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Cognitive Analytic Therapy for Bipolar Disorder:

A Pilot Randomized Controlled Trial

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The evidence base for treatment of bipolar affective disorder (BD) demands the evaluation of new psychotherapies in order to broaden patient choice. This study reports on the feasibility, safety, helpfulness and effectiveness of cognitive analytic therapy (CAT). In a pilot randomised controlled trial, BD patients in remission were randomised to either receiving 24 sessions of CAT (N=9) or treatment as usual (N=9) and were assessed in terms of symptoms, functioning and service usage over time. In the CAT arm no adverse events occurred, 8/9 completed treatment, 5/8 attended all 24 sessions and 2/8 were categorised as recovered. The most common helpful event during CAT was recognition of patterns in mood variability, with helpfulness themes changing according to phase of therapy. No major differences were found when comparing the arms over time in terms of service usage or psychometric outcomes. The study suggests that conducting further research into the effectiveness of CAT in treating BD is warranted and guidance regarding future trials is provided.

Practitioner points:

- Treating BD with CAT appears feasible and safe.
- Retaining fidelity to the reformulation, recognition and revision structure of CAT appears useful.
- Participants stated that across the phases of CAT, focussing on patterns of mood variability was consistently helpful.

In Bipolar Affective Disorder (BD) highly recurrent and episodic periods of mania (depending on the severity or whether there is psychosis) or hypomania and periods of profound depression predict clinically significant shifts in energy/activity levels that disrupt abilities to occupy and perform day-to-day roles and tasks (DSM-5; APA, 2013). Bipolar I is characterized by an extreme manic or mixed episode and a major depressive episode and Bipolar II by one or more major depressive episodes and at least one episode of hypomania - with possible periods of euthymia between episodes. Judd et al. (2005) noted that psychosocial disability in BD fluctuated in parallel with such changes in affective symptom severity. Lifetime prevalence for BD is 1.3-1.6% and BD is equally common across the genders (NIMH, 2012). Lithium (and other mood stabilising medications) persist as the pharmacological treatments of choice (Young & Hammond, 2007). However, pharmacological adherence is problematic in 20-60% of cases (Adams & Scott, 2000), with high relapse rates, continuing difficulties and on-going psychosocial impairment common outcomes (Miklowitz & Scott, 2009).

Judd et al. (2003) showed that BD patients also commonly suffer inter-episodic depressive symptoms even when medicated. A recent review of cognitive impairments (Deglas et al. 2015) found that during acute phases, deficiencies were most commonly found in cognitive flexibility, with deficits in working memory typically occurring during remission phases. Meta-analysis has shown that psychological therapies effectively augment pharmacology in reducing relapse rates (Scott, Colom & Vieta, 2007), with an associated recognition of the need to integrate psychotherapy into BD care-packages (Shannon & Swarbrick, 2010). However, even in specialist Secondary Care services, less than one third of all BD cases receive any form of psychotherapy, highlighting high levels of unmet patient needs (Wittchen, Jacobi, Rehm, Gustavsson, Svensson, Jönsson, & Steinhausen, 2011) and also a lack of suitably trained therapists (Salcedo et al. 2016).

Psychological treatments of BD have evolved beyond early versions whose sole purpose centred on increasing medication adherence. Contemporary psychological treatments for BD can be characterised by treatment intensity. A 'low intensity' approach to BD is defined by the delivery of a small number of brief sessions focussing on psychoeducation regarding treatment adherence, stress management, symptom awareness and substance abuse (Colom et al. 2003). 'High intensity' psychological therapies are more traditional and so adopt a formulation–driven treatment approach, with a greater number of longer sessions (Clark, Layard, Smithies, Richards, Suckling & Wright, 2009). The evidence base for psychotherapy for BD reflects six main models (see Salcedo et al. 2016 for a review) which have been tested in clinical trials; psychoeducation (N=12 trials), cognitive behavioural therapy (N=9 trials), interpersonal and social rhythm therapy (N=2 trials), dialectical behaviour therapy (N=2 trials), mindfulness based cognitive therapy (N=3 trials) and family therapy (N=3 trials). Outcomes can be negatively affected by comorbidity with other psychiatric disorders; the frequent comorbidity of personality disorder complicates the course of BD and also responsivity to treatment (Latalova, Pasko, Kamaradova & Ociskova, 2013).

A conclusion drawn from the Salcedo et al. (2016) review of empirically supported psychotherapies for BD was that patients may well be suited to differing interventions for BD and that associated matching and choice were clinically important. Given the extant evidence concerning inter-episodic residual symptoms (Judd et al. 2003), cognitive impairment (Deglas et al. 2015), comorbidity (Krishnan, 2005) and impaired functioning (Judd et al. 2005), there is a need to develop and evaluate new applications of existing therapies (or develop bespoke therapies), in order to broaden access to effective therapies. The recent Aas et al. (2016) systematic review noted that childhood trauma was a known risk factor for BD, in addition to trauma tending to generate more severe clinical presentation over time (e.g. earlier age at onset, increased risk of suicide and substance misuse). The role of interpersonal

relationships and self-concept is central to the ongoing management of BD (Goldberg & Harrow, 2005), with BD patients reporting significantly more interpersonal problems compared to community controls (Drieling, Scherer-Klabunde, Schaerer, Biedermann, Post & Langosch, 2010). Whilst interpersonal and social rhythm therapy has an interpersonal element (i.e. via emphasising the bidirectional nature of mood and interpersonal events), it does not make explicit use of the therapeutic relationship as a means of analysing (and changing) intra and interpersonal difficulties that are often related to childhood trauma. There is therefore a clear clinical need to trial a relational therapy for BD that can additionally formulate the role of childhood trauma. The rationale for taking a more relational approach, is that if a therapy was able to facilitate changes in the relationship the BD patient has with themselves, the disorder and/or their broader interpersonal relationships, then the stress-diathesis model of BD (Scott, 2001) would state that this had the potential to change the dynamics of BD itself (or at least the manner in which the patient copes with the disorder).

Cognitive analytic therapy (CAT) was developed in response to the need for short-term therapies in pressured public services (Ryle, 1995) and in the UK is a popular integrative therapy distinct in its explicit relational focus and methods (Ryle & Kerr, 2002). The model has evolved from one for treating neurotic problems, to one which is typically used to treat complex and enduring mental health problems, particularly that of personality disorder in Secondary Care services (Ryle, Kellett, Hepple & Calvert, 2014). For complex difficulties, a routine CAT contract consists of 24 weekly sessions plus four follow-ups (spaced over 6-months). Calvert & Kellett's (2014) systematic review found that the CAT evidence base was generally founded on moderate to high quality outcome studies in typically complex clinical populations.

Theoretically, CAT draws on personal construct (Kelly, 1956) and object relations theory (Ryle, 1991). Cognitive analytic theory asserts that negative mental representations of self, others and the world are developmentally formed by early neglectful or abusive interactions with significant others (Ryle & Kerr, 2002). Such internalised, early object relations are termed *reciprocal roles* that influence how people anticipate, experience, enact and react to relational dynamics. The theory also suggests that patients have learnt a repertoire of reciprocal roles and *target problem procedures* (TPPs; commonly referred to as traps, snags and dilemmas; Ryle & Kerr, 2002) to 'survive' childhood adversity/trauma, but which are currently maladaptive (Clarke & Llewelyn, 1994).

Clinically, CAT follows a three-phase process; (1) narrative and diagrammatic *reformulation* of the presenting problem to enable a shared understanding both of the developmental origins of difficulties and their current maintainers, (b) a *recognition* phase wherein the patient becomes more aware of their roles and procedures via self-monitoring and (c) a final *revision* phase in which change methods are collaboratively designed in order to change patterns and roles (Ryle, 1995). *Exits* are the active change methods of CAT developed during the revision phase that support the patient in revising maladaptive procedures, with the therapist aiming to offer a containing, non-collusive experience throughout – exits also include analysis of *enactments* of roles and procedures occurring within the therapeutic relationship (Bennett & Parry, 2004). The change methods of CAT are catholic and can be drawn from any approach, as long as they are grounded in the reformulation of the patient (Kellett, 2012).

The evolution of CAT for more complex presentations has been stimulated by the development of the multiple self-states model (MSSM; Ryle, 1995). A self-state is defined by the presence of key affect, particular beliefs concerning self/others and the degree to which the patient is in touch with (and in control of) core feelings (Bedford, Davies &

Tibbles, 2009). Theoretically, the MSSM conceptualises BD therefore as the lack of integration of a constellation of opposing/contrasting self-states and associated self-state switching (Kerr, 2001) which is captured in the diagrammatic reformulation. Shannon and Swarbrick (2010) defined characteristic BD self-states as manic euphoria, controlled superiority, masked remission, critical shaming, psychotic anger, dismissing and rejected depression. A typical CAT formulation of BD would therefore use the MSSM to reflect the hierarchical structure of both preferred (manic or hypomanic) and dreaded (depressed) self-states, associated interpersonal status (e.g. in depression; losing, failing and impotent) and identity positions (e.g. in mania; winner, unique and special). State switching is an involuntary strategy used to block out consciousness of unwanted information, which dictates the observable fixed/unhelpful reactions and responses (Elzinga, Phaf, Ardon & van Dyck, 2003; Dalenberg et al. 2012). As the MSSM captures both the manic and depressed elements of BD (Fountouakis, 2008; Shannon & Swarbrick, 2010), it meets Castle et al's (2009) demand for BD treatments to have the capacity to simultaneously formulate and treat both poles of BD.

The evidence of CAT for BD is limited to one previous study. Kerr (2001) reported a case series (N=4) of the application of CAT with treatment resistant hypomania with residual psychotic symptoms, in which two of the patients had a good qualitative outcome. The study highlighted that the CAT model was useful in comprehending what was previously seen as 'psychotic psychopathology' in terms of the MSSM and that CAT reformulation was both containing and also helped to reduce disturbed/non-compliant behaviours. This current study sought to expand on this initial uncontrolled evidence; meta-analytic evidence of a weighted mean effect size across a variety of outcome measures of $d_+ = 0.83$ for CAT (Ryle et al., 2014) also provided an empirical foundation stone.

Medical Research Council (MRC) guidelines state that pilot trials are essential prior to any major trial seeking to evaluate a complex intervention such as psychotherapy (Lancaster et al. 2010). The current study met the definition of an external pilot trial, as it was a stand-alone pilot study (i.e. not the first stage of a larger trial), whose method included a randomisation procedure (Arnold, et al. 2009; Arain, Campbell, Cooper & Lancaster, 2010). The trial was also pragmatic because all participants were seen as an aspect of routine service delivery. The primary aim was to provide preliminary evidence regarding the feasibility, safety, and helpfulness of CAT for BD, alongside testing the trial procedures themselves (recruitment, treatment, ability to follow-up patients and appropriateness of measures). As the study also involved randomisation, a secondary aim was to compare outcomes (with treatment as usual). The purpose was not to provide a definitive test of the efficacy of CAT for BD on an a priori specified primary outcome measure (Thabane et al. 2010). This pilot rather sought to test the potential and feasibility of CAT with BD in preparation for a larger clinical trial and so providing some initial evidence of a new approach to treating BD in a frequently neglected population (Wittchen et al. 2011).

Method

Design and randomization

The study design was a pragmatic randomized controlled trial, with BD patients randomised to either CAT or treatment as usual (TAU) within standard public sector care. After initial diagnostic assessment, the psychiatrist undertaking the assessment communicated key assessment details to the trial coordinator. Patient randomization to either arm of the trial was then completed by a computer-generated random allocation method undertaken by an independent body (School of Health and Related Research (ScHARR); Sheffield, UK). A straight randomisation process was used (i.e. no feedback was given concerning

randomisation to the assessors. If patients were allocated to CAT, the trial coordinator made direct contact with a study therapist who then offered therapy. Psychometric outcomes were taken at four points in time; (1) pre CAT, (2) immediately post CAT, (3) at 6-months follow-up and (4) at 12-months follow-up. Patients in the TAU arm completed measures over a matched course of time.

Sample and recruitment

Potential participants had to have an extant clinical diagnosis of BD and also be under the care of psychiatric services. Potential participants were recruited from community mental health teams within Manchester Mental Health and Social Care Trust in the UK and were treated within a specialist psychotherapy service. The service offers various forms of evidenced based psychotherapies across a variety of diagnoses and BD would not normally routinely excluded. The majority of the service's work concerns treatment of personality disorder. Figure 1 illustrates that N=21 BD patients were referred and considered for eligibility; three of whom were excluded (2 declined to participate and 1 had a recent bereavement). All patients referred to the trial underwent psychiatric assessment prior to randomisation to ensure Bipolar I or II diagnosis, via the Structured Clinical Interview for DSM Disorders (SCID-I; First, Williams, Spitzer & Gibbon, 2007). This was also used to assess the rate of co-morbidities with other diagnoses. The diagnostic assessments were completed by psychiatrists trained in SCID assessment for the purposes of the study. Assessing psychiatrists received supervision on each case prior to making definitive diagnostic decisions to ensure consistency - and also did not act as therapists within the trial.

Participants were excluded if they were exhibiting; (a) a current hypomanic or manic episode, (b) a current moderate or severe depressive episode, (c) current continuous and severe substance misuse, (d) poor command of English, (e) a learning disability, (f) current or

recent past (within 6 months) treatment of their BD with a formal psychotherapy or psychoeducative programme and finally (g) involvement in another psychological or pharmacological treatment trial and were in the follow up phase. Patients who were in remission were chosen for the trial because, (1) this population has been studied in the early stages of testing other models, (2) as the focus of the trial was on feasibility, safety and effectiveness this meant that CAT sessions did not get used on the containment of acute episodes, (3) evidence from the Scott CBT trial found that psychological therapies were less efficacious when focussed on containing BD relapse (Scott et al. 2006) and (4) sub-syndromal depressive symptoms are associated with significant impairment in BD (Judd et al. 2005).

Intervention; treatment as usual

The control condition was TAU that included drug treatments (mood stabilizers, antidepressants and anti-psychotics) as recommended by NICE guidelines for BD (NICE, 2006). Participants in the TAU arm were therefore seen for regular outpatient treatment reviews with psychiatrists and had regular contact with community psychiatric nurses (CPN) acting as care coordinators. Type and dose of medication was not recorded. As TAU participants consented to not engaging in other psychological therapy during the trial, on completion of the study, all TAU patients were offered CAT. Therefore, the control condition was a waitlist control (Elliott & Brown, 2002).

Intervention; cognitive analytic therapy

Participants in the experimental treatment arm of the trial received TAU, plus a course of CAT. All therapies were delivered by Association of Cognitive Analytic Therapy (ACAT) accredited CAT practitioners and psychotherapists (N=5). All therapists attended weekly individual clinical supervision for trial patients with an ACAT accredited supervisor and trainer. Consistent with the CAT model for complex patients (Ryle & Kerr, 2002), treatment

consisted of 24 weekly fifty-minute one-to-one sessions, followed by four follow-up sessions (at one, two, three and six-months post-therapy). CAT is delivered in three distinct stages: reformulation (sessions 0-6), recognition (sessions 6-12) and revision (sessions 12-24). During the reformulation stage, narrative and diagrammatic reformulations of BD were co-constructed. Narrative reformulations reformulated the experiences and traumas leaving patients prone to BD and were also used to predict potential alliance ruptures and anticipated unhelpful enactments within the therapeutic relationship (Ryle & Kerr, 2002). Diagrammatic reformulations involved mapping of BD self-states and associated procedures, and are referred to as sequential diagrammatic reformulations (SDRs). The recognition stage entailed self-monitoring of self-states and associated target problem procedures to improve awareness of reciprocal role relational dynamics (self-self; self-other; other-self) creating and maintaining BD self-states. The final revision stage centred on change and entailed the collaborative development of 'exits', which were labelled on the SDR and practised between sessions as homework (e.g. experimenting with being more behaviourally active when a mood decent cycle was recognised or analysis of an enactment within the therapeutic relationship). All patients were invited to write an ending letter following CAT, to mirror the 'goodbye letter' written by therapists. Follow-up sessions entailed checking in on patient progress and reinforcing and revisiting the exits developed during therapy.

Intervention; treatment fidelity

CAT treatment fidelity was assessed via the Competence in Cognitive Analytic Therapy measure (CCAT; Bennett & Parry, 2004). The CCAT is a valid and reliable measure of CAT therapeutic competency. The CCAT is scored across ten domains, with a global CCAT score =>20 being the cut-off score for competent CAT. Each therapist in the trial had a CCAT completed on one of their treatment sessions, with treatment sessions chosen at random. An accredited ACAT supervisor and trainer (independent of the research process) completed

CCAT ratings. The mean CCAT score was 34.16 (SD = 5.49); all sessions sampled were above the competency cut-off score (Bennett & Parry, 2004).

Outcome measures

Researchers not involved in providing CAT or TAU and blind as to allocation collected primary and secondary measures.

Primary outcome measures

The primary outcome measures concerned feasibility, safety and helpfulness. Feasibility of CAT was calculated via the mean number of CAT sessions attended and the treatment dropout rate. Patient safety (Duggan et al. 2014) was monitored via adverse events monitoring in both arms of the trial on three indices; (1) crisis team involvement, (2) hospitalisation days and (3) a reliable deterioration on the CORE-OM (see measures section). Helpfulness of CAT was measured on responses to the Helpful Aspects of Therapy form which is a valid and reliable index of therapeutic helpfulness (Llewelyn, 1988). The HAT asks participants (a) to describe the helpful or hindering event(s) that occurred in the session and (b) to rate the identified event(s) from 0 (hindering) to 9 (helpful).

Secondary outcome measures

The secondary measures comprised further indices of service utilisation and psychometric outcomes. Service utilisation measures included: the number of psychiatry outpatient and community psychiatric nurse (CPN) appointments offered and attended. For all service usage measures, comparisons were made between the 12-month period preceding entry into the study and the 12-month period immediately following therapy. The following clinician and self-report valid and reliable psychometric outcome measures were administered: Beck Depression Inventory-II (BDI-II; Beck, Steer & Brown, 1995; a self-report measure of depression severity), Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979; a clinician report measure of the severity of depression for patients with

mood disorders), Bech-Rafaelson Mania Rating Scale (BRMRS; Bech et al. 1979; a clinician report assessment of current mania), Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM; Evans et al. 2000; a self-report measure of psychological distress), Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002; a self-report measure of functioning) and Personality Structure Questionnaire (PSQ; Pollock et al. 2001; a self-report measure of identity disturbance and state-shifting). The PSQ is a CAT-specific outcome measure derived from the MSSM, which has a caseness cut-off of 26-28 (Berrios, Kellett, Fiorani & Poggioli, 2016) and is sensitive to change (Kellett, Bennett, Ryle, & Thake, 2013).

Qualitative analyses

Thematic analysis was conducted by SM on the qualitative descriptions of helpfulness events named on the HAT (Llewelyn, 1988) following CAT sessions. Thematic analysis is a research method used to identify, analyse and report patterns/themes within qualitative data (Boyatzis, 1998). The analysis was carried out following Braun & Clarke's (2006) phase approach to data analysis; (1) familiarisation with the helpfulness data in order to understand what was in the data and what was interesting about what was helpful, (2) development of initial codes to identify features of the helpfulness data that were relevant to the overall research question, paying particular attention to repetitive patterns or themes, (3) individual codes were then analysed to consider how they may be combined to form broader theme levels - at the end of this phase, a collection of helpfulness themes (and sub-themes) was created and all extracts of data were then coded in relation to these, (4) themes were then reviewed and refined to ensure thematic clarity and associated sharp distinctions between themes and finally, (5) naming of themes as a summary of the helpfulness thematic results.

SM created and maintained a reflexivity journal to document close reflections on the helpfulness data. The reflexivity journal was used to repeatedly review the qualitative

analysis during research supervision to reflect on emerging patterns, themes and concepts found in the helpfulness data. The reflexivity diary also logged any concerns with the analysis, observations and parallels with the CAT theoretical framework and any issues with the coding process. Emerson, Fretz & Shaw's (1995) recommendations for coding fieldwork notes were used to draw particular attention to the following: (a) what were participants saying about specific helpful approaches or strategies in sessions and (b) how did participants describe and understand what had been helpful in the session? SK acted as the outside reviewer of the reflexivity journal through evaluating the overall themes and in confirming the details of textual excerpts (Hosmer, 2008). The final themes identified from the thematic analysis were then compared according to the different phases of CAT (i.e. reformulation, recognition and revision stages), in order to examine whether helpfulness themes changed according to phase of therapy. Frequency counts of themes are used to illuminate which aspects of helpfulness were the most common according to which phase of therapy and HAT helpfulness scores are used to show a 'helpfulness rating' for each theme. This created a mean and SD for each theme, in order to illustrate how helpful the theme was according to the reformulation, recognition and revision stages of CAT.

Quantitative analyses

Descriptive statistics are provided for CAT and TAU over time for both service usage and secondary outcome measures in order to compare outcomes. Mann-Whitney U tests were used to compare service usage. Treatment outcomes in the study arms on the secondary outcome measure were compared via repeated-measures ANOVAs on post-treatment and follow-up assessments (6 and 12-months). In order to provide a conservative estimation of treatment effects, intention-to-treat analyses were conducted using the last observation carried forward method (LOCF; Carpenter & Kenward, 2008). Post-hoc t-tests were then used to examine significant group-time interactions. Uncontrolled effect sizes (Cohen's d_+)

were calculated for secondary outcome measures to demonstrate the size of the effect in each arm. Effect sizes were calculated using the follow-up change score during CAT divided by the pre-intervention SD (Westbrook & Kirk, 2005). Between-group effect size comparisons were achieved by dividing the difference between TAU and CAT outcomes post-therapy (or at follow-up) by the pooled standard deviation. Effect sizes were considered with Cohen's (1992) power primer that denotes $d_+ = .20$ as a "small" effect, $d_+ = .50$ as a "medium" effect, $d_+ = .80$ as a "large" effect. The degree of psychological change achieved during CAT was then categorised on the CORE-OM using the reliable change index (RCI; Jacobson & Truax, 1991). Reliable and clinically significant change is increasingly taken as a credible index of psychological recovery (Barkham, Stiles, Connell & Mellor-Clark, 2012). Clinically significant change was deemed to have occurred when the pre-post CORE-OM score reduced from the clinical ($\geq$10 score) to a non-clinical (<10 score) population (Evans, Margison & Barkham, 1998). In accordance with extant RCI recommendations (Evans et al. 1998), reliable improvement was recorded when an individual patient's pre-post score on the CORE-OM improved by equal to or more than 1.96 times the SE_{diff}; a reliable change index of 5 was therefore adopted (Connell et al., 2007).

Results

Treatment feasibility

Figure 1 displays the entry of patients into the trial (organised according to CONSORT recommendations; Moher et al., 2001), showing that eighteen patients were randomised to either CAT or TAU. All randomized patients were subsequently analysed using an intention-to-treat approach. The CAT group consisted of 7 females and 2 males with an average age of 48.33 (sd = 9.84) years; 8 of the CAT participants had a BD1 diagnosis and 1 had a BD2

diagnosis and all were prescribed medication. The TAU arm consisted of 7 females and 2 males, with in average age of 45.66 (sd = 12.55) years; 8 of the TAU participants had a BD1 diagnosis and 1 had a BD2 diagnosis and all were prescribed medication. There were no significant differences in terms of age (p = .62) or gender distribution (p = .72) between the two arms of the trial. Co-morbidity was common; 4/9 (44.4%) of CAT patients and 6/9 (65.2%) of TAU patients met diagnostic criteria for at least one other psychiatric diagnosis, but there was no difference in the rate of psychiatric comorbidities (p = .14) between the arms. In the CAT arm, nine patients started therapy, with one participant transferred to a different service after 7-months, due to relocating. In the TAU arm, four patients dropped out of the study. Two patients in both arms were lost to follow-up. In the CAT arm, 8/9 patients completed full treatment (treatment completion rate = 88.8%). In terms of sessional attendance, 5/8 (62.5%) patients attended every one of their 24 CAT sessions - the median and mean number of CAT sessions attended was 22 (91.66% of sessions attended), with a mode of 24 sessions attended.

Insert figure 1 here please

Treatment helpfulness

Thematic analysis of HAT forms for CAT patients identified seven themes; (1) recognition of mood variability, (2) the experience of narrative feedback, (3) building and use of SDRs, (4) identifying exits, (5) psychotherapeutic support, (6) recognition of progress and (7) uneventful session. Table 2 contains textual excerpts in order to illuminate the theme identified. The frequency of helpful event themes and also the mean helpfulness ratings for each theme across the reformulation, recognition and revision phases of CAT are reported in Table 3. Results illustrate that uneventful sessions were an infrequent occurrence regardless of phase and ratings of helpful events were typically high.

During the reformulation stage of CAT, the most commonly occurring helpful event was when therapists helped patients to recognize patterns in their mood variability (event n = 24). This continued to be a common helpful event across recognition (event n = 7) and revision (event n = 16) phases. Co-construction of SDRs generated the highest mean helpfulness score (8.50) during the reformulation phase. During the recognition stage of CAT, the most frequent helping events were when patients were able to recognise the initial progress being made within therapy and also to start on generating exits (event n=13). Again, use of SDRs generated the highest helpfulness ratings during the recognition phase. Consistent with the model, an increase in exit work was evidenced over the phases, with the highest frequency of exit work taking place in the final revision stage (event n =17). This increase in helpful exit events is mirrored by active use of the SDR also being a frequent event in the final revision phase (event n = 14). The 'experience of narrative feedback' theme covered the reformulation letter during the early stages of the therapy (event n =5) and the goodbye letter delivered at termination of the revision stage (event n =5).

Insert tables 1 and 2 here

Treatment safety

Descriptive statistics for adverse events and service usage for CAT and TAU are presented in Table 3. When the 12-month period preceding entry into the study was compared to the 12-month period immediately following therapy, no differences in service usage or adverse events (hospitalization; 1 participant in each arm) were apparent. No single patient in the CAT and one patient in the TAU arm were seen by the crisis team.

Insert table 3 here

Treatment effectiveness

Table 4 contains mean scores, effect sizes and within and between group comparisons on the secondary outcome measures at baseline, end of treatment, 6 and 12-months follow-up. End of treatment effect sizes (d_+) in the CAT group were generally medium sized, whilst for TAU effect sizes (d_+) were generally small. End of treatment between-group effect size estimates generally indicated small treatment effects in favour of CAT. At 6 and 12-month follow-up, treatment effects generally demonstrated equivalence of outcomes. However, on the PSQ at 6-month follow-up there was a medium between-group effect size favouring CAT. The repeated-measures ANOVAs found that for both CAT and TAU significant improvements on secondary outcomes occurred over time (as measured by the BDI, CORE-OM and PSQ). Time x group interactions were non-significant for all outcome measures, across all measurement points, indicating no significant differences in treatment outcomes between CAT and TAU. Again, an exception to this was found regarding PSQ scores at 6-months follow-up; a significant interaction of time and group was observed. However, a post-hoc two-tailed t-test did not indicate that CAT resulted in significantly larger PSQ treatment effects than TAU at 6-month follow-up ($t = 1.25$, $df = 16$, $p = 0.23$). Figure 2 provides a visual representation of pre-post CORE-OM outcomes for both arm of the trial. Two CAT participants demonstrated clinically significant and reliable change (i.e. scoring beneath the cut-off line and also outside the no change tramline) and were therefore classified as 'recovered' post-treatment. No TAU participants met the criteria for recovery. The majority of CAT (n = 6) and TAU (n =7) participants, had a 'stasis' outcome (i.e. scoring within the

no change tramlines). No participants (TAU or CAT) had a reliable deterioration in psychological distress.

Insert table 4 and figure 2 here

Discussion

This study reported findings from the first pilot trial of CAT for BD and so makes a contribution by (a) showing that CAT is a safe, feasible and helpful form of psychological therapy for BD in routine care and (b) by adding to the emerging CAT evidence base (Calvert & Kellett, 2014). The value of pilot trials is widely recognised (Whitehead, Sully & Campbell, 2014), particularly so in difficult-to-treat conditions such as BD and also when the treatment being tested is anticipated to be complicated to deliver and/or to engage with. In terms of feasibility evidence, results suggest that participants found CAT to be engaging as high numbers of sessions were attended and also treatment contracts were typically completed. There was also preliminary evidence of CAT being a safe intervention for BD, as the service usage outcomes were similar to TAU and no patients in the CAT arm had a reliable deterioration in psychological distress during treatment (Duggan et al. 2014). The trial procedures themselves did not highlight any major issues (e.g. during recruitment or in terms of outcome measures). Analysis of the secondary outcome measures suggested few stark differences between the arms, but a trend for a moderate effect in CAT and a small effect in TAU. In both arms of the trial comorbidity was common; strong associations are common between BD and substance abuse, cyclothymia, anxiety, personality disorders, ADHD and also eating disorders (Krishnan, 2005).

Treatment feasibility is multifaceted (Tickle-Degnen, 2013), but an important aspect is whether patient's can and do complete treatment. The feasibility of providing CAT to BD patients was evidenced by the high average sessional attendance rate (over 90 %) and the low

treatment dropout rate (12.2%). 5/8 CAT participants attended every session offered in the contract, suggesting sustained therapeutic engagement. Treatment completion has previously been found to be an important predictor of outcome (Cahill et al. 2003). BD patients are often characterised as often difficult to engage in psychological treatment (Basco & Rush, 2005) and so the attendance findings for CAT are encouraging.

Another aspect of feasibility is the patient experience of the therapy (Tickle-Degnen, 2013). In order to assess the helpfulness of CAT for BD in greater detail, a thematic analysis was completed on named helpful events in HAT forms, with six helpfulness themes emerging (with one theme of uneventful sessions). Across the three phases, the theme of CAT helping patients to recognize patterns within their mood variability was a consistent finding. Part of the recognition phase of CAT entails enabling patients to occupy an 'observing eye' position, from which they can notice previously automatic or stereotyped relational patterns (Ryle & Kerr, 2002). This is based on the object relations procedural sequence approach (Ryle, 1991) and encourages CAT therapists to name and map patterns of thoughts, feelings and behaviour emerging from reciprocal roles. This allows patients to 'stand back' and recognise when patterns or role positions are about to happen, are happening or have just happened. Within treatment of BD, this CAT approach seemed helpful to patients in recognising the patterns reliably creating shifts in their mood states. The helpfulness results would reflect the CAT clinical method; engage the patient in rapid reformulation of the self-states and procedural patterns of their BD as the foundation stone upon which enhanced recognition can then facilitate 'exit work.' Finally, in terms of feasibility, the Salcedo et al. (2016) review noted the dilemma of the availability of empirically-supported treatments for BD, but the lack of suitably qualified therapists to provide them. All therapists in the current trial were qualified to the level of at least a 'CAT practitioner' which entails a 2-year therapy qualification (8 closely supervised cases and associated coursework) as an addition to a core therapy training

in another modality. Attempting to deliver CAT for BD would be unwise without appropriate training and supervision, whilst there needs not to be a bottle-neck of provision, due to a lack of appropriately qualified therapists.

The outcome comparison between CAT and TAU highlighted some intriguing differences in terms of PSQ outcomes (Pollock et al. 2001). At 6-month follow-up there was a medium between-group effect size favouring CAT with a significant time x group interaction (tempered by a subsequent non-significant t-test). The PSQ is a measure of identity confusion/state-switching theoretically grounded in the MSSM (Berrios et al. 2016) and results suggest that CAT patients at follow up were reporting less state-switching. This finding would encourage both the use of the MSSM to conceptualise BD and also the need to consider the PSQ as the primary outcome measure in future trials of CAT for BD. On the CORE-OM two of the CAT participants achieved 'recovery' status on the CORE-OM, suggesting a marked individual change in psychological distress not apparent for any single participant in TAU. The within group changes on the secondary outcome measures apparent in the TAU arm may have been due to engagement in the research process itself (Godin, Germain, Conner, Sheeran & Delage, 2012) and there is meta-analytic evidence that wait-times in wait-list control trials are associated with improvement (Hesser et al. 2011). It is noticeable that the changes that did occur were found solely on the self-report measures. This may reflect that the participants felt that change had occurred, but assessors did not share in this opinion. Indeed, meta-analytic evidence notes that clinician-rated and self-report outcomes measures for depression are non-equivalent and that different symptoms are better suited to one or the other, and so clinical trials should include both (Cuijpers, Li, Hoffman & Andersson, 2010). The lack of change in manic and depressive symptoms in the current study may have been due to the participant sample being drawn from patients currently in remission.

In terms of methodological weaknesses and future directions, the small number of participants randomized to the study arms (and also subsequent unequal attrition within the arms) is certainly the most critical. Whilst the sample size was appropriate for the pilot nature of the study (Julious, 2005), larger samples would be needed in future studies to detect consistent significant differences in outcome between study arms and also compare cost and health economic outcomes. The factors creating stasis outcomes are worthy of examination (Kellett, Webb, Wilkinson, Bliss & Hardy, 2016). Personality disorder co-morbidity would be an important covariate in the analysis of future studies (Latalova, Pasko, Kamaradova & Ociskova, 2013) and stringent assessment of comorbid physical and psychological disorders is indicated (Krisnan, 2005). Furthermore, the rate of previous BD episodes, impulsivity (Etain et al. 2013), childhood adversity (Aas et al. 2016) and type and dosage of current pharmacology should be recorded in future trials. Extensive trial selection criteria were employed which reduces the generalisability of the current findings (Rothwell, 2006). The follow-up period could have been longer to more effectively index long-term outcomes. The CCAT data were restricted to one session per therapist and therefore wider CCAT analysis (e.g. one session per phase of CAT per patient) would have been preferable. Although CAT theory dictates a 'three-phase approach' and the helpfulness data were analysed accordingly, in clinical practice there is often overlap between phases. Because in the current study the participants randomised to CAT received greater amounts of care (by dint of attending for therapy), then future trials need to compare CAT with another active psychological treatment (in medicated participants) to equalise the amount of care in the arms. In terms of supporting patient choice, a patient-preference randomised control trial (Howard & Thornicroft, 2006) would be the ultimate test of treatment acceptability between the psychotherapies for BD.

In conclusion, this study reported outcomes the first pragmatic pilot trial of CAT for BD with findings providing initial evidence of feasibility, subjective helpfulness and safety.

The CAT effect size results (although admittedly preliminary due to the small sample size) are encouraging. Results imply that future CAT studies with BD would not suffer from issues with recruitment. Patients were also willing to be randomised, but future studies need to develop effective mechanisms to reduce dropout rates (Oldham, Kellett, Miles & Sheeran, 2012) and also capture long-term follow-up outcomes. CAT specific factors such as early collaborative narrative and diagrammatic reformulation were found to be most helpful which mirrors the early Kerr (2001) BD evidence'. Whitehead et al. (2014) stated that pilot trials should determine whether a *clinically meaningful* effect has taken place. The authors propose that this has been found here for CAT for BD and so this pilot study functions as a foundation stone upon which future properly powered and controlled studies can now be conducted.

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Figure 1. *Consort summary*

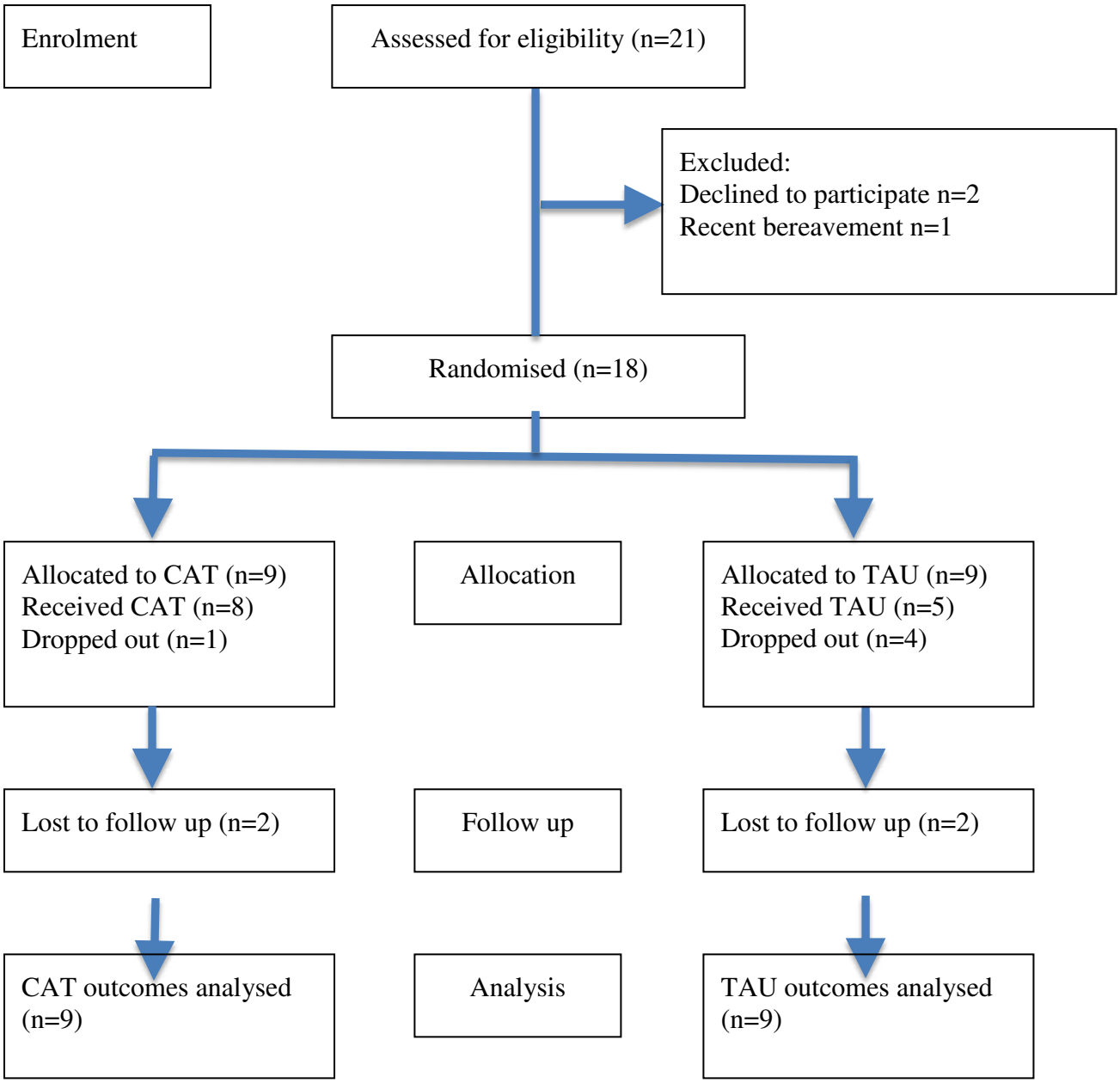

Table 1. *Themes and quotes from the Helpful Aspects of Therapy measure*

Theme	CAT participant quote
Recognition of patterns of mood variability	*'It was mentioned that I need to recognise my mood and it helped me a bit'* *'Seeing and being allowed to express feelings of wanting to commit suicide when depressed'* *'Describing the differences between a bad day and depression'* '*To really start to pick apart the whole area of suicidal self-harming thoughts/impulses of my illness'*
Experience of narrative reformulation	*'Therapist writing me the letter about all we've talked about'* *'Teasing out my mother and fathers individual characters and the relationships I have with them as a result'* *'From listening to what I was saying and the therapist reflecting back in the letter, I came to realise I'd moved quite quickly in this attempted quest for promotion'* *'Therapist writing me the letter about all we've talked about'* '*It picked up the hardness of facing re-building my life'*
Building and use of SDR	*'Therapist making me recognise some things about myself and how I am in relationships on the map'* *'Talking about my story and drawing a map of my thoughts'* *'Map of thoughts'*
Identifying exits	*'Found an exit'* *'Finding exits'* *'Talking about exits'* '*Finding exit for frozen'*
Psychotherapeutic support	*'Just talking, with no holding back and in confidence, about things I would never speak about'* *'The most important thing was me actually attending, when it was the last thing I wanted to do'* *'Therapist responded timely to my request for help for a phobia of wasps'* *'Something therapist said/asked triggered a very rapid mood change from confident and buoyant to slightly fearful and sad. Therapist responded immediately showing he had noticed it and was very empathetic'*
Recognition of progress	*'Looked at improvements I had made (i.e. doing*

	less planning)' *'To be reminded that I am doing well'* *'Talking about doing well'*
Uneventful session	*'Nothing eventful'* *'Nothing today really'* *'In this session, I was in a very low mood so explained this to therapist. For this reason, I have nothing to say on the form today and feel it necessary to explain this.'*

Table 2. *Frequency (count) and degree (HAT mean and SD) of helpfulness during CAT for BD*

Theme	Reformulation Phase			Recognition Phase			Revision Phase		
	Count	Mean	SD	Count	Mean	SD	Count	Mean	SD
Recognition of patterns of mood variability	24	8.05	1.05	7	7.75	0.97	16	8.70	0.47
Experience of narrative reformulation	5	7.66	0.57	3	8.00	0.00	5	8.75	0.50
Building and use of SDR	4	8.50	0.57	6	8.83	0.40	14	8.23	1.23
Identifying exits	11	7.84	0.80	13	7.85	0.89	17	7.73	1.40
Psychotherapeutic support	3	7.75	0.95	5	8.50	0.54	8	7.62	1.59
Recognition of progress	0	0	0.00	13	8.10	0.99	11	8.63	0.67
Uneventful session	4	-	-	2	-	-	3	-	-

Table 3. *Adverse event and service usage*

	CAT (N = 9)		TAU (N = 9)		CAT vs. TAU
Measure of service usage	*M*	*SD*	*M*	*SD*	Comparing pre-post change[a] *U* (*p*)
Number of clinic appointments attended					
Pre-treatment	4.00	3.46	3.66	2.34	
Post-treatment	3.33	2.34	3.33	2.95	34.50 (.61)
Number of clinic appointments missed					
Pre-treatment	0.44	0.73	0.33	0.50	
Post-treatment	0.33	0.70	0.33	0.50	39.00 (.93)
CPN appointments attended					
Pre-treatment	12.00	13.10	8.22	11.44	
Post-treatment	11.00	13.72	25.2	39.95	33.50 (.55)
CPN appointments missed					
Pre-treatment	0.55	1.01	0.22	0.44	
Post-treatment	0.55	0.88	1.22	1.78	35.00 (.67)
Number of inpatient admissions					
Pre-treatment	0.11	0.33	0.11	0.33	
Post-treatment	0.00	0.00	0.11	0.33	40.50 (1.0)
Number of inpatient days					
Pre-treatment	2.88	8.66	27.66	83.00	
Post-treatment	0.00	0.00	6.55	19.66	40.00 (1.0)
Number of CHRT admissions					
Pre-treatment	0.00	0.00	0.33	0.70	
Post-treatment	0.00	0.00	0.11	0.22	31.50 (.44)
Number of CHRT days					
Pre-treatment	0.00	0.00	2.66	7.63	
Post-treatment	0.00	0.00	0.77	2.33	31.50 (.44)

[a] between-group comparison of pre to post-treatment change scores (CAT vs. TAU).
CPN = community psychiatric nurse, CHRT = crisis resolution home treatment.

Table 4. *Secondary outcome measure analyses*

	Within-group outcomes and analyses						Between-group analyses (CAT vs. TAU)		
	CAT (N = 9)			TAU (N = 9)				Repeated-measures ANOVAs (*F*)	
Variable and time Point	*M*	*SD*	ES	*M*	*SD*	ES	Between -group ES	Time[c]	Time x treatment[d]
BDI									
BL	29.00	14.92		28.44	14.77				
EOT	19.33	17.58	0.65	23.78	14.58	0.32	0.28	7.86*	0.96
6-FU	24.00	18.30	0.34	24.89	15.40	0.24	0.05	5.51*	0.16
12-FU	20.67	20.77	0.56	21.22	17.48	0.49	0.03	7.31*	0.40
MADRS									
BL	13.33	8.30		13.77	6.96				
EOT	13.77	12.27	-0.05	12.66	9.27	0.16	-0.06	0.24	0.96
6-FU	12.89	10.87	0.05	13.56	11.57	0.03	0.06	0.03	0.003
12-FU	13.78	12.27	-0.05	11.78	10.46	0.29	-0.18	0.15	0.36
BRMRS									
BL	0.44	0.88		0.00	0.00				
EOT	0.00	0.00	0.50	0.22	0.66	-	0.47	0.36	3.27
6-FU	0.00	0.00	0.50	0.00	0.00	-	0.00	2.29	2.29
12-FU	0.00	0.00	0.50	0.00	0.00	-	0.00	2.29	2.29
CORE-OM									
BL	17.88	7.88		19.33	8.70				
EOT	14.33	8.73	0.55	16.33	9.57	0.34	0.22	9.72**	0.07
6-FU	15.00	9.54	0.37	15.22	9.60	0.47	0.02	9.70**	0.30
12-FU	13.33	10.72	0.58	15.66	9.78	0.42	0.23	8.08*	0.09
WASA									
BL	28.78	10.87		27.78	12.50				
EOT	24.44	14.00	0.40	26.78	10.66	0.08	0.19	1.18	0.69
6-FU	23.44	13.94	0.49	25.00	11.79	0.22	0.12	4.38	0.44
12-FU	23.67	12.65	0.47	23.33	14.11	0.36	0.03	3.17	0.02
PSQ									
BL	28.22	6.96		27.44	5.55				
EOT	22.56	9.35	0.81	26.22	5.82	0.22	0.47	8.43*	3.51
6-FU	22.00	11.43	0.89	27.33	5.72	0.02	0.59	7.14*	6.65*
12-FU	25.00	8.38	0.46	26.44	5.73	0.18	0.20	3.51	0.97

Note. *p <.05; **p <.01; ***p <.001.

ES = effect size estimate, SD = standard deviation, - = not possible to calculate, BL = baseline, EOT = end of treatment, 6-FU = 6-months follow-up, 12-FU = 12-months follow-up. [a] Within-group effect size estimates calculated as pre-treatment mean minus the post-treatment mean, divided by the pre-treatment standard deviation.[b] Between-group effect size estimates calculated as the post-treatment TAU mean, minus the post-treatment CAT mean, divided by the pooled post-treatment standard deviation.[c, d] (df = 1, 16).

Figure 2. *Plot of pre-post CORE-OM outcomes in the arms of the trial.*