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Improving implementation of evidence based practice for people with psychosis through training the wider workforce: Results of the GOALS feasibility randomised controlled trial

Helen Waller[a,e,*], Sabine Landau[b], Miriam Fornells-Ambrojo[a,c,e], Suzanne Jolley[a], Paul McCrone[d], Rikesh Halkoree[e], Nedah Basit[e], Catherine Iredale[e], Catherine Tunnard[c], Darshan Zala[d], Tom J.K. Craig[d,1], Philippa Garety[a,1]

[a] Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
[b] Department of Biostatistics, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
[c] University College London, UK
[d] Department of Health Service and Population Research, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
[e] South London and Maudsley NHS Foundation Trust, UK

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ABSTRACT

Background and objectives: There is a pressing need to improve access to evidence-based practice for people with psychosis. The primary aim of this study was to assess clinical feasibility of a manualised, evidence-based CBT intervention (GOALS) targeting a personalised recovery goal, delivered by the frontline workforce, following brief training. Secondly, we aimed to conduct preliminary statistical analyses of key outcomes and costs.

Methods: The GOALS study is a feasibility randomised controlled trial (ISRCTN 73188383). 75 participants with current psychosis were recruited and randomly allocated to receive either treatment as usual alone or with GOALS therapy.

Results: Brief training enabled frontline staff to deliver the therapy according to protocol and 74% of therapy participants partially or fully achieved their goals. There were significant improvements with a moderate effect size of 0.56 on goal attainment. However, preliminary statistical analyses found no significant differences between groups on our primary outcome of activity levels or other secondary outcomes Health economic analysis found that point estimates of costs, controlling for baseline costs, implied savings (even including intervention costs), but the difference was not statistically significant.

Limitations: The study was designed as a feasibility RCT, and therefore the results of secondary estimates of efficacy effects should be treated with caution.

Conclusions: This approach holds promise in supporting people with psychosis to reach personal recovery goals, cost effectively.

1. Introduction

For many with psychosis, the process of recovery and re-engaging with life goals is impeded by persisting symptoms, low mood, anxiety and stigma. Therefore, facilitating the achievement of valued goals is vital, supporting service users to build a sense of meaning, connectedness, hope, optimism and empowerment, which form key aspects of recovery in mental health (Le Boutillier et al., 2011; Leamy, Bird, Le Boutillier, Williams & Slade, 2011).

There are evidence-based psychological therapies available for psychosis which are effective (Burns, Erickson, & Brenner, 2014) in supporting clients to reach personal goals and are recommended in international best practice guidelines (Kreyenbuhl, Buchanan, Dickerson, & Dixon, 2010; National Institute for Health and Care Excellence, 2009; National Institute for Health and Care Excellence, 2014), but there is a severe implementation problem (van der Gaag, 2014). A key barrier is a lack of trained therapists able to deliver therapies within routine services (Berry & Haddock, 2008; Pilling &

* Corresponding author. Department of Psychology, Institute of Psychiatry, Psychology & Neuroscience, PO Box 77, Henry Wellcome Building, De Crespigny Park, London, SE5 8AF, UK.
E-mail address: helen.harding@kcl.ac.uk (H. Waller).
[1] Joint last authors.

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Price, 2006; Prytys, Garety, Jolley, Onwumere & Craig, 2011). Such therapies, including cognitive behaviour therapy (CBT) often involve many sessions delivered by therapists following lengthy and costly training: costs and workforce training pose severe challenges to their implementation in the USA as in Europe and the UK (Beidas et al., 2016; Stewart et al., 2016). It has been argued that future implementation should focus on training the wider workforce to deliver therapy as part of routine clinical practice. There is a need to evaluate the feasibility of implementing structured, manualised brief evidence-based CBT therapies, requiring less formal training, that can be readily disseminated (Thase, Kingdon, & Turkington, 2014). CBT for psychosis encompasses a wide rage of treatment targets (Morrison & Barratt, 2010), including specific symptoms, processes and personal goals (Fowler et al., 2009; Freeman et al., 2015). Comorbid mood disorders are highly prevalent in psychosis: although estimates vary, research suggests that around 40% and 50% of people with psychosis also meet criteria for an anxiety disorder or depression respectively (Achim et al., 2011; Buckley, Miller, Lehrer, & Castle, 2009). These comorbidities are also associated with negative impacts on psychotic symptoms (Hartley, Barrowclough, & Haddock, 2013; Vorontsova, Garety, & Freeman, 2013). Brief, structured evidence-based therapies are available for anxiety and depression; namely graded exposure and behavioural activation, and there is evidence for the effectiveness of their delivery by staff with less formal therapy experience and therefore at a lower cost (Richards et al., 2016). This model of delivery has been used in the UK as part of a 'stepped care' model allowing increased access to psychological therapies in people with anxiety and depression (Chan & Adams, 2014; Gyani, Shafran, Layard, & Clark, 2013). In those with psychosis, these therapies are typically delivered as part of a tool box of evidence-based therapies, where therapy is targeting anxious avoidance or depression-related inactivity as barriers to personal goals; aiming to increase social inclusion and engagement in meaningful activities (Fowler et al., 2009; Morrison & Barratt, 2010). However, it is not known whether this type of therapy could be delivered by staff with less formal therapy training to clients with psychosis.

1.1. The GOALS study

The present study aims to examine the feasibility of training the frontline workforce, rather than accredited psychological therapists, to deliver targeted, brief evidence-based therapy in routine community services for people with psychosis. In the UK, this workforce typically provides a clinical case and crisis management function (known as 'care coordination'), comprising psychiatric nurses, occupational therapists, and social workers. Many teams also include clinical assistant posts or internships (typically psychology graduates) supervised by qualified staff. Training the community team workforce to deliver manualised interventions is increasingly recommended and researched (Gaughran et al., 2013; Priebe et al., 2013).

The therapy follows a structured protocol, with a manual developed and modified as part of an initial pilot study (Waller et al., 2012, 2015), using evidence-based behavioural techniques of graded exposure and behavioural activation, adapted for use in clients with psychosis (e.g. including reference to psychotic symptoms and simplified in order to suit all clients, including those with associated cognitive problems). Therapy targets a personalised recovery goal over 8 sessions (plus a one-month booster session), for which either comorbid anxiety or depressive symptoms are a barrier to achievement. Training is brief: only 12 h over two days followed by ongoing case supervision. The therapy manual and training materials were piloted: seven members of frontline staff from a range of professional backgrounds were trained and delivered the therapy to 12 people with a diagnosis of psychosis and comorbid symptoms of anxiety and/or depression, impeding achievement of personal goals. The results were promising, with high rates of goal achievement and improvement in activity levels, depression, negative symptoms of psychosis and general wellbeing (Waller et al., 2012).

The present study is a feasibility randomised controlled trial of this intervention: GOALS (Getting On top of Anxiety and Low Mood and So reaching your goals). The primary aims were to establish the clinical feasibility of the intervention, in terms of participant recruitment and satisfaction with treatment, uptake of training and delivery of therapy and progress towards goals. A secondary aim was to provide preliminary estimates of efficacy effects on key outcomes including activity levels, goal attainment, anxiety and depression and a preliminary health economic analysis.

2. Methods

2.1. Study design and procedures

The design is a single-blind, feasibility RCT comparing treatment as usual (TAU) and GOALS + TAU intervention. The trial was registered before commencing recruitment in Current Controlled Trials, ISRCTN: 73188383. Ethical approval was given by London Chelsea National Research Ethics Committee (ref: 12/LO/1523). No significant changes were made to the methods after trial commencement. The sample size calculation, randomisation, blinding, data monitoring and assessment of safety were as described in the published trial protocol (Waller et al., 2014). Outcome assessments were completed by trained research workers prior to randomisation (baseline), 12 weeks (post-therapy) and 18 weeks (follow-up). Following completion of baseline assessments, randomisation was performed independently by the King's Clinical Trials Unit, using an online system (at a 50:50 ratio at the level of the individual; stratified according to problem focus (either anxiety or depression); random permuted blocks varied in size from three to six). The research assessors, statistician and health economist remained blind to allocation. Only the research coordinator (HW) was unblind, in order to enrol participants, allocate therapy and supervise trained staff. Participants in the GOALS + TAU group were allocated to begin therapy immediately.

2.2. Participants

Power calculations (see Waller et al., 2014) suggested 66 participants should be recruited; in practice we recruited 75 participants from adult community secondary care services in one UK National Health Service (NHS) Trust (South London and Maudsley NHS Foundation Trust) between March 2013 and February 2015. Inclusion criteria were: diagnosis of Schizophrenia Spectrum disorder or currently experiencing psychotic symptoms; comorbid symptoms of anxiety and/or depression; wanting to increase activity levels. Those meeting the following criteria were excluded: receiving CBT within last three months; primary diagnosis of organic mental health problem or substance dependency.

2.3. Interventions

2.3.1. TAU

Participants allocated to TAU received usual treatment in primary and secondary care. They were offered GOALS therapy after completing the final trial assessment.

2.3.2. GOALS + TAU

Participants received eight sessions of the GOALS intervention, plus a 'booster' session one month later, with a trained staff member. Sessions were approximately one hour, weekly, following a structured manual, with step-by-step guidance for each session, plus weekly client handouts. Sessions took place in participants' local mental health service teams, in their homes and/or out in the community, where appropriate (e.g. when practising new skills). Key aspects included education on symptoms of anxiety/depression, and maintenance factors of avoidance and reduced activity levels respectively; setting a SMART (specific, measurable, achievable, rewarding, timely) therapy goal;

breaking the goal into smaller, manageable steps; working towards these steps; use of coping techniques when difficulties arise. Weekly homework tasks were set and trained staff gave participants a reminder call between sessions to check in on progress.

2.4. Assessments

2.4.1. Feasibility

Participant recruitment and acceptability were assessed through the number of those approached who declined treatment, plus attrition rates. Feasibility of training and delivery were assessed by number and proportion of those completing training, by workforce role, who delivered the intervention. Treatment adherence and fidelity were assessed in the GOALS + TAU group through records of therapy attendance, therapist attendance at supervision and examination of a sample of audiotaped recordings of therapy sessions scored against fidelity indicators within the therapy manual. Progress towards goals was assessed by sessional ratings of goal attainment. Satisfaction and acceptability of the therapy was assessed through separate semi-structured interviews conducted by research workers and trained service users.

2.4.2. Efficacy

The following outcomes were assessed at each time point, using validated measures with good reported reliability. Unless otherwise stated, higher scores indicate less favourable outcomes. Additional checks of inter-rater reliability were made on 20% of all semi-structured interview measures, involving ratings made by researchers: high levels of inter-rater reliability were found.

The primary outcome was the Time Budget Measure (Jolley et al., 2005, 2006); a semi-structured interview, used to assess weekly activity levels (range: 0–112, where higher scores indicate higher activity levels, requiring more planning, complexity and effort), validated for use specifically in people with psychosis. The choice of primary outcome was guided by the focus on activation/prevention of anxious avoidance and by our pilot data (reference). Secondary outcomes were the Choice of Outcome in CBT for Psychosis measure (a patient-rated and patient co-designed outcome measure, CHOICE) (Greenwood et al., 2010) assessed goal attainment (one item) and clinically meaningful outcomes in CBT for psychosis (11 items; all range from 0 to 10; higher scores indicate more favourable outcomes); the Hospital Anxiety and Depression Scale (HADS) (Snaith, 2003) measures of anxiety and depression (the inclusion criteria for this study included a clinical cut-off score of 8 for either anxiety and/or depression); A modified version of the Mobility Inventory (MI) (Chambless, Caputo, Jasin, Gracely, & Williams,1985) assessed anxious avoidance. Participants identified five key avoided areas from 26 situations listed in the MI, rated according to how often they are avoided, alone or accompanied; the Positive and Negative Syndromes Scale (PANSS) (Kay, Fiszbein, & Opler, 1987) and the Psychotic Symptoms Rating Scales (PSYRATS) (Haddock, McCarron, Tarrier, & Faragher, 1999) assessed psychotic symptoms; a 10-item version of the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-10) (Barkham et al., 2013) measured clinical distress; the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (Tennant et al., 2007) measured well-being (higher scores indicate greater self-reported well-being); the Manchester Short Assessment of Quality of Life (MANSA) (Priebe, Huxley, Knight, & Evans, 1999): a 12-item measure of quality of life (higher scores indicate greater self-reported quality of life); the Social and Occupational Functioning Assessment Scale (SOFAS) (American Psychiatric Association, 1994) is a clinician-rated single score of social and occupational functioning (higher scores indicate better functioning).

2.5. Analysis

2.5.1. Feasibility analysis

Recruitment and acceptability parameters and adherence and fidelity measures in the GOALS + TAU group were assessed descriptively. Relevant parameters (proportions, medians etc.) were estimated.

2.5.2. Statistical analysis

Statistical analyses were conducted in Stata and SPSS (IBM Corp, 2011; StataCorp, 2013). Regression modelling was employed to compare outcomes between trial arms at 12 and 18 weeks, including estimates of effects sizes (with associated 95% CIs) and statistical significance tests for a preliminary efficacy assessment. Outcomes at 12 or 18 weeks formed the dependent variable and the explanatory variables included the trial arm (i.e. GOALS + TAU or TAU), the randomisation stratifier (main problem focus, i.e. anxiety or depression) and baseline values of the outcome to gain extra precision. Normality assumptions of regression models were checked for all outcomes using residual diagnostics. Logistic regression was used to examine whether any baseline variables were predictive of missingness at 12 weeks, and within the intervention arm only, Fisher's exact test was used to assess the predictive power of insufficient receipt of therapy. Only PSYRATS Hallucinations was found to be predictive of missingness at 12 weeks at a liberal 10% significance level. However, there was clear evidence for a relationship between missingness and therapy completion (therapy was classed as 'insufficient' if participants had completed $\leq$ 4 sessions). 'Insufficient' GOALS therapy predicted missingness in the intervention group (only 2 of the 28 classed as having 'sufficient' therapy had a missing value at 12 weeks contrasting with 6 of the 10 classed as having 'sufficient' therapy; Fisher's exact test $p = .002$). Therefore to generate analyses that are valid under missing at random (MAR) assumptions with the insufficient therapy receipt being allowed to predict missingness, we employed 100 multiple imputations (Sterne et al., 2009), using the chained equations procedure.

2.5.3. Health economic analysis

Use of health, social care and criminal justice services was measured using an adapted version of the Client Service Receipt Inventory (Beecham & Knapp, 2001), recorded at baseline for the previous 4-months and follow-up. Service use data were combined with unit cost information for 2013/14 taken from a nationally recognised source (Netten & Curtis, 2014). Costs were adjusted for inflation, but not discounted. 18-week costs were compared, controlling for baseline, using a bootstrapped regression model to account for the likely skewed distribution of the residuals.

3. Results

Participant baseline clinical and demographic characteristics are summarised in Table 1. All distributions appear reasonably balanced across trial arms, and reflect the diversity of the target population.

3.1. Primary aim: clinical feasibility of intervention

3.1.1. Recruitment

166 participants were referred (see Fig. 1); 118 agreed to meet for eligibility screening. Of those screened, 89 (75.4%) met inclusion criteria. Of those eligible at initial screen, 79 (88.8%) gave consent to take part and 75 (94.9%) of these were randomised. Attrition rates were low: 65 (86.7%) and 70 (93.3%) participants completed assessments at 12 and 18 weeks respectively. Recruitment ceased once sufficient numbers of participants were recruited, based on the power calculation.

3.1.2. Staff training

There was a good uptake of training but lower rates of utilizing training to deliver therapy: 53 staff members completed training; 27

Table 1
Baseline clinical and demographic characteristics by trial arm and for the whole participant sample.

Variable	GOALS + TAU Intervention (N = 38)	TAU (N = 37)	Total Sample (N = 75)
Median age in years (range)	39 (20–69), N = 38	32 (19–66), N = 37	37 (19–69), N = 75
Median age leaving education in years (range)	17 (13–31), N = 37	18 (14–25), N = 35	18 (13–31), N = 72
Median years in contact with mental health services (range)	12 (0–39), N = 36	6 (0–54), N = 37	10 (0–54), N = 73
Gender:			
Female	15 (39.5%)	17 (46.0%)	32 (42.7%)
Male	23 (60.5%)	20 (54.0%)	43 (57.3%)
Ethnicity:			
White	20 (52.6%)	14 (37.8%)	34 (45.3%)
Black	12 (31.6%)	18 (48.7%)	30 (40.0%)
Asian	3 (7.9%)	2 (5.4%)	5 (6.7%)
Other	3 (7.9%)	3 (8.1%)	6 (8.0%)
Diagnosis:			
Schizophrenia type disorder	28 (73.7%)	29 (78.4%)	57 (76.0%)
Mood disorder with psychotic symptoms	7 (18.4%)	5 (13.5%)	12 (16.0%)
First episode psychosis	3 (7.9%)	3 (8.1%)	6 (8.0%)
Marital status:			
Divorced/Separated	3 (7.9%)	2 (5.4%)	5 (6.7%)
Married/Cohabiting	6 (15.8%)	2 (5.4%)	8 (10.7%)
Single	29 (76.3%)	33 (89.2%)	62 (82.7%)
Current employment status:			
Unemployed	35 (92.1%)	34 (91.9%)	69 (92.0%)
Employed	2 (5.3%)	2 (5.4%)	4 (5.3%)
Voluntary/unpaid work	1 (2.6%)	1 (2.7%)	2 (2.7%)
CBT in previous year:			
No	30 (90.9%)	25 (89.3%)	55 (90.2%)
Yes	3 (9.1%)	3 (10.7%)	6 (9.8%)
Service pathway:			
Early Intervention	9 (23.7%)	15 (40.5%)	24 (32%)
Recovery	29 (76.3%)	22 (59.5%)	51 (68%)

went on to work with one or more supervised therapy cases. Of these, only four (14.8%) were in case management roles, 10 (37.0%) were other health professionals (e.g. occupational therapists, vocational specialists) and 13 (48.1%) were graduate psychologists in clinical assistant/internship posts. The workforce had little previous therapy experience (median previous days CBT training = 2; range = 0–20), but most had experience working with psychosis (median years in psychosis services = 2.5; range = 1–20).

3.1.3. Treatment adherence and fidelity

At post-treatment and follow-up, participants attended a median of 6 (range = 0–8) and 8 (range = 0–9) therapy sessions respectively. Therapy was classed as 'insufficient' if participants had completed ≤ 4sessions: at follow-up 10 (26.3%) of the 38 participants had 'insufficient therapy'. Clinical assistants delivered the highest mean number of sessions and percentage of cases rated as 'sufficient therapy' (median = 9 sessions, range = 0–9; 20 cases (83.3%)), followed by case managers (median = 7 sessions, range = 0–8; 3 (75%)) and other health professionals (median = 4.5 sessions, range = 0–9; 5 (50%)). Supervision attendance was high, with sufficient attendance (fortnightly meetings) in 33 of the 38 therapy cases (86.8%). Audio recordings were rated for fidelity to five key aspects of the therapy protocol (rated as 0 (incomplete), 1 (partially complete) or 2 (complete), giving a total score ranging from 0 to 10 for each session) in 60 therapy sessions. Inter-rater reliability was high: the average measures ICC for the fidelity ratings, based on 12 recorded sessions, was 0.92, $F(11,12) = 13.21$, $p < .001$. Fidelity was high, with a mean total session rating of 8.73 (sd = 1.31). Closer examination of fidelity ratings however indicated the protocol was followed around goal setting and achievement, but the most commonly missed aspects of therapy related to establishing links between the chosen goal and anxiety/depression.

3.1.4. Progress towards goals

Of the 38 participants randomised to GOALS + TAU, 18 (47.4%) achieved their goal, 10 (26.3% partially achieved their goal) and 10 (26.3%) did not achieve their goal. All participants who made no progress towards their goal were in the 'insufficient therapy' group. Common goals concerned health and exercise (21.1% of goals), socialising (21.1%) and hobbies/interests (23.7%).

3.1.5. Participant satisfaction and feedback

Participants reported high levels of treatment satisfaction, particularly valuing progress made towards goals, therapist support, and therapy materials.

3.1.6. Adverse events

There were seven adverse events documented across the study period: six in the TAU group (2 emergency psychiatric admissions; 1 physical health hospital admission; 3 Emergency room visits, without admission) and one in the GOALS + TAU group, but rated unrelated to the intervention (emergency room visit, following burglary).

3.2. Secondary aim: preliminary efficacy assessment

3.2.1. Outcomes by trial arm and assessment time point

Estimated effect sizes for various outcomes and time points are shown in Table 2. There was no effect on our primary outcome of activity, measured by the Time Budget Measure. There was a significant improvement, on our secondary outcome of goal attainment, with an estimated moderate effect size of 0.56 at follow-up, favouring the GOALS + TAU group. All other differences between the two trial arms at either post-intervention or follow-up were estimated to be of small effect size (< 0.35) and tested not statistically significant at a liberal 10% level.

3.2.2. Health economic analysis

Numbers of participants using services and their mean estimated costs are presented in Table 3, across both trial arms and at the two measured time points (four months prior to baseline and the four months between baseline and follow-up). At baseline, total cost in the GOALS + TAU group is almost twice as high as TAU, but over follow-up it is around a third lower compared to TAU. Costs at follow-up were £890 lower in the intervention group (controlling for baseline costs), which was however not statistically significant (bootstrapped 95% CI -£2313 to £150).

4. Discussion

Monotherapy with medication is no longer the optimal treatment choice for people with psychosis. However, internationally there is a severe implementation challenge in extending access to additional evidence-based practices for this group.

The results suggest one such recovery-oriented evidence-based practice, GOALS therapy, is suitable for people with psychosis in community settings: the majority of those screened met eligibility criteria (75.4%), and a high proportion of those gave consent (94.9%) and completed the study (93.3% completed follow-up assessments), indicating a fit with the target population. All participants who had 'sufficient therapy' were able to achieve or partially achieve their personal recovery goal, within an average of 8 sessions, which they had been unable to achieve independently. Achievement of personally meaningful goals is an important part of the recovery process from severe mental illness in that it is likely to instil hope for the future, build

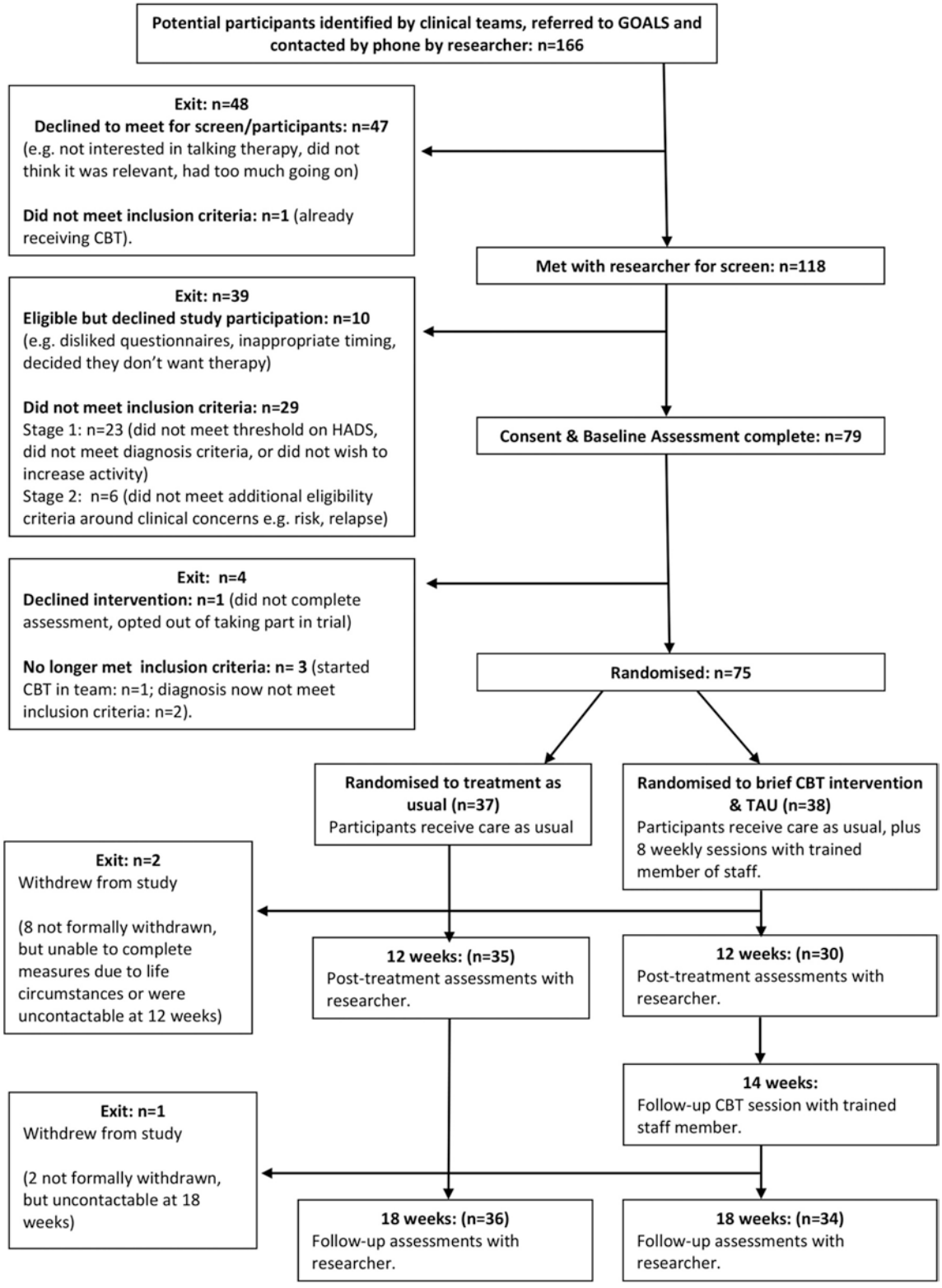

Fig. 1. GOALS study CONSORT diagram.

a sense of empowerment and confidence in one's coping abilities, and make connections with others and the local community (Le Boutillier et al., 2011; Leamy et al., 2011). Participants gave positive feedback regarding treatment satisfaction: results of a full qualitative analysis of this feedback will be reported elsewhere.

Our preliminary statistical analyses mirrored the feasibility data, indicating a moderate effect size on attainment of a personal recovery goal, favouring the GOALS + TAU group. Interestingly, this positive goal attainment was not reflected in change in activity levels on the Time Budget Measure, our predefined primary outcome measure. This may reflect some insensitivity of the measure to meaningful but subtle changes in activity in one specific goal-related domain, which will be important to consider when choosing the most appropriate measures for future trials. There was also unexpectedly little impact on anxiety and

Table 2
Intention-to-treat analysis.

Outcome	12 weeks		18 weeks	
	Estimated group difference (GOALS-TAU), 95% CI and associated significance test in brackets	Standardised effect size and 95% CI[a]	Estimated group difference (GOALS-TAU), 95% CI and associated significance test in brackets	Standardised effect size and 95% CI[a]
Time Budget Measure:	0.93 [−4.74, 6.61]; ($t(58) = 0.33$, $p = .74$)	0.07 [−0.35, 0.49]	1.16 [−5.45, 7.78]; ($t(63) = 0.35$, $p = .73$)	0.09 [−0.41, 0.58]
CHOICE goal	0.62 [−0.67, 1.91]; ($t(57) = 0.96$, $p = .34$)	0.26 [−0.28, 0.81]	1.33 [0.02, 2.64]; ($t(60) = 2.03$, $p = .046$)	0.56 [0.01, 1.11]
CHOICE total	2.91 [−4.95, 10.78]; ($t(56) = 0.74$, $p = .46$)	0.14 [−0.24, 0.52]	2.99 [−5.15, 11.12]; ($t(62) = 0.73$, $p = .47$)	0.14 [0.25, 0.53]
HADS:				
Depression	0.21 [−1.86, 2.29]; ($t(54) = 0.21$, $p = .84$)	−0.06 [−0.55, 0.68]	0.19 [−1.67, 2.06]; ($t(61) = 0.21$, $p = .84$)	0.06 [−0.49, 0.61]
Anxiety	0.78 [−1.20, 2.76]; ($t(55) = 0.79$, $p = .44$)	0.19 [−0.29, 0.67]	0.35 [−1.68, 2.37]; ($t(61) = 0.34$, $p = .73$)	0.09 [−0.41, 0.58]
Mobility Inventory (5 key areas)				
Avoidance alone	−0.13 [−0.55, 0.30]; ($t(60) = -0.61$, $p = .54$)	−0.15 [−0.63, 0.35]	−0.08 [−0.48, 0.32]; ($t(61) = -0.40$, $p = .69$)	−0.09 [−0.55, 0.37]
Accompanied	0.07 [−0.36, 0.51]; ($t(58) = 0.33$, $p = .74$)	0.06 [−0.31, 0.44]	0.01 [−0.39, 0.42]; ($t(61) = 0.06$, $p = .95$)	0.01 [−0.33, 0.36]
PANSS:				
Positive Symptoms	−0.35 [−2.05, 1.35]; ($t(53) = -0.41$, $p = .68$)	−0.07 [−0.40, 0.26]	−0.65 [−2.53, 1.23]; ($t(62) = -0.69$, $p = .49$)	−0.13 [−0.49, 0.23]
Negative Symptoms	−0.43 [−2.40, 1.54]; ($t(58) = -0.44$, $p = .66$)	−0.08 [−0.47, 0.30]	−0.92 [−2.84, 0.99]; ($t(62) = -0.97$, $p = .34$)	−0.18 [−0.55, 0.19]
General	2.08 [−0.45, 4.62]; ($t(57) = 1.65$, $p = .11$)	0.31 [−0.07, 0.68]	−0.27 [−2.95, 2.42]; ($t(60) = -0.20$, $p = .84$)	−0.04 [−0.44, 0.36]
PSYRATS:				
Hallucinations	0.62 [−4.39, 5.62]; ($t(57) = 0.25$, $p = .81$)	−0.04 [−0.31, 0.40]	−0.61 [−5.03, 3.81]; ($t(62) = -0.28$, $p = .78$)	−0.04 [−0.35, 0.27]
Delusions	−0.12 [−2.93, 2.70]; ($t(54) = -0.08$, $p = .93$)	−0.02 [−0.37, 0.34]	1.30 [−1.93, 4.54]; ($t(60) = 0.80$, $p = .42$)	0.17 [−0.25, 0.58]
CORE general distress	1.42 [−1.45, 4.29]; ($t(55) = 0.99$, $p = .33$)	0.18 [−0.19, 0.55]	2.10 [−0.81, 5.01]; ($t(63) = 1.44$, $p = .16$)	0.27 [−0.10, 0.64]
WEMWBS well-being	0.17 [−3.41, 3.75]; ($t(54) = 0.09$, $p = .93$)	0.02 [−0.38, 0.41]	−1.58 [−5.42, 2.27]; ($t(59) = -0.82$, $p = .42$)	−0.17 [−0.60, 0.25]
MANSA Quality of Life	−0.41 [−4.50, 3.68]; ($t(56) = -0.20$, $p = .84$)	−0.04 [−0.42, 0.34]	−1.07 [−5.62, 3.49]; ($t(61) = -0.47$, $p = .64$)	−0.10 [−0.52, 0.32]
SOFAS Functioning	−1.01 [−3.78, 1.76]; ($t(54) = -0.73$, $p = .47$)	−0.11 [−0.42, 0.19]	2.07 [−1.20, 5.34]; ($t(64) = 1.26$, $p = .21$)	0.23 [−0.13, 0.59]

Key: CI, confidence indicator; CHOICE, Choice of Outcome in CBT for Psychoses; HADS, Hospital Anxiety and Depression Scale; PANSS, Positive and Negative Syndrome Scale; PSYRATS, Psychotic Symptom Rating Scales; CORE, Clinical Outcomes in Routine Evaluation; WEMWBS, Warwick-Edinburgh Mental Wellbeing Scale; MANSA, Manchester Short Assessment of Quality of Life; SOFAS, Social and Occupational Functioning Assessment Scale.

[a] Standardised effect sizes were calculated by dividing group difference estimates and associated 95% confidence interval limits by the baseline standard deviation (sd) of the measure.

Table 3
Number of participants using services and mean estimated cost of services in past four months.

Service	Baseline, n (%); mean 2013/14 cost (sd)		18-wk follow-up, n (%); mean 2013/14 cost (sd)	
	GOALS + TAU (n = 38)	TAU (n = 37)	GOALS + TAU (n = 34)	TAU (n = 36)
GOALS intervention	–	–	34 (100); £482 (261)	–
General practitioner	27 (71); £67 (70)	24 (65); £111 (144)	24 (71); £73 (91)	27 (75); £82 (109)
Psychiatrist	30 (79); £203 (217)	27 (73); £146 (220)	25 (74); £140 (141)	18 (50); £113 (205)
Other doctor	5 (13); £16 (58)	3 (8); £16 (85)	6 (18); £36 (88)	5 (14); £31 (114)
Psychologist	7 (18); £72 (222)	7 (19); £113 (391)	7 (21); £59 (142)	8 (22); £92 (236)
Home treatment/crisis team	11 (29); £120 (391)	3 (8); £44 (186)	2 (6); £43 (173)	1 (3); £7 (43)
Social worker	7 (18); £27 (67)	11 (30); £42 (99)	3 (9); £13 (48)	8 (22); £44 (103)
Mental health nurse	32 (84); £251 (254)	33 (89); £223 (207)	29 (85); £151 (151)	27 (75); £220 (271)
Occupational therapist	4 (11); £11 (38)	6 (16); £13 (34)	7 (21); £24 (52)	10 (28); £82 (170)
Other professionals[a]	13 (34); £970 (4756)	22 (59); £272 (625)	14 (41); £61 (141)	13 (36); £220 (271)
Day care[b]	12 (32); £646 (2878)	19 (51); £428 (986)	12 (35); £425 (1307)	20 (56); £1040 (2930)
Inpatient care	4 (11); £1402 (4909)	2 (5); £138 (596)	0 (0); £0 (0)	4 (11); £1040 (2930)
Criminal justice	1 (3); £1 (7)	0 (0); £0 (0)	3 (9); £8 (28)	2 (6); £11 (45)
Medication	37 (97); £245 (362)	36 (97); £269 (443)	34 (100); £360 (561)	34 (94); £251 (408)
Mean (SD) Total Costs	**£4030 (£7021)**	**£1811 (£1524)**	**£1766 (£1462)**	**£2610 (£3586)**

Key: sd, standard deviation.
[a] Includes contact with drug and alcohol advisor and other counsellor/therapist services.
[b] Includes contact with drug and alcohol service, day care centre, drop-in centre, self-help/support group, leisure centre and adult education classes and other day care services.

depression, despite our earlier positive pilot data and in contrast to research examining similar approaches in those with common mental disorders (Richards et al., 2016). However, whilst staff kept to the protocol when setting and working towards recovery goals, they were less likely to make links to difficulties associated with mood: this finding has informed a number of subsequent modifications to both the training and manual, to enhance targeting of anxiety and depression. The health economic analysis was however promising: the cost point estimates, after controlling for baseline differences, imply savings, even including intervention costs, although in this feasibility study the difference is not statistically significant.

The findings have important implications for the model of therapy delivery and its limitations, which is reported and discussed in more detail elsewhere (Garety et al., 2018). In summary, all frontline staff who saw a study participant were able to deliver the therapy to protocol and support participants attending sufficient therapy sessions to reach a personal goal. However, there were differences between workforce roles, specifically those with and without case and crisis management responsibilities. Despite positive evaluations of the training package and enthusiasm to try out the GOALS therapy under supervision, a large proportion of staff in case management roles felt unable to take on a study participant following training citing time pressures and the need to prioritise crisis work. Clinical assistants not carrying case or crisis management responsibility in contrast worked with most participants, had highest levels of fidelity to the therapy protocol, and highest rates of participant session attendance and goal attainment, despite having the least previous mental health training or experience in psychosis services. We suggest that improving service quality by widening access to evidence-based psychological therapies for psychosis requires a realistic approach, and there is a case for developing a new frontline entry level workforce with roles dedicated at least in part to protocolised brief therapy delivery, as has been successfully undertaken in the UK for those with common mental disorders by the development of Psychological Well-Being Practitioner roles (Chan & Adams, 2014; Gyani, Shafran, Layard, & Clark, 2013).

4.1. Limitations

The GOALS Study was designed as a feasibility, rather than definitive randomised controlled trial, and therefore the results of the statistical analysis should be treated with caution. For the majority of trained staff members, their study participant was their first ever therapy case. Supervision attendance was also considered part of the training process, so there is a possibility that with more experience and hands on learning through supervision, staff would become more proficient in therapy delivery.

Following the findings from the feasibility data and experience of delivering training and supervision modifications have been made to the protocol and training package. For example, given the finding that trained staff tended to commonly struggle to make links between personal goals and anxious avoidance/depression-related inactivity, training has been lengthened to include further teaching on this. In addition, both training and the therapy manual have more information on basic therapy techniques such as the use of socratic questioning rather than more didactic approaches. Further, additional areas of troubleshooting difficulties were added to the therapy manual and client handouts, based on common difficulties arising in the study. Finally, a more flexible approach to the number of therapy sessions has been suggested, since not all participants needed the full number of sessions to reach their goal, whilst others needed additional sessions.

4.2. Conclusions

This feasible and low cost intervention thus has great potential to widen access to evidence-based practice for people with psychosis, if a modified approach, based on the findings of the current study, is shown to be cost–effective in a larger trial in routine services.

Declaration of interest

The authors report no declaration of interests.

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