Constructing shared understanding - A grounded theory exploration of team case formulation from multiple perspectives

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<u>CHAPTER 1:</u> SYSTEMATIC REVIEW

A systematic review of randomized-controlled trials evaluating mindfulness-based psychological therapies for psychosis

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For Submission to Schizophrenia Research

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D. Clin.Psy.)

TITLE

A systematic review of randomized-controlled trials evaluating mindfulness-based psychological therapies for psychosis

ABSTRACT

Background: Mindfulness-based psychological therapies are increasingly used with people with psychosis-spectrum disorders. They have been suggested to have potential to improve outcomes for this group. A number of randomized-controlled trials (RCTs) have now been conducted to assess their effectiveness.

Objective: To identify, summarize and evaluate RCTs comparing a mindfulness-based intervention to a control condition for people with psychosis-spectrum disorders to determine their efficacy for this population.

Data sources: A systematic review of articles identified by searching MEDLINE, EMBASE, PsychINFO, PsychARTICLE, CINAHL, Google Scholar, and Clinical Trial Registers (e.g. Cochrane Central Register of Controlled Trials, Current Controlled Trials Ltd.) from < 1980 to May 2014. Additionally, relevant journals and reference lists were hand-searched and clinical experts contacted to identify eligible studies.

Results: A total of 12 articles describing 11 studies were identified, comprising a total of 599 participants with affective and non-affective psychotic disorders, with a mean age of 36.5 years (range 25.8 – 43.2). 54.2% of the sample were male. The interventions included Mindfulness training, Mindfulness-based Cognitive Therapy, Acceptance and Commitment Therapy, Compassion Focused Therapy, Dialectical Behaviour Therapy, amongst others. The descriptive summary of study characteristics and outcomes indicated significant heterogeneity between studies. Furthermore, evaluation of risk of bias using the Cochrane Collaboration Risk of Bias tool indicated significant risk of bias amongst included studies, with only three being rated as low risk while the remaining eight studies were rated as having high risk of bias.

Conclusion: High levels of heterogeneity between and high risk of bias within individual studies make it difficult to determine efficacy of and draw conclusions about the use of mindfulness-based interventions for psychosis-spectrum disorders at this point. Further research comprising larger samples and more standardized use of interventions is needed to be able to compare studies more meaningfully in order to determine clinical implications.

Keywords: psychosis, mindfulness, RCT, systematic review

INTRODUCTION

There is now consistent evidence that Cognitive Behavioural Therapy for psychosis (CBTp) is associated with robust small to moderate effects on outcomes including overall psychiatric symptoms (Jauhar et al., 2014), positive symptoms (Wykes et al., 2008), delusions and hallucinations (van der Gaag et al., 2014). Recent guidance from the National Institute for Health and Care Excellence (NICE, 2014) recommends CBT as an individual treatment in psychosis particularly where there are persisting positive and negative symptoms. Since these pioneering studies of CBTp, there has been increasing interest in mindfulness-based psychological therapies.

Mindfulness-based Cognitive Therapy (MBCT, Segal et al., 2002), Mindfulness-based Stress Reduction (MBSR) therapy (Kabat-Zinn, 1990), Acceptance and Commitment Therapy (ACT, Hayes et al., 1999), Compassion Focused Therapy (CFT, Gilbert, 2009), Loving-kindness meditation (Salzberg, 1995), and Dialectical Behaviour Therapy (DBT, Linehan, 1993) can be seen as falling under the category of mindfulness-based psychological therapies. These approaches vary in their components and main foci (e.g. meditation-based, acceptance-based or compassion-based) but what they all have in common is an emphasis on alleviating psychological distress by changing one's relationship to thoughts and feelings (as opposed to challenging them as in traditional CBT) by cultivating a mindful, non-judgemental attitude to one's experiences. For this purpose, they all tend to include some form of meditation practice (e.g. retraining

attention by using mindfulness meditation), behavioural practice (e.g. taking a loving-kindness stance towards self and others), and cognitive strategies (e.g. reflection on transitory nature of events) aimed at training the mind in order to manage and reduce distressing affect (Singh et al., 2008). Mindfulness is an important ingredient in all of these approaches.

Previous systematic reviews provided evidence that some third-wave approaches or aspects of them when combined with treatment as usual (TAU) are helpful in reducing symptom-related distress and re-hospitalisation rates in people with psychotic disorders, as well as increasing feelings of self-efficacy (Davis & Kurzban, 2012; Helgason & Sarris, 2013). However, these studies only looked at mindfulness and meditation approaches used in combination with other routine treatment. In a recent systematic review, Khoury et al. (2013) combined the results of studies exploring the effectiveness of mindfulness-based psychological therapies in the treatment of people with psychotic disorders, used exclusively rather than in combination with another psychological intervention. The authors concluded that mindfulness-based interventions have a moderate effect with regards to treating negative symptoms, and can be beneficial when combined with pharmaceutical treatment (Khoury et al., 2013). A significant limitation of this review was the inclusion of uncontrolled and non-randomized trials. Almost half of the studies included did not use a control group, which makes it difficult to draw clear conclusions about effectiveness of an intervention.

Aim of the study

Therefore the current study aimed to build on previous reviews by undertaking a review of randomized-controlled trials (RCTs) of mindfulness-based therapeutic approaches in the treatment of psychosis-spectrum disorders, addressing the following questions:

1. What is the evidence for mindfulness-based approaches improving outcomes for people with affective and non-affective psychosis/psychosis-spectrum disorders compared to any control?
2. What is the evidence regarding risk of bias amongst those studies included in the review?

METHODS

Eligibility criteria

Inclusion criteria: studies that i) included participants with a diagnosis of an affective or non-affective psychosis-spectrum disorder (e.g. schizophrenia, schizoaffective disorder, bipolar disorder, first-episode psychosis etc), ii) compared a mindfulness-based therapeutic approach (e.g. ACT, MBCT, CFT, DBT, or any other mindfulness-based approach) with a comparator (e.g. TAU), iii) used a randomised-controlled trial (RCT) design, and iv) were published in peer-reviewed journals between 1980 and May 2014. No language restrictions were imposed. No limits were placed on age of participants or severity or duration of illness.

Exclusion criteria: studies that i) included participants with a primary diagnosis of non-psychotic psychiatric disorders, learning disability, psychosis secondary to a general medical condition or organic pathology, or a primary diagnosis of substance-induced psychosis, (ii) were using a study design other than RCT, i.e. non-clinical/analogue, uncontrolled, observational, qualitative or case studies, iii) were unpublished.

Outcomes

Outcomes included General clinical improvement, Psychiatric symptom changes, Rehospitalisation/crisis contacts, Depression and Anxiety, Social Functioning and Quality of life, Positive and Negative Affect, and Processes and mechanisms of change as relevant to the studies included in the review.

Search strategy

Studies were identified by searching electronic databases and trial registers, and by manually searching reference lists of eligible articles and journals. No limits were applied for language or date of publication. The search was completed in May 2014. The following computerized databases were searched: Ovid MEDLINE (R) In-process & Other Non-indexed Citations and Ovid MEDLINE (R) < 1980 to May 2014; EMBASE < 1980 to May 2014; PsychINFO < 1980 to May 2014; PsychARTICLE < 1980 to May 2014; CINAHL < 1980 to May 2014; and Google Scholar < 1980 to May 2014. The last search was run on May 18th 2014. In addition,

Clinical Trial Registers (Cochrane Central Register of Controlled Trials (CENTRAL), ClinicalTrials.Gov, Current Controlled Trials Ltd., and the Australian and New Zealand Clinical Trials Registry) were also searched. The following search terms were used: *Mindfulness or meditat*; Mindfulness-based; acceptance and commitment therapy; acceptance-based; compassion; compassion-focused; compassionate mind training; loving-kindness; person-based cognitive therapy; dialectical behaviour therapy; third-wave therap** combined with *psychosis or psychotic; psychotic disorder*; schizophreni*; schizoaffective disorder*; schizophrenia-spectrum disorder*; bipolar disorder*; manic depression*. See Appendix 1.2 for example of electronic search.

Hand searches of journals (e.g. British Journal of Clinical Psychology, Behaviour Research and Therapy, Schizophrenia Bulletin) and references of pertinent articles were undertaken following the electronic search to ensure no relevant articles were missed. Following identification of the final list of eligible studies, experts in the field were consulted with regards to its completeness.

Study selection

Assessment for the purpose of study selection was undertaken primarily by the author (JH) and involved the screening of titles and abstracts of all search results in the first instance. The application of predefined eligibility criteria aided the exclusion of studies. Further exclusions were made following the screening of full-text articles, aided by consultation with an independent reviewer (AG). The list of studies to be included was finalized following consultation with experts in the field.

Data Extraction

A data extraction sheet was developed based on the Cochrane Consumers and Communication Review Group's data extraction template (2013). The extraction sheet was pilot-tested on two of the included studies (selected randomly), reviewed by an independent reviewer (AG) and refined accordingly (Appendix 1.3). Information extracted from each trial included characteristics of trial participants, methodology (including recruitment and allocation process, type of interventions, and type of outcome assessment), and results of the study. As outlined above,

information on risk of bias was also collected and included in a separate Risk of Bias form.

Assessment of risk of bias in included studies

All studies selected were assessed for risk of bias using the Cochrane Collaboration Risk of Bias tool (Higgins et al., 2011a) to ascertain the validity of estimated treatment effect. The use of this tool is recommended by The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions (Liberati et al., 2009). This involved assessing the studies for potential sources of bias in areas that have been found to skew estimation of treatment effect, namely allocation of participants (i.e. sequence generation and allocation concealment), blinding, completeness of outcome data, selective outcome reporting and any other source of bias (e.g. baseline imbalance) threatening internal validity. A data extraction sheet was developed accordingly (Appendix 1.4). Nine of the studies were rated independently by two reviewers (JH and AG), using the extraction sheet. Inter-rater agreement was achieved by resolving any disagreements in discussion between them, where necessary. The remaining two studies were rated by one reviewer (JH) only because the second reviewer (AG) had been involved in these studies and could therefore not give independent judgement. Furthermore, trial reports were compared to original trial register protocols, where available, to assess for other potential sources of bias (e.g. any post hoc decisions made by authors). The outcome of this assessment overall was used to judge the quality of individual studies and the validity of the evidence provided by them. This was included in the synthesis of the studies, informing the conclusions drawn from this review with regards to the overall evidence-base.

Synthesis of results

Synthesis of the results included a summary of the characteristics of included studies (including participants, interventions, methodology and risk of bias). The outcomes of the studies were summarized by grouping them under areas of outcome and measures used (e.g. psychiatric symptoms, therapy-specific outcomes etc), and reporting the overall results accordingly. This approach to synthesis was deemed appropriate and most meaningful given the heterogeneity of included studies.

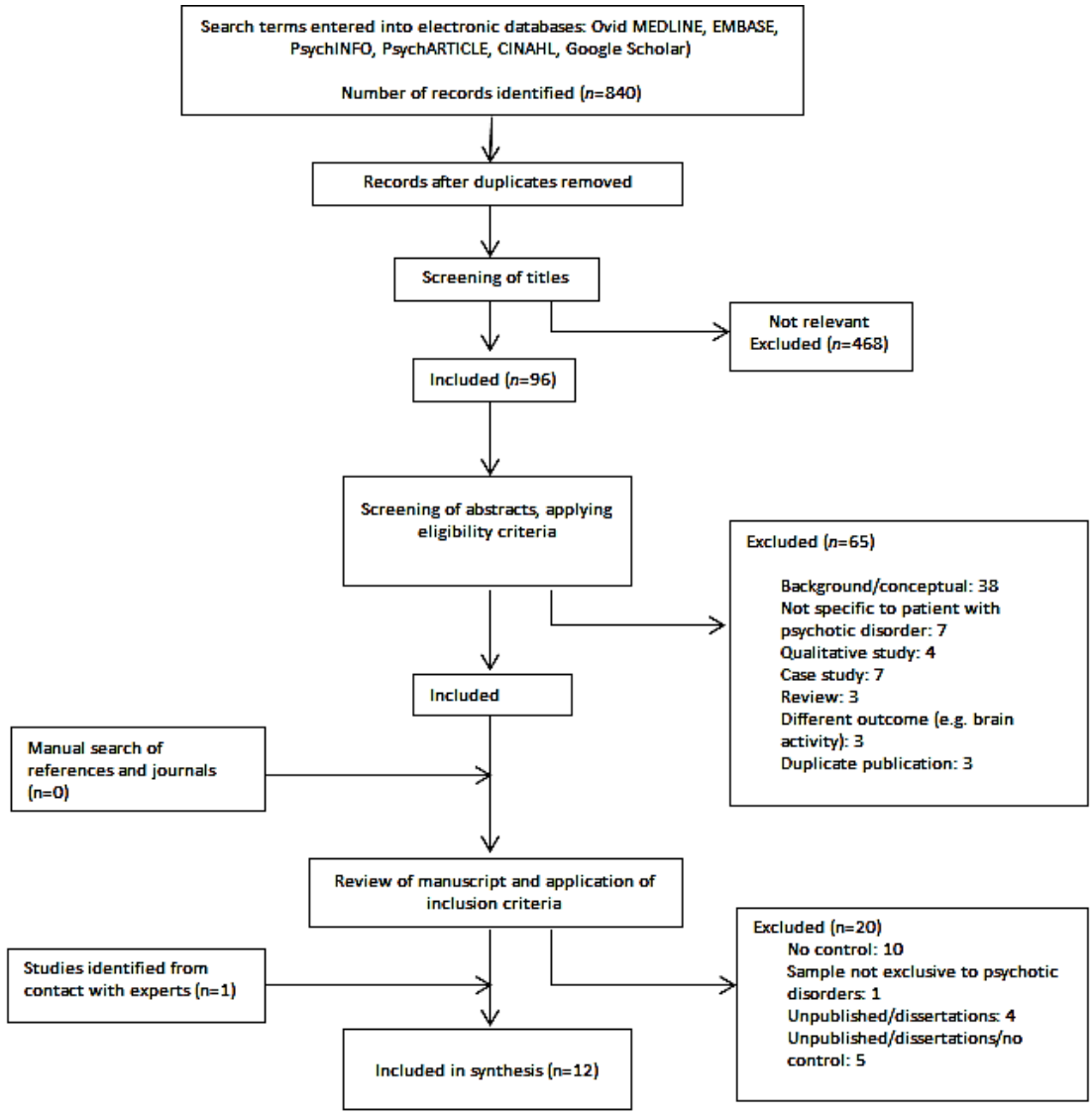
RESULTS

Search and study selection

The search and study selection process is summarized in Figure 1 below. The initial search of electronic databases using the search terms outlined above resulted in 840 titles initially, 564 once duplicates were removed. Of these, 468 were excluded following screening of titles because it appeared that they clearly did not meet the criteria (e.g. being non-clinical, not pertaining to either a psychosis-spectrum sample or mindfulness-based approach, or addressing a completely different area). Applying the eligibility criteria, the abstracts of the remaining 96 studies were then assessed, which resulted in another 65 exclusions. Reasons for exclusions are outlined below (Fig. 1).

The full-text manuscripts of the 31 included studies were then screened. Before further exclusions were made the abstracts of these studies were reviewed by another reviewer (AG) and agreement reached on the final number of studies to be included in the review. Of these 31 manuscripts, 20 were excluded from selection leaving 11 manuscripts describing 10 studies for inclusion into the review. Manual screening of the reference lists of these studies and hand-search of relevant journals did not result in any further studies to be included. Before synthesis was undertaken, feedback was sought on the final list of studies from experts in the field of ACT, CFT and mindfulness-based approaches. This generated one trial that recently had been published online to be included.

Figure 1: Flowchart of the article selection process



Included studies

In total, 12 manuscripts describing 11 studies met inclusion criteria: Bach & Hayes (2002) and Bach, Hayes & Gallop (2012); Braehler, Gumley, Harper, Wallace, Norris & Gilbert (2013); Chadwick, Hughes, Russell, Russell & Dagnan (2009); Chien & Lee (2013); Chien & Thompson (2014); Gaudiano & Herbert (2006); Langer, Cangas, Salcedo & Fuentes (2011); Perich, Manicavasagar, Mitchell, Ball & Hadzi-Pavlovic (2013); Shawyer, Farhall, Mackinnon, Trauer, Sims, Ratcliff, Larner, Thomas, Castle, Mullen & Copolov (2012); Van Dijk, Jeffrey

& Katz (2013); White, Gumley, McTaggart, Rattrie, McConville, Cleare & Mitchell (2011). The included studies are summarized in Table 1.

Study/participant characteristics

Combined the studies comprised a total of 599 adult participants (before attrition rates), with an average of 54 participants per study (range 22-107). Based on data from ten studies, the mean age of the participants was 36.5 years (range 25.8 – 43.2). No data were provided on the age of 95 participants (15.9%) (Perich et al. 2012). Based on nine studies, 54.2% (n=300) of the sample were male, while 45.8% (n=254) were female. Two studies (Chadwick et al., 2009, Langer et al., 2011; n=45, 7.5%) did not provide information on gender. Information on ethnicity was provided by four studies (n= 187; 31.2%) and included Caucasian non-Hispanic (n=60) (Bach & Hayes, 2002/Bach et al., 2012), African-American (n=36) (Gaudiano & Herbert, 2006) and White British (n=66) (Braehler et al., 2012; White et al., 2011). Four studies stated country of birth, with participants born in China (n=203; 33.9%) (Chien & Lee, 2013; Chien & Thompson, 2014), Spain (n=23; 3.8%) (Langer et al., 2011), Australia (n=138; 23.0%) (Perich et al., 2013; Shawyer et al., 2012) and Canada (n=26; 4.3%) (Van Dijk et al., 2013). One study did not provide any information on ethnic background/country of origin (n=22; 3.7%) (Chadwick et al., 2009). Inclusion criteria were stated by all 11 studies.

Nine studies provided detailed information on diagnoses within their samples. These included primary diagnoses of schizophrenia (n=324; 54.1%), other non-affective psychosis (n=10; 1.7%), schizoaffective disorder (n=35; 5.8%), schizoaffective disorder manic type (n=1; 0.2%), mood disorder with psychotic features (n=32; 5.3%), depressive psychosis (n=9; 1.5%), bipolar disorder with psychosis (n=2; 0.3%), delusional disorder (n=5; 0.8%), psychosis NOS (n=10; 1.7%), bipolar disorder mania and psychosis (n=1; 0.2%), bipolar disorder depression and psychosis (n=2; 0.3%), bipolar disorder type I (n=69; 11.5%), bipolar disorder type II (n=49; 8.2%), bipolar NOS (n=1; 0.2%).

Secondary diagnoses included anxiety disorder (n=83; 13.9%), substance related disorder (n=38; 6.3%), borderline intellectual functioning (n=10; 1.7%), personality disorder (n=19; 3.2%), ADHD (n=3; 0.5%), and major medical condition (n=33; 5.5%). Two studies (Gaudiano & Herbert, 2006; Langer et al 2011) did not

provide detailed information other than broad the diagnostic term of ‘psychotic disorder’ (n=63; 10.5%). Medication was reported by eight studies, while three studies omitted this information (Bach & Hayes, 2002/Bach, Hayes & Gallop, 2012; Shawyer et al., 2012; White et al., 2011). Information on educational level was explicitly stated for 58.9% (n=353) of the total sample by five studies (Chien & Lee, 2013; Chien & Thompson, 2014; Gaudiano & Herbert, 2006; Perich et al., 2013; White et al., 2011). Employment status for 239 participants (39.9%) was reported by six studies (Chadwick et al., 2009; Gaudiano & Herbert, 2006; Langer et al, 2011; Perich et al., 2013; Shawyer et al., 2012; White et al., 2011), with 65.3% (n=156) of these participants being unemployed, 30.4% (n=73) in full-time or part-time employment, 3.8% (n=9) working causally or unpaid, and 0.3% (n=1) studying.

Most studies used a purposive/convenience sampling approach, recruiting from various sites, including psychiatric inpatient (20%; n=120) (Bach & Hayes, 2002/Bach et al., 2012; Gaudiano & Herbert, 2006), community mental health services/outpatient clinics (38.1%; n=228) (Braehler et al., 2013; Langer et al., 2011; Shawyer et al., 2012; Van Dijk et al., 2013), and local community (15.8%; n=95) (Perich et al., 2013). Two studies (33.9%; n=203) attempted to recruit representative samples from the wider population by randomly selecting from all eligible participants in the area (Chien & Lee, 2013; Chien & Thompson, 2014). One study (White et al., 2011) did not provide exact figures, but recruited its sample (n=27; 4.5%) from various sites (community mental health teams, early intervention services for psychosis, a medium-secure forensic service, and psychiatric rehabilitation services). One study (Chadwick et al, 2009; n=22; 3.6%) did not specify recruitment site. Seven studies included a flow-chart of the recruitment process and participant flow (Braehler et al., 2012; Chadwick et al, 2009; Chien & Thompson, 2014; Gaudiano & Herbert, 2006; Perich et al., 2013; Shawyer et al., 2012; White et al., 2011). Attrition rate was reported by all eleven studies, with eight providing further explanations for attrition (Bach & Hayes, 2002/Bach et al., 2012; Braehler et al., 2012; Chadwick et al, 2009; Chien & Thompson, 2014; Gaudiano & Herbert, 2006; Langer et al., 2011; Perich et al., 2013; Shawyer et al., 2012). Only one study compared the characteristics of the participants who defaulted from treatment (White et al., 2011).

Table 1: Study Characteristics

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
Bach & Hayes (2002) *Bach et al (2012)*	Inpatients (80) with schizophrenia/ psychosis diagnosis, experiencing positive symptoms - North American *(n=51 of original n=80 available for 1 year FU)*	39.35	63.75	ACT + TAU (40/35) (individual) *n=36 remained*	TAU (40/35)	12.5 /12.5	4 - 45-50 min each	4 *12*	Hospitalisation rate; Self-rating of psychotic symptoms (frequency, distress and believability of symptoms)	ACT group had significantly lower rate of rehospitalisation at 4 month follow-up and showed significantly higher symptom reporting and lower symptom believability when compared to TAU. *Participation in ACT was significantly associated with reduced rehospitalisation at 1 year post discharge after controlling for length of previous and current hospitalization.*
Braehler et al. (2012)	Outpatients (40) with schizophrenia-spectrum disorder diagnoses - British (Scottish)	41.76	55	CFT+TAU (22/18) (group)	TAU (18/17)	12.5 / 18	16 (average of 12 attended) - 2 hrs each	N/A	Narrative Recovery Style Scale (NRSS); Clinical Global Impression-Improvement Scale (CGI-I); Personal Beliefs about Illness Questionnaire (PBIQ-R); Fear of Recurrence Scale	CFT was associated with significantly greater observed clinical improvement and significant increases in compassion. Increases in compassion were significantly associated with reductions in depression and in perceived social marginalization.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
									(FoRSe); Positive and Negative Affect Scale (PANAS); BDI-II	
Chadwick et al. (2009)	Outpatients (22) with schizophrenia diagnosis, experiencing distressing psychotic experiences (voices or delusions) - British	41.6	Missing	MT (11/9) (group)	WL (11/9)	14 / 18	10 sessions (average of 6 attended) - length of session not stated + 5 weeks of home Practice (not formally assessed)	N/A	Clinical Outcomes in Routine Evaluation (CORE) Southampton Mindfulness Questionnaire (SMQ), Southampton Mindfulness Voices Questionnaire (SMVQ) Psychiatric Symptom Rating Scale (PSYRATS) Beliefs about Voices Questionnaire revised (BAVQ-r)	Participants in the mindfulness group showed significant improvement in clinical functioning and mindfulness of distressing thoughts and images post-intervention, however, no change was observed in psychotic symptoms and beliefs about voices. Effects not significant at group comparison level.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
Chien & Lee (2013)	Outpatients (96) with schizophrenia diagnosis - Chinese	25.8	55	MBPP + TAU (48/45) (group)	TAU (48/45)	6 / 6	12 sessions - 2 hrs each	18	Brief Psychiatric Rating Scale (BPRS) Specific Level of Functioning Scale (SLOF) Social Support Questionnaire (SSQ-6) Insight and Treatment Attitudes Questionnaire (ITAQ) Rehospitalisation	Attendance of MBPP was associated with significant change in symptom severity, illness insight, and length of rehospitalisation at post intervention, while functioning and number of rehospitalisation improved significantly only at the 18- month follow-up.
Chien & Thompson (2014)	Outpatients (107) with schizophrenia diagnosis - Chinese	25.8	57	MBPP (36) (group)	CP (36) Usual Care (35)	4 / 5.5	12 fortnightly 2-hour sessions	24	Brief Psychiatric Rating Scale (BPRS) Specific Levels of Functioning Scale (SLOF) 6-item Social Support Questionnaire (SSQ6) Insight and Treatment Attitudes Questionnaire (ITAQ).	MBPP group showed significantly greater improvement in Insight and Treatment Attitudes, Specific Levels of Functioning, Brief Psychiatric Rating Scale, and duration of hospital readmissions. No significant effects were noted for Social Support and frequency of readmission. In original trial protocol published on ClinicalTrials.Gov frequency of readmissions was specified as the primary outcome of the study. This was not reported in the published manuscript.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
									Frequency and duration of readmissions to psychiatric hospital over the previous 6 or 12 months at Times 1–4 were collected from clinic records.	
Gaudiano & Herbert (2006)	Inpatients (40) with psychotic disorder or affective disorder with psychotic symptoms - North-American, predominantly African-American (88%)	40	64	ACT+ETAU (19/14) (individual)	ETAU (21/15)	27.5 / 26	5 sessions (average of 3 attended) - 1 hr each	4 (ONLY for rehospitalisation)	Brief Psychiatric Rating Scale (BPRS) Clinical Global Impression-Improvement Scale (CGI-S) Self-ratings of psychotic symptoms (frequency, distress and believability of symptoms) Sheehan Disability Scale (SDS) Rehospitalisation	Positive changes in affective severity, global improvement, distress associated with hallucinations, social functioning, and overall clinically significant symptom improvement was observed in the ACT group at discharge. Frequency or severity of psychotic symptoms was not affected. Rehospitalisation rate was in favour of ACT (38% reduction), but not significant. There was some indication that change in believability of hallucination in ACT was related to changes in distress.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
Langer et al. (2011)	Outpatients (?) (23) with diagnosis of schizophrenia spectrum disorders - Spanish	34.3	Missing	MBCT (11/7) (group)	WL (12/11)	17 / 36	8 sessions (average attendance not stated) - 1 hr	N/A	Clinical Global Impression-Schizophrenia Scale (CGI-SCH); Acceptance and Action Scale (AAQ II); Southampton Mindfulness Questionnaire (SMQ)	No significant effects were observed in any measure between the groups, except in mindfulness response to stressful thoughts and images within the MBCT group.
Perich et al. (2013)	Outpatients (95) with diagnosis of bipolar disorder (I, II or NOS) - Australian	Missing	34.7	MBCT +TAU (n=48/34) (group)	TAU (n=47/25)	37% / 29%	8 sessions (average of 7 session attended)	3, 6, 9 and 12	Young Mania Rating Scale (YMRS) Montgomery-A˚sberg Depression Rating Scale (MADRS) Composite International Diagnostic Interview (CIDI) Depression Anxiety Stress Scales (DASS) State/Trait Anxiety Inventory (STAI) Dysfunctional	MBCT did not reduce time to recurrence of depressive or hypo/manic episodes over a 12-month follow-up period, nor was it associated with a reduction in mood symptom severity scores. However, MBCT was associated with a reduction in state and trait anxiety and levels of stress, indicating benefits to bipolar disorder patients with comorbid anxiety.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
									Attitudes Scale 24 (DAS-24) Response Style Questionnaire (RSQ) Mindful Attention Awareness Scale (MAAS)	
Shawyer et al (2012)	Outpatients (?) (43) with schizophrenia-spectrum disorders - Australian	39	56	ABCBT (21/19/16) (individual)	Befriending (22/19/17)	23/ 23.8	15 sessions (average of 12 attended) - 50 min each	6	Positive and Negative Syndrome Scale (PANSS) Selected items of Psychotic Symptom Rating Scales (Auditory Hallucinations) (PSYRATS) Modified Global Assessment of Functioning scale (Modified GAF) Quality of Life Enjoyment and Satisfaction Questionnaire Voices	No differences found between groups regarding confidence to resist harmful commands or in ability to cope with them. However, a significant limitation of the stud: only 41% of sample reported compliance to harmful command hallucinations at baseline. No significant differences observed between the groups in any of the outcomes (i.e. changes in illness severity, better functioning, reduction in distress, or improvement of quality of life). No significant therapy-specific differences observed between the groups. Within-group analyses indicated significant improvements on positive and negative symptomatology, acceptance of auditory hallucinations, and significant improvement in

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
									Acceptance and Action Scale (VAAS) Subscales of the Voices Questionnaire-Revised (BAVQ-R) commands Insight Scale Recovery Style Questionnaire (RSQ)	global functioning in treatment group, while control group showed significant improvements in acceptance of command hallucinations. Both groups showed improvements in disruption caused by positive symptoms and in quality of life.
Van Dijk et al. (2013)	Outpatients (?) (26) with bipolar I or II diagnosis - Canadian	43.2	25	BDG + TAU (13/12)	WL (13/12)	7 / 7	12 sessions (average attendance not stated) - 90 min each	N/A	Beck depression inventory II (BDI II) Mindfulness-based self-efficacy scale (MSES) Affective control scale (ACS)	Attenders of DBT group showed significant Improvements in affective control and mindfulness self-efficacy compared to waitlist control. There was also a trend towards reduction in depressive symptoms noted in the treatment group.
White et al. (2011)	Outpatients and inpatients (27) with diagnosis of psychosis-spectrum disorder - British	34	77.8	ACT + TAU (14) (individual)	TAU (13/10)	11% / 0%	10 sessions (average attended not reported) - 1 hour each	N/A	Hospital Anxiety and Depression Scale (HADS) Positive and Negative Syndrome Scale (PANSS) Acceptance and Action Questionnaire II	Participants in the ACT group had significantly fewer crisis contacts over 3 months trial period compared to TAU, and at post treatment showed significantly greater reduction in negative symptoms, fewer cases of depression and a significant increase in mindfulness skills. Changes in mindfulness skills correlated positively with changes in depression.

Study	**Type participants (n)**	**Age** (mean years)	**Gender** (male %)	**Treatment group** (n = total/after attrition)	**Comparison group(s)** (n = total/after attrition)	**Attrition** (Total % / treatment group %)	**Number of sessions**	**Follow-up** (months)	**Outcome measures**	**Results**
									(AAQ II) Kentucky Inventory of Mindfulness Skills (KIMS) Working Alliance Inventory (Short Form Revised; WAI-SR)	

ACT = Acceptance and Commitment Therapy; ABCT = Acceptance-based cognitive-behavioural therapy; BDG = Dialectical Behaviour therapy-based psychoeducational group; CFT = Compassion-focused therapy; CP = conventional psychoeducation programme; ETAU = enhanced treatment as usual; MBCT = Mindfulness-based cognitive therapy; MBPP = Mindfulness-based psychoeducation programme; MT = Mindfulness training; TAU = treatment as usual; WL = Waiting list.

Five of the included studies were feasibility trials (Braehler et al., 2012; Chadwick et al, 2009; Chien & Lee, 2013; Gaudiano & Herbert, 2006; Langer et al., 2011), three were pilot studies (Bach & Hayes, 2002; Van Dijk et al., 2013; White et al., 2011) and three were full scale trials (Chien & Thompson, 2014; Perich et al, 2013; Shawyer et al., 2012). Six studies (Bach & Hayes, 2002/ Bach et al., 2012; Chien & Lee, 2013; Chien & Thompson, 2014; Gaudiano & Herbert, 2006; Perich et al., 2013; Shawyer et al., 2012) used a follow-up design (between 4 to 24 months), while five did not. Four studies explored the use of an acceptance-based therapeutic approach (Bach & Hayes, 2002/Bach et al., 2012; Gaudiano & Herbert, 2006; Shawyer et al., 2012; White et al., 2011), five studies that of a mindfulness-based approach (Chadwick et al, 2009; Chien & Lee, 2013; Chien & Thompson, 2014; Langer et al., 2011; Perich et al., 2013), one study that of a compassion-focused approach (Braehler et al., 2012) and one study looked at a dialectical behaviour therapeutic intervention (Van Dijk et al., 2013). Seven of the interventions were delivered in group format (Braehler, et al., 2013; Chadwick, et al., 2009; Chien & Lee, 2013; Chien & Thompson, 2014; Langer et al., 2011; Perich et al., 2013; Van Dijk et al., 2013), while four consisted of individual one-to-one sessions (Bach & Hayes, 2002; Gaudiano & Herbert, 2006; Shawyer et al., 2012; White et al., 2011).

Dimensions of outcome

The impact of the mindfulness-based approaches on outcomes for people with psychosis-spectrum disorders was investigated based on areas of outcomes explored in the included studies (General clinical improvement, Psychiatric symptom changes, Rehospitalisation/crisis contacts, Depression and Anxiety, Social functioning and Quality of life, Positive and Negative Affect, Processes and mechanisms of change).

General clinical improvement

Measures of general clinical improvement were used by three studies (Braehler et al., 2012; Chadwick et al., 2009; Gaudiano & Herbert, 2006) to assess the impact of the treatment condition. Two studies used the *Clinical Global Impression-Improvement Scale (CGI-I)* (Braehler et al., 2012; Gaudiano & Herbert; 2006) for this purpose. Braehler et al. (2012) found a significant change in terms of

general clinical improvement in favour of the CFT treatment group, with 65% of the participants being rated as having improved compared to TAU (5%) at post-intervention ($p< 0.001$, $r=-0.68$). Gaudiano & Herbert (2006) however did not find a significant group difference in people with schizophrenia when considering pre and post mindfulness intervention scores versus waitlist. In Chadwick et al.'s (2009) study, scores on the *Clinical Outcomes in Routine Evaluation (CORE)* indicated significant improvement in clinical functioning in people with schizophrenia when considering pre and post mindfulness intervention scores ($p<.013$), however, no significant group effect was found when comparing to waitlist control.

Psychiatric symptom changes

Changes in general psychiatric symptom severity was considered as an outcome by four studies, comparing treatment conditions to controls. Three of these studies (Chien & Lee, 2013; Chien & Thompson, 2014; Gaudiano & Herbert, 2006) used the *Brief Psychiatric Rating Scale (BPRS).* Chien & Lee's (2013) study indicated a significant improvement of general psychiatric symptom severity for people with schizophrenia receiving Mindfulness-based psychoeducation program (MBPP), found at post-treatment as well as at 18-month follow-up. Chien & Thompson (2014) found an effect in favour of MBPP over Conventional psychoeducation programme (CPEP) and Usual care ($F=4.36$, $P = 0.005$). The BPRS score of the MBPP group increased more significantly from Times 1 to 4 (MBPP v. CPEP group, mean differences were 4.1, 6.7 and 11.1 (s.e.=0.9–3.0) and MBPP v. usual care group, mean differences were 6.1, 13.9 and 18.8 (s.e.=1.9–4.5) at Times 2–4, respectively). Gaudiano & Herbert (2006) did not find a significant difference on the BPRS total score between groups attending the ACT intervention or receiving ETAU only.

A number of studies considered change in psychiatric symptoms more specific to psychotic symptom severity. One study (Langer et al., 2011), using the *Clinical Global Impression-Schizophrenia Scale (CGI-SCH),* did not find significant differences between MBCT group and waitlist controls. Two studies used the *Positive and Negative Syndrome Scale (PANSS)* (Shawyer et al., 2012; White et al., 2011). While Shawyer et al (2012) did not find any significant group differences in PANSS scores between Acceptance-based cognitive therapy (ABCT) and

Befriending in people with schizophrenia-spectrum disorders, within-group analyses indicated significant improvements of PANSS total scores at post-treatment and at 6 months follow-up in favour of the treatment group. In White et al.'s (2011) study, there was no significant difference between the groups with regards to positive symptoms at the end of treatment, but a significant reduction in negative symptoms was found in the ACT attenders ($t=-2.36$, $df = 19$, $p < 0.05$). Three studies specifically considered changes in positive psychotic symptoms (Chadwick et al., 2009; Gaudiano & Herbert, 2006; Shawyer et al., 2012). *The Psychotic Symptom Rating Scales (PSYRATS)* were used by two studies for this purpose (Chadwick et al., 2009; Shawyer et al., 2012). Attendance of Mindfulness training did not result in significant improvements of positive symptoms at the end of treatment in Chadwick et al's (2009) study when compared to waitlist controls and when within-group changes were considered. Shawyer et al. (2012) used the auditory hallucination subscales of the PSYRATS only and also did not find significant group differences between ABCT and Befriending group. Both of these studies also used the *Beliefs about voices questionnaire revised (BAVQ-R)*, but neither found a significant change in psychotic symptoms and beliefs about voices after Mindfulness training or ABCT when comparing to controls. Two studies (Bach & Hayes, 2002; Gaudiano & Herbert, 2006) used *Self-ratings* of psychotic symptoms to evaluate change in frequency of positive symptoms, change in distress related to and believability of them over time. In Bach & Hayes (2002), symptom reporting was higher in ACT participants ($p < .016$) at 4 months follow up, but believability of symptoms decreased significantly compared to controls, $F(1,29) = 4.36$, $p = .05$. Distress related to symptoms also decreased however this was not significant when compared to TAU. In Gaudiano & Herbert (2006), significant improvement of distress related to symptoms was found in people attending individual ACT sessions compared to ETAU participants ($F1;26 = 4:62$, $p<0.05$), however hallucination frequency or believability were not affected significantly in this group. Within the ACT attenders a significant main time effect of decrease in believability of hallucinations was found ($F1; 13 = 5:56$, $p<0.05$) and further analysis indicated that change in hallucination believability was an independent predictor of change in distress after controlling for change in frequency. Perich et al (2013) investigating the impact of MBCT on severity and time to recurrence of bipolar symptoms used the *Young Mania Rating*

Scale (YMRS) over various time-points to assess changes specific to hypo/manic episodes. No significant difference between MBCT and TAU conditions was found with regards to severity or recurrence of manic symptoms.

Rehospitalisation/crisis contacts

Four studies considered rehospitalisation as an outcome when measuring impact of mindfulness-based interventions (Bach & Hayes 2002/Bach et al 2012; Chien & Lee 2013; Chien & Thompson, 2014; Gaudiano & Herbert, 2006), while one study looked at number of crisis contacts during treatment (White et al (2011). In Bach & Hayes (2002), ACT participants had a significantly lower rate of rehospitalisation during 4 months follow-up compared to TAU (Wilcoxon's statistic: (1, N = 70) = 4.26 $p < .05$), and remained out of hospital significantly longer than TAU ($F(1,60) = 4.74$, $p= .03$). This benefit was maintained at 12 months (Bach et al., 2012). Chien & Lee (2013) also found a significant change with regards to number ($p<.01$) and duration ($p<.001$) of hospitalisation, however this was only apparent at 18 months follow-up. Chien & Thompson (2014) did not find an effect on number of readmissions for MBPP compared to conventional psychoeducation programme (CPEP) and usual care. However, MBPP was associated with reduced duration of admissions. The duration of readmissions to hospital in the MBPP group were significantly reduced from Times 1 to 4 ($F=4.8$, $p = 0.004$), (MBPP v. CPEP group, mean differences (days) were 0.5, 3.5 and 5.1 (s.e. = 0.2–1.8) and MBPP v. usual care group, mean differences were 4.1, 7.2 and 10.0 (s.e.=1.2–4.9) at Times 2–4, respectively). In Gaudiano & Herbert (2006) rehospitalisation rates were lower in the ACT group at 4 months follow-up (28% of ACT compared to 45% of ETAU), however this was not significant. White et al (2011) compared number of crisis contacts of participants receiving ACT or TAU and found that the ACT group had significantly lower number of crisis contacts for the duration of treatment ($Z = -2.24$, $p < 0.05$).

Depression and Anxiety

Levels of depressive symptoms were considered as a primary outcome by three studies (Van Dijk et al., 2013; Perich et al., 2013; White et al., 2011). The *Beck Depression Inventory II (BDI II)* was used by Van Dijk et al. (2013) as an outcome

measure, with the results indicating a significant reduction in depression severity between DBT-group participants with bipolar disorder and waitlist controls (χ^2 = 6.75, p = .0009). However, when baseline differences in depression were controlled for significance dissipated, though a trend in favour of the treatment group remained. Perich et al (2013) did not find a significant difference between participants with bipolar disorder attending either a MBCT group or receiving TAU with regards to levels of depression, anxiety, and stress as measured by the *Depression Anxiety Stress Scales (DASS)* at post-treatment and at up to 12 months follow up. However a trend was noted on the stress subscale for treatment by time in favour of MBCT group (F = 1.864, P = 0.088). This study also used the *Dysfunctional Attitudes Scale 24 (DAS-24)* and the *Response Style Questionnaire (RSQ)*. MBCT participants showed a significant improvement over time on the achievement subscale of the DAS-24 (F = 2.534, p = 0.03), but not on the other subscales, while response style was not affected significantly, as assessed by comparing scores on the RSQ. In addition, Perich et al (2013) were interested in investigating the impact of MBCT on severity and time to recurrence of depression as part of bipolar disorder. Consideration of scores on *Montgomery-A˚sberg Depression Rating Scale (MADRS)* over various time-points did not identify a significant difference between MBCT and TAU with regards to time to recurrence or number of recurrent depressive episodes. One study (White et al., 2011) used the *Hospital Anxiety and Depression Scale (HADS)* but did not find significant differences between people with psychosis-spectrum disorders attending individual ACT sessions or receiving TAU with regards to changes in symptoms of either depression or anxiety at post-treatment. There was however a trend towards significance for depression with (t= -2.09, df = 19, p = 0.051) in favour of the ACT group. Post-hoc analyses compared caseness of depression and anxiety pre and post-intervention and found that a significantly smaller number of individuals in the ACT group met caseness for depression post treatment (from 8 to 2 individuals) compared to TAU (likelihood ratio χ^2=5.00, p <0.05). There was no significant difference in change in caseness for anxiety in any group.

Impact of treatment on anxiety symptoms was specifically explored by Perich et al. (2013) who used the anxiety section on the *Composite International Diagnostic Interview (CIDI)* to measure the presence of an anxiety disorder at baseline and at 12

months. No significant difference was found in people with bipolar disorders attending MBCT or receiving TAU with regards to whether or not diagnostic criteria for an anxiety disorder were met. Scores on the *State/Trait Anxiety Inventory (STAI)* however pointed towards a significant reduction in state anxiety over time in people receiving MBCT when the groups were compared.

Social functioning and Quality of life

Change in general functioning and/or quality of life following intervention were explored by four studies (Chien & Lee, 2013; Chien & Thompson, 2014; Gaudiano & Herbert; 2006; Shawyer et al., 2012). Chien & Lee (2013) and Chien & Thompson (2014) used the *Specific Level of Functioning Scale (SLOF)* and the *Social Support Questionnaire (SSQ-6).* In Chien & Lee (2013) scores on the SLOF indicated a significant change following MBPP with regards to general functioning apparent at 18 months follow-up, but there were no significant group differences with regards to levels of social support available (SSQ-6). Chien & Thompson (2014) found that MBPP was associated with improved functioning (F=4.98. p=0.004) but not social support. Specifically, the MBPP group increased more significantly from Times 1 to 4 (MBPP v. CPEP group, mean differences were 12.0, 22.7 and 30.8 (s.e. = 3.0–4.9) and MBPP v. usual care group, mean differences were 26.2, 47.3 and 57.8 (s.e. = 4.8–7.6) at Times 2–4, respectively). Gaudiano & Herbert (2006), using the *Sheehan Disability Scale (SDS),* found significant differences on the social subscale (F1;26 =9.09, p<0.01) in favour of ACT, but there were no significant differences on work or family subscales. One study (Shawyer et al., 2012), using the *Modified Global Assessment of Functioning scale (Modified GAF),* found significant improvements of general functioning in people with schizophrenia-spectrum disorders following ACT at 6 months follow-up (p<.05). However, between-group scores on the *Quality of Life Enjoyment and Satisfaction Questionnaire* (Feelings and General Activities subscales) were not significant.

Positive and Negative Affect

Two studies considered changes in affect as an outcome (Braehler et al., 2012; Van Dijk et al (2013). Braehler et al. (2013), using the *Positive and Negative Affect Scale (PANAS),* did not find any significant changes when comparing scores

on this measure between groups as well as within. Van Dijk et al (2013) were interested in the impact of DBT-based intervention on affective control in people with bipolar disorder using the *Affective control scale (ACS)*, but did not find a significant treatment effect in terms of affective control between DBT intervention group and waitlist controls. However, scores improved in both groups over time.

Processes and mechanisms of change

Mindfulness. Four studies specifically looked at changes in mindfulness in response to treatment (Chadwick et al., 2009; Perich et al., 2013; Van Dijk et al., 2013; White et al., 2011). Chadwick et al (2009) used the *Southampton Mindfulness Questionnaire (SMQ)* and found that attendance of the mindfulness group intervention led to significant improvement in mindfulness of distressing thoughts and images in people with schizophrenia having distressing psychotic experiences ($p<.037$), as assessed at endpoint. However, this was not significant at group comparison level. This study also used the *Southampton Mindfulness Voices Questionnaire (SMVQ).* Results on this measure were non-significant, both at group and group comparison level. Attendance at MBCT group intervention in Perich et al. (2013) did not result in significant changes in trait mindfulness as assessed by the *Mindful Attention Awareness Scale (MAAS).* In Van Dijk et al. (2013) comparison of total scores of the *Mindfulness-based self-efficacy scale (MSES)* did not show significant differences between people in the DBT-based psychoeducation group or waitlist group with regards to improved perception of mindfulness self-efficacy. However, total scores increased more for the intervention group (interaction x group $F=9.41$, $p=.006$), particularly in the subscales of Interpersonal, Avoidance and Mindfulness. White et al (2011) used the *Kentucky Inventory of Mindfulness Skills (KIMS)* to explore therapy-specific changes and associations between change scores in general outcome and therapy-specific effects and found a significant difference in scores between people attending ACT and receiving TAU ($t= 2.66$, $df =21$, $p <0.05$). Results also showed significant relationships between the depression subscale of the HADS and change scores for the KIMS Total score ($r=-0.66$, $p <0.05$), andKIMS subscales of Describing ($r=-0.70$, $p <0.05$) and Acting with awareness ($r=-0.72$, $p <0.01$).

Compassion. One study (Braehler et al., 2012) investigated therapeutic changes specific to CFT in terms of its impact on compassion and avoidance using the *Narrative Recovery Style Scale (NRSS).* They also explored associations between those constructs and a number of clinical outcomes post-intervention by considering scores on the NRSS and BDI II, *Personal Beliefs about Illness Questionnaire (PBIQ-R),* and *Fear of Recurrence Scale (FoRSe).* Overall, CFT participants showed significantly more compassion in their narratives compared with TAU participants ($U = 75$, $Z = -2.43$, $p = 0.015$, $r = -0.42$), with a significant increase in compassion ($r = 0.59$; $Z = -2.36$, $p = 0.02$). Reduction in avoidance was moderate ($r = 0.41$) but not significant. In the CFT group, an increase in compassion was significantly associated with reductions in BDI depression ($r = -0.77$; $p = 0.001$), PBIQ entrapment ($r = 0.56$; $p = 0.031$), PBIQ shame ($r = 0.57$; $p = 0.027$), PBIQ social marginalization ($r = 0.74$; $p = 0.002$), FoRSe intrusive thoughts ($r = 0.58$; $p = 0.022$), and FoRSe fear of relapse ($r = 0.52$; $p = 0.045$).

Psychological flexibility. Two studies used the *Acceptance and Action Questionnaire II (AAQ II)* to compare changes in psychological flexibility between treatment groups (White et al., 2011; Langer et al., 2011). Neither of these studies found a significant difference between the groups with regards to acceptance and experiential avoidance. Shawyer et al (2012) used the *Voices Acceptance and Action Scale (VAAS)* to assess change in acceptance-based attitudes and actions associated with auditory hallucinations but no significant differences between groups were found. They also explored the impact of ABCT with regards to level of involvement with auditory command hallucinations and beliefs about the omnipotence of voices as measured by subscales on the SHER and BAVQ-R. No significant differences between the groups were found. The same was true for changes in recovery style as assessed by *Recovery Style Questionnaire (RSQ)*.

Insight. Given that core components of mindfulness-based approaches are to increase awareness and develop cognitive flexibility to enhance recovery, increase of illness awareness (i.e. illness insight) could be seen as an outcome associated with intervention process changes. It is therefore summarized under this heading. Three studies looked at changes in illness insight (Chien & Lee 2013; Chien & Thompson, 2014; Shawyer et al., 2012). Chien & Lee (2013) and Chien & Thompson (2014) both used the *Insight and Treatment Attitudes Questionnaire (ITAQ).* Chien & Lee

(2013) found a significant change in terms of insight in people with schizophrenia at post-treatment compared to TAU ($p<.001$). Chien & Thompson (2014) also found an overall effect in favour of MBPP ($F=6.52$, $p = 0.001$).The ITAQ score of the MBPP group increased more significantly from Times 1 to 4 than in the other two groups (MBPP v. CP group, mean differences were 0.7, 3.0 and 5.0 (s.e. = 0.3–1.9) and MBPP v. usual care group, mean differences were 1.7, 4.9 and 6.5 (s.e. = 0.6–2.4) at Times 2–4, respectively). Shawyer et al (2012) however did not find any significant difference between people attending ACT or Befriending with regards to insight, using an *Insight Scale*, however, insight appeared to improve significantly for the experimental group following ACT ($p<.05$ for experimental group).

Risk of bias in included studies

A risk of bias assessment was undertaken for all included trials. Table 2 provides an overview of the reviewers' judgements about each risk of bias item for each included study. Appendix 1.5 provides an overview of how the judgements were reached.

Table 2 - illustrating author's judgements about each risk of bias item for each included study

Allocation

All studies reported random assignment of participants to treatment conditions. However, only five studies (Braehler et al., 2013; Chien & Thompson, 2014; Perich et al., 2013; Shawyer et al., 2012; White et al., 2011) provided details of the process used for this purpose and were rated as low risk of bias. The remaining six studies were judged to have unclear risk of bias due to insufficient description of the randomization process. With regards to allocation concealment, only five studies had a low risk of bias (Chien & Thompson, 2014; Perich et al., 2013; Shawyer et al., 2012; Van Dijk, 2013; White et al., 2011), while the risk was unclear in five studies, failing to provide sufficient information. One study (Gaudiano & Herbert, 2006) was rated to have high risk of selection bias as allocation was not concealed.

Blinding

None of the studies were double-blind due to the nature of these trials. While double-blinding is generally an important way to prevent bias, this, by default, is not possible in trials assessing the effectiveness of psychological therapeutic interventions such as the studies included in this review. It was therefore decided to rate all of the studies as having low risk of bias with regards to the performance bias criteria due to lack of relevance of this to the studies under review. Two studies were rated low risk with regards to detection bias as they went through considerable efforts to blind outcome assessors, formally assessed effectiveness of blinding and made attempts to rectify any breaches (Shawyer et al., 2012; White et al., 2011). Seven studies were rated as having unclear risk of detection bias, with two studies not providing any information about blinding of outcome assessors, while the remaining four described that process but did not give indication of whether the effectiveness of blinding attempts was assessed, nor how breaches were managed. The remaining two studies (Bach & Hayes, 2002/Bach et al., 2012; Gaudiano & Herbert, 2006) were judged to have high risk of detection bias as outcome assessors were not blind to allocation.

Incomplete outcome data

Seven studies had a low rate of attrition and were therefore deemed to have low risk of bias with regards to completeness of outcome data. However, two of these (Chien & Lee, 2013; White et al., 2011) failed to provide reasons for drop-outs. One study had an unclear risk of attrition bias (Van Dijk et al., 2012) as no information was provided, while the remaining three studies were rated as having high risk of bias in this area due to high attrition rates (>30%) (Braehler et al., 2012; Langer et al., 2011; Perich et al., 2013).

Selective reporting

Risk of reporting bias was deemed low for five studies as no selective reporting apparent (Braehler et al., 2012; Perich et al., 2013; Shawyer et al., 2012; Van Dijk et al., 2013; White et al., 2011). Three studies were judged to have unclear risk of bias with regards to selective reporting. Two of these failed to provide sufficient detail with regards to explaining some of the reported results (Chadwick et al., 2009; Chien & Lee, 2013), while one study's (Chien & Thompson, 2014) reporting of the results deviated from the description on the registered trial protocol. The remaining three studies (Bach & Hayes, 2002/Bach et al., 2012; Gaudiano & Herbert, 2006; Langer et al., 2011) omitted reporting of some of their outcomes or reported the results of post-hoc analyses selectively. These studies were therefore judged to have high risk of reporting bias.

Other potential sources of bias

Three of the studies (Chien & Thompson, 2014; Perich et al., 2013; Shawyer et al., 2012) were judged to have low risk of bias with regards to other potential sources. The remaining eight studies were rated as high risk of bias due to small sample size, significant group differences at baseline, lack of clarity regarding sample selection/issues of pre-selection, variation of amount of treatment received, speculative interpretations of mechanism underlying results or lack of controlling for other variables (e.g. past treatment history or ongoing psychotherapy).

Assessment of protocol registers

Four studies had registered their trial post-study on trial registers (Chien & Thompson, 2014; Perich et al., 2013; Shawyer et al., 2012; White et al., 2011). Two

of these deviated from their originally registered protocol on some aspects. In one study (White et al., 2011) there was a change in terms of exclusion criteria between protocol and published report, while in the other sample size was smaller than the one originally aimed for (Perich et al., 2013). Neither of these deviations was deemed as significantly introducing bias impacting on outcome of trials.

Overall risk

Based on the above assessment, the majority of studies were judged to have a high risk of bias overall. Only three studies were deemed low risk of bias (Chien & Thompson, 2014; Shawyer et al., 2012; White et al., 2011).

DISCUSSION

Summary

The aim of this review was to identify, summarize and appraise RCTs of mindfulness-based therapeutic approaches in the treatment of psychosis-spectrum disorders in order to further understanding of the existing evidence-base of these approaches for use with this population, building on previous reviews (e.g. Khoury et al., 2013). Khoury et al.'s (2013) meta-analysis indicated a moderate effectiveness of mindfulness-based interventions in treating negative symptoms and suggested their use combined with pharmaceutical treatment. However, the review included uncontrolled and non-randomized studies and did not undertake a rigorous assessment of risk of bias of the included studies. The current review aimed to address these limitations by including RCTs only and assessing risk of bias more rigorously by using the Cochrane risk of bias tool (Higgins et al., 2011a). The current review identified 11 studies (based on 12 manuscripts) in an extensive literature search, comprising a total sample of 599 inpatients and outpatients with psychosis-spectrum disorders. Similar to Khoury et al.'s (2013) review, there was considerable heterogeneity between the included studies with regards to areas such as type and format of mindfulness-based approach used (e.g. group or individual) and length of intervention (ranging between 4 to 16 sessions), as well as significant variation in terms of assessed outcome/type of outcome measures used and quality of

included studies. In light of this, it was felt more meaningful to examine the studies individually and then synthesise their findings in descriptive format as opposed to combining them by use of statistical method. As such, overall conclusions on the basis of combined results could not be made. Individual studies found some significant results and positive trends in favour of the treatment conditions compared to controls, suggesting potential benefits of mindfulness-based interventions with regards to e.g. reduction and duration of rehospitalisation, change in general symptom severity and functioning, trends towards reduction in depressive symptomatology and some links between increased compassion and/or psychological flexibility and reduced depression. However, the majority of results of between-group comparisons were non-significant. More importantly, risk of bias within individual studies was high. Only three studies were judged low in terms of risk of bias, while the rest were deemed to have an overall high risk of bias. For the majority of these studies issues of bias particularly relevant to the overall validity of estimated treatment effect were identified in the areas of detection bias (blinding outcome assessors) and other sources of bias (mainly small sample size, interpretation of results, group differences at baseline, and unclear pre-selection processes). As such, it is difficult to make concrete judgements about the effectiveness or draw clear conclusions with regards to benefits of mindfulness-based approaches for people with psychotic-spectrum disorders based on these studies. It is of note that studies with low risk of bias did not find significantly greater treatment effects. In fact, two of the three studies with an overall low risk of bias did not yield significant results, while the third one was moderate in their treatment effectiveness. However, it needs to be considered that the majority of the included studies were either feasibility or pilot studies and as such sample sizes were small. It may be that treatment effects would have been more significant with larger samples.

Limitations

This review has a number of limitations. Firstly, it did not include unpublished studies (grey literature) as such the possibility of publication bias may have to be considered. However, given that the current review did not allow for overall conclusions about treatment effectiveness this may not be as significant. Furthermore, judgement of risk of bias of included studies was, in most cases, based

on the assessment of two reviewers. While this allowed for a degree of inter-rater reliability, it could be argued that more independent raters could have been consulted to reduce potential risk of reviewer bias. However, given time limitations this was difficult to achieve. As indicated, the included studies had a high level of heterogeneity. While this limited the scope for a more rigorous analysis, it reflects the current state of the literature in the field. Lastly, while the reviewer undertook an extensive search of the literature, there still may be studies that were missed.

Conclusions

As outlined above, the heterogeneity and particularly high risk of bias in RCTs assessing the use of mindfulness-based interventions in psychosis-spectrum disorders does not allow for concrete judgements about the effectiveness of these approaches. As such, the outcome of the current review does not indicate a superiority over or equality with other evidence-based treatments for psychosis-spectrum disorders, such as CBTp at this point in time. Recommendations regarding the routine use or incorporation of these treatments into best practice guidelines are therefore premature. However, given potential benefits indicated by the studies and the absence of adverse effects associated with their use with a psychosis population, they should be available as a choice to people with psychosis-spectrum disorders. Clearly, more rigorous studies, addressing important areas of bias such as using larger sample sizes and more consistency in the application and format of different mindfulness-based interventions are needed to build on the existing evidence-base and gain greater insight into the mechanisms underlying them.

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CHAPTER 2: MAJOR RESEARCH PROJECT

Constructing shared understanding - A grounded theory exploration of team case formulation from multiple perspectives

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TITLE

Constructing shared understanding - A grounded theory exploration of team case formulation from multiple perspectives

ABSTRACT

Objectives: The use of formulation in teams is becoming increasingly established. Yet, research into this area is still limited. This study set out to explore team formulation from multiple perspectives in the context of an early intervention first episode psychosis service.

Method: A social constructionist version of grounded theory was used to explore experiences of team formulation and care of fifteen participants (clinical psychologists, other multidisciplinary team members, and service-users), using semi-structured interviews. A phased approach to data collection and analysis facilitated theoretical sampling and triangulation. Transcripts were subjected to line-by-line and focused coding to support the development of categories grounded in the data.

Results: An emerging model of team formulation arose from the data, comprised of two levels - 'value and function' and 'processes' - that were interrelated and made up of sub-themes. 'Value and function' of team formulation ultimately was to improve engagement and care for service-users at risk of arrested recovery. This was seen to be facilitated by 'constructing understanding' and 'broadening perspectives', resulting in 'flexibility, consistency and empathy' that allowed for person-centred care planning and the establishment of better relationships with service-users. Team formulation involved and required staff to 'negotiate roles' and 'manage uncertainty'. The data indicated the importance of a system or space that promotes the development of mutuality of meaning and shared understanding.

Conclusions: This study indicated the systemic value of team formulation in supporting people who have difficulties engaging with services and staff working with them. The emerging model derived provides a meaningful departure point to develop a more comprehensive theory of team formulation that could provide a foundation for improving, developing and disseminating this practice.

Keywords: team formulation, recovery, psychosis, grounded theory

INTRODUCTION

Case formulation has been recognized as central to the implementation of psychological interventions since the emergence of the scientist-practitioner model in the 1960s (Butler, 1998). It is an approach increasingly valued by professionals within psychiatry, psychology, psychotherapy and counselling. Definitions of formulation can vary depending on professional background and therapeutic approach. It can be summarized as "[ ] a hypothesis about a person's difficulties, which draws from psychological theory" (Johnstone & Dallos, 2014, p. 5). The Division of Clinical Psychology (DCP) (2010, p. 5) describes it as "[ ] the summation and integration of the knowledge that is acquired by the assessment process that may involve psychological, biological and systemic factors and procedures". Integrating empirical evidence and theory, it constitutes a hypothesis about the causes, triggers and perpetuators influencing someone's psychological, interpersonal and behavioural problems (Eells, 2006b). It is proposed that the understanding derived may then facilitate a more tailored, individualized approach to care as opposed to a standardized one based on diagnostic categories (Aston, 2009). Furthermore, it may help predict potential barriers and challenges to intervention, for example by facilitating understanding of service-users' ability to build and maintain therapeutic alliances and engage with services (Sturmey, 2009). In practice, formulation is seen as an on-going process that arises from assessment and collaboration with service-users and teams (Johnstone & Dallos, 2014). Reflectiveness is important to ensure that the developing formulation is a meaningful account of service-user's difficulties (DCP, 2011). Various professional bodies have identified psychological case formulation as a core professional competency for clinical psychologists, e.g. Health Professions Council (HPC) (2009) and British Psychological Society (BPS) (2010).

Increasingly, formulation is used in multidisciplinary teams (MDT), both in the community and inpatient settings. Team formulation refers to the process of

constructing a shared understanding of an individual's difficulties and resources for effective change within a group or team (Johnstone & Dallos, 2014). It has been argued that it can lead to a more holistic and psychosocial understanding of a service-user by incorporating views and ideas from different disciplines, which may then facilitate a more consistent and person-centred approach to intervention promoting recovery (Onyett, 2007). Professional practice guidelines, e.g. Good Practice Guidelines on the use of psychological formulation (DCP, 2011) and Health & Care Professions Council criteria (HPC, 2009), recommend a formulation-based approach to be taken in teams, with clinical psychologists having an active role in promoting and facilitating this.

According to Johnstone (2014), important properties of team-based formulation include availability of specifically allocated time, presence and contributions of all MDT members, and space that allows the team to think freely and creatively, drawing on their own clinical experience, knowledge and intuition. It is seen to be a space in which members of staff are able to reflect on their struggles with a particular service-user and explore their emotional responses, including issues of transference and counter-transference. Team formulation may therefore be of particular value for teams working with people with complex needs whose interpersonal and relational style and response to care may be experienced as challenging by staff and at odds with attempts to support them in their recovery. For example, insecure attachment styles, particularly avoidant/dismissive type, have been found to be more common in people with psychosis, impacting on their ability to form relationships that allow them to express their needs and seek help effectively (Tait, Birchwood & Trower, 2004). Instead, they may engage in avoidant coping, such as 'sealing over', complicating their engagement with services, treatment and ultimately recovery. This can heighten staff levels of stress and frustration, which may impact on their response to the person, for example leading to more coercive treatments (Thornicroft et al., 2013). Therefore, team formulation may be invaluable to staff working with difficult to engage service-users, helping to make sense of behaviours and responses in order to better support them. For example, understanding an individual's attachment style and the implications of that with regards to forming relationships and help-seeking may allow teams to understand

their struggles better and become more flexible and person-centred in their response, hence prevent disengagement and better support recovery (Gumley et al., 2010).

Despite increasing emphasis placed on using formulation in teams the research evidence-base is still limited (Johnstone & Dallos, 2014). A small number of qualitative studies, service evaluations and audits have explored its use and indicate potential benefits as well as challenges related to team formulation. In a qualitative study, Summers (2006) interviewed twenty-five staff of different disciplines (including psychiatrists, nurses, support workers and therapists), working in a team providing care for people with severe mental illness on a ward of a high-dependency rehabilitation service. Staff viewed formulations as valuable to gain a better understanding of service-users, which was seen to lead to better care planning, staff-service-user relationships, staff satisfaction and team working. There was some dissatisfaction with a lack of translating the derived understanding into practice consistently. However, staff felt that they had become more tolerant and able to respond with patience and empathy towards service-users; a finding which was supported by Wainwright & Bergin (2010). In another qualitative study, Christofides et al. (2011) interviewed ten clinical psychologists working in an adult inpatient setting about their experiences of using formulation within MDT and found similar results. Clinical psychologists felt that shared formulation facilitated a broader and more consistent understanding of service-users in the team, and promoted reflectiveness in staff. Psychologists did however express some uncertainty with regards to clearly defining their role when supporting formulation more informally. In a follow-up study by Hood et al. (2013) non-psychology staff members equally expressed positive experiences of team formulation, valuing it for increasing their understanding of service-users and their behaviours. Non-psychologist MDT staff interviewed in Dexter-Smith et al. (2010) highlighted the value of team formulation with regards to combining perspectives from different professional backgrounds. In addition to benefits outlined above, this was felt to help emotional containment of staff working in stressful environments. Another evaluation indicated possible benefits with regards to reduction in staff sickness (Down, 2010). Consistently, time constraints were identified as a major barrier to implementing team formulation. An interesting finding in Summers (2006) related to differences in staff views about the nature of the derived understanding being ‘fact’

and therefore formulation leading to clear management solutions versus 'provisional hypotheses' with the formulation giving room to speculate and discuss ideas.

Overall, these studies offer valuable insight into staff experiences of using formulation within MDT, highlighting benefits and challenges. However, consistency is lacking between them in how team formulation was implemented, ranging from informal to formal methods. This makes it difficult to draw overall conclusions about the utility of team formulation more generally and to identify more general principles underlying this process. Furthermore, these studies explored team formulation from one particular point of view only, either that of staff more generally, or clinical psychologists more specifically. Yet, formulation is based on communication and interaction between different members of staff, service-users and, where relevant, family members/carers, developing dynamically within the discourse taking place between these individuals. It is therefore likely that the process of formulation may be experienced differently from different perspectives. Additionally, formulation is suggested to have the potential to improve service-users' experience of care, facilitating recovery. Exploring team formulation from only one perspective makes it difficult to fully grasp the complexity and benefits of this process overall, and to understand its value for the people involved in it individually. It appears that a comprehensive exploration of the process of team formulation requires the use of a methodological approach that actively promotes triangulation, thus allowing for the exploration of the perspectives of everyone involved in the process in a dynamic and flexible way.

Point of departure

As outlined above, service engagement and engagement with staff is central to recovery (Tait, Birchwood & Trower, 2004). Team formulation may be an important tool to facilitate that. The point of departure for the current study therefore was to explore experiences of team formulation in a team where this is a central part of routine clinical practice, particularly for service-users that have difficulties engaging with the service. Given the collaborative nature of team formulation, multiple perspectives including those of clinical psychologists, other mental health staff and service-users were explored. As clinical psychologists' take an active role in facilitating team formulation this was the most logical departure point. From there,

a stepped approach to qualitative enquiry was taken, allowing for the involvement of other staff members and service-users in a top-down, but dynamic and flexible fashion.

Service context

The study was set in the context of an early intervention (EI) first episode psychosis service in Glasgow. Working with this complex client group, team formulation is a firmly established routine practice as part of weekly MDT meetings within this service. As indicated above, insecure attachment style has been found to be more prevalent in this client group and has been linked to poorer outcome due to its impact on coping style (e.g. sealing over) and service engagement (Gumley et al., 2014). Service engagement here refers to level of adherence, collaboration and help-seeking, which has been found to be poorer in people with psychosis and insecure attachments (Tait, Birchwood & Trower, 2004). Bearing these developmental and interpersonal complexities in mind, the task of establishing and maintaining supportive and collaborative working relationships and providing appropriate biopsychosocially informed care to service-users can be challenging for staff working in this service. It may trigger feelings of professional ineffectiveness and frustrations that can make it difficult to maintain a compassionate stance. More importantly, failure to respond in a way that facilitates service engagement can significantly reduce the potential for recovery for service-users to whom this is challenging (Gumley et al., 2014). As such, the service has adopted the routine use of the Service engagement scale (SES) (Tait, Birchwood & Trower, 2002) in order to identify service-users at risk of arrested recovery. A high score on this scale prompts an additional reformulation meeting, aiming to increase the team's understanding of barriers to recovery for that individual and highlighting alternatives to responding.

METHOD

Grounded theory methodology

Grounded Theory (GT) is a qualitative method widely used. It may be defined as "the discovery of theory from data systematically obtained from social

research" (Glaser & Strauss, 1967, p. 2), a way to learn about the "worlds we study and a method for developing theories to understand them" (Charmaz, 2006). Given the subject of study, a social constructionist version of GT (Charmaz, 2006) was used. This version has its roots in 'social interactionism' (Mead, 1934), which assumes that the meanings people give to situations determine human behaviour. These meanings are influenced by history, culture and language, and actively constructed within social interactions, mediated by an interpretive process used by each person. Hence, meaning is to be viewed as a constructed process. As a result, GT arises from the interaction between researcher and participants – it is actively constructed, rather than representing an objective reality. In this way, reflexivity with regards to the researcher's and participants' interpretations is actively promoted and an integral part of making sense of the data. To increase methodological rigour, credibility and utility, criteria for improving the quality of qualitative research (e.g. data triangulation) have been considered in the design and implementation of the qualitative study (Guion, 2002; Golafshani, 2003; Walsh & Downe, 2006).

Participants

Participants were purposively sampled and included five clinical psychologists, four non-psychologist staff members, and six service-users. Eight of the participants were male and seven female, with age ranging from 24 – 54 (Table 1). Given the research approach, sample size did not need to be determined. Rather, data collection continued until sufficiency was deemed to be reached. All participants were recruited from an EI first episode psychosis service in Glasgow that comprises three teams. All of the staff members who had agreed to take part in the study participated in the interview. Of the nine service-users who agreed to take part, three did not. One experienced deterioration in mental state and was therefore unable to take part in the study, while the other two decided subsequently that they did not wish to participate, without stating reasons.

<u>Table 1:</u> Participant details

	Gender	Role
Participant 1	Male	Clinical psychologist
Participant 2	Female	Clinical psychologist
Participant 3	Male	Clinical psychologist
Participant 4	Male	Clinical psychologist
Participant 5	Female	Clinical psychologist
Participant 6	Female	Community psychiatric nurse
Participant 7	Female	Occupational therapist
Participant 8	Female	Support worker
Participant 9	Male	Community psychiatric nurse
Participant 10	Male	Service-user
Participant 11	Female	Service-user
Participant 12	Male	Service-user
Participant 13	Female	Service-user
Participant 14	Male	Service-user
Participant 15	Male	Service-user

Procedures

Recruitment of staff involved the introduction of the researcher and provision of brief information about the study to the MDT at a team meeting. This was followed by emailing or approaching staff in person, providing more detailed information about the study. They were given time to consider participation before being asked to take part. All of the service-user participants approached had been rated on the SES as having difficulties engaging with the service, hence being at risk of arrested recovery (as outlined above). They had already consented to participate in this qualitative evaluation as part of a wider CSO funded study of implementation of a novel Integrated Care Pathway for early psychosis (CZH/3/5, Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis), which had been granted ethical approval (11/AL/0247; Appendix 2.2). Prior to approaching these participants, it was checked that they were able to take part by seeking out the opinions of key staff members involved in their care. They were then contacted via telephone by a research assistant familiar to them and invited to take

part. Inclusion criteria required that all participants were involved with the EI service, and able to consent to and participate in the study. All participants gave informed consent (see Appendices 2.4 and 2.5), which also included the recording of interviews and possible publication of quotes, and the assurance of confidentiality, anonymity and voluntary participation.

Guided by the subject of interest and research method, a stepped approach to data collection was adopted, proceeding in three stages (Figure 1). As such recruitment was undertaken in three phases.

Sensitivity to context

Commonly in GT, literature review is undertaken after analysis is formed. Despite awareness of the debate regarding this (as outlined by Charmaz, 2003), relevant literature on team formulation was reviewed before commencing data collection. This was required by the research proposal form needed for a clinical psychology doctorate course. This review was seen as sensitizing the researcher to gaps in knowledge (Hutchison, 1993). However, aware of the importance of approaching the research area without preconceptions or pre-formed ideas, reviewed literature did not form the basis of emerging theory, but served as a guide for initial sampling, procedure and developing initial interview questions. Open discourse was encouraged during the initial interviews to gain insight into participants experiences with formulation and care. A stepped approach of data collection ensured that interview questions remained flexible while being adapted to evolving theoretical understanding. For example, based on emerging themes following the first phase of interviewing the researcher reflected on the socially constructed nature of MDT formulation and the dominance of particular staff 'voices' due to hierarchical order which led to theoretical sampling of non-senior staff members in phase two to allow 'quieter' staff voices to be heard. Interview schedules for each phase were informed by analysis of data collected in the phase preceding it (Appendix 2.6).

Furthermore, to stay sensitive to context, the project was supported and actively guided by the existing Principal Investigators Steering Group, made up of senior staff members representing all teams in the service, comprising psychiatrists, psychologists and nurse team leaders. This group is responsible for oversight and management of the wider CSO funded study (see above) and has been granted

managerial approval. They provided advice and feedback (e.g. development of semi-structured interview schedules). Liaising with them was hoped to ensure the project fitted with the social context in which it was situated, for example by receiving advise on setting of and approach to recruiting and interviewing the different participant groups.

In addition, the researcher attended MDT formulation sessions in each team and two training days on using compassionate reformulation to be sensitized to processes, issues and understandings of formulations by staff in these settings.

Commitment and rigour

A total of fourteen interviews with fourteen participants, lasting between 15 and 65 minutes each, were undertaken and then transcribed by the researcher. Transcription took around 3-12 hours each. The length of interviews was flexible, guided by participants' engagement and preference. The majority lasted between 45-60 minutes. One service-user preferred providing information in written format instead of being interviewed, resulting in a total of fifteen transcripts that were analysed.

After each interview, the researcher documented personal reflections to encourage reflexivity, for example with regards to potential bias introduced by personal role in the social construction of interview discourse. Furthermore, memos were written from the outset where initial coding ideas were noted. Combined, this documentation facilitated the simultaneous involvement of the researcher in data collection and analysis, shaping subsequent data collection decisions and construction of emerging themes. The fifteen transcripts were manually coded line by line and then subjected to focused coding. This in-depth engagement with the data ensured that emerging tentative categories remained grounded in the data. Continued memo writing and recording of thoughts about emerging categories helped to advance codes and sensitised the researcher to areas in need of clarification or further exploration.

Table 2: Example of line-by-line coding (codes eventually subsumed by the category of 'Value and Function')

Transcript text	***Line Codes***
So, it's a way of actually saying "This is a real person!"As opposed to a patient, maybe. And uhm "Do we, can we know what uhm - - ultimately uh is motivating this person, is, can we get to know this person!" You know, so I think it's that kind of - - uhm - - - it's just that kind of increased, it's that space to think about someone - - in a way that uhm - - frees up or validates - - an individual's attempts to engage with them. "I know, I feel like know this person! I feel I can think about them - - I feel like what I'm doing with this person makes sense - - there's a rationale for doing it! There's some theory, or something that's backing us up, in terms of our, of our intervention."	*Seeing the person, not a patient* *Understanding motivations* *Getting to know the person* *Having space to think* *Opening up and validating* *Attempting to engage* *Knowing the person* *Having space.* *Validating practice; Having a rationale* *Backing up intervention*

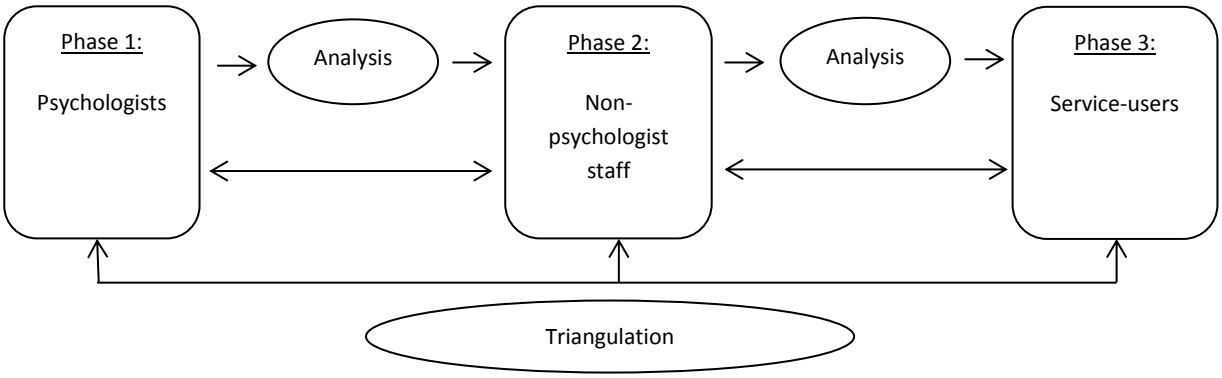
Transcript 4, p 13, 343-356

The method of constant comparison was used throughout the analysis process, examining data for similarities and differences within and between interviews, for example between statements, incidents, and codes. The process of comparative analysis and writing of more advanced memos facilitated clarification of emerging theoretical ideas to allow for systematic categorization of the data. For example, this process helped to identify shared properties between 'wanting answers' and 'understanding of process' leading to these themes becoming integrated meaningfully in the sub-category of 'negotiating roles'. The emerging categories and ideas were discussed in bi-weekly meetings with the researcher's supervisor. All transcripts and key memos were reviewed and a subset of the interviews coded by the supervisor. This helped to validate emerging categories, reducing researcher bias, while keeping them focused and grounded in the data.

During the first phase of analysis (psychologist interviews), the interview formed the basis for emerging theoretical ideas, feeding into theoretical sampling used in phase 2 to help elaborate and further explore emerging conceptualisations. Theoretical sampling continued following phase 2 until theoretical sufficiency was

achieved. In line with Dey (1999), theoretical sufficiency was indicated when no new relationships or codes emerged from the data analysis and categories were deemed to be coping adequately with new data, without requiring continual revision. In an attempt to avoid forcing data into categories to reach sufficiency, the researcher remained open and flexible, revisiting earlier data and, if required recoded them whenever questions about emerging categories emerged. Triangulation of the different views of professionals and service-users was used to develop a more comprehensive understanding of the subject of study and enabled determination of fit and relevance of emerging categories through methods of constant comparison. Data triangulation between different groups was judged to be an acceptable way to reduce bias and ensure a level of internal validity (Guion, 2002; Golafshani, 2003).

Figure 1: Phased approach to data collection and analysis



Transparency and coherence

The researcher remained aware of the context in which the interviews occurred throughout. The study was carried out as part of her doctorate in clinical psychology. Her relative inexperience clinically allowed for the participants to be in the position of experts. The researcher had some experience of working with people with psychosis and a sound understanding of individual case formulation, as well as an emerging knowledge of team formulation due to her studies and placement experiences over the past three years. During the research period of approximately 18 months, the researcher completed an advance practice placement in one of the teams in which the research was set. This meant that some of the staff participants

were known to the researcher, either from joint team working or clinical supervision. Also, the researcher was not a detached observer but active participant of the research by taking part in the team's discussions and practices. The interest in the subject of study developed on the back of increasing experience of working in different settings and MDTs, and being exposed to different team practices and approaches to working with service-users with complex presentations. It spurred on a desire to better understand the process of team formulation and the potential value to staff and service-users. The excerpts were chosen on the basis of having facilitated pivotal insight, for example on the links between' role clarity' and 'felt pressure', or for explaining variation in the theory.

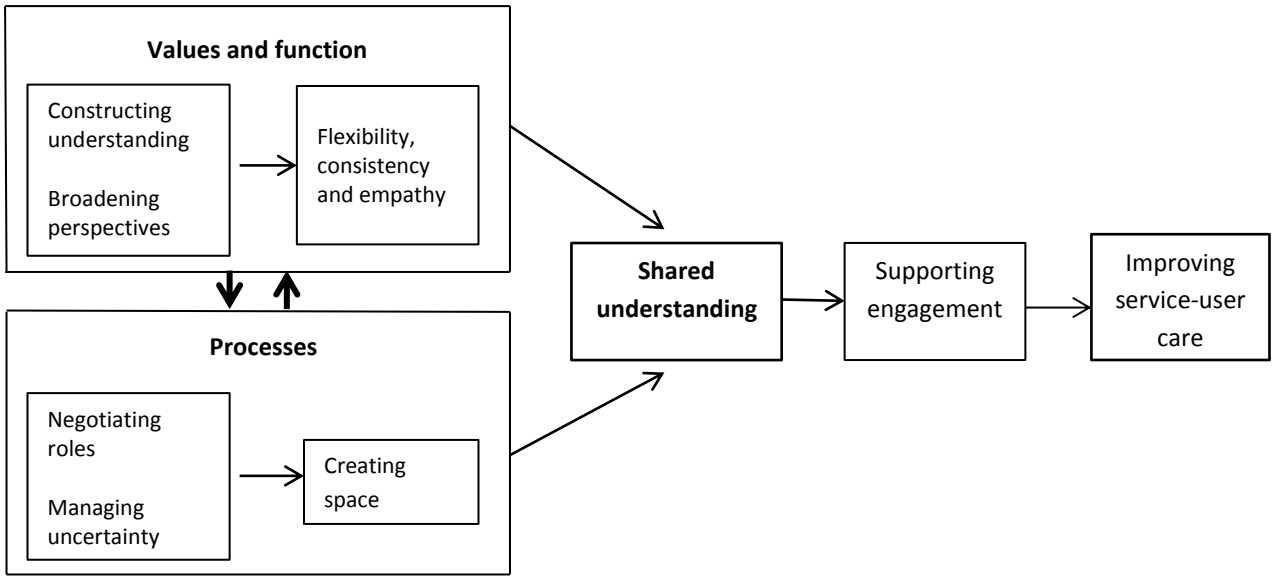
Reflections and experiences throughout the research process were discussed regularly in supervision with the researcher's supervisor. The researcher was a novice to GT, and her relative inexperience with the method required her to be supervised more closely.

FINDINGS

For clarity, all dialogue is given in verbatim and italic. The researcher's speech is in bold type and her responses are in parenthesis (e.g. ***uhum***). Pauses in speech are indicated by dashes - , whereby one dash equals a one second pause. Interruptions in speech are indicated by slashes / assigned to the person being interrupted. Unfinished sentences are indicated by dots.

Derived from these data an emerging model of team formulation is constructed, which outlines the value of and important functions underlying formulation as well as key processes underpinning its practice and implementation. The over-riding theme emerging in participants explorations of their experiences was that of 'Shared understanding', underpinned by sub- categories of 'Value and function' as well as 'Processes'. Shared understanding was seen to support better engagement and ultimately better service-user care to support recovery.

<u>Figure 2:</u> Emerging model of team formulation



Core category: Shared understanding

Constructing and deriving a shared understanding of a service-user in his/her system was seen as a fundamental part and outcome of team formulation, facilitating a broader view and opening up alternatives for responding. Particularly to support the development of working relationships and promote engagement with service-users to whom this is difficult. As such, shared understanding was seen as central to interactions between service and service-user and staff and service-user. At the same time, shared or mutual understanding with regards to the concept of formulation, its purpose and process, emerged as an important property with regards to the experience of team formulation, and the negotiations it demanded of staff.

Value and Functions

As indicated, ultimately, the function and value of team formulation was understood as supporting engagement; the establishment and maintenance of working relationships with service-users to whom this is difficult to help the team to better support their recovery. Essentially, team formulation was valued for providing a place to which concerns about a particular service-user can be brought to and better understood in order to generate alternatives to the service's approach to that person.

And I think it get, it [compassionate reformulation] does give us an avenue to explore and think about - - the patients that traditionally haven't done very well in the service, and probably won't do very well in other services, that are often very difficult to engage and how we can engage them differently. (Participant 2, p 30, 783-787)

In order to achieve the overall aim of improving care for people at risk of arrested recovery, a number of processes were seen as essential. Fundamental was the construction of a better and shared 'understanding' of the service-user and the factors that may obstruct recovery. This was facilitated by a process of 'broadening perspectives', which was seen as important to promote change in the way the team respond to a service-user and plan interventions. As such, team formulation was constructed as serving an important function with regards to increasing understanding that can facilitate alternative responding and planning of MDT care.

Understanding

Staff participants valued team formulation for providing an opportunity to share and integrate information derived from multidisciplinary practice and viewpoints. It was described to facilitate the construction of a fuller understanding of a service-user, an opportunity to 'get to know' a person better, and help the team to make sense of their responses by integrating various factors. For example consideration of how developmental history and attachment style can impact on people's interpersonal and help-seeking style.

*And I suppose that through formulation - - - - I suppose you kinda notice - - like people fling bits up and, you know, when their putting it on the boards and things like that and you're sharing all that information - - sometimes kinda gives you a better understanding - - of - - the person - - - and what it's - - I suppose - - give you an understanding of them and some of how the - - behaviour why they do things. (**Yeah**) - - - I suppose that's kinda makes a bit more sense. - - So I think - - it gives you a bit more understanding - - of the person.* (Participant 8, p 2 33-56)

Shared understanding was a theme emerging in service-user accounts, mirroring themes present in staff constructions. Service-users described consistency in staff responses that made them feel 'known' and met their needs. A mental model shared by the team and the service-user emerged as important for building relationships that feel acceptable to the service-user.

[Keyworker]'s pretty well in the know about the my passage in life - - ehm Celtic history and things like that. And the lady that came the other time actually asked me about these things! And I think at times that is what I need - just for somebody to listen to my ramblings, you know what I mean? (Participant 10, p 19, 585-599)

Broadening perspectives

Essential to the construction of a shared understanding was the process of opening up perspectives. The multidisciplinary context played an important role here, with people from different professional backgrounds chipping in to facilitate a broader, more integrative and holistic view of a person as opposed to one based on a singular perspective. It was constructed as a way to facilitate flexibility of thought.

I think that that's a strength of formulation as well - - that way of - - - - I think when you're working with someone quite often you, you can get quite entrenched in it - - and then it takes someone who's not involved to actually say: "Wait a minute, have you thought of that?" (Participant 6, p 5, 140-144)

Team formulation offered a way of constructing a more comprehensive narrative, incorporating multiple schools of thought (e.g. psychological, psychiatric, social) leading to a more truly biopsychosocial understanding as opposed to a singular perspective that can limit and constrain resources for responding. It allowed for the recognition of the complexity of human suffering and resultant needs, and as such opened up scope for more varied responding. In this way, team formulation may have an important role in shifting cultures, particularly in areas of mental health previously dominated by a medical view.

*For me in particular I think uhm - - sharing - - the uhm - - the focus, or spreading the focus out a bit and bringing in more psychosocial issues - - uhm is an integral part of the formulation process! (**Umhum**). If that wasn't happening - - then I think it'd become, very quickly, - - very biologically, medically-driven - - treatment - - team.* (Participant 3, p 31, 818-823)

However, the scope of team formulation with regards to broadening perspectives has the potential to go beyond understanding of the individual service-user. Team formulation provided a place in which staff can make sense of their experience and their own responses. It was recognized that working with a complex client group, particularly one where engagement is difficult or where the service-users responses are at odds with treatment approach, can be challenging for staff.

I suppose, what I think is helpful is that it - - ahh, for example, if I was stuck with somebody - - - - - so you're presenting the information and I think what's what's good is that other people - - - - pick up on the information that you're presenting - - - - and - - - it may be that I know…that I'm sitting with something that's not feeling quite right, - - - - that's a bit frustrating and I'm not quite sure why. - - And it's that opportunity to get the whole story out, or as much as you can of the story out, and other people who can pick up those aspects and come in with suggestions as to why that may be. And that I think is is really helpful - - for me. (Participant 7, p 10, 293-302)

Reflection on staff member's own emotional response may be an important component of team formulation and core with regards to establishing relationships with service-users. For example, consideration of a service-users help-seeking style in the context of a team discussion and construction of a fuller understanding of that helped staff to take a different perspective. It facilitated reappraisal of the meaning of behaviours and situations, which served an important function in alleviating difficult feelings, leading to a shift in staff's ability to be more empathic towards themselves and service-users.

*I think increasing the team's compassion and empathy – cause I really think the formulations do that when they're working well. They definitely do - - make people feel more sympathetic for the patient and more able to understand why the person might annoy them, or frustrate them, or not answer their calls, or whatever. - - And to be able to reappraise that as 'not personal', to be so that so you can actually see staff using it to almost de-personalize - - the patient's reactions (**mm-hm**), rather than it's about them being a useless nurse, it's not at all! It's about this person having real difficulties with - - you know, emotional contact or interpersonal relationships or whatever. So you can see people understanding it and therefore - - just that generally taking the heat out of the whole situation and looking after the person.* (Participant 2, p 17, 418-431)

As such, team formulation served an important systemic role. It facilitated a broader understanding of systems, the way in which different components in a system interact and where they are blocked. In this context, the system referred to relates to the service-user suffering from psychosis. It is the system this person is embedded in, made up of the service-user, the team, and the family/social environment, which in turn is embedded in a wider system (for example the political and economic system). As in any system, change in one subsystem or component will have an effect on the other components (Bertanlaffy, 1968). That is, enhanced understanding of the service-user and reappraisal of the meaning of their behaviour can alleviate emotional responses of staff in a way that allows them to relate differently to a service-user and respond in a more helpful way, which in turn may facilitate better engagement.

*I think you have to you have to include - - - the keyworker or, you know, the team - - uh in the formulation - - in kind of in a similar way that you might include a family in an individual's formulation (**mm-hm**). So, in in a way it's a, kind of a, I suppose it's just an extension of the system around a - - particular patient. Uhm, so you're trying to include as much of that because you're working with all of it a lot of the time.* (Participant 4, p 5, 129-134)

Flexibility, consistency and empathy

Responding was an important theme in participants' reflections on team formulation. The broadening of perspectives and resultant shared understanding was constructed as providing the basis for discourse about current way responding, and alternatives to that.

*I think, you know, when the team has a shared sort of mental model - - of - - the service-user in their family context, in their developmental context etcetera. When when the service has a kind of flexible model of that it means that - - uhm - - the service can respond flexibly (**uhum**) but also consistently as well. So it means that, you know, if the keyworker is off -- and the service-user contacts the service there's a continuity of care because of the shared narrative - - about the service-user. It means that, if there's a crisis - - you know, there's there's the a kind of resource that the keyworker has; in terms of kind of flexibility of thinking, but also flexibility of support within the team to enable, you know, a kind of a a - - to enable the service to respond flexibly in crisis, rather than to respond in a kind of more kneejerk way.* (Participant 1, p 15/16, 459-471)

Importantly then, team formulation may bring about responding characterized by flexibility, consistency and empathy. All of these aspects are essential components for engaging and building relationships that feel safe and supportive, and as such are fundamental for facilitating engagement. Consistency creates a sense of reliability which may be particularly important for service-users whose attachment histories have been barren of this. Equally, empathic and compassionate responding is essential for establishing supportive relationships, tying in with feeling accepted and safe. As such, team formulation can serve an important function in facilitating the establishment of relationships that can support recovery.

Consistency and trusting relationships were important themes emerging in service-user accounts. All of the service-users highlighted the importance of these aspects to be at the core and fundamental to their recovery. Having someone there that understands them and responds to their needs consistently and appropriately appeared to facilitate a sense of trust and safety.

*It's just patience, more or less for me. They had - - just for to talk to, somebody to talk to. [Keyworker] - - she does my depot, as well (**right**) - - which I get every three weeks. And - - [keyworker] - - she just it's just the relationship we built up. And it's amazing! - - - It's amazing. I get her every week. I talk to her about everything I wanna I talk to her and I can tell her everything, really (**uhum**). - - Eh that was that's been good - a good healthy relationship.* (Participant 11, p 2, 32-45)

Equally, the process of constructing a shared narrative and broadening perspectives was seen as a process that facilitated flexibility with regards to responding; allowing a response attuned to the individual and his/her family's needs, rather than prescriptive or limited (e.g. based on a diagnostic category).

*I was in when I was in the [hospital] - - eh I kept thinking about the twin towers - - and - - eh [keyworker] came in and spoke to me about it and it really put me at ease! - - It really put me at ease. And the support they've gave me since I came out of hospital. They've been times when I heard voices - - and times when I haven't been hearing voices. - - But at times when I have been hearing voices [the service] has been there to talk me through it. And come and visit me and make sure I'm alright. (**Uhum**). And also they've helped me when I've been getting psychotic thoughts, - - to stop the psychotic thoughts as well and nip them in the bud before they get worse.* (Participant 13, p 4, 111-124)

Giving direction

For staff, team formulation was also valued for providing possible solutions or direction. It was seen as a way to support the team with difficult to engage service-users by giving them a platform to discuss struggles and concerns, make sense of this and offer or receive advice about possible alternatives to responding and intervention. For some, team formulation was constructed as essentially solution-focused, a 'means to an end', directing treatment planning, providing answers, and helping to solve problems. Others constructed the value of the process in a broader sense, which included constructing a story, getting to know a service-user, widening perspectives, getting support with and validation of their work, and

facilitating more holistic and person-centred responding to support someone's recovery. Differences with regards to people's understanding of the purpose of formulation shaped their expectations of the process, as elaborated on below.

I s'pose trying to - - work out at a kinda what's the best kind of care plan to be going with and…Quite often we'll have patients who you think: "Well - - BFT might be an appropriate intervention but also individual psychology might be an appropriate - - intervention. Or occupational therapy might be an appropriate intervention." - - I s'pose the formulation process is - - well it prioritizes things a bit - - more clearly. Uhm uhm - - - - - - - and I think, you know, it - - they kinda highlight gaps where - - we know or we haven't actually - - had this conversation with the person's parents or we haven't had this conversation with - - somebody else. It opens up different avenues to - - work and to - - uh I s'pose it can help us also with, you know, just engaging with some of the people who are a bit more difficult to engage. - - We can - - - - - get a bit more insight as to to why they're difficult to engage - - and work around that. (Participant 9, p 9, 250-267)

In this way, team formulation took an important place in treatment planning and the provision of a person-centred and shared approach to care. Importantly, service-users felt included in this process and experienced their care as flexible as opposed to fixed and predetermined.

I feel that throughout my time with [the service] there was always a pretty clear plan in place to help me. I feel that I was always given the opportunity to discuss what this plan should involve and give feedback on what I felt was working and what I felt was not so useful. (Participant 15, p 3, 60-64)

Ultimately, team formulation was understood as a means to construct a shared narrative that facilitated a broader systemic view and identification of barriers within the system. This was providing a context in which flexibility and consistency in understanding and response could develop to support the team and service-user in their attempts towards recovery. Importantly, it provided a context for developing important prerequisites for better relationships between service-service-user, staff-

service-user and potentially staff-service. Simultaneously, it gave scope to develop flexibility and the establishment of a care plan responsive and better attuned to the needs of a service-user. As such, team formulation was constructed as an important tool to support person-centred care and fundamentally support recovery.

Processes

As described above, team formulation was a valued practice overall, seen to be serving an important function in supporting the team, individual staff members and service-users in their journey of recovery. Importantly, the data provided insight into and highlighted processes that underpin the construction of team formulation, needing to be negotiated or managed by staff in order to achieve the above goal. This related to expectations and uncertainty.

Negotiating roles

Team formulation was a context that required negotiation and clarification of roles and tasks. It was a context where different professional roles were played out, for example by utilizing and appreciating expertise and experience from the different disciplines. However, the data indicated a level of uncertainty with regards to one's role and place in the production of formulation, which led to blurred expectations. Team formulation appears to necessitate clarity about what is expected of each staff member and the process itself.

*I don't know, I don't know if people expect or even, like the psychologists say "Right ok this is, you know, like a clear plan, this is what we should do". But I don't know if that's necessarily…it should be still multi-disciplinary and - - - I don't know if they expect - - psychology to come to some conclusion at the end about - - what they're doing or where it goes or (**uhm**) - - or how their treatment goes, I don't know.* (Participant 8, p 12/13, 361-367)

Clarity about professional roles was linked to clarity of expectations held internally by staff as well as perceived expectations of their performance placed on them by others. The level of clarity around this shaped the way team formulation was experienced. Lack of clarity with regards to one's role in the process and

expectations deriving from this had the potential to give rise to difficult emotions such as doubts over professional competency, or feeling under pressure or exposed.

*As keyworker however, I think sometimes there is - - a felt pressure - - to come with all the information - - at your finger-tips (**uhum**) - - when [ ] we are doing the formulation. - - - And although [ ] we talk about these things as a team - - - - we talk about that that's not possible and that, you know, that we're not gonna have all that ahm, I do sometimes feel that pressure ahm when when you when you don't have all the information at your fingertips. Even though logically you know it's it's not possible. You know some of the clients that we work with that perhaps are seeking asylum or have no family or whatever whatever whatever we can't we can't possibly have all that information there. Ahm so logically, you know, I know that but but sometimes there is still a felt pressure when - - you know you're you you don't know - - things that folk are asking you.* (Participant 7, p 3/4, 76-90)

Team formulation also gave rise to negotiations of expectations related to the role of the process itself. Comparing two reflections on the use of compassionate reformulation (below) gave valuable insight into the way in which differences in understanding influence expectations and the experience of the process. Team formulation therefore required staff to manage uncertainty and negotiate meaning. This supported the need for clarity and shared understanding of the process of team formulation.

*And often it's really difficult - - for staff working with people when they see that - - they're stuck, and they're not getting better. [ ] So - - they uhm they can come and talk about all of that - - (**mm-hm**) in a safe place, with no expectation that, at the end of it - - we have to have an answer!* (Participant 5, p 10, 320-326)

This excerpt was contrasted with the following:

But with the compassion - - reformulation - - I think there's maybe a sense within the team that - - we don't have that [direction]. It's somebody we don't know, somebody we don't understand - - and we talk about what we don't know, what we don't

understand. - - And we probably don't come away with that same sense of - - - knowing where we going next. Sometimes it helps us understand that there isn't uhm much else that we can…you know the path that we're on is the path that we're gonna have to stay on. But I think - - there's an expectation that - - it would be - - providing more answers then it perhaps does. (Participant 9, p 2/3, 48-57)

What emerged from the accounts overall was the need for staff to negotiate roles, meaning and expectations and that this can be challenging. Clarity and shared understanding therefore appear paramount. As such, fundamental to team formulation appears to be the availability of a space or system that allows staff to articulate concerns and uncertainties. A process that enables clarification of roles and tasks in order to facilitate mutual or shared understanding about what everyone contributes and what is expected from the process.

Managing uncertainty

Uncertainty and the need to tolerate and manage this appeared to be an inevitable component of team formulation. This related to processes involved as well as the outcome of it, namely the process of exploration and the construction of a hypothesis about someone. Both have uncertainty as inherent properties; while simultaneously serving to reduce it. In order to understand someone's difficulties of engagement or with building relationships requires exploration of the systemic factors contributing to it, including e.g. staff feelings and responses. It requires openness, reflection and willingness to explore and make inferences about the unknown. This then can facilitate understanding that may direct the team towards a solution However, as with any formulation, the understanding constructed remains a hypothesis, not a truth. While this is a practice familiar to, say, psychologists, it may be less so for other disciplines, therefore being potentially harder to tolerate and accept. This then can impact on their engagement with the process.

So that's that's always ahm a bit of a concern of mine that - - we'll be speculating and and throwing ideas on the table - which I think is very much what ahm - - - formulation can be about I think…that's you know what…that it's…formulation

*allows us to do that! - - (**Uhum)**. - - But I do worry sometimes that speculation does become fact!* (Participant 7, p 5, 119-124)

Unfamiliarity may be underlying some of this. But participants' accounts also indicated the role that heightened levels of stress can play. Working with a complex client group, with people who are very unwell and whose recovery is slow or stagnant can add urgency to staff's sense of having to achieve a change, and lead to a desire of getting clear answers and solutions. Uncertainty may be particularly difficult to tolerate when stress and anxiety levels are high, when staff feel unable to support a person in their recovery. However, what emerges from these data is that exploration and construction of hypotheses are necessary processes to be able to generate ideas and solutions. As such, the management and tolerance of uncertainty appear to be core parts of team formulation. Again, what seems vital is for team formulation to provide a space that feels safe enough for staff to express their concerns, to articulate their unease with these practices and develop ways to manage uncertainty around that.

Creating space

As indicated by the construction of participants' experiences of team formulation, 'space' was an essential ingredient - the availability of space in which people felt included and free to explore, safe and non-pressured. A space that has the potential to provide a context for processes to occur, unfold and be negotiated as required in order to achieve mutuality of understanding of the person and the process of team formulation.

[…] For me that reflective space has certain properties to it - - It's a space that is well defined - - and - - it's a space that kind of feels safe - - free from judgement […] It's a space where people feel free to express their views and express their opinions […] both positive and negative. And it's a space that - - - encourages and values curiosity and exploration. And for that reason you have to have the kind of the feeling of safeness and non-judgement that go along with with that. I think that's a really crucial aspect of team formulation and the team formulation process. (Participant 1, p. 10, 260-267)

It was acknowledged that having space was important for essential ingredients of team formulation, namely reflection and exploration, but that it can be challenging to provide this space. The availability of space was at the mercy of factors internal and external to staff and the team, including practical aspects such as having enough time, procedures used for facilitating formulation, and organisational stressors, as well as ability of staff to engage.

So, I think that's a challenge of trying to do the best that you can within the, you know, a short, fairly short period of time - - and trying to make sure that everyone feels their voice is heard. (Participant 5, p 24, 634-637)

DISCUSSION

This study set out to explore experiences of team formulation and care from multiple perspectives, including MDT staff and service-users, in the context of an EI service for people experiencing first episode psychosis. Team formulation is a firmly established practice in this service, supporting work with this complex population. Using a social constructionist approach of GT (Charmaz, 2003; 2006), this study constructed an emerging model of team formulation in collaboration with the participants. Arising from the data, two levels comprising this model were established: the 'value and function' of team formulation and 'processes' involved in it.

The narratives indicated that team formulation was a valued practice overall. Ultimately, its value and function was understood to lie in the construction of a shared understanding that helps the team to support service-users who have been identified as at risk of arrested recovery due to difficulties engaging with the service. Fundamental to the construction of a shared understanding was the process of broadening perspectives, of taking a systemic view. In this way, the findings are in line with benefits highlighted by previous studies into the use of team formulation (e.g. Dexter-Smith, 2010; Hood et al., 2013). As in other studies (e.g. Summers, 2006; Wainwright & Bergin, 2010; Christofides et al., 2012), the data highlighted

the value of team formulation for promoting empathy, better relationships with service-users, and interventions more attuned to their needs. Importantly, this study advanced understanding by pointing towards processes underlying this, such as more flexible, yet consistent responding from the team. In this way, team formulation may have the potential to promote the establishment of better relationships with service-users to whom this may be difficult. Importantly, increasing knowledge of the role of developmental factors was seen as valuable in helping the team to understand service-users responses. Equally, broadening understanding to include and address wider systemic factors, such as the role of service's and staff's responses, was core in helping staff to make sense of interpersonal challenges. An important addition to the existing literature about team formulation has been the emerging understanding of processes underpinning this practice, including negotiation of roles, managing uncertainty and creating space. It emerged that *doing* team formulation by itself was not enough, but that it required staff to engage with and negotiate processes in order to construct it. What emerged was that this can be experienced as challenging by staff, and therefore influence their ability and willingness to engage in formulation and essential components of such (e.g. exploration). It highlights the importance to develop systems or space in team formulation where these processes and related concerns can be articulated in order to facilitate a shared understanding that clarifies and results in mutuality of expectations. In this way, potential strains involved in doing formulation for staff may be reduced, thereby increasing or easing their engagement with the process. The availability of a space that feels safe and facilitates exploration has been emphasized by Johnstone (2014) as a core ingredient of team formulation. While the importance of such space was indicated by these data also, it highlighted challenges inherent in establishing and maintaining reflective space due to various factors, such as time pressures or team dynamics. Consideration of the context of working with service-users with complex difficulties and the impact that has on staff also seems important here. Staff participants acknowledged the challenges and stresses related to working with this group, and particularly with service-users who struggle to engage with them and with treatment. Difficulty engaging service-users may be challenging to staff for various reasons, including doubts regarding their competency and concern for the service-user (e.g. consideration of the link between duration of untreated psychosis and poorer

outcome). The felt pressure and anxiety resulting from this may have important implications for staff's way of responding. Indeed, a recent study into the use of advance statements indicated that staff tended to resort back to more limited and coercive treatments in the face of crisis as opposed to taking a more flexible and person-centred approach (Thornicroft et al., 2013). Importantly, increased stress and pressure may significantly impact on staff's ability to engage in reflective practice and the process of exploration due to a felt urgency to act. Some participants highlighted the way in which heightened stress led to a more action-driven approach to formulation, a desire to get answers and solutions as opposed to exploring. While it is important to be mindful of this, it simultaneously strengthens the case for using team formulation to help reduce some of the strain for staff by finding ways to engage this group.

Clinical implications and future directions

The model emerging from this exploration has provided important insight into team formulation and processes underpinning it. This may be of value to help advance this practice and its application in order to improve outcomes for individuals at risk of arrested recovery. For example, by developing team processes and space in which staff experiences with and concerns about formulation can be addressed and mutual understanding reached. It also may provide a point of departure towards developing a more comprehensive model and theory of team formulation to facilitate further, more rigorous research into its use (e.g. outcome studies) and promote dissemination of this approach to other services.

Limitations

The constructed model of team formulation presented here was based on fifteen participants' perspectives and the researcher's analysis of this. The results are one possible construction of these data, and the current presentation bound to the context and conditions of this study (Hutchinson, 1993). Any given text permits infinite interpretations; therefore lengthy excerpts were included here to allow readers to make their own interpretation. It could be argued that further respondent validation may have been beneficial. However, the researcher was aware that data collected in response validation is subject to the same process of interpretation

(Bloor, 1997). To strengthen validity, triangulation and review of the data by a second person were used (Guion, 2002). While valuable insight into team formulation was gained, causal relationships cannot be assumed. Any suggested relationships require further quantitative evaluation in order to make inferences of causality. Having used a social constructionist approach to GT (Charmaz, 2003; 2006) the researcher has emphasized reflexivity throughout to stay aware of her own role in and contribution to the process of construction. Still, her professional role, proximity to the service and participants, and personal beliefs need to be taken into account.

The analysis of service-user accounts alongside those of professionals and triangulation between these two groups proofed to be challenging. Service-users in this service are not actively part of team formulation and as such were interviewed about their experiences of care, while staff participants were interviewed about their experiences of formulation. The difference in interview topics between the staff and service-user participants may account for the difficulties encountered when constructing the data and clearly limit the links that can be made across data. On reflection, it may have been more meaningful to analyse and construct these data separately.

It may be argued that other qualitative methods could have been employed for this study. While Interpretative Phenomenological Analysis (IPA) (Smith, 1996) is an approach specifically developed to explore psychological worlds, committed to people's lived experience, it focuses on small, homogenous sampling and does not specifically aim to generate a theory or explanatory framework (Smith, Flower & Larkin, 2009). Increasing a more theoretical understanding of team formulation by exploring the experiences from multiple perspectives was however the aim of this study. GT allows for theory generation by taking a phased approach to data collection and using memos to create theoretical links across heterogeneous accounts. It was therefore felt suitable for managing the wealth of data derived in this study. A possible alternative may have been Framework Analysis (FA) (Richie & Spencer, 1994). Like GT, FA is a method that generates theoretical understanding firmly grounded in participants' accounts, allowing for flexibility during data collection and analysis to adjust to emerging theoretical concepts, and allows working with comprehensive sets of data making links across accounts (Srivastava &

Thomson, 2009). Unlike GT, FA has scope to answer questions more specifically and allows for more generalizability. As such, it would have allowed for the incorporation of existing understandings of team formulation and a more directive approach, which may have been valuable. However, given the lack of consensus currently present with regards to applications of team formulation, FA would have been difficult to be applied in this context.

Conclusion

In summary, this study constructed an emerging model of team formulation in the context of an EI first episode psychosis service. The importance of shared understanding of a service-user and his/her needs, as well as the process of formulation has been highlighted. In order to achieve this, reflective space allowing for articulation and negotiation of roles and uncertainty are central to arrive at a shared understanding and mutuality of meaning. Further, fundamental processes underlying the establishment of working relationships attuned to individual needs have been outlined (e.g. broadening perspective and increasing flexibility, consistency and empathy).

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CHAPTER 3: ADVANCED CLINICAL PRACTICE I – REFLECTIVE CRITICAL ACCOUNT

To say or not to say – When does communication become unethical?

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (D. Clin.Psy.)

ABSTRACT

This reflective account describes a challenge I faced with regards to striking the appropriate balance between communicating and sharing information in a team, while staying in my professional role and keeping up good ethical practice. I have chosen to reflect on an experience I had while on placement in an adult specialist service that highlighted this challenge. It describes a situation of information-sharing about a specific service-user between me and two other professionals in a shared office space. The way this person was being discussed in an open space left me feeling uncomfortable and uneasy. Using a number of models of reflection helped guide my reflection in a way that facilitated learning about a number of important issues, including ethical practice, relevance of identifying and exploring difficult emotions, making sense of dynamics, taking a broader view, and the way that organisational and systemic factors can influence behaviour. This exercise allowed me to lift my understanding of a specific situation to a more advanced level, facilitating learning about how to enhance my own clinical practice and inform better care in the wider system.

CHAPTER 4: ADVANCED CLINICAL PRACTICE II – REFLECTIVE CRITICAL ACCOUNT

Increasing access to mental health services and offering choice to service users - the challenge of putting psychology on the agenda in a multidisciplinary team

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ABSTRACT

This reflective account describes the challenge I have faced of finding ways to promote psychological understanding in a service stretched to its capacities where the medical view is still predominant. The experience I have chosen is the discussion of a new referral at the weekly MDT meeting that highlighted this challenge very clearly to me. The experience allowed me not only to clarify my own professional identity, it has also given me scope to reflect on current challenges faced by services, demand and capacity issues, and the way in which this may impact on person-centred approaches to care. It has given me the opportunity to think about different service delivery models and approaches to meet current challenges, MDT work and the role of psychologists within that. Making use of reflective models helped guide my reflection in a way that facilitated learning to allow me to generalize my acquired understanding to my clinical practice and the wider context, and helped me identify important areas for continued professional development to help prepare me to meet the challenges faced by services with regards to increasing access to psychological therapies in the future.

APPENDIX 1 – Systematic Review

Appendix 1.1 - Author Guidelines for Submission to *Schizophrenia Research*

***SCHIZOPHRENIA RESEARCH* - Guide for Authors** (For full details see: http://www.elsevier.com/journals/schizophrenia-research/0920-9964/guide-for-authors)

Aims and scope:

Schizophrenia Research provides rapid publication of new international research that contributes to the understanding of schizophrenia and related disorders. The journal brings together previously separated biological, clinical and psychological research on this disorder, and stimulates the synthesis of clinical and research data into cohesive hypothesis.

Presentation of manuscript:

Please write your text in good English (American or British usage is accepted, but not a mixture of these). Italics are not to be used for expressions of Latin origin, for example, in vivo, et al., per se. Use decimal points (not commas); use a space for thousands (10 000 and above).

Provide the following data on the title page (in the order given).

Title. Concise and informative. The title should indicate the main point of the manuscript. Note that titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

Abstract. A concise and factual abstract is required (maximum length 250 words for full-length papers or 100 words for short communications). The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separate from the article, so it must be able to stand alone. References should therefore be avoided, but if essential, they must be cited in full, without reference to the reference list. Non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Keywords. Immediately after the abstract, provide a maximum of six keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

Abbreviations. Define abbreviations that are not standard in this field at their first occurrence in the article: in the abstract but also in the main text after it. Ensure consistency of abbreviations throughout the article.

Arrangement of the article

Subdivision of the article. Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ?), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction. State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Experimental/Materials and methods. Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described. Statistical tests used for evaluation of data should be briefly explained. In case of experimental studies, animals used should be described, including information on breed, breeder, sex, age, weight and the maintenance conditions. Special chemicals and their sources should be grouped under a separate sub-heading. For drugs generic names should be used; trade names may be given in brackets where the drug is first mentioned. In case of a new drug, a chemical description (formula) should be given. The form of a drug used should also be indicated.

Results. In this section the findings should be described clearly, concisely, and in logical order without extended discussions of their significance. Only in case of short communications, the results and discussion sections may be combined. Results should usually be presented in graphic or tabular form, rather than discursively. There should be no duplication in text, tables and figures. Experimental conclusions should normally be based on adequate numbers of observations with statistical analysis of variance and the significance of differences. The number of individual values represented by a mean should be indicated.

Discussion. This section should present conclusions to be drawn from the results accompanied by an assessment of their significance in relation to previous work. Speculative discussion is not discouraged, but the speculation should be based on the data presented and identified as such. In general, the discussion should be as concise as possible.

References

Citation in text
Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Appendix 1.2: Search strategy: Ovid MEDLINE (May 14th, 2014)

01. (mindfulness or meditat*).mp.
02. mindfulness-based.mp.
03. compassion.mp.
04. (acceptance and commitment therapy).mp.
05. compassion-focused.mp.
06. loving-kindness.mp.
07. person-based cognitive therapy.mp.
08. acceptance-based.mp.
09. compassionate mind training.mp.
10. dialectical behaviour therapy.mp.
11. third-wave therapies.mp.
12. third-wave therapy.mp.
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. (psychosis or psychotic).mp.
15. psychotic disorder*.mp.
16. schizophreni*.mp.
17. schizoaffective disorder*.mp.
18. schizophrenia-spectrum disorder*.mp.
19. bipolar disorder*.mp.
20. manic depression.mp.
21. 14 or 15 or 16 or 17 or 18 or 19 or 20
22. 13 and 21

[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

Appendix 1.3: Data Extraction Form: Characteristics of included studies

Study:		
Participant characteristics	Sampling	
	Recruitment site	
	Number of participants	
	Age	
	Gender	
	Ethnicity	
	Diagnosis	
	Presenting problem (inclusion criteria)	
	Inclusion/exclusion criteria	
	Education level	
	Employment status	
	Medication	
	Treatment history	
	Attrition rate	
	Setting	
	Country	
Trial characteristics	Year of publication	
	Type of study	
	Design	
	Allocation	
	Blinding	
	Duration	
	Therapist qualifications	
	Type of outcome measures	
	Follow-up time in weeks	
Characteristics of	Number of participants	

the Intervention	Type of treatment	
	Treatment protocol	
	Length of treatment	
	Attendance (N sessions)	
	Length of assigned home practice	
	Quality of home practice	
	Treatment setting	
Characteristics of the comparison group	Number of participants	
	Type of control	
	Type pf treatment	
	Length of treatment	
Outcome	Aim(s) of the study	
	Key outcome(s)	
	Other outcome(s)	
Results	Attrition/participant-flow	
	Primary analysis	
	Secondary analysis	
	Other outcomes/results	
	Summary/Conclusions	
Notes *(e.g. any omissions/missing data?)*		

Appendix 1.4: Data extraction sheet – Risk of bias

Study name:

Bias	**Author's judgement** *(Level of risk (e.g. low, unclear etc)*	**Support for judgement** - *Brief explanation of what judgement was based on (e.g. 'no information provided'; 'all stated outcomes were reported')*
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and personnel (performance bias)		
Blinding of outcome assessment (detection bias)		
Incomplete outcome data (attrition bias)		
Selective reporting (reporting bias)		
Other bias • E.g. study design flaws?		

• E.g. data collection was stopped early? • Etc.		
Overall Risk:		

Registered protocol?

	Y/N	Protocol same as reported? (Y/N)	Risk of bias (Y/N)	What differed?
Current Controlled Trials Ltd				
Clinicaltrials.gov				
Australian and New Zealand Clinical Trials Registry (www.anzctr.org.au)				

Appendix 1.5: Table of risk of bias judgements

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
Bach & Hayes (2002) ***Bach et al (2012)***	**Unclear** Randomized, but not reported how 'Those who agreed to participate were randomly assigned (40 per condition) to receive treatment as usual (TAU) or the ACT intervention plus TAU'.	**Unclear** Not described	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**High** 'Baseline measures were collected by one of the investigators (Patricia Bach) immediately after the participant signed the consent form agreeing to participate in the study. Follow-up measures were collected by the participant's case manager or by one of the investigators (Patricia Bach).'	**Low** Days to index hospitalisation were available for 30 TAU participants (86%) and 33 ACT participants (94%). 'Four participants in each condition moved out of the area, and 1 in each condition died. Rehospitalisation data were available for 35/40 for each condition. Conceivably these 8 participants could have been hospitalised elsewhere.'	**High** Secondary outcomes: (symptom frequency, distress and believability) – Figure 4 presents believability ratings. No such figures presented for frequency and distress. Post hoc analyses of subgroups of ACT participants based on their reporting of symptom frequency are selective, comprise small n and lack statistical power for comparisons.	**High** Frequency of reporting symptoms is reinterpreted as a measure of acceptance of symptoms for subsequent analyses of distress, believability and speculation regarding mechanisms of rehospitalisation. No measure of other variables Previous psychological therapy history unclear Some received	**High** Due to detection bias and selective reporting.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
						In the follow-up paper post-discharge hospitalization data for 1 year were available for 51 of the 64 participants (80%) with previous hospitalization information. This is 51 of original sample of 80 (64%). Imputation of missing data reduced 1-year hazard rate from 254% to 97%.	psychotherapy in hospital – no details provided	
Braehler et al. (2012) ***Rated by JH only***	**Low** 'Recruitment, randomization, and running of groups in the three localities were staggered. When a block of at least 12 participants had been recruited in one locality,	**Unclear** Not described.	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**Unclear** 'A research assistant (SW) conducted assessments prior to randomization (self-report measures, Recovery Narrative Interview) and following	**High** In total, data for n=15 (CFT group) and n=17 (TAU) were included in final analysis (CFT attrition=31%) 'Attrition from CFT was 18% (4 of 22). The four CFT	**Low** No selective reporting identified.	**High** Small sample size Not controlling for other variables, e.g. treatment history.	**High** Small sample size and incomplete data.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	Independent randomization was conducted by AG using a web-based computer-generated permuted procedure (http://www.randomization.com). The first two groups were randomized at a ratio of 1:1 to CFT + TAU or TAU alone; the third block was randomized at a ratio of 2:1 in favour of the group to ensure a CFT group size of at least seven members.'			completion of the group or respective wait (self-report measures, Recovery Narrative Interview, Clinical Global Impression Scale). The research assistant was masked to the allocation of participants. Further efforts to maintain the mask included locating the assessor in a building separate from clinical staff and advising participants not do disclose allocation in the follow-up interview. No formal evaluation of the masking was undertaken/effectiveness of blinding was not formally assessed.' (p 7)	participants, who were unwilling or unable to complete post-assessments, had all dropped out of the therapy within the first four sessions. One TAU participant and three CFT participants refused the recording of the interview at post-assessment due to feelings of paranoia. The 18 completers attended for an average of 12 sessions (SD = 3.6). One person in the CFT condition died of natural causes as determined by post-mortem examinations. There were no suspected unexpected serious			

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
					adverse reactions over the course of the trial.' (p 9) 'In the CFT condition, post-assessment data were missing for five participants on self-report and for a further two on the interview. One TAU participant had failed to fully complete PBIQ and BDI and refused the interview at post-assessment. All data available for this participant were included in the analyses.' (p 7)			
Chadwick et al. (2009)	**Unclear** 'The North Wales Organization for Randomized Trials in Health then allocated them at random between	**Unclear** No details provided	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the	**Unclear** No details provided of who conducted assessments.	**Low** 21 participants randomised, 18 analysed for 'primary analysis'. Drop outs from trial and intervention	**Unclear** All primary analysis outcomes reported according to aims of study. Secondary analysis	**High** Small highly selective convenience sample of n = 22 (from 35). Study aims to determine	**High** Small sample size and uncertainty about blinding assessor.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	group- based mindfulness training and a waiting list for this therapy.' (p 404). No further details provided. One participant allocated to waiting list due to ongoing medical problems and was removed from randomisation and feasibility analysis. Abstract is inconsistent with this (n = 22 rather than 21).		effectiveness of psychological therapeutic interventions.		not analysed. Primary outcome specified as clinical functioning (CORE). Reasons for drop-outs stated: 'Two people dropped out: one between assessment and the group starting (he began using heroin again) and one after one session (found it difficult to be in a group)'. (p 408)	of within group therapy improvements on n = 15 of those who complete 6 or more sessions (does that include WL participants? Not clearly stated)	effect size estimates for larger RCT however not clear whether such a small sample size is adequate to determine sample size estimation. 9 participants attended at least 6 sessions – bias due to attending limited sessions?	
Chien & Lee (2013)	**Unclear** Participants were randomly allocated, however procedure was not described. 'After their written consent had been obtained after a full	**Unclear** No information provided.	**Low** Rated as low due to lack of relevance of this criteria in this context, given the nature of trials assessing the effectiveness of psychological	**Unclear** 'One trained research assistant who was blind to the group assignment administered the pre-test and two post-tests.'	**Low** High rate of follow-up according to n's cited in Table 1. Low drop-out rate (6%). No description of missing data across measures.	**Unclear** Unclear specification of primary and secondary outcomes, hence difficult to determine.	**High** Unclear how participants were selected (ie 96 out of 337) - additional selection bias? 'A total of 1,082 Chinese patients	**High** Insufficient information to judge risk of bias.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	explanation of the study, the participants were assigned randomly to receive usual care or the MBPP plus usual care.' (p 377)		therapeutic interventions.	However, no description of procedures utilised to protect the blind, report unblindings, or actions taken in the event of an unblinding.		"This trial was designed to test the effects of a mindfulness-based psychoeducation program (MBPP) for Chinese patients with schizophrenia on their symptom severity, illness insight, and psychosocial functioning. " (p 376) Then later "Based on recent psychoeducation studies (2,6,7), this sample size was required to detect any significant difference between the groups with repeated measures at a 5% significance level with a power of 90% and 25%	with schizophrenia who were attending three outpatient clinics were eligible for the study, and 337 (31%) agreed to participate. Of these, 96 (29%) were randomly selected for participation. No significant differences in socio- demographic characteristics were found between the study groups and the 241 nonparticipants.' (p377) No assessment of other variables, e.g. past treatment history/pre-experience with mindfulness.	

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
						potential attrition (10). " (p 377) Then later still "MBPP was tested for effectiveness with patients whose schizophrenia had endured less than five years, with the goal of reducing the likelihood of relapse or further psychotic episodes." (p 377) Also not clear how hospitalisation data were collected.		
Chien & Thompson (2014)	**Low** Simple Randomisation 'After giving their written consent, patients were asked to draw a	**Low** Simple randomisation by sealed envelope.	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of	**Unclear** 'An independent trained research nurse performed the outcome measurements using a set of questionnaires	**Low** Good follow-up	**Unclear** All outcomes clearly reported however not reported according to original Clinical Trials. Gov protocol	**Low** Pre-randomisation selection. 'Of approximately 1085 eligible patients with schizophrenia (15%	**Low**

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	sealed opaque envelope, in which a labelled number card indicated the group to which they were assigned.'		psychological therapeutic interventions.	before treatment allocation (Time 1), at 1 week (Time 2), 12 months (Time 3) and 24 months (Time 4) following the 6-month interventions. Both the assessor and clinic staff were masked to treatment allocation. ' Breaks to blindness not reported, methods of concealment not reported.			of this patient population) attending three out-patient clinics in the largest geographical region (New Territories) of Hong Kong, 515 (48%) were successfully contacted. Of these, 450 (87%) agreed to participate and 107 (24%) were then randomly selected.' 'From each clinic, those eligible patients who agreed to participate were listed in alphabetical order and then selected randomly from the list (n = 35–36 per clinic), using a computer-generated random	

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
							numbers table.'	
Gaudiano & Herbert (2006)	**Unclear** Used randomization, however, method not clearly described 'Simple randomization without blocking or stratification based on a computer generated list was used without concealment.'	**High** 'Simple randomization without blocking or stratification based on a computer generated list was used without concealment.'	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**High** Raters were not blinded 'Assessors and staff were not blind to treatment allocation' (p 431). + 'therapist at times also acted as the assessor at post-treatment in both conditions.'(p 432)	**Low** 40 randomised and 29 analysed at end of treatment (>25% attrition) MVA conducted to evaluate missing-ness. Intent-to-treat (ITT) analyses also were conducted to examine the reliability of completer analyses. Using SPSS Missing Value Analysis software. 40 randomised, 38 complete treatment, 29 completers. Some reasons for loss of participants were stated: 'Of the 38 participants	**High** It was hypothesized that the ACT group would show greater improvement on symptom measures at post-treatment and decreased rehospitalization rates at follow-up. Also, exploratory analyses were conducted to examine theoretically derived correlates of symptom change. Selective reporting of psychotic symptom measures particularly hallucinations distress.	**High** Gender differences emerged between groups and gender was related to relationships and BPRS measures (e.g. differences in type and severity of psychiatric symptoms). ACT group also had higher BPRS affect measures. No table presenting social and demographic characteristics of samples. Small sample size # of ACT sessions limited (3) and varied (determined by participants lengths of stay) as such protocol	**High** Due to high risk of selection, detection, and other bias.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
					who completed treatment, post-treatment data were missing for nine participants due to their unexpected discharge from the unit before completing the assessments. One participant later withdrew from the ACT condition and one from the ETAU condition. Therefore, post-treatment completer analyses were conducted on the remaining 15 participants in the ETAU condition and 14 participants in the ACT condition.' (p 424/425)		feasibility cannot be determined or overall effect reliably stated Outcome measures: some are self-raters and done in front of assessor who is also therapist – social desirability effect?	

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
Langer et al. (2011)	**Unclear** Randomly allocated, however procedure not described, hence uncertain how effective. 'Twenty-three patients meeting the above criteria were selected to participate; 12 were randomly assigned to the control group and the other 11 to the experimental group.' (p 2)	**Unclear** Insufficient information/not specified	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**Unclear** Insufficient information regarding procedure and effectiveness of blinding. 'clinician who conducted the assessment was blind to which group participants belonged, and independent of the MBCT therapist'. (p 3)	**High** High attrition rate from intervention (36%): Final sample consisted of 7 participants in the experimental group the control group. 'Two participants in the experimental group withdrew from the study. The first withdrew after the second session, saying he saw no benefit in the meditation. The second withdrew after the sixth session and, when contacted by telephone about his departure, remarked that he wanted a rest from El Timón (and therefore the group therapy	**High** Poor presentation of data. Outcomes are not stated explicitly at the beginning but then two of the used measures are not specifically reported on/included in discussion or conclusions.	**High** Very small sample, highly selective (both AG and JH) TAU not described No control of other variables, e.g. previous experience with mindfulness/PT treatment? No information about presenting problem, lengths or severity of illness etc.	**High**

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
					they provided). Two other patients attended the sessions irregularly, less than 50% of the time, and were therefore excluded from the post-treatment analysis. One participant in the control group did not wish to complete the questionnaires post-treatment.'(p 2)			
Perich et al. (2013)	**Low** 'Central randomization was conducted by an independent researcher who was not involved with the trial conducting the randomization process using a	**Low** 'Assignment of treatment condition was concealed until after the baseline assessment interviews were completed.' (p 336)	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**Unclear** 'Interview assessments of the YMRS and MADRS were conducted by an independent rater blind to the participant's treatment allocation. Any material that may	**High** Attrition rate high (38%) = significant amount of missing data 'Fourteen participants (29%) (including 10 drop outs; see Fig. 1) did not complete the	**Low** 'An intention-to-treat (ITT) analysis was conducted using the sample of 95 participants who had enrolled in the study at baseline. Survival curves and relapse rates were assessed using the	**Low** N/A	**High** Due to high attrition rate.

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	computer-generated randomization list. A block design was used for randomization sequencing with 16 participants in each block (eight per condition). The randomization sequence was created by a statistician not associated with the research study.' (p. 336)			have identified participant allocation was concealed.' (p. 336) However, no description of procedures utilised to protect the blind, report unblindings, or actions taken in the event of an unblinding.	MBCT condition requirements, and 22 (47%) (including 18 drop outs; see Fig. 1) did not complete TAU requirements'. (p. 338) Reasons stated: MBCT: travel restrictions, too symptomatic, personal commitments TAU: Dissatisfaction with allocation, too symptomatic, conflicting work and personal commitments.	Cox pro- portion hazard regressions model examining the time (weeks) to first recurrence during the 12-month follow-up period using number of prior bipolar disorder episodes as a covariate in the model.' For the dimensional analyses, a mixed linear model (MLM) using the restricted maximum likeli-hood estimator (REML) was fitted in PAWS (44). The MLM allowed all available data to be used without excluding missing data. Furthermore, the MLM did not require the imputation of any		

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
						data. The ITT analysis included an assessment of the primary and secondary outcome measures. Measurement points included pre-, mid-, and post-treatment and then 3-, 6-, 9-, and 12-month follow-up post-treatment.'		
Shawyer et al (2012)	**Low** 'Randomization was by variable length blocks. Sequences of fixed length blocks were generated using the first random generator at www.randomization.com. Switching between blocks was determined by an additional random sequence	**Low** 'Assignment of participants to conditions was undertaken by the study statistician who worked independently of staff involved in the recruitment, assessment and management of participants in the study.' (p 3)	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**Low** 'Considerable efforts were made to ensure that the blindness of raters was maintained. Offices, data storage and travel logs of raters and therapists were kept separate and clinical staff and participants were regularly reminded not to divulge	**Low** Low rates of incomplete outcome data. 'Attrition was low with only three participants withdrawing from the study. Two participants withdrew from Befriending after five and eight sessions	**Low** All outcomes reported that were relevant and reasons for omission given. 'Compliance with harmful command hallucinations did not prove viable as an outcome measure. Although 93% (40/43) of the sample had	**Low** Good control of treatment integrity: 'An audit of a random sample of 31 audiotaped therapy sessions was also undertaken by an independent auditor who was blind to all participant data and to the audiotape	**Low**

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
	generated by the same method. A similar procedure was used to generate assignments to treatments for participants initially assigned to the waitlist condition.' (p. 3)			details of their therapy to the raters. Raters were asked to classify participants into a treatment condition before and after each assessment and to indicate their level of confidence. All breaches in blindness were recorded and addressed by changing the rater wherever possible.' (p 3) 'Breaches in blindness occurred on 22 occasions across the 97 assessments where blindness was relevant. By changing the rater, corrective action was able to be taken in all but 5 of	respectively. Both participants reported that intrusions or commands from auditory hallucinations contributed to the decision to withdraw. One of these participants also felt that his paranoia worsened as a result of the social contact. The third participant withdrew from TORCH after three sessions due to gaining work interstate. In addition to these withdrawals, two participants received fewer than 15 sessions. One TORCH participant received 12 sessions and one	experienced harmful commands in the past, only 64% (25/39) of this group had ever complied and, at baseline, less than half the sample (18/43) had complied'. 'Our primary measures were therefore limited to confidence to resist obeying harmful commands and confidence in coping with commands'. (p 7) SHER outcomes omitted	randomization procedure. Tape randomisation was stratified according to therapist, therapy (TORCH or Befriending), stage of individual therapy (early: sessions 1e8; late: sessions 9e15) and therapist experience (early vs late case). To assess the quality of TORCH sessions and confirm that Befriending sessions did not include TORCH techniques, sessions were rated using an adaptation of the Cognitive Therapy Scale for Psychosis (CTS-Psy - Haddock et al., 2001). [ ] A clinical psychologist (NT) who was blind to	

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
				these situations.' (p 7) Note: Raters guessed allocation: no longer recommended as a method to ensure blindness.	Befriending participant received 9 sessions. It appeared that in both cases, difficult and chaotic personal circumstances reduced the motivation and ability to attend appointments.' (p 5)		participant data and audiotape selection procedure performed the ratings and assigned each session to either the TORCH or Befriending group. The tape auditor was very experienced in CBT for psychosis and familiar with ACT. In addition, he received approximately 7 h training on the measures and the TORCH and Befriending treatments.' (p 5)	
Van Dijk et al. (2013)	**Unclear** Randomized, using manual procedure/simple randomization	**Low** 'Once consent was obtained and baseline data collected from 26 patients, they were	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials	**Unclear** Not specifically stated It was implied, possibly:	**Unclear** Attrition rate stated: 7% (12 of 13 completed trial); 86% of sessions were attended.	**Low** All patients who were eligible to participate in the DBT group were randomized to	**High** Small sample size Group differences - Control group was more depressed.	**High** Due to 'unclear risk' for detection and attrition bias as well as high risk of other bias

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
		randomly assigned to intervention and control (wait-list) groups. Group assignments were placed in sealed envelopes by a hospital staff person who was not involved in the study. Study identification numbers were assigned and recorded on the master list, which was kept separate from consents and completed questionnaires to ensure that data would remain anonymous; and data were considered to be confidential.' (p 387)	assessing the effectiveness of psychological therapeutic interventions.	'Study identification numbers were assigned and recorded on the master list, which was kept separate from consents and completed questionnaires to ensure that data would remain anonymous; and data were considered to be confidential.' (p 387) 'Data were extracted by the group facilitator and entered into SPSS 17.0 by a researcher using study identification numbers; no identifying information was reviewed or	However: No reasons for either weren't stated; No CONSORT reported; No df for main analyses reported	enter the group immediately (intervention group) or to wait 12 weeks until the next group (wait-list control). In this way, all patients had the opportunity to participate in the group intervention. Given the small number of patients (13 assigned per group; 12 per group completed questionnaires and completed the study), secondary analysis was conducted using an additional 56 patients who completed the BDG (total n 1⁄4 75) to increase study power and allow for confirmation of the RCT results	'Randomization to intervention and control groups resulted in similar groups except for mean scores on the BDI-II (see Table 3). Subjects in the control group reported higher scores or greater depression compared to the intervention group t = -2.2, p = .038).' (p389) – however, this was controlled for (p 390)	

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
				entered by the researcher.' (p 387) But: who collected post-data? Not stated.				
White et al. (2011) ***Rated by JH only***	**Low** 'Once baseline assessments had been completed, participant details were passed to AG who undertook computerised randomisation using a predetermined schedule of permuted blocks of random size. The research therapist then communicated the outcome of randomisation to each participant schedule of permuted blocks of random size' (p 3)	**Low** Following randomization 'the research therapist then communicated the outcome of randomisation to each participant.' (p 3)	**Low** Rated as low due to lack of relevance of this criteria in this context given the nature of trials assessing the effectiveness of psychological therapeutic interventions.	**Low** 'Participants completed assessment measures with a Research Assistant.' 'Participants met with a researcher (JMcT, LR, and DMcC) on a monthly basis to complete the self-report general outcome and therapy-specific measures. The assessors were all blind to treatment allocation.' (p 3) 'Overall, blindness was breached on 9 occasions (n = 7 for	**Low** Total: 11% (ie 3 participants, all from TAU) – reasons not stated Attrition rate was low – acceptable amount outcome data available	**Low** No obvious omissions or selective reporting	**High** Small sample size No use of diagnostic interview Receipt of psychological intervention for some – not checked/controlled for	**Low** Small sample size is an issue, but acceptable as feasibility study

	Random sequence generation (selection bias)	**Allocation concealment** (selection bias)	**Blinding of participants and personnel** (performance bias)	**Blinding of outcome assessment** (detection bias)	**Incomplete outcome data** (attrition bias)	**Selective reporting** (reporting bias)	**Other bias**	**Overall risk**
				the ACT arm; n =2 for the TAU arm) during the trial. For all but two of these individuals, further follow-up assessments were completed by another researcher who remained blind to allocation.' (p 3)				

APPENDIX 2: – Major Research Project

Appendix 2.1: Guidelines for submission to *Qualitative Research Journal*

QUALITATIVE RESEARCH JOURNAL – Author guidelines

For full information see:
http://www.emeraldgrouppublishing.com/products/journals/author_guidelines.htm?id=qrj

Manuscript requirements

Please prepare your manuscript before submission, using the following guidelines:

Article Title	A title of not more than eight words should be provided.
Structured Abstract	Authors must supply a structured abstract on the **Article Title Page**, set out under 4-7 sub-headings Maximum is 250 words in total (including keywords and article classification, see below).
Headings	Headings must be concise, with a clear indication of the distinction between the hierarchy of headings. The preferred format is for first level headings to be presented in bold format and subsequent sub-headings to be presented in medium italics.
References	References to other publications must be in **Harvard** style and carefully checked for completeness, accuracy and consistency. This is very important in an electronic environment because it enables your readers to exploit the Reference Linking facility on the database and link back to the works you have cited through CrossRef.

Appendix 2.2: Evidence of Ethical Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 3
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Professor Andrew I Gumley
Professor of Psychological Therapy
University of Glasgow
Mental Health and Wellbeing
Academic Centre
Gartnavel Royal Hospital
Glasgow G12 0XH

Date 30 Jun. 11
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Professor Gumley

Study title: **Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis**

REC reference: **11/AL/0247**

Thank you for your letter of 17 June 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
GP/Consultant Information Sheets	1	12 April 2011
Interview Schedules/Topic Guides	1	12 April 2011
Investigator CV		
Other: Letter from Funder		26 January 2011
Participant Consent Form	1	12 April 2011
Participant Consent Form: Carer	2	17 June 2011
Participant Information Sheet	2	17 June 2011
Participant Information Sheet: Carer	2	17 June 2011
Protocol	2	17 June 2011
Questionnaire: Clinician Rating of Alcohol Use Disorder		
Questionnaire: Drug Use Questionnaire		
Questionnaire: Clinician Rating of Drug Use Disorder		
Questionnaire: Service Engagement Scale		
Questionnaire: Service Attachment Questionnaire		
Questionnaire: The Process of Recovery Questionnaire		
Questionnaire: Experience of Care Giving Inventory		
Questionnaire: The Alcohol Use Disorders Identification Test		
REC application		14 April 2011
Referees or other scientific critique report		19 August 2010
Response to Request for Further Information		17 June 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

Notifying substantial amendments
Adding new sites and investigators
Progress and safety reports
Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/AL/0247	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Liz Jamieson

Liz Jamieson
Committee Co-ordinator
On behalf of Eoin MacGillivray, Vice Chair

Enclosures: List of names and professions of members who were involved in the review
"After ethical review – guidance for researchers"

Copy to: Dr Erica Packard, NHS Greater Glasgow and Clyde

West of Scotland REC 3

Attendance at Sub-Committee of the REC meeting on 28 June 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Bernadette Campbell	Primary Care Support Nurse	Yes	
Mr Eoin MacGillivray	Lay Member - Vice Chair	Yes	
Dr Angus McFadyen	Reader in Health Statistics	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Liz Jamieson	Committee Co-ordinator

Appendix 2.3: Evidence of R&D Management Approval

Coordinator/Administrator: Dr Erica Packard/Ms Elaine O'Donnell
Telephone Number: 0141 211 6208
E-Mail: erica.packard@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

3 August 2011

Dr Ian Kevan
ESTEEM North East
21-23 Hydepark Business Centre
60 Mollinsburn Street
Glasgow
G21 4SF

NHS GG&C Board Approval

Dear Dr Kevan,

Study Title:	**Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis.**
Principal Investigator:	**Dr Ian Kevan**
GG&C HB site	**ESTEEM North East**
Sponsor	**NHS Greater Glasgow and Clyde**
R&D reference:	**GN11CP130**
REC reference:	**11/AL/0247**
Protocol no: (including version and date)	**V2; 17/06/11**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

NHS
Greater Glasgow and Clyde

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

EPackard

Dr Erica Packard
Research Co-ordinator

Cc Prof Andrew Gumley

Coordinator/Administrator: Dr Erica Packard/Ms Elaine O'Donnell
Telephone Number: 0141 211 6208
E-Mail: erica.packard@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

3 August 2011

Dr Kathryn Sowerbutts
ESTEEM North West
21-23 Hydepark Business Centre
60 Mollinsburn Street
Glasgow
G21 4SF

NHS GG&C Board Approval

Dear Dr Sowerbutts,

Study Title:	**Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis.**
Principal Investigator:	**Dr Kathryn Sowerbutts**
GG&C HB site	**ESTEEM North West**
Sponsor	**NHS Greater Glasgow and Clyde**
R&D reference:	**GN11CP130**
REC reference:	**11/AL/0247**
Protocol no: (including version and date)	**V2; 17/06/11**

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NHS
Greater Glasgow and Clyde

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Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

EPackard

Dr Erica Packard
Research Co-ordinator

Cc Prof Andrew Gumley

Coordinator/Administrator: Dr Erica Packard/Ms Elaine O'Donnell
Telephone Number: 0141 211 6208
E-Mail: erica.packard@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

3 August 2011

Mr Gerry McKelvie
ESTEEM South
150 Brand Street
Glasgow
G51 1DH

NHS GG&C Board Approval

Dear Mr McKelvie,

Study Title:	**Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis.**
Principal Investigator:	**Mr Gerry McKelvie**
GG&C HB site	**ESTEEM South**
Sponsor	**NHS Greater Glasgow and Clyde**
R&D reference:	**GN11CP130**
REC reference:	**11/AL/0247**
Protocol no: (including version and date)	**V2; 17/06/11**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

NHS
Greater Glasgow and Clyde

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Packard

Dr Erica Packard
Research Co-ordinator

Cc Prof Andrew Gumley

Appendix 2.4: Participant Information Sheet and Consent Forms

Appendix 2.4.1: Staff Participant Information Sheet

Compassionate Recovery: Individualised Support in Early Psychosis (CRISP)

Participant Information Sheet (Clinical Staff: Version 1, 23rd July 2012)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with others if you wish. We advise that you take at least 24 hours to decide whether to take part in the study.

What is the research about?

This study will attempt to explore the experience that staff have had in the implementation of formulation as part of an Integrated Care Pathway.

Who is being asked to take part?

Clinical staff working within Esteem First Episode Psychosis Service will be invited to take part.

Why have I been asked to take part?

You have been asked to take part because you are currently working within Esteem First Episode Psychosis Service and have direct clinical experience of using Compassion Focussed Recovery interventions.

Do I have to take part?

No. Taking part is entirely up to you. If you do participate you are free to terminate involvement at any time without giving a reason and without your decision impacting in any way with the research team or your employer.

What would be involved?

You will be asked to sign a consent form prior to taking part in the study and will be provided with a copy of this. You would then arrange to meet with the research nurse on an individual basis at a venue of your choice.

Next two semi-structured interviews exploring your experiences will be conducted. These will last for approximately 45minutes to one hour each. There is flexibility in the content of the semi-structured interview so that you can discuss issues of particular relevance to you.

Interviews will be audio recorded, transcribed into print and then analysed by the research team. You will receive a copy of the transcription and of the researchers' analysis of the interview so that you will be able to provide verbal and/or written comments on this.

Will I be identifiable in the transcription discussion or in any verbal or written report?

No. You will not be personally identifiable in the typed transcription (you will be given a pseudonym) or in any subsequent written account. The audio recordings will not be heard by anyone other than the transcribers and University of Glasgow research staff. All audio recordings will be stored securely in locked premises and on password protected computers. Audio recordings will be destroyed following transcription of the study.

Are there any risks or benefits to taking part?

The study is attempting to evaluate the impact of introducing formulation within an Integrated Care Pathway from a staff perspective. We hope that the information you provide will help us to improve the experience for staff and inform us about any changes that may be required for the future.

There is not anticipated to be any adverse effects from participating in this research.

What will happen to the results of the study?

Once the study is completed we will produce a report that will describe the findings of the study. We will aim to disseminate the report to professionals by submitting the report for publication in professional and academic journals. We will also present the findings to Esteem First Episode Psychosis Service staff through a feedback event.

Who is organising and funding the research?

The University of Glasgow and NHS Greater Glasgow & Clyde will organise the research. Funding is already in place provided by the Scottish Government's Chief Scientist Office.

Who has reviewed the study?

The study has been reviewed by the University of Glasgow to ensure that it meets standards of scientific conduct. It has also been reviewed by the Chief Scientist Office to determine whether it was suitable to receive Scottish Government funding. The West of Scotland Research Ethics Committee 3 has also reviewed the study to ensure that it meets standards of ethical conduct.

Can I speak to someone who is independent of the study?

Yes you can. Professor Tom McMillan who is not involved in the study can answer questions or give advice. His telephone number is 0141 211 3920.

What if I want to make a complaint?

If you want to make a complaint about any aspect of this study, please contact:

Professor Andrew Gumley

Mental Health & Wellbeing
University of Glasgow
Admin Building
Gartnavel Royal Hospital,
1055 Great Western Road
Glasgow G12 0XH

0141-211-3927

Appendix 2.4.2: Staff Participant Consent Form

Staff Participant Identification Number: _____

Staff Participant Consent Form (Version 1, 23/07/2012)

Title of Project: Compassionate Recovery: Individualised Support in Early Psychosis (CR: ISP)

Box		Please Initial
1.	I confirm that I have read and understand the information sheet dated..... (version 1, 23/07/2012) for the above study. I have had the opportunity to consider the, information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without any effect on my employment.	☐
3.	I agree to take part in a qualitative interview exploring my experiences of formulation as part of an Integrated Care Pathway.	☐
4.	I agree that this interview can be audio recorded and transcribed.	☐
5.	I agree to review my completed transcription report and provide comments as appropriate to the research team so that any amendments can be made.	☐
6.	I agree to my transcribed data being stored for up to 5 years and used for further data analysis.	☐

_____	_____	_____
Name of Staff Participant	Date	Signature
----------	----------	----------
Name of research staff taking consent.	Date	Signature

When completed, 1 for participant; Original to be retained in research site file;

Appendix 2.4.3: Service-user participant information sheet

Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP)

Contact:
Professor Andrew Gumley
Academic Unit of Mental Health and Wellbeing,
University of Glasgow,
Gartnavel Royal Hospital,
Academic Centre,
University of Glasgow,
Glasgow G12 0XH
0141 211 3927

Participant Information Sheet (Version 2, 17th June 2011)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. We advise that you take at least 24 hours to decide whether to take part in the study.

What is the research about?

In an earlier study of recovery amongst service users of the ESTEEM First Episode Psychosis Service we found that many service users experience a very large improvement in their mood (e.g. feeling depressed) and their symptoms (e.g. hearing voices and feeling suspicious and paranoid). This occurred within six months of contact with our service. We found that a smaller proportion of service users experienced some delay in their recovery and this was reflected in problems such as being withdrawn from others, not having pleasure from activities and finding day to day tasks a problem. We discovered that one important potential cause of this delay in recovery was a poorer quality of relationship between the service user and the service.

We want to improve outcome for all our service users and therefore we are implementing an Integrated Care Pathway to ensure that your needs are routinely and carefully assessed regularly throughout your journey of recovery after your first contact with ESTEEM. Our Integrated Care Pathway has been designed to ensure that we regularly assess your symptoms (e.g. hearing voices, feeling suspicious etc), your mood (feeling depressed), your use of alcohol and drugs, the quality of your recovery (how you feel about your recovery in terms of valued activities and relationships) and the quality of your relationship with the service. These assessments ensure that we can work with you to get the right combination of help for you, in a way that is tailored to you at the most appropriate time in your journey of recovery.

Who is being asked to take part?

We are asking all service users who are supported by ESTEEM to consent to take part in this study.

Why have I been asked to take part?

You have been asked to take part because you are being currently supported by the ESTEEM First Episode Psychosis Service.

Do I have to take part?

Do I need to take part?

No. Taking part is entirely up to you. If you do not wish to take part it will not affect any treatment that you currently receive. Also, if you do decide to take part, you are able to change your mind and withdraw from the study at any time without it affecting your care either now or in the future.

What will happen next if I want to take part?

If you decide to take part in the study after reading this information sheet and after you have your questions answered by the researcher, the researcher will confirm that you wish to take part and arrange to complete a consent form. We are going to ask you to consent to three things.

1. You will be asked to consent to the research team using data taken from routinely collected assessments, which are conducted as part of the ESTEEM Integrated Care Pathway. This will involve our researcher having access to your casenotes.

2. You will be asked to consent to being approached to participate in an interview exploring your experiences of recovery. This is an optional aspect of the research. The interview will last about an hour and will explore your experiences of recovery and your experiences of the ESTEEM service.

Since the interview will explore your experiences of recovery it will therefore cover events and feelings that are potentially emotionally upsetting. You do not have to talk about these experiences if you do not want to. Participation in this aspect of the study is optional.

The interview will be recorded and transcribed. After your interview has been transcribed we will destroy the recording and ensure that any personal details contained within the transcription of the interview will be removed. We will use quotations in subsequent reports and publications but it will not be possible to identify you through these.

3. You will be asked your consent to approach a person (e.g. family member) who is most closely involved in supporting you on a day to day basis in your recovery. We are keen to explore their experiences of supporting you and their experiences of the ESTEEM service. Participation in this aspect of the study is optional.

Are there any risks or benefits to taking part?

The study is evaluating the impact of introducing an Integrated Care Pathway to improve outcomes for all service users who are seen by the ESTEEM service. We hope that the research will be of benefit to you by improving the service you receive. There is a possibility that talking about some of these issues in the interview may be emotionally upsetting.

What about confidentiality?

Yes. The information you provide us with will be treated confidentially. All recordings and transcriptions will be stored on a password-protected computer. Your name and any information that could identify you will not appear in any reports. With permission from you, your GP will be informed that you are taking part in the study.

If you share information that makes the research team concerned for your safety or the safety of other people, we may be required to tell others involved in your care (e.g. your key-worker or psychiatrist). We will always notify you beforehand if we are going to do this, and explain why.

What will happen to the results of the study?

Once the study is completed we will produce a report that will describe the findings of the study. You will not be identified in any report or publication. The report will not include any personal details of the people who took part; it will only describe what happened to the groups of people who received different types of treatment.

Who is organising and funding the research?

The University of Glasgow and NHS Greater Glasgow & Clyde will organise the research. The Scottish Government's Chief Scientist Office will fund the study.

Who has reviewed the study?

The study has been reviewed by the University of Glasgow to ensure that it meets standards of scientific conduct. It has also been reviewed by the Chief Scientist Office to determine whether it was suitable to receive Scottish Government funding. West of Scotland Research Ethics Committee 3 has also reviewed the study to ensure that it meets standards of ethical conduct.

Can I speak to someone who is independent of the study?

Yes you can. Professor Tom McMillan who is not involved in the study can answer questions or give advice. His telephone number is 0141 211 3920.

What if I want to make a complaint?

If you want to complain about any aspect of this study, please contact:

Professor Andrew Gumley
Academic Unit of Mental Health and Wellbeing,
University of Glasgow,
Gartnavel Royal Hospital,
Academic Centre,
University of Glasgow,
Glasgow G12 0XH
0141 211 3927

The NHS complaints system is also available at 0141 201 4500.

Thank you.

Appendix 2.4.4: Service-user participant consent form

PARTICIPANT CONSENT FORM (Version 2: 17th June 2011)

Title of Study: **Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP)**

Contact Address: *Academic Unit of Mental Health and Wellbeing, Academic Centre, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH*

Please Initial Box

1. I confirm that I have read and understood the information sheet about the study dated 17/06/11 (Version 2) ☐

2. I confirm that I have had an opportunity to consider the information, ask questions about the study, and have had these answered satisfactorily. ☐

3. I understand that my participation in the study is voluntary and that I am free to withdraw from the study at any time, without giving any reason, and without my medical care or legal rights being affected. ☐

The following items are core: If you do not consent to all of these, then we regret we cannot include you in the study. I consent to:

4. I give consent for the research team to have access to my case notes, solely for the purposes of the research study described in the Participant Information Sheet dated 17/06/11 (Version 2) ☐

5. Having the information that I provide as part of my routine care stored on a confidential electronic database, to which investigators and responsible individuals from the research team and representatives of the Sponsor (NHS Greater Glasgow & Clyde) will have access (with the proper approvals) for research and quality assurance purposes. ☐

The following items are optional. You can take part even if you do not consent to these. I consent to:

5. Taking part in a qualitative interview exploring my experiences of recovery and of the ESTEEM service ☐

6. That this interview will be recorded and transcribed. Following transcription the original recording will be destroyed and all personal data removed from the transcription ☐

7. I understand that it may be difficult or upsetting to talk about my experience of recovery, and that I will have access to professional support if this is required. ☐

8. That a member of the research team can contact the person most involved in supporting me on a day to day basis named ……..[INSERT NAME HERE] ☐

9. I agree for my GP to be informed of my participation in the above study. ☐

10. Being contacted in the future by a member of the CR:ISP team to discuss possible participation in further research arising from this study. I affirm that this will not commit me in any way to taking part in further research. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed, original to be kept in case notes. Copies for participant and researcher file.

Thank you for taking part in the study.

Appendix 2.5: Interview Schedules

2.5.1. Interview schedule Phase 1 – Clinical Psychologists

Preamble:
Thank you very much for taking the time to meet with me today. As you know I'm interested to explore with you, your experiences of multidisciplinary (MDT) case formulation in the context of the ESTEEM service. I will be particularly interested to explore your experiences in developing case formulation, the benefits of this and the challenges this creates for your role in the service. As part of the qualitative interview process I will be digitally recording this interview in order for me to transcribe it later. Any information pertaining to you such as your name or the names of others will be fully annonymised at this stage. I will use quotations to illustrate important themes emerging in the research but you will not be identifiable through them in any reports or publications. The interview will take around 45 minutes but should you wish to stop for any reason or take a break please do not hesitate to let me know.

Have you any questions before we begin?

1. Tell me about your role in the service?

2. Tell me about your experience using case formulation with the clinical team?

   Probe: - Team-based formulation (5 P's; Compassionate Reformulation)
   - Working with individual member of staff

3. What have been the strengths of MDT formulation?

4. What have been the challenges of MDT formulation?

5. How do you see MDT formulation develop over time?

Example Probe, follow-up questions:

a) Can you give me an example of that?
b) Can you describe the situation?
c) How did you deal with that?
d) How did others respond?
e) What was the outcome?

2.5.2. Interview schedule Phase 2 - non-psychology MDT staff

Preamble

Thank you very much for taking the time to meet with me today. As you know I'm interested to explore with you, your experiences of multidisciplinary (MDT) case formulation in the context of the ESTEEM service. I will be particularly interested to explore your experiences in developing case formulation within the team, and your view of case formulation more generally, with regards to benefits of this and the challenges it creates for your role in the service. As I said, I'm interested in your experience with and view of case formulation not your knowledge of it.

Any information that you are sharing with me is confidential and will only be shared with people directly involved in this research project. As part of the qualitative interview process I will be digitally recording this interview in order for me to transcribe it later. Any information pertaining to you, such as your name or the names of others, will be fully anonymised at this stage. I will use quotations to illustrate important themes emerging in the research but you will not be identifiable through them in any reports or publications. The recording will be deleted once the study is completed.

The interview usually takes around 45 minutes but should you wish to stop for any reason or take a break at any point please do not hesitate to let me know. How much time do you have available today? Have you got any questions before we begin?

1. Tell me about yourself.

   Probe:

   - Job
   - Length of time in the service

2. Tell me about your experiences of case formulation within the service.

   Probe:

   - Doing a formulation of one of your cases.
   - Taking part in formulating other keyworker's cases.

3. How is formulation helpful?

   Probe:

   - What does it do?
   - In what way?
   - What facilitates helpful formulation?

4. Can formulation be unhelpful?

   Probe:

   - What hinders the process of formulation?

5. How do you see your role in formulation?

6. What suggestions do you have about doing case formulations in teams in the future?

2.5.3. Interview schedule Phase 3 - Service-users

Preamble

Thank you very much for being one of the people that have agreed to meet with me for this part of the study. Thank you for taking the time! As you know, I'm from the University of Glasgow and I'm interested to hear about your experiences with the Esteem service. I will be particularly interested to explore with you your experiences of the care and support you received/are receiving. It is not about you rating the service, but telling me about your experiences with it. Everything that you tell me is confidential and will not be shared with anyone outside the research team. It will not be fed back to the service and/or individual staff members at Esteem. Have you got any concerns about this?

As part of the qualitative interview process I will be digitally recording this interview in order for me to transcribe it later. Any information pertaining to you such as your name or the names of others will be fully anonymised at this stage. I will use quotations to illustrate important themes emerging in the research but you will not be identifiable through them in any reports or publications. This recording will be deleted once the study is completed. Is that ok with you?

The interview takes around 45 minutes but should you wish to stop for any reason or take a break at any point please do not hesitate to let me know. How are you doing today? Do you think you'll be ok with 45 minutes? How much time do you have available today? Have you any questions before we begin?

1. **Can you tell me a little bit about yourself?**
    - When were you first seen by ESTEEM?
    - Who do you see and how often?

2. **Can you tell me about the help you receive from ESTEEM?**
    - What kinds of difficulties have you sought help for?
    - What has changed for you over time? / What has gotten better for you over time?

3. **How would you describe your relationship with Esteem?**
    - What support do you receive?
    - With whom do you work?
    - Do you feel you're working together?
    - Do you agree about what help/support/assistance or care plan is needed and what is currently in place/currently being done?

4. **Do you have any suggestions to give to the service?**

Appendix 2.6: Major Research Project Proposal

Major Research Project Proposal

Title

Shared understanding – Exploring experiences of case formulation from multiple perspectives within the context of an early intervention service

Abstract

Case formulation is seen as central to psychological interventions by a range of professionals, and its use supported by good-practice guidelines (e.g. British Psychological Society, 2010). Increasingly, multidisciplinary teams (MDT) are adopting a formulation-based approach to allow for more consistent and effective care. However, the research evidence-base for formulation is limited. There have been some qualitative studies exploring the use of formulation within teams by interviewing members of staff. However, the process of developing formulations is complex, requiring collaboration between staff, service-users and family members. The overall aim of this study therefore is to explore experiences of case formulation from various perspectives in the context of an early intervention service. It is proposed that grounded theory would allow for the flexibility and openness needed to explore individual's experiences in depth, while bringing everyone's views together within theory emerging. Taking a staged approach, interviews would be conducted with clinical psychologists, psychiatrists, mental health staff, service-users and families. Constant comparison between the data sets and active involvement of a local steering group is hoped to enhance methodological credibility and sensitivity to context. This study would have the potential to increase understanding of the value of team formulation to improve outcomes for service-users.

Introduction

Formulation has been recognized as central to the implementation of psychological interventions since the emergence of the scientist-practitioner model in the 1960s (Butler, 1998). It is a skill increasingly valued by a range of professionals within psychiatry, psychology, psychotherapy and counselling. Definitions of 'formulation' vary to some degree, depending on professional background and therapeutic approach. In short, it can be summarized as a 'hypothesis about a person's difficulties, which draws from psychological theory' (Johnstone & Dallos, 2006). Eells (2007) defined formulation as 'a way of making sense of an individual's psychological, interpersonal, emotional and behavioural

difficulties by examining and linking a broad range of biopsychosocial influences, drawing from empirical evidence and theory, and considering causes, precipitants and maintaining factors'. This then allows for a more tailored, individualized approach to treatment as opposed to a standardized one based on diagnostic categories (Aston, 2009). It has been argued that a good formulation not only enhances the understanding of an individual's current difficulties, but also helps predict potential challenges to intervention, for example by facilitating understanding service-users' ability to build and maintain therapeutic alliances and engage with services (Sturmey, 2009). In practice, formulation is an on-going process that arises from assessment and collaboration with service-users and teams. It is important for practitioners to be reflective throughout this process and to ensure that the developing formulation is an accurate and meaningful account of the service-user's problem (Division of Clinical Psychology, DCP, 2011). Various professional bodies have identified psychological case formulation as a core professional competency for Clinical Psychologists (e.g. Health Professions Council, 2009; British Psychological Society, 2010; Division of Clinical Psychology, 2010).

Increasingly, formulation is being used in teams, both in the community and inpatient settings. Good-practice guidelines support this trend by recommending a formulation-based approach in multidisciplinary teams (MDT), with clinical psychologists taking an active role in promoting and facilitating this (DCP, 2011). Team formulation can enable shared understanding of an individual's difficulties and resources for effective change, thereby allowing for a consistent, more effective team approach to intervention (Oynett, 2007, in Christofides et al., 2011). For example, consideration of an individual's attachment style can facilitate understanding of his or her help seeking style and ability to engage with services (Gumley et al., 2010). Incorporating this into a formulation can help teams to respond in a way that prevents disengagement, thus better support recovery. In addition, shared formulation can help team members to feel supported and contained, and can be invaluable for addressing and overcoming difficulties when working with complex and/or challenging cases (DCP, 2011).

Despite the established use of formulation within psychological therapies, its promotion by professional bodies, and a general view of its benefits in MDT, the research evidence-base surrounding formulation is limited. This is both in terms of promoting shared understanding of service-users within teams as well as outcomes for the individual

(Johnstone & Dallos, 2006). The available evidence regarding individual use of formulation is inconclusive, and for use of formulation within MDT almost non-existent (Christofides et al., 2011).

With regards to individual therapy, a few studies have compared manualized with individualised, formulation-driven therapeutic approaches in an attempt to determine the benefits of using formulation. For example, Jacobsen et al. (1989) compared manualized with individualised formats of behaviour therapy for couples and found a slightly better maintenance of improvements after six-months in the individualised group. Contrarily, other studies have found a superior effect of manualized approaches over individualised ones (e.g. Schulte et al., 1992; Emmelkamp et al., 1994). However, a weakness of these studies may be that internal processes of the therapists involved were not explored (Jacobsen et al., 1989). That is, experienced therapists may inadvertently have used formulation, even in the manualized intervention group. Chadwick et al. (2003) aimed to assess the impact of case formulation as part of CBT treatment of anxiety and depression in psychosis. For this purpose, measures of distress were compared pre- and post-formulation-sharing, and therapists and service-users' views of this process explored within semi-structured interviews. No significant effect was found with regards to levels of distress, and the qualitative data indicated mixed feelings about the usefulness of formulation in service-users, but positive ones in therapists. Interestingly, therapeutic alliance was rated to be affected positively by therapists but not by service-users. A subsequent study by Morberg Pain et al. (2008) highlighted the complexity around service-users' experience of formulation, with some exhibiting positive and others negative emotional reactions to the formulation process. These studies highlight some interesting aspects regarding experiences of formulation-sharing, e.g. possible differences in value of it for therapists and service-users. However, both studies treated case formulation as intervention per se, rather than viewing it as part of the essential pre-treatment stage. Yet, Dunn et al. (2011), investigating the effectiveness of CBT for psychosis (CBT-P) by assessing its component parts, concluded that only full therapy (consisting of assessment, formulation and active change methods in CBT-P) appears to lead to significant benefit and change for the service-user, not assessment and formulation (i.e. partial therapy) by itself.

Studies addressing use of formulation within MDT have tended to evaluate its benefits and limitations by exploring staff perspectives. For example, Summers (2006) interviewed 25

staff of different disciplines (including psychiatrists, nurses, support workers and therapists), all working within the same team providing care for patients with severe mental illness on a ward of a high-dependency rehabilitation service. The results indicated that staff viewed formulations as valuable, helping them to gain a better understanding of their patients, which led to better care planning, staff-patient relationships, staff satisfaction and team working. Psychologists' views were not obtained in this study. In another qualitative study, Christofides et al. (2011) interviewed 10 clinical psychologists about their experiences of using formulation within MDT and found similar results. Clinical psychologists felt that shared formulation allowed for more consistent and coordinated care and promoted reflectiveness and active peer support within teams.

Overall, these studies offer valuable insight into staff perspectives about using formulation within MDT. Yet, they explore one particular point of view only, either that of staff more generally, or clinical psychologists more specifically. However, the process of formulation within MDT should be embedded in communication and interaction between staff of various disciplines, service-users and, if relevant, family/carers. Team formulation develops dynamically within the discourse taking place between these individuals and may be experienced differently from different perspectives. As such, exploring team formulation from only one perspective makes it difficult to fully grasp the complexity and benefits of this process overall, and to understand its value for the people involved in it individually. It therefore is difficult to draw conclusions about the value of MDT formulation overall. It appears that a comprehensive exploration of the process of team formulation requires the use of a methodological approach that actively promotes triangulation, thus allowing for the exploration of the perspectives of everyone involved in the process in a dynamic and flexible way.

Point of departure

The point of departure for the current study is to explore experiences of formulation from multiple perspectives including clinical psychologists, other mental health staff, service-users and families in the context of an early intervention service. Given clinical psychologists' active role in facilitating and guiding the process of team formulation this appears to be the most logical departure point for this type of exploration. From there, a stepped approach to qualitative enquiry will be taken that allows for the involvement of other key staff members, service-users and carers in a top-down, but dynamic and flexible

fashion. This in turn will allow for triangulation and the emergence of theory in a bottom-up fashion, giving insight into the role of formulation in planning and organising MDT care.

Method

Grounded Theory methodology

Grounded Theory (GT) is a qualitative method widely used. It may be defined as 'the discovery of theory from data systematically obtained from social research' (Glaser and Strauss 1967: 2). It allows for the discovery of meaning and underlying processes of a phenomenon by interpretatively considering each individual's perspective. Given the subject of study, and consistent with previous qualitative work in recovery after psychosis (Boyd & Gumley, 2007; Svanberg, Gumley & Wilson, 2010), the use of a social construction version of GT (Charmaz, 2003) appears to be the most suitable methodology for exploring the topic of interest. This version has its roots in 'social interactionism' (Mead, 1934), which assumes that it is the meanings people give to situations which determine human behaviour. These meanings are influenced by history, culture and language, and actively constructed within social interactions, mediated by an interpretive process used by each person. Hence, meaning is to be viewed as a constructed process. As a result, GT arises from the interaction between researcher and participants – it is actively constructed, rather than representing an objective reality. The existence of a unidimensional external reality is not assumed (Charmaz 2000).

To increase methodological rigour, credibility and utility, criteria for improving the quality of qualitative research would be considered in the design and implementation of the qualitative study (Walsh & Downe, 2006).

Participants

In order to meaningfully explore the aim stated above, it is proposed for the project to purposively sample clinical psychologists, key staff members (including psychiatrists, nursing staff, occupational therapists and support workers), service-users and their family members and/or carers. These will be recruited from the ESTEEM First Episode Psychosis Service in Glasgow, a service where MDT case formulation is central to clinical practice. Given the research approach, sample size need not be determined. Rather, data collection will continue until saturation of the topics emerging from the interviews, as required by a

GT approach, is reached. Inclusion criteria will require that all participants are or have been involved with ESTEEM, and are able to consent to and participate in the study.

Sensitivity to context

Relevant literature on use of MDT formulation will be reviewed in depth before commencing data collection, which will allow identifying gaps in knowledge. In line with the proposed methodology of GT, reviewed literature is not to form the basis of an emerging theory, but rather will serve as a guide for developing initial interview questions. Open discourse will be encouraged during the initial interviews to gain insight into participants perspective of using formulation for planning and organising care. A stepped/phased approach of data collection will ensure that interview questions remain flexible and are adapted to evolving theory. Such an approach further will allow the exploration of different perspectives from different groups, facilitating triangulation (see below).

It is hoped that the project can be supported and actively guided by the existing Principal Investigators Steering Group (PI Steering Group), providing advice and feedback in terms of practical concerns and data analysis (e.g. the development of the semi-structured interview). This group is responsible for oversight and management of a wider CSO funded study of implementation of a novel Integrated Care Pathway for early psychosis (CZH/3/5, Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis) and has been granted ethical approval (11/AL/0247) and managerial approval. Liaising with the PI Steering Group is hoped to ensure the project fits in with the social context it is meant to take place in, for example by advising on how to best go about interviewing the different participant groups.

Health & Safety Issues (Researcher/Participant)

Participants will be interviewed in clinic settings within an NHS service (i.e. ESTEEM). As such, existing local health and safety guidelines and procedures will be followed at all times to ensure participants' and researcher's wellbeing. Furthermore, staff on site (that know participants and researcher well) will be available for debriefing, emotional support and advice as required. Every attempt will be made to identify and minimise risk before and while participants are being interviewed. Refer to Health & Safety Form (Appendix 1) for more details.

Ethical Issues

The project is part of a wider funded study (CSO, Compassionate Recovery: Individualised Support in early Psychosis (CR:ISP) Implementing improvement strategies based on an Integrated Care Pathway for Early Psychosis: CZH/3/5, Appendix 2) and has received ethical approval (11/AL/0247, Appendix 3) including the qualitative component described in this proposal. The protocol for this study is attached to demonstrate that this proposal builds significantly on the original description of the qualitative component (Appendix 4). We will inform the sponsor of the study (Dr Erica Packard, NHS Greater Glasgow & Clyde) of the interview development at each stage of the project and based on their advice we will apply any amendments to ethics as appropriate.

Participation, as per Research Ethics and R&D approval, will be voluntary and informed. Informed consent will be obtained of all participants (see Information sheets and Consent Forms, Appendices 5, 6 and 7). Recruitment will be sensitive to avoid coercion. All data, verbal and written, will be treated in accordance with NHS Greater Glasgow & Clyde guidelines on data protection. Service-user and carer participants have already provided informed consent and have been advised about the potential use of anonymous quotations within the written report as well as the boundaries of confidentiality, determined by duty of care (refer to Appendix 6 and 7). Refer to Health & Safety form (Appendix 1) for more details.

Procedure

Data collection and analysis

As outlined above, it is proposed for the data collection to proceed in four stages (or phases), whereby data analysis will follow each phase and inform the interview questions for the next phase (or group of participants). As such, the emerging theory will unfold dynamically and flexibly out of triangulation between the different data sets, thereby staying true to the spirit of GT. The following way of proceeding is proposed:

Phase 1:

Development of semi-structured interview questions (with guidance from steering group and supervisors). The researcher will then go on to conduct in-depth qualitative interviews with clinical psychologists, exploring experiences of formulation and reformulation. A particular focus on the role of case formulation in planning care, impact on psychologists

practice and on team practice may be a useful way to structure these interviews (See Appendix 8 for initial interview).Following transcription and qualitative analysis of the collected data, the results (i.e. emerging themes) are used to modify and inform the content and structure of the phase 2 interview, in collaboration with members of the existing PI Steering group.

Phase 2

In-depth interviews will be conducted with a purposive sample of staff exploring experiences of formulation and reformulation. A particular focus on the role of formulation in planning care and the impact on team and clinical practice may be a useful way to structure these interviews, however the outcome of the phase 1 analysis will be predominant in determining the content of the phase 2 interview.

Following transcription and qualitative analysis of the collected data, the results (i.e. emerging themes) are used to modify and inform the content and structure of the phase 3 interview (based on phase 1 and 2 analyses), in collaboration with members of the existing PI Steering group.

Phase 3

In-depth interviews will be conducted with a purposive sample of service-user participants who have already given informed consent (See Appendix 6 for Participant Information Sheet and Consent Form). The content of the interviews will have arisen from phase 1 and phase 2 analyses, but a particular focus on exploring experiences of recovery is suggested.

Following transcription and qualitative analysis of the collected data, the results (i.e. emerging themes) are used to modify and inform the content and structure of the phase 4 interview (based on phase 1, 2 and 3), in collaboration with members of the existing PI Steering group.

Phase 4

In-depth interviews will be conducted with family members/carers (See Appendix 7 for Participant Information Sheet and Consent Form). Interview contents and structure with be informed by phases 1, 2 and 3, but a particular focus on exploring experiences of recovery is suggested.

Data Analysis

Following the principles of GT, the data analysis will start with line-by-line coding and the more significant and frequent codes emerging from this process are extracted. The use of constant comparative methods and memos written throughout the interpretative process will guide further theoretical sampling and help to raise the codes to conceptual categories. When categories are deemed to be coping adequately with new data, without requiring continual revision and when no new relationships or codes are emerging from the data analysis, the process of theory generation will have met 'theoretical sufficiency' (Dey, 1999). The triangulation of the different views of service users, carers and professionals will be used to develop a more comprehensive understanding of the role of formulation within MDT through methods of constant comparison rather than as a measure of internal validity (Mays & Pope, 2000). GT will then be constructed as a synthesis of categories, memos and relationships between concepts noted in the process of data analysis.

Settings and Equipment

A suitable setting for data collection to take place may be at ESTEEM. Digital recording equipment will be used to record the interviews. An encrypted laptop will be used for transcription and storage of collected data.

Financial Issues

Equipment needed (digital recorder, foot pedal, and encrypted lap top) will be requested for borrowing from department. Photocopying and printing (including white paper) will come at an estimated cost of £ 19.75. Refer to Equipment & Cost Form (Appendix 9).

Timetable

1.	Finalise initial interview protocol	April 2013
2.	Clinical Psychology Interviews	May – June 2013
3.	Mental Health Staff Interviews	August – October 2013
4.	User and Carer interviews	January – February 2014
5.	Final data analysis	March – April 2014
6.	Final draft of report	June 2014

Practical Applications

Exploration of using team formulation is hoped to yield valuable insight into its effectiveness and value to improve outcomes for difficult to engage service-users within the context of an early intervention service for first episode psychosis. It may give important indicators on how to optimize the delivery of this approach there. Furthermore, the outcomes can inform the development of theory to promote dissemination of this approach to other services and also enable the development of a training package to help mental health staff, service users and families work together to develop service models that enable individualised and collaborative care planning. On a wider scale, it can provide additional support and help advance the evidence-base for use of formulation within teams.

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Appendix 2.7: – Plain English summary

Title

Constructing shared understanding - A grounded theory exploration of team case formulation from multiple perspectives

Background

Case formulation (CF) is a way of making sense of a person's current problems based on an individualised understanding of their sources of strength and resilience, development, life history, relationships, coping, current social and cultural context. CF is central to planning psychological therapies. Increasingly, CF is being used by multidisciplinary teams as an alternative or as an addition to diagnosis to provide a more comprehensive understanding of a person in order to better plan care. There has been little research into the use of team formulation and how this is experienced by mental health staff and service-users.

Research Aim

The aim of the current study was to explore experiences of CF from multiple perspectives within a service that promotes a formulation-based approach within their team.

Methods

Fifteen participants were recruited from the ESTEEM First Episode Psychosis Service in Glasgow. The participants were clinical psychologists, mental health staff and service-users. Inclusion criteria required that all participants were or have been involved with ESTEEM, and were able to consent to and participate in the study.

This was a qualitative study using Grounded Theory (GT) methodology. Qualitative research involves analysis of data such as words (e.g. from interviews) as opposed to numbers. It gives insight into people's actual experiences. In this study, the researcher collected data by interviewing participants individually. Staff

experiences of CF and service-users experiences of recovery in the context of the service were explored. The interviews were recorded, transcribed and analysed using GT. GT is a systematic method that aims to generate a theoretical understanding to explain how an aspect of the social world "works". It does not start with a hypothesis but allows meaning to be constructed jointly by the researcher and the participants. Analysis includes the identification of themes in the data that help advance the understanding of the phenomenon under study.

Main Findings

By exploring participants' experiences, this study gave insight into the value and function of team formulation as well as processes involved in it. Team formulation was seen to help the team support service-users that struggle to engage with the service and treatment and are therefore at risk of poorer recovery. Gaining a fuller understanding of a service-user and broadening the team's perspectives was seen to lead to more flexible, consistent and empathic responding, facilitating person-centred care planning and the establishment of better relationships with service-users. The study indicated that doing team formulation was not always easy for staff due to uncertainties around what was expected of them in this process and having to accept that CF offers a hypothesis about the causes and maintaining factors of a person's problems and do not always reflect a "truth". In this way CF is continually revised and updated. The data indicated the importance of a space that allows staff to articulate these concerns, and helps to clarify role expectations to arrive at a shared understanding of team formulation and its processes.

Conclusions

The understanding derived from this study can provide a foundation for a more comprehensive theory of team formulation that is needed to support further research and help improve, develop and disseminating this practice to other services.