Abstract

Objectives. Interventions delivered by Psychological Wellbeing Practitioners in IAPT are based on low intensity translations of cognitive behavioural therapy (CBT). Recently, a version of guided self-help (GSH) based on cognitive analytic therapy (CAT) has been developed and found to be effective. **Methods**. This trial will employ a partially randomised patient preference trial (PRPPT) methodology in a routine Improving Access to Psychological Therapies (IAPT) service. Participants will be assessed with the MINI to ascertain a diagnosis of an anxiety disorder. Participants will be offered the intervention they choose (i.e. CAT-GSH or CBT-GSH) and those participants that are undecided will be randomised. Treatment will be six to eight 35-minute sessions in each arm. The primary outcome measure is the Beck Anxiety Inventory (BAI), with secondary outcome measures of the IAPT minimum dataset and indices of service utilisation. Participants will be followed up at 8-weeks and 24- weeks. **Planned analyses.** Choice, treatment completion, dropout and step-up rates will be summarised via a CONSORT diagram. If there are no differences between randomised and preference participants within each form of GSH, then these groups will be collapsed to form a two-arm trial. The primary analysis will compare between-arm standardised effect sizes on the BAI measure, using Cohen's d_+ at 8 and 24-week follow-up. Between arm BAI outcomes at 8 and 24-week follow-up will also be compared using ANCOVA, controlling for baseline BAI at screening. The proportions in each arm achieving reliable and clinical change on the BAI will be established, with interviews exploring the change process with participants achieving a reliable pre-post change on the GAD-7. **Conclusions.** The utility of patient preference trials in mental health services are discussed and the necessary further development of robust evidence concerning low intensity interventions is highlighted.

Stepped-care service design is advocated in the National Institute for Health and Clinical Excellence (NICE) guidelines for anxiety (NICE, 2011). The Improving Access to Psychological Therapies (IAPT) initiative is a large-scale (national) attempt to systematize stepped care principles for the treatment of depression and anxiety, enabling the treatment of large numbers of patients each year across over 200 IAPT services in England. Stepped care follows the principle of offering the least restrictive and least intensive evidence-based intervention as a first line treatment, followed by more intensive and costly interventions for those who require ongoing care (Bower & Gilbody, 2005). First-line interventions in IAPT services are conceptualised as 'low intensity' treatment, which typically involves 6-8 sessions of guided self-help (GSH) based on cognitive-behavioural principles. According to stepped care principles, Step 1 involves an initial assessment by general practitioners or other healthcare providers, Step 2 involves low intensity GSH interventions, and Step 3 involves more intensive psychological therapies.

Clinical guidelines emphasize the need to offer a choice of treatments to patients experiencing common mental health problems, since different interventions may suit different patients. The range of therapies available at Step 3 in IAPT services has increased to include a range of therapies including cognitive behavioural therapy (CBT), interpersonal psychodynamic psychotherapy and other approaches (Perfect, Jackson, Pybis & Hill, 2015). However, this expansion in patient choice has not been mirrored at Step 2 of IAPT services, since currently available guided self-help interventions are based on CBT principles and delivered in the form of computerized CBT, group-based CBT, or individual low intensity CBT. To address this lack of patient choice, Meadows and Kellett (2017) developed a manualised version of cognitive analytic therapy (CAT-GSH) for delivery across the range of anxiety disorders. CAT-GSH was shown to have high adherence to GSH principles, generated low dropout rates, was easy to deliver and was clinically effective with a durable short-term effect. The evidence base for high intensity CAT for anxiety disorders is supported by clinical trials (Boogar, Rezaei & Yosefi, 2013) and cohort studies (Tzouramanis, 2010). The effectiveness of CAT for the treatment of common mental health

problems also appears to be comparable to CBT and counselling in primary care settings (Marriott & Kellett, 2014). However, CAT outcomes research has tended to mostly focus on the treatment of complex trauma and personality disorders, and its evidence base for the treatment of common mental disorders and particularly anxiety disorders is still scarce. Recent studies lend support to CAT as an effective way to treat symptoms of depression in primary care settings (Kellett et al., 2019), but less is known about the potential effectiveness of CAT for anxiety disorders.

When it is impossible to blind patients to treatment allocation in clinical trials, a potential major confound is that the effects reported may more possibly reflect the influence of patients' preferences, rather than true therapeutic efficacy (Torgerson & Sibbald, 1998). When those with strong treatment preferences refuse participation, the generalisability of the study is limited (Howard & Thornicroft, 2006). When preferences are assessed in trials, this tends to be limited to simply noting participants' preferences (without these having an influence in treatment allocation), often using single-item questions and Likert scales of preference strength (King et al., 2005). In partially randomized patient preference trials (PRPPT), participants receive detailed information on available treatment choices; those with strong preferences receive the therapy they want and can be observed as usual for all study outcomes, whilst those without a strong preference are randomized (O'Connor et al. 1987). To our knowledge the PRPPT approach has never been applied in a clinical trial of guided self-help. The objective of the present PRPPT is to contrast the efficacy and clinical durability of two differing types of manualised GSH (CAT-GSH versus CBT-GSH) for anxiety disorders delivered at step 2 of an IAPT service.

Methods

Study setting, methodology and recruitment

The design is a partially randomised patient preference design (Torgerson, & Sibbald, 1998). The study will take place in a single site: the Oldham IAPT service hosted by Pennine Care NHS Foundation Trust. When a patient is referred to the IAPT service at the routine telephone triage (and are suitable for a step 2 intervention) they will be offered the option to participate in the trial. If the

person is interested, then they will be offered a trial eligibility interview. Figure 1 illustrates the recruitment process using a CONSORT diagram and figure 2 provides the SPIRIT summary.

Inclusion and exclusion criteria

At the trial eligibility interview, potential participants will be screened with the shortened version the Mini International Neuropsychiatric Interview (MINI; Sheehan et al., 1997) to establish a diagnosis of an anxiety disorder. Participants will be included if they: (a) have self-referred or been referred by their General Practitioner or other health or social care professional for the treatment of a common mental health problem, (b) meet criteria for an anxiety disorder based on the MINI (c) have clinically significant symptoms above the established cut-off on the BAI anxiety measure – see measures section; (d) want to engage in GSH to address their anxiety disorder, and (e) are motivated to engage in treatment and can attend six sessions of face-to-face GSH. Participants will be excluded if they: (a) are currently engaging in another IAPT step 2 intervention, (b) do not currently meet criteria for an anxiety disorder, (c) do not meet caseness on the BAI, (d) meet criteria for depression and a comorbid anxiety disorder, where the depression is more severe and is the patient's main concern, (e) have a severe/chronic mental health problem and are already involved in psychiatric or secondary care mental health services and (f) have a diagnosis of social phobia or PTSD (IAPT guidelines indicate that these disorders are treated at step 3) and (g) the GSH sessions require an interpreter and (h) are unable to read and write. Overall, the rationale for focussing the trial on anxiety disorders was because the CAT-GSH was originally developed solely for the treatment of anxiety disorders and also the acknowledged brevity of evidence of CAT anxiety outcome studies.

Interventions

The interventions will be delivered by qualified Psychological Wellbeing Practitioners (PWPs). The CBT-GSH will follow the IAPT structured 6-8 session treatment protocol and associated client workbooks for anxiety (Richards & Whyte, 2011). This is treatment as usual (TAU) in the IAPT service for patients with mild-to-moderate anxiety at step 2. CAT-GSH is a structured low intensity

psychological intervention based on the principles of cognitive analytic therapy (Meadows & Kellett, 2017). The six-to-eight CAT-GSH sessions are as follows: (1) identifying anxiety snags, traps and dilemmas and associated self-monitoring homework; (2) eliciting reciprocal roles from early experiences and associated self-monitoring homework; (3) linking the past to the present and writing a CAT problem statement; (4) creating a CAT diagrammatic reformulation of the anxiety and associated self-monitoring homework; (5) identifying exits/change methods associated self-practice homework; (6) working on endings and relapse prevention.

Intervention differentiation, fidelity and competency

The difference (and the patient choice) aspect of the trial is that the CBT-GSH and CAT-GSH systematically differ in the following ways: (a) CBT-GSH works primarily with the here-and-now and CAT-GSH works with the past and the here-and-now, (b) CBT-GSH relies on an effective therapeutic relationship, but does not explicitly make use of transference and counter-transference in the therapeutic relationship, whilst CAT-GSH does work with the therapeutic relationship and makes use of transference and counter-transference in the self-help exercises and (c) CAT-GSH is based on a dialogical and relational theoretical model and CBT-GSH is based on a cognitive-behavioural theoretical model. Patient choice will be supported through a detailed information sheet containing descriptions of each form of GSH. This information sheet has been through five iterations with practicing PWPs to ensure treatments and randomisation are presented in equipoise. The strength of the preference is not measured in the trial, but is rather recorded as a strict choice. The low intensity treatment competency scale (Kellett et al., 2019) will be used to assess treatment competency in each arm. One session per participant will be randomly selected for audio-recording and associated competency assessment, using a random number generator by Graphpad (2005).

Primary outcome measure

Beck Anxiety Inventory (BAI; Beck, Epstein, Brown & Steer 1988). The BAI is a brief (21 item; score range 0-63) is a well validated outcome measure for anxiety. BAI is scored as 0–9 normal or no anxiety, 10–18 mild to moderate anxiety, 19–29 moderate to severe anxiety and 30–63 severe

anxiety. A significant reliable change on the BAI is a change score of >=10 points. The BAI will be collected at the eligibility screening interview, and at 8-weeks and 24-weeks follow-up. The BAI was selected as the primary outcome measure because of (a) its excellent psychometric properties and (b) as the measure is a good index of anxiety severity in primary care patients across a variety of anxiety disorders (Muntingh, van der Feltz-Cornelis, van Marwijk, Spinhoven, Penninx, & van Balkom, 2011). This method ensures that the primary outcome measure in this trial (BAI) is independent to the GAD-7 measure that is routinely reviewed by therapists and patients to monitor response to treatment, thus circumventing potential demand characteristics, social desirability bias and serial dependency between repeated measures using the GAD-7 questionnaire.

Secondary outcome measures

Secondary data will include the number of sessions attended (i.e. minimal attendance 1-2 sessions, moderate attendance 3-5 and full 6-8 session completion), dropout rate (percentage of participants not completing) and stepping-up rate (percentage of participants stepped up following GSH to step 3). Employment status; as part of the IAPT minimum dataset (MDS) participants will be asked three closed questions concerning their employment and disability benefit status. IAPT MDS measures will be collected at each session, and at 8-weeks and 24-weeks follow-up and consists of the *Generalised Anxiety Disorder-7 (GAD-7;* Spitzer, Kroenke, Williams & Lowe, 2006*), Patient Health Questionnaire-9* (PHQ-9; Kroenke, Spitzer & Williams, 2001), *Work and Social Adjustment Scale* (WSAS; Mundt, Marks, Shear & Greist, 2002) and the *IAPT Phobia Scale*. There will be no extra burden on PWPs as the IAPT MDS is collected as a part of routine practice and the study coordinator will collect all the follow-up data.

Sample Size

All analyses will be conducted on an intention-to-treat basis. Assuming a 'small' effect size of f=.2, a significance level of alpha=.05 with two study arms providing data at three time points (assessment, short and long-term follow-up) a total sample size of *N*=134 gives 80% power to test for differences between CAT-GSH and CBT-GSH. This effect size has been selected *a priori*,

informed by the psychotherapy trials literature which consistently indicates that outcome differences between psychological interventions are most often non-significant and small in magnitude (e.g., see Cuijpers, Van Straten, Andersson, & Van Oppen, 2008; Cuijpers, Karyotaki, de Wit, & Ebert, 2019).

If there are differences between those who have a preference for CAT-GSH and CBT-GSH and those choosing to be randomised this will necessitate a four-arm trial; (a) preference for CAT-GSH, (b) randomised to CAT-GSH, (c) preference for CBT-GSH and (d) randomised to CBT-GSH. The sample size would increase to *N*=188 for a four-arm patient preference trial.

Allocation

This trial will employ a patient preference methodology (Torgerson & Sibbald, 1998), with those participants who do not have a treatment preference being allocated to either CAT-GSH or CBT-GSH using block randomisation by a third party not directly involved in the treatment of study participants. It is impossible to blind both the participants and PWPs to treatment allocation. Allocation to either form of GSH will be recorded in a separate location in the patient data log.

Data collection, quality and management

The Study Coordinator will be trained in the administration of the MINI. Research screening interviews will be conducted face-to-face and the follow-ups will be collected via the telephone. PWPs will receive a 2-day training package on how to effectively deliver the CAT-GSH intervention. The feasibility and acceptability of the training will be assessed through attendance monitoring at the training and satisfaction with the training. A monthly 1.5-hour clinical supervision group will support the delivery of CAT-GSH and a monthly 1.5-hour clinical supervision group will support the delivery of the CBT-GSH. Data entry will be checked using a 5% double entry procedure. Anonymised measures data will be stored on a University of Sheffield password-protected secure server, with only named people having access. Names of participants on consent forms are stored separately from data in locked filing cabinets in the Trust. A separate key

linking names to ID numbers used in data files will be stored on a password-protected file on a secure server, accessible by named personnel only.

Statistical analysis

The analysis will follow the Ward et al. (2000) approach of analysing whether there are any differences between randomised and preference within the arms and if there are no differences between these groups then collapsing the within-arm groups to form a two-arm trial. We will also analyse the comparison between the two randomised and two preference arms alone. The planned analyses are as follows based on intention-to treat principles: (a) CONSORT of patient preferences to demonstrate choice, response, completion, step-up, follow-up and dropout rates in each arm, (b) comparative anxiety (BAI) treatment effect sizes in each arm at short and long-term follow-up calculated and compared based on Cohen's d+, (c) comparative treatment recovery rates (based on clinical and reliable change using the reliable change index with the BAI) in each arm at short and long-term follow-up and (d) ANCOVA of between arm differences over time on primary and secondary outcomes. To test the robustness of the results, we will repeat the analysis using longitudinal multilevel modelling, where repeated outcome measures (level 1) are nested within cases (level 2), controlling for baseline severity and introducing a group variable along with a group*time interaction term (the latter being the primary hypothesis test). All analyses will be carried out by a researcher who will be blind to group allocation.

Qualitative interviewing and analysis

At short-term follow-up (8-weeks), participants will be invited to participate in qualitative interviews concerning their experience of the intervention they have received. A purposive sampling strategy will be used to ensure relatively equal distributions of participants according to random allocation and gender. Only those participants that that have a reliable and clinically significant pre-post change on the GAD-7 will be eligible for this interview. The rationale for using the GAD-7 for the qualitative aspect of the study was that a BAI outcome was being collected at 8-weeks, and we wanted to be able to interview participants at 8-weeks and therefore needed to use

the post treatment GAD-7 outcomes to direct this. The rationale for only selecting 'recovered' participants on the GAD-7 is that the study seeks to understand how GSH works – when there is sufficient evidence that is has worked and this will also enable a comparison of the change process between the theoretical models. Ten interviews from patients recovered following CAT-GSH and ten interviews for participants recovered following CBT-GSH will be conducted. The interview will be guided by the Change Interview (Elliott; 2010; adapted for the GSH context). Digitally recorded follow-up change interviews will be transcribed verbatim and analysed using two types of data-driven thematic analysis (TA), as described by Boyatzis (1998); hybrid TA and inductive TA. First, using hybrid TA, research-driven themes relating to the feasibility and acceptability of CAT-GSH and CBT-GSH will be developed (Boyatzis, 1998). Second, using inductive TA, themes that maximally differentiate how and why change has occurred during each type of GSH will be developed.

Trial monitoring

The monthly trial steering committee comprising of the study coordinator, principal investigator and the chief investigator will collect and assess any adverse events for participants in the trial. Adverse events are defined as a participant reporting suicidal ideation (with associated intent and planning) and/or risk of self-harm, supported by patient self-report on the PHQ-9 item regarding suicidal ideation (item 9) or other disclosures made which raise serious concerns about participant's elevated risk to self or others.

Ethics

The study has been ethically reviewed: IRAS reference number, 240751. The study has been pre-registered: ClinicalTrials.gov identifier: NCT03730532. The study is supported with a research grant provided by the Association of Cognitive Analytic Therapists. Any protocol amendments will be communicated and approved via IRAS and the participant information altered accordingly. Informed consent will be achieved from participants via a study consent form as part of the research screening process by the study coordinator.

Discussion

Patient-preference trials remain relativity rare in mental health research despite the efforts to increase patient choice in clinical services. Extensive evidence exists concerning CBT-GSH, whilst sound research evidence concerning the acceptability, effectiveness and efficacy of other forms of GSH (i.e. those underpinned by different theoretical models) has lagged behind. Determining patient preferences is an important aspect of clinical trial design. It is acknowledged that the PRPPT design does not insulate against outcomes being affected by the influence of uncontrolled confounders in the preference groups (Halpern, 2003). The strength of this trial is that it is pragmatic and being conducted within an IAPT service, and therefore the results will be generalizable to other step 2 IAPT services that use GSH in a one-to one format. Clearly, the trial has less generalizability to those step 2 IAPT services that primarily use a psychoeducational group treatment format approach or where all the GSH interventions are delivered telephonically. Delivery of step 2 interventions are less researched then step 3 interventions and this imbalance needs to be addressed and rebalanced. On completion, the finding from the trial have the potential to make a significant contribution to the expanding IAPT step 2 evidence base.

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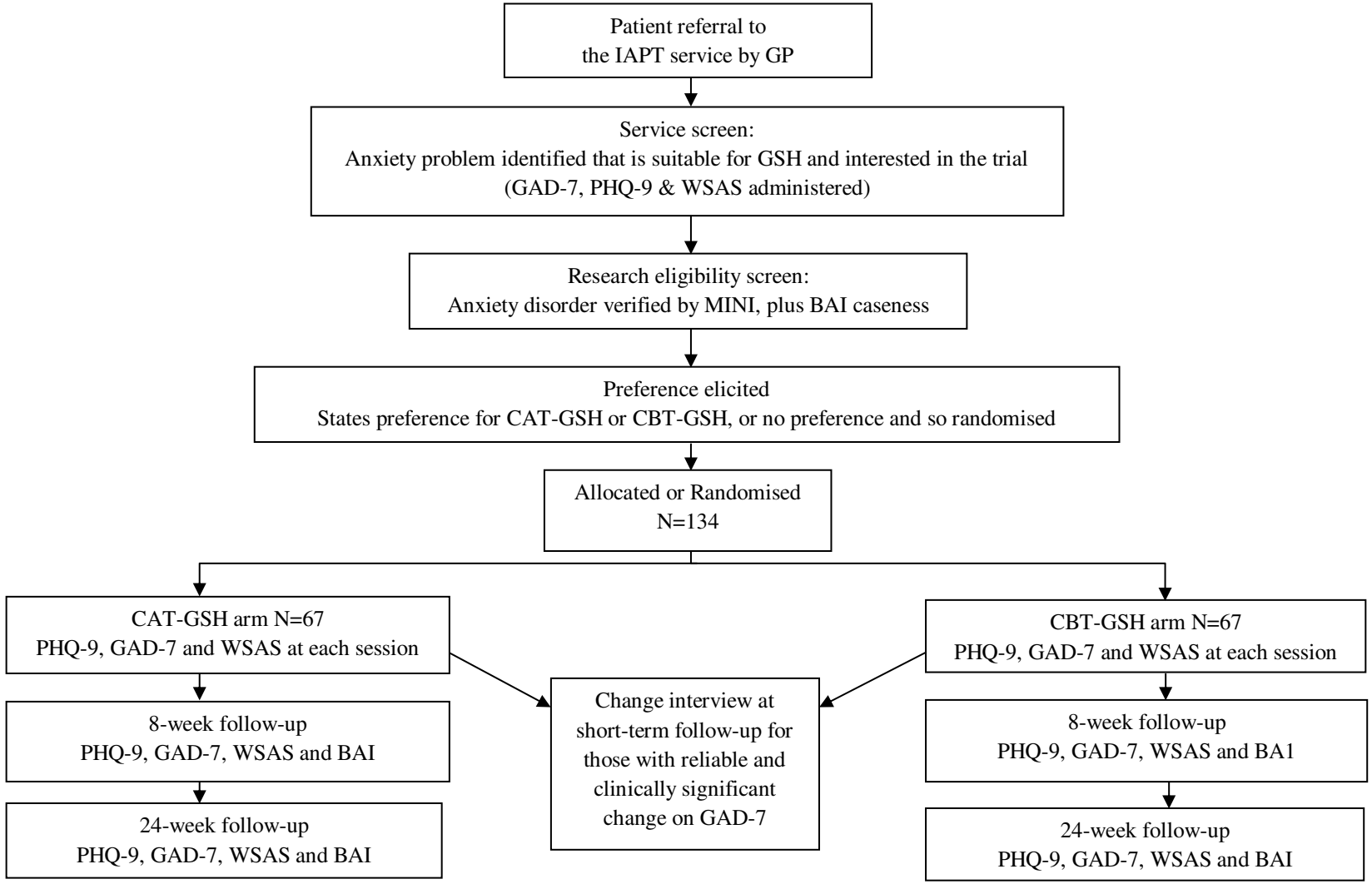
Figure 1: Study flow diagram of referral, screening and allocation of patients



PHQ-9: Patient Health Questionnaire-9; GAD-7: Generalised Anxiety Disorder-7; WSAS: Work and Social Adjustment Scale, BAI: Beck Anxiety Inventory, MINI: Mini International Neuropsychiatric Interview

Figure 2: SPIRIT diagram of assessments at enrolment, allocation, treatment sessions and 8-week and 24-week follow-up

	STUDY PERIODS									
	Enrolment	Allocation	Post allocation							
TIME POINTS			Session 1	Session 2	Session 3	Session 4	Session 5	Session 6	8-week follow-up	24-week follow-up
Enrolment										
Eligibility screening	X									
Informed consent	X									
Baseline assessment	X									
Allocation		X								
INTERVENTIONS										
CBT-GSH			◆	—	—	—	—	◆		
CAT-GSH			◆	—	—	—	—	◆		
ASSESSMENTS										
Treatment preference	X									
MINI	X									
BAI	X								X	X
PHQ-9			X	X	X	X	X	X	X	X
GAD-7			X	X	X	X	X	X	X	X
WSAS			X	X	X	X	X	X	X	X
Change interview									X	

CBT-GSH: Cognitive behaviour therapy guided self-help
CAT-GSH: Cognitive analytic therapy guided self-help
MINI: Mini International Neuropsychiatric Interview
BAI: Beck Anxiety Inventory
PHQ-9: Patient Health Questionnaire-9
GAD-7: Generalised Anxiety Disorder-7
WSAS: Work and Social Adjustment Scale