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Complete List of Authors:	Beck, Alison; University of Newcastle, School of Medicine & Public Health; NHMRC Centre for Research Excellence in Mental Health and Substance Use Baker, Amanda; University of Newcastle, School of Medicine & Public Health; NHMRC Centre for Research Excellence in Mental Health and Substance Use Jones, Steven; Lancaster University, Spectrum Centre for Mental Health Research, Division of Health Research, Faculty of Health and Medicine Lobban, Fiona; University of Lancaster, Division of Health Research Kay-Lambkin, Frances; University of Newcastle, School of Medicine & Public Health; NHMRC Centre for Research Excellence in Mental Health and Substance Use Attia, John; Hunter Medical Research Institute, Banfield, Michelle; Australian National University
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Exploring the Feasibility and Acceptability of a Recovery-focused Group Therapy Intervention for Adults with Bipolar Disorder: Trial Protocol

Dr Alison K Beck[a,b] alison.beck@newcastle.edu.au [Corresponding Author]

Prof Amanda Baker[a,b] amanda.baker@newcastle.edu.au

Prof Steven Jones[d] s.jones7@lancaster.ac.uk

Prof Fiona Lobban[d] f.lobban@lancaster.ac.uk

A/Prof Kay-Lambkin[a,b] frances.kaylambkin@newcastle.edu.au

Prof John Attia[e] john.attia@newcastle.edu.au

Dr Michelle Banfield[c] michelle.banfield@anu.edu.au

a. School of Medicine & Public Health, University of Newcastle, NSW, Australia (Postal Address: Level 5, McCauley Centre, Edit St, Waratah, NSW, 2298)

b. NHMRC Centre for Research Excellence in Mental Health and Substance Use, NSW, Sydney, NSW, Australia

c. Centre for Mental Health Research, Australian National University, Canberra, ACT, Australia

d. Spectrum Centre for Mental Health Research, Lancaster University, Lancaster, UK

e. Clinical Research Design, IT, and Statistical Support (CReDITSS) Unit, University of Newcastle, NSW, Australia

Abstract

Introduction: Improving accessible, acceptable recovery-oriented service provision for people with bipolar disorder is an important priority. Mindfulness and acceptance-based cognitive and behavioural therapies (or 'third wave' CBT) may prove fruitful due to the considerable overlap between these approaches and key features of personal recovery. Groups also confer therapeutic benefits consistent with personal recovery and may improve recovery-oriented service provision by adding another modality for accessing support. The primary objective of this trial is to explore the feasibility and acceptability of a new recovery-focused group therapy intervention for adults with bipolar disorder. This is the first published feasibility assessment of a time-limited recovery-focused group therapy intervention for bipolar disorder.

Methods/ analysis: This protocol describes an open feasibility study, utilising a pre- versus post- treatment design and nested qualitative evaluation. Participants will be recruited from the Central Coast region of New South Wales, Australia from primary care providers, specialist mental health services, non-government organisations and via self-referral. The primary outcomes are feasibility and acceptability as indexed by recruitment, retention, intervention adherence, adverse events (if any) and detailed consumer feedback. Clinical outcomes and process measures will be assessed to inform future research. Primary outcome data will utilise descriptive statistics (e.g. summarizing recruitment, demographics, attendance, attrition and intervention adherence). Secondary outcomes will be assessed using repeated-measures analysis of covariance across all time points (including change, effect size and variability).

Ethics and Dissemination: Ethical approval has been granted by the Northern Sydney Local Health District HREC (HREC/16/HAWKE/69) and The University of Newcastle HREC (H-2016-0107). Findings will be used to improve the intervention per user needs and preferences, and inform what amendments and/ or information are required before a follow-on trial would be possible. This study contributes to a growing body of innovative, recovery-oriented innovations of psychological treatments for adults with bipolar disorder.

Registration: Australian New Zealand Clinical Trials Registry
Registration Number: ACTRN12616000887471
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Strengths and Limitations of This Study

- The study involves a relatively small number of participants from a limited geographic region and is being conducted with no comparison group and a limited follow up period.
- Although group therapy can be of benefit for adults with experience of BD several logistical challenges may interfere with recruitment to and conduct of the group.
- The proposed intervention is theory driven, incorporates evidence based principles and strategies and will be developed to reflect expert opinion from consumers, clinicians and researchers.
- Intervention duration and setting has also been selected to reflect the central pathway for accessing community based psychological treatment in Australia, thereby minimising the gap between research and 'real world' practice.
- Innovation in the psychological treatment of BD is an important priority and there is a need for improved access to recovery-focused interventions, findings from the current study will contribute to both.

Keywords: Bipolar Disorder, Recovery, Anxiety, Group Therapy, Psychological Intervention, Third wave CBT

BACKGROUND AND RATIONALE

Recovery

The concept of recovery is central to the delivery and evaluation of services for mental health and alcohol and other drugs [AOD (1, 2)]. Although recovery is personal, common themes include hope, understanding, empowerment and living a meaningful, satisfying life (3-5). Accordingly, recovery extends beyond traditional clinical definitions which focus on reduced symptomatology, hospitalisation and medication compliance (4, 5). There is a corresponding need for evidence based psychosocial treatment approaches to better reflect this evolution in service provision. Recent recovery-focused innovations for bipolar disorder (BD) include individual Recovery-focused CBT [RfCBT;(6)]; "Living with Bipolar" [a web based self-management intervention;(7)]; and ORBIT [Online, recovery-focused, bipolar individual therapy(8)]. Preliminary findings support the feasibility, acceptability and potential effectiveness of these recovery-focused interventions (6, 8, 9).

Mindfulness and Acceptance Based Behavioural Therapies

Drawing from several positive findings in BD (10) and severe mental illness more broadly (11) we are particularly interested in the application of mindfulness and acceptance based cognitive and behavioural therapies (or 'third wave' CBT) to treatment innovation in BD [see (12) for a review of these approaches]. 'Third wave' approaches integrate acceptance and mindfulness with CBT (13). Importantly, there is clear concordance between elements of personal recovery (e.g. awareness, understanding, empowerment, valued living) and key targets of 'third wave' approaches, including a) improved awareness of the experience of and reaction to internal events (thoughts, feelings, memories, urges and/ or bodily sensations), b) developing a less reactive and more considered stance toward internal events and c) living life in a chosen and personally meaningful way (12, 13). Moreover, as BD is typically characterised by comorbid conditions [most commonly anxiety and/ or substance misuse; (14)], the transdiagnostic processes targeted by 'third wave' approaches may prove a particularly fruitful avenue for improving recovery outcomes for people with lived experience of BD.

Group Therapy

Group based interventions confer a range of clinical benefits consistent with recovery-oriented service provision [e.g. universality, belonging, shared understanding, giving and receiving emotional support, hope and modelling (15)]. Recent protocols lend preliminary support to the utility of mindfulness and acceptance informed groups [e.g. (16, 17)]. However, in contrast to principles of recovery-focused care, published protocols have not been developed in collaboration with service users, detailed qualitative feedback has not been sought and assessment of personal recovery outcomes has yet to be undertaken. Accordingly, an important opportunity exists to improve recovery-focused service delivery.

Research Question

What is the feasibility and acceptability of a recovery-focused group therapy (RfGT) intervention for adults with BD?

Objectives

Primary Objectives

To provide preliminary evidence regarding the feasibility and acceptability of delivering and evaluating a RfGT intervention for adults with BD. Specifically, to:

1. Investigate

   a. Whether clinicians will refer adults with BD into a RfGT intervention
   b. Whether adults with BD will self-refer into a RfGT intervention
   c. Whether adults with BD are willing to participate in feasibility (and follow-on) research evaluations of the RfGT intervention
   d. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility, withdrawal and/ or non-attendance
2. Explore the acceptability of the RfGT intervention as indexed by
   a. Number of sessions attended and level of engagement
   b. Detailed participant feedback to explore their experience of and satisfaction with the RfGT intervention
   c. Number and type of adverse events (if any)
3. Explore the feasibility and acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments)

Secondary Objectives

Secondary objectives will inform the design of future research and include exploring:

1. The feasibility of recruiting participants with BD who also have experience of anxiety and substance related comorbidities
2. What 'treatment as usual' is likely to consist of and potential similarities/ differences to the RfGT intervention
3. The most appropriate primary outcome measure – informed by a combination of detailed participant feedback, feasibility data and effect size estimates
4. Potential mechanisms of change – to understand the processes that may underlie the impact of the RfGT intervention

In accordance with guidelines for developing and evaluating complex interventions (18), the current feasibility study represents vital preparatory work designed to maximise the success of any large scale follow-on evaluation by

   a. Producing an intervention that is acceptable to service users
   b. Identifying barriers and facilitators to effective recruitment, retention and data collection
   c. Informing estimates of recruitment, retention, engagement, adherence and effect size of the intervention across a range of outcome variables.

No pre-specified criteria will be set for determining feasibility of a follow-on evaluation. Rather, our decision-making process will be informed by published guidelines for systematically appraising and responding to feasibility data [the ADePT Framework,(19)]. Specifically, barriers to a large-scale evaluation will be explored, including what amendments and/ or information would be needed to improve the success of a follow-on evaluation and the (im)practicality of addressing these. This information will be used to determine whether a main study is a) not feasible, b) feasible pending modifications to study protocol or c) feasible as is.

Trial Design

An open feasibility study, utilising a pre-versus post- treatment design and nested qualitative evaluation

METHODS

Participants, Interventions and Outcomes

Eligibility

Potential participants will undergo a brief screening assessment (over the phone, Skype or in person, as per participant preference) to ensure that all inclusion and no exclusion criteria are met. Should a participant be deemed ineligible due to a current acute mood episode, if there is sufficient time left in the recruitment period, the potential participant will be offered the option of being re-contacted by the research team to re-assess mood stability (Figure 1).

Inclusion criteria

- Aged 18-65
- Meeting DSM-V criteria for BD (BD I, BD II, Cyclothymia, Other [Un]Specified)
- Able to comprehend English at a level sufficient to complete self-report instruments and clinical interview
- Willing to have RfGT sessions audio recorded

Exclusion criteria

- Current acute mood episode (as per DSM-V criteria for mania or depression)
- Current suicidal ideation with intent (as per clinical judgement following discussion with the potential participant and the research team)
- Unable or unwilling to provide informed consent

Participants will not be excluded due to concurrent treatment (pharmacological or non-pharmacological). Information regarding any concurrent treatment will be collected at baseline and each follow-up occasion.

Sample Size

Based on clinical and research experience we expect that 20 participants will allow us to reliably inform our aim of evaluating the feasibility and acceptability of delivering and evaluating a RfGT intervention. Allowing for attrition of approximately 20% [e.g.(20)], the recruitment target is set at 24. This sample will afford the opportunity to deliver two to three sets of closed intervention groups. Group size (i.e. 8-12 participants per therapy group), has been chosen to reflect 'real world' practice by mirroring the maximum group size subsidised by the Australian government (n=10). The proposed sample size is comparable to published feasibility trials of psychological interventions in BD (8) and above the recommended acceptable floor (n=10 per study arm) for feasibility studies (21).

Recruitment

Potential participants for the proposed RfGT intervention will be sourced from across the Central Coast, NSW. The Central Coast is predominantly urban region and contains approximately 1.5% of the Australian population. Recruitment sources will include:

- The R.E.A.D. Clinic, Erina, NSW.
- Other inpatient, residential, community, outpatient and clinical health organisations, including private, public and not for profit mental health, drug and alcohol and general health services (e.g. general practitioners, psychiatrists, community mental health teams, community health centres, not for profit organisations, residential rehabilitation and inpatient units) located within the borders of the Central Coast Local Health District.
- Advertisements (e.g. online, local media, flyer/ pamphlets, study website)

A member of the research team will contact the principals, directors, case managers and/ or other relevant staff contacts of the above organisations, with information about the study. Should they wish their organization to cooperate with the study, staff members will be asked to provide written information to individual members whom they deem to be an

appropriate candidate for the proposed study. If that member or client is interested in participating, based on the information provided, he or she will then voluntarily contact the research team. Alternatively, should the potential participant wish to be contacted directly by a member of the research team, they may choose to complete a "consent to contact" form. At this point, it is made clear that people are only consenting to the research team contacting them to discuss the possibility of participating in the study, as opposed to consenting to participate in the study itself. To maximise participant access, the study will also be advertised online, in local media and via posters and leaflets distributed across willing organisations. Interested participants will then able to voluntarily contact the research team to obtain further information.

Enrolment

Individuals who fulfil the requirements of the screening interview will be invited to attend an appointment to conduct the baseline assessment (Figure 1). To enhance engagement, baseline assessments will be conducted by the lead facilitator (Clinical Psychologist, AKB). Following completion of the baseline assessment, consecutively eligible participants will be assigned a unique alphanumeric code, offered a brief orientation/ overview of the programme and invited to participate in the RfGT intervention.

Participant Reimbursement

Consistent with Australian guidelines for acknowledging the time and value of consumer participation (22), participants will be offered modest reimbursement (for any time, travel and inconvenience associated with participation in study assessments) of up to a total of $40 (or equivalent in gift cards) for the baseline assessment ($20), mid-therapy ($10) and post-therapy ($10) assessments. They will also receive eight sessions of fee-free, consumer-driven, evidence-informed RfGT.

Study Intervention

Development

The RfGT intervention will be developed through collaboration between clinicians, consumers and researchers. It will be an iterative process, guided by (a) principles and strategies adopted by 'third wave' psychosocial approaches [including Mindfulness Based Cognitive Therapy (23); Mindfulness Based Relapse Prevention (24); Acceptance and Commitment Therapy, (25); Dialectical Behaviour Therapy,(26); Compassion-focussed therapy,(27); Acceptance Based Behavioural Therapy for Generalised Anxiety Disorder, (28)], (b) clinical practice guidelines and published evidence regarding effective and essential components of psychological support for BD and common comorbidities (including anxiety and substance misuse) and (c) expert opinion from consumers, clinicians and researchers. Consumer feedback on the importance, relevance, content and format of the proposed RfGT intervention will be explored through a series of focus groups.

Description

The RfGT intervention will be delivered in addition to any usual treatment (pharmacological and/ or psychological). The RfGT intervention will utilise a combination of group discussion, guided discovery, in-session mindfulness practice and homework activities. To ensure that the intervention is collaborative, and respectful of client autonomy, personal choice and responsibility over behaviour change, a motivational interviewing framework will guide the delivery of all sessions.

Intervention content will be selected to support the following treatment objectives

a) Increase awareness of personally held values
b) Strengthen awareness of what group members are already doing that is consistent with these values and support them to continue and/ or expand these actions (as needed)
c) Increase awareness of how group members typically respond to strong internal events (thoughts, feelings and/ or physical sensations), explore the short and long term costs and benefits and (as needed) explore potential opportunities for change

Our first two aims are informed by the importance of personally meaningful change in recovery-focused service provision (4). There is a longstanding appreciation of the relationship between valued action and personal wellbeing within person centred therapeutic approaches (29). Valued action refers to living life in a chosen and meaningful way, guided by what truly matters to the individual [i.e. what they want to stand for, how they want to be with themselves, others and the world (30)]. Over recent years this seemingly intuitive link between valued action and wellbeing [indexed by vitality, mental health and functional outcomes) has been empirically validated (31)]. Moreover, increasing evidence has demonstrated a positive relationship between valued action and functioning following psychological treatment for adults with experience of trauma (32); long-standing symptoms of panic disorder (33) and schizophrenia, anorexia, borderline personality disorder or BD (34). Lack of values clarity (uncertainty about personally held values) and lack of awareness (difficulty noticing actions that are consistent with personally held values) represent two key factors that can undermine valued action (30). Accordingly, as per our first two treatment objectives, these represent key targets of the RfGT intervention.

The third treatment objective of the RfGT intervention is guided by reinforcement sensitivity theory (35, 36). Briefly, three interconnected systems have been implicated in emotion regulation. The Behavioural Activation System (BAS) motivates us to seek out rewarding and/ or desirable experiences and work towards goals. Conversely, The Behavioural Inhibition System (BIS) helps to protect us from unpleasant and/ or undesirable experiences by motivating us to withdraw and/ or avoid. Finally, The Fight/ Flight/ Freeze system works in concert with the BIS to help protect us from threat. Although our understanding of the exact nature and function of emotion regulation systems continues to evolve, altered BIS/ BAS sensitivity has been implicated in risk of depressive and (hypo)manic episodes [(37, 38)] and also progression to BD amongst at risk individuals (39). Of note, these systems have also been linked to common comorbid conditions, including problematic substance use [altered BIS/ BAS sensitivity; (40)] and anxiety (altered BIS/ fight/ flight/ freeze sensitivity; (41)].

Guided by the reinforcement sensitivity theory (35, 36), we seek to use group discussion and guided discovery to explore and normalise any identified vulnerability toward actions driven by urges to withdraw (in response to unpleasant experiences), approach (in response to pleasant experiences) and protect (in response to threatening experiences). Mindfulness skills will be used to strengthen awareness of these urges; the preceding external (e.g. situations/ context, people, places) and associated internal (e.g. thoughts, feelings and sensations) experiences and subsequent actions taken. Learning theory and personally held values will be used to guide group discussion surrounding the short and long term costs and benefits of identified actions. Specifically, the short-term benefits of actions performed in response to each type of urge (e.g. pleasure, relief, safety) will be elicited and the role of any immediate benefits in strengthening the behaviour explored. The short and long-term impact on personally held values will be explored and used to guide discussion around whether/ when a change in response may be useful. The role of evidence based strategies [e.g. self-monitoring; arousal modulation; distress tolerance; graded exposure; stabilising routine etc.; (42)] in supporting desired changes will be explored. Final sessions will focus on developing individual wellness plans.

Dosage and Administration

The intervention will consist of eight RfGT sessions (two hours per session, plus a 15-30-minute mid-session break) held over eight weeks. We have chosen eight sessions to allow flexibility for future iterations to incorporate participant feedback regarding intervention timing and content and remain within the proposed ten session maximum. All sessions will be led by the same Clinical Psychologist (Dr Alison Beck) and Co-facilitated by the same Masters Level Trained Clinical Psychologist Registrar (Nathan Beehag). Prior to the first session (i.e. upon completion of baseline assessments) all participants will be provided with a brief orientation to the group program by the lead facilitator and assigned a task to complete in preparation for the first session. Participation is completely voluntary and participants are free to withdraw from the intervention at any time and/ or decline to participate in any intervention element. Pending the outcome of the study, the treatment manual will be available upon request.

Integrity

All group therapy sessions will be audio recorded and rated for intervention fidelity by a trained, independent researcher not involved in intervention delivery or participant assessment. A 20% sample will be re-rated by a second, trained independent researcher for inter-rater reliability. Assessors will receive training in the assessment instruments and will have (at a minimum) Masters level training in psychology. Group facilitators will participate in regular supervision, consisting of weekly self-reflection (e.g. experience of delivering the group, challenges, successes and questions) which will be distributed to all study investigators for comment/ feedback. Written feedback will be supplemented by regular phone consultations with AB (fortnightly or 'as needed').

Study Setting

Baseline assessments and the RfGT intervention will be conducted at a community-based private psychology clinic (The R.E.A.D. Clinic) located at Erina, on the Central Coast, NSW, Australia. Post-treatment follow-up assessments will be conducted at the R.E.A.D. Clinic, or remotely (over the phone or Skype; as per participant preference). Aside from the Client Services Receipt Inventory (which will be administered over the phone by a trained research assistant) mid-treatment assessments will be completed online.

Outcomes

Feasibility and acceptability

To address the primary objective of evaluating the feasibility and acceptability of delivering and evaluating a RfGT intervention for BD, the following data will be collected throughout the trial:

1. Enrolment – including the number of participants referred, the proportion who were eligible and the number consented
2. Frequency, duration and source of referrals (self vs. various service providers across each month of the trial)
3. Number of group therapy sessions attended (and the reasons for any non-attendance)
4. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility/ withdrawal
5. Number of assessments completed; amount of missing data and detailed participant feedback regarding acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments)
6. Number and type of adverse events (if any)

7. Detailed participant feedback to explore their experience of and satisfaction with the RfGT intervention and study methods.

Guided by the ADePT Framework (19), we aim to inform our feasibility assessment by exploring what worked well and what worked less well within the three overarching domains of intervention, study design and setting/ context. Barriers to a large-scale evaluation will be explored, including what amendments and/ or information would be needed to improve the success of a follow-on evaluation and the (im)practicality of addressing these. This information will be used to determine whether a main study is a) not feasible, b) feasible pending modifications to study protocol or c) feasible as is.

Clinical outcomes and process measures

To address our secondary aim of informing the design of any follow-on evaluation, several clinical outcomes and process measures (Table 1 and detailed below) will also be assessed to explore the following parameters:

1. The number of participants who also demonstrate comorbid anxiety and substance (mis)use (as indexed by clinical interview and self-reported experience)
2. Concurrent treatment and support services accessed by study participants (including type, amount, frequency and duration)
3. The most appropriate primary outcome measure
4. Potential mechanisms of change - including (i) mindfulness (ii) experiential avoidance (iii) meaningful action (iv) impulsivity and/ or (v) behaviours and/ or attitudes towards medication

Clinical outcome measures- interviewer administered.

The Structured Clinical Interview for DSM-V disorders [SCID-V; (43)] is a semi-structured interview for making the major DSM-V Axis I diagnoses. The instrument is designed to be administered by a clinician or trained mental health professional and can take up to 90 minutes to complete (given a history of comorbidity). We will administer the mood, psychotic, substance use, anxiety and differential diagnosis modules at baseline to confirm BD diagnosis and provide information about concurrent conditions.

The Longitudinal Interval Follow-Up Evaluation [LIFE;(44)] is a semi-structured interview and rating system for assessing the longitudinal course of psychiatric illness. The SCID-LIFE includes items from the SCID, the Hamilton Depression Rating Scale [HDRS; (45)] and the BecheRafaelsen Mania Rating Scale [MAS;(46)]. Separate severity ratings for mania and depression are generated using a six-point psychiatric status rating. Scores will be used to assess time to first episode of depression and mania, number of weeks out of episode (< 4) and number of weeks without impairment (< 2).

Health service and medication use will be assessed using an adapted version of the Client Service Receipt Inventory (CSRI) – 'Generic' UK Mental Health (47). The content of this inventory has been updated to reflect key sources of mental health expenditure in Australia [e.g. (48)]. These data will allow us to identify elements of 'treatment as usual' utilised by study participants across the trial, and provide some insight into costing.

The Social and Occupational Functioning Assessment Scale [SOFAS; (49)] is a 100 point scale used by the clinician to rate current social and occupational functioning on a continuum from excellent to grossly impaired, with lower scores reflecting poorer functioning. Unlike other widely used global rating scales (e.g. Global Assessment of Functioning), the SOFAS is designed to provide an index of social and occupational functioning independent of the overall severity of psychological symptoms – this is particularly important in the current study considering the likely heterogeneity of symptoms and severity. A global rating scale has been chosen in preference to the multi-domain assessment of functioning recommended in the DSM-V (i.e. WHO-DAS 2.0) to streamline assessment and minimise burden.

Clinical outcome measures- self-report.

The Brief Quality of Life in Bipolar Disorder Questionnaire [QoL.BD; (50)] is the condensed 12-item version of a 56 item instrument designed to specifically assess quality of life in individuals with BD (50). Preliminary evidence supports the feasibility, reliability and validity of this tool for assessing BD specific quality of life (50).

The Bipolar Recovery Questionnaire [BRQ;(3)] is a 36-item questionnaire designed to assess personal recovery, specifically, as it pertains to adults with BD-I or BD-II. Preliminary evidence supports the psychometric properties of this tool (3).

The short-form version of the Depression, Anxiety and Stress Scales [DASS-21;(51)] is a 21 item version of the original 42 item DASS (51). It includes three, seven item self-report scales designed to measure emotional states of depression, anxiety and stress. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/ involvement, anhedonia and inertia. The anxiety scale assesses autonomic arousal, tension, situational anxiety and subjective experience of anxious affect. The stress scale is sensitive to chronic, non-specific arousal (e.g. difficulty relaxing, agitation, irritability). Each item is rated on a 4-point scale of severity/ frequency over the preceding one week. The DASS-21 demonstrates sound reliability and validity (52) and Australian normative data are available.

The Alcohol, Smoking and Substance Involvement Screening Test [ASSIST 3.1;(53)] is an eight-item questionnaire designed to screen for the use (3 month and lifetime) of tobacco, alcohol, cannabis, cocaine, amphetamine type stimulants, sedatives and sleeping pills, hallucinogens, inhalants, opioids and 'other' drugs. The ASSIST generates a risk score (lower, moderate, high) for each substance category. It was originally designed to be administered by a health worker, but preliminary evidence supports the feasibility (54), reliability and validity (55, 56) of self-report administration.

The EuroQol five dimensions' questionnaire (EQ-5D) is a widely-implemented instrument for assessing health related quality of life and estimating quality-adjusted life years in cost-utility analyses. This five item self-report inventory assesses five domains of quality of life (mobility, self-care, usual activities, pain/discomfort and anxiety/ depression). We will use the newest version - the EQ-5D-L (57). To correct potential ceiling effects associated with the original version, the EQ-5D-L uses five (relative to three) response categories to assess the severity of problems experienced (no problem, slight, moderate, severe, extreme).

Process measures.

The Five Facet Mindfulness Questionnaire-SF [FFMQ-SF;(58)] is a 24-item version of the FFMQ (59). It comprises five domains (observing; describing; acting with awareness; non-judging of experiences and non-reactivity to experiences), which can also be summed to produce an overall score. Higher scores reflect greater mindfulness. Each item is rated on a five-point scale from one (never or very rarely true) to five (very often or always true) in terms of what is 'generally true for you'. Evidence supports the reliability, validity and sensitivity to change of this condensed version of the FFMQ (58).

The Acceptance and Action Questionnaire [AAQ-2; (60)] is a seven-item questionnaire designed to assess experiential avoidance vs psychological flexibility, with higher scores reflecting greater experiential avoidance. The AAQ-2 has demonstrated good internal consistency and test-retest reliability (60, 61).

The Valuing Questionnaire [VQ; (62)] is a ten item self-report inventory designed to assess the extent of past values enactment over the preceding one week. It comprises two factors, progress (awareness of and enactment on what is truly important) and obstruction (disruption to valued living arising from avoidance, distraction and/ or inattention). Preliminary evidence supports the psychometric properties of this instrument (62).

The Positive Urgency Measure [PUM; (63)] is a 14-item self report measure of positive urgency – the tendency to act impulsively in response to positive moods. Each item

is rated on a four point Likert scale from one (agree strongly) to four (disagree strongly). The scale demonstrates sound psychometric properties, including high internal consistency [α = 0.94-0.95, (63); α = 0.82, (64)] and PUM scores have been associated with addictive behaviours [e.g. gambling and drinking; (65)].

The Urgency, Premeditation, Perseverance and Sensation Seeking (UPPS) Impulsive Behaviour Scale (66) is a 45-item self-report inventory designed to assess impulsivity across dimensions of the Five Factor Model of Personality. In accordance with prior research [e.g. (67)] we will use the 12-item urgency subscale as an index of impulsive behaviour in response to negative affect, including difficulty resisting craving and temptation. As per the PUM, each item is rated on a four point Likert scale from one (agree strongly) to four (disagree strongly). The Urgency Subscale demonstrates high internal consistency [e.g. α = 0.86-0.89; (68) and (67) α = 0.89].

The Self-Control Schedule (69) is a 36-item self-report inventory designed to assess the use of different self-control methods to solve behavioural problems (including 'self-statements'/ cognitions; problem solving; delaying immediate gratification and belief in self-efficacy). Each item is rated from minus three to plus three, with higher scores indicating greater utilisation of self-control methods. Good reliability and validity is reported by the author (69). Preliminary findings also support the sensitivity of the instrument for detecting change after psychological therapy for BD (70).

The Medication Adherence Rating Scale [MARS; (71)] is a 10 item (yes/no) self report instrument designed to assess behaviour and attitude toward medication over the preceding one week. The instrument is designed to be scored from zero to ten, with higher scores indicating greater medication adherence.

Therapeutic alliance.

The Group Session Rating Scale [GSRS; (72)] is a four-item visual analogue scale, designed to be a brief tool to assess group-therapy alliance. The items assess 'relationship', 'goals and topics', 'acceptability of approach' and 'overall fit' are ranked from low to high according to pre-specified anchors. GSRS scores are obtained by measuring the marks made by the client and summing the lengths (nearest cm) of each line (maximum total score = 40). Evidence supports the reliability and concurrent validity of this instrument for use in substance use populations (73).

Adherence to treatment protocol

Adherence to recovery-oriented service provision will be guided by the Recovery-oriented Service Self-Assessment (74). The ROSSAT was developed by the Mental Health Coordinating Council in consultation with consumer advocacy group Being as a mechanism for workers (75) and organisations (76) to assess their level of recovery-oriented service provision. Item content reflects six key indicators of recovery-oriented service provision identified during the ROSSAT development process [relationships; respectful practice; consumer self-directed focus; belief in consumers recovery; obtaining and sharing knowledge and information; and participation and social inclusion; (4)].

Both RfGT facilitators will complete the ROSSAT Tool for workers (75) after sessions one, four and eight. This tool comprises 37 items across four domains: values, principles and philosophy underpinning service provision; recovery-oriented service provision; workers' responsibilities, roles and attributes; education and training. Each item is rated on a five point Likert scale from one (needs significant development) to five (outstanding achievement). Objective assessment will also be conducted by having an independent assessor rate all audio recordings of the RfGT sessions against a subscale (recovery-oriented service provision) of the corresponding ROSSAT Tool for organisations (76). Each item is rated on a four point Likert scale from one (needs significant development) to four (outstanding achievement).

Adherence to intervention content will be guided by a checklist specifically designed for the current study. The checklist will reflect the key aims, activities and discussion points for each RfGT session. At the end of each session facilitators will be asked to rate the degree to which each item was addressed and to note any deviations. An objective rating of this checklist will also be undertaken by an independent assessor based on their review of session audio recordings. As the intervention is grounded in CBT, audio-recordings will also be rated for fidelity using the Cognitive Therapy Scale – revised version (77).

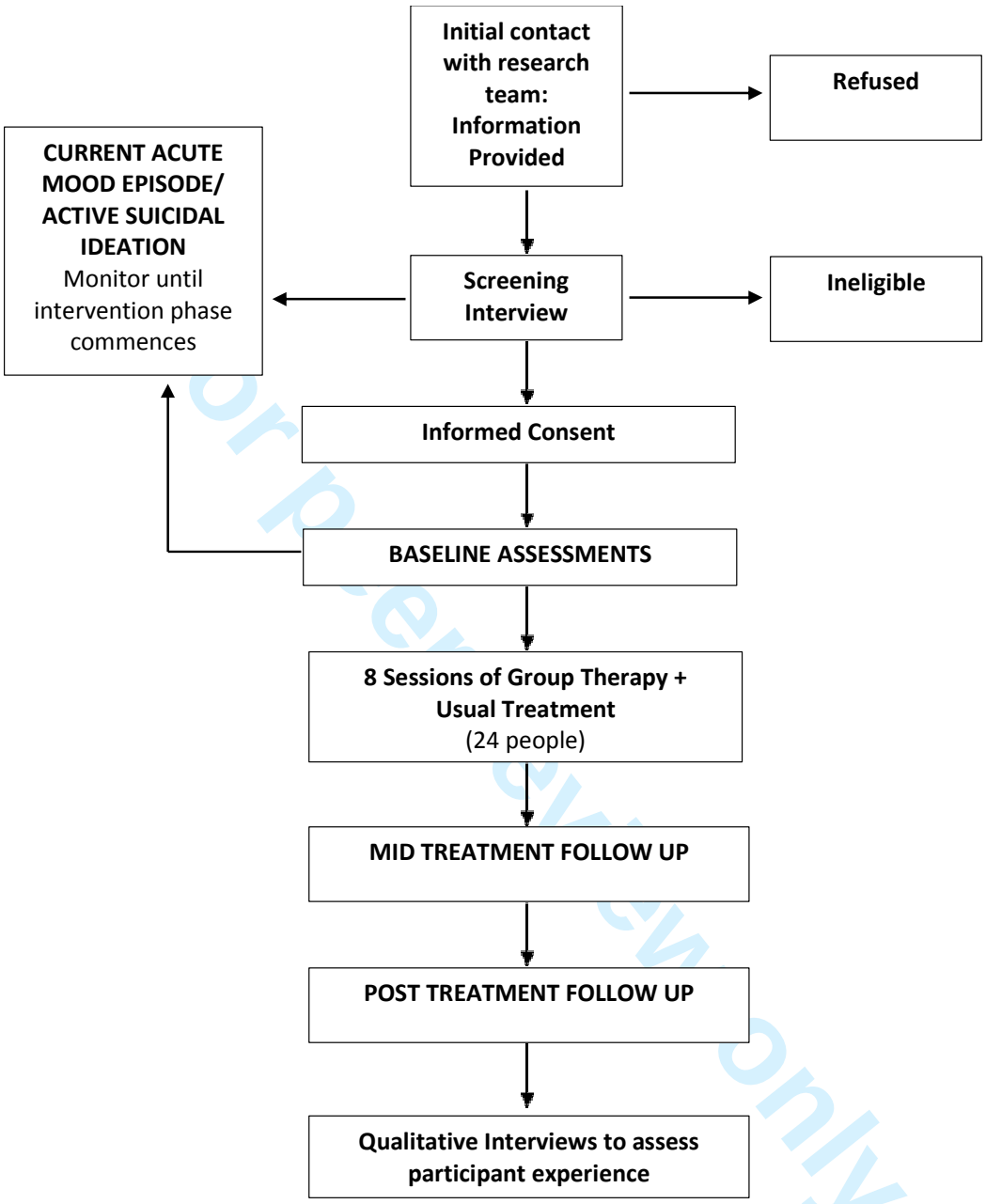

Figure 1. Participant Timeline

Table 1. Schedule of participant assessments

	Pre-Intervention		Intervention Phase	Follow-Up Phase	
	Screening	Baseline	Each session	Mid Treatment	Post Treatment
Inclusion/ Exclusion Criteria	✓				
Informed Consent		✓			
Demographics (e.g. age, education, employment and marital status)		✓			
Clinical history (e.g. family history of mood disorder, age at onset and number of affective episodes)		✓			
Client Services Receipt Inventory		✓		✓	✓
SCID (Lifetime/ 12 months)		✓			
Brief Quality of Life – Bipolar Disorder		✓		✓	✓
Bipolar Recovery Questionnaire		✓		✓	✓
SCID-LIFE (3 months)					✓
Depression, Anxiety and Stress Scales (21 item version)		✓		✓	✓
The Alcohol, Smoking and Substance Involvement Screening Test (v3.1)		✓		✓	✓
The Five Facet Mindfulness Questionnaire- Short Form		✓		✓	✓
The Acceptance and Action Questionnaire (v2)		✓		✓	✓
The Valuing Questionnaire		✓		✓	✓
Positive Urgency Measure		✓		✓	✓
UPPS Impulsive Behaviour Scale – Urgency Subscale		✓		✓	✓
The Self-Control Schedule		✓		✓	✓
The Medication Adherence Rating Scale		✓		✓	✓

EuroQol five dimensions' questionnaire		✓		✓	✓
The Group Session Rating Scale			✓		

LIFE: The Longitudinal Interval Follow-up Evaluation; SCID: The Structured Clinical Interview for DSM-V disorders; UPPS: Urgency, premeditation, perseverance and sensation seeking

Data Collection, Management and Analysis

Data Collection

To facilitate engagement and working alliance the baseline assessment will be conducted face-to-face at the R.E.A.D. Clinic by the lead facilitator. Post-treatment follow-up assessments will be conducted face-to-face or remotely (e.g. Skype, telephone) as per participant preference, by a trained research assistant not involved in intervention delivery. Aside from the Client Services Receipt Inventory (which will be administered over the phone by a trained research assistant) mid-treatment assessments will be completed online.

Interviewer administered instruments will be collected in hard copy and electronic formats (i.e. hard copy scanned into a computer and/ or directly entered into an electronic database). Baseline and follow-up self-report questionnaires will be collected on-line (e.g. using Survey Monkey or similar). As the BRQ (3) utilises a visual analogue scale, this questionnaire will be completed by hand and returned electronically (e.g. faxed, scanned or photographed and returned by email). The score will be calculated and entered into an electronic database. The GSRS (72) also employs a visual analogue scale. Hard copies will be completed by intervention participants at the end of each group therapy session. The score will be calculated and entered into an electronic database. Group therapy sessions will be audio recorded using hand-held audio-recorders. Audio files will be uploaded onto a secure electronic server for storage and analysis.

Data Management

Data entry will be performed by AKB. All hard copy data will be entered into Microsoft Excel. All data collected online will be downloaded and saved into the Excel database. Several mechanisms will be used to ensure data integrity, including referential data rules, valid values and range checks. Data query reports will be used to check for errors in data entry. Identified queries will be cross checked against the original data source. A log of any changes made to the original data source or electronic database will be maintained throughout the trial.

Statistical Methods

The following statistical analysis plan has been developed in collaboration with the Clinical Research Design, IT and Statistical Support (CReDITSS) Unit at the University of Newcastle. Considering the primary aim of exploring feasibility and acceptability, we expect that outcome data will primarily utilise descriptive statistics (summarizing recruitment, demographics, attendance, attrition and intervention adherence). For the secondary outcomes, i.e. scores on various measures at baseline, mid-treatment, and at post-treatment follow-up, we intend to use repeated-measures analysis of covariance across all time points (including change, effect size and variability); this will minimise the number of statistical tests and reduce the risk of inflated type I error. These models will include group, time, and group X time interaction terms. This approach also provides an omnibus test, which if significant, will reduce type I error when doing post-hoc analyses of pairwise contrasts, e.g. baseline vs midpoint, baseline vs post treatment values.

Monitoring

Potential Harms

Dealing with Risk

We acknowledge that discussing mood and related experiences may be associated with feelings of distress. Accordingly, participants will be offered a 'support call' 24-48 hours after each assessment occasion to assess any adverse impact of the assessment process. In the event that a participant raises concerns about feelings of distress, this will be documented and responded to as per guidelines for reporting adverse events (see below) and/ or assessing and responding to suicide risk [as appropriate; (78)].

Although suicidal ideation is a common feature of BD (79) and not necessarily accompanied by intent and/ or attempt (79, 80) regular risk assessment will be undertaken throughout the study. Risk of suicide will be assessed at screening and then at each assessment occasion (and as needed, at each follow-up 'support call'). Consistent with NSW Health Guidelines for assessing and managing risk of suicide (78), in the first instance, a hierarchy of screening questions will be utilised, and as needed, supplemented by a follow-up comprehensive risk assessment. Any participant endorsing suicidal ideation will be asked whether they would like written information about available support services (e.g. Lifeline and Suicide Call Back Service), and/ or a self-help 'tip sheet' developed by the suicide call back service.

Adverse Events

An adverse event (AE), also referred to as an adverse experience, will be defined as any unfavourable/ unintended psychiatric occurrence in a study participant necessitating acute or crisis intervention – whether it is considered to be intervention-related or not. 'Psychiatric occurrence' will be defined in terms of any change in mental state that precipitates acute care and/ or crisis intervention. This may include suicidality, self-harm, acute mood episode and/ or intoxication from alcohol and/ or substances.

A subset of AEs will be classified as 'serious adverse events' and will require expedited reporting. Serious adverse events will be defined as

- Any AE resulting in hospitalisation
- Any AE resulting in persistent or significant disability/ incapacity
- When the untoward psychiatric occurrence is life threatening (NOTE: The term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- When the untoward psychiatric occurrence results in death

Adverse events will be assessed at each follow-up occasion via questions pertaining to treatment history. Any instance of acute/ crisis intervention will be documented by the research assistant and reported to the responsible HREC. The lead facilitator of the RfGT intervention (AKB) will also document and report any utilisation of acute/ crisis intervention they learn about while delivering the intervention.

The University of Newcastle HREC will be informed about any adverse events, unforeseen events and complaints within 72hours of learning about them. The relevant University of Newcastle template for reporting trial events will be used. The reports will be independently reviewed by the University of Newcastle HREC (sub)committee or Executive to determine whether the event is trial related and the appropriate course of action. If the HREC (sub)committee or Executive deems further information is required, it will request this from:

a) An independent expert in the area; or
b) The co-ordinating Investigator

Adverse event reports and outcomes will also be reported to the NSLHD-HREC for independent review.

Data Monitoring

An independent data safety monitoring board will not be convened. The current study is a one-arm trial of a non-invasive psychological intervention, that will be developed in close consultation with consumers to reflect evidence based principles and strategies. It will be delivered in the context of 'treatment as usual', does not involve experimental administration of medicine or experimental therapeutic devices and no interim analyses are planned. For each assessment occasion, AKB will review the first three assessments and every one in five thereafter for completeness and accuracy. To inform feasibility assessment a log will be maintained of any missing data, errors in administration and corrective feedback provided to study assessors.

Auditing

Written updates and project meetings will be held at least quarterly, or more frequently as needed. Written updates and meetings will focus on consumer involvement, intervention development, recruitment rates, treatment fidelity, progress with follow−ups, discussion of adverse events (if any), data management and project timelines. Identified problems will be discussed and potential solutions posed.

Discussion

In accordance with calls to improve the transparency and quality of complex behaviour change research (81), the current paper details the protocol for an open feasibility study of a recovery-focused group therapy intervention for adults with experience of BD. Preliminary evidence supports the feasibility and acceptability of recovery-focused interventions in BD (6, 8, 9). Mindfulness and acceptance based therapies also show promise (16, 17, 82). To our knowledge, only one other group therapy protocol has combined these approaches for treatment of BD (currently being investigated by a team at the University of Exeter, However, unlike the current study, the THRIVE protocol specifically targets individuals who experience rapid cycling and at 16 sessions, is less practical for an Australian healthcare setting. As this is the first trial whereby recovery-oriented and third-wave approached have been combined into a time-limited (i.e. ≤ 10 sessions) group therapy intervention for adults with BD, feasibility assessment is warranted. Specifically, to identify what challenges would undermine the success of a follow-on evaluation, explore the practicality of addressing these and discuss the best pathway forward (18). Accordingly, this study reflects vital preparatory work to maximise the success of any future full scale evaluation, and conversely, to curtail further investment in an untenable proposal.

Strengths

Feasibility studies represent an important, but often under-utilised and under-reported phase of intervention development and evaluation (18). This feasibility study was prospectively registered and is reported here in accordance with best practice recommendations for intervention protocols (83). Interpretation of outcome data will be informed by published guidelines (19) and recommendations will be made regarding what further information and/ or amendments to the intervention, context and / or design would be needed to maximise the success of a follow-on evaluation (and the practicality of same).

Innovation in the psychological treatment of BD is an important priority and there is a need for improved access to recovery-focused interventions (10). Findings from the current study will contribute to both. The proposed intervention is theory driven, incorporates evidence based principles and strategies and will be developed to reflect expert opinion from

consumers, clinicians and researchers. Intervention duration and setting has also been selected to reflect the central pathway for accessing community based psychological treatment in Australia, thereby minimising the gap between research and 'real world' practice. Additional strengths include our carefully characterised sample, use of an independent assessor to conduct follow-up assessments, structured attempt to characterise treatment as usual and comprehensive fidelity assessment.

Limitations

Some limitations are also apparent. Firstly, although group therapy can be of benefit for adults with experience of BD (84), our decision to utilise a closed group format is not without logistical challenges. For example, participant flow must be sufficient to form a group within a reasonable timeframe, as risk of drop-out has been found to increase with increased wait-time [e.g. (85)]. Furthermore, if attrition remains high, membership of closed groups may diminish such that the group itself is no longer viable. Secondly, utilising a private facility to deliver the intervention may inadvertently impact study recruitment. For example, beliefs by service users and/ or providers surrounding private psychology (e.g. high cost, unsuitable for severe mental illness) may interfere with willingness to refer. However, from a translational perspective, as private psychology providers represent a key mechanism for accessing psychological support in Australia, willingness of individuals and/ or service providers to refer to a private facility is an important feasibility question. Thirdly, detailed qualitative evaluation of acceptability is also currently limited to group members. Pending acceptability at the level of the client, further research would be needed to explore acceptability to health care providers. The study will also involve a relatively small number of participants from a limited geographic region (Central Coast, NSW Australia). However, the proposed sample size is within the range of related feasibility studies [e.g. (8)] and above the acceptable floor (n=10 per study arm) for feasibility studies (21). Finally, this is an open trial with no comparison group and limited follow-up period. Although this design is appropriate for addressing our objectives of feasibility and acceptability (86), pragmatic considerations (funding and time constraints) meant that the current protocol was amended from a pilot RCT with three-month post treatment follow-up [see (87) for details of original registration on the ANZCTR].

Conclusions

Treatment innovation in BD is an important priority (10). Improved focus on personally meaningful recovery relative to traditional clinical outcomes is needed. To accommodate individual needs and preferences, choice over treatment modality is important (88). Group therapy confers a range of therapeutic benefits including universality, belonging, giving and receiving emotional support, modelling, practicing interpersonal skills and bonding (15). Group therapy also represents a considerable under-utilised resource within the Australian primary healthcare setting [representing less than 1% of Medicare funded services with a Clinical Psychologist in 2015; (89). To ensure that the proposed intervention is directly transferrable to existing models of time-limited, government subsidized mental health care in Australia, a protocol with a maximum of ten sessions is needed. The current study represents an important step in bridging the gap between research and clinical practice by working closely with consumers to develop an acceptable intervention that is also accessible under existing service delivery models.

Ethics and Dissemination

Research Ethics Approval

This study has been approved by the Northern Sydney Local Health District HREC, reference number RESP/16/45; HREC/16/HAWKE/69 and The University of Newcastle HREC, reference number H-2016-0107.

Protocol Amendments

Any amendments will be submitted to the Northern Sydney Local Health District HREC for review and registered with the University of Newcastle HREC prior to implementation as per HREC guidelines. AKB will oversee the submission of amendments and associated update of trial registration. Version control using protocol identifiers and dates, and a list of amendments will be maintained to track the history of amendments and identify the most recent version of study documentation.

Informed Consent

Potential participants will receive written information about the study, in the form of a flyer and/ or patient information and consent form (PICF) posted online; in client areas at the R.E.A.D. Clinic; in client areas at other community and outpatient clinical health organisations and/ or offered by their health professional and/ or support worker. Individuals interested in hearing more about the study can then voluntarily contact the research team (AKB, NB or MB) for further information, or elect for their health professional/ support worker to provide their contact details to the research team. Interested clients will then be provided with further information about the study, and the opportunity to have any questions addressed. If they remain interested in participating, AKB will provide them with a copy of the information and consent form (hard or soft copy as per participant preference) and arrange a convenient time to complete the screening interview.

Confidentiality

Participant data will be labelled with a unique alphanumeric code. All hardcopy data will be securely stored in a locked filing cabinet. All electronic data and data sets will be password protected and stored on a secure university server (ownCloud). The encrypted file containing the link between participant details and each unique alphanumeric code will be password protected, stored separately to study data and accessible only to key research personnel. At the completion of the project, the encrypted document containing participant codes and associated participant contact details will be destroyed. In accordance with the Research Data and Materials Management Procedure (University of Newcastle, 2015) this non-identifiable data will then be retained for a minimum of 20 years after date of publication or termination of the study.

Competing Interests Statement

We have read and understood BMJ policy on declaration of interests and declare the following interests: Dr Alison Beck is the CI and will be responsible for conducting the baseline assessments and group therapy intervention. She is also a contract clinical psychologist at the R.E.A.D. Clinic Erina, where the research is to be conducted. Nathan Beehag (co-facilitator) is a contract psychologist at the R.E.A.D. Clinic. The nature of the study minimises the likelihood of potential conflict of interest, in that study participation involves routine elements of psychological assessment (completion of self report questionnaires, clinician administered questionnaires and clinical interview) and participation does not require participants to change their current involvement with services. Furthermore,

there are no financial conflicts of interest as study funding is independent from Dr Beck's and Mr Beehag's income from the R.E.A.D. Clinic. No other authors have competing interests to declare.

Access to Data

Data management and sharing will be overseen by AKB. All named investigators will have access to the cleaned data set. Data sharing will be managed using ownCloud. In accordance with the Research Data and Materials Management Procedure (University of Newcastle, 2015) the final data set will be managed using Cr8it. Cr8it is available within ownCloud and will allow ongoing access to a copy of the study data after it is submitted to the University of Newcastle's repository.

Ancillary and Post-Trial Care

Throughout the study participants will not be asked to change any of their usual treatment. They will also be able to access additional treatment and/ or services as per usual. As this is a one-arm feasibility study, no provisions for post-trial access to the intervention will be made. The proposed RfGT intervention will be developed in close consultation with consumers and will utilise non-invasive, evidence based psychological strategies. In the unlikely event of harm, participants enrolled into the study will be covered as per the conditions set out in The University of Newcastle Medical Malpractice & Professional Indemnity and Public Liability insurance policies.

Dissemination Policy

At the time of consent, all study participants will be invited to indicate whether they wish to receive a summary of findings. A written lay summary will be produced and sent to study participants. The results will also form the basis of several articles that will be submitted to peer reviewed journals to be considered for publication. A list of potential publications will be generated at the beginning of the trial and author order and respective contribution agreed upon. All authors will be required to fulfil the criteria set out within the recommendations of the International Committee of Medical Journal Editors (90). Findings will also be disseminated via conference, seminar, in-house and/or poster presentations. A summary of findings and links to journal articles and other publications/ presentations resulting from the study may also be published on academic, health and/ or consumer oriented websites. A copy of all publications arising from this study will be housed in the University of Newcastle online repository. As appropriate, this study will be used to inform grant applications to fund future investigations.

Trial Registration, Funding and Protocol Details

Trial Register	Australian New Zealand Clinical Trials Registry
Registration Number	ACTRN12616000887471
Date of Registration	06/07/2016
Secondary Identifying Numbers: Universal Trial Number	U1111-1184-8003
Funding Statement: Source(s) of monetary or material support	Dr Beck is supported by a stipend from the NHMRC Centre of Research Excellence in Mental Health and Substance Use (APP1041129; G1200943). In-kind support (therapy room) is provided by the R.E.A.D. Clinic. Dr Banfield is supported by Australian Research Council Discovery Early Career Researcher

	Award DE150100637. No funding provider had direct involvement in study design; the collection, analysis and interpretation of data; the writing of this protocol paper; or the decision to submit this article for publication.
Primary sponsor	Dr Alison Beck
Secondary sponsor	The University of Newcastle
Contact for public and scientific queries	Dr Alison Beck Alison.Beck@newcastle.edu.au Postdoctoral Research Associate School of Medicine & Public Health University of Newcastle & NHMRC CREMS Level 5, McCauley Building Calvary Mater Hospital Waratah, NSW 2298 (02) 4033 5690 (reception) Clinical Psychologist R.E.A.D. Clinic 20/24 Karalta Rd, Erina, NSW 2250 (02) 4363 6600 (reception)
Public title	Recovery-focused group therapy: Exploring a new treatment for adults with experience of bipolar disorder
Scientific title	Exploring the feasibility and acceptability of a recovery-focused group therapy intervention for adults with a bipolar spectrum disorder
Countries of recruitment	Australia
Health condition studied	Bipolar disorder
Intervention	Recovery-focused Group Therapy (RfGT) Eight weekly two hour sessions of RfGT in addition to any usual treatment No comparison condition
Selection Criteria	Inclusion • Aged 18-65 • Meeting DSM-V criteria for BPSD (BP I, BPII, Cyclothymia, Other [Un]Specified) • Able to comprehend English at a level sufficient to complete self-report instruments and clinical interview • Willing to have group therapy sessions audio recorded Exclusion • Acute mood episode (as per DSM-V criteria for mania or depression) currently or in the preceding four weeks • Current suicidal ideation with intent • Unable or unwilling to provide informed consent
Study Type	An open feasibility study, utilising a pre-versus post- treatment design and nested qualitative evaluation
Anticipated date of First Enrolment	June 2017
Target Sample Size	24
Recruitment Status	Recruiting

Primary Outcomes	Outcome Name: Feasibility and Acceptability Method of measurement: 1. Enrolment – including the number of participants referred, the proportion who were eligible and the number consented 2. Frequency, duration and source of referrals (self vs. various service providers across each month of the trial) 3. Number of group therapy sessions attended (and the reasons for any non-attendance) 4. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility/ withdrawal 5. Number of assessments completed; amount of missing data and detailed participant feedback regarding acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments) 6. Number and type of adverse events (if any) 7. Detailed participant feedback Timepoint: Throughout the trial
Key Secondary Outcomes	Clinical Outcomes (Baseline, mid-treatment and/ or post-treatment follow-up): • Quality of life (The Brief Quality of Life in Bipolar Disorder Questionnaire and The EuroQol-five dimensions' questionnaire) • Self-reported recovery (The Bipolar Recovery Questionnaire) • Relapse (The Longitudinal Interval Follow-Up Evaluation) • Self-reported symptoms of depression, anxiety and stress (short-form version of the Depression, Anxiety and Stress Scales) • Level of risk associated with alcohol and/ or other substances (The Alcohol, Smoking and Substance Involvement Screening Test) • Social and occupational functioning (The Social and Occupational Functioning Assessment Scale) Process Measures: (Baseline, mid-treatment and/ or post-treatment follow-up): • Mindfulness (The Five Facet Mindfulness Questionnaire – Short Form) • Psychological flexibility (Acceptance and Action Questionnaire – Version 2) • Valued Action (The Valuing Questionnaire) • Medication adherence (The Medication Adherence Rating Scale) • Impulsivity (The Positive Urgency Measure; The Urgency Subscale of the Urgency, Premeditation, Perseverance and Sensation seeking scale and The Self-control Schedule) Process Measures: (Weekly during RfGT) • Therapeutic alliance (The Group Session Rating Scale)
Protocol Version	1.4 (19 July 2017)

Author Contribution

AKB is trial coordinator and led the development of the study protocol, RfGT intervention and manuscript in collaboration with all investigators listed. All investigators contributed to study design, selection of assessment instruments and informing the duration and content of the group therapy intervention. Specifically, AB contributed expertise on motivational interviewing and multiple health behaviour change; SJ contributed expertise on recovery focused interventions in bipolar disorder; FL contributed expertise on the conduct and process of group therapy interventions in bipolar disorder; FKL contributed expertise on cognitive behaviour therapy for severe mental illness and potential opportunities for integrating technology (e.g. self-monitoring); MB provided expertise from the perspective of a person with lived experience of bipolar disorder (including co-facilitating focus groups with AKB)– ensuring that the perspective of the service user was represented throughout all stages of the research process. JA led the statistical analysis plan and contributed to study design (e.g. advising on sample size and outcome measures). In summary, all authors made substantial contributions to study conception and design. All authors also offered critical revisions to the manuscript for important intellectual content, have approved the final version of this manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Submission Declaration

The work has not been published previously, is not under consideration for publication elsewhere, is approved by all authors and if accepted, will not be published elsewhere in the same form, in English or any other language, without the written consent of the copyright-holder.

Acknowledgements

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

Exploring the Feasibility and Acceptability of a Recovery-focused Group Therapy Intervention for Adults with Bipolar Disorder: Trial Protocol

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Exploring the Feasibility and Acceptability of a Recovery-focused Group Therapy Intervention for Adults with Bipolar Disorder: Trial Protocol

Dr Alison K Beck[a,b] alison.beck@newcastle.edu.au [Corresponding Author]

Prof Amanda Baker[a,b] amanda.baker@newcastle.edu.au

Prof Steven Jones[d] s.jones7@lancaster.ac.uk

Prof Fiona Lobban[d] f.lobban@lancaster.ac.uk

A/Prof Kay-Lambkin[a,b] frances.kaylambkin@newcastle.edu.au

Prof John Attia[e] john.attia@newcastle.edu.au

Dr Michelle Banfield[c] michelle.banfield@anu.edu.au

a. School of Medicine & Public Health, University of Newcastle, NSW, Australia (Postal Address: Level 5, McCauley Centre, Edit St, Waratah, NSW, 2298)

b. NHMRC Centre for Research Excellence in Mental Health and Substance Use, NSW, Sydney, NSW, Australia

c. Centre for Mental Health Research, Australian National University, Canberra, ACT, Australia

d. Spectrum Centre for Mental Health Research, Lancaster University, Lancaster, UK

e. Clinical Research Design, IT, and Statistical Support (CReDITSS) Unit, University of Newcastle, NSW, Australia

Abstract

Introduction: Improving accessible, acceptable recovery-oriented service provision for people with bipolar disorder is an important priority. Mindfulness and acceptance-based cognitive and behavioural therapies (or 'third wave' CBT) may prove fruitful due to the considerable overlap between these approaches and key features of personal recovery. Groups also confer therapeutic benefits consistent with personal recovery and may improve recovery-oriented service provision by adding another modality for accessing support. The primary objective of this trial is to explore the feasibility and acceptability of a new recovery-focused group therapy intervention for adults with bipolar disorder. This is the first published feasibility assessment of a time-limited recovery-focused group therapy intervention for bipolar disorder.

Methods/ analysis: This protocol describes an open feasibility study, utilising a pre- versus post- treatment design and nested qualitative evaluation. Participants will be recruited from the Central Coast region of New South Wales, Australia from primary care providers, specialist mental health services, non-government organisations and via self-referral. The primary outcomes are feasibility and acceptability as indexed by recruitment, retention, intervention adherence, adverse events (if any) and detailed consumer feedback. Clinical outcomes and process measures will be assessed to inform future research. Primary outcome data will utilise descriptive statistics (e.g. summarizing recruitment, demographics, attendance, attrition and intervention adherence). Secondary outcomes will be assessed using repeated-measures analysis of covariance across all time points (including change, effect size and variability).

Ethics and Dissemination: Ethical approval has been granted by the Northern Sydney Local Health District HREC (HREC/16/HAWKE/69) and The University of Newcastle HREC (H-2016-0107). Findings will be used to improve the intervention per user needs and preferences, and inform what amendments and/ or information are required before a follow-on trial would be possible. This study contributes to a growing body of innovative, recovery-oriented innovations of psychological treatments for adults with bipolar disorder.

Registration: Australian New Zealand Clinical Trials Registry
Registration Number: ACTRN12616000887471
Date of Registration: 06/07/2016

Strengths and Limitations of This Study

- The study involves a relatively small number of participants from a limited geographic region and is being conducted with no comparison group and a limited follow up period.
- Although group therapy can be of benefit for adults with experience of BD several logistical challenges may interfere with recruitment to and conduct of the group.
- The proposed intervention is theory driven, incorporates evidence based principles and strategies and will be developed to reflect expert opinion from consumers, clinicians and researchers.
- Intervention duration and setting has also been selected to reflect the central pathway for accessing community based psychological treatment in Australia, thereby minimising the gap between research and 'real world' practice.
- Innovation in the psychological treatment of BD is an important priority and there is a need for improved access to recovery-focused interventions, findings from the current study will contribute to both.

Keywords: Bipolar Disorder, Recovery, Anxiety, Group Therapy, Psychological Intervention, Third wave CBT

BACKGROUND AND RATIONALE

The concept of recovery is central to the delivery and evaluation of services for mental health and alcohol and other drugs [AOD (1, 2)]. Although recovery is personal, common themes include hope, understanding, empowerment and living a meaningful, satisfying life (3-5). Accordingly, recovery extends beyond traditional clinical definitions which focus on reduced symptomatology, hospitalisation and medication compliance (4, 5). There is a corresponding need for evidence based psychosocial treatment approaches to better reflect this evolution in service provision. Recent recovery-focused innovations for bipolar disorder (BD) include individual Recovery-focused CBT [RfCBT;(6)]; "Living with Bipolar" [a web based self-management intervention;(7)]; and ORBIT [Online, recovery-focused, bipolar individual therapy(8)]. Preliminary findings support the feasibility, acceptability and potential effectiveness of these recovery-focused interventions (6, 8, 9).

Drawing from preliminary findings of the potential benefit in BD (10, 11) and severe mental illness more broadly (12) we are particularly interested in the application of mindfulness and acceptance based cognitive and behavioural therapies (or 'third wave' CBT) to treatment innovation in BD [see (13) for a review of these approaches]. 'Third wave' approaches integrate acceptance and mindfulness with CBT (14). Importantly, there is clear concordance between elements of personal recovery (e.g. awareness, understanding, empowerment, valued living) and key targets of 'third wave' approaches, including a) improved awareness of the experience of and reaction to internal events (thoughts, feelings, memories, urges and/ or bodily sensations), b) developing a less reactive and more considered stance toward internal events and c) living life in a chosen and personally meaningful way (13, 14). Moreover, as BD is typically characterised by comorbid conditions [most commonly anxiety and/ or substance misuse; (15)], the transdiagnostic processes targeted by 'third wave' approaches may prove a particularly fruitful avenue for improving recovery outcomes for people with lived experience of BD.

Group based interventions confer a range of clinical benefits consistent with recovery-oriented service provision [e.g. universality, belonging, shared understanding, giving and receiving emotional support, hope and modelling (16)]. Recent protocols lend preliminary support to the utility of mindfulness and acceptance informed groups [e.g. (17, 18)]. However, in contrast to principles of recovery-focused care, published protocols have not been developed in collaboration with service users, detailed qualitative feedback has not been sought and assessment of personal recovery outcomes has yet to be undertaken. Accordingly, an important opportunity exists to improve recovery-focused service delivery.

Research Question

What is the feasibility and acceptability of a recovery-focused group therapy (RfGT) intervention for adults with BD?

Objectives

Primary Objectives

To provide preliminary evidence regarding the feasibility and acceptability of delivering and evaluating a RfGT intervention for adults with BD. Specifically, to:

1. Investigate
    a. Whether clinicians will refer adults with BD into a RfGT intervention
    b. Whether adults with BD will self-refer into a RfGT intervention
    c. Whether adults with BD are willing to participate in feasibility (and follow-on) research evaluations of the RfGT intervention
    d. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility, withdrawal and/ or non-attendance
2. Explore the acceptability of the RfGT intervention as indexed by

a. Number of sessions attended and level of engagement
b. Detailed participant feedback to explore their experience of and satisfaction with the RfGT intervention
c. Number and type of adverse events (if any)

3. Explore the feasibility and acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments)

Secondary Objectives

Secondary objectives will inform the design of future research and include exploring:

1. The feasibility of recruiting participants with BD who also have experience of anxiety and substance related comorbidities
2. What 'treatment as usual' is likely to consist of and potential similarities/ differences to the RfGT intervention
3. The most appropriate primary outcome measure – informed by a combination of detailed participant feedback, feasibility data and effect size estimates
4. Potential mechanisms of change – to understand the processes that may underlie the impact of the RfGT intervention

In accordance with guidelines for developing and evaluating complex interventions (19), the current feasibility study represents vital preparatory work designed to maximise the success of any large scale follow-on evaluation by

a. Producing an intervention that is acceptable to service users
b. Identifying barriers and facilitators to effective recruitment, retention and data collection
c. Informing estimates of recruitment, retention, engagement, adherence and effect size of the intervention across a range of outcome variables.

No pre-specified criteria will be set for determining feasibility of a follow-on evaluation. Rather, our decision-making process will be informed by published guidelines for systematically appraising and responding to feasibility data [the ADePT Framework,(20)]. Specifically, barriers to a large-scale evaluation will be explored, including what amendments and/ or information would be needed to improve the success of a follow-on evaluation and the (im)practicality of addressing these. This information will be used to determine whether a main study is a) not feasible, b) feasible pending modifications to study protocol or c) feasible as is.

Trial Design

An open feasibility study, utilising a pre-versus post- treatment design and nested qualitative evaluation

METHODS

Participants, Interventions and Outcomes

Eligibility

Potential participants will undergo a brief screening assessment (over the phone, Skype or in person, as per participant preference) to ensure that all inclusion and no exclusion criteria are met. Should a participant be deemed ineligible due to a current acute mood episode, if there is sufficient time left in the recruitment period, the potential participant will be offered the option of being re-contacted by the research team to re-assess mood stability (Figure 1).

Inclusion criteria

- Aged 18-65
- Meeting DSM-V criteria for BD (BD I, BD II, Cyclothymia, Other [Un]Specified)
- Able to comprehend English at a level sufficient to complete self-report instruments and clinical interview
- Willing to have RfGT sessions audio recorded

Exclusion criteria

- Current acute mood episode (as per DSM-V criteria for mania or depression)
- Current suicidal ideation with intent (as per clinical judgement following discussion with the potential participant and the research team)
- Unable or unwilling to provide informed consent

Participants will not be excluded due to concurrent treatment (pharmacological or non-pharmacological). Information regarding any concurrent treatment will be collected at baseline and each follow-up occasion.

Sample Size

Based on clinical and research experience we expect that 20 participants will allow us to reliably inform our aim of evaluating the feasibility and acceptability of delivering and evaluating a RfGT intervention. Allowing for attrition of approximately 20% [e.g.(21)], the recruitment target is set at 24. This sample will afford the opportunity to deliver two to three sets of closed intervention groups. Group size (i.e. 8-12 participants per therapy group), has been chosen to reflect 'real world' practice by mirroring the maximum group size subsidised by the Australian government (n=10). The proposed sample size is comparable to published feasibility trials of psychological interventions in BD (8) and above the recommended acceptable floor (n=10 per study arm) for feasibility studies (22).

Recruitment

Potential participants for the proposed RfGT intervention will be sourced from across the Central Coast, NSW. The Central Coast is predominantly urban region and contains approximately 1.5% of the Australian population. Recruitment sources will include:

- The R.E.A.D. Clinic, Erina, NSW.
- Other inpatient, residential, community, outpatient and clinical health organisations, including private, public and not for profit mental health, drug and alcohol and general health services (e.g. general practitioners, psychiatrists, community mental health teams, community health centres, not for profit organisations, residential rehabilitation and inpatient units) located within the borders of the Central Coast Local Health District.
- Advertisements (e.g. online, local media, flyer/ pamphlets, study website)

A member of the research team will contact the principals, directors, case managers and/ or other relevant staff contacts of the above organisations, with information about the study. Should they wish their organization to cooperate with the study, staff members will be asked to provide written information to individual members whom they deem to be an appropriate candidate for the proposed study. If that member or client is interested in participating, based on the information provided, he or she will then voluntarily contact the research team. Alternatively, should the potential participant wish to be contacted directly by a member of the research team, they may choose to complete a "consent to contact" form. At this point, it is made clear that people are only consenting to the research team contacting them to discuss the possibility of participating in the study, as opposed to consenting to participate in the study itself. To maximise participant access, the study will also be advertised online, in local media and via posters and leaflets distributed across willing

organisations. Interested participants will then able to voluntarily contact the research team to obtain further information.

Enrolment

Individuals who fulfil the requirements of the screening interview will be invited to attend an appointment to conduct the baseline assessment (Figure 1). To enhance engagement, baseline assessments will be conducted by the lead facilitator (Clinical Psychologist, AKB). Following completion of the baseline assessment, the chief investigator will assign consecutively eligible participants with a unique alphanumeric code. Participants will then be offered a brief orientation/ overview of the programme and invited to complete a values based task in preparation for the first group.

Participant Reimbursement

Consistent with Australian guidelines for acknowledging the time and value of consumer participation (23), participants will be offered modest reimbursement (for any time, travel and inconvenience associated with participation in study assessments) of up to a total of $40 (or equivalent in gift cards) for the baseline assessment ($20), mid-therapy ($10) and post-therapy ($10) assessments. They will also receive eight sessions of fee-free, consumer-driven, evidence-informed RfGT.

Study Intervention

Development

The RfGT intervention will be developed through collaboration between clinicians, consumers and researchers. It will be an iterative process, guided by (a) principles and strategies adopted by 'third wave' psychosocial approaches [including Mindfulness Based Cognitive Therapy (24); Mindfulness Based Relapse Prevention (25); Acceptance and Commitment Therapy, (26); Dialectical Behaviour Therapy,(27); Compassion-focussed therapy,(28); Acceptance Based Behavioural Therapy for Generalised Anxiety Disorder, (29)], (b) clinical practice guidelines and published evidence regarding effective and essential components of psychological support for BD and common comorbidities (including anxiety and substance misuse) and (c) expert opinion from consumers, clinicians and researchers. Consumer feedback on the importance, relevance, content and format of the proposed RfGT intervention will be explored through a series of focus groups.

Description

The RfGT intervention will be delivered in addition to any usual treatment (pharmacological and/ or psychological). The RfGT intervention will utilise a combination of group discussion, guided discovery, in-session mindfulness practice and homework activities. To ensure that the intervention is collaborative, and respectful of client autonomy, personal choice and responsibility over behaviour change, a motivational interviewing framework will guide the delivery of all sessions.

Intervention content will be selected to support the following treatment objectives

a) Increase awareness of personally held values
b) Strengthen awareness of what group members are already doing that is consistent with these values and support them to continue and/ or expand these actions (as needed)
c) Increase awareness of how group members typically respond to strong internal events (thoughts, feelings and/ or physical sensations), explore the short and long term costs and benefits and (as needed) explore potential opportunities for change

Our first two aims are informed by the importance of personally meaningful change in recovery-focused service provision (4). There is a longstanding appreciation of the relationship between valued action and personal wellbeing within person centred therapeutic approaches (30). Valued action refers to living life in a chosen and meaningful way, guided by what truly matters to the individual [i.e. what they want to stand for, how they want to be with themselves, others and the world (31)]. Over recent years this seemingly intuitive link between valued action and wellbeing [indexed by vitality, mental health and functional outcomes) has been empirically validated (32)]. Moreover, increasing evidence has demonstrated a positive relationship between valued action and functioning following psychological treatment for adults with experience of trauma (33); long-standing symptoms of panic disorder (34) and schizophrenia, anorexia, borderline personality disorder or BD (35). Lack of values clarity (uncertainty about personally held values) and lack of awareness (difficulty noticing actions that are consistent with personally held values) represent two key factors that can undermine valued action (31). Accordingly, as per our first two treatment objectives, these represent key targets of the RfGT intervention.

The third treatment objective of the RfGT intervention is guided by reinforcement sensitivity theory (36, 37). Briefly, three interconnected systems have been implicated in emotion regulation. The Behavioural Activation System (BAS) motivates us to seek out rewarding and/ or desirable experiences and work towards goals. Conversely, The Behavioural Inhibition System (BIS) helps to protect us from unpleasant and/ or undesirable experiences by motivating us to withdraw and/ or avoid. Finally, The Fight/ Flight/ Freeze system works in concert with the BIS to help protect us from threat. Although our understanding of the exact nature and function of emotion regulation systems continues to evolve, altered BIS/ BAS sensitivity has been implicated in risk of depressive and (hypo)manic episodes [(38, 39)] and also progression to BD amongst at risk individuals (40). Of note, these systems have also been linked to common comorbid conditions, including problematic substance use [altered BIS/ BAS sensitivity; (41)] and anxiety (altered BIS/ fight/ flight/ freeze sensitivity; (42)].

Guided by the reinforcement sensitivity theory (36, 37), we seek to use group discussion and guided discovery to explore and normalise any identified vulnerability toward actions driven by urges to withdraw (in response to unpleasant experiences), approach (in response to pleasant experiences) and protect (in response to threatening experiences). Mindfulness skills will be used to strengthen awareness of these urges; the preceding external (e.g. situations/ context, people, places) and associated internal (e.g. thoughts, feelings and sensations) experiences and subsequent actions taken. Learning theory and personally held values will be used to guide group discussion surrounding the short and long term costs and benefits of identified actions. Specifically, the short-term benefits of actions performed in response to each type of urge (e.g. pleasure, relief, safety) will be elicited and the role of any immediate benefits in strengthening the behaviour explored. The short and long-term impact on personally held values will be explored and used to guide discussion around whether/ when a change in response may be useful. The role of evidence based strategies [e.g. self-monitoring; arousal modulation; distress tolerance; graded exposure; stabilising routine etc.; (43)] in supporting desired changes will be explored. Final sessions will focus on developing individual wellness plans.

Dosage and Administration

The intervention will consist of eight RfGT sessions (two hours per session, plus a 15-30-minute mid-session break) held over eight weeks. We have chosen eight sessions to allow flexibility for future iterations to incorporate participant feedback regarding intervention timing and content and remain within the proposed ten session maximum. All sessions will

be led by the same Clinical Psychologist (Dr Alison Beck) and Co-facilitated by the same Masters Level Trained Clinical Psychologist Registrar (Nathan Beehag). Prior to the first session (i.e. upon completion of baseline assessments) all participants will be provided with a brief orientation to the group program by the lead facilitator and assigned a task to complete in preparation for the first session. Participation is completely voluntary and participants are free to withdraw from the intervention at any time and/ or decline to participate in any intervention element. Pending the outcome of the study, the treatment manual will be available upon request.

Integrity

All group therapy sessions will be audio recorded and rated for intervention fidelity by a trained, independent researcher not involved in intervention delivery or participant assessment. A 20% sample will be re-rated by a second, trained independent researcher for inter-rater reliability. Assessors will receive training in the assessment instruments and will have (at a minimum) Masters level training in psychology. Group facilitators will participate in regular supervision, consisting of weekly self-reflection (e.g. experience of delivering the group, challenges, successes and questions) which will be distributed to all study investigators for comment/ feedback. Written feedback will be supplemented by regular phone consultations with AB (fortnightly or 'as needed').

Study Setting

Baseline assessments and the RfGT intervention will be conducted at a community-based private psychology clinic (The R.E.A.D. Clinic) located at Erina, on the Central Coast, NSW, Australia. Post-treatment follow-up assessments will be conducted at the R.E.A.D. Clinic, or remotely (over the phone or Skype; as per participant preference). Aside from the Client Services Receipt Inventory (which will be administered over the phone by a trained research assistant) mid-treatment assessments will be completed online.

Outcomes

Feasibility and acceptability

To address the primary objective of evaluating the feasibility and acceptability of delivering and evaluating a RfGT intervention for BD, the following data will be collected throughout the trial:

1. Enrolment – including the number of participants referred, the proportion who were eligible and the number consented
2. Frequency, duration and source of referrals (self vs. various service providers across each month of the trial)
3. Number of group therapy sessions attended (and the reasons for any non-attendance)
4. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility/ withdrawal
5. Number of assessments completed; amount of missing data and detailed participant feedback regarding acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments)
6. Number and type of adverse events (if any)
7. Detailed participant feedback to explore their experience of and satisfaction with the RfGT intervention and study methods.

Guided by the ADePT Framework (20), we aim to inform our feasibility assessment by exploring what worked well and what worked less well within the three overarching domains of intervention, study design and setting/ context. Barriers to a large-scale evaluation will be explored, including what amendments and/ or information would be needed to improve the

success of a follow-on evaluation and the (im)practicality of addressing these. This information will be used to determine whether a main study is a) not feasible, b) feasible pending modifications to study protocol or c) feasible as is.

Clinical outcomes and process measures

To address our secondary aim of informing the design of any follow-on evaluation, several clinical outcomes and process measures (Table 1 and detailed below) will also be assessed to explore the following parameters:

1. The number of participants who also demonstrate comorbid anxiety and substance (mis)use (as indexed by clinical interview and self-reported experience)
2. Concurrent treatment and support services accessed by study participants (including type, amount, frequency and duration)
3. The most appropriate primary outcome measure
4. Potential mechanisms of change - including (i) mindfulness (ii) experiential avoidance (iii) meaningful action (iv) impulsivity and/ or (v) behaviours and/ or attitudes towards medication

Clinical outcome measures- interviewer administered.

The Structured Clinical Interview for DSM-V disorders [SCID-V; (44)] is a semi-structured interview for making the major DSM-V Axis I diagnoses. The instrument is designed to be administered by a clinician or trained mental health professional and can take up to 90 minutes to complete (given a history of comorbidity). We will administer the mood, psychotic, substance use, anxiety and differential diagnosis modules at baseline to confirm BD diagnosis and provide information about concurrent conditions.

The Longitudinal Interval Follow-Up Evaluation [LIFE;(45)] is a semi-structured interview and rating system for assessing the longitudinal course of psychiatric illness. The SCID-LIFE includes items from the SCID, the Hamilton Depression Rating Scale [HDRS; (46)] and the BecheRafaelsen Mania Rating Scale [MAS;(47)]. Separate severity ratings for mania and depression are generated using a six-point psychiatric status rating. Scores will be used to assess time to first episode of depression and mania, number of weeks out of episode (< 4) and number of weeks without impairment (< 2).

Health service and medication use will be assessed using an adapted version of the Client Service Receipt Inventory (CSRI) – 'Generic' UK Mental Health (48). The content of this inventory has been updated to reflect key sources of mental health expenditure in Australia [e.g. (49)]. These data will allow us to identify elements of 'treatment as usual' utilised by study participants across the trial, and provide some insight into costing.

The Social and Occupational Functioning Assessment Scale [SOFAS; (50)] is a 100 point scale used by the clinician to rate current social and occupational functioning on a continuum from excellent to grossly impaired, with lower scores reflecting poorer functioning. Unlike other widely used global rating scales (e.g. Global Assessment of Functioning), the SOFAS is designed to provide an index of social and occupational functioning independent of the overall severity of psychological symptoms – this is particularly important in the current study considering the likely heterogeneity of symptoms and severity. A global rating scale has been chosen in preference to the multi-domain assessment of functioning recommended in the DSM-V (i.e. WHO-DAS 2.0) to streamline assessment and minimise burden.

Clinical outcome measures- self-report.

The Brief Quality of Life in Bipolar Disorder Questionnaire [QoL.BD; (51)] is the condensed 12-item version of a 56 item instrument designed to specifically assess quality of life in individuals with BD (51). Preliminary evidence supports the feasibility, reliability and validity of this tool for assessing BD specific quality of life (51).

The Bipolar Recovery Questionnaire [BRQ;(3)] is a 36-item questionnaire designed to assess personal recovery, specifically, as it pertains to adults with BD-I or BD-II. Preliminary evidence supports the psychometric properties of this tool (3).

The short-form version of the Depression, Anxiety and Stress Scales [DASS-21;(52)] is a 21 item version of the original 42 item DASS (52). It includes three, seven item self-report scales designed to measure emotional states of depression, anxiety and stress. The depression scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/ involvement, anhedonia and inertia. The anxiety scale assesses autonomic arousal, tension, situational anxiety and subjective experience of anxious affect. The stress scale is sensitive to chronic, non-specific arousal (e.g. difficulty relaxing, agitation, irritability). Each item is rated on a 4-point scale of severity/ frequency over the preceding one week. The DASS-21 demonstrates sound reliability and validity (53) and Australian normative data are available.

The Alcohol, Smoking and Substance Involvement Screening Test [ASSIST 3.1;(54)] is an eight-item questionnaire designed to screen for the use (3 month and lifetime) of tobacco, alcohol, cannabis, cocaine, amphetamine type stimulants, sedatives and sleeping pills, hallucinogens, inhalants, opioids and 'other' drugs. The ASSIST generates a risk score (lower, moderate, high) for each substance category. It was originally designed to be administered by a health worker, but preliminary evidence supports the feasibility (55), reliability and validity (56, 57) of self-report administration.

The EuroQol five dimensions' questionnaire (EQ-5D) is a widely-implemented instrument for assessing health related quality of life and estimating quality-adjusted life years in cost-utility analyses. This five item self-report inventory assesses five domains of quality of life (mobility, self-care, usual activities, pain/discomfort and anxiety/ depression). We will use the newest version - the EQ-5D-L (58). To correct potential ceiling effects associated with the original version, the EQ-5D-L uses five (relative to three) response categories to assess the severity of problems experienced (no problem, slight, moderate, severe, extreme).

Process measures.

The Five Facet Mindfulness Questionnaire-SF [FFMQ-SF;(59)] is a 24-item version of the FFMQ (60). It comprises five domains (observing; describing; acting with awareness; non-judging of experiences and non-reactivity to experiences), which can also be summed to produce an overall score. Higher scores reflect greater mindfulness. Each item is rated on a five-point scale from one (never or very rarely true) to five (very often or always true) in terms of what is 'generally true for you'. Evidence supports the reliability, validity and sensitivity to change of this condensed version of the FFMQ (59).

The Acceptance and Action Questionnaire [AAQ-2; (61)] is a seven-item questionnaire designed to assess experiential avoidance vs psychological flexibility, with higher scores reflecting greater experiential avoidance. The AAQ-2 has demonstrated good internal consistency and test-retest reliability (61, 62).

The Valuing Questionnaire [VQ; (63)] is a ten item self-report inventory designed to assess the extent of past values enactment over the preceding one week. It comprises two factors, progress (awareness of and enactment on what is truly important) and obstruction (disruption to valued living arising from avoidance, distraction and/ or inattention). Preliminary evidence supports the psychometric properties of this instrument (63).

The Positive Urgency Measure [PUM; (64)] is a 14-item self report measure of positive urgency – the tendency to act impulsively in response to positive moods. Each item is rated on a four point Likert scale from one (agree strongly) to four (disagree strongly). The scale demonstrates sound psychometric properties, including high internal consistency [α = 0.94-0.95, (64); α = 0.82, (65)] and PUM scores have been associated with addictive behaviours [e.g. gambling and drinking; (66)].

The Urgency, Premeditation, Perseverance and Sensation Seeking (UPPS) Impulsive Behaviour Scale (67) is a 45-item self-report inventory designed to assess

impulsivity across dimensions of the Five Factor Model of Personality. In accordance with prior research [e.g. (68)] we will use the 12-item urgency subscale as an index of impulsive behaviour in response to negative affect, including difficulty resisting craving and temptation. As per the PUM, each item is rated on a four point Likert scale from one (agree strongly) to four (disagree strongly). The Urgency Subscale demonstrates high internal consistency [e.g. α = 0.86-0.89; (69) and (68) α = 0.89].

The Self-Control Schedule (70) is a 36-item self-report inventory designed to assess the use of different self-control methods to solve behavioural problems (including 'self-statements'/ cognitions; problem solving; delaying immediate gratification and belief in self-efficacy). Each item is rated from minus three to plus three, with higher scores indicating greater utilisation of self-control methods. Good reliability and validity is reported by the author (70). Preliminary findings also support the sensitivity of the instrument for detecting change after psychological therapy for BD (71).

The Medication Adherence Rating Scale [MARS; (72)] is a 10 item (yes/no) self report instrument designed to assess behaviour and attitude toward medication over the preceding one week. The instrument is designed to be scored from zero to ten, with higher scores indicating greater medication adherence.

Therapeutic alliance.

The Group Session Rating Scale [GSRS; (73)] is a four-item visual analogue scale, designed to be a brief tool to assess group-therapy alliance. The items assess 'relationship', 'goals and topics', 'acceptability of approach' and 'overall fit' are ranked from low to high according to pre-specified anchors. GSRS scores are obtained by measuring the marks made by the client and summing the lengths (nearest cm) of each line (maximum total score = 40). Evidence supports the reliability and concurrent validity of this instrument for use in substance use populations (74).

Adherence to treatment protocol

The schedule of fidelity assessments is detailed in Table 2. Adherence to recovery-oriented service provision will be guided by the Recovery-oriented Service Self-Assessment (75). The ROSSAT was developed by the Mental Health Coordinating Council in consultation with consumer advocacy group Being as a mechanism for workers (76) and organisations (77) to assess their level of recovery-oriented service provision. Item content reflects six key indicators of recovery-oriented service provision identified during the ROSSAT development process [relationships; respectful practice; consumer self-directed focus; belief in consumers recovery; obtaining and sharing knowledge and information; and participation and social inclusion; (4)].

Both RfGT facilitators will complete the ROSSAT Tool for workers (76) after sessions one, four and eight. This tool comprises 37 items across four domains: values, principles and philosophy underpinning service provision; recovery-oriented service provision; workers' responsibilities, roles and attributes; education and training. Each item is rated on a five point Likert scale from one (needs significant development) to five (outstanding achievement). Objective assessment will also be conducted by having an independent assessor rate all audio recordings of the RfGT sessions against a subscale (recovery-oriented service provision) of the corresponding ROSSAT Tool for organisations (77). Each item is rated on a four point Likert scale from one (needs significant development) to four (outstanding achievement).

Adherence to intervention content will be guided by a checklist specifically designed for the current study. The checklist will reflect the key aims, activities and discussion points for each RfGT session. At the end of each session facilitators will be asked to rate the degree to which each item was addressed and to note any deviations. An objective rating of this checklist will also be undertaken by an independent assessor based on their review of

session audio recordings. As the intervention is grounded in CBT, audio-recordings will also be rated for fidelity using the Cognitive Therapy Scale – revised version (78).

Participant Timeline

Table 1. Schedule of Participant Assessments

	Pre-Intervention		Intervention Phase	Follow-Up Phase	
	Screening	Baseline	Each session	Mid Treatment	Post Treatment
Inclusion/ Exclusion Criteria	✓				
Informed Consent		✓			
Demographics (e.g. age, education, employment and marital status)		✓			
Clinical history (e.g. family history of mood disorder, age at onset and number of affective episodes)		✓			
Client Services Receipt Inventory		✓		✓	✓
SCID (Lifetime/ 12 months)		✓			
Brief Quality of Life – Bipolar Disorder		✓		✓	✓
Bipolar Recovery Questionnaire		✓		✓	✓
SCID-LIFE (3 months)					✓
Depression, Anxiety and Stress Scales (21 item version)		✓		✓	✓
The Alcohol, Smoking and Substance Involvement Screening Test (v3.1)		✓		✓	✓
The Five Facet Mindfulness Questionnaire- Short Form		✓		✓	✓
The Acceptance and Action Questionnaire (v2)		✓		✓	✓
The Valuing Questionnaire		✓		✓	✓
Positive Urgency Measure		✓		✓	✓
UPPS Impulsive Behaviour Scale – Urgency Subscale		✓		✓	✓
The Self-Control Schedule		✓		✓	✓
The Medication Adherence Rating Scale		✓		✓	✓

EuroQol five dimensions' questionnaire		✓		✓	✓
The Group Session Rating Scale			✓		

LIFE: The Longitudinal Interval Follow-up Evaluation; SCID: The Structured Clinical Interview for DSM-V disorders; UPPS: Urgency, premeditation, perseverance and sensation seeking

Table 2. Schedule of Fidelity Assessments

	Group Facilitators	Fidelity Assessor
ROSSAT	✓[a, b]	✓
Study Checklist	✓	✓
CTS-R		✓

CTS-R: Cognitive Therapy Scale – revised version; ROSSAT: Recovery-oriented Service Self-Assessment;
a. After sessions one, four and eight only; b. Recovery subscale only

Data Collection, Management and Analysis

Data Collection

To facilitate engagement and working alliance the baseline assessment will be conducted face-to-face at the R.E.A.D. Clinic by the lead facilitator. Post-treatment follow-up assessments will be conducted face-to-face or remotely (e.g. Skype, telephone) as per participant preference, by a trained research assistant not involved in intervention delivery. Aside from the Client Services Receipt Inventory (which will be administered over the phone by a trained research assistant) mid-treatment assessments will be completed online.

Interviewer administered instruments will be collected in hard copy and electronic formats (i.e. hard copy scanned into a computer and/ or directly entered into an electronic database). Baseline and follow-up self-report questionnaires will be collected on-line (e.g. using Survey Monkey or similar). As the BRQ (3) utilises a visual analogue scale, this questionnaire will be completed by hand and returned electronically (e.g. faxed, scanned or photographed and returned by email). The score will be calculated and entered into an electronic database. The GSRS (73) also employs a visual analogue scale. Hard copies will be completed by intervention participants at the end of each group therapy session. The score will be calculated and entered into an electronic database. Group therapy sessions will be audio recorded using hand-held audio-recorders. Audio files will be uploaded onto a secure electronic server for storage and analysis.

Data Management

Data entry will be performed by AKB. All hard copy data will be entered into Microsoft Excel. All data collected online will be downloaded and saved into the Excel database. Several mechanisms will be used to ensure data integrity, including referential data rules, valid values and range checks. Data query reports will be used to check for errors in data entry. Identified queries will be cross checked against the original data source. A log of any changes made to the original data source or electronic database will be maintained throughout the trial.

Statistical Methods

The following statistical analysis plan has been developed in collaboration with the Clinical Research Design, IT and Statistical Support (CReDITSS) Unit at the University of Newcastle. Considering the primary aim of exploring feasibility and acceptability, we expect

that outcome data will primarily utilise descriptive statistics (summarizing recruitment, demographics, attendance, attrition and intervention adherence). For the secondary outcomes, i.e. scores on various measures at baseline, mid-treatment, and at post-treatment follow-up, we intend to use repeated-measures analysis of covariance across all time points (including change, effect size and variability); this will minimise the number of statistical tests and reduce the risk of inflated type I error. These models will include group, time, and group X time interaction terms. This approach also provides an omnibus test, which if significant, will reduce type I error when doing post-hoc analyses of pairwise contrasts, e.g. baseline vs midpoint, baseline vs post treatment values. Level of significance will be set at $P < 0.05$.

Monitoring

Potential Harms

Dealing with Risk

We acknowledge that discussing mood and related experiences may be associated with feelings of distress. Accordingly, participants will be offered a 'support call' 24-48 hours after each assessment occasion to assess any adverse impact of the assessment process. In the event that a participant raises concerns about feelings of distress, this will be documented and responded to as per guidelines for reporting adverse events (see below) and/ or assessing and responding to suicide risk [as appropriate; (79)].

Although suicidal ideation is a common feature of BD (80) and not necessarily accompanied by intent and/ or attempt (80, 81) regular risk assessment will be undertaken throughout the study. Risk of suicide will be assessed at screening and then at each assessment occasion (and as needed, at each follow-up 'support call'). Consistent with NSW Health Guidelines for assessing and managing risk of suicide (79), in the first instance, a hierarchy of screening questions will be utilised, and as needed, supplemented by a follow-up comprehensive risk assessment. Any participant endorsing suicidal ideation will be asked whether they would like written information about available support services (e.g. Lifeline and Suicide Call Back Service), and/ or a self-help 'tip sheet' developed by the suicide call back service.

Adverse Events

An adverse event (AE), also referred to as an adverse experience, will be defined as any unfavourable/ unintended psychiatric occurrence in a study participant necessitating acute or crisis intervention – whether it is considered to be intervention-related or not. 'Psychiatric occurrence' will be defined in terms of any change in mental state that precipitates acute care and/ or crisis intervention. This may include suicidality, self-harm, acute mood episode and/ or intoxication from alcohol and/ or substances.

A subset of AEs will be classified as 'serious adverse events' and will require expedited reporting. Serious adverse events will be defined as

- Any AE resulting in hospitalisation
- Any AE resulting in persistent or significant disability/ incapacity
- When the untoward psychiatric occurrence is life threatening (NOTE: The term "life-threatening" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe)
- When the untoward psychiatric occurrence results in death

Adverse events will be assessed at each follow-up occasion via questions pertaining to treatment history. Any instance of acute/ crisis intervention will be documented by the research assistant and reported to the responsible HREC. The lead facilitator of the RfGT

intervention (AKB) will also document and report any utilisation of acute/ crisis intervention they learn about while delivering the intervention.

The University of Newcastle HREC will be informed about any adverse events, unforeseen events and complaints within 72hours of learning about them. The relevant University of Newcastle template for reporting trial events will be used. The reports will be independently reviewed by the University of Newcastle HREC (sub)committee or Executive to determine whether the event is trial related and the appropriate course of action. If the HREC (sub)committee or Executive deems further information is required, it will request this from:

a) An independent expert in the area; or
b) The co-ordinating Investigator

Adverse event reports and outcomes will also be reported to the NSLHD-HREC for independent review.

Data Monitoring

An independent data safety monitoring board will not be convened. The current study is a one-arm trial of a non-invasive psychological intervention, that will be developed in close consultation with consumers to reflect evidence based principles and strategies. It will be delivered in the context of 'treatment as usual', does not involve experimental administration of medicine or experimental therapeutic devices and no interim analyses are planned. For each assessment occasion, AKB will review the first three assessments and every one in five thereafter for completeness and accuracy. To inform feasibility assessment a log will be maintained of any missing data, errors in administration and corrective feedback provided to study assessors.

Auditing

Written updates and project meetings will be held at least quarterly, or more frequently as needed. Written updates and meetings will focus on consumer involvement, intervention development, recruitment rates, treatment fidelity, progress with follow−ups, discussion of adverse events (if any), data management and project timelines. Identified problems will be discussed and potential solutions posed.

Discussion

In accordance with calls to improve the transparency and quality of complex behaviour change research (82), the current paper details the protocol for an open feasibility study of a recovery-focused group therapy intervention for adults with experience of BD. Preliminary evidence supports the feasibility and acceptability of recovery-focused interventions in BD (6, 8, 9). Mindfulness and acceptance based therapies also show promise [(17, 18, 83), see also (10) for a recent systematic review]. To our knowledge, only one other group therapy protocol has combined these approaches for treatment of BD (currently being investigated by a team at the University of Exeter, However, unlike the current study, the THRIVE protocol specifically targets individuals who experience rapid cycling and at 16 sessions, is less practical for an Australian healthcare setting. As this is the first trial whereby recovery-oriented and third-wave approached have been combined into a time-limited (i.e. ≤ 10 sessions) group therapy intervention for adults with BD, feasibility assessment is warranted. Specifically, to identify what challenges would undermine the success of a follow-on evaluation, explore the practicality of addressing these and discuss the best pathway forward (19). Accordingly, this study reflects vital preparatory work to maximise the success of any future full scale evaluation, and conversely, to curtail further investment in an untenable proposal.

Strengths

Feasibility studies represent an important, but often under-utilised and under-reported phase of intervention development and evaluation (19). This feasibility study was prospectively registered and is reported here in accordance with best practice recommendations for intervention protocols (84). Interpretation of outcome data will be informed by published guidelines (20) and recommendations will be made regarding what further information and/ or amendments to the intervention, context and / or design would be needed to maximise the success of a follow-on evaluation (and the practicality of same).

Innovation in the psychological treatment of BD is an important priority and there is a need for improved access to recovery-focused interventions (11). Findings from the current study will contribute to both. The proposed intervention is theory driven, incorporates evidence based principles and strategies and will be developed to reflect expert opinion from consumers, clinicians and researchers. Intervention duration and setting has also been selected to reflect the central pathway for accessing community based psychological treatment in Australia, thereby minimising the gap between research and 'real world' practice. To this end, we have also chosen to recruit participants with a bipolar spectrum disorder (i.e. relative to limiting to BD-I and/ or BD-II) to reflect both the heterogeneity and diagnostic ambiguity that is often characteristic of patients who present to primary care settings (85, 86). Furthermore, our decision to exclude participants from the group if they are experiencing a current episode of depression or mania (i.e. relative to specifying a symptom threshold) means that our sample is more likely to reflect the between episode symptoms that often characterise the course of BD. Additional strengths include our carefully characterised sample, use of an independent assessor to conduct follow-up assessments, structured attempt to characterise treatment as usual and comprehensive fidelity assessment.

Limitations

Some limitations are also apparent. Firstly, although group therapy can be of benefit for adults with experience of BD (87), our decision to utilise a closed group format is not without logistical challenges. For example, participant flow must be sufficient to form a group within a reasonable timeframe, as risk of drop-out has been found to increase with increased wait-time [e.g. (88)]. Furthermore, if attrition remains high, membership of closed groups may diminish such that the group itself is no longer viable. Secondly, utilising a private facility to deliver the intervention may inadvertently impact study recruitment. For example, beliefs by service users and/ or providers surrounding private psychology (e.g. high cost, unsuitable for severe mental illness) may interfere with willingness to refer. However, from a translational perspective, as private psychology providers represent a key mechanism for accessing psychological support in Australia, willingness of individuals and/ or service providers to refer to a private facility is an important feasibility question. Thirdly, detailed qualitative evaluation of acceptability is also currently limited to group members. Pending acceptability at the level of the client, further research would be needed to explore acceptability to health care providers. The study will also involve a relatively small number of participants from a limited geographic region (Central Coast, NSW Australia). However, the proposed sample size is within the range of related feasibility studies [e.g. (8)] and above the acceptable floor (n=10 per study arm) for feasibility studies (22). Finally, this is an open trial with no comparison group and limited follow-up period. Although this design is appropriate for addressing our objectives of feasibility and acceptability (89), pragmatic considerations (funding and time constraints) meant that the current protocol was amended from a pilot RCT with three-month post treatment follow-up [see (90) for details of original registration on the ANZCTR].

Conclusions

Treatment innovation in BD is an important priority (11). Improved focus on personally meaningful recovery relative to traditional clinical outcomes is needed. To accommodate individual needs and preferences, choice over treatment modality is important (91). Group therapy confers a range of therapeutic benefits including universality, belonging, giving and receiving emotional support, modelling, practicing interpersonal skills and bonding (16). Group therapy also represents a considerable under-utilised resource within the Australian primary healthcare setting [representing less than 1% of Medicare funded services with a Clinical Psychologist in 2015; (92). To ensure that the proposed intervention is directly transferrable to existing models of time-limited, government subsidized mental health care in Australia, a protocol with a maximum of ten sessions is needed. The current study represents an important step in bridging the gap between research and clinical practice by working closely with consumers to develop an acceptable intervention that is also accessible under existing service delivery models.

Ethics and Dissemination

Research Ethics Approval

This study has been approved by the Northern Sydney Local Health District HREC, reference number RESP/16/45; HREC/16/HAWKE/69 and The University of Newcastle HREC, reference number H-2016-0107.

Protocol Amendments

Any amendments will be submitted to the Northern Sydney Local Health District HREC for review and registered with the University of Newcastle HREC prior to implementation as per HREC guidelines. AKB will oversee the submission of amendments and associated update of trial registration. Version control using protocol identifiers and dates, and a list of amendments will be maintained to track the history of amendments and identify the most recent version of study documentation.

Informed Consent

Potential participants will receive written information about the study, in the form of a flyer and/ or patient information and consent form (PICF) posted online; in client areas at the R.E.A.D. Clinic; in client areas at other community and outpatient clinical health organisations and/ or offered by their health professional and/ or support worker. Individuals interested in hearing more about the study can then voluntarily contact the research team (AKB, NB or MB) for further information, or elect for their health professional/ support worker to provide their contact details to the research team. Interested clients will then be provided with further information about the study, and the opportunity to have any questions addressed. If they remain interested in participating, AKB will provide them with a copy of the information and consent form (hard or soft copy as per participant preference) and arrange a convenient time to complete the screening interview.

Confidentiality

Assessment data will be labelled with a unique alphanumeric code. All hardcopy data will be securely stored in a locked filing cabinet. In accordance with University Policy and Ethical Approval, all electronic data and data sets will be password protected and stored on a secure university server (ownCloud). The encrypted file containing the link between participant details and each unique alphanumeric code will be password protected, stored separately to study data and accessible only to key research personnel. At the completion of the project, the encrypted document containing participant codes and associated participant contact details will be destroyed. In accordance with the Research Data and Materials Management Procedure (University of Newcastle, 2015) this non-identifiable data will then be retained for a minimum of 20 years after date of publication or termination of the study.

Competing Interests Statement

We have read and understood BMJ policy on declaration of interests and declare the following interests: Dr Alison Beck is the CI and will be responsible for conducting the baseline assessments and group therapy intervention. She is also a contract clinical psychologist at the R.E.A.D. Clinic Erina, where the research is to be conducted. Nathan Beehag (co-facilitator) is a contract psychologist at the R.E.A.D. Clinic. The nature of the study minimises the likelihood of potential conflict of interest, in that study participation involves routine elements of psychological assessment (completion of self report questionnaires, clinician administered questionnaires and clinical interview) and participation does not require participants to change their current involvement with services. Furthermore,

there are no financial conflicts of interest as study funding is independent from Dr Beck's and Mr Beehag's income from the R.E.A.D. Clinic. No other authors have competing interests to declare.

Access to Data

Data management and sharing will be overseen by AKB. All named investigators will have access to the cleaned data set. Data sharing will be managed using a secure university server (ownCloud). In accordance with the Research Data and Materials Management Procedure (University of Newcastle, 2015) the final data set will be managed using Cr8it. Cr8it is available within ownCloud and will allow ongoing access to a copy of the study data after it is submitted to the University of Newcastle's repository.

Ancillary and Post-Trial Care

Throughout the study participants will not be asked to change any of their usual treatment. They will also be able to access additional treatment and/ or services as per usual. As this is a one-arm feasibility study, no provisions for post-trial access to the intervention will be made. The proposed RfGT intervention will be developed in close consultation with consumers and will utilise non-invasive, evidence based psychological strategies. In the unlikely event of harm, participants enrolled into the study will be covered as per the conditions set out in The University of Newcastle Medical Malpractice & Professional Indemnity and Public Liability insurance policies.

Dissemination Policy

At the time of consent, all study participants will be invited to indicate whether they wish to receive a summary of findings. A written lay summary will be produced and sent to study participants. The results will also form the basis of several articles that will be submitted to peer reviewed journals to be considered for publication. A list of potential publications will be generated at the beginning of the trial and author order and respective contribution agreed upon. All authors will be required to fulfil the criteria set out within the recommendations of the International Committee of Medical Journal Editors (93). Findings will also be disseminated via conference, seminar, in-house and/or poster presentations. A summary of findings and links to journal articles and other publications/ presentations resulting from the study may also be published on academic, health and/ or consumer oriented websites. A copy of all publications arising from this study will be housed in the University of Newcastle online repository. As appropriate, this study will be used to inform grant applications to fund future investigations.

Trial Registration, Funding and Protocol Details

Trial Register	Australian New Zealand Clinical Trials Registry
Registration Number	ACTRN12616000887471
Date of Registration	06/07/2016
Secondary Identifying Numbers: Universal Trial Number	U1111-1184-8003
Funding Statement: Source(s) of monetary or material support	Dr Beck is supported by a stipend from the NHMRC Centre of Research Excellence in Mental Health and Substance Use (APP1041129; G1200943). In-kind support (therapy room) is provided by the R.E.A.D. Clinic. Dr Banfield is supported by Australian Research Council Discovery Early Career Researcher

	Award DE150100637. No funding provider had direct involvement in study design; the collection, analysis and interpretation of data; the writing of this protocol paper; or the decision to submit this article for publication.
Primary sponsor	Dr Alison Beck
Secondary sponsor	The University of Newcastle
Contact for public and scientific queries	Dr Alison Beck Alison.Beck@newcastle.edu.au Postdoctoral Research Associate School of Medicine & Public Health University of Newcastle & NHMRC CREMS Level 5, McCauley Building Calvary Mater Hospital Waratah, NSW 2298 (02) 4033 5690 (reception) Clinical Psychologist R.E.A.D. Clinic 20/24 Karalta Rd, Erina, NSW 2250 (02) 4363 6600 (reception)
Public title	Recovery-focused group therapy: Exploring a new treatment for adults with experience of bipolar disorder
Scientific title	Exploring the feasibility and acceptability of a recovery-focused group therapy intervention for adults with a bipolar spectrum disorder
Countries of recruitment	Australia
Health condition studied	Bipolar disorder
Intervention	Recovery-focused Group Therapy (RfGT) Eight weekly two hour sessions of RfGT in addition to any usual treatment No comparison condition
Selection Criteria	Inclusion • Aged 18-65 • Meeting DSM-V criteria for BPSD (BP I, BPII, Cyclothymia, Other [Un]Specified) • Able to comprehend English at a level sufficient to complete self-report instruments and clinical interview • Willing to have group therapy sessions audio recorded Exclusion • Acute mood episode (as per DSM-V criteria for mania or depression) currently or in the preceding four weeks • Current suicidal ideation with intent • Unable or unwilling to provide informed consent
Study Type	An open feasibility study, utilising a pre-versus post- treatment design and nested qualitative evaluation
Anticipated date of First Enrolment	June 2017
Target Sample Size	24
Recruitment Status	Recruiting

Primary Outcomes	Outcome Name: Feasibility and Acceptability Method of measurement: 1. Enrolment – including the number of participants referred, the proportion who were eligible and the number consented 2. Frequency, duration and source of referrals (self vs. various service providers across each month of the trial) 3. Number of group therapy sessions attended (and the reasons for any non-attendance) 4. Retention to the study (including screening, baseline, intervention and follow-up) and reasons for ineligibility/ withdrawal 5. Number of assessments completed; amount of missing data and detailed participant feedback regarding acceptability of data collection methods (including the number, frequency, duration, content and delivery method of study assessments) 6. Number and type of adverse events (if any) 7. Detailed participant feedback Timepoint: Throughout the trial
Key Secondary Outcomes	Clinical Outcomes (Baseline, mid-treatment and/ or post-treatment follow-up): • Quality of life (The Brief Quality of Life in Bipolar Disorder Questionnaire and The EuroQol-five dimensions' questionnaire) • Self-reported recovery (The Bipolar Recovery Questionnaire) • Relapse (The Longitudinal Interval Follow-Up Evaluation) • Self-reported symptoms of depression, anxiety and stress (short-form version of the Depression, Anxiety and Stress Scales) • Level of risk associated with alcohol and/ or other substances (The Alcohol, Smoking and Substance Involvement Screening Test) • Social and occupational functioning (The Social and Occupational Functioning Assessment Scale) Process Measures: (Baseline, mid-treatment and/ or post-treatment follow-up): • Mindfulness (The Five Facet Mindfulness Questionnaire – Short Form) • Psychological flexibility (Acceptance and Action Questionnaire – Version 2) • Valued Action (The Valuing Questionnaire) • Medication adherence (The Medication Adherence Rating Scale) • Impulsivity (The Positive Urgency Measure; The Urgency Subscale of the Urgency, Premeditation, Perseverance and Sensation seeking scale and The Self-control Schedule) Process Measures: (Weekly during RfGT) • Therapeutic alliance (The Group Session Rating Scale)
Protocol Version	1.4 (19 July 2017)

Author Contribution

AKB is trial coordinator and led the development of the study protocol, RfGT intervention and manuscript in collaboration with all investigators listed. All investigators contributed to study design, selection of assessment instruments and informing the duration and content of the group therapy intervention. Specifically, AB contributed expertise on motivational interviewing and multiple health behaviour change; SJ contributed expertise on recovery focused interventions in bipolar disorder; FL contributed expertise on the conduct and process of group therapy interventions in bipolar disorder; FKL contributed expertise on cognitive behaviour therapy for severe mental illness and potential opportunities for integrating technology (e.g. self-monitoring); MB provided expertise from the perspective of a person with lived experience of bipolar disorder (including co-facilitating focus groups with AKB)– ensuring that the perspective of the service user was represented throughout all stages of the research process. JA led the statistical analysis plan and contributed to study design (e.g. advising on sample size and outcome measures). In summary, all authors made substantial contributions to study conception and design. All authors also offered critical revisions to the manuscript for important intellectual content, have approved the final version of this manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Submission Declaration

The work has not been published previously, is not under consideration for publication elsewhere, is approved by all authors and if accepted, will not be published elsewhere in the same form, in English or any other language, without the written consent of the copyright-holder.

Acknowledgements

We gratefully acknowledge the volunteers of ACACIA: The ACT Consumer and Carer Mental Health Research Unit, for their valuable feedback on the RfGT Intervention. Thanks also to The R.E.A.D. Clinic for providing facilities to conduct study assessments and intervention delivery and The Centre for Mental Health Research, Australian National University for providing facilities to conduct the focus groups.

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Figure Legends

Figure 1. Participant Timeline

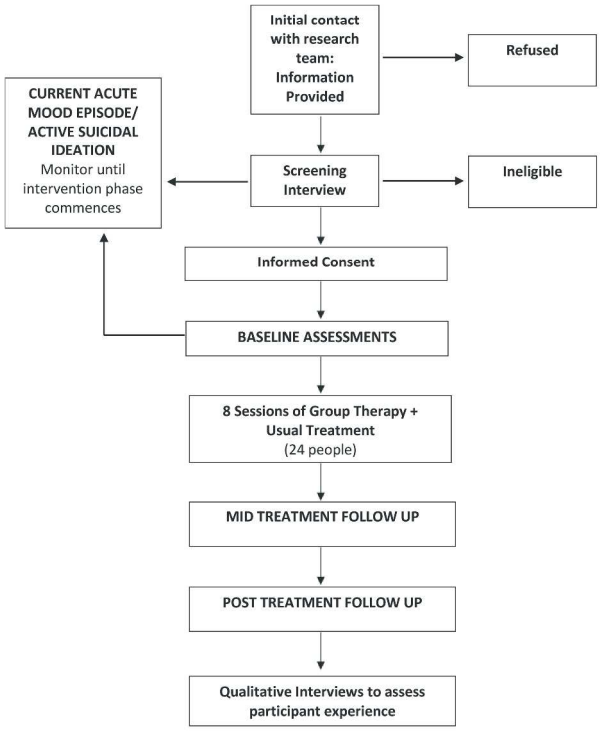

Figure 1. Participant Timeline

297x420mm (300 x 300 DPI)

Table 2

CONSORT checklist of information to include when reporting a pilot trial

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1-2
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Study Protocol Only – This item will be reported in the outcomes paper

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Participants:			
4a	Eligibility criteria for participants		4-5
4b	Settings and locations where the data were collected		8 and 15
4c		How participants were identified and consented	5-6 and 19
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		6-8
Outcomes:			
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-14
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Study Protocol Only – This item will be reported in the outcomes paper
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	4 and 9
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	5
7b	When applicable, explanation of any		17

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		NA – open feasibility study
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA – open feasibility study
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		NA – open feasibility study
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		NA – open feasibility study
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		NA – no blinding – participants aware they are participating in group therapy. But follow-up assessor was independent (not involved in intervention delivery) – page 15
11b	If relevant, description of the similarity of		NA – open feasibility study

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	interventions		
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	15
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	NA
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Study Protocol Only – This item will be reported in the outcomes paper
13b	For each group, losses and exclusions after randomisation, together with reasons		Study Protocol Only – This item will be reported in the outcomes paper
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		Study Protocol Only – This item will be reported in the outcomes paper Methods pertaining to recruitment and follow-up are detailed on pp 5-6 and 13

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	Study Protocol Only – This item will be reported in the outcomes paper
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Study Protocol Only – This item will be reported in the outcomes paper
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Study Protocol Only – This item will be reported in the outcomes paper
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Study Protocol Only – This item will be reported in the outcomes paper
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	NA
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	Study Protocol Only – This item will be reported in the outcomes paper

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		Study Protocol Only – This item will be reported in the outcomes paper Methods pertaining to potential harms are detailed on pp 16-17
19a		If relevant, other important unintended consequences	As above
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	16 – and will be discussed in greater detail in the outcome paper
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	16 - – and will be discussed in greater detail in the outcome paper
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Study Protocol Only – This item will be reported in the outcomes paper
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	Study Protocol Only – This item will be reported in the outcomes paper

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	2
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	Study Protocol Only – This item will be reported in the outcomes paper
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		20-21
26		Ethical approval or approval by research review committee, confirmed with reference number	2 and 19

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.