an immediate (ITG) or delayed treatment group (DTG). Following this, a 2 session GSH intervention was provided by one of two PCGMHWs, with a review session to decide on the need for further intervention. The delayed treatment group began the intervention 8 weeks after the screening and the primary outcome was CORE-OM scores after 8 weeks.

Results: 63 patients were allocated to the ITG, 59 to the DTG. Analysis of covariance, carried out on an intention to treat basis, showed a significant treatment effect, $F(1,98) = 15$, $p < 0.001$, and a comparison of means at 8 weeks showed a significant difference, $t(116) = 2.1$ (95% CI: 1.1, 5.9) , $p = 0.042$ with an effect size, d, = 0.375. Taking the two groups together, CORE-OM scores for patients who completed the intervention reduced between screening and the review session by an average of 7.9 (95% CI: 6.3, 9.5), effect size of 1.2. Between screening and the review session, 47% showed a reliable and clinically significant improvement.

Conclusions: The study provides some support for the effectiveness of a 2 session GSH intervention and a stepped care service model.

INTRODUCTION

In recent years there have been significant service delivery and clinical developments to address the long standing problem of poor access to psychological interventions. These include developing briefer, or minimal, interventions that can be provided by practitioners without specialised training in formal psychological therapy, sometimes called paraprofessionals. There is some evidence that paraprofessionals can be as effective as professionals in providing treatment programmes for anxiety and depression (Bright, Baker and Neimeyer, 1999; Den Boer, Wiersma, Russo and van den Bosch, 2005). In the UK, the development and provision of brief, low intensity interventions has been promoted by treatment guidelines from the National Institute for Health and Clinical Excellence (NICE) which recommends Cognitive Behavioural Therapy (CBT) based guided self-help interventions for patients with mild to moderate anxiety (NICE, 2004) and depression (NICE, 2009).

Role of guided self-help in improving access to psychological therapies

In terms of models of service delivery, NICE guidance recommends that self-help interventions for anxiety and depression are provided as part of a stepped care model. Stepped care involves providing the least intensive (and therefore least costly) interventions first and only if these prove to be unsuccessful should more intensive interventions be offered (Davison, 2000; Lovell and Richards, 2000). It therefore has the potential to improve services in terms of accessibility and efficiency, but the effectiveness of these low intensity interventions in routine services should be established. In the UK the provision of guided self-help and other low intensity interventions within a stepped care service model also form a key part of the new Improving Access

to Psychological Therapies (IAPT) services, which has received significant investment (Department of Health, 2007). Low intensity interventions are provided by workers such as primary care graduate mental health workers (PCGMHWs) and Psychological Wellbeing Practitioners (PWPs). Both these roles have been developed in the UK to provide CBT based interventions such as guided self-help for patients with mild to moderate common mental health problems. They are not trained as therapists but receive training and ongoing clinical supervision to provide low intensity interventions. They therefore differ from paraprofessionals who may not have received any training or supervision. There is encouraging evidence of the effectiveness of low intensity interventions in an IAPT pilot site (Richards and Suckling, 2009), but controlled trials are required.

Effectiveness of self-help interventions

Meta-analyses support the effectiveness of self-help interventions for anxiety and depression (Bower, Richards and Lovell, 2001; Cuijpers, 1997; Gould and Clum, 1993; Marrs, 1995; Scogin, Hanson and Welsh, 2003) and a review of research into self-help approaches for mental health problems supports the effectiveness of CBT-based self-help materials for anxiety, depression, bulimia nervosa and binge eating disorder (Lewis, Anderson, Araya et al, 2003). Despite this evidence, a number of key questions remain, such as the type and amount of guidance required, effective models of provision and cost effectiveness. Also, there are still relatively few adequately powered controlled studies of guided self-help, and some controlled studies have failed to demonstrate clear benefits (e.g. Mead, Macdonald, Bower, Lovell, Richards, Roberts and Bucknall, 2005). To evaluate the effectiveness of

guided self-help in the context of stepped care and the new IAPT services it is important to carry out controlled trials in routine services.

The importance of good quality effectiveness research in routine services to complement efficacy research has been widely advocated (e.g. Roth and Fonagy, 1997; Shadish et al 1997, Shadish, Navarro, Matt, & Phillips, 2000). In order to establish experimental control, clinical trials tend to exclude patients with co-morbidities (e.g. Westen and Morrison, 2001) and these are often the very patients seen in routine services. For example, co-morbid anxiety and depression are particularly common (Roy-Byrne, Katon, Broadhead et al, 1994) and are associated with poorer compliance with and response to treatment (Lecrubier, 1998). One way of ensuring controlled studies reflect the variety of patients seen in routine practice is with pragmatic RCTs which tend to have fewer exclusion criteria and less emphasis on diagnostic assessment (Hotopf, 2002). It is also widely acknowledged that collection of routine service outcomes can provide practice based evidence to compliment efficacy studies and support the benchmarking of services (Barkham and Margison, 2007) and is an example of clinically representative research (CRR, Shadish et al, 1997).

Consistent with this approach, the purpose of this study is to evaluate a two session model of guided self-help (GSH) for patients with mild to moderate anxiety and/or depression using a pragmatic RCT. The provision of the intervention was consistent with the stepped care model advocated in the NICE guidelines for anxiety and depression (NICE, 2004, 2009). The provision of self-help material (without guidance) was compared with an enhanced condition where 2 sessions of guidance was provided. Further

practice based evidence is provided on routinely collected outcomes for patients who were not part of the trial.

METHOD

Design

The study used a pragmatic randomised controlled trial (RCT) design, with a wait list control group to ensure all participants received the intervention. One group received the two session intervention within eight weeks following the initial screening by the service. The delayed intervention comparison group received the same intervention after a delay of eight weeks after the initial screening. The primary outcome was CORE-OM scores at 8 weeks after the first screening session.

Setting

The research was carried out within a primary care mental health team in West Yorkshire, UK. This locality has a population of approximately 320,000 and is made up of a small city and towns based around former mining communities. The proportion of BME population is relatively small. The service received approximately 3000 referrals per year, mainly from General Practitioners. Referred patients were seen for an initial screening assessment, usually within two weeks of the referral, and sign-posted to various local services and therapy options, one of which was guided self-help.

Procedure

At the screening assessment, carried out by an experienced mental health professional, appropriate patients were given one or more self help booklets developed by the Northumberland Tyne and Wear NHS Trust (available at http://www.ntw.nhs.uk/pic/leaflet.php?s=selfhelp). Those patients fitting the

inclusion criteria were referred for the GSH intervention and given an information sheet and consent form regarding the research. Those opting into the intervention and the research were randomly assigned to either an immediate or delayed treatment control condition using a random allocation computer programme. This was carried out by a researcher independent of the service and concealed from those deciding on eligibility for the study (those clinicians carrying out screening assessments).

The ITG were seen for the first GSH session within 3 weeks of the screening, the DTG 8 weeks after screening. Those not opting into the research still received the GSH intervention. Figure 1 shows the flow of patients through the study. Outcome measures were completed on 5 occasions: at initial screening, at each of the 2 guided self-help sessions, at the review session, and by post at 3 months follow up. At the review session a decision was made about whether the patient could be discharged, whether they should receive more GSH sessions or whether they should be referred to another service for intervention.

----------Figure 1 about here ----------

Inclusion criteria

Following referral to the service, patients were assessed for suitability for the intervention by an experienced mental health professional in the team. The team was set up to receive referrals for mild to moderate mental health

problems, with more severe problems being referred directly to Community Mental Health teams or Psychological Therapies Services. Assessors were given inclusion and exclusion criteria which included positive indicators of suitability for a guided self help intervention. Inclusion criteria were presenting with anxiety and/or depression as a main presenting problem and with an onset within the last year, reasonable literacy skills, English as a first language, motivation for some self-directed change and identification of problems and goals to work on. Patients were excluded if they were experiencing obsessive compulsive disorder, post traumatic stress disorder or substance misuse as the main presenting problem, because the intervention was not considered appropriate to address these problems. Patients with psychosis and those who were actively suicidal were also excluded. These decisions were made within the screening assessment and no formal diagnostic assessments were carried out, reflecting routine practice.

Measures

The 34 item Clinical Outcomes in Routine Evaluation (CORE-OM: Evans, Connell, Barkham, Margison, Mellor-Clark, McGrath and Audin, 2002) was used as the outcome measure in this study. It was being used routinely within the service so its use reduced the impact of the study on the routine service provision. The CORE-OM is a self report measure of global psychological distress, and includes items reflecting subjective well-being, problems or symptoms, life/social functioning and risk to self and others. All items are rated on a 0 to 4 point scale indicating degree of agreement with the statements. Scores were calculated by multiplying the average item scores by 10, giving a scoring range of 0 to 40. The clinical cut off for caseness is 10

and above, with severity cut offs of 15 for moderate, 20 for moderately severe and 25 for severe. A 5 point change represents a statistically reliable change (Barkham, Stiles, Connell et al 2008).

The intervention

The guided self-help intervention was provided by two primary care graduate mental health workers (PCGMHWs). These were both psychology graduates and had completed a post graduate certificate in primary care mental health, which included training in CBT based guided self-help. They were supervised by an accredited cognitive behavioural therapist. At the initial screening patients were given one or more self-help booklets and the patients were asked to bring this material to their first GSH session. The most frequently provided booklets were 'Depression' (27), 'Depression and Low Mood' (48), 'Panic' (42) and 'Stress and Anxiety' (78). The guided self-help intervention involved two 60 minute sessions with the GPCMHW and a thirty minute follow up session. All sessions were face to face. The first session involved a discussion of the problems the patient had been experiencing and agreement of goals the patient would like to achieve. The GPCMHW then worked through the self-help material with the patient to identify helpful techniques that may enable the patient to achieve one or more of their goals. The second meeting was three weeks after the first and involved a review of the techniques and a discussion around how these could be refined to bring the patient closer to achieving their goals. The patient was offered a third appointment two weeks later to review progress and decide if a further more intensive intervention was required.

Sample size calculation

The sample size target was 64 per group. This was based on the sample required to detect a medium effect size between the two groups at a statistical significance of 0.05 and 80% power (Cohen, 1992). An alternative sample size calculation was also conducted, based on the detection of a reliable change of 5 points on the CORE-OM (Barkham et al, 2008) between the two groups after 8 weeks. Assuming a standard deviation of 6.5, based on previous studies with similar populations (Barkham et al, 2008), a standardized difference of 0.77 was calculated. Using the nomogram provided by Altman (1982), the total sample size required to detect this standardized difference with 80% power using a cut off for statistical significance of 0.05 is approximately 52, 26 in each group. Although the sample size of 64 per group was considered realistic, it was not achieved because recruitment to the study ended prematurely due to both the PCGMHWs leaving their posts.

Analysis

The primary outcome measure was CORE-OM scores at 8 weeks. Analysis was carried out on an intention to treat basis, using last observation carried forward (LOCF). Comparisons between the immediate treatment and delayed group at 8 weeks were based on analysis of covariance, with CORE-OM scores at screening as covariates. Pre and post intervention CORE-OM scores were compared using t tests.

Figure 1 shows the numbers attending each session and the data available for each group at each stage.

Ethical approval and funding.

The study was given approval by the local NHS ethics committee and by the NHS Trust providing the service. The study was not supported by an external research grant.

RESULTS

Pre treatment characteristics.

Comparing those included in the study (n=122) and those excluded, due to not opting into the intervention (n=55) or the research (n=87), there were no significant differences in age (37.8 for the included group vs 38.6 for those excluded, $t(251) = 0.46$, $p = 0.64$), gender (62% female vs 69% female, Chi-square = 2.7, df = 2, $p = 0.44$), CORE-OM scores at screening (included group mean 18.6, sd = 6.4 vs excluded group mean 18.3, sd = 7.9, $t(187) = 0.18$, $p = 0.86$).

For the patients who were included in the study, CORE-OM clinical scores at screening indicated 92% of patients were above the cut off for caseness (10) and 16% were above the severe cut off (25). Table 1 shows the baseline characteristics of the two groups. This includes the main presenting problems and the frequency of self-help booklets provided which is a proxy for presenting problems. The table shows there were no significant differences between the ITG and DTG in age, gender, CORE-OM scores at screening. It also shows similar numbers of main presenting problems and self-help booklets provided.

---------- Table 1 in here ----------

Adherence and patient flow

Figure 1 shows the flow of patients through the study and the rates of attrition. In total, 17 patients dropped out after screening (7 in the ITG and 10 in the DTG), so did not attend the first GSH session despite opting into the intervention and the research. A further 20 patients dropped out after the first GSH session (11 in the ITG and 9 in the DTG), and 15 dropped out after the second GSH session (9 in the ITG and 6 in the DTG). As a consequence of this, at 8 weeks, primary outcome measures were available on 34/59 for the ITG and 49/59 for the DTG. Figure 1 also shows that CORE-OM assessments were not always completed even when patients attended sessions.

Clinical outcomes

Table 2 shows the CORE-OM scores (with last observations carried forward for missing data) for the two groups at screening and 8 weeks.

---------- Table 2 in here ----------

For the primary outcome measure, CORE-OM scores after 8 weeks, Analysis of Covariance, on an intention to treat basis with CORE-OM scores at screening as the covariate, showed a significant treatment effect, $F(1, 98) = 15.0$, $p < 0.001$. A comparison of means showed a significant difference, $t(116) = 2.1$ (95% CI: 1.1, 5.9), $p = 0.042$, with an effect size, Cohen's $d = 0.375$.

For all patients who completed the intervention, there was a reduction in mean scores of 7.9 (95% CI: 6.3, 9.5), effect size of 1.2, between screening and the GSH review session. Taking the two groups separately, there was a reduction in mean scores between screening and the review session of 8.0 (95% CI: 5.7, 10.3) for the ITG and of 7.8 (95% CI: 5.3, 10.2) for the DTG. There were significant reductions in CORE-OM scores between the screening and the first guided self help session for the two groups combined, $t(87) = 5.6$, $p < 0.001$ and for both groups separately: ITG, $t(46) = 3.8$, $p < 0.001$; DTG, $t(40) = 4.1$, $p < 0.001$.

For all patients, there was no significant change between GSH review session and 3 month follow up on the limited data available, $t(25) = 0.27$, $p = 0.79$.

Reliable and clinically significant change

Comparing CORE-OM scores at screening and the review session, 28 of 59 patients (47%) showed reliable and clinically significant improvement (RCSI), moving from above to below the cut off of 10 for caseness and showing improvements of 5 or more points. Just one patient, in the ITG, had a reliable deterioration of more than 5 points on the CORE-OM.

Service outcomes after the GSH intervention

Data on the need for further intervention was available on 81 of the patients. Of these, 34 (42%) were discharged after the 3 GSH sessions, 10 were given one further session, 4 given two further sessions, and 7 given four to nine further sessions. Therefore of the 81, 64 (79%) were discharged after 3 to 12 GSH sessions. Of the remaining patients, 12 (15%) were referred for further formal psychological therapy and 2 returned to the practitioner who carried out the screening for further support/monitoring.

Practice based evidence on patients not included in the trial

As the CORE-OM was routinely used as an outcome measure within the service, outcome data was available for some patients who received the intervention but did not opt into the RCT. This data is presented to compare outcomes of patients included in the RCT with that of routinely collected practice based evidence (Barkham and Margison, 2007) from patients receiving the same intervention from the same practitioners. For 25 patients with CORE-OM data at screening and the GSH review session, there was a reduction in mean scores of 7.2 (95% CI: 3.9, 10.5), effect size of d = 0.9, and 10 of 25 patients (40%) showed RCSI, moving from above to below the cut off of 10 for caseness and showing improvements of 5 or more points. No patients showed a reliable deterioration of 5 or more points.

DISCUSSION

This study lends support to the effectiveness of a two session guided self-help intervention provided by PCGMHWs. However, a number of issues should be acknowledged to put these findings into context. Using intention to treat analysis, a medium effect size (Cohen, 1988) of 0.375 was found on the main outcome measure at eight weeks but this may have been an under-estimate of the effect of the intervention because in the last observation carried forward method pre intervention scores were carried forward as post intervention scores. The effect size compares to average treatment effects of 0.41 in a meta-analysis of six trials of pure self-help in primary care settings (Bower, Richards and Lovell, 2001) and a meta analysis of bibliotherapy for anxiety and depression suggested effect sizes of 0.84 (Den Boer et al, 2004).

There was a significant improvement between screening and the first GSH session for both groups. This could have been due to the fact that patients were improving without any intervention or could have been due to benefits of having been given self-help information at the screening session. The impression of the GPCMHWs was that very few patients had looked at the self-help materials prior to the first GSH session, suggesting the provision of the self-help materials alone was not effective. In any case, the improvement prior to the first GSH session reinforces the importance of controlled studies in routine services to separate out treatment effects.

For those patients who completed the intervention, there was an effect size of 1.2 between screening and the GSH review session but clearly not all this effect can be attributed to the GSH sessions. The study used a relatively short intervention and it is possible that the effect size would have been larger with an intervention using more sessions, perhaps of a shorter duration. This is supported by Richards and Suckling (2009) who report effect sizes of 1.38 for depression (measured by the PHQ-9, Patient Health Questionnaire) and 1.41 for anxiety (measured by the GAD-7, Generalised Anxiety Disorder Assessment) in an IAPT demonstration site, with the length of interventions averaging 5.15 sessions over a mean time of 2h and 45 minutes.

This pragmatic RCT provides information on outcomes in a real-world clinical setting but with some experimental control, including random allocation. It therefore represents a balance between internal and external validly. In terms of internal validity, both groups were similar on those baseline characteristics measured but the pragmatic nature of the study meant that no formal diagnostic assessments were carried out and relatively broad inclusion criteria

were used. Despite similarities between the two groups in terms of frequency of presenting problems and the type of self-help booklets given at screening, it is possible that the two groups were not matched in terms of diagnosis. The most significant limitation of the study was the rate of attrition. This reflected the realities of routine practice but a consequence was that at the primary outcome point, data was available for 54% of the ITG and 83% for the DTG. Another limitation of this study was the incomplete follow up clinical outcome data which means no clear conclusions can be drawn on longer term effectiveness of the intervention.

In addition to the group comparison, the study presents further data worthy of consideration and which relates to the outcomes observed in this real world service setting. Firstly, the outcomes for the two groups in the RCT were similar, with both achieving similar reductions in mean scores between screening and the review session. This suggests the wait for the delayed group did not adversely affect the outcome. Secondly, data was presented on the outcomes of 25 patients who did not opt into the RCT but who did complete the CORE-OM as part of routine outcome monitoring. These patients showed an effect size of 0.9, lower than the 1.2 for the patients in the RCT. There was also a slightly lower proportion of patients who showed a RCSI (40% vs 47%). This suggests some attenuation of outcomes in patients in the routine service compared to those included in the RCT. Such attenuation of practice based studies compared to efficacy studies has been found in terms of effect sizes but practice based studies tend to do as well as efficacy studies in terms of RCSI rates (Cahill, Barkham & Stiles, in press). In this study the difference was unlikely to be due to any differences in the

intervention which was provided by the same practitioners, although this cannot be ruled out as the practitioners were aware of the research status of the patients. It is also possible that patients opting for the research were on average more motivated to engage in self-help but this is only speculation. Data was available on service outcomes with 42% of patients being discharged after the two session GSH intervention, a further 37% discharged after further GSH interventions provided by the GPCMHW and just 15% being referred on to formal psychological therapy, mainly CBT, considered a high intensity intervention in the UK IAPT service model. This suggests GSH, a low intensity intervention provided by GPCMHWs without training in formal psychological therapy, was considered to be sufficient for most patients. It therefore supports the stepped care service model.

Finally, in considering how this study fits into the wider evidence base for guided self-help, it is important to recognize that there will be many factors influencing the effectiveness of self-help interventions. These may include the service context, referral process, problem severity and type, type of self-help materials used, the training and competence of the facilitator, number, length and structure of sessions etc. It is difficult to identify moderators of effective self-help interventions using meta-analytic approaches (Gellatly, Bower, Hennessy, Richards, Gilbody and Lovell, 2007), so it is important to complement efficacy studies with effectiveness studies in routine services, such as this one, to investigate the effectiveness of the interventions in the particular clinical setting in which it is provided.

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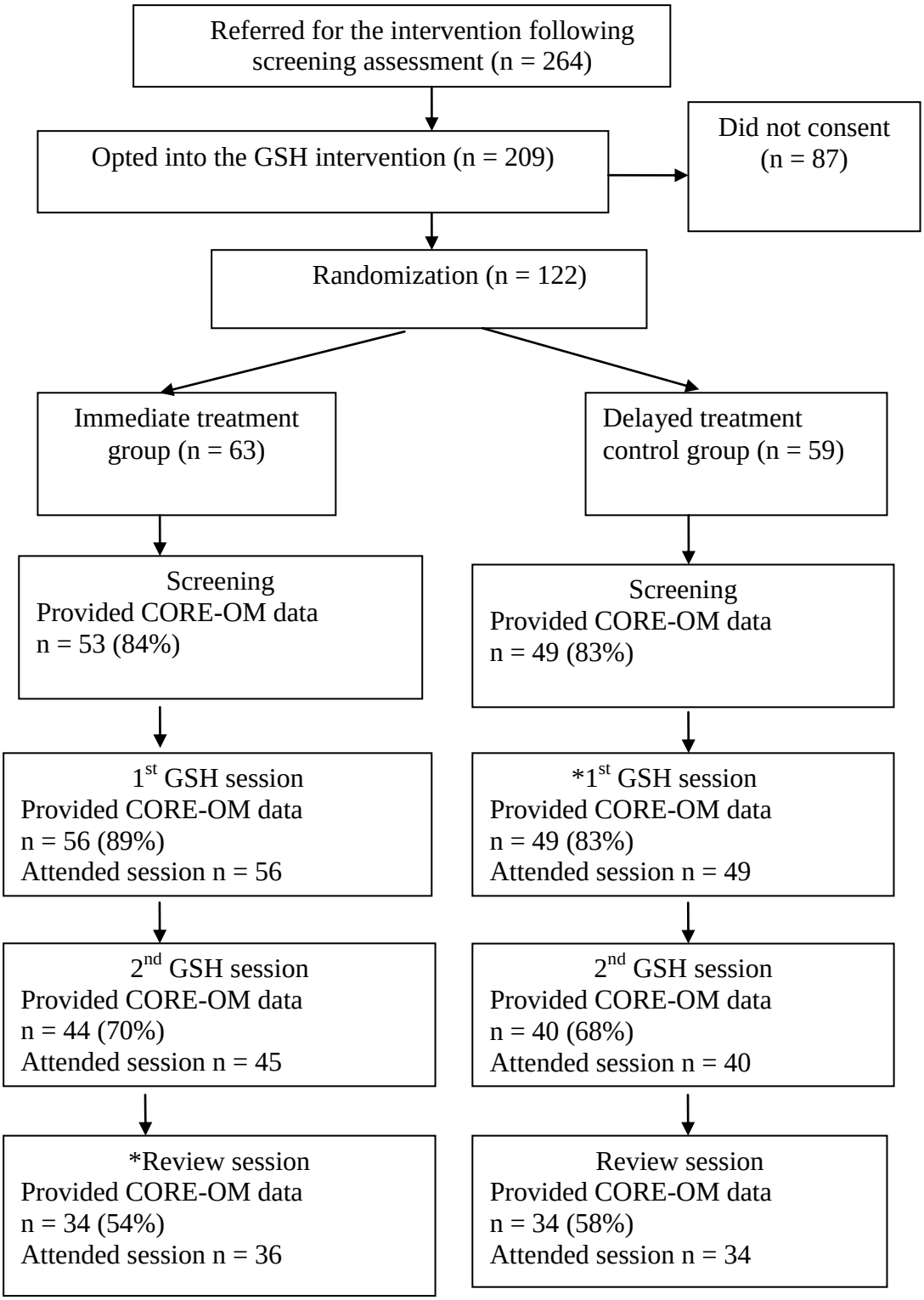
Figure 1. CONSORT diagram showing flow of patients through the study



*Main outcome comparison at 8 weeks

Table 1. Baseline characteristics of the participants and CORE-OM scores at screening and 8 weeks

	Immediate treatment group (n = 63)	Delayed treatment control group (n = 59)	
Age, years: mean (s.d.)	38.8 (12.8)	40.6 (13.1)	t (122) = 0.77, p = 0.44
Gender: % females	60%	64%	x^2 = 3.16, df = 2, p = 0.37
CORE-OM: Mean (s.d.)	18.9 (6.6)	18.4 (6.0)	t (100) = 0.42, p = 0.68
Main presenting problems			
Anxiety (inc, GAD)	26	25	
Depression	22	26	
Anxiety and depression	26	21	
Panic	25	28	
Self-help booklet given at screening			
Depression	22	15	
Depression and low mood	37	40	
Panic attacks	28	32	
Stress and anxiety	57	62	
Stress	7	8	

Table 2. CORE-OM scores for the immediate treatment and delayed treatment control group at screening and at 8 weeks

	CORE-OM at screening Mean (SD)	Intention to treat (LOCF) CORE-OM at 8 weeks Mean (SD)
Immediate treatment group	18.9 (6.6) n = 53	12.3 (8.7) n = 53
Waiting list control group	18.4 (6.0) n = 49	15.3 (7.6) n = 49