Developing a recovery focused therapy for older people with bipolar disorder

This thesis is submitted for the degree of PhD in Health Research

Division of Health Research, Faculty of Health and Medicine, Lancaster University

Dr Elizabeth Tyler, ClinPsyD, PGcert, BSc Hons

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Abstract

Background

There has been little research into the psychosocial needs of older people living with bipolar disorder (BD). There is evidence to suggest that psychological treatments developed for working aged adults are effective. These treatments may not be acceptable or effective for an older population due to differences in presentation in later life.

Aims

The overarching aim of the thesis was to develop a recovery focused therapy (RfT) for older people with BD. The main aims were to: improve our understanding of how BD presents in older adults, identify whether any potential adaptations were needed to an existing therapy (RfT) to meet the needs of an older adult population and to evaluate the feasibility and acceptability of RfT for older adults (RfT-OA) with BD.

Methods

Study one was a systematic review of psychosocial functioning and quality of life in older people with BD. Study two was a qualitative study, using focus group methodology, to increase our understanding of BD in later life and inform the development of RfT-OA. Study three was a mixed methods study to evaluate the feasibility and acceptability of RfT-OA.

Results

The results from study one indicate that older adults demonstrate a wide range of functioning. Study two found that older adults with BD reported changes in their symptomatology, physical health and cognition. They proposed a number of specific adaptions for delivering RfT-OA including techniques to enhance memory and learning and recommendations for the therapist including: nurturing pre-existing strengths and work focused on building assertiveness and

confidence. The findings from study three largely support the feasibility and acceptability of RfT-OA. Clinical assessment measures provided evidence of a signal for effectiveness on a range of outcomes including: mood symptoms, time-to-relapse and functioning.

Conclusions

The findings suggest that RfT-OA is feasible, acceptable and has the potential to improve a range of outcomes for older adults with BD.

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List of abbreviations

AMRS	Altman Mania Rating Scale
APA	American Psychiatric Association
BD	Bipolar Disorder
BD I	Bipolar Disorder Type I,
BD II	Bipolar Disorder Type II
BD-NOS	Bipolar Disorder not otherwise specified
BMJ	British Medical Journal
BPS	British Psychological Society
BRQ	Bipolar Recovery Questionnaire
CBT	Cognitive Behavioural Therapy
CES-D	Center for Epidemiologic Studies: Depression Scale
CPN	Community psychiatric nurse
CTU	Clinical Trials Unit
DSM	Diagnostic and Statistics Manual of Mental Disorders
EOBD	Early-onset bipolar disorder
FAST	Functioning Assessment Short Test
FFT	Family focused therapy
GAF	Global Assessment of Functioning Scale
HDRS	Hamilton Depression Rating Scale
ICD	International Classification of Diseases
IPSRT	Interpersonal Social Rhythm Therapy
ISS	The Internal State Scale
LIFE	Longitudinal Interval Follow-up Evaluation
LOBD	Late-onset bipolar disorder
MANSA	Manchester Short Assessment of Quality of Life
MDQ	Mood Disorder Questionnaire
MOCA	Montreal Cognitive Assessment
MRC	Medical Research Council
MAS	Mania Rating Scale
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research

NIMH	National Institute of Mental Health (NIMH)
PPI	Patients and public involvement
PSP	Personal & Social Performance Scale
QOL	Quality of Life
QoL.BD	Quality of Life in Bipolar Disorder scale
RCT	Randomised Control Trial
RfT	Recovery focused therapy
RfT-OA	Recovery focused therapy for older adults
SCID	Structured Clinical Interview for DSM
SD	Standard Deviation
SCS	The Strauss–Carpenter Scale
SF-36	Short Form 36 Health Survey Questionnaire
SOFAS	Social Occupational Functioning Scale
SPIRIT	Standard Protocol Items: Recommendations for Intervention Trials
SRQR	Standards for Reporting Qualitative Research
SSC	Specialist supportive care
SURG	Service user reference group
TAU	Treatment as usual
TSC	Trial steering committee
UK	United Kingdom
US	United States of America
WAI	The Working Alliance Inventory
WHO	World Health Organisation
WHOQOL-BREF	The World Health Organisation Quality of Life scale
WSAS	Work & Social Adjustment Scale

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Declaration by Student

I, Elizabeth Tyler, declare that this thesis is my own work, and has not been submitted in the same form for the award of a higher degree elsewhere.

Two of the papers from the thesis chapter four (DOI: 10.1136/bmjopen-2021-049829) and chapter five (DOI: 10.1136/bmjopen-2015-010590) have been published in BMJ Open. The article in chapter three has been submitted to the Journal of Affective Disorder Reports and the article in chapter six is under review at BJPsych Open.

The Statement of Authorship outlines my contributions towards the research and writing of this thesis, as well as confirmation from other authors regarding their contributions.

Name: Elizabeth Tyler

Date: 29.03.2022

Statement of authorship

A full statement of authorship is provided for each multi-authored manuscript in the present thesis. This is accompanied by written certification by the authors of each chapter. The principal author of all these chapters is the PhD candidate, Elizabeth Tyler (ET). The project's primary supervisor was Professor Steven H. Jones (SHJ). The student was also supervised by Professor Fiona Lobban (FL) and statistical supervision was provided by Dr Christopher Sutton (CS). Professor Ken Laidlaw (KL) provided input into the trial protocol. Professor Sheri Johnson (SJ) and Professor Colin Depp (CD) provided input into the trial protocol and the trial paper. Rita Long (RL) conducted the focus groups with ET and provided input into the qualitative focus group paper. Bogdan Hadarag (BH) provided input into the systematic review paper and the trial paper. Deborah Duncan (DD) provided input into the trial paper.

Chapter three: A systematic review of psychosocial functioning and quality of life in older people with bipolar disorder

Author contributions: ET designed the study, wrote the protocol, conducted the literature searches, screened the articles, extracted the data, conducted the analysis and wrote the manuscript. SHJ and FH contributed towards the study development and protocol, proofed, edited and approved the final manuscript. BH conducted the article screening, proofed and approved the final manuscript.

Chapter four: Developing a recovery-focused therapy for older people with bipolar disorder: qualitative focus group study

All authors contributed to development and preparation of the study design and topic guide. ET and RL conducted the focus groups. ET led the analysis, with contributions from FL and SHJ. ET wrote the draft of the manuscript, which was proofed, edited and approved by FL, SHJ and RL.

Chapter five: A feasibility randomised controlled trial of Recovery focused Cognitive Behavioural Therapy for Older Adults with bipolar disorder (RfCBT-OA): Study protocol

Contributors: ET, SHJ FL and CS contributed towards the design of the study. ET wrote the manuscript. SHJ, FL, CS, SJ proofed and edited the manuscript. CS provided statistical advice. CD, KL and SJ provided supervision and expertise for the intervention described in the manuscript.

Chapter six: A pilot randomised controlled trial to assess the feasibility and acceptability of recovery focused therapy for older adults with bipolar disorder

Author Contribution: ET, SHJ, FL and CS designed the study. ET, DD and BD collected, inputted and analysed data. CS provided statistical expertise and supervision. ET wrote the manuscript. SHJ, FL, CS, SJ, CD proofed and edited the manuscript. SHJ, CD, SJ provided expertise for the intervention described in the manuscript.

Certification by other authors

The signatures below provide certification from the other authors that the stated contributions to the thesis are accurate, and permission is granted for the candidate to include these manuscripts into the thesis.

CHAPTER ONE

Introduction

1.1 Overview

Bipolar disorder (BD) was traditionally perceived as a genetic/ biological illness, with periods of stability in-between episodes. This led to medications such as lithium being offered as the primary treatment for mood stabilisation (Scott, 1995). The last three decades has led to an increased awareness of the role that psychological and social factors play in the development and course of BD (Tyler & Jones, 2015). Numerous studies have reported that life events, both positive and negative, are associated with the onset, severity and duration of BD episodes (Alloy et al., 2005; Johnson & Roberts, 1995). There is also evidence to suggest that stressful life events may be a consequence of living with BD (Hosang et al., 2012), which provides additional evidence for the need to develop effective strategies to cope with such events.

A National Institute of Mental Health (NIMH) report, published in 1990, called for the development of effective psychosocial interventions for people living with BD. Since then, there has been a rapid development of psychological interventions for younger people with BD, with an increasing evidence base indicating their effectiveness (Oud et al., 2016). There has been very little research or service development for older people living with BD. The purpose of this thesis was to develop a psychological therapy to meet the needs of an older adult population. This chapter provides an introduction to BD with an emphasis on the development of psychological therapies for working aged adults. Following this, there is a review of the evidence in relation to older people with BD and a rationale for why a tailored, psychological therapy specifically for this cohort was developed.

1.2 Bipolar Disorder

"When you are high, it is tremendous. Shyness goes, the right words and gestures are suddenly there, the power to seduce and captivate others a felt certainty. Feelings of ease, intensity, power, well-being, financial omnipotence and euphoria now pervade one's marrow. But somehow, this changes. The fast ideas are far too fast and there are far too many, overwhelming confusion replaced by fear and concern. You are irritable, angry, frightened, uncontrollable, and enmeshed totally in the blackest caves of mind … It goes on and on and finally there are only

other people's recollections of your behaviour – your bizarre, frenetic, aimless behaviour …" An individual's account of living with BD, in Goodwin & Jamison (1990).

1.2.1 Diagnosis

Bipolar disorder (BD), previously known as manic depression, is characterised by episodes of mania or hypomania and depression. According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5; American Psychiatric Association, 2013) there are two primary subtypes; BD I, where at least one manic episode must be present, major episodes of depression are typical but not necessary for a diagnosis. The second primary subtype, BD II, where at least one hypomanic episode and one major depressive episode must be present to confirm a diagnosis. A manic episode is characterised by an 'abnormally and persistently elevated, expansive, or irritable mood' (APA, 2013). DSM-5 specifies three additional symptoms (four if the mood is irritable) are required to meet criteria including a decreased need for sleep, increased self-esteem, an increase in goal directed activity e.g., work, school, socially, being more talkative (or the pressure to keep talking) and distractibility. The symptoms must be severe enough to cause a significant impact on the person's usual level of functioning and last for more than a week. A person with hypomania will experience similar symptoms to mania, however, they do not last as long (at least four days) and they do not impact on functioning. If the person has psychotic features or they require hospitalisation, then the episode will be classified as manic rather than hypomania.

Other subtypes include cyclothymia where individuals experience symptoms of hypomania or depression, but the episodes are not severe enough to meet full DSM-5 diagnostic criteria. The DSM-5 introduced the "BD not otherwise specified" category where individuals have symptoms characteristic of BD I, BD II and cyclothymia but do not meet diagnostic criteria. This new category has caused contention regarding the reduced threshold for diagnosis, with assertions that it causes more confusion than clarity and has the potential to lead to either premature treatment or overtreatment (Purse, 2020).

1.2.2 Epidemiology

In a worldwide mental health survey (Merikangas et al., 2011), lifetime prevalence rates were 0.4% for BD I, 1.4% for BD II, 1.4% for subthreshold BD and 2.4% for BD spectrum conditions. These rates appear to be consistent across diverse cultures and ethnic groups (Grande et al.,

2016), however access to mental health care varies considerably across countries (Merikangas et al., 2011). BD I affects both men and women equally, however BD II appears to be more prevalent in women (Nivoli et al., 2011).

Over 60% of individuals with BD report that they received between one to four prior diagnoses before their BD diagnosis (Scott et al, 2011), often waiting up to 10 years to receive a BD diagnosis (Baethge et al., 2003; Hirschfield et al., 2003; Ghaemi et al., 2002). BD is often initially diagnosed as major depressive disorder. Once manic symptoms emerge or they begin to impact on functioning and therefore individuals may present in services, a diagnosis of BD may occur. This delay in diagnosis has an impact on the start of appropriate treatment and in some cases the use of anti-depressants can increase the development of manic symptoms (Fritz et al., 2017).

1.2.3 Age of onset

BD is usually experienced first in early adulthood, however, onset in both childhood and older adulthood may also occur. A recent systematic review investigating age-at-onset in BD found a trimodal age-at-onset distribution with early, mid and late-onset subgroups (Bolton et al., 2021). The majority (45%) of participants displayed an average age at onset of 17.3 years (SD = 1.91), classed as early onset. Thirty-five percent displayed an average age at onset of 26.0 (S.D = 1.72), classed as mid-onset. A further 20% of participants were deemed 'late-life-onset' (>40 years of age). Age of onset has been recognised as an important factor in the course and outcome of BD (Bolton et al., 2021). Early, versus late, age of onset is associated with a greater likelihood of prior suicide attempts and psychotic features (Bellivier et al., 2001), a longer delay in access to treatment, higher severity of depression and increased levels of comorbid anxiety and substance abuse (Agnew-Blais & Danese, 2016; Joslyn et al., 2016).

1.2.4 Course of BD

Individuals may present with either a hypomanic, manic or a depressive episode first, which is typically followed by repeated episodes, separated by periods of euthymia (a relatively neutral mood). Research studies have indicated though that a significant number of people continue to have residual symptoms during these inter-episode periods (Judd et al., 2005; Grover et al., 2021) which can impact on social, occupational and cognitive functioning (Judd et al., 2005; Altshuler et al., 2006; Marangell, 2004; Samalin et al., 2016; Samalin et al., 2017;). The presence of residual symptoms of mania and depression are associated with a shorter time to recurrence

of manic and depressive episodes, respectively (Meyer, 2006; Perlis et al., 2006). A 15-year follow-up study (Judd et al., 2002; Judd et al., 2003) found individuals with BD I (Judd et al., 2002) and BD II (Judd et al., 2003) experienced euthymia for approximately half of the study period. Depression was the most predominant mood state and was reported for 31% (Judd et al., 2002) and 52% (Judd et al., 2003) of the time period for the studies respectively. Hypomania, manic and mixed episodes were reported for 1.6% (Judd et al., 2002) and 10% (Judd et al., 2003) of the study duration.

1.2.5 Functioning and quality of life

BD has been ranked at the 12th leading cause of disability worldwide by the World Health Organization (WHO). Approximately 22 million individuals with BD experience moderate or severe disability (World Health Organisation, 2004). Poor functioning is considered one of the biggest drivers of disability in people with BD (Sanchez-Moreno et al., 2009). Only one out of three individuals who have their first manic episode regain psychosocial functioning at one year follow-up (Tohen et al., 2000). This indicates that functional outcomes are impaired from the start and should be a priority for therapeutic interventions (Bonnin et al., 2019).

Individuals with BD report a range of problems with functioning, including reduced social contact (Bauwens et al., 1991), poor familial relationships (Shapira et al., 1999) and high rates of unemployment (Morselli et al., 2004). Poor work functioning has been reported, with a lack of continuity in work history, interpersonal problems at work and stigma in the workplace (Mikchalak et al., 2007). The negative effects can also impact on caregivers who report high levels of distress in relation to day-to-day activities and maintaining relationships (Goossens et al., 2008). Male gender and older age appear to be factors that are associated with worse functional impairments (Sanchez-Moreno et al., 2018), whilst being married and having a higher socioeconomic status has been associated with better functional outcomes (Wingo et al., 2010).

Alongside poorer functioning, individuals with BD on average also experience low quality of life compared to the general population (Abraham et al., 2014; Sierra et al., 2005, Dean et al., 2004) both during episode, and inter-episode periods (e.g. IsHak et al., 2012 and Michalak et al., 2005). Sylvia et al. (2017) found that individuals presenting with more severe depression, irritability and psychiatric comorbid conditions experienced lower levels of quality of life. Individuals with multiple previous episodes typically experience poorer outcomes, including functioning and quality of life (Magalhães et al., 2012).

1.2.6 Psychological therapy

Historically, individuals living with BD were not offered psychological therapies for three key reasons (Scott, 1995). Firstly, BD was perceived to be primarily a biological 'illness', with medications such as lithium prescribed as the main treatment for the condition. Secondly, there was a misconception that individuals with BD made a full inter-episode recovery and returned to their usual level of functioning (Juruena, 2012). Thirdly, psychoanalysts expressed ambivalence regarding the appropriateness of psychotherapy for individuals with BD. For example, Fromm-Reichman (1949) wrote a brief paper attempting to explain why her colleagues were reluctant to engage in therapy with individuals with BD. Fromm-Reichman (1949) suggested that people with BD were manipulative, superficial, lacked interpersonal relatedness and were too dependent on the therapist. There were, however, others that argued strongly for the use of psychological approaches for people living with BD (e.g., Goodwin and Jamison, 1990).

The National Institute for Mental Health (NIMH; Prien & Potter., 1990) report was a turning point for the development of psychological approaches for BD. There was growing recognition that individuals with BD continued to relapse despite sustained lithium treatment (Prien & Potter., 1990; Burgess et al., 2001). NIMH (1990) concluded that 40% of people with BD did not report a significant improvement in clinical symptoms or the risk of relapse, despite continued lithium use and therefore medication was not an acceptable standalone treatment. The NIMH report recommended the development of effective psychological treatments for individuals living with BD (Prien & Potter, 1990). As a consequence, there has been a growing recognition of the importance of psychological treatment for BD and a rapid development of psychological therapies. Structured psychological therapies are now recommended in the UK National Institute of Clinical Excellence Guidelines for all individuals with BD (NICE, 2014).

A systematic review informing the NICE guidelines for BD evaluated the efficacy of psychological interventions for adults with BD (Oud et al, 2016). They included 55 randomised controlled trials and found moderate quality evidence that individual psychological interventions are effective for people with BD, with reduced relapse rates at post-treatment and follow-up and a reduction in hospital admissions (Oud et al., 2016). Low-quality evidence was associated with group interventions, with lower relapses of depression at post-treatment and follow-up, and family psychoeducation was associated with reduced symptoms of depression and mania (Oud et al, 2016).

The NICE guidelines for BD (2014) recommend individuals with BD are offered a structured psychological intervention (individual, group or family) to prevent relapse and to manage persisting symptoms between episodes of mania and depression. NICE (2014) recommend that the intervention should be designed specifically for BD, with a published, evidence-based manual describing how it should be delivered. NICE (2014) also recommend that a family intervention is offered when a person with BD is living or has close contact with their family in line with the NICE guideline on psychosis and schizophrenia in adults (NICE, 2014).

1.2.6.1 Psychoeducation

Psychoeducation involves working alongside the person to increase their knowledge of BD and to enable them to self-manage their condition, prevent relapse and improve their long-term outcomes. Psychoeducation usually involves the presentation of information on topics such as mood monitoring, lifestyle and medication use by a health professional such has a community psychiatric nurse (CPN), either individually or in a group setting. Individual, face-to-face psychoeducation has been found to increase time to any relapse by 8.5 weeks (Lobban et al., 2010) and lead to improvements in social functioning and rates of employment (Perry et al., 1999). A recent systematic review of 47 studies (38 studies with individuals with BD and 9 studies with family members) found that psychoeducation was associated with a lower number of new mood episodes, a reduction in the number and the length of stay during hospitalisations and improved adherence to drug treatment (Rabelo et al., 2021).

1.2.6.2 Interpersonal Social Rhythm Therapy

Interpersonal Social Rhythm Therapy (IPSRT) was developed by Ellen Frank, with a primary focus on stabilising circadian rhythm disruptions which are common for people experiencing BD and contribute to mood instability (Harvey, 2011). The main goal of IPSRT is to stabilise a person' social rhythms (e.g., sleep patterns, social and daily activities) alongside improving the quality of interpersonal relationships and a person's satisfaction with their social role (Frank, 2007). A randomised controlled trial compared IPSRT with intensive clinical management (both groups also received pharmacotherapy) with individuals acutely manic, mixed or depressed (Frank et al., 2005). After acute stabilisation, treatment groups were randomised again for a two-year maintenance phase. They found individuals in the IPSRT group had a longer time to relapse during the acute phase and better vocational functioning in the maintenance phase. Additionally, they found the delay of recurrences were more marked in individuals who had

stabilised their daily or nightly routines during acute treatment phase (Frank et al., 2005). More recently, Inder et al. (2014) conducted an RCT and compared IPSRT to manualised specialist supportive care (SSC) in medication stable adults and young adults with BD. They found both groups improved on outcome measures, including depression symptoms, manic symptoms and social functioning. However, there were no significant differences on outcome measures between IPSRT and SSC at the one-year post-baseline follow-up.

1.2.6.3 Family Focused Therapy

Family Focused Therapy (FFT) is a modification of the family-focused therapy originally developed for the treatment of schizophrenia (Goldstein & Miklowitz, 1995). Families are usually offered 21 sessions of FFT, over a nine-month time period. Therapy consists of several stages, beginning with psychoeducation about the causes, symptoms and role of medication. Families learn a range of different coping responses and draw on the evidence surrounding negative and critical family reactions which can sometimes trigger relapses (e.g., expressed emotion). Families also learn different ways of communicating and problem solving in an attempt to reduce conflict and resolve problems. A paper, summarising data from eight RCTs with adults and adolescents, reported that the combination of FFT and mood stabilising medications have led to: faster times to recovery from mood episodes, reductions in recurrences and a reduction in the levels of symptom severity. This is when compared to briefer forms of psychoeducation and medications, over a one to two-year time period (Miklowitz & Chung, 2016).

1.2.6.4 Cognitive behavioural therapy

Approximately 16-24 sessions of cognitive behavioural therapy (CBT) are usually offered, over a six-month period to account for clinical complexity and to allow the clinician time to apply new skills across different mood states (Tyler & Jones, 2015). CBT for BD comprises of four key areas, the first is psychoeducation, where clients are provided with information about the vulnerability stress approach to their BD experiences. The second is the use of cognitive behavioural skills to cope with early warning signs. Clients are taught to identify changes in mood and behaviours and develop a programme of strategies to intervene and prevent progression into full clinical episodes. The third is recognising the importance of routine and sleep which involves working with the client to improve stability in these areas. The final component is dealing with long-term vulnerabilities, where themes such as autonomy and high-achievement can be identified and explored to test out less rigid beliefs (Tyler & Jones, 2015). A number of RCTs of individual CBT

have been published (e.g., Lam et al., 2003, 2005; Ball et al., 2006). Traditional CBT has been most effective for people who are not experiencing an acute episode, leading to a reduction in depressive symptoms and preventing relapse (Lam et al, 2010).

1.2.6.5 Recovery focused therapy for BD

Traditionally the majority of BD psychological interventions have been focused on outcomes targeting clinical improvement, such as a reduction in relapse or the frequency and severity of mood episodes. Clinical recovery has been based upon individuals not meeting the criteria for a mood episode and therefore has been considered unlikely and in some cases, impossible (Leonhardt et al., 2017). Over the last four decades, the recovery movement, led by service users, has challenged the concept of clinical recovery and called for a new approach. Individuals with personal experience of severe mental health problems, including BD have questioned traditional clinical targets and highlighted the importance of personal recovery outcomes (Jones et al., 2010; Pitt et al., 2007). Personal recovery refers to "*a way of living a satisfying, hopeful, and contributing life even with limitations caused by illness, while developing new purpose or meaning"* (Anthony, 1993). The recovery movement recognises the rights of people living with mental health conditions to participate fully in mainstream society and is supported by international and national policy, (e.g., National Institute of Mental Health, 1999; Department of Health, 2011; 2009). This has led to a shift from recovery outcomes being solely based on symptom eradication and 'cure', towards building strength and resilience in an individual, enabling them to take control of their life and mental health problems and have personal responsibility for their recovery (Roberts & Wolfson, 2004).

A CBT approach has traditionally viewed the client as a 'vulnerable' person, in need of therapy to remedy underlying deficits. In RfT, the person is viewed in terms of their strengths, with the right to live their life as they see fit. There is an explicit emphasis on client focused goals rather than a presumption that relapse is the primary target of therapy. RfT is formulation driven, rather than applying a similar model of BD across clients. The therapy focuses on working alongside clients to identify meaningful, personal goals that can be symptom-related, or focus on other areas of their life such as relationships, social engagement or work. During the initial sessions, the therapist and client work together to develop a shared understanding of recovery and how working towards goals that are of personal value, may have a significant impact on the person's life. Developing an idiosyncratic formulation is a fundamental part of the process, ensuring the therapy approach is consistent with the person's needs. During the intermediate

sessions, the intervention is focused on the co-design of tools to help the person achieve their goals. This may include CBT techniques focused on monitoring and adapting mood, thoughts and behaviours which are applied to facilitate possible coping strategies, plus tools from compassionate focused therapy and mindfulness. There may be a focus on understanding the positive and negative aspects of hypomania and working with unrealistically positive ideas. There is a consideration of the wider functioning issues in relation to recovery and this may include the development of problem-solving techniques. During the final sessions there is the development and completion of the recovery plan. The client and therapist work together to summarise the therapy sessions, including a plan for post-therapy. The recovery plan can be written in the client or the therapist's voice and this is negotiated prior to completion. The document can be shared with anyone involved in the client's care at their discretion.

Recovery focused therapy has been developed in partnership with service users consulting on the draft content, format and supporting materials for the intervention (Jones et al., 2012). A pilot study confirmed the feasibility and effectiveness of the intervention and found that RFT significantly improved personal recovery, and improved time to relapse compared to treatment as usual for working aged adults (Jones et al., 2015).

1.3 Older adults with BD

The previous section focused on research primarily developed for younger people with BD. The following section concentrates on research developed for older people living with BD, which is still in its infancy. The majority of this research has used a cut off age of 60 years and above to define older people with BD, which is congruent with the United Nations definition of older age (United Nations, 2013). A report on older adults living with BD from the International Society for Bipolar Disorders Task Force (Sajatovic et al, 2015) now recommends using 50 years and above as a cut off instead, which is based on the need to study the condition across the life-span, not just a healthy cohort that have survived into older adulthood.

1.3.1 Epidemiology and diagnosis

Epidemiological studies indicate that BD I and BD II affects approximately 0.5-1.0% of older adults (Hirschfield et al., 2003; Kessler et al., 2005; Unutzer et al., 1998). Community and population-based surveys report a significant decline in prevalence of BD in later life, however, the proportion of people in psychiatric hospitals appears consistent across age groups (Depp &

Jeste, 2004). Depp and Jeste (2004) estimate approximately 6% of older people attending outpatient clinics and/or community mental health services have a diagnosis of BD and 8-10% of older adults with BD are psychiatric inpatients. It is unclear why BD is less common in this community and may be the result of excess mortality or diagnostic difficulties (Depp & Jeste, 2004). The applicability of diagnostic criteria used in the ICD-10 (World Health Organisation, 1993) and the DSM-5 has been questioned (Ljubic et al., 2021). Presentations such as frailty or the occurrence of physical illnesses may produce symptoms of both depression and mania (Brooks et al., 2005). Furthermore, symptoms of dementia such as delusions (Cipriani et al., 2014), mood changes (Cipriani et al., 2015), sexual disinhibition (Cipriani et al., 2016) can often mirror those seen in people displaying symptoms of mania.

1.3.2 Definition of older adults with BD

A recent review paper (Ljubic et al., 2021) summarising the current knowledge on epidemiology, clinical features and treatment of older people with BD indicates the heterogenous nature of the condition and proposes four distinct subgroups. (1) early-onset BD (EOBD) where the person had a typical age of onset in adolescence or early adulthood and they have grown old with BD. (2) late-onset BD (LOBD), where the person did not experience any manic symptoms before late life, but they have their first episode after the age of 50. (3) LOBD with an earlier "pseudo-unipolar" course where a person experiences their first hypomanic or manic episode after the age of 50, although they may have had a history of depression. (4) Secondary manias which are the result of pharmacological side effects or a somatic illness and can occur at any stage of life.

A meta-analysis found that there was no difference between EOBD and LOBD in the rate of mixed episodes, rapid cycling or psychotic symptoms in older adults. However, EOBD was associated with a longer delay to treatment, greater severity of depression and higher levels of substance use and comorbid anxiety compared to LOBD (Joslyn et al., 2016). Depp and Jeste (2004) also found that LOBD was associated with less familial history of affective disorders and a higher frequency of neurological risk than EOBD. Consistent with this, a study found individuals with LOBD may have more extensive and severe cognitive impairments compared to those with EOBD (Martino et al., 2013).

1.3.3 Course

Studies investigating the long-term course of BD are rare, however previous suggestions that BD 'burns out' in later life (Winokur et al., 1969) have been refuted by longitudinal research (Angst & Preisig, 1995). Angst and Preisig (1995) followed a cohort of 209 inpatients with BD over 40 years until the median age of 68. At the final follow-up, 16% of the participants had fully recovered (they had not experienced an episode in the past 5 years), 26% were scoring below 60 on the Global Assessment of Functioning (GAF; Endicott et al, 1976) without experiencing episodes in the past five years, 36% were presenting with recurring episodes, 16 were displaying a chronic course and 7% had committed suicide. Additionally, they found participants had experienced 10 episodes on average, with 56% of these associated with a hospital admission. There appears to be decreased rates of suicide in older people with BD based on findings which indicate a higher completed suicide risk for individuals under the age of 35 years old (Tsai et al., 2020). Researchers have indicated that older adult BD included in these samples may represent a 'survivor cohort' (Depp and Jeste, 2004).

1.3.4 Clinical features

The polarity of BD in later life appears to shift towards depression, with less time spent in manic states compared to younger individuals with BD (Nivoli et al., 2014; Coryell et al., 2009). There is evidence to suggest that older adults with BD experience a decreased severity of manic symptoms (Chen et al., 2017), with a lower prevalence of psychotic features (Chen et al., 2017; Kessing, 2006) compared to younger adults with BD. A recent focus group study which included older adults living with BD found that overall, the group reported more lows than high mood in their later years. The majority of the group indicated that their episodes of mania were not as intense as when they were younger (Tyler et al., 2021).

Mood episodes in later life may be triggered by a number of factors including life stressors, physical illnesses and prescription medications (Chen et al., 2017). There is evidence to suggest that older people with BD may be at increased risk of stressful life events in response to changes in their housing, careers, role within the family and finances, compared to younger individuals with BD (Chen et al., 2017). However, there is still inconclusive evidence with regards to the presence or absence of a clinical pattern which differentiates older and younger people with BD (Ljubic et al., 2021).

1.3.5 Physical and cognitive changes

In late life, BD is associated with cognitive dysfunction even when individuals are euthymic (Depp et al., 2007; Gildengers et al., 2007; Gildengers et al., 2009). Gildengers et al. (2012) found that compared to non-psychiatric populations, individuals with BD presented with increased neuro-psychological deficits compared to individuals with major depressive disorder, particularly with information processing speed and executive functioning. However, all participants were receiving psychotropic medications that may also affect cognition. Kessing and Anderson (2004) found that, on average, the rate of dementia tended to increase by 6% for every episode leading to an admission for individuals with BD.

The prevalence of medical comorbidities increases with age, which can lead to the use of multiple medications (Dols et al., 2014). Lehmann and Rabbins. (2006) found that 86.3% of individuals over the age of 65 had a medical co-morbidity. Rise et al (2016) conducted a systematic review and found that older people with BD were at increased risk for cardiovascular, respiratory diseases and endocrinological abnormalities compared to age-matched controls.

1.3.6 Service use

Bartels et al. (2000) report that older adults with BD have higher symptom severity, use almost four times the total use of mental health services and are four times more likely to get admitted than older people with unipolar depression. Taking these factors together it is clear that addressing BD in older adults should be a high priority for healthcare researchers and clinicians. In practice however there has been very little research or service development for older adults with BD (Charney et al., 2003; Depp & Jeste, 2004; Sajatovic et al., 2015) which is reflected in the paucity of published studies evaluating psychosocial interventions for older adults with BD (McBride & Bauer, 2007; Depp & Jeste, 2004; Sajatovic et al., 2015). Increasing knowledge to inform the development and delivery of tailored, evidence-based services for older people with BD is crucial. Research indicates that the needs of older people with mental health problems are better met within geriatric services compared to general, adult mental health (Abdul-Hamid et al., 2015).

1.3.7 Clinical guidelines

Clinical guidelines use available research evidence to translate research trials into useful, every day, clinical practice. A review of 34 international BD guidelines, representing 19 countries (Dols et al., 2016) found that the majority did not have a separate section for older people with BD. Those that had a separate chapter, were recommendations based on medication and somatic aspects, with only one country (the Netherlands) including recommendations for psychotherapy. This finding is partly attributable to the lack of evidence from clinical trials conducted with older people with BD (Nair, 2002). The NICE guideline for BD (2014) mentions older people four times, three times in relation to medication and once in relation to psychological therapies where it states to "ensure that older people with bipolar disorder are offered the same range of treatments and services as younger people with bipolar disorder". However, clinical services where strategies developed for younger adults are generalised to older people may fail to meet the needs of an older population (Warner, 2015). Treatments may not be appropriate based on significant differences within the presentation of older people living with BD. Older adults with BD have different needs compared to a younger cohort due to a higher prevalence of medical comorbidities, complex psychosocial challenges and sensitivity to treatment-related adverse effects (Sajatovic et al., 2015).

1.3.8 Psychological Treatments for older adults with BD

Traditionally, older adults have been subject to negative stereotypes and over generalisations (e.g., too old to change) which may have prevented their access to psychological therapies (Satre et al., 2006). These beliefs stem back to Freud's early work where he wrote that learning ceases after the age of 50 (Freud, 1905/1953). This pessimism for change in later life continued decades later with the 'loss-deficit model of aging' (Berezin, 1963) which views getting older as a series of losses, with depression as an inevitable outcome. However, more recent studies exploring the attitudes of mental health professionals suggest that they are more positive than previously assumed (Knight et al., 2006). Lee et al. (2003) found that UK based trainee clinical psychologists showed positive attitudes in general towards working with older people, with many seeing the work as both challenging and rewarding.

Most research on psychological interventions for older people has focused on depression. Evidence suggests that CBT is effective at reducing depressive symptoms compared to active control interventions (Wilson et al., 2008). There is also an evidence base for the effectiveness

of CBT in the treatment of anxiety disorders (Barrowclough et al., 2001; Stanley et al., 2003). Granholm et al. (2005) compared cognitive behavioural skills training versus TAU for middle and older age individuals with schizophrenia(N=76), using an RCT design. (Granholm et al., 2005). They found that those receiving the intervention achieved greater cognitive insight and improved social functioning. Most of the literature on psychosocial interventions developed for older people with BD has been taken from mixed aged studies or is based upon interventions developed for older people with various serious mental health problems (e.g., schizophrenia, schizoaffective disorder, depression and BD).

In the US, a randomised control trial compared the effectiveness of 'The Helping Older People Experience Success (HOPES)' intervention versus treatment as usual for older people (mean age = 60.2), with a range of serious mental health problems (28% schizophrenia, 28% schizoaffective disorder, 20% bipolar disorder, 24% major depression). HOPES intervention comprised of one-year of weekly skills training classes, twice-monthly community practice trips and monthly nurse preventive healthcare visits. This was followed by followed by a one-year maintenance phase of monthly sessions. They found HOPES improved community living skills, functioning, self-efficacy and reduced psychiatric symptoms and negative symptoms one year after the maintenance monthly sessions finished. (Bartels et al., 2013). However, it is not clear what the outcomes were specifically for individuals with BD who may face unique challenges in later life as detailed in earlier in the chapter.

Also in the US, a small pilot medication adherence skills training (MAST-BD) intervention was developed specifically for older adults with BD. Participants (mean age = 60) were offered a 12-week manualised group intervention with a combination of educational, motivational, medication management skills and symptoms management training. Depp et al. (2006) found that MAST-BD led to improvements in medication adherence and management, depressive symptoms and quality of life for older people with BD. Neither of these two studies targeted personal recovery, which is now highlighted in national policy (e.g., Department of Health, 2009, Department of Health, 2011), international guidelines (e.g., National Institute of Mental Health, 1999) and the NICE guidelines for BD (NICE, 2014).

1.4 Aims of the thesis

Since the publication of the NIHM report in 1990 there has been a rapid development of the number of psychological interventions for individuals with BD. However, the development of

psychological interventions specifically for older people with BD has been sparse. The NICE guidelines for BD recommend that older people are offered the same treatments as younger people. However, this may not be appropriate due to differences in presentation. Additionally, strategies developed for younger adults may fail to meet the needs of an older population (Warner, 2015). There is evidence to suggest that psychological interventions are effective for older people with depression (e.g., Wilson et al., 2008), anxiety (e.g., Barrowclough et al., 2001; Stanley et al., 2003) and schizophrenia (Granholm et al., 2005). There are also indications that psychosocial interventions developed for individuals with a range of serious mental health problems (Bartels et al., 2013) and medication adherence training for older people with BD (Depp et al., 2006) can be effective on a range of outcomes.

The overarching aim of the thesis was to develop a recovery focused intervention for older people with BD. The idiosyncratic nature of RfT offers the flexibility to work with a range of problems, based on the client's needs. There is a focus on building strength and resilience, enabling a person to take control of their life. This approach was considered highly appropriate as older people present with a range of complex needs and have been subject to negative stereotypes (Satre et al., 2006) and pessimism about the possibility of change in later life (Freud, 1905/1953). To the researcher's knowledge, this is the first project to actively involve older people with BD in the process of developing a psychological intervention specifically for their cohort. This approach aligns with the principles of recovery within mental health care which highlights the importance of a person taking control of their own life, developing individual coping strategies and actively working to maintain wellbeing, rather than being a passive recipient of professional healthcare (Owens et al., 2011).

The main aims of the project were to:

- Improve our understanding of how BD presents in older adults
- Identify any potential adaptations to an existing RfT developed for younger people with BD to meet the needs of an older population
- Evaluate the feasibility and acceptability of RfT for older adult with BD

To achieve this, the thesis includes three studies, designed to complement one another and address the lack of research and service development in the area. Study one (Chapter three) is a systematic review of psychosocial functioning and quality of life in older people with BD. The main aims of the review were to increase our understanding of how BD presents in later life and

identify whether there are any measures that have been psychometrically examined for reliability or validity using an older adult BD sample. The specific research questions were:

1. What measures have been used to assess quality of life and psychosocial functioning in older adults with bipolar disorder?
2. What is the distribution of psychosocial functioning and quality of life scores for older people with bipolar disorder for the most widely used measures?

Study two (Chapter four) is a focus group study and the key aims were to explore the extent to which the original RfT intervention was acceptable to older adults with BD, identify whether any adaptations were needed to the existing manual and understand what type of support older adults wanted from a therapist during therapy. Additionally, due to the lack of research in the area, the focus groups also aimed to explore the experience of BD in later life, including the concept of recovery. The specific research questions were:

1. How do older adults experience BD in later life?
2. What is the experience of recovery in later life?
3. Does RfT need to be adapted for older people?
4. What are the specific adaptations needed to develop RfT-OA?
5. What do older people with BD want from a therapist delivering RfT-OA?

The findings from the focus groups contributed towards the development of the intervention with a specific set of clinical recommendations for therapists delivering RfT for older adults with BD.

Study three (Chapters five and six) is a pilot randomised controlled trial of RfT-OA versus treatment as usual. The key aims of the study were to assess the feasibility and acceptability of recovery focused therapy for older adults with bipolar disorder. The specific research questions were as follows:

1. Would clinicians refer older adults into an RCT?
2. Would older adults self-refer into an RCT?
3. Would older adults with BD consent to participate in an RCT of a psychological intervention offered in addition to usual treatment vs usual treatment
4. Would older adults with BD complete follow-up assessments in a randomised controlled trial?
5. Would older adults adhere to RfT-OA?

6. What were participants' experiences of receiving RfT-OA?
7. What is the most appropriate primary outcome measure for a future trial?
8. What is an estimate of the sample size for a future trial?

CHAPTER TWO

Methodology

The aim of this chapter is to provide a rationale for the chosen methodology and the methodological decision-making, based upon the philosophical underpinnings of this research. The ontological and epistemological considerations underpinning the chosen approach and subsequent research methods will be discussed, based on the researcher's philosophical position. Following this, the three research studies and rationale for the chosen methods will be discussed.

2.1 Ontological and Epistemological perspectives

2.1.1 Ontological perspective

Ontology is the philosophical study of the nature of the reality. The ontological position of the researcher can shape the methodological decision making and is closely related to how data is collected (Oliver, 2010). There are two dominant ontological positions: realism and irrealism (Fryer, 2020). The methodological approach chosen can depend on whether the researcher believes that there is an external, independent reality (realism) or whether they believe that there are only experienced, constructed realities that are not independent of the observer (irrealism). This will then affect whether a quantitative, qualitative or mixed methods approach is chosen. If the assumption is that knowledge is real, objective and there to be captured, then it can be observed and measured using a quantitative approach. If knowledge is assumed to be idiosyncratic, subjective and experiential, then a qualitative approach may be more appropriate.

2.1.2 Epistemological perspective

Epistemology is the philosophical study of knowledge and how knowledge is obtained. Research is focused on gaining new knowledge and therefore the researcher's epistemological stance is also central to the methodological decision making. The way knowledge is acquired depends on the methodology and equally, the consistency and precision of the methodology is directly linked to the strength of the new knowledge gained (Jackson, 2013). There are two main positions in epistemology, objectivist and subjectivist. An objectivist position is built on the assumption that we can observe the world and produce truthful knowledge. In contrast, a subjectivist would argue that the world cannot be explored from a purely objective stance and that knowledge gained is theory dependent, which is subjective and individually constructed.

2.1.3 Philosophical position

A philosophical position includes both ontology and epistemology. The two dominant philosophical positions are positivism, a combination of realism and objectivism and constructivism, a combination of irrealism and subjectivism (Fryer, 2020). Positivism dominated social science research for decades and is based on the assumption that we can measure social phenomena by observation because human behaviour is determined and moderated by external factors. Positivism is a deductive approach as it is based on the idea that research is used to generate and test out hypotheses based on existing theories and draw generalisable conclusions based on the validity of the results (Byrman, 2016). In comparison, constructivism is an inductive approach, which begins with observations and proposes theories based upon these (Byrman, 2016). It is based on the idea that knowledge is 'constructed' but is contingent on our perception and human experience and therefore the knowledge produced does not necessarily reflect an external reality.

Prior to undertaking the research, the researcher acknowledged an independent, real world, while recognising that there were multiple layers of reality which exist and operate, some of which may be independent of our awareness and knowledge. The researcher also acknowledged that reality is historically and socially constructed through our experience. The researcher's position was therefore aligned with a critical realist, a combination of realism and subjectivism (Fryer, 2020) which situates itself between positivism and constructionism. Critical realism is a philosophy that grew from a critique of positivism by the philosopher, Roy Bhaskar. In contrast to constructivism, it states that reality is independent of the mind (Bhaskar, 1975). Critical realism assumes that the evidence we observe can come close to reality, however this reality is subjective and constructed through our experiences. This philosophical approach has driven the original research aims and the methodological choices throughout the research process. A critical realist approach allows a holistic exploration of phenomena, based on a number of different research questions that use multiple research methods (Walsh & Evans, 2014).

The overarching aim of the thesis was to develop a recovery-focused therapy for older people with bipolar disorder (BD). The researcher had worked with people living with BD for a number of years prior to starting the thesis. During this time, classification tools such as the Structured Clinical Interview for DSM IV (First et al, 1997) and Structured Clinical Interview for DSM-5 (SCID-5; First et al., 2015) had been used as a way of categorising people's experiences of living with BD. Some individuals welcomed a diagnosis as it provided an explanation for their experiences and validate their mood experiences (Tyler & Jones, 2015) and access to specific treatment and

services. There are, however, drawbacks of using classification tools as some people will present with the same symptoms and receive a different diagnosis, based on the person completing the interview (Allsopp et al., 2019). A diagnosis can also cluster together a person's symptoms, experiences and problems and therefore lose the idiosyncratic nature of their difficulties, which may encompass a loss of identity and stigma (Tyler & Jones, 2015). The researcher used the SCID-5 as a baseline assessment in the trial as it is a standardised framework and meant that the study could be comparable to others that have used a similar framework. The researcher also used the Montreal Cognitive Assessment (Nasreddine, 2005) as a way of screening for mild cognitive impairments. As discussed in the introduction, the symptoms of dementia can often mirror those seen in people displaying symptoms of mania (Cipriani et al., 2014) which has led researchers to question the use of the DMS-5 with older people with BD (Ljubic et al., 2021). Whilst recognising the helpful framework such tools can provide, the researcher also acknowledged the bias of using such tools and questioned their validity in capturing real-life experiences. Consequently, mixed methods were employed to access participants different versions of reality and provide a more balanced view.

The main aims of the PhD were to improve our understanding of how older people with BD experience BD, identify any adaptations needed to an existing recovery focused therapy developed for younger people who experience BD, and to evaluate the feasibility and acceptability of recovery focused therapy for older adults who experience BD. These aims were driven by knowledge of existing theories regarding the presentation of BD in later life, adaptations for older people with other mental health conditions and the effectiveness of psychological interventions for younger cohorts with BD. The work was informed from the outset by the researcher's knowledge of what works for younger people with BD and also what works for other older people with mental health conditions. However, there was limited knowledge about older people with BD and therefore the researcher wanted to explore factors that may be particularly significant for this client group. To account for this, the researcher employed a mixed methods approach with a combination of qualitative and quantitative methods to address the aims of the work and follow both a deductive and inductive approach.

The researcher had prior knowledge that recovery focused therapy (RfT) was beneficial for younger people with BD in terms of both personal recovery and mood symptoms (Jones et al., 2015) and therefore hypothesised that it may be feasible and acceptable for older people with BD. The researcher also had pre-existing knowledge that interventions had been adapted for older people with other mental health conditions (e.g., depression; Laidlaw et al., 2008), due to changes that can occur in later life. Therefore, the researcher designed a number of focus groups

to assess the acceptability of the original RfT intervention (deductive approach) and explore other factors that may be important for the specific client group (inductive approach). A randomised controlled trial (RCT) was designed, to test out the hypothesis that the intervention would be feasible and acceptable (deductive approach), however qualitative approaches were used to gain a further insight into the acceptability of the intervention and research processes by interviewing people that took part in the therapeutic process (inductive approach). The data from the quantitative measures of acceptability were combined with the qualitative interviews to provide a deeper level of understanding on the acceptability of the intervention and the research processes, and how this varied between individuals and across different contexts from which people were recruited. Critical realist RCTs have the potential to overcome traditional RCT deigns by employing methods to account for the individual interpretation and the influence of social context (Porter et al., 2017).

2.2 Overview of thesis methods

Mixed methods research involves using more than one different type of research method, either combining qualitative and quantitative or a mix of different quantitative or qualitative methods (Brannen, 2005). Mixed methods have become increasingly popular within health research due to the level of complexity that health problems present. It has been argued though that quantitative and qualitative methods are situated within particular paradigms (e.g., quantitative with positivist and qualitative with subjectivist) with claims they have no common standard of measurement and they are incompatible (Kuhn, 1970; Lincoln, 1990). However, it is now accepted that mixed methods can offer the opportunity to gather data from different perspectives and uncover relationships that exist between the layers of multifaceted research questions (Shorten & Smith, 2017). Using a mixed methods design also has its advantages over a single design as it can overcome the weaknesses of inherent in quantitative or qualitative approaches alone, provide information that cannot be answered by a single method and allows for the triangulation of information (Teddlie & Tashakkori, 2009).

Study one uses quantitative methods and was a systematic review of measures of psychosocial functioning and quality of life used in studies with older people with BD. Study two and study three followed a two-phase mixed methods design, referred to as an exploratory design (Greene et al., 1989). This is where the qualitative data is used during the first phase to inform quantitative methods used in the second phase. In this case, the qualitative data from the focus group study was used to inform the intervention development for study three. Study three used

an embedded mixed methods design where one set of data, provides additional data in a study based primarily on the other data type (Creswell et al., 2003). In this case, the intervention was delivered as part of the randomised controlled trial and qualitative interviews were completed to provide a further insight into the acceptability of the intervention and research processes and how these varied for different individuals and contexts.

2.3 Study one

The aims of study one were to increase our understanding of how BD presents in later life and to identify whether there were any measures that have been psychometrically examined for reliability or validity using an older adult BD sample. The specific research questions were:

1. What measures have been used to assess quality of life and psychosocial functioning in older adults with bipolar disorder?
2. What is the distribution of psychosocial functioning and quality of life scores for older adults?

A systematic review design was chosen as this is the gold standard for searching, collating, critiquing and summarising the best available evidence with regards to a clinical question (Liberati et al., 2009; Aromataris et al., 2014). Systematic reviews use rigorous, standardised methods to select and access articles to ensure that the results are both reliable and meaningful (Munn et al., 2018). Whist systematic reviews are often used as a valid evidence based to inform clinical guidelines; they are also used to identify research gaps in our understanding of a specific field.

A systematic review design was considered appropriate for study one, based on the specific research questions. The researcher also had pre-existing knowledge regarding the evidence for older people with BD and was aware that there may be gaps in the literature. This was compared to a recent systematic review of functioning with working age adults which found 379 research articles using 38 different types of social and occupational functioning measure (Akers et al., 2019). The systematic search strategy identified what measures have been used to assess quality of life and psychosocial functioning in older adults with BD and the means and standard deviations were extracted for most widely used measures. Table 1 details the research methods used. The protocol was pre-registered on PROSPERO and a copy can be found in appendix A.

Research Question	Approach	Research design	Method	Data	Analysis
What measures have been used to assess quality of life and psychosocial functioning in older adults with bipolar disorder?	Quantitative	Review	Systematic-review	Total number of quality of life and functioning measures used across the studies	Summary statistics
What is the distribution of psychosocial functioning and quality of life scores for older people with bipolar disorder for the most widely used measures?	Quantitative	Review	Systematic-review	Means and Standard deviations extracted for most widely used measures	Pooled means and standard deviations

Table 1: Research methods for study one

Table 2 details the eligibility criteria for the study. The review only included studies with individuals who have a formal diagnosis of BD. This was so the results of the study could be as comparable as possible. The cut-off age for participants in the studies was 50 years or over. This was based on recommendation from a report on older-age BD from the International Society for Bipolar Disorders Task Force (Sajatovic et al., 2015). The report highlighted that although most studies use 60 years and over to define older age BD, emerging data indicates that to fully understand BD in later life, we need to study across the lifespan, not just the healthy cohort who have survived into older age. The review only included studies that have been peer reviewed in published journals as they have been through a rigorous process of evaluation, compared to grey literature. Finally, the review only included articles written in the English language, as there were no resources for translation. This is a limitation as potentially studies conducted in other countries were excluded and therefore the results may not be generalisable.

2.3.1 Data analysis

The studies were synthesised by tabulating key characteristics and providing a narrative synthesis in relation to the review question. A copy of the data extraction form can be found in appendix B). The total number of studies using quality of life and psychosocial functioning measures were reported. Where studies used the same measure, a cross study mean and SD was calculated to identify the distribution of scores across the studies. The means and SDs were

pooled, weighted based on their study sample size according to Cohen's formula (Cohen, 1988; Zientek & Yetkiner, 2010). Table 2 summarises the research methods used during study one.

Included	Exclude
The study includes a sample of individuals diagnosed with BD I or II with a formal diagnosis according to Diagnostic and Statistical Manual (DSM-III, DSM-IIIR, DSM-IV, DSM-IV-TR & DSM-V) or the International Classification of Diseases (ICD-9 or ICD-10) *or* a sample of mixed diagnoses which reported the scores of those with BD separately' The study includes participants over the age of 50 or a sample of mixed ages which reported the scores of those over the age of 50 separately (based on the International Society for Bipolar Disorders Task Force (Sajatovic et al, 2015) recommendations to define older adults with BD ≥50 years). The study includes a quantitative measure of psychosocial functioning or quality of life. The study is published in a peer-reviewed journal as a full article or short report.	Editorials, comments, letters to the editor, book chapters, case series, or dissertations/theses (i.e., grey literature). The article is not written in the English language as there are no resources for translation.

Table 2: Eligibility criteria for study one

2.4 Study two

The key aims of study two were to explore the extent to which the original RfT intervention was acceptable to older adults with BD, to identify whether any adaptations were needed to the existing manual and what support older adults wanted from a therapist during therapy. The study also aimed to explore the experience of BD in later life, including the concept of recovery. The specific research questions were:

6. How do older adults experience BD in later life?
7. What is the experience of recovery in later life?
8. Does RfT need to be adapted for older people?
9. What are the specific adaptations needed to develop RfT-OA?
10. What do older people with BD want from a therapist delivering RfT-OA?

2.4.1 Sampling and sample size

Focus group methodology was chosen as the researcher was interested in hearing about the topics from a diverse range of perspectives, moderating the participant discussions from an external role (Bloor et al., 2001). Purposive sampling was used as this is a recommended approach when focus group discussion relies on participants ability and capacity to provide relevant information (Morgan, 1997). Purposive sampling is a form of non-probability sampling, where the sample is selected with a purpose in mind rather than randomly selected (Trochim, 2006). The researcher purposively aimed to recruit individuals who were over the age of 60 with a diagnosis of BD or a relative or a friend of an older person with BD. Individuals taking part in the focus groups were recruited via a confidential database of people who had previously been involved in research studies and were potentially interested in becoming involved in future studies at the Spectrum Centre, called "Spectrum Connect" (https://www.lancaster.ac.uk/health-and-medicine/research/spectrum/research/getting-involved/#d.en.405681). This may have led to a selection bias as all of the individuals had prior interest in taking part in research studies and the results may not be generalisable to the population. The Standards for Reporting Qualitative Research (SRQR) were adhered to an found in appendix C.

2.4.2 Eligibility criteria

- Age 60 or above
- A diagnosis of BD or a relative or friend of an older adult with BD
- The capacity to provide informed consent
  Sufficient English language skills to read the information sheet and take part in the discussions.

The cut-off age of 60 was chosen due to the overarching aim of the thesis to develop an intervention for older people with BD. The age 60 was chosen at the time, based on the United Nations (2013) definition of OA and in line with best practice (Laidlaw et al., 2008; Stanley et al., 2003). However, as detailed above, the task force paper published in 2015 (Sajatovic et al., 2015) recommend using 50 and above now as a cut-off age to capture a greater understanding across the lifespan. Friends and relatives were invited to take part as they often play a key role in older people's lives and it was thought they would broaden the focus group discussions. To assess capacity to consent, individuals were provided with an information sheet (see appendix D) about the study and given at least 24 hours to read the details. The researcher then contacted the

potential participants and they were given the opportunity to talk about the study and whether they understood what it meant to take part in the study. If the potential participant was able to understand and communicate their decision regarding taking part to the researcher, capacity to consent was achieved (see appendix E for consent form). The study did not have the resources for a translator, therefore only individuals who had sufficient English language skills were able to take part in the discussions were included. This is a limitation of the study and means the results may not be generalisable to other cultures.

The aim was to recruit approximately 6–12 participants, consistent with focus group methodology (Morgan, 1997). The researcher aimed to recruit both males and females as evidence suggests that mixed gender groups can improve the quality of discussion (Freitas et al., 1998). All interested individuals were invited to attend each of the three focus groups.

2.4.3 Topic guide

The topic guide was developed with the research team, which included the service user researcher who had experience of living with BD. This was considered a crucial part of the process, as their lived experience allowed insight into the realities of living with BD and they were able to offer a broader perspective on the topics which may have been more salient for the focus group discussions. The topic guide (see appendix F) was designed to loosely structure the groups and lead the discussions. Different topics were explored in groups 1 and 2 and during group 3 the researcher revisited the 6 different topics to gather additional information.

2.4.4 Data collection

Prior to the commencement of the study, the researcher had been supervised by SHJ who developed the original RfT approach. This had provided a comprehensive insight into the therapy and potential benefits. The researcher was also involved in a case study looking at the application of RfT for individuals with a more established diagnosis of BD. The researcher was therefore aware that they were approaching the focus group study with a set of preconceived ideas about the concept of personal recovery and the potential benefit of RfT for this client group. The researcher aimed to facilitate the focus groups in an open manner, so participants felt comfortable to give open and honest feedback about their ideas about personal recovery and the intervention.

The first focus group was facilitated by the researcher and the service user representative. Unfortunately, the service user researcher was not able to attend the subsequent groups and therefore the researcher facilitated these alone. This may have had an impact on the results of

the study, as participants in group one may have felt more comfortable with the service user researcher present and therefore more willing to share their thoughts and opinions, compared to groups 2 and 3.

2.4.5 Analysis

The focus groups were transcribed and analysed thematically using framework analysis (Richie & Spencer, 1994). Framework analysis has become an increasingly popular way to analyse primary qualitative data in the area of healthcare (Dixon-Woods, 2011). Framework was considered a better choice than thematic analysis for the focus group data as it allows for both deductive and inductive coding, emphasising how both prior issues and emergent data driven themes should drive the analytic framework development (Parkinson et al., 2016). This approach fitted with the aims of the study where there were predefined areas to explore (e.g., the adaptions) but the researcher also wanted to be open to exploring new ideas. The interview topic guide was used as a starting point to develop the categories for the framework. Five topics formed the original framework which included living with BD in later life, experience of recovery in later life, adapting RfT for older people, what support people want from a therapist during therapy and the relationship with relatives and health professionals.

Richie and Spencer (1994) outline five stages of framework analysis; familiarisation, identifying a framework, indexing, charting, and mapping and interpretation. The lead researcher read and reread the three transcripts to aid the process of familiarisation. Any emergent early impressions and ideas which seemed of potential interest and significance were noted on the side of the transcripts. Once this was completed the initial coding of transcript one was completed by the lead researcher (ET), using the original framework based on the topic guide and any emerging codes and themes were noted. Transcript 1 was also read and coded (indexed) independently by two members of the research team (SHJ) and (FL). Gale et al. (2013) maintain that at least two researchers should independently code the first few transcripts. In this case, SHJ and FL were only able to code the first of the three. However, ET, SHJ and FL met to discuss why the coded sections had been interpreted as meaningful. Any new codes were discussed, and the theoretical framework was developed based on these. At this stage, it would have been beneficial to the analysis to involve a service user representative, as they would have potentially offered an alternative viewpoint, ensuring one particular perspective did not dominate (Gale et al, 2013). The new framework was then applied to transcripts two and three. A further meeting took place between ET, SHJ and FL to discuss any more amendments to the framework, based

on the emergence of new codes. The final framework was representative of the data collected from all three focus groups.

When analysing and interpreting the results from the focus groups, the researcher highlighted the potential role of bias and aimed to ensure that the results were an accurate reflection of the participants ideas, rather than based on the team's personal views on the topic. The participants were positive about the development of the RfT-OA intervention, however, there were mixed views about the concept of personal recovery. There appeared to be a division in the group with some individuals questioning the concept of recovery in later life and they appeared to be more aligned to the traditional view of clinical recovery. However, some identified with the more personal concept of recovery and reported a range of strategies to support their recovery journey. Both of these viewpoints were highlighted in the results and the subsequent paper to ensure that this was taken into consideration when delivering RfT-OA and for future work in the area. Additional supporting quotes can be found in appendix G.

Table 3 summarises the research methods used during study two.

Research Question	Approach	Research design	Method	Data	Analysis
How do older adults experience BD in later life?	Qualitative	Focus group study	Focus Group	Focus group transcripts	Framework analysis
What is the experience of recovery in later life?	Qualitative	Focus group study	Focus group	Focus group transcripts	Framework analysis
Does RfT need to be adapted for older people?	Qualitative	Focus group study	Focus group	Focus group transcripts	Framework analysis
What are the specific adaptations needed to develop RfT-OA?	Qualitative	Focus group study	Focus group	Focus group transcripts	Framework analysis
What do older people with BD want from a therapist delivering RfT-OA?	Qualitative	Focus group study	Focus group	Focus group transcripts	Framework analysis

Table 3: Research methods used in study two

2.5 Study three

The aim of study three was to evaluate the feasibility and acceptability of RfT-OA for older people with BD. RfT-OA was developed specifically for use during study three, using the existing RfT manual and the findings from the focus group conducted during study two. The study used pre-specified criteria to interpret the findings in terms of feasibility and acceptability outcomes for progression to a definitive RCT (see chapters five and six). The development of RfT-OA followed the recommendations of the Medical Research Council (MRC) guidance on the development and evaluation of complex interventions for health (Craig et al., 2013) as there are specific recommendations for the progression to a definitive trial. The recommendations also aim to help the researcher select the appropriate methods when designing interventions. The MRC guidance emphasises the importance of assessing feasibility and acceptability, which can highlight any aspects of the intervention that may need to be modified before a definitive trial.

The guidance recommends that during the feasibility and piloting stage, the development and evaluation process should include testing procedures (e.g., randomisation), estimating both recruitment and retention rates and determining sample sizes. This is important as it helps prepare for a larger scale study by producing valuable evidence that certain procedures work or it can help avoid wasting large amounts of resources on a study that is unlikely to answer the research question (National Institute for Health Research, 2022). The MRC guidance also encourages the use of a mixture of quantitative and qualitative methods to understand any potential barriers to participation. The study was consistent with the CONSORT extension for pilot and feasibility trials (Eldridge et al., 2016). Please see appendix H for CONSORT checklist.

The study had a number of different research questions:

1. Would clinicians refer older adults into an RCT?
2. Would older adults self-refer into an RCT?
3. Would older adults with BD consent to participate in an RCT of a psychological intervention offered in addition to usual treatment vs usual treatment
4. Would older adults with BD complete follow-up assessments in a randomised controlled trial?
5. Would older adults adhere to RfT-OA?
6. What were participants experiences of receiving RfT-OA?
7. What is the most appropriate primary outcome measure for a future trial?
8. What is an estimation of the sample size for a future trial?

2.5.1 Study design

The study was a parallel, two-armed randomised controlled trial comparing up to 14 sessions of RfT-OA in addition to treatment as usual (TAU), versus TAU alone, with an embedded (nested) qualitative study to explore the acceptability of RfT-OA and research processes. An RCT design was considered the most appropriate to explore the piloting of the study procedures for progression to a future definitive, effectiveness trial. Randomised control trials are considered the most reliable evidence on the effectiveness of interventions because of the rigorous processes used during the conduct which minimise the risk of confounding factors influencing the results (Akobeng et al., 2005). The randomisation process is also an advantage as it prevents any deliberate manipulation of results. Participants are assigned during RCTs to specific groups randomly. This prevents the researcher subconsciously assigning individuals to specific groups if it seems they would get more benefit. If the researcher was able to do this, then the outcome of the study may appear more positive and the results would be skewed. Using an RCT design is also beneficial as the two groups can be directly compared against one another. For example, in the current study, the researcher could identify whether there were any differences in the completion of outcome measures, based on the assignment of the groups.

Realists have criticised traditional RCTS for not explaining the causal relationships that are identified by not taking into account the influences of individual factors or social context (Porter et al, 2017). The final set of data in RCTs is based upon central tendencies (e.g., means) and therefore this does not account for heterogeneity within the sample, leading to a loss of subjective information about the participants. In the present study, individuals had a diagnosis of BD, however, their subjective experiences of the intervention may have been very different and therefore this does bring into question how representative the mean is at an individual level. To account for this, the researcher adopted a critical realist stance and planned qualitative interviews with participants to understand their subjective experience. Another problem with RCTs is that they do not take into account the history of each participant. Individuals who sign up to research studies, especially those who self-refer, may be more highly motivated and have tried other treatment options prior to taking part. This means that it may be difficult to generalise the results to the rest of the population.

Research Question	Approach	Research design	Method	Data	Analysis
Will clinicians refer older adults with BD into an RCT?	Quantitative	Experimental	Randomised Controlled Trial	Total number of clinician referrals	Summary statistics
Will older adults with BD self-refer into an RCT?	Quantitative	Experimental	Randomised Controlled Trial	Total number of self-referrals	Summary statistics
Will eligible older adults with BD consent to participate in an RCT of a psychological intervention offered in addition to TAU vs TAU	Quantitative	Experimental	Randomised Controlled Trial	Total number of older adults who provide consent	Summary statistics
Will older adults with BD complete their follow-up assessments at 24 and 48 weeks?	Quantitative	Experimental	Randomised Controlled Trial	Repeated questionnaire measures (see table for schedule)	Summary statistics
Will older adults adhere to the RfT-OA intervention?	Quantitative	Experimental	Randomised Controlled Trial	Total number of sessions attended	Summary statistics
What are participants experiences of receiving RfT-OA?	Mixed Methods	Experimental Phenomenology	Randomised Controlled trial Nested qualitative study	Rating likert scales Semi-structured interviews	Summary statistics Content analysis
What is the most appropriate primary outcome measure for a future trial?	Mixed methods	Experimental Phenomenology	Randomised controlled trial Nested qualitative study	Repeated questionnaire measures (see table for schedule) Semi-structured interviews	Summary statistics Linear Models Cox Regression Content Analysis
What is an estimation of the sample size for a future trial?	Quantitative	Experimental	Randomised controlled trial	Repeated questionnaire measures (see table for schedule)	Summary statistics Correlations

Table 4: Research methods used during study three

2.6 Study three - Quantitative methods

2.6.1 Sample Size

Purposive sampling was used in the study as the sample was selected with a particular purpose in mind (Trochim, 2006). The researcher aimed to recruit individuals who had a diagnosis of BD and were over the age of 60. Participants were recruited from a number of different sources including NHS Trusts in the North-West, service user support groups (e.g., Bipolar UK), Spectrum Connect (a confidential database at the Spectrum centre which has contacts for over 500 people with lived experience of BD), social media sites (e.g., Facebook; see appendix I for poster and flyer). The recruitment target was set at 50 participants in accordance with recommendation for sample sizes for feasibility / pilot trials (Lancaster et al., 2004).

2.6.2 Eligibility criteria

Inclusion	Exclusion
A diagnosis of BD (I or II) according to the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders (SCID-5) research criteria Not in a current episode of mania, hypomania, depression or mixed episode in the last month Aged 60 or above Sufficient English language skills to comprehend the assessments and intervention content.	Receiving concurrent psychological therapy A score of less than 22 on the Montreal Cognitive Assessment (MOCA, Nasreddine, 2005).

Table 5: Eligibility criteria for study three

For the present study, participants needed to meet criteria for BD according to the DSM-5. As discussed earlier, using a diagnostic tool such as the DSM-5 can be helpful for research purposes as they are standardised frameworks used to classify mental health diagnoses. This means results from the study could be compared to other similar studies who have used the same framework. However, an individual's subjective experience can be lost within the diagnosis. Individuals taking part in the study were also required to be out of episode. If a person taking part was experiencing a manic or depressive episode, it would be hard to identify the impact of the intervention. If the participants mood is relatively stable at baseline, it means the results are more comparable across the groups. Participants were also excluded if they were receiving psychological therapy at the time of the study, so the impact of the specific intervention could be assessed. Participants had to score 22 or above on the MOCA (see appendix J) as a score of

21 or below indicates the presence of a mild cognitive impairment on the measure. This would mean that individuals may not have been able to comprehend the assessments or the intervention content.

2.6.3 Data collection

The main aim of the trial was to evaluate the feasibility and acceptability of RfT-OA and identify whether progression to a definitive trial was feasible. Therefore, data was collected on the number of referrals per month, the recruitment sources (self-referral and clinician route), the number of people assessed for eligibility and consented. Participant retention was evaluated during assessment, intervention and follow-up periods (12, 24, 36 and 48 weeks) including completion of outcome measures. Pre-specified criteria were used to interpret the findings in terms of feasibility and acceptability outcomes for progression to a definitive RCT using a traffic light system (green; feasible: amber; feasible with modifications: red; stop), which can be found in both the protocol and the trial paper (chapters five and six)

Additional outcomes were also collected during therapy to assess the therapeutic alliance including the Working Alliance Inventory – short form, client and therapist version (Tracey & Kokotovic, 1989; see appendix K) and participants also rated the therapy on two scales: 1) how useful they found the therapy from 0 (not at all) to 10 (extremely); 2) whether they would recommend the therapy to a friend experiencing similar problems from 0 (definitely not) to 10 (definitely yes). See appendix L for the Likert scales. This information was combined with the therapy retention rates and the data from the qualitative interviews as a way of further assessing the acceptability of the intervention.

2.6.4 Baseline and follow-up outcome measures

The Structured Clinical Interview for DSM-5, research version (SCID-5-RV; First et al., 2015) was delivered at baseline and multiple clinical and functional outcome measures were used to assess participant attrition rates and to provide preliminary data on outcomes. Table 5 provides a list of the measures used and Table 6 and 7 provide an overview of when each outcome was collected. The specific measures were chosen based on the previous study evaluating RfT for younger people with BD (Jones et al., 2015) and also in consultation with experts in both the BD (SHJ, FL, SJ) and ageing field (KL, CD) prior to the development of the study protocol. The final set of outcome measures was agreed by the service user researcher representative. They were considered to be relevant to their BD experiences and representative of the outcomes they would like to change during therapy.

Observer measures (see appendix M*)

- Modified Longitudinal Interview Follow-up (SCID-LIFE; Keller et al., 1987), incorporating the Structured Clinical Interview for DSM-5, research version (SCID-5-RV; First et al, 2015) the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960), the Bech-Rafaelsen Mania Scale (MAS; Bech-Rafaelson et al., 1978).
- Personal & Social Performance Scale (PSP; Morosini, 2000)

Self-report measures (see appendix N)

- Bipolar Recovery Questionnaire (BRQ; Jones et al., 2013)
- Quality of Life in Bipolar Disorder scale (QoL.BD; Michalak & Murray, 2010)
- Internal State Scale (ISS; Bauer et al., 1991)
- Centre for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977)
- Work & Social Adjustment Scale (WSAS; Mundt et al., 2000)
- World Health Organisation Quality of Life scale (WHOQOL-BREF: WHOQOL Group., 1995)

*The SCID-5-RV and SCID-LIFE are not included in the appendices due to copyright issues

Measure		Follow up period (weeks)					
	Baseline	**12**	**24**		**36**	**48**	
	Face to face	**Phone**	**Phone**	**Postal/ online**	**Phone**	**Phone**	**Postal/ online**
SCID	*						
MoCA	*						
SCID-LIFE	*	*	*		*	*	
HDRS	*	*	*		*	*	
MAS	*	*	*		*	*	
PSP	*	*	*		*	*	
BRQ	*			*			*
QoL.BD	*			*			*
ISS	*			*			*
CES-D	*			*			*
WSAS	*			*			*
WHOQOL-BREF	*			*			*

Table 6: Schedule of assessments for baseline and outcome measures

	Time point		
Measure	Session 3-4	Session 7-8	Session 13-14
WAI Client	*	*	*
WAI Therapist	*	*	*
Likert scale			*

Table 7: Schedule of assessment for additional therapy outcome measures

2.6.5 Analysis - Feasibility and acceptability data

The key focus of the trial was based on issues of feasibility and acceptability of the intervention. The majority of the analysis therefore was based around summary statistics used to estimate key parameters: rates of recruitment, sources of recruitment, demographics of sample, and retention to therapy and follow-up assessments.

2.6.6 Analysis - Clinical outcome data

The trial was not powered to detect effectiveness; however, statistical techniques were employed to see if there was a signal and to identify a potential primary outcome measure for a future trial. Linear models were used to assess the effect of RfT-OA vs TAU alone on each continuous outcome measure, with baseline value of the relevant measure as covariate. Time to first relapse was analysed using time to event methods, including Kaplan-Meier plots and the proportional hazards regression model, with time since last episode as covariate. Separate analyses were performed for three types of relapse (any episode, depressive or manic). The focus of the analysis was point estimation with 95% confidence intervals, rather than statistical significance. P values were reported in the appendix of the trial paper for data completeness (see appendix O).

To determine a sample size needed for a future trial, pooled standard deviations (SDs) for each continuous outcome, and median time to relapse, were used to estimate key parameters needed (in conjunction with data from other relevant trials (e.g., Walters et al., 2019). Correlations between baseline and follow-up for the continuous outcomes were also estimated as substantial correlations can be used to reduce the target sample size if linear modelling techniques are used for analysis.

Each of the potential primary outcome measures were assessed in relation to their sensitivity to change, completion rates and acceptability and this was explored during the qualitative interviews.

2.7 Study three - Qualitative methods

To determine the acceptability of the intervention and the research processes, quantitative data (e.g., number of sessions attended and dropouts) was combined with data from a set of qualitative interviews. The data from the interviews was also used as part of the process of trying to identify an appropriate primary outcome measure for use in a future definitive trial. If participants had expressed strong opinions about a particular measure, then this would have impacted on the choice of primary outcome measure for a future trial.

2.7.1 Sampling and sample size

The aim was to purposively sample 10-15 individuals who had received RfT-OA across key characteristics (e.g., age, gender, attendance rates) to create a diverse sample of people and

include people who both completed the intervention and also those who dropped out. This was important so there was a balanced view which was not purely based on people that had completed the intervention.

2.7.2 Data collection

A semi-structured interview (see appendix P for topic guide) was developed by the researcher and another member of the research team (SHJ). Semi-structured interviews were chosen as the aim was to subjectively explore the participants experience of the intervention. They also allow for more flexibility than a structured interview as interesting areas which arise during the interview can be explored further. The interviews were completed by a master's student in the department as the lead researcher delivered the majority of the therapy, therefore this may have influenced the participants' willingness to provide open and honest feedback regarding the therapy and research processes. All participants were provided with a d information sheet about the study (see appendix Q) and gave written consent (see appendix R). Interviews were audio-recorded and transcribed prior to analysis.

2.7.3 Analysis

The interviews were analysed using content analysis as the researcher was interested in finding out whether there were certain patterns in the data. Content analysis was chosen as it quantifies the meaning of the text and the frequency certain themes occur. However, it has been criticised as being too reductive, tending to simplify the data which can be problematic when there are complex themes. The researcher followed the four main stages: the decontextualisation, the recontextualisation, the categorisation, and the compilation of the data (Bengtsson, 2016). During decontextualisation, the researcher familiarized themselves with the data which included reading the interviews a number of times to get a sense of what ideas and impressions were coming through. The data was broken down into 'meaning units' which are sentences or paragraphs which contain aspects related to one another, based on the original aims of the interview (Graneheim & Lundman, 2004). Each 'meaning unit' was labelled with a code, known as 'open coding process' (Berg, 2011). The codes generated were both deductive, based on the original questions from the interview and inductive based on the information from the participant responses. During recontextulisation, the researcher returned to the interviews to check whether all of the content of the interviews had been covered in relation to the original aim. The interviews were re-read, alongside the 'meaning units' and any unmarked text was excluded if it did not correspond with the original aims of the study. During categorisation, the meaningful units of data were condensed, this is where the number of words is reduced without

losing content (Graneheim & Lundman, 2004). A number of different themes were created from the meaningful units as a way of categorising the data. The data was summarised and supporting quotes have been presented in the appendix of the main paper (see appendix S).

2.8 Research Rigour

Research rigor was considered at all stages throughout the thesis. Each of the three studies were carefully planned to ensure they were conducted to a high standard.

2.8.1 Study one

The systematic review used a rigorous systematic search strategy that was transparent and reproducible which is expected as part of research rigor (Liberati et al., 2009). The researcher met with a topic expert librarian to develop searches and to select the optimal combination of databases to maximise the search retrieval. Research indicates that including a librarian at this stage increases the rigor of the evidence produced (Rethlefsen et al., 2015).

Once the results of the searches were obtained and a rigorous screening process took place to ensure the correct articles were included in the final results. All titles and abstracts (N= 2663) were screened by the lead reviewer and an independent secondary reviewer. There was substantial agreement between the lead reviewer and secondary reviewer ($\kappa = 0.631$;95% CI, 0.564 to 0.699, $p < .0005$). 105 papers were eligible for full text screening, 33% of these were also screened by the secondary reviewer with 100% agreement.

2.8.2 Study two

A number of steps were taken to ensure research rigor and establish trust and confidence in relation to the findings from study two. To ensure credibility of the results, the research team were reflexive in their approach, acknowledging their past history and any potential biases they may have held with regards to the development of the intervention. Reflexivity in qualitative research is viewed to be one of the critical pillars of qualitative research (Fontana, 2004). During the focus groups, the researcher asked open, non-directive questions, maintaining a sense of awareness and openness to the answers provided. As discussed earlier in the chapter, this reflective stance was also maintained during the analysis and write up. it

was important to demonstrate the participants' mixed views about certain concepts (e.g., their view of recovery in later life), not just the preferential view of the researchers involved.

Another strategy to ensure rigor involved checking interview transcripts with all members of the supervisory team and ensuring that the final framework was a representative of the entire data set collected from the three focus groups. Finally, credibility of the results was also demonstrated by using anonymised participant quotes to illustrate the research findings.

2.8.3 Study three

Rigorous processes were used throughout the development and the delivery of the RCT during study three. As detailed earlier in the chapter, the development of RfT-OA followed the recommendations of the Medical Research Council (MRC) guidance on the development and evaluation of complex interventions for health (Craig et al., 2013). The study was consistent with the CONSORT extension for pilot and feasibility trials (Eldridge et al., 2016), enhancing the transparency of the research methods. Randomisation was conducted by a clinical trials unit, independent of the principal investigator. The study had an independent trial steering committee (TSC) to ensure that the trial processes were conducted to the rigorous standards. The TSC focused specifically on the progress of the trial, adherence to the protocol, and the rights, safety and well-being of the participants. Finally, service user involvement was present throughout the development of the trial. It was also present throughout the delivery of the RCT with an independent service user reference group (SURG) ensuring the trial was fully anchored within service user experience.

2.9 Public and patient involvement

It is widely acknowledged by policy makers, researchers and funders that patients and the public should be involved in research (Greenhalgh et al., 2019). Greenhalgh et al. (2019) suggest the three main arguments for involvement, which include firstly, the idea that patents have the right to input into the research for their condition. Secondly, that patients and the public bring a real world and lived experience view, which can improve the relevance of research, improve recruitment and retention of participants, widen the representation of people involved in research studies and improve the dissemination of findings beyond academia. Thirdly, that knowledge is co-constructed, beyond a university setting, which increases accountability and transparency of the research and may attract more resources as a consequence.

Service user involvement has been an integral part of the thesis. Prior to developing the research proposal, the researcher had been involved as both a researcher and a trial therapist on a number of studies at the Spectrum Centre. During this time, both service-users and health professionals had highlighted the lack of appropriate research opportunities (and also therapeutic options) available for people over the age of 60 with a diagnosis of BD. This feedback was an important part of the study process as it led the researcher to begin to explore the area of older people living with BD. Initial investigations exposed a significant lack of research and service development for this specific client group.

A service user researcher from the Spectrum Centre reviewed the initial proposal prior to submission and gave detailed feedback, especially regarding the plans for the development of the intervention. Their real-world view helped shape the course of the research and improve the relevance. Once the project started, the service user researcher acted as a representative throughout and was involved in all of the stages, ensuring the research was relevant and methods were suitable. The service user representative reviewed the ethical proposal and the participant information sheets, flyers and consent forms. The service user representative also co-facilitated one of the focus groups with the researcher (unfortunately they could not attend group two or three).

The participant information sheets, flyers and consent forms were also reviewed at the Spectrum Centre's advisory panel. This is a group of individuals with lived experience of mental health problems who meet on a regular basis to ensure the work carried out is relevant and focused on the needs of people living with BD. The advisory panel made decisions about the way that the information was presented on the information sheets, flyers and consent forms, ensuring it was an acceptable format and easily accessible to those who were interested.

A service user reference group (SURG) was formed after the focus groups were conducted which was comprised of six older adults with lived experience of BD. The researcher met with the SURG four times, where they consulted on the development and evaluation of the intervention. This included the development of the intervention and therapy handouts. They also advised on strategies for communicating the information effectively to ensure an inclusive and impactful dissemination strategy.

Whilst there are numerous benefits of involving service users, there have been concerns that PPI can be tokenistic in nature (Domecq et al., 2014). The researcher aimed to promote collaborative, active engagement during the focus groups and work with individuals with lived

experience as equals. On reflection, service users were not involved in all of the aspects of the decision making regarding the final intervention offered during study three. Separate meetings took place with the research team to conduct the analyses and a service user should have been involved to offer a potentially different perspective. The researcher undertook tasks such as literature searches alone and separate meetings took place with the research team to finalise adaptions to the original RfT intervention. In hindsight, service user involvement should have been present at all stages of the intervention design to ensure that it was truly co-created.

2.10 Ethics

In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. The research protocol was approved by Lancaster University and the UK National Health Service (NHS) Ethics Committee process (REC ref: 15/NW/0330). Ethical and research governance procedures were adhered to in accordance with the regulations of these bodies as well as the British Psychological Society (BPS, 2009). Service user representatives advised on study protocols and materials to ensure they were acceptable, sensitively worded and included enough information for a person to make informed consent. The research was carried out in a sensitive manner and confidentiality was maintained throughout.

2.10.1 Consent

All potential participants were provided with a detailed information sheet for each study (see appendix T for RCT information sheet and appendix U for the consent form). This was so they had all of the information they needed to make a fully informed decision about taking part in the study. They were then given the opportunity to ask any questions about the study. If individuals were happy to proceed, they signed a consent form. The consent forms were lengthy as they needed to cover a number of different areas. The researcher noticed that people were signing the consent form without fully reading the statements. To address this, the researcher read the statements to the individuals to ensure they fully understood their involvement, prior to providing consent.

2.10.2 Withdrawal

The researcher was aware that it might be difficult for some participants to withdraw from the study due to feeling the pressure to continue their involvement or to want to please the researcher / therapist. To account for this, participants were reminded throughout the research

process and therapy sessions that their participation was voluntary, and they were free to withdraw at any point without giving any reasons or experiencing any consequences.

2.10.3 Confidentiality

Confidentially was maintained throughout the research process. All participants were assigned a unique ID code which was used on any hard copies of the questionnaires, on any study databases and during the data analysis. Participants gave their consent to use anonymised quotes as part of the focus groups and qualitative interviews. However, as the sample sizes were smaller in both the focus groups and the qualitative interviews, it would be easier to identify individual participants. To account for this, the demographic information in the focus group was grouped together so their anonymity could be maintained.

2.10.4 Potential distress

The research involved people who have a diagnosis of BD and who are therefore considered to be vulnerable adults. It was important to ensure that they were not caused any undue distress as a result of the study. The researcher had substantial experience of conducting both research interviews and therapeutic interventions prior to the commencement of the study. Some of the questions in the SCID and SCID-LIFE interviews were of a personal nature and had the potential to induce distress. To minimise any risk of distress, prior to the start of the interview, the researcher discussed the nature of the questions. They reassured the participants that they could have a break or stop at any time if they found the experience distressing. If there was any upset during the interview, a call 24 hours after completion was offered by the researcher.

2.11 Researcher reflexivity

Krueger and Casey (2014) suggest that individuals may be more likely to share information with people that are more like themselves. I was aware of the potential differences in age, gender, ethnicity and background between myself and the participants when designing and delivering the study. I was therefore approaching the research from a somewhat ‘outsider’ perspective being a younger Asian female. I do however have a very close family member who has BD and have grown up witnessing the impact of living a life with BD. This lived experience has driven an interest in working in the field from an early age and has at times provided an ‘insider’ position. I was aware during the focus groups to remain neutral and not offer personal views, which felt difficult at times, especially when there were certain topics that felt very relevant. My role in the focus groups was to be on the periphery and facilitate an open conversation with

participants. The use of the topic guide helped me to maintain a neutral stance throughout. During therapy, my role changed and where helpful and appropriate for the client, I was able to share a little about my 'insider' knowledge of the complexities of living a life with BD. Over the years, I have become aware that my ability to empathise and understand from an 'insider' perspective has significantly enhanced my therapeutic relationships with clients. This was evident during the delivery of the intervention during the trial and reflected by the high attendance during my therapy sessions.

As discussed earlier in the chapter, the supervisory team (SHJ and FL), had prior experience of running a RfT trial with younger individuals with BD and I had been involved in a case series of RfT for individuals with a more established diagnosis of BD. We were aware that we were bringing our own history to the planning and the conduct of the research. Throughout the research process, we reflected on this and aimed to involve service users at various stages of the thesis to ensure that we were developing a study that was tailored to their specific needs, not based on our own preferences as researchers.

The development of a psychological therapy for older people with BD has had both a significant personal and professional impact. Prior to starting the research, I had worked with people with BD for a number of years. I was aware of some of the difficulties they had experienced with accessing psychological therapy, partly due to previous assumptions regarding the medical / biological underpinnings. Alongside this, older people have been subject to stereotypes, which may have affected their access and uptake of psychological therapies. Developing an intervention for a group of individuals who had experienced stigma based on their age and diagnosis felt very important to me, and much needed. I still feel very motivated and driven to develop the work further so there is equal access to evidence-based care for everyone who experiences mental health difficulties, regardless of diagnosis or age. On a personal level, my relative will move into later life and knowing that I can contribute towards the development of an intervention that is potentially beneficial for her, feels a great privilege.

During the course of the thesis, I have learnt a lot about myself as a researcher. Whilst being very driven to develop a therapy for older people, there have been times where I have had to challenge my own assumptions about older age. I have gained a lot from working with older people and learnt so much about the possibility of change in later life. Older people have faced many different obstacles throughout their life lived with BD and with this in mind, therapy should always start with a focus on their strength, resilience and wisdom.

CHAPTER THREE

A systematic review of psychosocial functioning and quality of life in older people with bipolar disorder

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A systematic review of psychosocial functioning and quality of life in older people with bipolar disorder

Dr Elizabeth Tyler: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK (corresponding author: e.tyler@lancaster.ac.uk)

Professor Fiona Lobban: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK.

Mr Bogdan Hadarag, Division of Health Research, Lancaster University, Lancaster, UK.

Professor Steven Jones: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK.

Corresponding author: Dr Elizabeth Tyler: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, LA1 4YX, UK. Email: e.tyler@lancaster.ac.uk

ABSTRACT

Background

There is evidence to suggest that older people with BD are more likely to demonstrate poor levels of functioning and score lower on well-being scales compared to non-clinical controls, even when in remission (Depp et al, 2006). To our knowledge, this is the first review paper to identify how quality of life and functioning has been measured in an older adult BD population.

Methods

We conducted a systematic review of studies including a quantitative measure of psychosocial functioning or quality of life and older people over the age of 50 with a formal diagnosis of BD I or II.

Results

Eleven studies were included in the review. They reported using seven different measures of psychosocial functioning and three measures of quality of life. The most commonly used measure of functioning was the Global Assessment of Functioning Scale (GAF) which was used in seven of the studies.

Limitations

The review used a comprehensive and systematic search strategy, however, very few eligible studies were available for review. The pooled analyses and reported means must be interpreted with caution due to the relatively small sample sizes.

Conclusions

There was significantly variability across the GAF, indicating that older people with BD are presenting with a wide range of functioning, ranging 'major impairment' to 'superior' scores. No existing validated measure assessing the psychosocial functioning or quality of life of older people with BD could be identified. Such a tool should be developed for use in future research with older adults with BD.

Keywords

Bipolar disorder, older adult, psychosocial functioning, quality of life, systematic review

BACKGROUND AND RATIONALE

Bipolar Disorder (BD) is a mood disorder, characterised by episodes of depression and mania or hypomania, affecting approximately 2.4% of the global population (Merikangas et al, 2011). BD is classified as a lifelong, recurrent condition, associated with functional decline and a reduction in quality of life (Michalak et al, 2005; Bonnín et al, 2012). It has been ranked as one of the top 20 causes of the global disease burden (Vos T et al, 2013). Previous studies have shown there is considerable functional impairment in adults with BD, even whilst their mood is stable (e.g., Rosa et al, 2008; Goetz et al, 2007; Strakowski et al, 2000). Similarly, studies have found that quality of life is impaired when individuals are both in episode and euthymic (e.g. IsHak et al. 2012 and Michalak et al, 2005).

Currently, the impact of living with BD in older adulthood has received far less attention than the adult population. There is evidence to suggest BD in later life may be more complex, with poorer cognitive functioning compared to non-clinical older adults (Gildengers et al, 2007), which may impact on functioning and lead to social, domestic, recreational and financial difficulties (Chen et al, 2017). There are also high levels of medical co-morbidity, (Lala et al, 2012, Tsai et al, 2009), with a higher risk for cardiovascular and respiratory conditions compared to aged matched controls (Rise et al, 2016). This may impact on quality of life as individuals are not able to engage in activities that they previously found enjoyable (Tyler et al, 2021). Depp et al. (2006) found that older people with BD were more likely to demonstrate poor levels of functioning and score lower on well-being scales compared to non-clinical controls, even when in remission. The negative effects on a person's functioning and quality of life can not only impact on the individual, but also the caregivers. The role can be extremely challenging and impact upon the caregiver's own quality of life (dos Santos et al, 2017).

The report from the International Society for Bipolar Disorders Task Force (Sajatovic et al, 2015) cites the lack of research and service development focused on older adults with BD. Given that the number of older people living with BD will increase dramatically over the next few decades due to our aging population (United Nations, 2019) and that there is improved awareness of the condition (Hein et al, 2020), it is important to increase our understanding of BD in later life. Sajatovic et al. (2015) stipulate that our understanding must progress from generalising information from mixed age groups to studies developed specifically for the older adult BD population.

To address the lack of research in the area, the present study aimed to identify how psychosocial functioning and quality of life have been measured in older adults with BD. Once studies have

been identified, data will be extracted to summarise levels of functioning and quality of life across studies that have included older people with BD. The purpose of this is to increase our understanding of the condition and help identify whether there are any measures that have been psychometrically examined for reliability or validity using an older adult BD sample for future research with this population.

Aims and objectives

The current study aims to explore ways to assess quality of life and psychosocial functioning in older adults with BD. The objectives are to identify what measures have been used to assess quality of life and functioning with older people with BD and to describe the distribution of psychosocial functioning and quality of life scores for widely used measures.

Research questions

1. What measures have been used to assess quality of life and psychosocial functioning in older adults with BD?
2. What is the distribution of psychosocial functioning and quality of life scores for older people with BD for the most widely used measures?

METHODS

Protocol registration

The protocol was pre-registered on PROSPERO 2020 CRD42020200169. Available from: https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=200169

Eligibility criteria

Inclusion

Studies were included if they:

- Included a sample of individuals diagnosed with BD I or II with a formal diagnosis according to Diagnostic and Statistical Manual (DSM-III, DSM-IIIR, DSM-IV, DSM-IV-TR & DSM-V) or the International Classification of Diseases (ICD-9 or ICD-10) ***or*** a sample of mixed diagnoses which reported the scores of those with BD separately
- Included participants over the age of 50 ***or*** a sample of mixed ages which reported the scores of those over the age of 50 separately (based on the International Society for

Bipolar Disorders Task Force (Sajatovic et al, 2015) recommendations to define older adults with BD ≥50 years).

- Included a quantitative measure of psychosocial functioning or quality of life

Were published in a peer-reviewed journal as a full article or short report.

Exclusion criteria

Studies were excluded if they were:

- Editorials, comments, letters to the editor, book chapters, case series, or dissertations/theses (i.e., grey literature).
- Not written in the English language due to no resources for translation.

Search methods and Information sources

The review adopted a comprehensive search strategy. Search terms were informed by previous Cochrane reviews for BD (e.g. Justo et al, 2007; Morriss et al, 2007) and functioning (Crotty et al, 2010) and systematic reviews investigating quality of life (e.g. Warkentin et al, 2014). Limiters in search engines were set to include peer reviewed studies, studies in the English Language, human participants only. There were no limiters set on publication date.

Search terms

Group one

“bi polar” OR “bi-polar” OR bipolar OR “mania*” OR “hypomani*” OR “mood disorder*” OR “mood disturbance*” OR “mood swing*” OR “affective disorder*” OR “affective illness*”

Group two

“older adult” OR “older person” OR “old age” OR “elderly” OR “elderly person” OR “senior” OR “geriatric*” OR “retire*” OR “pension*” OR "over 50" OR “older adult” OR “older person” OR “old age” OR “elderly” OR “elderly person” OR “senior” OR “geriatric*” OR “retire*” OR “pension*”

Group three

“psycho social” OR “psycho-social” OR “psychosocial” OR “psychological functioning” OR “social functioning”

Group four

"health-related quality of life" OR "health related quality of life" OR "quality of life measure" OR "QOL"

The group terms were also combined with the appropriate MeSH headings / subject headings in each database. The search method was as follows: group one AND group two AND group three OR group four.

Databases Medline, PSYCH-INFO, AMED and CINAHL were chosen following discussion with a University of Lancaster Librarian as their topic areas were within the scope of the review. Highly relevant papers were identified by the research team and test searches took place in February 2021 to ensure they were retrieved using the search strategy. The final database search took place at the end of April 2021. The reference lists of included articles were screened to identify any more potential eligible papers for the review.

Study selection

The lead reviewer (ET) and a second reviewer (BH) independently screened all of the titles and abstracts. Any inconsistencies were shared with the wider team and discussed until an agreement was attained. Cohen's Kappa was used to assess the agreement between the two reviewers at the title and abstract screening stage.

The lead reviewer (ET) checked eligibility of all full texts using the inclusion and exclusion criteria. Additionally, the second reviewer (BH) independently assessed 30% of full texts. Extracted information included; type of study, study sample (e.g., age range, diagnosis, setting), the specific measure of psychological functioning or quality of life, the mean and/or median, standard deviation and/or range of scores. Please see supplementary information for an example of the data extraction form.

Data analysis

The mean and/or median, standard deviation and/or range of scores from each included study sample were extracted from the included articles (see table 1). Where studies used the same measure, a cross study mean and SD was calculated to identify the distribution of scores across the studies. The means and SDs were pooled and weighted based on their study sample size according to Cohen's formula (Cohen, 1988; Zientek and Yetkiner, 2010).

RESULTS

2663 titles were initially identified (once duplicates were removed) and screened by the lead reviewer and an independent secondary reviewer (BH) by title and abstract. There was substantial agreement between the lead reviewer and secondary reviewer ($\kappa = 0.631$;95% CI, 0.564 to 0.699, $p < .0005$).

105 papers eligible for full text screening, 33% of these were screened by the secondary reviewer with 100% agreement. The final number of papers included in the review was 11. The most common reason for exclusion at this stage was not reporting results for the older people taking part in the study. The number of studies excluded are shown in figure 1.

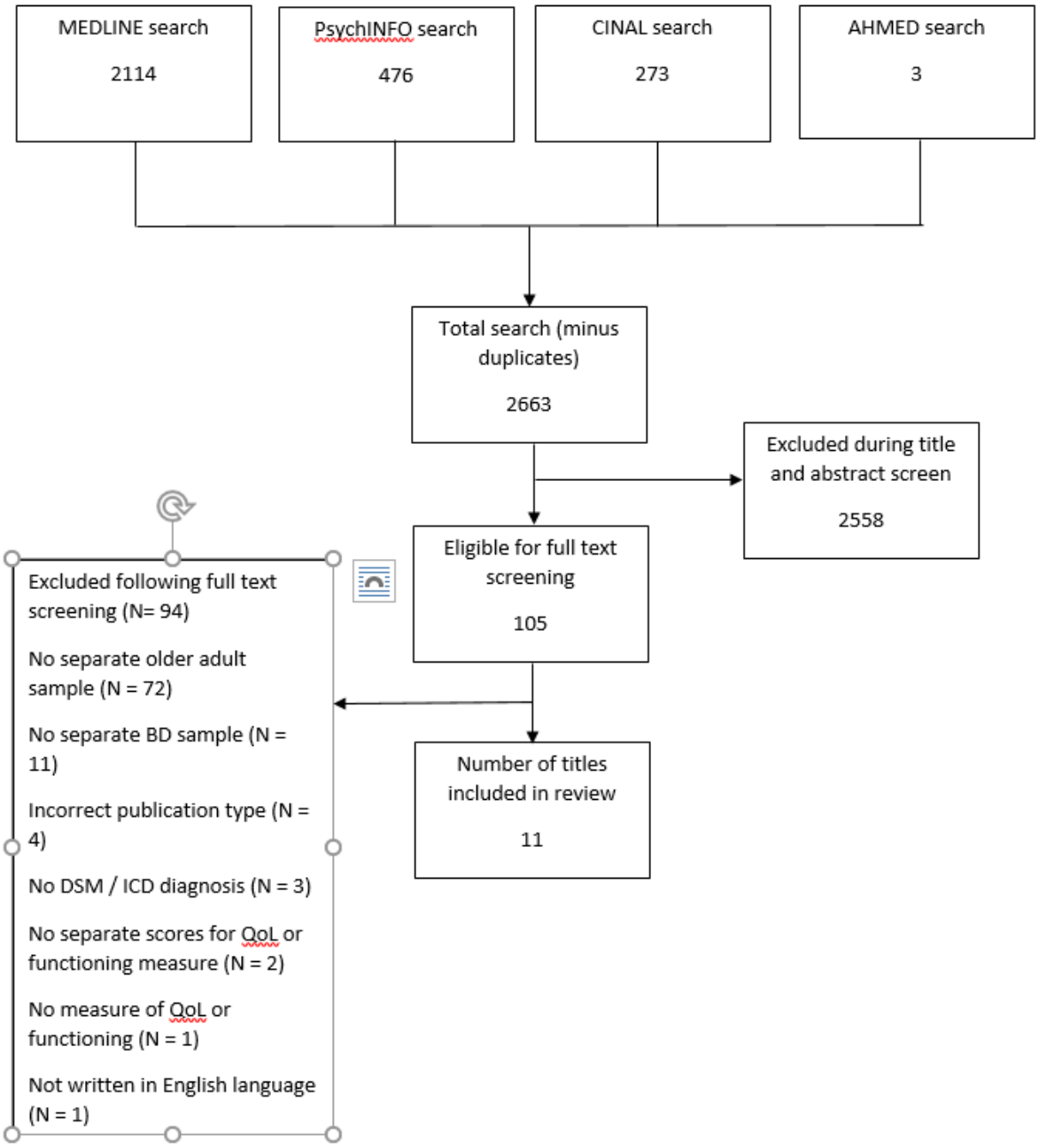

Figure 1: Flow diagram

Authors and date	Study title	Study location	Study type	N	Age (s.d)	Gender % female	Diagnosis / Classification system	Current mood state	Quantitative measure	Mean (s.d)	Median (IQR)
Comes et al. (2017)	Functional Impairment in Older Adults With Bipolar Disorder	Barcelona, Spain	Observational, cross-sectional	33	68.7 (8.5)	51.5%	A formal diagnosis of BDI or BD II according to the DSM-IV	Euthymic	Functioning Assessment Short Test (FAST)	19.2 (11.4)	Not available from paper
Dautzenberg et al. (2015)	The care needs of older patients with bipolar disorder	Amsterdam, Netherlands	Cross-sectional	78	68.5(7.8)	48.7%	A formal diagnosis of BDI or BD II according to the DSM-IVTR	60% of the sample were in remission	The Global Assessment of functioning (GAF) Manchester Short Assessment of Quality of Life (MANSA)	GAF = 65.0 (11.2) MANSA = 61.9 (8.2) 5.2 per item	Not available from paper
Depp et al. (2007)	Medication adherence skills training for middle-aged and elderly adults with bipolar disorder: development and pilot study	San Diego, California	Quasi-experimental clinical trial	21	60.0 (6.1)	24%	A formal diagnosis of BDI or BD II according to the DSM-IV	Unknown	Short-Form of the Medical Outcomes Study Quality of Life Scale (SF-36)	SF-36 Physical functioning - 70.3 (24.4) SF-36 Role limitations – physical health - 59.4 (41.7)	Not available from paper
Dols et al. (2014)	Psychiatric and Medical Comorbidities: Results from a	Amsterdam, Netherlands	Cross-Sectional	101	69.0 (7.8)	53.4%	A formal diagnosis of BDI or BD II	Unknown	Global Assessment of	63.1 (11.8)	Not available from paper

	Bipolar Elderly Cohort Study						according to the DSM-IV		Functioning (GAF)		
Liao et al. (2020)	Differences in outcomes between older community-dwelling patients with bipolar disorder and schizophrenia with illness onset at young age	Taipei, Taiwan	Cross-Sectional	113	59.8 (5.5)	59%	A formal diagnosis of BDI or BD II according to the DSM-IV	A score ≤5 on the Young Mania Rating Scale and Hamilton Depression Rating Scale total score <7 continuously for 2 months	Global Assessment of Functioning (GAF) The Strauss–Carpenter Scale (SCS).	GAF = 75.7 (10.2) SCS = 12.3 (3.0)	Not available from paper
Martino et al. (2018)	Neurocognitive heterogeneity in older adults with bipolar disorders	Buenos Aires, Argentina	Cross-Sectional	66	63.7 (8.0)	68.2%	A formal diagnosis of BDI or BD II according to the DSM-IV	Euthymic	The General Assessment of Functioning (GAF)	77.8 (10.8)	Not available from paper
Martino et al. (2013)	Neurocognitive functioning in early-onset (EO) and late-onset (LO) older patients with euthymic bipolar disorder	Buenos Aires, Argentina	Cross-Sectional	EO = 20 LO = 20	EO = 69.1 (6.7) LO = 66.9 (6.6)	EO = 90% LO = 75%	A formal diagnosis of BDI or BD II according to the DSM-IV	Euthymic	The General Assessment of Functioning (GAF)	EO = 76.4 (12.8) LO = 72.5 (9.9)	Not available from paper
Orhana et al. (2018)	The relationship between cognitive and social	Amsterdam, the Netherlands	Cross-Sectional	63	66.0 (10.0),	49%	A formal diagnosis of BDI or BD II according to the	Unknown	Social and Occupational Functioning Assessment Scale	Not available from paper	65 (15) 35–85

	functioning in older patients with bipolar disorder						DSM-IVTR		(SOFAS) The Social Participation Scale (SPS)		12 (4), 5–17
Parikh and Panse (2020)	Quality of life in elderly bipolar disorder patients	Maharashtra, India	Cross-Sectional	100	68.2 (5.8)	41%	A formal diagnosis of BD according to the ICD-10 DCR criteria	Behaviourally stable during clinical interview	World Health Organization quality of life-BREF	53.4	Not available from paper
Tsai et al. (2007)	Cognitive impairment in later life in patients with early-onset bipolar disorder	Taipei, Taiwan	Cross-Sectional	52	66.0 (6.5)	75%	A formal diagnosis of BDI according to the DSM-IV	Euthymic	Global Assessment of Functioning (GAF) Strauss–Carpenter score (SCS)	GAF = 69.6 (12.2) SCS = 10.8 (3.4)	Not available from paper
Tsai et al. (2009)	Cognitive Dysfunction and Medical Morbidity in Elderly Outpatients With Bipolar Disorder	Taipei, Taiwan	Case–control study	59	71.1 (5.9)	66.1%	A formal diagnosis of BDI according to the DSM-IV	Euthymic	Global Assessment of Functioning (GAF) scale Community Psychiatric Rating Scale (CPS)	GAF = 68.0 (10.8) CPS = 13.9 (4.7)	Not available from paper

Table 1: Summary of key study characteristics

Description of included studies

11 papers were included in the review (see Table 1) with a total of 726 participants, including nine cross-sectional studies (Comes et al, 2017; Dautzenberg et al, 2015; Dols et al, 2014; Liao et al, 2020; Martino et al, 2018; Martino at el, 2013; Orhan et al, 2018; Parikh and Panse, 2020; Tsai et al, 2007), one case-control study (Tsai et al, 2009) and one quasi-experimental clinical trial (Depp et al, 2007). Studies were carried out in countries across the world including; the US, Taiwan, India, Argentina, the Netherlands and Spain. Sample sizes varied from 20-113.

Participants mean ages ranged from 59.8 (s.d. 5.5) to 71.1 (s.d. 5.9) years with seven out of 11 studies having higher proportions of women than men (range from 52% to 90%). Ten out of the 11 studies included individuals diagnosed with BD I or II according to Diagnostic and Statistical Manual (DSM-IIIR, DSM-IV, DSM-IV-TR) and one study used the International Classification of Diseases (ICD-10 DCR) criteria.

Question 1

What measures have been used to assess quality of life and psychosocial functioning in older adults with BD?

11 papers reported using 10 different measures of psychosocial functioning and quality of life since 1997, which is the date that the first paper included in the review was published (see table 1). This includes seven measures of functioning and three measures of quality of life. The most commonly used measure of functioning was the Global Assessment of Functioning Scale (GAF) which was used in seven of the papers. The second most used measure was the Strauss-Carpenter Scale (SCS) which was used in two of the studies.

Measure name	Overall number of uses
Global Assessment of Functioning	7
The Strauss–Carpenter Scale	2
Social and Occupational Functioning Assessment Scale	1
Functioning Assessment Short Test	1
The Social Participation Scale	1
Community Psychiatric Rating Scale	1
Short-Form of the Medical Outcomes Study Quality of Life Scale SF-36	1
Manchester Short Assessment of Quality of Life	1
World Health Organization quality of life-BREF quality of life assessment	1

Table 2: List of functioning and quality of life measures used in the 11 papers.

Question 2

What is the distribution of psychosocial functioning and quality of life scores for older people with BD?

The most frequently used measure was the Global Assessment of Functioning (GAF; Endicott et al, 1976) which is used to rate social, occupational, and psychological functioning. The GAF measures how much an individual's symptoms affect their day-to-day life on a scale of 0 to 100. The higher the score on the GAF, the better the person's level of functioning. The pooled GAF score (see table 2) of 70.18 (s.d = 11.10), is based on data from 509 older people with BD and indicates an individual who has*; 'some mild symptoms or some difficulty in social, occupational or school functioning, but generally functioning pretty well and has some meaningful interpersonal relationships*' (American Psychiatric Association, 1994). The pooled analysis for the GAF indicates that 68% of the sample scored between 81.28 and 59.08 (one standard deviation above / below the mean), 13.5 % scored between 81.28 and 92.38 and 47.98 and 59.08 (two standard deviations above / below the mean) and 2.5% scored between 92.38 and 103.48 and 47.98 and 36.88 (three standard deviations above / below the mean). However, there is a ceiling effect as individuals cannot score above 100 on the scale. A score of between 71 and 80 represents someone who has "*no more than a slight impairment in social, occupational or school functioning (e.g., temporarily falling behind in school work) which* significantly contrast with individuals scoring lower on the scale with a score of between 31–40 representing '*some impairment in reality testing or communication, or major impairment in several areas such as work or school, family relations, judgement, thinking or mood".*

The Strauss–Carpenter Scale (SCS; Strauss and Carpenter, 1972) was used in two studies (Liao et al, 2020 and Tsai et al, 2007). It is a prognostic scale, measuring four areas of functioning; hospitalisation, work, social activity and symptoms, scored out of a possible 16, with an established cut-off point of 14 for remission (Alberich et al, 2016). The pooled SCS score (see table 2) from 165 older people with BD was 11.97, below the cut-off point for remission. The pooled analysis indicates that 68% of the sample scored between 15.09 and 8.85 (one standard deviation above / below the mean), 13.5 % scored between 15.09 and 18.21 and 8.85 and 5.73 (two standard deviations above / below the mean) and 2.5% scored between 18.21 and 21.33 and 5.73 and 2.61 (three standard deviations above / below the mean). This finding suggests significant variability in scores on the SCS, with approximately 16% of individuals scoring above the cut-off point for remission according to Alberich et al. (2016).

Measure	Number of studies with data	Combined N	Pooled age	Pooled mean	Pooled SD
The Global Assessment of Functioning	7	509	66.00	70.18	11.10
The Strauss-Carpenter Scale	2	165	61.74	11.97	3.12

Table 3: Pooled analysis of most widely used measures.

Three quality of life measures were found across the 11 studies included. Scores on these measures ranged across the studies. Parikh and Panse (2020) used the WHOQOL-BREF scale and the mean score was 53.40, indicating poor quality of life for older adults (Silva et al, 2014). The SF-36 was used in Depp et al. (2007) study and consists of eight scaled scores, transformed into a 0-100 scale, with the lower the score indicating more disability. The scores ranged from a low 31.3 (SF-36 Role limitations – emotional health) to a higher 70.3 (SF-36 Physical functioning). Quality of life was evaluated in Dautzenberg et al. (2015) study using the Manchester Short Assessment of Quality of Life (MANSA; Priebe et al. 1999) which rates satisfaction with various aspects of life. The MANSA score was 5.2 which is the mean of the 12 individual item scores, ranging from 1 (very dissatisfied) to 7 (very satisfied).

DISCUSSION

The aim of the review was to identify how quality of life and psychosocial functioning has been measured in older people with BD and to identify whether there were any measures that have been psychometrically examined for reliability or validity using an older adult BD sample for future research with this population. Once identified, we aimed to describe the distribution of scores for the most widely used measures to improve our understanding of how the condition presents in later life.

In this systematic review, we identified seven measures of psychosocial functioning and three measures of quality of life, across 11 research studies. This low volume of research contrast with findings from adults of working age with BD. Akers et al. (2019) identified 379 research studies reporting 38 different measures of social and occupational functioning, published since 1981. With regards to quality of life, a recent systematic review and meta-analysis of cross-sectional

case-controlled studies including adults with BD found 23 eligible studies and reported four different measures of quality of life (Pascual-Sánchez et al, 2019).

The most frequently used measure in this review was the GAF, used in seven of the studies included. The GAF is a global measure of functioning not specifically validated for use with individuals with BD. Only two of the seven functioning measures identified, the SCS and the Functioning Assessment Short Test (FAST; Rosa et al, 2007) have been psychometrically examined for reliability or validity using a BD only sample. None of the three quality of life measures (WHOQOL-BREF, SF-36 and MANSA) identified have been validated using a BD sample. Furthermore, none of the ten measures identified in this review have been psychometrically examined for reliability or validity in an older adult BD only sample.

The GAF was also the most frequently used measure found in Akers et al. (2019) review, with 166 overall uses since 1981 with working age adults. In the current review, the pooled average GAF score was 70.2 (s.d = 11.10), indicating individuals "*experiencing some mild symptoms or some difficulty in social, occupational or school functioning".* The pooled score for working aged adults was 63.63 (s.d =12.68) which falls into the same category as that for the older adults, albeit slightly lower. Similarly, to Akers et al (2019), there was significantly variability across the scale, indicating that some older adults were presenting with *'major impairments in several areas'*, however, others were scoring at the top of the scale with '*superior functioning in a wide range of activities'"*. These findings support the existing literature focused on working aged adults where BD is associated with significant impairments in areas of functioning such as work, family and social life (Sanchez-Moreno et al, 2009). There are, however, also a proportion of individuals with BD that maintain at least adequate levels of occupational and social functioning whilst living with the condition (MacQueen et al., 2009). There is also evidence to suggest that some individuals with BD exhibit higher levels of functioning compared to the general population and excel in areas such as creativity (Goodwin and Jamison, 2007; Johnson et al, 2012).

One advantages of the GAF is its wide-ranging scale, which allows representation for individuals scoring on the higher end of the scale. A recent study (Lomastro et al, 2020) with adults with BD, aged 18-65 years found that having a diagnosis of BD II, a higher educational level, and better performance in verbal memory, attention, and executive functions independently predicted high psychosocial functioning (scoring 90 or more on the GAF). Developing an understanding of the factors that influence higher functioning for older people with BD is important. This will

increase our understanding of the condition in later life and help shape effective therapeutic interventions for those presenting with lower levels of functioning.

The GAF was eliminated from the DSM-5 in 2013 for a number of reasons, including the observations that the overall score often correlates with the person's severity of symptoms, rather than the levels of impairment (Gold, 2014). This has been supported by a number of studies that have found that the GAF might be mediated by symptoms (Samara et al. 2014; Suzuki et al. 2015). Interestingly, studies included in the present review where the sample is euthymic (indicating a neutral mood with few symptoms), have a higher average score on the GAF, representing a better level of functioning, compared to those where the current mood state was unknown. The Social and Occupational Functioning Assessment Scale (SOFAS; Rybarczyk, 2011) was developed from the GAF and included in the Diagnostic and Statistical Manual for Mental Disorders 4th Edition (American Psychiatric Association, 2000). The SOFAS gives a more accurate portrayal of functioning as it is independent of the person's severity of psychological symptoms (Rybarczyk, 2011). Only one of the studies (Orhan et al, 2018) included in the current review used the measure, however Aker's et al (2019) found the SOFAS was used in 29 different research studies with working aged adults.

The SCS was used in two of the studies in the present review. In Aker's et al's 2019 review, they found the SCS had been used 18 times since 1981, with four uses in the past 10 years, demonstrating a reduction in its use over time. The SCS has now been psychometrically examined for reliability or validity using a BD only sample (Alberich et al, 2016) and therefore we may see an increase in the use of the measure in BD research. Alberich et al (2016) established a cut-off score of 14 for remission, with a higher score indication better functioning. The pooled score for this review was 11.97, indicating individuals were still having some mild difficulties with functioning, and consistent with the pooled scored from the GAF. A disadvantage of the SCS is it does not provide a range of functioning levels only a cut off for remission. Therefore, scales such as the GAF and SOFAS have an advantage as they have a wide range of possible scores which can indicate both problematic and superior functioning, allowing more insight into the person's presenting difficulties.

Only three quality of life measures were found across the 11 studies included. The scores on the measures ranged across the studies. Parikh and Panse, (2020) used the WHOQOL-BREF scale and reported scores indicating poor quality of life for older adults, whereas Dautzenberg et al (2015) used the MANSA which indicated moderate satisfaction with various aspects of life. Depp et al (2007) used the SF-36 which consists of eight scales and reported a range of scores from

low to higher levels of perceived health and well-being (Depp et al.,2007). Limited conclusions can be drawn from the findings due to the small number of studies including a quality of life measure and the inconsistent pattern of scores.

The findings from the current systematic review confirm previous reports that the impact of BD on older adults and its relationship with psychosocial functioning (Nivoli et al., 2014) and quality of life (Parikh and Panse, 2020) has received little attention. This finding for older adults with BD mirrors a review focused on the quality of life of older people in general staying at home as they age, rather than aging in residential care. They found a small number of studies reported the assessment of quality of life (Vanleerberghe et al, 2017), even though a number of international action plans focused on aging highlight the importance of improving quality of life for people as they age (World Health Organisation, 2015; Tesch-Roemer, 2012; Malva and Bousquet, 2016). A recent review found 44 available quality of life instruments for use with people with mental health problems (van Krugten et al, 2021). Only one of the 44 was developed specifically for older people, the World Health Organization Quality of Life Questionnaire – Older Adults Module (Power et al, 2005) and this was not used in any of the studies in this review. Therefore, it appears that there are a wide range of quality-of-life instruments available for younger people, compared to measures developed specifically for an older adult population.

Strengths and Limitations

There are a number of strengths to this review. A comprehensive and systematic search strategy to identify relevant papers was used. All identified titles and abstracts were double screened by two reviewers, with substantial agreement. Thirty-three percent of eligible papers for full text screening were also screened by both reviewers, with 100% agreement. However, very few eligible studies were identified to review, therefore the pooled analyses and reported means must be interpreted with caution due to the relatively small sample sizes. Secondly, the mood state of included participants was unknown in a number of the studies. Participants may have been symptomatic which may have affected their score on the GAF and the pooled analysis for the study. Additionally, studies written in another language were excluded from the review due to resource constraints for interpretation and therefore the results may not be generalisable.

CONCLUSION

The present systematic review identified very few studies reporting the assessment of psychosocial functioning and quality of life in older people with BD, especially when compared to working aged adults with BD (Akers et al, 2019). The GAF was the most frequently used

measure of functioning, used in seven of the 11 studies included in the review. There was significantly variability across the scale, indicating that older people with BD are presenting with a wide range of functioning, consistent with working aged adults (Akers et al, 2019). More studies focused on understanding functioning and quality of life for older people with BD are needed, particularly as the effects can not only impact on the individual, but also the caregivers (dos Santos et al, 2017). As no existing validated measure assessing psychosocial functioning or the quality of life of older people with BD could be identified, such a tool should be developed for use in future research with the population.

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DECLARATIONS

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CHAPTER FOUR

Developing a recovery-focused therapy for older people with bipolar disorder:

A qualitative focus group study

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Developing a recovery-focused therapy for older people with bipolar disorder:

A qualitative focus group study

Dr Elizabeth Tyler : Lancaster University Division of Health Research, Lancaster, UK

Professor Fiona Lobban : Lancaster University Division of Health Research, Division of Health Research, Lancaster University, Lancaster, UK

Ms Rita Long: Lancaster University Division of Health Research, Lancaster University, Lancaster, UK

Professor Steven Jones : Lancaster University Division of Health Research, Lancaster University, Lancaster, UK

Corresponding author: Dr Elizabeth Tyler: e.tyler@lancaster.ac.uk

ABSTRACT

Objectives: As the world's population ages and there is increased awareness of Bipolar Disorder (BD) the number of older people living with the condition will rise substantially. There is no current evidence base for the effectiveness of psychological interventions for older adults with BD. This focus group study explored a number of topics to inform the development and delivery of a recovery-focused therapy (RfT) for older adults with BD.

Design: A qualitative focus group study.

Setting: Three focus groups were conducted at a University in the North-West of England.

Participants: Eight people took part in the focus groups; six older adults with BD, one carer and one friend.

Results: Participants responses clustered into 6 themes: 1) health and age-related changes in later life, 2) the experience of BD in later life, 3) managing and coping with BD in later life, 4) recovery in later life, 5) seeking helping in the future 6) adapting RfT for older people.

Conclusions: Participants reported a range of health and age-related changes and strategies to manage their BD. Participants held mixed views about using the term 'recovery' in later life. Participants were in agreement that certain adaptations were needed for delivering RfT for older adults, based upon their experience of living with BD in later life. The data collected as part of the focus groups has led to a number of recommendations for delivering RfT for older adults with BD.

ARTICLE SUMMARY

Strengths and limitations of this study

To our knowledge this is the first study to involve older adults with BD to shape and develop a psychological intervention specifically for their cohort.

The study was designed and conducted in consultation with service user representation throughout, enhancing the quality, value and the relevance of the study.

The clinical recommendations for delivering RfT for older adults have been developed in partnership with individuals with lived experience of BD, carers and healthcare professionals.

The individuals with lived experience taking part in the group were not representative of all older people with BD. They were all White British and all had (or had retired from) a professional working background.

BACKGROUND

Approximately 25% of individuals living with Bipolar Disorder (BD) are age 60 or over (1). As the world's population ages (2) and awareness of the condition increases, the number of people living with BD into later life is expected to rise substantially. Research indicates that older adult specific services are better placed to meet the needs of those with mental health problems in later life, when compared to general adult services (3). The National Institute for Health and Care Excellence BD guideline (4) suggests that older adults with BD should be offered the same treatments as younger people, however there appear to be unique, clinical characteristics that feature in the older population (5), that may impact on their needs and response to treatment (6).

Older people with BD follow a chronic and persistent course (7), with recurrent mood episodes continuing beyond the age of 70 (8). The clinical features include poorer cognitive functioning, even during periods of mood stability (9), which may impact on functioning, leading to problems with finances, domestic roles, mobility and social and recreational activities (7). Rise et al's (10) systematic review found that older people with BD are more likely to present with conditions such as diabetes mellitus, cancer, thyroid disorder and hypertension compared to age matched controls. Older people with BD may be twice as likely to experiences stressful life events compared to healthy controls such as changes in familial structure, retirement, housing and finances (11), which can act as triggers for mood episodes (7). Studies have found that older people with BD are more likely to experience depressive episodes (12, 13) and there is some evidence to suggest milder episodes of mania, compared to their younger counterparts (14)

At present, there is no evidence base for the effectiveness of psychological interventions for older adults with BD. The aim of the study was to conduct a number of focus groups with people with lived experience of BD in later life, to adapt a recovery focused therapy (RfT) intervention developed for younger adults (15), so it could be offered to people over the age of 60. The focus group work sits within a larger study which consists of two phases (16).

The key aims of the focus groups were to: (1) explore the extent to which the original RfT intervention was acceptable to older adults with BD, (2) identify whether any adaptations would be needed to the existing manual and what support older adults would want from a therapist during therapy, (3) explore the experience of BD in later life; including the relationship with relatives and health professionals and the concept of recovery with BD.

METHOD

Design

The study was approved by the UK NHS Ethics Committee process (REC ref: 15/NW/0330). The British Medical Journal (BMJ) and the Medical Research Council (MRC) recommend the incorporation of qualitative research in the process of complex intervention development (17, 18). Focus group methodology (19) was chosen because the researcher was interested in understanding the topics from a diverse range of perspectives, moderating the discussion from a peripheral role (20). The Standards for Reporting Qualitative Research (SRQR) were adhered to and a copy of the checklist can be found in the supplementary information (Supplementary file 1).

Patient and public involvement

Patients and public involvement (PPI) representatives were involved in the study design process from the outset. The team has a service user advisory panel, led at the time by RL. The panel provided feedback on the original grant application and reviewed study documents, including participant information sheets, consent forms and topic guides. At the end of the focus group, participants were invited to remain in the study and form the service user reference group (SURG) to contribute towards the design, implementation and dissemination at phase two.

Sampling and recruitment

Participants were recruited via a confidential database of individuals who have previously consented to being approached about potential involvement in research studies. To be eligible to take part in the study, participants were required to identify themselves as a person over the age of 60 living with BD or be a relative or a friend of an older adult with BD (to offer a diverse range of perspectives), have the capacity to provide informed consent and have sufficient English language skills to read the information sheet and take part in the discussions.

We aimed to recruit approximately 6-12 participants, a combination of males and females, to take part in the focus groups, consistent with focus group methodology (19, 21, 22). We intended to recruit at least 6 people with lived experience of BD in later life and additional carers, relatives or friends to broaden the discussion. All interested individuals were invited to attend each of the 3 focus groups.

Topic guide for focus groups

A topic guide was developed with the research team (ET, SHJ, FL and RL) and designed to loosely structure the focus group and lead the discussion. See supplementary file 2 for focus group topics and content. Different topics were explored in groups 1 and 2 (see table 1) and during group 3 the researcher re-visited all 6 topics to gather more rich and detailed information and ensure that all participants taking part had the opportunity to express their ideas on each of the areas. See table 2 for who attended each group.

Focus group	Topics explored
1	1. Overview of proposed therapy 2. Living with BD in later life 3. Experience of recovery in later life
2	4. Adapting RfT for older people 5. What support people want from a therapist during therapy 6. Relationship with relatives and health professionals
3	1. ALL Topics re-visited

Table 1: Focus group topics

Procedure

The groups were conducted at a University in the North-West of England and lasted for approximately 90 minutes, consistent with focus group methodology (19). The first focus group was facilitated by two members of the research team (a service user researcher and the lead researcher). The service user researcher was not able to attend groups 2 and 3 which were facilitated by the lead researcher alone. All groups were audio recorded, and transcribed prior to analysis. All participants provided written informed consent.

ANALYSIS

The focus groups were transcribed and analysed thematically using framework analysis (23), a popular way to analyse primary qualitative data in the area of healthcare (24). This allows for both deductive and inductive coding, with concepts or themes identified as coding categories *a priori* to be combined with other themes that emerge *de novo* (24). Five topics formed the original framework; living with BD in later life, experience of recovery in later life, adapting RfT for older people, what support people want from a therapist during therapy and the relationship with relatives and health professionals

Furber (25) identified five phases of framework analysis; familiarisation, a theoretical framework, indexing, charting and synthesis. The three transcripts were read and re-read by the lead researcher (ET) to aid the process of familiarisation, before undertaking the initial coding for transcript 1. Two members of the research team (SHJ and FL) independently read and coded (indexed) transcript 1. A meeting took place within the team (ET, SHJ and FL) to discuss the transcript, why the coded sections had been interpreted as meaningful and to discuss new codes and the development of the theoretical framework. The new framework was then applied to transcripts 2 and 3. Team meetings took place to discuss any further amendments to the framework, based on the emergence of new codes. The final framework was a representative of the entire data set collected from the 3 focus groups.

Reflexivity

The researcher was aware that they (and other members of the research team) were approaching the study with a set of pre-conceived ideas about the recovery focused approach and the direction of therapy. SHJ developed the original recovery focused CBT manual for an adult BD population. SHJ and FL were involved in a recently completed a trial exploring its feasibility and acceptability (8). Subsequently ET, SHJ and FL were involved in a case series looking at the application of this approach for individuals with a more established BD diagnosis. The researcher aimed to facilitate the discussion regarding these topics in an open fashion to ensure that the participants felt able to give open and honest feedback about the approach. Similarly, when analysing and interpreting the results, the role of potential bias was highlighted to ensure that the results were a true reflection of the participants ideas, rather than the team selecting the responses which aligned with their personal view on the topic.

RESULTS

Participants

All participants were invited to attended each focus group; however, this was not achievable due to their various commitments and therefore we were flexible in response to their availability. As shown in table 2, eight participants took part across the 3 focus groups attending 1-3 groups each; 6 service users with lived experience and 1 carer and 1 friend (who also had a diagnosis of BD and identified herself as moving into later life).

Participant number	**P001**	**P002**	**P003**	**P004**	**P005**	**P006**	**P007**	**P008**
Focus group attended	1,2	1,2,3	1	1,2	1,3	1,2	2,3	2
Age	48	73	77	67	77	49	71	67
Service user/ carer/ friend	Friend	Service user	Service user	Service user	Service user	Carer	Service user	Service user

Table 2: Participant characteristics for sample

Participants with lived experience ages ranged from 67 to 77 years (M = 72), with an established diagnosis, ranging from 8 to 38 years.

Participant characteristic	N (6)
Ethnicity	
White British	6
Gender	
Male	3
Female	3
Length of Diagnosis	
Less than 10 years	1
10-15 years	1
15-20 years	1
20-30 years	2
30+ years	1
Current occupation	
Retired	5
Director of a company	1
Occupation prior to retirement	
Director of a company	1
Company secretary	1
Teacher	1
University researcher	1
Nursing	1
Past experience of psychological therapy	
Yes	4
No	2
Type of therapy	
CBT	3
Mindfulness	1

Table 3: Participant characteristic for individuals with lived experience

PRELIMINARY THEME	FINAL THEME	SUB-THEME
LIVING WITH BD IN LATER LIFE	**HEALTH AND AGE-RELATED CHANGES IN LATER LIFE**	Cognitive symptoms Behavioural changes Physical symptoms Social network changes Loneliness and isolation
LIVING WITH BD IN LATER LIFE	**EXPERIENCE OF BD IN LATER LIFE**	Change in psychological symptoms Identity Stigma Guilt and shame
LIVING WITH BD IN LATER LIFE **RELATIONSHIP WITH RELATIVES AND HEALTH PROFESSIONALS**	**MANAGING AND COPING WITH BD IN LATER LIFE**	Psychological help Self-management Medication Distraction Importance of a meaningful activity Help from health professionals Help from relative
EXPERIENCE OF RECOVERY IN LATER LIFE	**EXPERIENCE OF RECOVERY IN LATER LIFE**	Person's concept of recovery Messages from health professionals about recovery Management strategies to achieve recovery Gaining a meaningful activity to aid recovery The importance of hope

SUPPORT FROM THE THERAPIST	**SEEKING HELP IN THE FUTURE**	Building relationship with therapist Therapist transparency Important goals for therapy Building on strengths and resilience Harder to seek help Time running out to change
ADAPTING RfT FOR OLDER PEOPLE	**ADAPTING RfT FOR OLDER PEOPLE**	Session length Memory and learning techniques Enhancing the therapeutic experience Using clear and simple language Making study materials interesting and accessible Booster sessions to optimise outcomes

Table 4: Themes

Themes

There was a great deal of rich data regarding how participants described perceived changes during their later years. Once the team met to code focus group 1, using a combination of both inductive and deductive analysis, they agreed that the framework should be revised to reflect the data. The original topic "living with BD in later life" was broadened to encompass 3 themes; "health and age-related changes in later life", "experience of BD in later life", "managing and coping with BD in later life", following an inductive approach. Initial topics of interest "relationship with relatives and health professionals" became subthemes within the new theme "managing and coping with bipolar in later life". The original topic "what support people want from a therapist" became a new theme "seeking helping in the future". The original topics of interest "experience of recovery in later life" and "adapting RfT for older people" became the final themes, following a deductive approach. Please see table 4 for the preliminary and final themes. Additional example quotes can be found in supplementary file 3.

Theme 1: **Health and age-related changes in later life**

In general, the group appeared to have experienced a number of changes in later life. These included physical problems (e.g., arthritis, back problems and hearing difficulties), cognitive changes (e.g. decline in memory, concentration and increased distractibility) and behavioural changes (e.g. not playing sport or reading any longer). There was a sense of frustration and sadness about not being able to engage in activities that they had previously enjoyed. What was interesting in this context, was how they made sense of these changes in relation to their BD diagnosis. With regards to their difficulties with memory and concentration, the group had trouble identifying whether this was part of the natural process of ageing or caused by their BD.

"Now how much of this is due to I'm getting older; how much is due to bipolar?" P002, FG2

This was particularly confusing as many people noticed differences in their memory depending on what mood state they were experiencing. So generally, when they felt low, they felt their memory difficulties worsened, however when their mood was higher some participants reported their memory problems appeared to dissipate.

"I am…on the ball. I can remember anything…As soon as my mood starts to dip then I start to not. I can't remember what I did the day before" P001, FG2"

The group reported changes in their family, work and social structure, meaning they had more time on their hands, which for some led to feelings of loneliness.

"I've lost such a lot of good friends…such a lot gone…I miss some of them around me" P004, FG1

Whilst changes in family, work and social structure are commonly reported by older adults (20), for this group having a life history of BD appeared to have had an additional impact. The group found having more time to themselves and dwelling upon events that had happened in the past (often related to situations that had arisen or been exacerbated by their behaviour whilst in a mood episode), led to feelings of guilt and shame. It was interesting that these stories were relayed with regrets that still felt quite raw, with people wishing they had behaved differently and treated family members with more respect.

"Coming to terms with events that have happened and you can't understand why that happened and why you did that….and with all the embarrassment to cope with" P001, FG1.

For other individuals in the group, not having to worry about the pressures of working life was seen in a more positive light with regards to the effect on their mood.

"I don't have the stress of working life… and probably the stress makes it worse" P007, FG3

Theme 2: **Experience of BD in later life**

The group all reported a lifelong history of mood instability. In general, they felt their experience of both mania and depression had changed over the years, although patterns of change varied. What was common to all was a need to make sense of why this change was happening. Some people felt that they had fewer episodes now they were older, whereas others felt they had more but they were shorter and milder. In general, the group felt that they experienced more lows than high mood currently and some individuals felt their depressions had worsened over time compared to when they were younger. With regards to their depression, one participant stated:

"I have a knock down every day, two hours. Not heavy but I just close down" P002, FG1

In relation to mania, the majority of the group felt that their episodes were not as intense as they had been previously. The carer in the group described how their relative's mania was less physical and more cognitive than previously:

"It wasn't physical…It was more lots of disturbed thoughts" P006, FG1

The impact of living a life with a persistent mental health problem was evident within the group. Over the years they felt they had experienced stigma from society and a change in their social networks.

"And people think because you're mentally ill, in inverted commas, that you need to be treated differently" P005, FG3

Some members of the group felt they were now struggling with their sense of identity which had impacted on their confidence and self-esteem.

"I think it loses itself because you can't do the things you did… who am I now? What have I got to contribute?" P002, FG3

This struggle appeared to be linked to the combined consequences of the ageing process and the repeated episodes over the lifespan where the regrets still felt salient.

"I have to say my confidence is zilch now because of the events" P002, FG3

However not all members of the group were experiencing these problems: one individual described himself as having a very *"solid identity…with that workload"* (P007, FG3) which he

attributed to the fact that he had a voluntary job. Another lady felt she had re-established her identity by going out and mixing with people and building up a community for herself:

"I'm a member of various organisations… I've got an activity every single day and I'm mixing with people and this helps enormously" *(P005, FG3).*

Here, the length of time since diagnosis does not appear to be a factor (P007 had a fairly recent time since diagnosis of 8 years and P005 received her diagnosis 26 years ago). Instead, having a role, a sense of purpose and belonging appears paramount to maintaining and enhancing a person's self-worth and resilience in later life.

Theme 3: **Managing or coping with BD in later life**

The group had used a range of strategies over the years to manage their BD, including medication, psychological therapies, and self-management strategies. All of the group (apart from the relative) reported that they were taking medication and in general felt it had helped to stabilise their episodes of BD. However, there were concerns about the effects of taking medication on their memory and concentration, which seemed to be intensifying as people were taking the medication over longer and longer periods of time.

Two members of the group had experience of their psychiatrist reducing their medication as they got older. They both felt that they had been over-medicated prior to the reduction.

"They saw I was a zombie and I didn't think I was capable of anything" (P005, FG1)

They both felt positive about the care that they had received from their psychiatrist in relation to the medication reduction.

The group acknowledged a change in approach over recent years with regards to psychological therapy and the majority of the group had some experience of psychological therapies (see table 1). A few members wondered about what other older friends with BD might think if offered a psychological approach.

"I'm not sure he would find that… a bit weird. A bit like whacky. Because he's nearly sixty, he's never been offered anything…." P001, FG1

Some members of the group felt they had learnt to manage their BD more effectively as they became older. Over the years, they felt they had learnt strategies to self-manage the condition through their own experience of living with BD and reading available information. They felt they

were able to stabilise themselves more quickly in response to mood fluctuations, reporting conscious lifestyle changes including looking for triggers.

"I read up on it and I learnt all my trigger points; I now identify the illness whereas before I just thought it was the way my life was going" P005, FG1

One participant attributed this change in self-management to her CPN. The enhanced sense of responsibility to manage her own condition appeared a key factor in building the therapeutic relationship. This appeared to be significantly different to the care she had received in the past.

"Having a really good CPN who has given me responsibility, and believes in me, has really helped" (P005, FG3).

However, another participant felt that they were still engaged in a struggle with professionals which had persisted over the years. There was a sense of disappointment and frustration regarding the ongoing battle with professionals and an awareness that stigma related to living a life with BD may still be evident within some services.

"We're still fighting professionals who don't believe that we are capable of what we truly are" P005, FG1

The group used distraction as a way of coping on a more day to day basis, reporting activities such as gardening or voluntary jobs as a way of keeping the mind occupied and not focusing on past events. However, one group member acknowledged how distraction only worked as a strategy in the short-term.

"If you're doing something that doesn't require a lot of concentration, these things come back to the mind" P002, FG1

There appeared to be a mixture of experiences in relation to the help that individuals had received from relatives and friends to cope with their BD over the years. Maintaining a strong and supportive network of people around the person with BD was highlighted as an important coping factor by a number of group members, particularly as the person reaches their later years as roles change (e.g., retirement, family structure changes) and loneliness can become apparent.

Participants were able to identify times where they had found input from a relative/ friend helpful:

"if I went on a low my partner, my mate, my working partner knew the symptoms and he'd tell me, you know … you've got to be careful…" P004, FG1

However, one participant felt that her episodes were triggered by her husband's behaviour and now he was no longer in the home, her mood was stable and she in a stronger position to cope with her BD episodes.

"I no longer have that trigger so I am stable" P005, FG3

Theme 4: **Experience of recovery in later life**

The concept of recovery in later life was introduced using the quote from the Scottish Recovery Network (see supplementary file 1). There appeared to be a division in the group with regards to their concept of 'recovery' in later life and their ability to recover with BD. Some participants questioned if the word recovery felt too final and a word like 'stability' may be more appropriate. These individuals were aligned with the traditional 'clinical' view of recovery and felt that being 'recovered' meant not experiencing any symptoms of BD in the future.

"Recovery means you're recovered…. You're cured and bipolar can't be cured…" P001, FG1

Recovering with BD felt like an unachievable aim:

"Something that I look for beyond the horizon" P002, FG1

In this sense, these participants questioned their ability to 'recover' in later life and to what degree they could move on and change. There appeared to be a link between their perception and messages they had received in the past about recovery.

"I've been told that you can never recover from bipolar" P002, FG1

However other members of the group felt they were 'recovered' or were in the process of recovering. One individual described how recovery for the mental health team was the person not going back into hospital, whereas for them it was getting back to work or engaging in a meaningful activity. Therefore, he was able to differentiate between the messages from professionals regarding 'clinical recovery' and their own personal recovery journey.

Participants who identified with the more personal concept of recovery reported a range of strategies to support their recovery journey; setting a goal and engaging in a meaningful activity felt important, alongside the use of medication and self-management strategies. They acknowledged how important hope was as part of their recovery journey.

"You need hope" (P004, FG1)

In general, there was this strong sense of wanting to contribute to society and look for new opportunities following their lifetime of repeated episodes and transition into later life.

"It's about setting out the right goals as well…isn't it?" (P004, FG1)

Despite having to deal with the combined societal stigma of BD, and becoming older, some people could clearly identify benefits from these simultaneous circumstances. There was a sense that they had really 'survived' the struggle with living a life with bipolar and could use this wealth of experience and knowledge to help their younger counterparts.

"Our experiences in life have given us knowledge that we can help other people much better…we know what works and what doesn't" (P005, FG1)

Others found it harder to see these benefits, and seemed to have their own stigma regarding becoming older and the limitations this puts on opportunities for personal growth and development:

"I'm not sure at my age just to what degree I can move on" (P002, FG1).

Theme 5: **Seeking help in the future**

Nearly all the members of the group had experience of psychological therapies in the past (see table 1). They were positive about the development of a tailored intervention specifically for their age group and they had some very clear ideas about the sort of relationship they would like with a potential therapist.

"They need to have listening skills. They need to be adapting body language and tone of voice and pitch of voice. They need to be empathic…they need to be aware of the sort of problems we face…be able to get our trust" P005, FG3

They wanted to be treated with dignity and respect, but there was an additional need in this group for there to be a shared understanding of the wealth of experience the older person with BD was bringing to the therapeutic relationship.

They wanted transparency when it came to acknowledging any differences between the therapist and the client with regards to age, gender, ethnicity and the therapist's lack of BD diagnosis. They felt it was very important for the therapist to spend time building a relationship, allowing time at the beginning and the end of the session to really get to know the person and their living history. It was felt more time might be needed for this as their histories were often longer and more complex as a result of their age.

"It's about having that personal relationship…It takes two to three sessions to get the confidence" P004, FG2

The group wanted the therapist to work on issues such as assertiveness, confidence building and improving competence, maintaining an encouraging stance throughout. This seemed to be driven by a need for the therapeutic process to help challenge some of the stigmatising views of older adults in our society:

"We need loads of encouragement and appreciation that we are valued members of society" P005, FG1

In relation to seeking help, participants reflected on their own experiences and wondered if they would only engage in therapy when they were in an episode, perhaps influenced by negative experiences of care in the past. The carer in the group felt their relative found it harder to seek help now she was older because the repeated episodes over time (and limited life-span) had led to a greater sense of hopelessness.

Theme 6: **Adapting RfT for older people**

With regards to the specific recovery-focused intervention, the group appeared positive in general about the development of the specific therapy. They felt that the optimum session time was 50 minutes to an hour. They felt that it was necessary to make some adaptations to the therapy, based upon their experiences of living with BD in later life and the changes they had experienced. With regards to memory difficulties, they felt using strategies such as repetition and association would be helpful and writing summaries at the end of each session and revisiting these at the beginning of the next session.

"When you get older, you know, with sight problems and hearing problems you just need more resources… things written down… sort of more back up" P008, FG2

They suggested using images, film or audio recordings as a way of enhancing a person's therapeutic experience.

The group emphasised the importance of using clear and simple language and making study materials accessible and visually interesting.

"Some large sort of text…if it's complicated, it could be simplified" P006, FG2

The group were mixed in their opinion of how many sessions, some suggesting 6-8 sessions would be optimal and others thought up to a year was needed. The group suggested that

booster sessions would be helpful at the end of therapy to re-visit strategies and enhance outcomes.

"If you've learnt some practical strategies…especially with CBT…then you've had some time to practice on your own" P008, FG2

DISCUSSION

The aim of this study was to better understand the experience of living with BD, the concept of recovery and to explore whether any adaptations were needed to the existing therapy RfT manual. The findings suggest that the group were experiencing similar health and age-related changes compared to other older people living with BD, such as changes in cognition (26) and an increase in physical health conditions (27, 28). The group also appeared to be experiencing the same issues as older people with other mental health issues such as losses, loneliness and isolation (29). However, the consequence of having more time on their hands in later life (due to a reduction in social networks and loss of roles (e.g. work) presented a specific challenge to this group of people. Time alone offered the opportunity to ruminate on negative events that had happened in the past which appear to be more salient in this group of people due to the nature of BD, raising issues such as guilt and shame. Interestingly, some participants felt a sense of stigma from mental health professionals and society in general which appeared to be enhanced by simultaneous condition of living with BD into older adulthood.

In general, the group reported an increase in lower mood which is consistent with previous research indicating older adults with BD present more predominantly with depressive symptoms (12, 13) and milder episodes of mania, consistent with previous research (14). Laidlaw, Kishita and Chellingsworth (30) highlight that depression is not an automatic outcome of old age or an inevitable response to challenges of ageing. Therefore, developing an understanding for the predominance of depressive symptoms for older people with BD is important.

There were differences in the group's concept of recovery and whether the term was useful to describe their experience of living and coping with BD over the life-span, based on whether they saw this as a clinical or personal concept. A study exploring the concept of recovery in older people versus younger people with mental health problems found that the older generation were not aiming towards a new or revised sense of identity (31). However, those who identified themselves as managing their difficulties competently felt they had sustained or recovered their sense of self. Findings from the current study support this as individuals who held positive views

about their recovery journey and were engaging in meaningful activities, were the ones who felt their self- identity and confidence was now intact.

Whilst the group appeared positive about the development of an intervention for this population, one member questioned how other older people may perceive it. Research has found that older adults with depression do hold positive opinions about psychological therapy and if offered a choice would prefer them over psychotropic medication (however they may be less likely to be offered or receive this; 32)

Considerations for clinical practice

The themes generated from the focus groups have led to a number of important recommendations for clinicians when delivering recovery focused therapy for older people with BD. There were consistencies with younger individuals' priorities for recovery, where hope has been highlighted as a key part of the recovery process (33). The group had clear ideas about what they would like from a therapist and wanted to work on areas of personal growth such as building assertiveness, confidence and competence. These targets identified with older people align with findings from Jones et al's (15) RfT trial with a younger cohort where improvements in personal recovery were associated with improvements in personal growth and self-esteem (34). The group identified a number of adaptions they thought would be helpful for RfT for older people, based upon their experience of living with BD in later life. These were consistent with guidelines developed for working with an older adult client group (30). There was a strong sense of the need to be valued and respected for their 'survival' of BD and the challenges which have presented throughout their lifespan. Knight and Laidlaw (35) identify 'wisdom' as a useful frame of reference when identifying and developing goals for working with older depressed people. Therefore, building upon a person's 'wisdom' and life skills learnt in the face of adversity feels like an important part of the therapeutic process with this client group.

This is the first study to involve older people with BD to shape and develop an intervention for their cohort, enhancing the quality, value and relevance of the recommendations. The recommendations have been used in the second phase of the programme of work which has evaluated RfT for older people in a randomised controlled trial (16). They also provide a helpful framework for clinicians working with older people with BD in wider clinical practice, based upon the service user's priorities. The recommendations are summarised in table 5 and map onto the 6 themes identified in the results section.

CONSIDERATIONS FOR DELIVERING RfT for older people
Recovery stance • Explore the person's concept of recovery (traditional versus personal recovery). (4) • Identify whether the word feels acceptable to use or find another to describe. (4) • Identify and build upon any pre-existing strategies which have helped the person progress on their recovery journey. (4) • Use 'hope' as a key message for helping a person progress towards their recovery goals. (4) **Symptom management** • Identify specific health and age-related changes which may be impacting upon a person's current presentation. (1) • Explore whether there has been a change in symptoms over time (e.g. more depressive state now) and how they have coped with this. (2) • Be aware that the consequence of repeated episodes over time (and limited life-span) may have led to a greater sense of hopelessness for change. (2) • Allow time to explore issues such a guilt and shame in later life and the impact upon mood episodes now. (2) • Explore the person's experience of receiving care from both relatives and health professionals and how this has affected their attitudes towards new opportunities for support. (3) **Specific adaptations** • Session length from 50 minutes to an hour. (6) • To enhance memory and learning; use strategies such as repetition and association and write summaries at the end of each session (revisiting these at the beginning of the next session). (6) • Use images, film or audio recordings as a way of enhancing a person's therapeutic experience. (6) • Use clear and simple language and making study materials accessible and visually interesting. (6) • Consider the use of booster sessions at the end of therapy to re-visit strategies and enhance outcomes. (6) **Therapist values** • Spend time building a relationship, exploring a longer and potentially more complex history, allowing time at the beginning and the end of the session. (5) • Treat the older person with dignity and respect, develop a shared understanding of the wealth of experience the person with BD brings to the therapeutic relationship (challenging any perceived stigma the person may identify with related to living with BD as an older person). (5) • Provide transparency and acknowledge any differences between the therapist and the client with regards to age, gender, ethnicity and the therapist's lack of BD diagnosis. (5) **Therapist focus** • Nurture pre-existing strengths and acknowledge the resilience already present of living a life with a long condition term. (5) • Work on building assertiveness, confidence and competence to manage bipolar related experiences, maintaining an encouraging stance throughout. (5)

Table 5: Considerations for delivering RfT for older people

*1= Health and age-related changes, 2= experience of BD in later life, 3 = managing and coping with BD in later life, 4 = experience of recovery in later life, 5 = seeking help in the future, 6 = adapting RfT for older people).

Strengths and Limitations

The service user researcher co-facilitated the first group with the aim of facilitating open and honest discussions. They were able to identify with a lot of the issues raised by the group and their presence in the first group may have had some impact on some of the discussions.

When drawing any conclusions from the data it is evident that there are a number of methodological limitations which must be addressed. The individuals with lived experience taking part in the group are not representative of all older people with BD. They were a small, self-diagnosed group of people from the north-west of England who had an active interest in taking part in the study. They were all White British and all had (or had retired from) a professional working background.

Finally, the study employed a careful analysis to explore patterns in the individual's accounts of experience. However, all studies that are based upon self-report are constrained by the context and also subject to recall bias.

CONCLUSIONS

The study aimed to explore a number of topics relevant to living with BD in later life and use this information to enhance the pre-existing recovery focused therapy for older adults. In general, the group were positive about the development of a therapeutic approach for this specific cohort. They were able to give insight into the realities of living with BD across the life-span. The group highlighted a number of challenges that they had faced; however, nurturing the resilience and wisdom developed as a product of coping with adverse circumstances appears to be a key part of what they want from the therapeutic process.

Word count: 5479

DECLARATIONS

Ethics approval and consent to participate

The study was approved by the UK National Health Service (NHS) Ethics Committee process (REC ref: 15/NW/0330). All participants were asked to provide written consent prior to the focus groups.

Consent for publication

An unsigned copy of the consent form is available on request. All participants signed the consent form which provided consent to participate in the study and for their anonymised data, including quotations to be used for publication.

Availability of data and materials

The focus group(s) content and topics are available as a supplementary file 1. There are also additional quotes in supplementary file 2. The transcripts cannot be published or made available if requested to protect the anonymity of the participants who took part in the focus groups.

Competing interests

None declared.

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Author contributions

All authors contributed to development and preparation of the study design and topic guide. ET and RL conducted the focus groups. ET led the analysis, with contributions from FL and SJ.

ET wrote the draft of the manuscript, which was proofed, edited and approved by FL, SJ and RL.

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CHAPTER FIVE

A feasibility randomised controlled trial of Recovery focused Cognitive Behavioural Therapy for Older Adults with bipolar disorder (RfCBT-OA): Study protocol

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A feasibility randomised controlled trial of Recovery focused Cognitive Behavioural Therapy for Older Adults with bipolar disorder (RfCBT-OA): Study protocol

Elizabeth Tyler, Fiona Lobban, Chris Sutton, Colin Depp, Sheri Johnson, Ken Laidlaw, Steven H Jones

Corresponding author: Elizabeth Tyler

The Spectrum Centre for Mental Health Research

Division of Health Research

Lancaster University

Lancaster, LA1 4YW.

Email: e.tyler@lancaster.ac.uk

Phone: 01524 593171

Fiona Lobban: The Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, LA1 4YW.

Chris Sutton: Lancashire Clinical Trials Unit, College of Health and Wellbeing, Brook Building, Room 413, University of Central Lancashire, Preston, PR1 2HE.

Colin Depp: Department of Psychiatry, School of Medicine of the University of California, San Diego (UCSD), 9500 Gilman Drive, La Jolla, MC: CA 92037-0603C.

Sheri Johnson: Department of Psychology, University of California, Berkeley, 3417 Tolman Hall, Berkeley, CA 94720-1650.

Kenneth Laidlaw: Norwich Medical School, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, NR4 7TJ.

Steven H Jones: The Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, LA1 4YW.

Key words: Bipolar disorder, ageing, randomised controlled trial, CBT, recovery

Word count: 5706

ABSTRACT

Introduction: Bipolar Disorder is a severe and chronic mental health problem that persists into older adulthood. The number of people living with this condition is set to rise as the UK experiences a rapid ageing of its population. To date there has been very little research or service development with respect to psychological therapies for this group of people.

Methods and analysis: A parallel two-arm randomised controlled trial (RCT) comparing a 14 session, six month recovery focused cognitive-behavioural therapy for older adults with bipolar disorder (RfCBT-OA) plus treatment as usual (TAU) versus TAU alone. Participants will be recruited in the North-West of England via primary and secondary mental health services and through self-referral. The primary objective of the study is to evaluate the feasibility and acceptability of RfCBT-OA, therefore a formal power calculation is not appropriate. It has been estimated that randomising 25 participants per group will be sufficient to be able to reliably determine the primary feasibility outcomes (e.g. recruitment and retention rates), in line with recommendations for sample sizes for feasibility/pilot trials. Participants in both arms will complete assessments at baseline and then every three months, over the 12 month follow-up period. We will gain an estimate of the likely effect size of RfCBT-OA on a range of clinical outcomes and estimate parameters needed to determine the appropriate sample size for a definitive, larger trial to evaluate the effectiveness and cost-effectiveness of RfCBT-OA. Data analysis is discussed further in the analysis section in the main paper.

Ethics and dissemination: This protocol was approved by the UK NHS Ethics Committee process (REC ref: 15/NW/0330). The findings of the trial will be disseminated through peer-reviewed journals, national and international conference presentations and local, participating NHS trusts.

Trial Registration: ISRCTN registry: ISRCTN13875321.

STRENGTHS AND LIMITATIONS

STRENGTHS

- First RCT to develop and test out a psychological intervention for older adults with bipolar disorder
- Development of a psychological intervention for a group of people who currently have no evidence-based care.
- RFCBT-OA has been developed in collaboration partnership with individuals with lived experience of bipolar disorder
- RfCBT-OA has the potential to improve outcomes for service users. This would save the NHS money through a reduction in use of mental health services.

LIMITATIONS

- No active treatment control arm

BACKGROUND

The UK population is ageing and this pattern is expected to continue into the next few decades (1). Current estimates suggest that approximately 10 million people in the UK are over 65 years old. The latest projections indicate that there will be 5½ million more older adults in the UK in 20 years' time and this number will have nearly doubled to 19 million by 2050 (2). Consequently, the number of older people living with chronic mental health problems is also set to rise substantially, including those with bipolar disorder (BD: 3).

There is limited research available on the presentation, course and treatment of BD in later life. Reasons cited for this lack of information include the increased mortality of younger individuals with BD, sampling biases in the research studies that are available, changes in the diagnostic criteria over time and differences in research settings where individuals are studied (4).

Available data indicates that rather than early theory suggestions that BD 'burns out' (5), the majority of individuals that experience early onset BD will follow a chronic and relapsing course into older adulthood (6). Older adults with BD may face additional challenges such as cognitive impairments (7) and a decline in health-related quality of life (8, 9). BD in later life is also associated with a high risk of suicide (10) and significant service costs. Bartels et al (11) reports that older adults with BD utilise almost four times the total use of mental health services and are four times more likely to be hospitalised than older people with unipolar depression.

Despite this evidence of the importance of BD in older adults there has been very little research or service development for this group particularly with respect to psychological therapies (12). The National Institute for Health and Care Guidance (NICE) bipolar disorder guideline (13) recommends that older adults should be offered the same treatment as younger people. However, there are no published studies evaluating psychosocial interventions for older adults with BD (14) and a number of reviews have highlighted the relative paucity of knowledge concerning our knowledge in this area (4, 15, 16).

Although research into psychological therapies for older adults with BD is lacking, there is evidence for the effectiveness of such interventions in adults of working age (3, 17, 18). Although recovery informed-interventions are now recommended by the UK government (19, 20) much of the available research to date has focussed on CBT and psycho-educational approaches designed to reduce relapse risk but with little explicit focus on functional outcomes including personal recovery. There is no single definition of 'recovery' in mental health. However, it is

based on the principle that it is possible for an individual to have a meaningful life, whilst living with a serious mental health problem. Unlike recovery from a physical illness, in mental health the person may aim for recovery, whilst still experiencing some of the symptoms of their problem. There is an emphasis on having a set of goals which may focus on re-establishing other areas in a person's life such as their work, relationships or social life.

A recent RCT study has shown that a recovery focused CBT intervention (RfCBT) for individuals with BD (below 65 years) is beneficial in terms of both functional and symptomatic outcomes (21). The present trial builds upon this work and has adapted RfCBT so that it specifically meets the needs of an older adult population (RfCBT-OA). Details of how these adaptations were achieved can be found in the intervention section.

We therefore intend to perform a randomised controlled trial to evaluate the effectiveness and cost-effectiveness of RfCBT-OA plus treatment as usual (TAU) compared with TAU. However, there are a number of uncertainties that we need to address prior to initiating that trial. Therefore, in this feasibility study, we plan to evaluate the feasibility and acceptability of the RfCBT-OA intervention and whether a full RCT is feasible. We will evaluate recruitment into the study (both self-referral and clinician referral), consent to participate and participant attrition rates (overall and each study arm separately) during assessment, intervention and follow-up periods and completion of outcome measures. We will also be measuring adherence to the intervention (number of therapy sessions attended, therapy drop out and feedback from qualitative interviews at the end of therapy). This will allow us to evaluate the acceptability of the intervention to the individuals taking part in the study. The trial will also provide initial data on the potential impact of the intervention (compared to current routine care) on a number of clinical outcomes and help to identify the most appropriate primary outcome (e.g. perceived recovery, time to relapse and mood symptoms) for a definitive clinical randomised controlled trial in the future.

METHOD

This protocol is guided by the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) 2013 Guidelines (22). The study was reviewed and approved by the UK NHS Ethics Committee process (REC ref: 15/NW/0330) and the study is registered with the ISRCTN registry: ISRCTN13875321. A model consent form is provided in Appendix 1.

Objectives

To determine the feasibility and acceptability of a recovery focused CBT intervention for older adults with bipolar disorder compared to treatment as usual.

The objectives of the study are to:

1. Investigate:
    a. whether clinicians working with older adults will refer participants into a randomised controlled trial;
    b. whether older adults will self-refer into a randomised controlled trial;
    c. whether older adults with BD will consent to participate in a randomised controlled trial of a psychological intervention;
    d. participant attrition rates (overall and each study arm separately) during assessment, intervention and follow-up periods

2. Determine the acceptability of the recovery focused intervention in terms of
    a. whether individuals adhere to and engage with the intervention;
    b. participants' experiences of the intervention

3. Identify the most appropriate primary outcome measure (e.g. recovery, time to relapse, quality of life) for a future trial

4. Estimate parameters needed to determine the appropriate sample size for a future trial to evaluate the effectiveness and cost-effectiveness of RfCBT-OA

Trial Design

A parallel two-arm randomised controlled trial (RCT) comparing a 14 session, six month RfCBT-OA intervention alongside treatment as usual (TAU) versus TAU alone. Participants in both arms of the study will complete assessments which will include a range of important clinical outcomes (e.g. recovery, time to relapse, quality of life) at baseline and then three monthly over the 12 month follow-up period. See Figure 1. Rater-blindness will be achieved by having an independent researcher from the Spectrum Centre team as ET will deliver the intervention.

A trial steering committee (TSC) will be formed at the beginning of the trial. It will consist of an independent chair, independent clinician (s), an independent statistician, a service user representative and the researcher. They will meet face to face on 4 occasions over the duration of the trial. The TSC will concentrate on progress of the trial, adherence to the protocol, and importantly the rights, safety and well-being of the trial participants. TSC will review any adverse events should these occur and will advise on adaptation or termination of the intervention should this be required.

Sample

Sample size

A formal power calculation is not appropriate as the primary purpose of the study is to evaluate the feasibility and acceptability of delivering the proposed intervention. It has been estimated that randomising 25 participants per group will be sufficient to be able to reliably determine the primary feasibility outcomes. The recruitment target has been set at 50 participants in line with recommendations for sample sizes for feasibility/pilot trials (e.g. 23) and to allow for expected attrition rates (see table 1). This number will also allow us to evaluate the other objectives of the trial; to assess the impact of the intervention on each of the outcome measures to estimate parameter necessary to design a main trial and will enable estimation of recruitment and retention parameters with sufficient precision. For example, recruiting 50 participants will enable estimation of the percentage attrition to within +/-10% if attrition is 15% or less and, if the consent rate is 80%, approaching 63 participants and recruiting 50 will enable estimation of the consent rate to within +/-10%.

Inclusion/ exclusion criteria

1) A diagnosis of BD (I or II) according to the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders (SCID; 24) IV research criteria
2) Not in a current episode of mania, hypomania, depression or mixed episode in the last month
3) Aged 65 or above
4) Sufficient English language skills to comprehend the assessments and intervention content

Exclusion criteria:

1) Receiving concurrent psychological therapy
2) A score of less than 22 on the Montreal Cognitive Assessment (25)

Recruitment

Referrals will be sought from participating NHS Trusts in the North West, UK, with support from the National Institute of Mental Health (NIHR) Clinical Research Network. This is a publicly funded national workforce that supports the recruitment of participants to nationally funded research studies. The lead researcher will contact managers in older adult community mental health teams, out-patient clinics, GP surgeries and primary care mental health teams. They will request to attend any planned team meetings and send the participant information sheet and referral information for distribution within the team. The researcher will follow-up any visits with a phone call and ask the health professional (e.g. psychiatrist, GP, care coordinators) to complete the referral information sheet and send it via email or post to the research team. All referrals received will be recorded on a confidential database and participants will then be approached to book a screening interview. The researcher will also visit service user groups (such as Bipolar UK, MIND and Rethink) in the local area. The researcher will take the study self-referral form and ask any interested participants to either complete the form in the group or send it back to the research team by post or email. Any self-referrals received will be recorded on a confidential database. The study will also be advertised through a well-established, confidential volunteering database at the Spectrum centre which has contact details for over 500 individuals that have either lived experience or an interest in BD as well as through social media such as Facebook and Twitter and in the media. Posters and leaflets will be distributed in both NHS and non NHS sites to maximise participant access.

Screening, Baseline and Randomisation

Once participants have expressed an interest in participating they will be contacted by a member of the research team to complete a brief screening interview. The screening interview will be conducted over the telephone and will consist of questions targeting inclusion and exclusion criteria. The Mood Disorder Questionnaire (26) will also be administered. This is a brief

self-report screening instrument that identifies individuals likely to have bipolar disorder. At this stage all participants will be asked to provide consent for the researcher to contact a nominated health care professional to obtain risk related information (e.g. GP, care coordinator). Individuals who meet the both the eligibility criteria and screen likely on the MDQ (26) will then be booked in for an initial assessment.

Assessments will take place at the Spectrum Centre or the participants home, according to preference. If required, private space for appointments may also be negotiated at willing primary, secondary and/ or voluntary organisations. At the initial visit, the study will be described to potential participants in full. The voluntary nature of participation will be emphasised, including the right to withdraw at any time.

Information collected during the initial assessment will be used to confirm eligibility. Once informed consent is obtained, the baseline assessment will be conducted by the researcher. The Montreal Cognitive Assessment (25) will be used as the first screening tool for eligibility as it is the least time consuming. The MoCA (25) assesses for cognitive impairment via multiple cognitive domains including attention, concentration, executive functions, memory, language, visuospatial skills, abstraction, calculation and orientation. If the participant scores 22 or above on the MoCA (25) then the SCID (24) interview will be carried out to confirm a diagnosis of BD. This will also identify whether they have had an episode in the past month, to provide demographic information and assess the number of previous episodes. Individuals who score below 22 on the MoCA (25) or do not meet the research criteria for BD or will be thanked for their time and informed that they do not meet the research criteria required to participate. They will be offered the option of joining Spectrum Connect (our participant panel) so that they can find out about future research/ activities that may be of greater relevance. If the participant meets criteria and wishes to take part, they will complete the baseline clinical outcome measures that are detailed below.

After baseline, the participant will be randomly allocated to either RfCBT-OA or TAU using an independent web-based computer generated randomised procedure called sealed envelope (‘http://www.sealedenvelope.com/) to aid allocation concealment. The randomisation process will be set up by Lancashire Clincial Trials Unit (CTU). After randomisation, the researcher will contact the nominated health care professional to inform them that the participant is taking part in the study. Intentional unblinding will only be allowed if necessary for patient safety, any unintentional unblinding will be recorded (including reason) and subsequent assessments

conducted by another blind researcher. Data entry procedures and storage will be overseen by the CTU. All personal information will be securely stored in line with NHS ethical approval.

The recovery focused CBT intervention

The original RfCBT manual was developed from key components of effective CBT interventions which include mood monitoring and awareness, regularisation of routines, enhancing prodromal coping and problem-solving training (27-31) and refined by qualitative research to capture experiences of recovery in bipolar disorder and through service user focus groups to ensure that the content, focus and delivery of the intervention was in tune with service user recovery priorities. The intervention places emphasis on maintaining a very flexible engagement approach with respect to initial rapport building and consideration of timing, duration and frequency of sessions. It is focused on helping individuals work towards goals that are of personal value to them, whether symptom related or about other areas of their lives such as work or social support. Initially the client and therapist develop a shared understanding of recovery and how working towards the recovery goals may have a significant impact on the individual's life. The intervention includes a significant formulation component, ensuring that any therapeutic approaches are consistent with the client's current needs.

Recovery focused therapy (32) has the following phases:

1) Introducing the recovery approach to clients
2) Collection of information about current and historical mood and functioning
3) Meaning and relevance of diagnosis
4) Identification of recovery informed therapy goals
5) Initial formulation of relationships between mood experiences and progress towards recovery goals
6) Identification and application of CBT techniques to address and facilitate positive coping
7) Consideration of wider functioning issues in relation to recovery
8) Development and completion of EWS plan
9) Development and completion of recovery plan
10) Sharing lessons from therapy with key stakeholders.

Although it is likely that most clients will engage with most of these elements the relative emphasis will depend on the individual goals and formulation of the particular client. An additional chapter has been developed for the manual so that it specifically meets the needs of an older adult population. This has been achieved by a review of current evidence for adapting psychological interventions for older adults with mental health problems. There has also been extensive consultation (focus groups and one-to one) with service users with lived experience of BD in later life, their relatives and experts in the field.

Data from the focus group has identified that individuals living with bipolar disorder in later life still experience episodes, however to varying degrees. Some find their episodes are more manageable and the symptoms are less intense, some feel that they are worse than when they were younger and are harder to control. Individuals taking part in the focus group felt that therapy in later life should focus on psycho-education, symptom management and also to consider wider areas of functioning such as achieving meaningful activity. This fits with the flexible, idiosyncratic approach that the recovery focused therapy offers. The older adults identified additional difficulties in later life such as physical health problems, memory difficulties key themes such as loneliness, losses and changes in role. These correspond with the current literature on adapting psychological therapies for older adults (e.g. 33, 34).

Therefore, key areas for adaptation in the new chapter focus on memory and learning, physical health difficulties and sensory impairments. A number of age-related themes such as cohort beliefs, role investments, intergenerational linkages and the socio-cultural context (34) are also discussed as potential areas of adaptation.

Outcomes

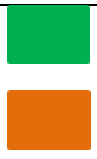
Feasibility and acceptability data

To address the primary objective and allow the evaluation of the feasibility and acceptability of delivering the recovery focused CBT intervention to older adults with BD a number of outcomes will be assessed. Setting benchmarks for feasibility data will be beneficial to inform a larger scale assessment of this intervention in the future (35).

Detailed information will be collected which will include the number of referrals received per month, the source of recruitment (health professional vs self-referrals), number of participants contacted, assessed for eligibility and consented into the trial. Reasons for non-eligibility or withdrawal of interest will be documented, where given. Retention of participants in both arms of the trial will be assessed during assessment, intervention and follow-up periods and the completion of outcome measures. Feasibility outcomes will be measured using detailed thresholds and a traffic light system described in table 1 below.

To determine the acceptability of the intervention, quantitative data (e.g. number of sessions attended and drop outs) will be combined with data from a set of qualitative interviews. These will be conducted to explore individuals' experiences of receiving RfCBT-OA intervention in more detail. A sample (approximately n=10-15) will take part in a topic-guided qualitative interview. The sample will be selected purposively across key characteristics (e.g. age, gender, attendance rates) to create a diverse sample of people which will include people who completed the intervention and also people who dropped out. It was felt that this number will provide sufficient data to provide additional information for the feasibility outcomes and the acceptability of the intervention. The interviews will also identify issues and strategies necessary to inform the design of a larger trial in the future.

The qualitative data, plus the feasibility trial data will help to allow us to achieve the other objectives of the study which are to identify the most appropriate primary outcome measure and to estimate parameters needed to determine the appropriate sample size for a future trial. Further details can be found in the analysis section.

Objective	**Measurement process**		**Feasibility outcome**
To estimate the recruitment rate	The recruitment rate is set at a number that is based on the maximum number of participants that the therapist can see per month. However the number of eligible participants recruited by self-referral and from each of the sites will be recorded on a monthly basis. This will inform the recruitment plan for a larger trial.		Feasibility will be shown where at least 3-4 participants are recruited per month (approximately 50 participants) over the 15 month recruitment window. If at least 2 participants are recruited per month (approximately 30 participants) or 4-5 participants are recruited in the last 6 months of the trial (if recruitment problems are overcome) then a future trial will be feasible but additional strategies will be identified to achieve target recruitment If less than an average of 2 participants are recruited per month (<25) over the recruitment period feasibility will not be demonstrated
To identify consent rate and reasons for non-recruitment	Number of referred participants that are eligible that choose not to consent into the trial will be recorded and reasons for		Feasibility will be shown if at least 80% of participants referred (self or clinician) consent into the trial If at least 60% of participants referred (self or clinician) consent into the trial then a future trial will be feasible if strategies to overcome

	refusal will be documented where offered		identified barriers are identified (including whether more individuals are consenting who self-refer or clinician refer). If less than 60% of participants referred do not consent into the trial then feasibility will not be demonstrated
To estimate the proportion of participants lost to follow-up and the reasons for loss to follow-up	The loss of participants during the follow-up period will be recorded, plus reasons for loss (if given)		Feasibility will be demonstrated if at least 70% of participants are retained at the 48 week follow-up If at least 50% or more participants are retained to follow-up at 48 weeks then a future trial will be feasible if strategies to overcome identified barriers are identified If less than 50% of participants referred do not consent into the trial then feasibility will not be demonstrated
To estimate the number of therapy sessions attended	The number of therapy sessions attended out of the 14 offered will be recorded		Feasibility will be demonstrated if all of the participants attend 6 or more sessions of the 14 offered If at least 75% of participants attend 6 or more sessions of the 14 offered a future trial will be feasible if strategies to overcome barriers are identified. If less than 75% of participants do not take up 6 or more of the therapy sessions offered then feasibility will not be demonstrated
To estimate the number of participants who drop out of therapy	The number of participants who drop out of the therapy sessions will be recorded		If at least 65% of the participants in the intervention arm complete therapy then feasibility will be demonstrated If 50% of participant in the intervention arm complete therapy then a future trial will be feasible if strategies to overcome dropout are identified. If less than 50% of participants in the intervention arm drop out of therapy then feasibility will not be demonstrated.
To assess the feasibility of delivering Rf-CBT-OA in a way that is acceptable to people with BD in later life	Interviews with 10-15 participants that have taken part in the intervention arm of the study to seek their views on the therapy		Feasibility will be demonstrated in the majority of participants indicate that the intervention is acceptable

* Based on the percentage of drop out of older adults (33% to 37%) in comparable studies investigating psychotherapeutic treatment for depression in later life (36-39) psychotherapeutic treatment trials.

- **Red** – Stop – main study not feasible
- **Amber** – Continue but modify protocol – feasible with modifications
- **Green** – Continue without modifications – feasible as is

Table 1: Feasibility outcomes thresholds

Clinical outcome data

The SCID (24) and MoCA (25) will be completed at baseline to confirm the participants' bipolar diagnosis. The follow-up period will be 12 months from initial randomisation. There will be regular three month assessments to evaluate bipolar relapse, bipolar symptoms and functioning

over the telephone. In addition to this an assessment of recovery, mood symptoms and quality of life will be completed at baseline, end of therapy and follow-up (6 months and 12 months). These self-report measures will be completed either by post or online (participant preference). See table 2 for assessment measure schedule.

Interviewer-rated measures

The Structured Clinical Interview for Diagnosis: Research Version (40) provides longitudinal information on DSM-IV episodes (major depression, mania, hypomania or mixed affective episode). It includes items from the SCID as well as the Hamilton Depression Rating Scale (HDRS; 41) and Mania Rating Scale (MRS; 42). The SCID-Life will be delivered every 3 months over the telephone following baseline to generate weekly scores of mania and depression on a 1-6 severity scale. Scores of 5/6 indicate presence of symptoms and impact on functioning that corresponds to symptom criteria for major mood episode as defined by the DSM-IV. Weekly scores will be used to examine the number of weeks out of episode (a score of 4 or less on SCID LIFE), number of weeks without impairment (a score of 2 or less on SCID LIFE) and time to first episode of depression and mania.

Personal & Social Performance Scale (43) The PSP is an interview schedule to assess functioning in the domains of socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behaviours. Good inter-rater reliability has been reported (43). It has been used previously to assess outcome in response to treatment for BD (22).

Self-report outcome measures

The Bipolar Recovery Questionnaire (BRQ; 44) is a self-report measure designed to assess personal experiences of recovery in bipolar disorder. The BRQ is scored out of 3600 (a higher score indicates a higher degree of self-rated recovery). The BRQ is internally consistent and reliable over test-retest period (44). There is also evidence that the BRQ is sensitive to change in a recovery focused CBT trial for early bipolar disorder (22).

The Internal State Scale (ISS; 45) is a 15 item self-report measure that assesses symptoms of mania and depression. It compromises of 4 subscales, activation, perceived conflict, well-being and depression. Each statement is rated based on how the individual has felt in the past 24 hours. A cut off score of > 200 on activation scale has been validated as indicative of the presence of (hypo)mania when accompanied by a score of >125 on the wellbeing scale. (45).

The Centre for Epidemiologic Studies Depression Scale (CES-D; 46) is a 20 item self-administered scale designed to measure depressive symptoms in the general population. The scale measures the major components of depressive symptomatology, including depressive mood, feelings of guilt and worthlessness, psychomotor retardation, loss of appetite, and sleep disturbance. Each item is scored on a four point Likert scale to determine a level of severity score: < 15 (no depression); 15-21 (mild to moderate depression); >21 (possibility of major depression).

Work & Social Adjustment Scale (WSAS; 47) is a brief 5-item measure of functioning in the domains of work, home management, social leisure, private leisure, and relationships. There is a maximum score of 40 (a higher score indicates higher severity of difficulties). It has been extensively used in longitudinal research on BD (e.g., 48, 49).

The World Health Organisation Quality of Life scale (WHOQOL-BREF; 50) comprises of 26 items, which measure the following broad domains: physical health, psychological health, social relationships, and environment. The scores from the four domains are transformed on a scale from 0 to 100.

Quality Of Life in Bipolar Disorder scale (QoL.BD; 51) is a 12 item disorder specific questionnaire used to assess quality of life in BD within several areas including physical, sleep, mood, leisure, spirituality, and identity. The QoL.BD is scored out of 60 (a higher score indicates higher perceived quality of life). Initial field testing of the Quality of Life in Bipolar Disorder supports use of the instrument as a feasible, reliable and valid disorder-specific quality of life measure for BD (51).

Measures to assess therapeutic alliance

The Working Alliance Inventory – Short form, therapist and client version (WAI; 52) is a 12 item questionnaire that measures the strength of the therapeutic alliance between both therapist and client. The WAI measures 3 dimensions of alliance; bond, goals, and tasks. Two versions of the WAI will be used; one specific for the client, and one for the therapist, both of which will be administered twice across the 14 therapy sessions. The WAI has received psychometric support, has good overall internal consistency (α=.94), and good internal consistency for each dimension of alliance, including bond (α=.84), goals (α=.88) and tasks (α=.90).

Measure		Follow up period (weeks)					
	Baseline	12	24		36	48	
	Face to face	Phone	Phone	Postal/ online	Phone	Phone	Postal/ online
SCID	*						
MoCA	*						
SCID-LIFE	*	*	*		*	*	
HDRS	*	*	*		*	*	
MRS	*	*	*		*	*	
PSP	*	*	*		*	*	
BRQ	*			*			*
ISS	*			*			*
CES-D	*			*			*
WSAS	*			*			*
WHOQOL-Bref	*			*			*
QoL.BD	*			*			*

Table 2: Assessment schedule

ANALYSIS

Feasibility

The key focus of the trial is on issues of feasibility and acceptability of the intervention. Much of the analysis will therefore be based around summary statistics used to estimate key parameters: rates of recruitment, demographics of sample, and retention to therapy and follow-up assessments. These summary statistics will be accompanied by 95% confidence intervals.

Clinical outcomes

In line with recommendations for sample sizes for feasibility/pilot trials (e.g. 5), obtaining outcome data from at least 80% (20) participants per group will be sufficient to address key objectives (such as the estimation of the standard deviation of a quantitative outcome or the proportion with a dichotomous outcome) with adequate precision.

Generalised linear mixed models will be used to assess the impact of the intervention on each of the continuous outcome measures to estimate parameters necessary to design the main trial. Time to first relapse will be analysed using time-to-event methods, including Kaplan–Meier estimation and the Cox proportional hazards regression model. Separate analyses will be performed for the three different types of recurrence (any, depressive and hypomanic/manic episodes). Analyses will be conducted on an intention-to-treat basis and key parameter estimates will be presented as point estimates with 95% confidence intervals.

A number of factors will be analysed to help identify a primary clinical outcome for a main trial (e.g. recovery, time to relapse and mood symptoms). Each measure will be assessed in relation to its sensitivity to change, completion rates and acceptability which will be explored further during the qualitative interviews.

Qualitative data

Data from qualitative interviews will be analysed using a process called thematic analysis (53, 54) which focuses on examining themes in the data and identifying implicit and explicit ideas. The qualitative transcripts will be read and coded using a coding frame that will be developed as the data analysis progresses. The codes will be organised into thematic headings and the data will be re-ordered and summarised into themes. The analysis will be crosschecked by another member of the research team to ensure validity.

Dissemination plans

The team intend to publish the outcomes from the trial in peer-reviewed journals but will also try to reach public audiences including people living with bipolar disorder through third sector events and contributions to third section publications as well as use of social media. No professional writers will be used and all authors will contribute substantively to final manuscripts.

DISCUSSION

This study aims to develop and test the feasibility and acceptability of the RfCBT-OA intervention for older people living with bipolar disorder. The data from the trial will allow us to determine rates of recruitment and retention and identify factors which may help improve these rates if a

future trial is feasible. The acceptability of the therapeutic intervention will be assessed by evaluating the therapy attendance rates, drop outs and feedback from the qualitative interviews. We will also be able to gain an estimate of the likely effect size of RfCBT-OA on a range of clinical outcomes. All of this data is essential to inform the design of a large scale trial. Detailed feasibility outcome thresholds have been set in table 1. These will need to be met in order to progress to a further, definitive evaluation trial of the clinical and cost effectiveness of RfCBT-OA.

The original recovery intervention, RfCBT (32) was developed in collaboration with individuals with lived experience of bipolar disorder. This included service user involvement in qualitative work on recovery experiences and a structure and format of the RfCBT intervention. As highlighted by Jones et al (32), engaging individuals with personal experience of bipolar disorder at this level fits with the model of recovery approaches as being empowering, individualised and grounded in the individual's own priorities and needs. The current RfCBT-OA intervention has been further refined by a group of older adults living with bipolar disorder and experts in the ageing field.

Strengths of the study include the development of an intervention for a group of people who currently have no evidence-based care. The Department of Health (55) states that older adults with mental health problems should have access to the same range of therapies as those people under the age of 65. This is not the case for people with BD. There are currently no published studies evaluating psychological interventions for older adults with BD and there is a clear need to develop an evidence base for this population.

The rapid aging of the population will make significant demands on healthcare services especially if the current lack of evidence-based treatments continues. The development of a recovery focused psychological intervention has the potential to improve outcomes for service users, helping them to develop a range of coping strategies and putting them more in control of managing their mental health problems. This would save the NHS money through a reduction in use of mental health services. The intervention also offers a flexibility to work on a range of outcomes. Focus group work with this population has identified that individuals are still experiencing episodes in later life and want the flexibility to work on both symptom management and other areas of their life. The recruitment for the study will take place across primary and secondary mental health services and through self-referral. There is the hope that

not restricting recruitment to specialist mental health services will allow a more representative sample.

There are a number of limitations to the study. Firstly, there is no active treatment control arm so any indications that the intervention is effective may not be specifically related to the recovery focused intervention per se. Secondly, the scale of the study allows a follow-up period of only six months following therapy. A longer follow-up period might have been more helpful to assess the impact of the intervention and whether individuals would complete assessment measures over a longer time period. However, the primary aim of the study is to assess the feasibility and acceptability of the intervention, therefore the six-month follow-up window is a first appropriate step to help to assess whether a further, definitive RCT is feasible in the future. Thirdly, as this is the first intervention study for older adults with BD, there are no well validated measures for this population. The bipolar related measures have not yet been specifically validated for use with an older adult population. However, the samples for the development papers for both the BRQ (44) and the QoL.BD (51) included people over the age of 60. Additionally, focus group data indicates that outcomes such as personal recovery and quality of life are still important over the age of 60.

Despite these limitations, if this intervention is feasible to deliver, it offers a promising step for a group of people that currently does not have access to evidence based psychological care.

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CHAPTER SIX

A pilot randomised controlled trial to assess the feasibility and acceptability of recovery focused therapy for older adults with bipolar disorder

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This article is under review with BJPsych Open. It is formatted to the specific requirements of the journal.

A pilot randomised controlled trial to assess the feasibility and acceptability of recovery focused therapy for older adults with bipolar disorder

Dr Elizabeth Tyler, Professor Fiona Lobban, Dr Christopher Sutton, Mr Bogdan Hadarag, Professor Sheri Johnson, Professor Colin Depp, Ms Deborah Duncan, Professor Steven H Jones

ABSTRACT

Background

Despite increasing evidence for effectiveness of individual psychological interventions for bipolar disorder (BD), research into what works for older adults with BD is lacking. We report the first randomised controlled trial of psychological therapy designed specifically for older adults with BD.

Aims

To evaluate the feasibility and acceptability of recovery-focused therapy, designed in collaboration with older people living with BD (RfT-OA).

Method

A parallel, two-armed RCT comparing up to 14 sessions of RfT-OA plus treatment as usual (TAU) for older adults with BD, versus TAU alone.

Results

Thirty-nine participants (67% female, mean age 67 years) were recruited over a 17-month time period. Feasibility and acceptability of recruitment, retention (>80% observer-rated outcomes at both 24 and 48-weeks) and intervention processes was demonstrated. The majority of participants started therapy when offered, adhered to the intervention (68% attended 14/14 sessions and 89% attended 6 of more sessions) and reported positive benefits. Clinical assessment measures provide evidence of a signal for effectiveness on a range of outcomes including mood symptoms, time-to-relapse and functioning. No trial-related serious adverse events were identified.

Conclusions

RfT-OA is feasible, acceptable and has the potential to improve a range of outcomes for people living with BD in later life. A large-scale trial is warranted to provide a reliable estimate of the clinical and cost effectiveness of RfT-OA.

Trial registration number: ISRCTN13875321

INTRODUCTION

Approximately 0.5%-1% of older adults live with Bipolar Disorder (BD) (1-3), placing significant and increasing demands on healthcare services (4). The UK National Institute for Health and Care Excellence (NICE) BD clinical guideline (5) states that older people with BD should be offered the same range of treatments as younger adults. Such treatments may not be appropriate due to significant differences in the nature of BD in later life. BD in older adults differs in presentation, is more complex, and is accompanied by high rates of physical comorbidities (6), and poorer cognitive function even during euthymia (7), which may significantly affect psychosocial outcomes (8). As cognitive functioning declines, older adults with BD may struggle to apply effective coping responses to difficult situations (7), including adopting more passive coping styles than nonclinical older adults (9). Despite these differences, few studies have evaluated psychological interventions developed for older people with BD. In the US, a psychosocial skills training programme for older people with various mental health problems (schizophrenia, schizoaffective disorder, depression and BD) improved community living skills, functioning, self-efficacy and reduced psychiatric symptoms (10). Additionally, medication adherence skills training led to improvements in medication adherence and management, depressive symptoms and quality of life for older people with BD (11). However, it is not clear from the first study what the outcomes are specifically for older people with BD and neither study targeted personal recovery which is highlighted in national policy (12, 13) and NICE guidelines (5).

Here we report on a recovery-focused therapy (RfT) intervention for BD, adapted to meet the needs of older adults. Unlike traditional therapies focused primarily on reducing clinical symptoms and relapse, RfT (14) supports people to live meaningful, satisfying, and purposeful lives alongside mental health difficulties. Research for working age adults has shown this approach is beneficial in terms of personal recovery and relapse outcomes (14). This is the first study to evaluate the feasibility and acceptability of RfT for older people living with BD.

METHOD

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures were approved by the UK NHS Ethics Committee process (Ref: 15/NW/0330). The study was pre-registered (ISRCTN13875321), and a study protocol informed by the SPIRIT Guidelines (15) pre-published

(16). The study is reported consistent with the CONSORT extension for pilot and feasibility trials (17; see Supplementary file 1).

Three study changes were necessary after protocol publication. Minimum age was reduced from >+ 65 to >= 60 based on the United Nations (18) definition of OA and in line with best practice (19, 20). The Structured Clinical Interview for DSM-5, research version (SCID-5-RV; 21) replaced the SCID IV (22). Outcome assessments were not conducted blind to allocation due to resource constraints.

Objectives

The aim was to evaluate the feasibility and acceptability of RfT-OA in an RCT design. The objectives were to:

1. Determine the feasibility of RfT-OA in terms of:
    A. whether clinicians would refer older adults into an RCT;
    B. whether older adults would self-refer into an RCT;
    C. whether older adults with BD would consent to participate in an RCT of a psychological intervention offered in addition to usual treatment vs usual treatment
    D. participant attrition rates (overall and by study arm) during assessment, intervention and follow-up.

2. Determine the acceptability of RfT-OA in terms of:
    A. whether individuals adhered to the intervention;
    B. participants' experiences of the intervention

3. Identify the most appropriate primary outcome measure for a future trial.

4. Estimate parameters needed to determine the sample size for a future trial.

Trial design

This was a parallel, two-armed randomised controlled trial comparing up to 14 sessions of RfT-OA in addition to treatment as usual (TAU), versus TAU alone, conducted across two NHS trusts in North-West of England. A nested qualitative study explored acceptability of RfT-OA.

Participants were allocated to trial arms using simple (1:1) randomisation by independent researchers at Lancashire Clinical Trials Unit (LCTU) using the "Sealed Envelope" randomisation

programme (www.sealedenvelope.com) after baseline assessment. The study was overseen by a Trial Steering Committee (TSC) and a Service User Reference Group.

Participants

A target of 50 participants (25 per treatment arm) was considered sufficient to obtain robust feasibility and acceptability information about trial procedures and the RfT-OA therapy and to allow for expected attrition rates (23; see table 2). Participants were recruited from NHS mental health services, voluntary groups, advertisements in local media and on the Bipolar UK website (https://www.bipolaruk.org), and from "Spectrum Connect", a confidential database (maintained by a research team at Lancaster University) of individuals who have previously consented to being approached about research studies. Recruitment happened: December 2016-January 2018 and May 2019-September 2019; final follow-up September 2020 due to the lead investigator's maternity leave. Interested individuals were screened for provisional eligibility using the Mood Disorder Questionnaire (MDQ; 24). Participants >=60 years old from the North-West who screened positive on the MDQ were invited to a baseline interview.

Eligibility interview

Written informed consent was obtained from all participants. They were assessed using the SCID-5-RV and the Montreal Cognitive Assessment (MOCA; 25) to confirm eligibility criteria and completed the observer-rated and self-report measures (see clinical and functional outcomes section).

Inclusion / exclusion criteria

Inclusion criteria: (a) >=60 years; (b) SCID-5-RV diagnosis of BD (I or II); (c) no current episode of mania, hypomania, depression or mixed episode in the last 4 weeks; (d) sufficient English fluency to consent, and take part. Exclusion criteria: (a) a MOCA score of <=22; (b) currently receiving psychological therapy.

RfT for older adults with bipolar

The original therapy manual was co-produced with adults with lived experience of BD (14), and adapted for this study with older adults (RfT-OA).

Adaptations for RfT-OA were informed by a literature review on adapting psychological interventions for older adults with mental health problems (26, 27), and three focus groups with older people with BD (28). Adaptations included: building confidence, competence and

assertiveness; greater emphasis on relationship with the therapist; allocating more time to explore extensive and complex histories; and explicit acknowledgement of the wealth of experience the older person with BD is bringing to the therapeutic relationship. Specific adaptations to enhance memory and learning included, repetition and using session summaries, consistent with existing literature (26, 27). Participants were offered 14 therapy sessions, with six or more considered an appropriate threshold for the therapeutic dose based on the original RfT study (14).

Treatment as usual

No changes were made to any other interventions. Psychiatric medication use and previous therapy experience were recorded.

Therapists

RfT-OA was delivered by three qualified clinical psychologists. ET delivered the majority of the therapy (n=17). FL and SHJ worked with 1 client each. All were trained in the use of RfT-OA and attended fortnightly peer supervision.

Key outcomes: Feasibility and acceptability

Information was collected on number of referrals per month, recruitment sources, number of people assessed for eligibility and consented. Participant retention was assessed during assessment, intervention and follow-up periods including completion of outcome measures. Pre-specified criteria were used to interpret the findings in terms of feasibility and acceptability outcomes for progression to a definitive RCT using a traffic light system (29).

Additional outcomes: feasibility and acceptability

Therapeutic alliance was assessed at the start (session 3/4), middle (sessions 8/9) and end of therapy (session 13/14) using the Working Alliance Inventory-Short form (therapist and client forms) (30).

Clients also rated the therapy on two scales: 1) how useful they found the therapy from 0 (not at all) to 10 (extremely); 2) whether they would recommend the therapy to a friend experiencing similar problems from 0 (definitely not) to 10 (definitely yes). Participants were given a copy of the scales and an envelope during their penultimate therapy session to return at the final session.

Clinical and functional outcomes

Multiple clinical and functional outcome measures were used to assess participant attrition rates, participant views of measures from qualitative interviews and to provide preliminary data on outcomes. Participants were followed from baseline with telephone interviews at 12, 24, 36 and 48-weeks (observer-rated measures) and at 24 and 48-weeks by post (self-report measures).

Observer-rated measures were the Personal and Social Performance Scale (PSP, 31) the SCID-5-RV (21), the Hamilton Rating Scale for Depression (HRSD; 32), the Bech-Rafaelsen Mania Scale (MAS; 33) and the modified Longitudinal Interview Follow-up (SCID-LIFE; 34) to assess time-to-relapse.

Self-report measures were the Bipolar Recovery Questionnaire (BRQ; 35), the Quality of Life in Bipolar Disorder Scale (QoL.BD; 36), the Internal State Scale (ISS; 37), the Centre for Epidemiologic Studies Depression Scale (CES-D; 38), the Work and Social Adjustment Scale (WSAS; 39) and the WHO Quality of Life Scale (WHOQOL-BREf; 40). The candidates for primary outcome measure were the HRSD, MAS, SCID-LIFE and the BRQ, based on the original RfT study (14).

Quality assurance

DD completed 18 telephone follow-up assessments whilst ET was on maternity leave. Inter-rater reliability between ET and DD was assessed at both baseline and follow-up.

Data analysis

Analyses were conducted using SPSS version 25 (IBM Corp, 41) and followed a pre-specified Statistical Analysis Plan, approved by the TSC.

Analysis was 'as randomised'. Summary statistics were used to estimate key parameters such as rates of recruitment, consent to the trial and retention to therapy and follow-up assessments. Linear models were used to assess the effect of RfT-OA vs TAU alone on each continuous outcome measure, with baseline value of the relevant measure as covariate. Time to first relapse was analysed using Kaplan-Meier plots and the Cox regression modelling, with time since last episode as covariate. Separate analyses were performed for three types of relapse (any episode, depressive or manic). The focus of the analysis was point estimation with 95%

confidence intervals, rather than statistical significance. P values have been reported in the appendix for completeness. For statistical models, missing data were assumed to be missing at random (dependent only on intervention group and baseline).

Pooled standard deviations for each continuous outcome, and median time-to-relapse, were used to estimate key parameters needed (in conjunction with data from other relevant trials (e.g., 42)) to determine the sample size needed for a future trial. Correlations between baseline and follow-up for the continuous outcomes were also estimated as substantial correlations can be used to reduce the target sample size if linear modelling techniques are used for analysis.

Qualitative interviews were analysed using content analysis (43) to understand participants' experiences of key aspects of the trial process and psychological intervention. Key points and supporting quotes are summarised in the results section and supplementary file 2.

Missing data

Missing items were imputed using a pro-rata strategy, provided that at least 75% of the items were available. The exception was the WHO-QOL BREF (38) where there is a pre-defined strategy for handling missing data. Please see supplementary file 3 for details.

RESULTS

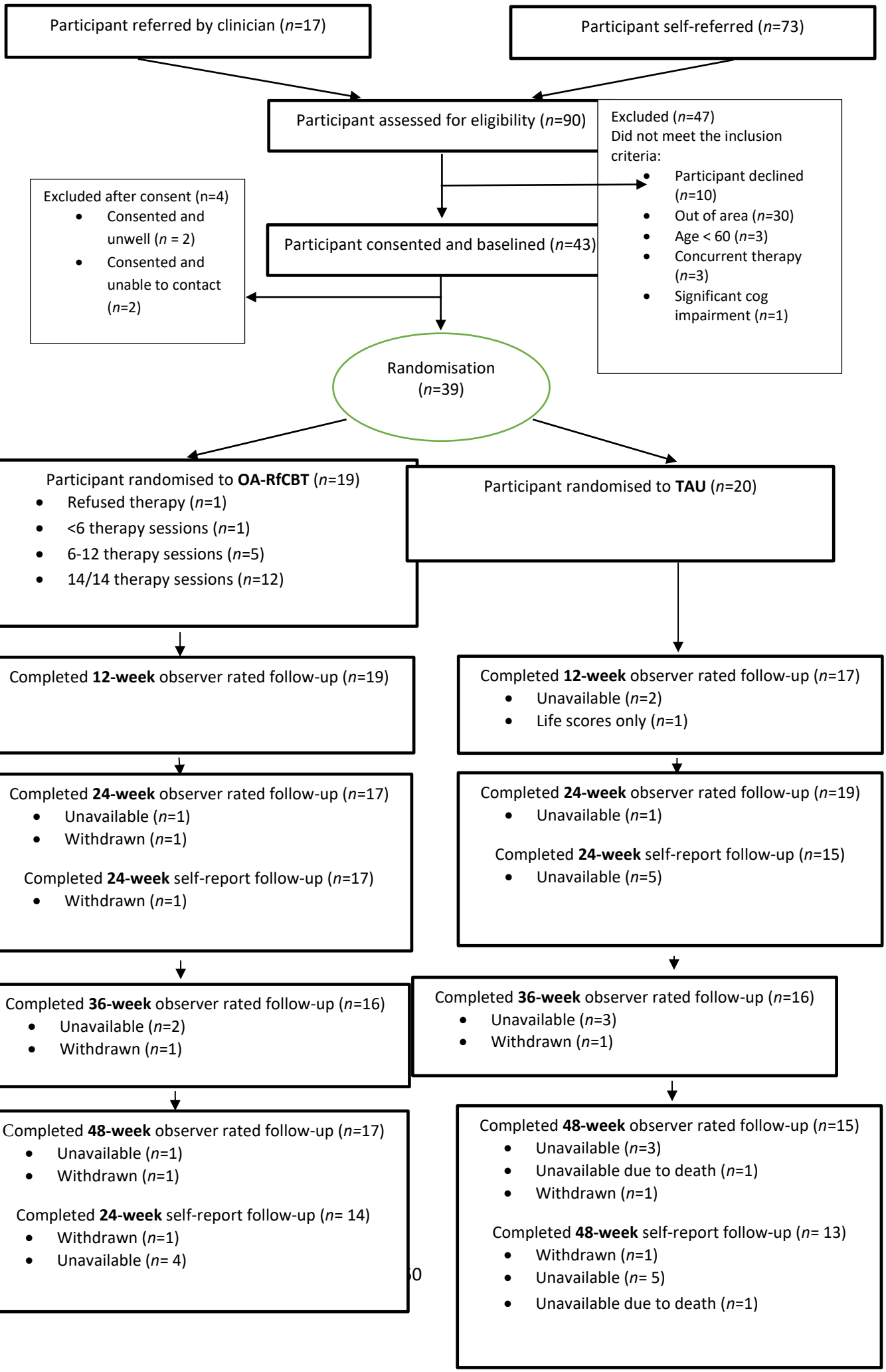
Participants

Thirty-nine participants were recruited and randomised (see table 1). The majority were white British (97%, n=38) and female (67 %, n=26) with average age 67 (s.d.=6) years. Most (74%, n=29) were in the "young old" age category of 60-69 (44). Most participants were diagnosed with BD I (87%, n=34) and average age of diagnosis was 48 (s.d.=11) years.

Mean MOCA score was 26 (s.d.=2), indicating mild to no cognitive impairment (23). Most participants reported physical health difficulties (64.1%, n=25), ranging from 0-6 difficulties (median=2), consistent with previous research (6).

Characteristic	RfT-OA, n=19	TAU, n=20
Age, mean (s.d.) Range	66 (5) 60-81	68 (6) 60-81
Gender Male, *n* (%) Female, *n* (%)	 9 (47) 19 (53)	 13 (65) 7 (35)
Marital Status Married or living with some as married, *n* (%) Widowed, *n* (%) Divorced/ annulled, *n* (%) Separated, *n* (%) Never married, *n* (%)	 11 (58) 2 (11) 6 (32) 0 0	 5 (25) 4 (4) 7 (35) 1 (5) 3 (15)
Number of children 0, *n* (%) 1, *n* (%) 2, *n* (%) 3, *n* (%) 4, *n* (%)	 2 (11) 0 12 (63) 3 (16) 2 (11)	 4 (20) 6 (30) 5 (25) 5 (25) 0
Diagnosis Bipolar I, *n* (%) Bipolar II, *n* (%)	 15 (79) 4 (21)	 19 (95) 1 (5)
Age of bipolar diagnosis, mean (s.d.) Range	49 (11) 31-80	47 (12) 22-72
On Medication Yes, *n* (%) No, *n* (%)	 18 (95) 1 (5)	 20 (100) 0
Number of medications, median Range	2 0-4	2 1-4
Type of medication Mood stabilizer, *n* (%) Anti-psychotic, *n* (%) Anti-depressant, *n* (%)	 15 (79) 6 (32) 8 (42)	 13 (65) 12 (60) 6 (30)
Physical health co-morbidities Yes, *n* (%) No, *n* (%) Missing, *n* (%)	 13 (68) 5 (26) 1 (5)	 12 (60) 7 (35) 1 (5)
Number of physical health problems, median Range	2 0-6	2 0-3
MOCA score, mean (s.d.) Range	26 (2) 22-29	25 (3) 22-30
Previous psychological therapy Never, *n* (%) CBT, *n* (%) Counselling, *n* (%) Psychotherapy, *n* (%) DBT, *n* (%) Psychoeducation group therapy, *n* (%)	 9 (47) 4 (21) 1 (5) 1 (5) 1 (5) 3 (16)	 11 (55) 4 (20) 4 (20) 1 (5) 0 0

Table 1: Participant demographic and clinical characteristics


Participant referred by clinician (n=17)
Participant self-referred (n=73)
Participant assessed for eligibility (n=90)
Excluded (n=47)
Did not meet the inclusion criteria:
Participant declined (n=10)
Out of area (n=30)
Age < 60 (n=3)
Concurrent therapy (n=3)
Significant cog impairment (n=1)
Excluded after consent (n=4)
Consented and unwell (n = 2)
Consented and unable to contact (n=2)
Participant consented and baselined (n=43)
Randomisation (n=39)
Participant randomised to OA-RfCBT (n=19)
Refused therapy (n=1)
<6 therapy sessions (n=1)
6-12 therapy sessions (n=5)
14/14 therapy sessions (n=12)
Participant randomised to TAU (n=20)
Completed 12-week observer rated follow-up (n=19)
Completed 12-week observer rated follow-up (n=17)
Unavailable (n=2)
Life scores only (n=1)
Completed 24-week observer rated follow-up (n=17)
Unavailable (n=1)
Withdrawn (n=1)
Completed 24-week self-report follow-up (n=17)
Withdrawn (n=1)
Completed 24-week observer rated follow-up (n=19)
Unavailable (n=1)
Completed 24-week self-report follow-up (n=15)
Unavailable (n=5)
Completed 36-week observer rated follow-up (n=16)
Unavailable (n=2)
Withdrawn (n=1)
Completed 36-week observer rated follow-up (n=16)
Unavailable (n=3)
Withdrawn (n=1)
Completed 48-week observer rated follow-up (n=17)
Unavailable (n=1)
Withdrawn (n=1)
Completed 24-week self-report follow-up (n= 14)
Withdrawn (n=1)
Unavailable (n= 4)
Completed 48-week observer rated follow-up (n=15)
Unavailable (n=3)
Unavailable due to death (n=1)
Withdrawn (n=1)
Completed 48-week self-report follow-up (n= 13)
Withdrawn (n=1)
Unavailable (n= 5)
Unavailable due to death (n=1)

Participants: qualitative interviews

All participants offered RfT-OA were invited to take part in the qualitative interviews. Eight participants took part: 2 women and 6 men, aged 61-72 (mean = 65), and attending 7-14 sessions of RfT-OA.

Key outcomes: Feasibility and acceptability

Consent, recruitment and retention

Table 2 summarises feasibility and acceptability outcomes and colour codes with a traffic light system (green; feasible: amber; feasible with modifications; red; stop). Ninety people were referred into the study, 17 by a clinician. Of the 88 screened for provisional eligibility, 41 did not meet the study criteria, 1 refused due to physical health difficulties and 3 individuals either cancelled or did not attend their baseline interview. Forty-three of 47 eligible participants consented to participate, although 2 then became unwell and 2 consented but then were uncontactable. Thus 39/47 eligible and consented participants took part in the trial (green).

Thirty-nine participants were randomised (29 via self-referral and 10 identified by a clinician) over 17-months; 2 participants per month (amber).

Retention for observer-rated measures was over 80% for each follow-up, with 82% (n=32) retention at 48-week follow-up (green). Retention for the self-report measures was over 80% at the 24-week follow-up and 69% (n=27) for the 48-week follow-up self-report (amber). One participant lost to follow-up died during the final follow-up period for reasons unrelated to the trial as confirmed by TSC.

Eight baseline interviews were double-rated by DD to assess whether participants met study criteria (age, MOCA score, a BD II or II diagnosis and to confirm the participant was not in a current episode). Fifteen follow-up interviews were also double-rated to assess whether the participants met criteria for a SCID-5-RV episode and type of episode during a follow-up period. There was 100% agreement regarding eligibility criteria for the follow-up interviews.

Therapy retention

Mean attendance was 12.2 (s.d=3.3) sessions. One participant did not start therapy, 89% (n=17) attended more than 6 sessions (amber) and 68% (n=13) attended 14/14 sessions (green).

Objective	Measurement process	Feasibility outcome	Final outcome
Estimate the recruitment rate	Recruitment rate is set at a number based on the maximum number of participants that the therapist can see per month. However number of eligible participants recruited will be recorded on a monthly basis to inform the recruitment plan for a larger trial.	**Green** - Feasibility will be shown where >= 3-4 participants are recruited per month over the 15-month recruitment window (n=~50). **Amber** - If >= 2 participants are recruited per month (approximately 30 participants) or 4-5 participants are recruited in the last 6 months of the trial (if recruitment problems are overcome) then a future trial will be feasible but additional strategies will be identified to achieve target recruitment **Red** - If less than < 2 participants are recruited per month (<25) over the recruitment period feasibility will not be demonstrated	**39 participants recruited over 17-months** **Average is 2.3 participants per month therefore strategies to overcome potential barriers will be identified.**
Identify consent rate and reasons for non-recruitment	Number of referred participants that are eligible that choose not to consent into the trial will be recorded and reasons for refusal will be documented where offered	**Green** - Feasibility will be shown if >= 80% of eligible participants referred consent into the trial **Amber** - If >= 60% of eligible participants referred consent into the trial then a future trial will be feasible if strategies to overcome identified barriers are identified (including whether more individuals are consenting who self-refer or clinician refer). **Red** - If < 60% of eligible participants referred do not consent into the trial then feasibility will not be demonstrated	**39 / 47 eligible participants consented into the trial.** **The consent rate is 83% therefore feasibility is demonstrated.**
Estimate the proportion of participants lost to follow-up and the reasons for loss to follow-up	The loss of participants during the follow-up period will be recorded, plus reasons for loss (if given)	**Green** - Feasibility will be demonstrated if >= 70% of participants are retained at the 48-week follow-up **Amber** - If >= 50% or more participants are retained to follow-up at 48-weeks then a future trial will be feasible if strategies to overcome identified barriers are identified **Red** - If < 50% of participants referred do not consent into the trial then feasibility will not be demonstrated	**32 / 39 participants completed the observer-rated measures at 48-weeks.** **The retention rate is 82% therefore feasibility is demonstrated.** **27/ 39 participants returned their self-report measures at 48-weeks. The retention rate is 69% therefore strategies to overcome potential barriers will be identified**
Estimate the number of therapy sessions attended	The number of therapy sessions attended out of the 14 offered will be recorded	**Green** - Feasibility will be demonstrated if all of the participants >= 6 sessions* of the 14 offered **Amber** - If >= 75% of participants >= 6 or more sessions of the 14 offered a future trial will be feasible if strategies to overcome barriers are identified. **Red** - If < 75% of participants do not take up 6 or more of the therapy sessions offered then feasibility will not be demonstrated	**17/19 participants attended 6 or more sessions.** **Attendance rate for 6 or more sessions is 89% therefore strategies to overcome potential barriers will be identified.**
Estimate the number of participants who drop out of therapy	The number of participants who drop out of the therapy sessions will be recorded	**Green** - If >= 65% of the participants in the intervention arm complete therapy then feasibility will be demonstrated **Amber** - If >=50% of participant in the intervention arm complete therapy then a future trial will be feasible if strategies to overcome dropout are identified. **Red** - If less than 50% of participants in the intervention arm drop out of therapy then feasibility will not be demonstrated.	**13/19 participants attended 14/14 sessions of RfCBT-OA.** **Completeness rate for therapy is 68%. Therefore feasibility has been demonstrated.**
Assess the feasibility of delivering Rf-T-OA in a way that is acceptable to people with BD in later life	Interviews with 10-15 participants that have taken part in the intervention arm of the study to seek their views on the therapy	Feasibility will be demonstrated if >50% of participants indicate that the intervention is acceptable	**>50% of participants indicated they valued the intervention** **The majority of participant felt the session number, length and location was acceptable.**

Table 2: Feasibility and acceptability outcomes

Additional outcomes: feasibility and acceptability

Therapeutic alliance

Alliance data was available from 15 clients at the start of therapy (mean=63, s.d.= 5), 8 in the middle of therapy (mean=66, s.d.=5) and 9 at the end (mean=65, s.d.=7). Alliance rated by the therapists was similar with 15 ratings at the start of therapy (mean=64, s.d.= 6), 8 in the middle (mean = 63, SD 7) and 9 at the end (mean=65, s.d.=6). Alliance ratings are similar to those observed for psychological therapy in younger BD cohorts (14, 45).

Client ratings of therapy

Data was available for 15 participants: the usefulness of therapy averaged 9 (s.d.=2) and the likelihood of recommending therapy averaged 9 (s.d.=1), meaning the participants found therapy very useful and were very likely to recommend to a friend.

Qualitative interviews findings (see supplementary file 2 for example quotes).

Participants' experiences of the intervention

The majority of participants indicated that they valued RfT-OA and highlighted its positive impact on their lifestyle, family and work relationships. One participant found it difficult to engage due to concurrent marital problems. Value was derived from both the recovery approach and learning strategies to manage emotions in a new way. The majority of participants felt 14 therapy sessions was enough. The participant who had not felt the benefit from the sessions attended 7 sessions and expressed that they would have liked more. Participants felt the session length of 50-60 minutes was sufficient and valued the flexibility of the sessions being offered at home, work or the university.

Research process

On the whole, participants found the research process acceptable, although 5/8 participants indicated they would prefer the follow-up appointments to be face-to-face rather than on the phone. Participants were positive about receiving and returning the self-report measures by post (see table 3). Participants did not express strong views on the acceptability and relevance of individual outcome measures.

	TAU N	TAU Mean	TAU s.d.	RfT-OA N	RfT-OA Mean	RfT-OA s.d.	Adjusted 95% CI for mean difference MD
Bipolar Recovery Questionnaire							
Baseline	19	2026.2	316.8	18	1914.8	352.2	
24-week follow-up	14	2248.0	359.8	16	2134.9	377.5	22.5 (-172.4 to 217.3)
48-week follow-up	12	2075.2	374.8	14	2136.2	345.3	62.9 (-238.3 to 364.0)
HRSD							
Baseline	20	5.0	4.5	19	4.5	4.0	
24-week follow-up	19	9.7	8.7	17	5.3	4.5	-4.2 (-8.9 to 0.5)
48-week follow-up	15	9.4	10.30	17	4.8	4.1	-4.2 (-9.8 to 1.4)
MAS							
Baseline	20	2.2	3.1	19	1.8	2.7	
24-week follow-up	19	3.9	5.2	17	1.7	2.2	-1.8 (-4.3 to 0.7)
48-week follow-up	15	2.6	2.9	17	1.0	1.5	-1.8 (-3.4 to -0.1)
	χ^2	**Df**	**Hazard ratio (HR)**	**Lower 95% CL HR**	**Upper 95% CL HR**		
Time to any relapse	10.1	3	0.23	0.07	0.73		
Time to manic relapse	6.1	3	0.44	0.13	1.51		
Time to depressive relapse	7.7	3	0.13	0.01	1.06		

N= number of participants, s.d = Standard deviation, CI = Confidence interval, MD= Mean difference, $\chi 2$ = Chi Squared, Df = Degrees of freedom, CL = Confidence limit

Table 3: Candidate primary outcomes measures (see supplementary file 4 for P-Values)

Clinical and functional measures

Effect size estimation for candidate primary outcome measures

BRQ

BRQ score in both groups increased to the 24-week follow-up which was numerically sustained in the intervention group and reduced in the TAU at 48-weeks. However, there is not a clear signal of potential clinical effectiveness. Pooled SD was 369.4 and 359.2 at 24 and 48-weeks respectively. The estimated correlation between the baseline and the 24-week scores was high (0.73), but there was no positive correlation between baseline and 48-week scores.

SCID-LIFE (Time-to-relapse)

RfT-OA participants had fewer depressive or manic relapses (18 TAU versus 7 RfT-OA), and demonstrated a longer median time-to-relapse (15.5 vs 8.5 weeks) during follow-up (See table 3).

Over 48-weeks, 17 participants experienced a depressive relapse (11 TAU versus 6 RfT-OA) and 8 a manic episode (7 TAU versus 1 RfT-OA).

HRSD

HRSD scores indicated mild depression on average in TAU at 24 and 48-week follow-ups, compared to no depression in RfT-OA. The pooled SD was 7.0 at 24-weeks and 7.6 at 48-weeks. The estimated correlation between the baseline and follow-up scores was very low (0.15 at 24-weeks and 0.04 at 48-week).

MAS

MAS scores remained low throughout, indicating low levels of mania. MAS score was lower in the RfT-OA group at both the 24-week and the 48-week follow-up compared to TAU, suggesting lower levels of mania following therapy. The pooled standard deviation was 4.1 at 24-weeks and 2.2 at 48-weeks. The estimated correlation between the baseline and the 24-week scores was 0.44, but there was no positive correlation between baseline and 48-week scores.

Completion rates for candidate primary outcome measures

BRQ

At baseline 39/39 participants completed the BRQ, although two questionnaires were missing >= 25% of the data; therefore 37 were included. At 24-weeks 31/39 questionnaires were returned, with one excluded from analyses due to missing item data. At 48-weeks 27/39 questionnaires were returned, with one excluded from analyses due to missing data.

Time-to-relapse, HRSD and MAS

Observer-rated assessments, measuring time-to-relapse and mood symptoms were completed at baseline, 12, 24, 36 and 48-weeks. Completion rates were 36/39 at 24-weeks and 32/39 at 48-weeks due to either participant dropout or unavailability.

Acceptability of candidate primary outcome measures

Participants did not give any specific feedback about particular questionnaires although they indicated that the questionnaires in general were easy to understand (see supplementary file 2).

Additional clinical outcomes

Additional clinical outcomes are reported in the Supplementary file 4 with higher mean scores observed in the PSP in RfT-OA at both 24-week and 48-week follow-ups, indicating higher levels of functioning. The other clinical outcome measures tended to favour RfT-OA, although this was not consistent across all measures and time-points.

DISCUSSION

This is the first study to develop and evaluate a psychological intervention specifically for older adults with BD, using an RCT design. RfT-OA was developed and designed in collaboration with individuals living with BD (28), enhancing the quality, value and the relevance of the study.

Feasibility and acceptability of RfT-OA

The findings from the study largely support the feasibility and acceptability of RfT-OA, evaluated against predefined criteria. It was possible to recruit 39 participants at a rate of 2.3 per month (amber progression zone). This was with the lead researcher as the sole recruiter, working part-time for the second half of the recruitment period. A well-resourced research team would be in a stronger position to enhance the recruitment rate (discussed further below). Retention to follow-up was strong and balanced across trial arms, with rates comparing favourably to previous BD and older adult depression trials (14, 19, 46). Intervention arm participants engaged with RfT-OA, demonstrating a significant commitment to therapy. Two participants did not attend 6 or more therapy sessions (amber), therefore strategies to overcome any potential barriers are discussed below. Interviews indicated that participants valued RfT-OA, corresponding with high client ratings of therapy usefulness and recommending to a friend. Alliance ratings were acceptable and comparable with younger BD cohorts (14, 45).

Primary outcome measure

Completion rates were higher for the observer-rated measures (e.g., time-to-relapse and mood symptoms; 86-90%), than for the self-report measures (e.g., the BRQ; 70-81%), although a number of strategies have been identified below to enhance self-report rates. Feedback from the interviews indicated that participants were positive about the data collection process and did not report any difficulties completing any of the measures. The MAS, HRSD and SCID-LIFE (time-to-relapse) demonstrated a signal of benefit, although the trial was not powered to test intervention effectiveness. Further consultation with older adults with BD will be needed to

identify which measure is most relevant to their experiences and what they would want to change during RfT-OA prior to confirming the most appropriate and meaningful primary outcome measure for a definitive trial.

Sample size for a future trial

To help determine the appropriate sample size for a future trial, pooled SDs for MAS and HRSD, and the median time-to-relapse were estimated. For the HRSD, a minimal-clinically important difference in a trial context is often deemed to be around 3 points (e.g., 47), with a SD of 7-8 points (consistent with our results). Using a conservative 8-point SD (standardised effect size=0.375), a sample size of 302 would be needed to achieve 90% power (two-sided 5% significance level using a two-sample t-test), inflated to 404 (202 per group) to allow for an anticipated 25% attrition. Baseline-outcome correlations were also estimated. These, however, were generally low; only that for the 24-week, MAS was sufficiently large to enable a useful reduction in target sample size. For both the HRSD and MAS, average scores were low throughout which may bring into question the appropriateness of these as the primary outcome. The estimated median time-to-relapse in TAU was 8.5 weeks, somewhat lower than previous research on a similar population (14 weeks; 48). Using a conservative median time-to-relapse of 18 weeks, if participants were followed up for relapse for 52 weeks (SCID-LIFE data with data from case notes where needed), using a Cox regression model (with 5% significance level) 320 participants would be needed to achieve 90% power to detect a hazard ratio of 2/3.

Limitations

There are a number of limitations to the study. Firstly, information on what constituted TAU was limited. Referral route, medication use and information on previous psychological therapy were collected to help define this; however, it would be useful to collect information regarding current level of care for a future trial. Secondly, it was not feasible to employ a blinded research assistant to carry out the assessment and follow-ups. Thirdly, data from people who had few or no sessions of RfT-OA was lacking for the qualitative interviews. Finally, this was a relatively small study, conducted in the North-West of England, with a predominantly White British sample. A definitive trial would need to recruit a more geographically and ethnically diverse sample to support generalisability of findings.

Learning for a future trial

There was substantially more interest from the self-referral recruitment route, compared to the clinical route. A well-resourced research team would be poised to form stronger links with

clinical teams, generating further interest and increasing the recruitment rate through both routes. A number of strategies have been identified from recent research to enhance completion rates for self-report measures, including providing detailed explanations regarding the importance of data completeness in recruitment materials, collecting multiple contact details and reminders via different methods (e.g., phone, text, post, email; 49). Preference for a face-to-face interview for follow-ups was highlighted in the qualitative interviews, therefore face-to-face, video or audio call could be offered to support completion of self-report measures. Paying participants for completing the measures could further enhance retention and is considered good practice with the National Institute for Health Research. Additionally, the observer measures may have been affected by bias. A definitive trial would be fully costed to employ independent, blind assessors to avoid any risks of bias. Finally, two participants did not attend 6 sessions of therapy due to one person becoming unwell and not stabilising before the end of the 6-month therapy window and one person dropped out due to personal reasons. In a future trial, the option of extending the therapy window will be considered with a view to re-engaging participants who dis-engage with therapy during the trial.

Conclusion

Despite these limitations, the trial was successful in demonstrating the feasibility and acceptability of recruitment, retention and intervention processes. The majority of participants started therapy when offered and adhered to the intervention, reporting positive benefits. The assessment measures provide evidence for a signal for effectiveness on a range of outcomes including mood symptoms, time-to-relapse and functioning. A definitive trial is now warranted to provide a robust estimate of the clinical and cost effectiveness of RfT-OA and to provide an important step for a group of individuals who, at present, do not have access to evidence-based psychological care.

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Data Availability: The data that support the findings of this study are available from the corresponding author, [ET], upon reasonable request. The transcripts from the qualitative interviews cannot be published or made available if requested to protect the anonymity of the participants who took part.

Author affiliations

Dr Elizabeth Tyler: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK (corresponding author: e.tyler@lancaster.ac.uk)

Professor Fiona Lobban: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK.

Dr Christopher Sutton: Division of Population Health, Health Services Research & Primary Care, University of Manchester, Manchester, UK.

Mr Bogdan Hadarag, Division of Health Research, Lancaster University, Lancaster, UK.

Professor Sheri Johnson: Department of Psychology, University of California, Berkeley, Berkeley, California, USA.

Dr Colin Depp: Department of Psychiatry, School of Medicine of the University of California, San Diego, San Diego, California, USA.

Ms Debbie Duncan: Division of Health Research, Lancaster University, Lancaster, UK.

Professor Steven Jones: Spectrum Centre for Mental Health Research, Division of Health Research, Lancaster University, Lancaster, UK.

CHAPTER SEVEN

Discussion

7.1 Overview

There is evidence to suggest that psychological interventions are effective for younger people with BD (Oud et al., 2016), but there have been limited efforts focused on older people with BD. This research aimed to increase our understanding of the condition and develop a psychological intervention for older people with BD

The main aims of the thesis were to: improve our understanding of how bipolar disorder (BD) presents in older adults, identify any potential adaptations to an existing recovery focused therapy (RfT) developed for younger people with BD to meet the needs of an older population and to evaluate the feasibility and acceptability of RfT for older adults with BD. The thesis included three studies, designed to complement one another and address the lack of research and service development in the area.

7.2 Key findings

Despite evidence to suggest individuals with BD demonstrate significant difficulties with functioning (Rosa et al., 2008) and an impaired quality of life (IsHak et al., 2012 and Michalak et al., 2005), study one found that there have been very few studies measuring psychosocial functioning and quality of life in older people with BD. Thus, this confirms existing findings that there is a lack of research focused on older adult with BD (Depp et al., 2004, Sajatovic et al., 2015). Study one found 11 eligible studies, using 10 different measures of psychosocial functioning and quality of life. This included seven measures of psychosocial functioning and three measures of quality of life. The most widely used measure was the Global Assessment of Functioning (GAF; Endicott et al, 1976) used in seven of the 11 studies. There was significant variability across the scale and the pooled GAF score was 70.18 (s.d = 11.10) which indicates an individual with '*some mild symptoms or some difficulty in social, occupational or school functioning*'. Developing an understanding of the factors that influence higher functioning, compared to lower functioning for older people with BD is important. This will increase our understanding of the condition in later life and help shape effective therapeutic interventions for those presenting with lower levels of functioning. The findings from the GAF are consistent with a review focused on working-aged adults with BD (Akers et al., 2019). Although, Akers et al. (2019) found 166 overall uses of the GAF with working aged adults which contrasts with the low volume of studies focused on older people with BD. Study one did not find any evidence to

suggest that there is an existing validated measure that assesses the psychosocial functioning or quality of life of older people with BD.

Study two found that older people with BD were experiencing the same range of age-related issues as older people with other mental health problems. These included an increase in physical health problems, changes in cognition and issues such as losses, loneliness and isolation. There appeared to be an additional impact of having lived a life with BD, with individuals reporting more time as they got older to dwell upon events from the past, leading to a negative impact on their mood. These events related to situations that had being exacerbated by their behaviour in a mood episode (e.g., engaging in risky behaviour). Participants reported a change in their BD symptomatology over the years, with some reporting fewer episodes now they were older, whilst others reporting more, although shorter and milder. In general, the group reported more low mood than high in later life. This finding is consistent with previous literature indicating older people with BD were more likely to present with a depressive predominant polarity (Nivoli et al., 2014). The majority of the group also felt their episodes of mania were not as intense as when they were younger which corresponds with previous research indicating older adults with BD experience a decreased severity of manic symptoms (Chen et al., 2017). Participants held opposing views regarding the concept of recovery in later life, based on whether they saw it as a personal or a clinical concept. Individuals who held positive views about their recovery journey and were engaging in meaningful activities, felt their self-confidence and identity were intact. The group were positive about the development of a psychological intervention for the population and had very clear ideas about what they wanted from a therapist and what adaptions would be helpful to consider for RfT-OA. These were consistent with general guidelines developed specifically for working with an older adult client group (Laidlaw et al., 2016). The focus groups led to a number of different recommendations for delivering RfT-OA.

Study three examined the feasibility and acceptability of RfT-OA. The study found that it was possible to recruit older adults with BD from both a clinician and self-referral route. Once recruited, the majority of people consented and were randomised to take part in the trial. Retention to follow-up was strong and balanced across both arms which compared positively with previous BD and older adult trials (e.g. Jones et al., 2015, Jones et al., 2018, Laidlaw et al., 2008). Participants demonstrated a significant commitment to therapy, with 89% of the sample attending six or more sessions and 68% attending 14/14 sessions offered. The qualitative data demonstrated that participants found RfT-OA acceptable and they highlighted the positive impact on lifestyle, family and work relationships. They appeared to value both the recovery approach and learning new strategies to manage their emotions in a different way. Findings

from the qualitative interviews corresponded with high client ratings of therapy usefulness and whether they would recommend RfT-OA to a friend. The trial was not powered to test intervention effectiveness, however the assessment measures provided evidence for a signal of effectiveness on a range of outcomes including mood symptoms, time to relapse and functioning. In comparison to Jones et al. (2015), the trial did not find evidence for a clear signal on the Bipolar Recovery Questionnaire (BRQ; 2012). Scores increased in both groups (indicating improved personal recovery) at the 24-week follow-up. The scores were sustained in the intervention arm and decreased in the TAU group at the 48 weeks follow-up. The lack of clear signal was surprising as findings from the focus groups indicated that older people with BD wanted to work on areas of personal growth such as building assertiveness, confidence and competence which align with items on the BRQ. A project is underway now to find out whether the BRQ accurately describes individuals in later life's experiences and whether the measure captures what older adults with BD would like to see change during therapy. Overall, the results from the trial suggest that RfT-OA is feasible, acceptable and has the potential to be effective on a number of different outcomes, as demonstrated by both the quantitative and qualitative data.

7.2.1 Understanding the overall findings through a critical lens

A critical realist approach was adopted as it encourages a holistic exploration of phenomena, based on different research questions that use multiple research methods (Walsh & Evans, 2014). Mixed methods were employed to access different versions of the participants reality and provide a greater depth of understanding of the outcomes and why such events had occurred. In the focus group study, individuals reported mixed views about recovery. Using a critical realism lens allowed a deeper investigation into the mechanisms and a broader understanding of why this difference had occurred. Further exploration identified that some individuals had received negative messages in the past from health professionals and their ability to move on. Those who identified with a more 'personal' concept of recovery reported engaging in a range of meaningful activities and felt their self- identity and confidence were still intact. Those who identified with the traditional 'clinical' view of recovery, had received negative messages in the past about their ability to 'recover' in later life. They were less positive about their journey and questioned their ability to move on and change.

A critical realist approach was used in the RCT to help understand the influence of context on the effectiveness of the intervention. A critical realist approach to the RCT allowed a deeper understanding of the outcomes and to learn what works for some and not for others. From a

feasibility perspective, the qualitative data allowed the researcher to look at the mechanisms and understand why some people were not completing the assessment data. The interviews demonstrated that some people had a strong preference for face-to-face interviews. This finding may explain why some people did not complete the follow-up interviews over the telephone or complete the self-report measures on their own at home. This finding extends the feasibility data and will help for future planning for a definitive trial.

As discussed previously, one of the drawbacks of using an RCT design is that average effect sizes are reported across groups (Deaton & Cartwight, 2018) and therefore the subjective, individual experience can be missed. There are, however, often outliers which can provide a rich source of understanding. One of the original aims was to use qualitative techniques to explore the outliers and see why some individuals did not attend any sessions of therapy/ only attended a few sessions, with an aim of understanding why some people did not want to engage in the therapy. At the end of the trial, there was only one person that did not take up any sessions, one person attended four sessions and one person dropped out after six sessions. Unfortunately, these people declined taking part in the qualitative interviews and therefore the researcher was not able to gain insight into why certain individuals did not want to take part in the therapy, which would have been useful for a future trial. Most people that took part in the qualitative interviews had attended a high number of therapy sessions. One person took part who attended seven sessions out of the 14 sessions offered. Their experience of the intervention appeared to be significantly different to those who attended a high number of sessions of therapy. Those who attended a high number reported a positive impact on lifestyle, family and work relationships and appeared to value the recovery approach combined with strategies to manage mood. The person who attended seven sessions discussed how having marital issues at the time of therapy impacted on their ability to attend the sessions and feel any real benefit, which led to them to decide to terminate the sessions. This individual interpretation and context allowed a deeper understanding into the findings and offered insight into why they dropped out prior to the end of therapy.

7.2.2 Findings in relation to theory

7.2.2.1 BD related theory

Illness staging is widely used within healthcare to predict the course, prognosis and treatment response for a range of conditions (Berk et al., 2017). Staging models in BD are based on the premise that psychopathology follows a predictable course from an early 'at-risk' stage, to later, end-stage manifestations (Berk et al., 2017).

Research findings indicate that individuals with late-stage BD (there is no clear definition but proposed as individuals who have experienced 10 or more episodes, Magalhaes et al., 2012), are subject to poorer outcomes. These include higher levels of functional impairments and perceived stigma, increased risk of relapse and chronic depressive symptoms and impaired quality of life (Magalhaes et al., 2012). With regards to treatment response, Scott et al's (2006) CBT trial found individuals who experienced 12 or more episodes of BD predicated a negative response to CBT. Taking this into consideration, Murray et al. (2021) postulated that traditional symptom-focused interventions may be less beneficial for individuals with late-stage BD.

The majority of individuals taking part in study three had lived with BD for a significant number of years, placing them within the late-stage category. RfT-OA was designed to specifically take into account older adults complex needs and the impact of living with BD over a lifetime. RfT-OA offers the flexibility to work with a range of outcomes, compared to traditional approaches that have been focused on symptom eradication and cure. The findings from the trial indicate that RfT-OA offers a promising alternative for individuals living with later-stage BD, with a signal for effectiveness on a range on outcomes (Tyler et al., 2022). This contrasts with the findings from Scott et al's (2006) trial where individuals with late-stage BD experienced a negative response to CBT and is consistent with Murray et al. (2021) that focusing primarily on symptoms during therapy may not be the best way of supporting people at this stage.

7.2.2.2 Ageing related theory

The activity theory of aging (Havighurst, 1961) is based upon the premise that the more activity a person engages with, the better they age. The theory places emphasis on the importance of social activity and suggests that a person's self-concept is related to the roles they hold (e.g., retirement and a loss of work role isn't too harmful if a person maintains other familial, recreational or voluntary roles). In contrast to the activity theory, the disengagement theory of aging (Cummings and Henry, 1961) posits that successful aging involves a voluntary disengagement from the social roles present in adult life. Interestingly the results from the focus group study in this thesis provided support for the activity theory as individuals who had experienced negative changes within their social networks were struggling with their sense of identity. In contrast those who still had a voluntary job and were re-building their social networks felt they were either re-establishing or already had a solid sense of identity. Additionally, rather than 'disengaging' from society, individuals from the focus groups had a

strong sense of wanting to contribute to society and look for new opportunities following a lifetime of living with BD and transition into later life.

As discussed in the introduction chapter, in Freud's early work where he wrote about learning ceasing after the age of 50 (Freud, 1905/ 1953), may have contributed to negative societal stereotypes and over generalisations (e.g., too old to change). These pessimistic views alongside theories such as the loss-deficit theory of aging (Berezin, 1963) discussed previously may have hindered access to psychological therapies for older people with mental health difficulties. One of the original objectives of the RCT in study three was to identify whether older people with BD would self-refer and consent into a trial that offered tailored psychological therapy. The results indicate that far more individuals came into the study through self-referral than through the NHS clinical route, demonstrating a motivation to engage in the trial. Additionally, if eligible, the majority of older adults with BD consented to take part. Once randomised to the therapy group, the majority of people attended all of the therapy sessions offered. These findings indicate that older people with BD want the opportunity to engage with psychological therapy when offered. Additionally, individuals that were offered the therapy and took part in the qualitative interviews reported a range of positive lifestyle changes. These finding directly contrast with Freuds early work and indicate that change and learning are clearly possible during the later stages of life.

7.3 Strengths and limitations

The research has a number of different strengths and limitations. They have been presented throughout the chapters and will be summarised here. One of the significant strengths of the research is the use of mixed methods. This approach fitted well with the researcher's philosophical position as a critical realist and the overall aims of the study. The researcher had pre-existing knowledge regarding the presentation of BD in later life, what adaptations had been made in previous research studies for older people with other mental health conditions and the effectiveness of psychological interventions for younger cohorts with BD. The work was informed from the outset due to the researcher's existing knowledge, however there was limited research regarding the presentation of BD in later life and what psychological therapies may be acceptable and effective for this client group. The researcher designed a two-phase, exploratory mixed methods study so that qualitative data from the focus groups could be used to shape the intervention used in the trial. Mixed methods were also used to assess the feasibility and acceptability of the intervention, combining data from the quantitative measures with the data from the qualitative measures. This resulted in a deeper level of understanding of

the intervention and research processes and how this varied between different individuals and across different contexts from the people who were recruited.

Whilst mixed methods have many different advantages, they have been criticised by purists of either qualitative or quantitative approaches who believe that mixing the two paradigms should not be attempted as they draw upon different philosophical positions (Johnson and Onwuegbuzie, 2004). There is however a growing recognition that it is possible to draw on both approaches to maximise the strengths and reduce the weaknesses within a single study (Creswell & Plano Clark, 2011). As a result, social research methods and methodology text books now include distinct sections devoted to combining methods (e.g., Creswell, 2008 and Bryram, 2012), leading to mixed methods research being described as a "third methodology" (Tashakkori &Teddlie, 2010b).

Mixed method approaches have also been criticised as the researcher is required to have knowledge of the various research methods used and a working knowledge of the analytic procedures and tools related to both approaches (Bazely, 2004). This knowledge requires time, training and funding (Creswell & Plano Clark, 2011). Prior to starting the research, the researcher had a lot of experience analysing quantitative data but limited experience working with qualitative data. As the research was undertaken over seven years and a training and development plan was fully funded by the National Institute of Health Research (NIHR) as part of the Doctoral Fellowship Programme, the researcher had adequate time and funding to undertake training in qualitative methods. There was also the opportunity to access additional training in some of the quantitative elements that were specific to the trial (e.g., survival analysis). Additionally, the researcher supervisors were experienced in both approaches and were able to supervise the use of both methodologies. The researcher also had additional support from a statistician to supervise some of the more complex analysis for the trial data.

A strength of study one is the comprehensive and systematic search strategy used. The researcher attended a three-day course at the University of York's Centre for Reviews and Dissemination which offered an in-depth introduction to systematic reviews and evidence synthesis methods. Attendance on the course ensured that the researcher felt prepared to identify a suitable research question, use PICOS criteria as a systematic approach, develop and register a protocol on the PROSPERO database, develop a comprehensive search strategy, learn techniques for data extraction and synthesise the results from a search. This resulted in a high-quality systematic review, with all titles and abstracts double screened by two reviews and 33% double screened at the full text stage. Unfortunately, there were limited numbers of studies

using a quality of life or psychosocial functioning measure and therefore the pooled analyses and means must be interpreted with caution due to the relatively small sample sizes.

The main strength of study two is the involvement of individuals with lived experience of BD in later life. As there were limited studies focused on developing psychological interventions for older people with BD, the researcher was interested in finding out individual's subjective accounts of their experiences of living with BD in later life and their feedback on the acceptability of the intervention. To the researcher's knowledge, this is the first study to involve older people with BD to help shape a psychological intervention specifically for their cohort. This approach fits with the underlying principles of recovery within mental health care which places emphasis on taking control of one's own life, developing individual coping strategies and actively working to maintain wellbeing, rather than being a passive recipient of professional healthcare (Owens et al., 2011). There are numerous benefits of involving service users in research including the empowerment of individuals with lived experience and the improvement on the quality, relevance and acceptability of the findings (Boote et al., 2002; Entwistle et al., 1998). However, there have been widespread concerns that patient and public involvement remains tokenistic in nature rather than really valuing service user input and involvement (Domecq et al, 2014). The researcher aimed to promote collaborative, active engagement during the focus groups and work with individuals with lived experience as equals. On reflection, service users were not involved in all of the aspects of the decision making regarding the final intervention offered during study three. Separate meetings took place with the research team to finalise adaptions to the original RfT intervention and tasks such as literature searches were undertaken by the researcher alone. On reflection, service user involvement should have been present at all stages of the intervention design.

One of the biggest challenges of running the focus groups was the participant attendance. The original aim was to run three separate focus groups with the same group of individuals. The researcher wanted to explore the different research questions in group one and two, then revisit the original questions in group three until a clear pattern emerged and theoretical saturation was achieved (Krueger, 1994). In reality, this was not achievable as individuals were not able to attend all three groups due to various commitments. This resulted in three different groups of individuals for each focus group with each participant having the opportunity to express their ideas on each of the original research questions. Additional focus groups with all participants in attendance would have been helpful to ensure that a clear pattern was emerging.

Sampling bias is a limitation of both study two and study three. All of the participants who took part in study two were recruited through the Spectrum Connect database and self-referred into the study. This is a confidential database of individuals who have signed up to take part in any future research studies of interest. This may have resulted in a highly motivated sample and all but one of the participants had retired from a professional working background. This is a constraint of the study and therefore the clinical recommendations developed from the focus groups may not encompass a diverse range of perspectives due to the relatively small sample size and the potential homogeneity of the participants. However, taking this into consideration, RfT-OA was also developed using the clinical recommendations alongside both relevant literature in relation to adapting psychological therapies for older adults and expert experience to try to mitigate this limitation.

With regards to potential sampling bias in study three, significantly more individuals self-referred (n=73), compared to via the clinical route (n=17) in study three. This resulted in 29/ 39 self-referred participants randomised to take part in the trial. The majority of the self-referred participants were not part of secondary mental health services and were managed solely by their GPs, which may have led to a higher functioning sample being recruited compared to previous BD intervention studies. In a future, definitive trial, a well-resourced research team would be prepared to build stronger links with clinical teams and ensure a more balanced recruitment strategy.

All of the participants taking part in study two were White British and all in study three were White, with 38/39, White British, living in the north-west of England. The results from both studies may not be generalisable to individuals from different backgrounds and cultures. This is a major limitation of the research as most modern psychotherapies, including CBT are underpinned by European-American values (Naeem et al., 2019; Stone et al., 2018). CBT for example involves exploring and modifying core beliefs, however these can vary across cultures (Tam et al., 2007). Our cultural and sub-cultural background can also influence beliefs about well-being, causes of mental health problems and help-seeking behaviours (Altweck et al., 2015; Hagmayer & Engelmann, 2014). An individual from a different cultural background therefore may have a different experience of living with BD in later life and may have different ideas about the type of help they want to manage their condition compared to a person from a White British background.

It was not feasible to employ a blinded research assistant to carry out the assessment and follow-ups as the research was funded via a personal award from the NIHR. As the main aims of

the trial were to explore the acceptability and feasibility of RfT-OA, testing procedures and investigating recruitment and retention rates, this was not considered to be an important factor relating to these outcomes. The researcher was aware of the allocation of research participants and therefore there may have been interviewer bias in relation to the completion of the outcome measures. Empirical evidence suggests that blinding in trials does make a difference (Karanicola et al., 2010). Schulz et al. (1998) found a significant difference in the size of the estimated treatment effect between trials that reported "double blinding" compared to those that did not ($p = 0.01$). Additionally, the researcher delivered the majority of the therapy during the trial and therefore the participants may have been subject to acquiescence bias. The Likert rating scales and the WAI (Tracey & Kokotovic, 1989) did include an equal ratio of positively and negatively framed items though and this may have reduced the opportunity for individuals to respond without considering the content (Krosnick, 1999).

Finally, the use of the Structured Clinical Interview for DSM-5, research version (SCID-5-RV; First et al., 2015) is both a strength and a limitation of study three. Diagnostic manuals such as the DSM-5 and the ICD-10 (World Health Organisation, 1993) were created to provide a definitive list of mental health conditions and provide a common language for mental health professionals. As discussed in the methodology chapter, diagnosis can provide a helpful framework for a person to navigate and understand their difficulties. However, a diagnosis sometimes does not fully fit a person's experiences and can lead to confusion and a person feeling labelled and stigmatised. There is also considerable heterogeneity in a wide range of psychiatric diagnoses, with two people receiving the same diagnosis without sharing any symptoms in common (Allsopp et al., 2019). The DSM-5 was used in study three to confirm whether individuals met criteria for the study. This included having a diagnosis of BD and their mood being stable at the time of the baseline interview. Individuals taking part in the study may have had very different experiences of living with BD, presented with different symptoms and still met criteria. The cut off for whether a person is in episode is also arbitrary, with 14 days for a depression episode and 7 days for a manic. A person may have had depressive or manic symptoms for a few days at the time of the baseline interview, however still met criteria for the study. Following the baseline interview, their symptoms may have exacerbated, leading them to experience a full-blown episode which may have potentially affected their response to the therapy and subsequent outcome measures.

7.4 Recommendations for clinical practice

The research highlights a number of recommendations for clinical practice:

1. International action plans focused on aging highlight the importance of improving quality of life for people as they age (World Health Organisation, 2015; Tesch-Roemer, 2012; Malva & Bousquet, 2016). It has also been argued that functional outcomes are more meaningful measures of response to treatment for individuals with BD compared to psychiatric rating scales (Keck, 2004). Clinicians working with older people with BD should be routinely measuring outcomes such as quality of life and functioning. Findings from the systematic review indicate that older people with BD demonstrate significant variability on these measures. Individuals scoring higher on the measures may provide some insight into the factors that influence superior functioning and quality of life and help shape effective therapeutic interventions for those scoring lower on the scales.
2. Clinicians working with older people with BD should explore the person's concept of recovery and whether this is aligned with the traditional 'clinical' view or a personal view. Findings from study two indicate that this can impact on a person's perception of their ability to make changes.
3. Older people with BD may experience a decline in their cognitive functioning, even whilst not in a mood episode. Clinicians working with older people with BD should use strategies such as repetition and association, writing summaries at the end of each session and revisit at the beginning of the next as identified by participants during study two.
4. The prevalence of visual impairment or hearing loss increases with age (Liu et al., 2021). Clinicians should use clear and simple language and make study materials accessible and visually interesting. Clinicians should also consider using images, films or audio recordings as a way of enhancing the therapeutic experience as highlighted by participants in study two.
5. Clinicians should spend time building relationships with older people with BD and allow more time to explore a longer and potentially more complex history as highlighted by participants in study two. Clinicians should be aware of the range of health-related and age-related changes that can occur in later life and the impact this may have on the person's symptom presentation as reported in study two.
6. Clinicians should treat older people with dignity and respect and develop a shared understanding of the wealth of experience the older person with BD brings to the therapeutic relationship. Nurturing the resilience and wisdom developed as a product

of coping with adverse circumstances should be a priority for therapy, as highlighted by participants in study two and consistent with Knight and Laidlaw's (2009) work with depressed older people.

7. Clinicians should support pre-existing strengths and identity areas such as assertiveness, confidence and competence building to manage BD related experiences as highlighted by participants in study two.
8. Psychological interventions for older people with BD should be designed and delivered, focusing on a range of outcomes, not solely clinical remission. Study three was not powered to test the intervention effectiveness, however there was a signal for a range of outcomes including mood symptoms, time to relapse and functioning.
9. Clinicians should encourage older people to take up opportunities such as taking part in research. Significantly more older adults self-referred into the trial compared to the clinician route which highlights a potential barrier and conflicts with a personal recovery approach where individuals are encouraged not to be passive recipients of their healthcare.
10. If clinicians choose to use outcome measures with older people with BD, they should consider filling out the measures in session rather than sending home as retention rates were higher for observer rated measures compared to the postal, self-report measures.

7.5 Recommendations for future research

The research presented in the thesis provides the foundation for a number of future research areas:

1. The systematic review conducted during study one did not find any evidence for an existing validated measure of psychosocial functioning or quality of life for older people with BD. There are existing measures that have been developed in conjunction with service users living with BD for a working age population such as the Bipolar Recovery Questionnaire (Jones et al., 2012) and the Quality of Life in Bipolar Disorder (QoL.BD) scale (Michalak and Murray., 2010). To the author's knowledge there is no existing measure developed specifically for older people with BD. Such as tool should be developed for future research with the population.
2. Further exploration of the themes identified in study two during the focus groups such as the experience of aging with BD and impact on symptoms and the concept of recovery in later life. This could be achieved using a mixed methods approach, for example

combining semi-structured interviews and questionnaire measures to provide a deeper level of understanding.

3. A study recruiting older people with BD from different cultural backgrounds and investigating the experience of ageing with BD and the type of help wanted to manage their condition in later life. This could be achieved using semi-structured interviews or focus group methodology.
4. Further consultation with older people living with BD is needed to identify an appropriate, meaningful outcome measure for a definitive trial.
5. A large-scale survey study recruiting individuals with BD across the older adult age span to explore functioning, quality of life and recovery. The results might indicate patterns within particular groups (e.g., age group, type of BD, course of BD) that relate to levels of functioning, quality of life and recovery.
6. A definitive trial comparing RfT-OA to treatment as usual is now warranted to provide a robust estimate of the clinical and cost effectiveness of RfT-OA and to provide an important step for a group of individuals who, at present, do not have access to evidence-based psychological care.

7.6 Final remarks

Older people have been subject to pessimism and stereotypes such as they are "too old to change". This may have hampered the development of psychological interventions for this population. The research presented in the thesis has demonstrated the significant difference in the amount of research and service use development focused on younger people compared to an older adult population. The research presents the first randomised controlled trial designed specifically for older people with BD, developed in conjunction with service users living with the condition. The findings largely support the feasibility and acceptability of a recovery focused psychological intervention for older people with BD. These findings represent an important step for a group of individuals, who at present, do not have access to evidence based psychological care.

8.1 Appendices

Appendix A

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Citation

Elizabeth Tyler, Steven Jones, Fiona Lobban, Bogdan Hadarag. A systematic review of psychological functioning and quality of life in people with later life bipolar disorder. PROSPERO 2020 CRD42020200169 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020200169

Review question

• What measures have been used to assess quality of life and psychosocial functioning in older adults with bipolar disorder?

• What is the distribution of psychosocial functioning and quality of life scores for older people with bipolar disorder?

Searches

The searches will be run in; MEDLINE, Psych-Info, AMED and CINAHL

Limiters will be set to include papers published in the English language, journal articles and human subjects only.

Group A

"bi polar" OR "bi-polar" OR bipolar OR "mania*" OR "hypomani*" OR "mood disorder*" OR "mood disturbance*" OR "mood swing*" OR "affective disorder*" OR "affective illness*"

This group will also be combined with the appropriate subject headings/MeSH headings in each database.

Group B

"older adult" OR "older person" OR "old age" OR "elderly" OR "elderly person" OR "senior" OR "geriatric*" OR "retire*" OR "pension*" OR "over 50" OR "older adult" OR "older person" OR "old age" OR "elderly" OR "elderly person" OR "senior" OR "geriatric*" OR "retire*" OR "pension*"

This group will also be combined with the appropriate subject headings/MeSH headings in each database.

Group C

"psycho social" OR "psycho-social" OR "psychosocial" OR "psychological functioning" OR "social functioning"

This group will also be combined with the appropriate subject headings/MeSH headings in each database.

Group D

"health-related quality of life" OR health related quality of life" OR "quality of life measure" OR "QOL"

This group will also be combined with the appropriate subject headings/MeSH headings in each database.

The search method will be as follows: Group A AND Group B AND Group C OR Group A AND Group B AND Group C

Types of study to be included

Inclusion Criteria:

• The study is published in a peer reviewed journal

• The study includes a quantitative measure of psychosocial functioning or quality of life

• Case control, cohort, cross-sectional and epidemiological studies will be included

• RCT studies will be included when they have published baseline data

• Studies written in the English language. Unfortunately, this review does have the resources to facilitate the translation of journal articles.

Exclusion Criteria:

• The study only reports qualitative data

• Editorials, comments, letters to the editor, book chapters, case series, and dissertations/theses (i.e. grey literature) will not be included in this review

Condition or domain being studied

The review focuses on studies that have used a quantitative measure of psychosocial functioning or quality of life in a sample of people over the age of 50 with a diagnosis of bipolar disorder.

Participants/population

Inclusion Criteria:

• The study includes a sample of individuals diagnosed with BD I or II with a formal diagnosis according to Diagnostic and Statistical Manual (DSM-III, DSM-IIIR, DSM-IV, DSM-IV-TR & DSM-V) or the International Classification of Diseases (ICD-9 or ICD-10).

• The study includes a sample of people with mixed diagnoses where the scores for individuals with BD are reported separately.

• The study includes individuals with BD who are 50 years or older.

• The study includes a sample of individuals with BD with mixed ages where the scores for those who are 50 years or older are reported separately.

Exclusion Criteria:

• The study sample does not have a diagnosis of BD

• The study sample is below the age of 50 years

• The study sample has mixed diagnoses and it is not possible to separate the scores of those with BD from the other diagnoses

• The study sample has mixed ages and it is not possible to separate the scores of those who are 50 years or older from the other age ranges

• The BD sample has a comorbidity that directly affects their cognitive functioning (e.g. dementia, brain damage or a learning difficulty).

Intervention(s), exposure(s)

Inclusion criteria:

• A quantitative measure of psychosocial functioning was used

• A quantitative measure of psychological functioning was used

• A quantitative measure of social functioning was used

• A quantitative measure of general functioning was used that focuses on psychosocial functioning

• A quantitative measure of quality of life was used

Exclusion criteria:

• No measure of psychosocial functioning was used

• No measure of quality of life was used

• The measure used in the study was assessing a type of functioning that was not relevant; e.g. cognitive functioning or executive functioning.

Comparator(s)/control
Not applicable

Main outcome(s)
To identify the measures that have been used to assess psychosocial functioning and quality of life in people over the age of 50 with BD.

To describe the distribution of psychosocial functioning and quality of life scores for older people with BD.

Measures of effect

Not applicable

Additional outcome(s)
None.

Measures of effect

Not applicable.

Data extraction (selection and coding) [1 change]

Results from the electronic searches in the databases MEDLINE, PsycINFO, AMED and CINAHL will be imported into Endnote. After deleting duplicates, the study titles, abstracts and full text articles will be searched by two independent reviewers for inclusion in the review. Studies included for analysis in the review will meet the criteria specified in questions 19, 20 and 22. Any disagreement in study selection will be resolved through discussion and consensus or by consulting a third reviewer.

Extracted information will include; type of study, study sample (e.g. age range, diagnosis, setting), the specific measure of psychological functioning or quality of life, the mean and/or median, standard deviation and/or range of scores. Data extraction will be verified by a second reviewer.

Risk of bias (quality) assessment
An appropriate tool will be identified depending on the type of study (e.g. cross-sectional, cohort, case-control) using the guidance from Ma et al (2020). The reviewers will independently assess the risk of bias and study quality. Disagreements between the two reviewers will be resolved through discussion and consensus.

Strategy for data synthesis [1 change]

Data synthesis will be conducted to identify the distribution of psychological functioning or quality of life across studies. The mean and/or median, standard deviation and/or range of scores from each included study sample will be extracted from the papers. Where studies have used the same measure of psychological functioning or quality of life, the means / median and standard deviation / range of scores will entered into SPSS. A mean/ median and standard deviation / range of scores will be calculated for each of these measures. The information will be displayed in a table and a narrative summary of the distribution of scores will be reported.

Analysis of subgroups or subsets
Not applicable

Contact details for further information
Dr Elizabeth Tyler
e.tyler@lancaster.ac.uk

Organisational affiliation of the review
Spectrum Centre for Mental Health, Division of Health, Lancaster University.

Review team members and their organisational affiliations
Dr Elizabeth Tyler. Spectrum Centre for Mental Health, Division of Health, Lancaster University
Professor Steven Jones. Spectrum Centre for Mental Health, Division of Health, Lancaster University.
Professor Fiona Lobban. Spectrum Centre for Mental Health, Division of Health, Lancaster University.
Mr Bogdan Hadarag. Lancaster University

Type and method of review
Narrative synthesis, Systematic review

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State the funder, grant or award number and the date of award

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Conflicts of interest

Language
English

Country
England

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Bipolar Disorder; Humans; Quality of Life

Date of registration in PROSPERO

18 August 2020

Date of first submission
21 July 2020

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.
The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
18 August 2020

Appendix B

Extraction using PICOS	Data items	Study
Patient	Number of participants Diagnosis of participants (including diagnostic tool used) Mean/ Median age of participants Current mood state (if reported) Gender split of participants	
Intervention	Brief description of intervention (if applicable)	
Comparator	Brief details of comparators and/ or controls (if applicable)	
Outcomes	Psychosocial functioning or quality of life measure used Mean/ Median and SD/ range of scores on measure	
Study design	Study title Study authors Year of publication Study aims Study location Study design	

Appendix C

Standards for Reporting Qualitative Research (SRQR)

http://www.equator-network.org/reporting-guidelines/srqr/

Title and abstract

	Page
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	2

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	4
Purpose or research question - Purpose of the study and specific objectives or questions	4 & 5

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	5
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	8
Context - Setting/site and salient contextual factors; rationale**	7
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	5 & 6
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	6, 7 & 8

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	6 & 7
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	8 & 9
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	7 & 8
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	7 & 8
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	7 & 8

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	10 - 23
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	10 -23 & supplementary quote table

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	21- 25
Limitations - Trustworthiness and limitations of findings	3 & 26

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	27
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	27

Appendix D

Version 1. 08/01/2015

Health Research | Lancaster University

Participant Information Sheet
Part 1

Title of project: Recovery focused therapy for older adults with bipolar disorder

We are inviting you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the aim of the study?

There has been very little research or service development for older adults with bipolar disorder particularly with respect to psychological therapies. However a recent RCT study from our group has shown a recovery focused CBT intervention (RfCBT) for individuals with BD (below 65 years) is beneficial in terms of both functional and symptomatic outcomes (Jones et al, 2014). The aim of this study is to design a recovery focused cognitive behavioural therapy manual for individuals over the age of 60 who are living with bipolar disorder. This will be achieved through adapting the intervention that was used for individuals under the age of 65. We would like to get input from individuals who are living with bipolar disorder in later life on how best to adapt it.

Why have I been chosen?

You have been chosen because you are either a person living with bipolar disorder in later life or you are relative of someone who has bipolar in later life.

Do I have to take part

No. It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at anytime without giving a reason. If you decide not to take part, or to withdraw from the study, it will not affect the standard of care you or your relative receives.

What does taking part involve?

We would like to invite you to take part in a focus group in which a group of individuals with bipolar and their relatives will come together to discuss (i) any previous experiences of psychological interventions for bipolar disorder, (ii) the concept of recovery, (iii) the recovery focused therapeutic

approach, (iv) commenting on the draft manual, including the acceptability for the client group (v) commenting on the mode of therapy delivery (e.g. timings, frequency and number of sessions, (vi) perceived barriers to using the package.

The group session will be recorded onto audio tape with your consent so that we can listen to the discussion again and make sure we have all the important points. However, you can ask for us to stop, replay and edit the tape at any stage. The recordings will be destroyed immediately after analysis. The group will take about 90 minutes in total, but can be done at your own pace. You have the chance to take breaks and ask questions throughout.

At the end of the group you will be given the opportunity to be part of a reference group that will comment on the ongoing development of the intervention to ensure that it is useful for relatives. You do not have to decide at this stage if you want to do this.

Will my taking part be kept confidential?

All information will be kept confidential unless there is any risk of harm to yourself or someone else, in which case the researcher has a duty to report this. Data management will conform to the 'Data Protection Act of 1998' with respect to data collection, storage and destruction. Any information about the group which leaves the hospital or elsewhere, will have your name and address removed, so that you cannot be recognised from it.

What are the possible risks of the study?

There is no reason to suspect that taking part in the study will cause you any harm.

What are the possible benefits of the study?

Taking part in this study may not benefit you personally. However, we hope the information we gain will allow us to design a psychological intervention that will help indivudals living with bipolar disorder in later life in the future.

What happens to the results of the research?

We expect to use the results of the study to design the recovery focused intervention. Also, we expect the findings to be published in psychological journals. If you would like more detailed information about the results, these will be made available to you directly.

Who is organising and funding the research?

The research has been funded by the National Institute for Health Research and is sponsored by Lancaster University.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by XXX

Contact for further information

If you have any concerns or questions about the study, please feel free to contact Dr Elizabeth Tyler on telephone number 01524 593171

Dr. Elizabeth Tyler
Spectrum Centre for Mental Health Research
Institute for Health Research
Lancaster University
LA14YT
e.tyler@lancaster.ac.uk

ndix E

CONSENT FORM

Recovery Focused Therapy for Older Adults with Bipolar Disorder Focus Groups

REC ref:

Name of Researcher: _____

Name of Participant: _____

Participant Number ☐☐☐☐☐☐

Please initial box

1. I confirm that I have read and understood the information sheet version number 1.0 dated 15/01/2015 for the above study and have had the opportunity to ask questions and have my questions answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from the study within 2 weeks of completing the interview, without giving any reason, and without my medical care or legal rights being affected. ☐

3. I give permission for the focus group to be recorded and transcribed so researchers can listen and identify common themes. ☐

4. I give permission for the research team to collect, store, analyse and publish information obtained from my participation in this study with the understanding that my personal details will be kept confidential and all data published will be anonymous. ☐

5. I give permission for my direct, anonymised quotations to be used if required to illustrate study findings in research publications. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (If different from Principal Investigator)	Date	Signature
_____	_____	_____
Name of Principal Investigator	Date	Signature

Appendix F

Focus group topics and content

Focus group 1

1. Icebreaker

Focus group 1 started with an icebreaker (participants went around the room introducing themselves and telling the group an interesting fact about themselves).

2. Recovery approach introduced

The recovery approach was introduced and handed out on a piece of paper, defined as:

"Recovery is being able to live a meaningful and satisfying life, as defined by each person, in the presence or absence of symptoms. It is about having control over and input into your own life. Each individual's recovery, like his or her experience of the mental health problems or illness, is a unique and deeply personal process." (Scottish Recovery Network)

Participants were asked to comment on:

- their thoughts about this quote
- the term 'recovery'
- what recovery meant to them in later life

3. Experience of living with bipolar disorder in later life

Participants were asked to talk about their experience of living with bipolar disorder in later life.

4. Ways of coping with bipolar disorder in later life

Participants were asked about different ways of coping with the condition (including support from relatives and health professionals) in later life.

Focus group 2

1. Introductions

Focus group 2 started with everyone introducing themselves again, with the chance for new participants to tell an interesting fact about themselves.

2. Introducing recovery focused CBT and the stages of therapy

Recovery focused CBT therapy was introduced to the participants and the stages of therapy were discussed:

1. Introducing the recovery approach to clients;
2. Collection of information about current and historical mood and functioning;
3. Meaning and relevance of diagnosis;

4. Identification of recovery-informed therapy goals;
5. Initial formulation of relationships between mood experiences and progress towards recovery goals;
6. Identification and application of CBT techniques to address and facilitate positive coping;
7. Consideration of wider functioning issues in relation to recovery;
8. Development and completion of early warning signs (EWS) plan;
9. Development and completion of recovery plan;
10. Sharing lessons from therapy with key stakeholders.

Participants were asked to comment on:

- whether they thought the approach would be helpful with older adults
- what the strengths and weaknesses of the approach were
- what modifications (if any) would be needed for an older population

2. Session structure

Participants were told that the intervention would be delivered in one-to-one sessions and asked:

- what else might be important to include in therapy sessions for older people
- what might make therapy more accessible and effective for older people

3. Experience of therapy

Participants were asked to comment:

- if they had experience of receiving psychological therapy
- what they had found helpful/ unhelpful when accessing care and support (e.g. CPN, psychiatrist, therapist, relative) in the past
- what help they would want in the future

Focus group 3

1.Introductions

Focus group 3 started with everyone introducing themselves again.

2. Topics

All of the topics above were re-visited in focus group 3 so the three participants who hadn't attended 1 or 2 were able to share their ideas.

Appendix G

Theme	Example quotes
Health and age-related changes in later life	"My concentration isn't very good and the sorts of books I read are different. I can't read anything particularly frightening" "I'm a bit slower but yeah, my memory is OK but like as soon as I get depressed, I get even worse" "When my moods alright so it's slightly elevated, I am … on the ball. I can remember anything…as soon as my mood starts to dip then I start to not…I can't remember what I did the day before" "I think my mood has an effect on my memory…it just gets hard as you get older" "Just my ability to remember things. It's in a limited way now. I put it down to the medication" "I think the only thing I actually do is to listen to the radio and read a certain amount" "We get fed up and we get frustrated and all those things because we can't do what we did" "As you get older there's a lot more…quite often you've got more health issues you've got to deal with...those things can isolate XXX quite a lot. So, when she feels more isolated it can affect mood" "Family members go and social situations change and health deteriorates" "Family structure does change…it's partly what upsets me, I suppose, when I'm in a low. You know, you look back...how many friends and how many family…have gone and you think Christ, you know, I'm the only one here. You don't expect to be the last one."

	"Such a lot gone. And you just think I miss some of them around me and I must get what I want to do done" "The peer thing reduces when you get older... I think the thing that loses, if you get a good peer situation, your identity…when your older, there's a little bit of a problem trying to find your identity". "You're lonely and perhaps not as sharp as you were. So maybe it's a little bit more difficult…maybe we want it but how do we go about it. How do I go about getting involved back in life again"
Experience of BD in later life	"I found that with my manic episodes it's taken me less time to get stable again as the years have gone by. So whether that's an indication that in later life that they will be able to recover quicker and they're not as severe, I don't know." "It counts up to about eight whereas before it went up to nine" "I'm mostly downers. Well if I get in the middle of a picture I'm painting and I'm like enjoying it, I get a high because it's made me really happy…but most of it…I go quiet" "As the depressions have got worse everything pretty much shuts down and I'm depressed" "When I'm on a high I feel like my minds looking up…but when I'm down, I feel like my mind's closed" "I think it loses itself because you can't do the things you did…I do sometimes, and I'm sure everyone does, feels as if well, who am I now? What have I got to contribute?" "Launching yourself out was no problem when you're young, you know, because confidence"

	"You've got to believe in yourself and you have low self-esteem when you've got bipolar. And people think because you are mentally ill…you need you need to be treated differently" "I've got bipolar but I don't go telling other people because I know that, particularly my age group…if you're got to declare a mental illness, it's like well you're not one of them" "It may be that...my psychological problems are sort of focused around get worse as they don't get solved or accepted all the time" "Coming to terms with events that have happened, and you can't understand why that happened and why you did that and why you did this. And with all the embarrassment to cope with" "Yeah, it's regret. Wishing that I'd been, behaved differently or treated somebody differently and that" "If you're doing something that doesn't require a lot of concentration, these things come back to the mind" "I think what's made a difference for my, for my mistakes is that I do have a living faith in God whom I can turn" "What you've got to remember is that if you've got bipolar all your life you've got secrets…you've got personal secrets" "And she kind of knows what she needs to do but there's a greater sense of hopelessness which might be just to do with less life span"
Managing and coping with BD in later life	"There's also been a change in, from my limited experience, that the medications seem to be only a, you know, pop a few pills.... that was the limit of it a while ago but there seems to be other areas being examined ...for example what you are doing"

	"I personally am terrified about what the medication – all the medication I'm on is going to do to me twenty years down the line... what effect it's going to have on my brain" "As you grow older you don't need the amount of medication that you had when you were younger" "Because of the medication being a lot more stable...Ive been able to undertake duties" "I'm able to stabilise myself, sort of consciously change, lifestyle changes, depending on what mood I'm in... act on it quickly and so that I can reach a level ground again" "I think it's a case of learning the illness and being able to manage the illness" "I've painted a lot of pictures which is of course therapeutic" "I think we are capable of doing an awful lot that people think we can't do and therefore we tend to play down our expectations and don't achieve our full potential...if people encourage us, it's surprising wheat we can achieve". "It's about setting out the right goals as well...what older people might be capable of and talking about the sort of things that might be in our own heads individually and whether they are achievable". "If you're having a good weeding session on the allotment, you're concentrating on what you're doing but if you're doing something that doesn't require a lot of concentration, these things come back to mind". "I actually need to be doing at least two things to have a chance of distracting myself. So one way I get through the day when I'm low is to have the radio on but I'm also reading something"

	"I'm in charge of health and safety... and it, well it keeps me mind occupied doesn't it? "I would expect health professionals to help you to bond to that community. I would expect them to know what is available to you, to signpost you" "As you get older you get more assertive with your professionals" "There is a difference now that the professionals treat me with respect and they ask my opinion and how often I want to see them" "The younger doctors that I've had dealings with have been brilliant – they've been entirely professional but they've also been informal" We're still fighting professionals who don't believe that we're capable of what we truly are and so we don't realise our full potential" "A lot of older people they often had a partner that's helped kind of co-helped them co-manage the illness. And when that partner goes, so when my relative died... I didn't realise at the time but he helped modify" "I've got a friend now...she phones me up in the morning at eight o'clock and says, how are you and we can be honest with one another"
Experience of recovery in later life	"This recovery we're just talking about... It's something that I look beyond the horizon" "I think the word recovery... you aim for recovery...I think it should be called stability, not recovery" "I don't think you ever recover...you manage it"

	"Recovery for my therapy team was for me not to go back into hospital... But for me recovery was I really wanted to get another job. It was really important to me" "I'm not sure at my age just to what degree I can move on really as time is flying by… I've been told you can never recover from bipolar" "There is a great difficulty with the word recovery with professionals in the past by they are coming round" "I'm a member of various organisations...I've got an activity every single day to do. And this helps... I'm out and about and I'm mixing with people and this helps enormously". "I think It's possible to be recovered and I reckon that I am recovered now...I have the right medication...and I self-manage. I have a healthy lifestyle and I meet a lot of people" "I've still got a life to live...I can meaningfully contribute to society" "I want to move on from this. There's something better than this. If we haven't got hope, we're just going to wallow" "You wouldn't want to recover if you didn't have hope"
Seeking help in the future	"I was thinking of having time round the therapy... having more time with an old person, sort of fifteen minutes before and fifteen minutes after... just being human together because it's hard doing therapy anyway" "It's about having that personal relationship. It takes two or three sessions to get the confidence" "I think as you get older, you perhaps become quicker at knowing whether you're going to click with somebody" "And we're not as impressable"

	"We can't be fooled too easily, can we?" "They need to have listening skills. They need to be adapting body language and tone of voice and pitch of voice. They need to be empathic. And they need to be aware of the sort of problems that we face. And they need to get to the cause" "You could raise the gender thing as an explicit issue... find out whether the client has any issues about the gender of the therapist" "The therapist should try to make you feel assertive. Train you to be assertive" "It's part of the therapist's duty to give you higher autonomy and assertiveness so you can fight your corner in a non-aggressive way but one that is assertive" "Therapy focused partly on older age needs to help people to improve competence in whatever area they wanted" "I think that could be a bit of a stumbling block for older people to be able to talk to younger people"
Adapting RfCBT for older people	"I think the idea of fifty minutes is partly that you can have a little bit of chant, you know, at the beginning. Sort of hello, how are you". "When you get older, you know, with sight and problems and hearing problems you just need more resources...things written down... sort of more back up" "She can't take lots of information in really quickly. So more time. Writing things down. Get her to write it down" "Can you break it down...into simple clear language" "Some large sort of text...if it's complicated it could be simplified"

	"You need to use more images" "It's more interesting to kind of ...engage with and it's easy to kind of, like you said about remembering things you have something to hang on to" "I think a video would be extremely useful...then you can … a disk that you can put in computer and you could watch on the screen an instruction" "If you have it once a fortnight, you've time to put into practice what's been said and what's been taught" "It's quite useful to have a gap...you've learnt some practical strategies...then you've had time to practice on your own...without the weekly backup" "The idea of a short-ish course and then maybe going back in"

Appendix H

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	4
	4c	How participants were identified and consented	4 & 5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	3
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	6, 10 & 11 (Table 2)
Sample size	7a	Rationale for numbers in the pilot trial	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	4
Allocation concealment	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	4

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	6 & 7
Results			
Participant flow (a diagram is strongly recommended)	13a	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	9 (Figure 1) & 10
	13b	For each group, losses and exclusions after randomisation, together with reasons	9 (Figure 1)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8 (Table 1)
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	8, 13, 14 & 15
Outcomes and estimation	17	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	15 (Table 3) and supplementary file 4
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Supplementary 4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	2 & 10
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	17
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	17
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	16 & 17
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	16 & 17
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3

Protocol	24	Where the pilot trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25
	26	Ethical approval or approval by research review committee, confirmed with reference number	3

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix I

Recovery Focused Therapy for Older Adults with Bipolar Disorder

★ Are you over the age of **60?**

★ Have you been diagnosed with **Bipolar Disorder?**

★ Do you live in the **North-West?**

Would you like the opportunity to take part in a study with the **potential** to receive up to six months of individual, recovery focused psychological therapy with a trained professional?

The Spectrum Centre for Mental Health Research, Lancaster University is conducting a study that may be of interest to you.

★ 25 people over the age of 60 with bipolar disorder will be offered a recovery focused CBT intervention for 6 months alongside current treatment.
★ We will compare their outcomes with 25 people who continued with their treatment as usual.
★ Both groups will be followed up for a 12 month period and asked to complete some telephone interviews and questionnaires.

WE ARE RECRUITING NOW! PLEASE CONTACT US USING THE DETAILS BELOW

Email
e.tyler@lancaster.ac.uk

Post
The Spectrum Centre
Division of Health Research
Lancaster University
Lancaster LA1 4YT

Phone 07967 837938

Website
www.spectrumcentre.org

THE SPECTRUM CENTRE

NHS
Greater Manchester Mental Health
NHS Foundation Trust

Lancashire Care NHS
NHS Foundation Trust

Health Research | Lancaster University

Recovery Focused Therapy for Older Adults with Bipolar Disorder

- ★ Have you been diagnosed with **bipolar disorder?**
- ★ Are you over the age of **60?**
- ★ Would you like the opportunity to take part in a study with the potential to receive up to six months of individual, recovery focused therapy?

The Spectrum Centre for Mental Health is running a study that may interest you

RECRUTING NOW! PLEASE CONTACT US USING THE DETAILS BELOW

Email
e.tyler@lancaster.ac.uk

Post
The Spectrum Centre
Division of Health Research
Lancaster University
Lancaster LA1 4YT

Phone
07967 837938

Website
www.spectrumcentre.org

Greater Manchester Mental Health NHS Foundation Trust

Lancashire Care NHS Foundation Trust

Health Research | Lancaster University

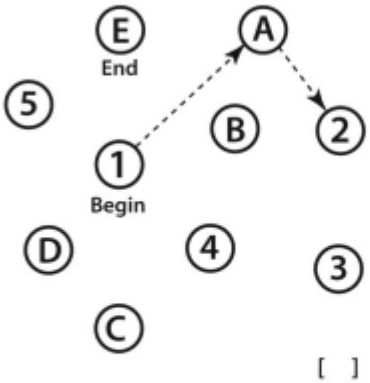
Recovery Focused CBT for OA with BD
31.2.17 (V2) Small flyer

Appendix J

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS



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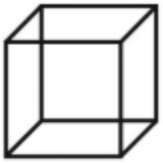


[ ] [ ]

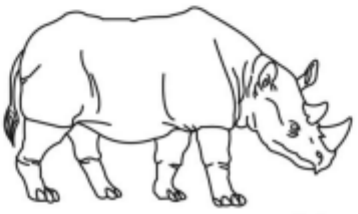
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

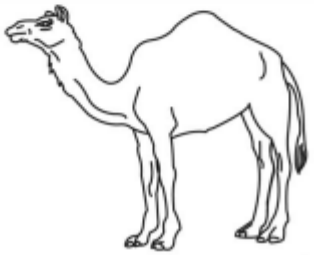
__/5

NAMING

[ ]



[ ]



[ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words **WITH NO CUE**	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

© Z.Nasreddine MD **www.mocatest.org** Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

Appendix K

Working Alliance Inventory

Short Form (C)

Instructions

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her therapist (counsellor). As you read the sentences mentally insert the name of your therapist (counsellor) in place of _____in the text.

Below each statement inside there is a seven point scale:

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

If the statement describes the way you always feel (or think) circle the number 7; if it never applies to you circle the number 1. Use the numbers in between to describe the variations between these extremes.

This questionnaire is CONFIDENTIAL; neither your therapist nor the agency will see your answers.

Work fast, your first impressions are the ones we would like to see. (PLEASE DON'T FORGET TO RESPOND TO EVERY ITEM.)

Thank you for your cooperation.

WA!(S)

1. _____ and I agree about the things I will need to do in therapy to help improve my situation.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
2. What I am doing in therapy gives me new ways of looking at my problem.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
3. I believe _____ likes me.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
4. _____ does not understand what I am trying to accomplish in therapy.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
5. I am confident in _____ 's ability to help me.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
6. _____ and I are working towards mutually agreed upon goals.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
7. I feel that _____ appreciates me.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
8. We agree on what is important for me to work on.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
9. _____ and I trust one another.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
10. _____ and I have different ideas on what my problems are.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
11. We have established a good understanding of the kind of changes that would be good for me.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
12. I believe the way we are working with my problem is correct.							
	1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always

WAI(S)

Working **A**lliance **I**nventory

Short Form T

Instructions

On the following pages there are sentences that describe some of the different ways a person might think or feel about his or her client. As you read the sentences mentally insert the name of your client in place of _____ in the text.

Below each statement inside there is a seven point scale:

1	2	3	4	5	6	7
Never	Rarely	Occasionally	Sometimes	Often	Very Often	Always

If the statement describes the way you ***always*** feel (or think) circle the number 7; if it ***never*** applies to you circle the number 1. Use the numbers in between to describe the variations between these extremes.

This questionnaire is **CONFIDENTIAL** neither your therapist nor the agency will see your answers.

Work fast, your first impressions are the ones we would like to see.
(PLEASE DON'T FORGET TO RESPOND TO ***EVERY*** *ITEM.*)

Thank you for your cooperation.

1. _____ and I agree about the steps to be taken to improve his/her situation.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
2. My client and I both feel confident about the usefullness of our current activity in therapy.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
3. I believe _____ likes me.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
4. I have doubts about what we are trying to accomplish in therapy.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
5. I am confident in my ability to help _____.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
6. We are working towards mutually agreed upon goals.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
7. I appreciate _____ as a person.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
8. We agree on what is important for _____ to work on.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
9. _____ and I have built a mutual trust.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
10. _____ and I have different ideas on what his/her real problems are.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
11. We have established a good understanding between us of the kind of changes that would be good for _____.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always
12. _____ believes the way we are working with her/his problem is correct.						
1 Never	2 Rarely	3 Occasionally	4 Sometimes	5 Often	6 Very Often	7 Always

Appendix L

How useful did you find the therapy sessions?

0 1 2 3 4 5 6 7 8 9 10

Not at all Extremely

Would you recommend the therapy to a friend who is experiencing similar problems?

0 1 2 3 4 5 6 7 8 9 10

Definitely not Definitely yes

Appendix M

Hamilton Depression Rating Scale (HDRS)

Reference: **Hamilton M. A rating scale for depression. J Neurol Neurosurg Psychiatry 1960; 23:56–62**

Rating Clinician-rated

Administration time 20–30 minutes

Main purpose To assess severity of, and change in, depressive symptoms

Population Adults

Commentary

The HDRS (also known as the Ham-D) is the most widely used clinician-administered depression assessment scale. The original version contains 17 items ($HDRS_{17}$) pertaining to symptoms of depression experienced over the past week. Although the scale was designed for completion after an unstructured clinical interview, there are now semi-structured interview guides available. The HDRS was originally developed for hospital inpatients, thus the emphasis on melancholic and physical symptoms of depression. A later 21-item version ($HDRS_{21}$) included 4 items intended to subtype the depression, but which are sometimes, incorrectly, used to rate severity. A limitation of the HDRS is that atypical symptoms of depression (e.g., hypersomnia, hyperphagia) are not assessed (see SIGH-SAD, page 55).

Scoring

Method for scoring varies by version. For the $HDRS_{17}$, a score of 0–7 is generally accepted to be within the normal range (or in clinical remission), while a score of 20 or higher (indicating at least moderate severity) is usually required for entry into a clinical trial.

Versions

The scale has been translated into a number of languages including French, German, Italian, Thai, and Turkish. As well, there is an Interactive Voice Response version (IVR), a Seasonal Affective Disorder version (SIGH-SAD, see page 55), and a Structured Interview Version (HDS-SIV). Numerous versions with varying lengths include the HDRS17, HDRS21, HDRS29, HDRS8, HDRS6, HDRS24, and HDRS7 (see page 30).

Additional references

Hamilton M. Development of a rating scale for primary depressive illness. Br J Soc Clin Psychol 1967; 6(4):278–96.

Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. Arch Gen Psychiatry 1988; 45(8):742–7.

Address for correspondence

The HDRS is in the public domain.

Hamilton Depression Rating Scale (HDRS)

PLEASE COMPLETE THE SCALE BASED ON A STRUCTURED INTERVIEW

Instructions: for each item select the one "cue" which best characterizes the patient. Be sure to record the answers in the appropriate spaces (positions 0 through 4).

1 DEPRESSED MOOD *(sadness, hopeless, helpless, worthless)*
- 0 [ ] Absent.
- 1 [ ] These feeling states indicated only on questioning.
- 2 [ ] These feeling states spontaneously reported verbally.
- 3 [ ] Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.
- 4 [ ] Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

2 FEELINGS OF GUILT
- 0 [ ] Absent.
- 1 [ ] Self reproach, feels he/she has let people down.
- 2 [ ] Ideas of guilt or rumination over past errors or sinful deeds.
- 3 [ ] Present illness is a punishment. Delusions of guilt.
- 4 [ ] Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

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3 SUICIDE

0 |__| Absent.
1 |__| Feels life is not worth living.
2 |__| Wishes he/she were dead or any thoughts of possible death to self.
3 |__| Ideas or gestures of suicide.
4 |__| Attempts at suicide (any serious attempt rate 4).

4 INSOMNIA: EARLY IN THE NIGHT

0 |__| No difficulty falling asleep.
1 |__| Complains of occasional difficulty falling asleep, i.e. more than ½ hour.
2 |__| Complains of nightly difficulty falling asleep.

5 INSOMNIA: MIDDLE OF THE NIGHT

0 |__| No difficulty.
1 |__| Patient complains of being restless and disturbed during the night.
2 |__| Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

6 INSOMNIA: EARLY HOURS OF THE MORNING

0 |__| No difficulty.
1 |__| Waking in early hours of the morning but goes back to sleep.
2 |__| Unable to fall asleep again if he/she gets out of bed.

7 WORK AND ACTIVITIES

0 |__| No difficulty.
1 |__| Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.
2 |__| Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).
3 |__| Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.
4 |__| Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

0 |__| Normal speech and thought.
1 |__| Slight retardation during the interview.
2 |__| Obvious retardation during the interview.
3 |__| Interview difficult.
4 |__| Complete stupor.

9 AGITATION

0 |__| None.
1 |__| Fidgetiness.
2 |__| Playing with hands, hair, etc.
3 |__| Moving about, can't sit still.
4 |__| Hand wringing, nail biting, hair-pulling, biting of lips.

10 ANXIETY PSYCHIC

0 |__| No difficulty.
1 |__| Subjective tension and irritability.
2 |__| Worrying about minor matters.
3 |__| Apprehensive attitude apparent in face or speech.
4 |__| Fears expressed without questioning.

11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching
cardio-vascular – palpitations, headaches
respiratory – hyperventilation, sighing
urinary frequency
sweating

0 |__| Absent.
1 |__| Mild.
2 |__| Moderate.
3 |__| Severe.
4 |__| Incapacitating.

12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

0 |__| None.
1 |__| Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.
2 |__| Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

13 GENERAL SOMATIC SYMPTOMS

0 |__| None.
1 |__| Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.
2 |__| Any clear-cut symptom rates 2.

14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

0 |__| Absent.
1 |__| Mild.
2 |__| Severe.

15 HYPOCHONDRIASIS

0 |__| Not present.
1 |__| Self-absorption (bodily).
2 |__| Preoccupation with health.
3 |__| Frequent complaints, requests for help, etc.
4 |__| Hypochondriacal delusions.

16 LOSS OF WEIGHT ***(RATE EITHER a OR b)***

a) According to the patient:	**b) According to weekly measurements:**
0 |__| No weight loss.	0 |__| Less than 1 lb weight loss in week.
1 |__| Probable weight loss associated with present illness.	1 |__| Greater than 1 lb weight loss in week.
2 |__| Definite (according to patient) weight loss.	2 |__| Greater than 2 lb weight loss in week.
3 |__| Not assessed.	3 |__| Not assessed.

17 INSIGHT

0 |__| Acknowledges being depressed and ill.
1 |__| Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
2 |__| Denies being ill at all.

Total score: |__|__|

The Bech-Rafaelsen Mania Scale (MAS) Manual

Item 1 Elevated mood

0: Not present
1: Slightly elevated mood, optimistic, but still adapted to situation
2: Moderately elevated mood, joking, laughing, however, somewhat irrelevant to situation
3: Markedly elevated mood, exuberant both in manner and speech, clearly irrelevant to situation
4: Extremely elevated mood, quite irrelevant to situation

Item 2 Increased verbal activity

0: Not present
1: Somewhat talkative
2: Clearly talkative, few spontaneous intervals in the conversation, but still not difficult to interrupt
3: Almost no spontaneous intervals in the conversation, difficult to interrupt
4: Impossible to interrupt, dominates the conversation completely

Item 3 Increased social contact (intrusiveness)

0: Not present
1: Slightly meddling (putting his/her oar in), slightly intrusive
2: Moderately meddling and arguing or intrusive
3: Dominating, arranging, directing, but still in context with the setting
4: Extremely dominating and manipulating, not in context with the setting

Item 4 Increased motor activity

0: Not present
1: Slightly increased motor activity (e.g., some tendency to lively facial expression)
2: Clearly increased motor activity (e.g., lively facial expression, not able to sit quietly in chair)
3: Excessive motor activity, on the move most of the time, but the patient can sit still if urged to (rises only once during interview)
4: Constantly active, restlessly energetic. Even if urged to, the patient cannot sit still

Item 5 Sleep disturbances

This item covers the patient's subjective experience of the duration of sleep (hours of sleep per 24-h periods). The rating should be based on the three preceding nights, irrespective of the administration of hypnotics or sedatives. The score is the average of the past three nights.

0: Not present (habitual duration of sleep)
1: Duration of sleep reduced by 25%
2: Duration of sleep reduced by 50%
3: Duration of sleep reduced by 75%
4: No sleep

Item 6 Work activities (distractibility)

Work activity should be measured in terms of the degree of disability or distractibility in social, occupational or other important areas of functioning.

0: No difficulties
1: Slightly increased drive, but work quality is slightly reduced as motivation is changing; the patient is somewhat distractible (attention drawn to irrelevant stimuli)
2: Work activity clearly affected by distractibility, but still to a moderate degree
3: The patient occasionally loses control of routine tasks because of marked distractibility
4: Unable to perform any task without help

Item 7 Irritable mood, hostility

0: Not present
1: Somewhat impatient or irritable, but control is maintained
2: Moderately impatient or irritable. Does not tolerate provocations
3: Provocative, makes threats, but can be calmed down
4: Overt physical violence; physically destructive

Item 8 Increased sexual activity

0: Not present
1: Slight increase in sexual interest and activity, for example, slightly flirtatious
2: Moderately increase in sexual interest and activity, for example, clearly flirtatious
3: Marked increase in sexual interest and activity, excessively flirtatious
4: Completely preoccupied by sexual interests

Item 9 Increased self-esteem

0: Not present
1: Slightly increased self-esteem, for example, overestimates slightly own habitual capabilities
2: Moderate increased self-esteem, for example, overestimates more clearly own habitual capabilities or hints at unusual abilities
3: Markedly unrealistic ideas, for example, believes he/she possesses extraordinary abilities, powers or knowledge (scientific, religious etc), but can quickly be corrected
4: Grandiose ideas which cannot be corrected

Item 10 Flight of thoughts

0: Not present
1: Somewhat lively in descriptions, explanations and elaborations without losing the connection with the topic of the conversation. The thoughts are thus still coherent
2: The patient's thoughts are occasionally distracted by random associations (often rhymes, slangs, puns, pieces of verse or music)
3: The line of thoughts is more regularly disrupted by diversionary associations.
4: It is very difficult or impossible to follow the patient because of the flight of thoughts; he or she constantly jumps from one topic to another

Item 11 Noise level

0: Not present
1: Speaks somewhat loudly without being noisy
2: Voice discernible at a distance, and somewhat noisy
3: Vociferous, voice discernible at a long distance, is markedly noisy or singing
4: Shouting, screaming; or using other sources of noise due to hoarseness

Participant no.
Date:
Interviewer:
Time point:

Personal and Social Performance Scale (PSP)

The validation of this scale has been published in the paper: Morosini P., Magliano L., Brambilla L., Ugolini S., Pioli R. (2000). Development, reliability and acceptability of a new version of the DSM-IV Social and Occupational Functioning Assessment Scale (SOFAS) to assess routine social functioning. *Acta Psychiatrica Scandinavica*, 101: 1-7.

CONTENT

a) Worksheet with instructions

b) Underlying questions

c) Vignettes for training purposes

A) WORKSHEET WITH INSTRUCTIONS

Source of information: _____

Please rate the patient on his/her level of functioning during the last month. Consider what the person is doing, taking into account if he/she needs help from others. Only if the initial activity you are investigating cannot be performed by the client in their own home, should you consider what they would do in a different setting.

Because area a, b and c include many subareas, score each area by taking into account the **worst** functioning during the period in the relevant area where the client has the **highest functioning**. For area a, subareas to consider are work or study and other socially useful activities (e.g. housework, voluntary work, "useful" hobbies such as gardening); for area b, subareas to consider are relationship with partner (only if the patient has a partner and usually lives with him/her), family relationships, social relationships; and for area c, subareas to consider are personal hygiene, care of one's appearance and way of dressing.

Other areas may be taken into account to define the score inside each 10 points interval such as self-management of the disorder, interests and information, instrumental activities as phoning, travelling.

So, in summary, the 4 main domains of functioning considered in this scale are a) Personal and social relationships; b) socially useful activities, including work and study; c) self-care; d) disturbing and aggressive behaviours.

There are two different sets of operational criteria to judge the degree of difficulties:
One for the **a-c** areas and one specific to the **d** area.

Degrees of severity areas a-c		Degrees of severity area d	
i)	Absent	i)	Absent
ii)	Mild, defined here as known **only to someone who is very familiar** with the person	ii)	Mild, corresponding to mild rudeness, unsociability or many instances of complaining
iii)	Manifest, but not marked, difficulties **clearly noticeable by everyone**, but not interfering substantially with the person's ability to perform his/her role in that area, given the person's socio-cultural context, age, gender and educational levels	iii)	Manifest, such as speaking too loudly or speaking to others in a too-familiar manner, or eating in a socially unacceptable manner
iv)	Marked, difficulties interfering heavily with role performance in that area; however, the person is still able to do something without professional or social help, although inadequately and/or occasionally; if helped by someone, he/she may be able to reach the previous level of functioning	iv)	Marked, insulting others in public, breaking or wrecking objects, acting frequently in a socially inappropriate but not dangerous way (e.g. stripping or urinating in public) <u>not occasionally</u>
v)	Severe, difficulties that make the person unable to perform any role in that area, if not professionally helped, or possibly make the person be at risk of causing harm to themselves; however, there are no survival risks	v)	Severe, frequent verbal threats or frequent physical assaults, without intention or possibility of causing severe injuries <u>not occasionally</u>
vi)	Very severe, impairments and difficulties of such intensity to endanger the person's survival. Suicide risk should be taken into account only as much as suicide rumination interferes with social functioning.	vi)	Very severe, defined as aggressive acts, aimed at or likely to cause severe injuries <u>not occasionally</u>. →To be considered as <u>only occasionally</u> the disturbing behaviour has to have taken place only once in the preceding week or 1-2 times in preceding month **and** mental health professionals and caregivers believe that it is very unlikely to happen again in the next six months. If the disturbing behaviour is judged "occasional" the score should be decreased by 1, e.g. severe becomes marked. An injury has to be considered "severe" if it would need to be treated in an emergency department if available.

The following table may be used to score the severity of problems in each main area.

		Absent	Mild	Manifest	Marked	Severe	Very Severe
a)	Socially useful activities, including work and study	☐	☐	☐	☐	☐	☐
b)	Personal and social relationships	☐	☐	☐	☐	☐	☐
c)	Self-care	☐	☐	☐	☐	☐	☐
d)	Disturbing and aggressive behaviours	☐	☐	☐	☐	☐	☐

Personal and Social Performance Scale (PSP) – Overall score instructions on the basis of the four main areas scores

100-91	Excellent functioning in all four main areas. He/she is held in high consideration for his/her good qualities, which he/she copes adequately with life problems and is involved in a wide range of interests and activities.
90-81	Good functioning in all four areas, presence of only common problems and difficulties.
80-71	Mild difficulties in one or more of the areas a-c.
70-61	Manifest, but not marked difficulties in one or more areas a-c or mild difficulties in d. For area a include here sheltered work, if the performance is good.
60-51	Marked difficulties in only one area a-c or manifest difficulties in d.
50-41	Marked difficulties in two or three of the areas a-c, or severe difficulties <u>in only one</u> area a-c <u>without</u> marked difficulties in the other two; no marked difficulties in d.
40-31	Severe difficulties <u>only</u> in one area a-c <u>and</u> marked difficulties in at least one of the other two; or marked difficulties in d.
30-21	Severe difficulties in two areas a-c; or severe difficulties in d, even if severe and marked difficulties in the areas a-c are absent.
20-11	Severe difficulties in <u>all</u> areas a-c; or very severe difficulties in d, even if severe difficulties in area a-c are absent. If the person reacts to external prompts, the suggested scores are 20-26; if not, they are 15-11.
10-1	Lack of autonomy in basic functioning with extreme behaviours, but without survival risk (scores 6-10) or with survival risk, e.g. death risk due to malnutrition, dehydration, infections, inability to recognise situations of marked danger (scores 5-1).

5) Overall score |___|___|___|

Summary meaning of PSP total score

71-100:	These ratings reflect only mild difficulties
31-70:	These ratings reflect varying degrees of disability
0-30:	These ratings reflect functioning so poor that the patient requires intensive support or supervision.

b) INSTRUCTIONS TO THE PSP RATERS TO COLLECT THE REQUIRED INFORMATION

This section reports the questions to be asked by the rater. If the answers are already known from the SCID, then there is no need to ask them again. However most questions will require an extra level of detail than the SCID requires, so inform the participant of this. Only if the participant specifically requests it, should the questions be directed to the relevant mental health professionals, relatives and other caregivers.

INTRODUCTION

1. If the questions are asked to the participant

I would now like to ask you some questions about the problems you may have in your daily life, especially about those problems you have had in the last month. Some questions may sound like ones I have previously asked, but I now require a few extra details. This will help us to better understand your needs and your treatment. I am interested to learn not only about the problems or difficulties you have had, but also the things you have been able to manage and achieve.

If the rater suspects that P in unable to answer the questions, he/she may assess his/her mental lucidity with the following questions:
How old are you? When were you born? What day of the week is today? What time of the day is it?

***(*NB Paranoid ideation or lack of insight are not a reason not to ask the questions you need to ask; however in this case other sources of information also have to be tapped; psychotic patients tend to overestimate their social functioning).**

2. If the questions are asked to a caregiver. *P stands for person to be assessed.*

Good morning/afternoon. I am …. I would like to ask you some questions about the problems P (*for instance* "your son") have in his/her daily life, especially about the problems he had in the last month. This will help us to better understand his needs and his treatment. I am interested to learn not only about the problems or difficulties he/she may have had, but also about the things he/she has been able to manage and achieve. Of course everything you will say will be protected by professional confidentiality and will not be discussed with people who are not involved a professionally interested in your treatment, not even with P (*for instance* "your son"), unless you ask us to do so or divulge information that would suggest a serious risk to P's life. The information may be used for research purposes, but P's identity and your identity will never be disclosed.

3. If the questions are asked to a (other) mental health professionals . *P stands for person to be assessed.*

Good morning/afternoon. I am …. I would like to ask you some questions about P's (*say P name*) functioning in his/her daily life, especially about the problems he/she may have had in the last month. I understand that you have had the opportunity to observe him and to speak to him/her. I am interested to know not only about his/her problems or difficulties, but also about the things he/she has been able to manage and achieve. The information may be used for research purposes, however in this case P's identity will never be disclosed.

The following questions are addressed to the participant; the construction should be changed according to the introductions and initial SCID questions asked. <u>Those underlined</u> should already be known from the SCID and demographics form – but you may have learnt more information than these, so don't ask any questions where the answers are already known. Stop when you have sufficient information to make the ratings on the 0-5 scales.

Rate the worst functioning during the last month in the participant's highest functioning subarea for each area a-c *(in area b, the subarea "relationship with partner" has to be considered only if the participant has a partner and usually lives with the partner).*

a) SOCIALLY USEFUL ACTIVITIES, INCLUDING WORK AND STUDY
a1) Work or study
<u>In the last month did you work? (*or* "Have you been to school?").</u> *If no*: go to a2
If yes: Where? How many days? How many hours a day? Have you had difficulties at work (at school), for instance with the other workers (students) or your manger (teachers)? Have you been punctual?

a2) Socially useful activities
Apart from work, did you do something that other people may find useful? For instance, did you help with a household task (cleaning the house, tidying things up, cooking)? Did you help to organize something or with gardening or sewing? Have you done any voluntary work?

If uncertain between mild and manifest, ask: ***How many people have noticed that you have had some problems at work (or study)?***

b) PERSONAL AND SOCIAL RELATIONSHIP
b1) <u>Do you have a partner (a spouse, or a boy/girl friend)?</u> *If no*: ask b2. *If yes:* Do you live together? How do you get along? Do you speak to each other? Do you have common plans?

b2) Family (different from partner)
In the last month have you been in touch with any of your relatives? *If no*: ask b3. *If yes*: How often have you seen them? Did you get along well or did you have problems? Do they help you? Do you help them?

If P lives in a residential facility: During leave from the residence or when your relatives came to visit you, did you get on well with them?

B3) Social relationships
How often do you go out to meet other people? Do you like meeting and speaking with other people? Do you take part in group activities? How many friends have you got that you see often? Are any of those patients or workers of the mental health service? Do you have somebody who can help you when you need it?

If uncertain between mild and manifest: ***How many people have noticed that you have some difficulties in social relationships?***

c) SELF CARE
c1) Personal hygiene
Have you been taking care of yourself as much as you normally do? *If yes:* judge personal hygiene from what can be observed. If unclear from observations use the following prompt questions: How often do you shower or bath a week? How often do you brush your teeth? *If no*: what have you been neglecting?

If the person being asked is not P: Have people complained about P's personal appearance in the last month?

If uncertain between mild and manifest: ***How many people have commented on your personal appearance?***

d) DISTURBING AND AGGRESSIVE BEHAVIORS
d1) Disturbing behaviour

In the last month did you behave in a way that some people may have thought rude or insensitive? Did you take something belonging to others without asking permission? Have you drunk too much? *If yes*: While drunk, did you do something that could annoy others?

In the last month, did you ever do something strange that other people may have found worrying? In the last month, have you spoken too loudly or had your music/TV so loud that others have complained? Did you ask other people for favours that you wouldn't usually ask for?

If uncertain between mild and manifest: ***How many people have noticed that you were behaving in a disturbing way for others?***

d2) Destructive and aggressive behaviour
In the last month did you ever lose control of your temper? Did you shout at anybody? Did you throw or destroy objects? Did you hit or hurt anybody? *If no*: stop here. *If yes*: How severe was it? Did you really want to hurt them? How often did it happen? Do you think that is going to happen again in the near future?

If uncertain between mild and manifest: ***How many people have noticed that you have some difficulties in self control?***

Appendix N

The Bipolar Recovery Questionnaire (BRQ)

The Bipolar Recovery Questionnaire has been developed in order to understand more about recovery in bipolar disorder; what recovery is and what can help or hinder recovery. The questionnaire has been developed by interviewing individuals with a diagnosis of bipolar disorder about their experiences of recovery. It is acknowledged that everybody is different and may have different experiences and views about recovery. Therefore not all of the statements on the questionnaire may apply to you.

When filling in the questionnaire, please consider how things have been for you in the last week in relation to your mental health and recovery. Please respond to the following statements by marking an "X" at the point on the line that best describes how much you agree with each statement.

	Strongly disagree	Disagree	Agree	Strongly agree
1. I struggle to make sense of the experiences I have had				
2. I have the resources to effectively manage my health				
3. I am content with who I am as a person				
4. I have little control over my mood				
5. I avoid taking on challenges in life that matter to me				
6. I see recovery as a life long process				
7. I think differently about some of my experiences now compared with when they first occurred				
8. I can access the help I need in order to stay well				
9. My experiences have made me the person I am today				
10. I recognise when I am in situations that aren't good for my wellbeing				
11. I am able to engage in a range of activities that are personally meaningful to me				

Please turn over and continue

	Strongly disagree	Disagree	Agree	Strongly agree
12. Recovery means forgetting about my mental health problems				
13. I am unsure about the reasons behind some of the experiences I have had				
14. I feel in control of the things that happen in my life				
15. I am productive in the things in life I engage in				
16. I depend on others to maintain my own well being				
17. I feel confident enough to get involved in the things in life that interest me				
18. I can have mood experiences and still get on with my life				
19. I can see where certain experiences I have had have come from				
20. I am able to decide when I need support from others in order to maintain my wellbeing				
21. I get little personal satisfaction out of the things in life I am involved in				
22. I have the knowledge to make informed decisions concerning treatment for my mental health				
23. I am unhappy with the person I have become				
24. I sometimes let my mood fluctuate if I have important tasks to do				
25. The high standards I set myself are unrelated to fluctuations in my mood				
26. I play a central role in maintaining my own well being				
27. I have the ability to achieve my goals in life				

Please turn over and continue

		Strongly disagree	Disagree	Agree	Strongly agree
28.	My ability to make informed choices about treatment is supported by my friends and family				
29.	I find it hard to engage in a range of activities that are valuable to me				
30.	I can still be in recovery even if I experience mood episodes in the future				
31.	Understanding where my mood experiences come from help me manage them				
32.	I have little control over the important decisions in my life				
33.	I am able to engage in a range of activities that are valuable to wider society				
34.	The knowledge I have gained enables me to look after myself				
35.	The activities I do make a difference to others				
36.	Being in recovery means that everything has to be going well in every aspect of my life				

Thank you for completing this questionnaire

The Brief Quality of Life in Bipolar Disorder (Brief QoL.BD) questionnaire

The following items ask about a range of experiences, behaviours, and feelings related to quality of life. Please tell us about your quality of life by rating how much you agree with each of the statements below. Circle the number that best describes your experience over the *last 7 days*. Do not spend too long on each item. It is your first impressions we are interested in.

	Over the past 7 days, I have…..	Strongly disagree **1**	Disagree **2**	Neutral **3**	Agree **4**	Strongly agree **5**
1	Felt physically well	1	2	3	4	5
2	Woken up feeling refreshed	1	2	3	4	5
3	Enjoyed things as much as I usually do	1	2	3	4	5
4	Had good concentration	1	2	3	4	5
5	Been interested in my leisure activities	1	2	3	4	5
6	Been interested in my social relationships	1	2	3	4	5
7	Practiced my spirituality as I wished	1	2	3	4	5
8	Had enough money for extras	1	2	3	4	5
9	Kept my home tidy	1	2	3	4	5
10	Felt accepted by others	1	2	3	4	5
11	Travelled around freely (e.g. using public transport)	1	2	3	4	5
12	Had a clear idea of what I wants and don't want	1	2	3	4	5

Name: _____ Date: _____

INTERNAL STATE SCALE (v.2)

For each of the following statements, please blacken the circle on the line that best describes the way you have felt over the past 24 hours. While there may have been some change during that time, try to give a single summary rating for each item.

Today my mood is changeable.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

Today I feel irritable.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

Today I feel like a capable person.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

Today I feel like people are out to get me.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

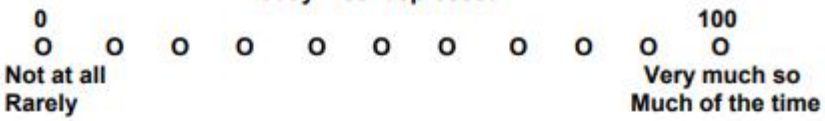
Today I actually feel great inside.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

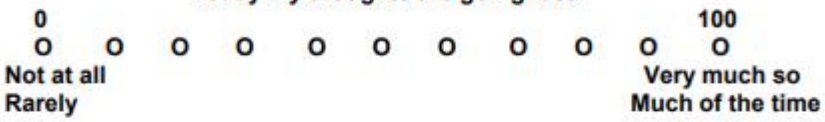
Today I feel impulsive.

0 100
O O O O O O O O O O O
Not at all Very much so
Rarely Much of the time

Today I feel depressed.

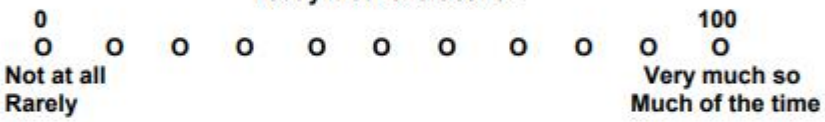


Today my thoughts are going fast.

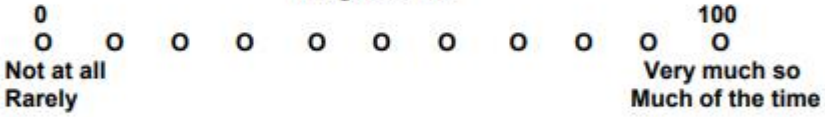


Today it seems like nothing will ever work out for me.

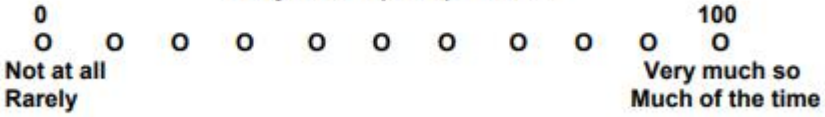
Today I feel overactive.



Today I feel as if the world is against me.



Today I feel "sped up" inside.



Today I feel restless.

Today I feel argumentative.

O O O O O O O O O O O

Not at all Very much so
Rarely Much of the time

Today I feel energized.

0 100
O O O O O O O O O O O

Not at all Very much so
Rarely Much of the time

Today I feel:

0 100
O O O O O O O O O O O

Depressed Normal Manic
Down High

Center for Epidemiologic Studies Depression Scale (CES-D), NIMH

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the Past Week			
	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	☐	☐	☐	☐
2. I did not feel like eating; my appetite was poor.	☐	☐	☐	☐
3. I felt that I could not shake off the blues even with help from my family or friends.	☐	☐	☐	☐
4. I felt I was just as good as other people.	☐	☐	☐	☐
5. I had trouble keeping my mind on what I was doing.	☐	☐	☐	☐
6. I felt depressed.	☐	☐	☐	☐
7. I felt that everything I did was an effort.	☐	☐	☐	☐
8. I felt hopeful about the future.	☐	☐	☐	☐
9. I thought my life had been a failure.	☐	☐	☐	☐
10. I felt fearful.	☐	☐	☐	☐
11. My sleep was restless.	☐	☐	☐	☐
12. I was happy.	☐	☐	☐	☐
13. I talked less than usual.	☐	☐	☐	☐
14. I felt lonely.	☐	☐	☐	☐
15. People were unfriendly.	☐	☐	☐	☐
16. I enjoyed life.	☐	☐	☐	☐
17. I had crying spells.	☐	☐	☐	☐
18. I felt sad.	☐	☐	☐	☐
19. I felt that people dislike me.	☐	☐	☐	☐
20. I could not get "going."	☐	☐	☐	☐

SCORING: zero for answers in the first column, 1 for answers in the second column, 2 for answers in the third column, 3 for answers in the fourth column. The scoring of positive items is reversed. Possible range of scores is zero to 60, with the higher scores indicating the presence of more symptomatology.

Work and Social Adjustment Scale (WSAS)

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems look at each section and determine on the **scale** provided how much your problem impairs your ability to carry out the activity. This assessment is not intended to be a diagnosis. If you are concerned about your results in any way, please speak to a qualified health professional.

If you are retired or choose not to have a job for reasons unrelated to your problem, tick here ☐

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly		Very severely

1. Because of my [problem] my ability to work is impaired. '0' means 'not impaired' and '8' means severely impaired to the point I can't/couldn't work. ☐

2. Because of my [problem] my home management (cleaning, tidying, shopping, cooking, looking after home or children, paying bills) is impaired. ☐

3. Because of my [problem] my social leisure activities (with other people e.g. parties, bars, clubs, outings, visits, dating, home entertaining) are impaired. ☐

4. Because of my [problem], my private leisure activities (done alone, such as reading, gardening, collecting, sewing, walking alone) are impaired. ☐

5. Because of my [problem], my ability to form and maintain close relationships with others, including those I live with is impaired. ☐

Total WASAS score = ☐

WHO/MSA/MNH/PSF/97.6
English only
Distr.: Limited

WHOQOL-BREF

PROGRAMME ON MENTAL HEALTH
WORLD HEALTH ORGANIZATION
GENEVA

For office use only

	Equations for computing domain scores	Raw score	Transformed scores*	
			4-20	0-100
Domain 1	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	=		
Domain 2	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	=		
Domain 3	Q20 + Q21 + Q22 ☐ + ☐ + ☐	=		
Domain 4	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	=		

* Please see Table 4 on page 10 of the manual, for converting raw scores to transformed scores.

I.D. number

ABOUT YOU

Before you begin we would like to ask you to answer a few general questions about yourself: by circling the correct answer or by filling in the space provided.

What is your **gender**? Male Female

What is your **date of birth**? _____ / _____ / _____
Day / Month / Year

What is the highest **education** you received?
None at all
Primary school
Secondary school
Tertiary

What is your **marital status**?
Single Separated
Married Divorced
Living as married Widowed

Are you currently **ill**? Yes No

If something is wrong with your health what do you think it is?_____illness/ problem

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.** For example, thinking about the last two weeks, a question might ask:

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1(G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither	Good	Very good

				poor nor good		
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

.....

.....

THANK YOU FOR YOUR HELP

Appendix O

	TAU N	TAU Mean	TAU s.d.	RfCBT-OA N	RfCBT-OA Mean	RfCBT-OA s.d.
QoL-BD						
Baseline	20	42.40	11.61	19	38.68	7.21
24 week follow-up	15	41.44	12.10	17	40.98	9.25
48 week follow-up	12	38.41	12.38	14	39.07	7.97
CES-D						
Baseline	20	21.85	12.42	19	23.66	9.20
24 week follow-up	14	18.50	9.33	16	17.31	7.63
48 week follow-up	13	21.10	11.27	13	21.85	9.34
Internal States Scale - Activation						
Baseline	18	178.33	119.82	19	95.26	100.41
24 week follow-up	14	137.86	97.99	17	93.53	104.88
48 week follow-up	11	133.64	100.33	13	47.69	65.47
Internal States Scale - Wellbeing						
Baseline	19	182.11	83.77	19	118.95	74.23
24 week follow-up	14	181.43	88.74	17	143.53	100.81
48 week follow-up	11	193.64	84.06	13	137.69	67.35
WASAS						
Baseline	20	19.69	13.17	18	19.83	10.58
24 week follow-up	15	14.88	12.97	17	16.31	10.49
48 week follow-up	8	17.38	13.99	13	14.77	6.67
WHO-QOL BREF – Physical						
Baseline						
24 week follow-up	19	56.05	21.22	19	53.98	15.50
48 week follow-up	13	63.05	24.79	17	57.35	19.43
	12	57.44	19.99	14	56.51	16.02
WHO-QOL BREF – Psychological						
Baseline	19	58.77	21.66	19	52.19	20.24
24 week follow-up	12	68.75	14.38	17	56.62	19.38
48 week follow-up	12	62.99	21.36	14	56.25	19.99
WHO-QOL BREF – Social						
Baseline	19	53.29	24.32	19	58.33	19.64
24 week follow-up	12	61.11	29.96	16	58.85	21.83
48 week follow-up	12	56.94	22.71	13	53.21	24.89
WHO-QOL BREF – Environmental						
Baseline	19	67.11	24.72	19	72.89	14.52
24 week follow-up	13	75.49	16.77	17	69.41	15.30
48 week follow-up	12	69.38	14.29	14	68.75	14.91
Personal and Social Performance Scale	20	71.90	10.68	19	75.42	10.02
Baseline	19	68.58	12.90	17	77.06	8.89
24 week follow-up	15	71.07	14.46	17	76.71	11.09
48 week follow-up						

Linear Models

Bipolar Recovery Questionnaire

RfCBT vs TAU	MD; 95% CI	P-value
24 week	22.471 (-172.446 to 217.387)	0.815
48 week	62.852 (-238.257 to 363.960)	0.670

Hamilton Rating Scale for Depression

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-4.207 (-8.949 to 0.536)	0.080
48 week	-4.206 (-9.780 to 1.368)	0.134

Bech-Rafaelsen Mania Scale

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-1.765 (-4.257 to -0.727)	0.159
48 week	-1.792 (-3.464 to -0.119)	0.037

Quality of Life in Bipolar Disorder Scale

RfCBT vs TAU	MD; 95% CI	P-value
24 week	3.145 (-2.991 to 9.281)	0.303
48 week	3.091 (-4.930 to 11.111)	0.434

Centre for Epidemiologic Studies Depression Scale

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-4.184 (-9.301 to 0.933)	0.105
48 week	-0.222(-8.217to 7.773)	0.955

Internal States Scale - Activation

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-14.983 (-81.288 to 51.323)	0.647
48 week	-61.100 (-133.209 to 11.009)	0.092

Internal States Scale - Well-being

RfCBT vs TAU	MD; 95% CI	P-value
24 week	34.832 (-27.774 to 97.438)	0.264
48 week	-34.143 (-106.724 to 38.437)	0.339

Work and Social Adjustment Scale

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-1.095 (-6.488 to 4.298)	0.681
48 week	-3.778 (-10.445 to 2.888)	0.248

WHO-QOL BREF – Physical

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-10.028 (-25.596 to 5.540)	0.197
48 week	-5.543 (-19.694 to 8.608)	0.426

WHO-QOL BREF - Psychological

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-3.592 (-14.352 to 7.168)	0.498
48 week	2.02 (-11.92 to 15.95)	0.767

WHO-QOL BREF – Social

RfCBT vs TAU	MD; 95% CI	P-value
24 week	3.123 (-13.450 to 19.703)	0.701
48 week	-2.597 (-16.284 to 11.091)	0.697

WHO-QOL BREF – Environmental

RfCBT vs TAU	MD; 95% CI	P-value
24 week	-2.559 (-9.882 to 4.765)	0.479
48 week	-1.846 (-10.141 to 6.450)	0.649

Personal and Social Performance Scale

RfCBT vs TAU	MD; 95% CI	P-value
24 week	5.786 (1.320 to 10.251)	0.013
48 week	2.644 (-3.518 to 8.806)	0.387

Key: CI = Confidence interval, MD= Mean difference

Cox Regression

Time to relapse - Any relapse

	$\chi 2$	Df	Exp(B)	Lower 95% CL	Upper 95% CL	P-Value
Time to any relapse	10.1	3	0.23	0.07	0.73	0.013

Time to relapse - Depression

	$\chi 2$	Df	Exp(B)	Lower 95% CL	Upper 95% CL	P-Value
Time to depressive relapse	7.7	3	0.13	0.01	1.06	0.057

Time to relapse - Mania

	$\chi 2$	Df	Exp(B)	Lower 95% CL	Upper 95% CL	P-Value
Time to manic relapse	6.1	3	0.44	0.13	1.51	0.195

Key: $\chi 2$ = Chi Squared, Df = Degrees of freedom , CL = Confidence limit

Appendix P

OLDER ADULTS WITH BIPOLAR DISORDER

QUALITATIVE INTERVIEW – TOPIC GUIDE

Questions

1. **What do you think has changed for you as a result of the therapy?**

Prompts

- Relationship with relative / partner/ friends / health professionals
- Daily life
- Mood management

2. **So you mentioned that the therapy has changed (XXX answer to question 1). How do you think that was achieved?**

Prompts

- Do you do anything differently now?
- Has it changed your perspective?
- Do you use any particular strategies (e.g. thought challenging, behavioural experiments, mindfulness, your early warning and coping plan)?

3. **I can see that you had XX number of sessions at home/ Spectrum centre. What did you think about this?**

   Prompts
   - Did you want more / less
   - Would you rather be seen in a different location?

4. **I can see you attended XX sessions. What were your thoughts about the length of sessions (50 minutes to an hour) / number of sessions (14)?**

   Prompts
   - Did you want more / less time in the session
   - Would you have liked more than 14 sessions / less than 14 sessions

5. **Why did you decide to take part in the research study?**

   Prompts
   - Interested in research
   - Helping other people out

6. **How did you find the research process?**

   Prompts
   - The study materials
   - The phone interviews
   - The questionnaires by post

7. **Is there anything that would have made taking part in the study easier for you?**

Appendix Q

Lancashire Care NHS
NHS Foundation Trust

Health Research | Lancaster University

Participant Information Sheet
Interview Study

Title of project: Recovery focused therapy for older adults with bipolar disorder

We would like to invite you to take part in an interview about your experiences of the recovery focused CBT intervention (RfCBT-OA). Before you decide whether or not to participate, it is important that you understand why this research is being carried out and what taking part will involve. Please take the time to read the following information carefully and discuss with others if you wish. You may download this sheet and print it off to read at your own convenience and discuss with others if you wish. If there is anything which is not clear or that you would like more information about please feel free to contact us. Contact details for the research team are at the end of this document.

What is the research project about?

This interview study aims to explore individuals' experiences of receiving the RfCBT-OA intervention in more detail and how acceptable the therapy was. Service users have been involved in designing this study.

Who will be taking part in this study?

Approximately 10 participants who have already taken part in the trial of RfCBT-OA will participate in this study. To enable us to explore how different people found the delivery of RfCBT-OA, we are inviting people to take part based on a range of characteristics, including age, gender and place of residence. The group will therefore include people who have withdrawn from the study, people who attended a lot of sessions and people who attended a few. The interviews will be either over the telephone or held in a location of your choice. This will be either at the Spectrum Centre for Mental Health, Lancaster University or in your own home.

Why have I been asked to take part?

You have been asked to take part because you have experience of receiving RfCBT-OA. Treatment development studies such as this study are useful in enable the development of psychological interventions which we hope will enhance recovery, functioning and quality of life, and reduce associated problems in bipolar disorder, such as relapse.

What will taking part involve for me?

If you do decide to take part in this study, a researcher will contact you by phone to explain more about the study and arrange an interview date. The interview will take place over the telephone, at your home, or some other place where you feel comfortable. The interview will take approximately 45-60 minutes. During the interview, we will ask questions about your experience of receiving RfCBT-OA, including what you found most useful, perceptions of the impact and outcome of receiving the intervention, value and acceptability of each of the outcome measures, reason for drop out (if appropriate), beliefs/attitudes towards mood swings and coping strategies following the intervention. You can take as many breaks as you like during the interview, and you can

stop at any time. Interviews will be digitally recorded, as this is necessary for us to analyse the data. The audio recordings can be edited and therefore you can ask for words to be deleted or replaced.

Do I have to take part?

You are under no obligation to take part in the interview even if you previously indicated that you would like to be contacted about it. If you do decide to take part, before you begin the study, you will be asked to complete a consent form. If you change your mind after giving consent you are free to withdraw from the study before or during the interview, or within 2 weeks after undertaking the interview, and do not need to provide a reason. It will be difficult to withdraw your data more than 2 weeks after the interview as qualitative analyses will be underway. If you do decide not to take part, or to withdraw, this will not affect any ongoing care you receive, or your ability to take part in any future research. You will be asked to complete a form giving your reason for withdrawing, but do not have to do so.

Will my personal details be kept confidential?

All the information that you give will be strictly confidential; the transcript of the interview will not be shown to anyone outside the research team. The information (data) collected will be anonymised, meaning that data will not be traceable to you.

All data will be stored securely either on paper, or password protected databases. Personal data will not be kept any longer than 12 months, and will be destroyed by this time. The tapes will be destroyed at the end of the study and any direct quotes used in the write up of the study will be done so in such a way so as not to identify individuals. Completely anonymous copies of transcripts may be retained for up to 10 years after the study.

It is important for us you are assured that all measures will be taken to guarantee the confidentiality and anonymity of your participation. However, you may disclose information that is relevant to safeguarding vulnerable individuals. If such information is disclosed, the data collection will cease, a member of the research team will discuss with you that confidentiality will be broken on this occasion, and the relevant bodies or individuals will be informed.

What are the potential advantages and disadvantages of taking part?

It is our experience of conducting similar interview-based research that participants value sharing their personal experiences. All individuals taking part in this study will be making a valuable contribution to understanding the experiences of bipolar disorder and this knowledge will then be used to help design specific and appropriate treatment interventions for people with bipolar disorder.

It is possible that talking about personal experiences may cause participants distress. The interviewer will be sensitive to this. Participants will have the opportunity to discuss any concerns at the end of the interview and will be free to stop the interview at any point. Following the interview the researcher will also offer the opportunity for a follow-up phone call the next day to ensure participants are feeling okay and to check whether there are any issues relating to the research which the participant wishes to discuss.

What will happen to the results of the research?

If you participate in this study you will be informed of the results at the end of the study. The findings will be presented at appropriate conferences and events and will be published in mental health journals and other publications with the aim of reaching a wide audience of mental health professionals and service users. Quotes from your interview may be used to illustrate the findings, however these findings will be anonymised and you will not be personally identifiable anywhere in the publication.

If the findings of this study indicate that the intervention works well for participants and is effective in enhancing recovery, functioning and quality of life, and reducing associated problems in bipolar disorder, such as relapse then we will use these results to seek funding for a larger scale clinical trial of RfCBT-OA.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. The committee that has reviewed this application is the RES Committee North West - Preston.

What if something goes wrong?

However, if you are harmed by taking part in this research, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

If you have any questions you are welcome to ask the researcher, whose contact details are listed at the end.

Complaints: If you wish to make a complaint you can contact:

Professor Steven Jones
Email: s.jones7@lancaster.ac.uk
Phone: 01524 593382.

If you would prefer to contact someone independent of the research with any concerns, please contact:

Professor Roger Pickup
Email: r.pickup@lancaster.ac.uk
Phone: 01524 593746

Harm: It is unlikely that you will be harmed by participating in this study. However, in the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Lancaster University but you may have to pay your legal costs.

Further Information
If you require any further information you can contact Elizabeth Tyler on telephone number 07967837938

e.tyler@lancaster.ac.uk

Spectrum Centre for Mental Health Research
Institute for Health Research
Lancaster University
LA14YT

Appendix R

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CONSENT FORM

Recovery Focused Therapy for Older Adults with Bipolar Disorder

REC ref:

Name of Researcher: _____

Name of Participant: _____

Participant Number ☐☐☐☐☐☐

Please initial box

1. I confirm that I have read and understood the information sheet version number 1.0 dated 12/02/2015 for the above study and have had the opportunity to ask questions and have my questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw from the study within 2 weeks of completing the interview, without giving any reason, and without my medical care or legal rights being affected. ☐
3. I understand that if I withdraw the information collected up to this point may still be used in the analysis and publication of this study. ☐
4. I agree to being contacted by the research team to arrange an interview appointment to discuss my experiences of receiving recovery focused CBT. ☐
5. I give permission for interviews with me to be recorded and transcribed so researchers can listen to these and identify common themes. ☐
6. I give permission for the research team to collect, store, analyse and publish information obtained from my participation in this study with the understanding that my personal details will be kept confidential and all data published will be anonymous. ☐
7. I give permission for my direct, anonymised quotations to be used if required to illustrate study findings in research publications. ☐
8. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (If different from Principal Investigator)	Date	Signature
_____	_____	_____
Name of Principal Investigator	Date	Signature

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Appendix S

Experience of intervention	
Positive impact on the lifestyle	*"A greater focus on what my lifestyle's like and what I'm doing and when I'm doing it…looking at sleep pattern, getting it undisturbed sleep now, so that was useful" (P002)*
Positive impact on relationships	*"I'm more relaxed around them, and they're more relaxed around me" (P003)* *"I've learnt to be perhaps more patient really with other people, um, and not be demanding of them… I still do rely on my husband a lot but I try not to over rely on him and expect him to do things that are too perfectionist" (P005)*
Recovery focused approach	*I thought it was well balanced and aimed at specific elements of your mental health er process of recovery …it's like giving out a silver bullet, that bullet that drives right to the centre of the problems (P003)*
Coping strategies to manage mood	*I think er if I feel down, I think um, I can… give myself permission to be down, er but be aware not to let it get into a spiral and do…somethings which are soothing, some things which are stimulating, you've got to make your choice at the time (P005)*
Difficulty engaging in therapy	*Not a lot has changed – we were going through marital problems at the time. We were too busy trying to sort ourselves out (P007)*
Therapist stance	*There were lots of intimate things we discussed…I didn't feel that there was any judgement there (P001)*
Session number	*"I think it was about right, 'cos you needed a couple of sessions just to get going and get to know what's happening and what the strategy is going to be" (P002)* *"I was a bit disappointed when it ended really but I recognise that you know it couldn't go on forever" (P001)* *"Only did 7 sessions – should have had more as it was not enough"*
Session location	*"I thought it was excellent, I couldn't believe it really when it was offered (to have the therapy sessions at home; P001)* *"I enjoyed it coming to work… because it reinforced when I said to people look XX is coming to work and we're going into this room … it reinforced to them my mental health conditions" P003*
Session timing (50-60 minutes)	*"It's very flexible, so it works, no longer though" (P003)* *"You can keep on track better over an hour...some people start going round in circles in less time… but I think an hour is about right" P005*

Research process	
Follow-up assessments	*"I prefer face to face any time" (P006)* *"It was ok on the phone but obviously face to face is better" (P001)*
Questionnaire by post	*"That was alright by post, that was ok" (P008)* *"online you can unclick them can't you if you think I've read that wrong...so it's easier to unclick and make it clear rather than think when you've ticked a box and scribbled it out" (P005)*
Completing the questionnaires	*"I filled in all the various forms that came" (P007)* *"questionnaires were fine, they were easy to understand and easy to get through" P005* *"I thought they were simple, even though it was a lot, it was easy to go through and none of it was challenging" (P003)*

Appendix T

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Participant Information Sheet
Part 1

Title of project: Recovery focused therapy for older adults with bipolar disorder

We are inviting you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information carefully and discuss it with others if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please do not hesitate to ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the aim of the study?
The aim of the study is to investigate the effectiveness of a psychological intervention compared to the effectiveness of standard treatment for individuals who have a diagnosis of bipolar disorder and are over the age of 60.

Why have I been asked to take part?
You have been asked to take part because you have received a diagnosis of bipolar disorder and are over the age over 60, you live within the North West of England and you have expressed an interest in taking part in the study.

Do I have to take part?
No. It is up to you whether or not you take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at anytime without giving a reason. Should you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis. If you decide not to take part, or to withdraw from the study, it will not affect the standard of care you receive.

What does taking part involve?

Initial assessment
If you agree to take part you will first be asked to meet with a researcher and complete an interview and a series of questionnaires which will ask you about your experiences of mood episodes in the past, about how you are currently feeling and about how you think about and feel about the experiences associated with bipolar disorder. This will take approximately 2 hours.

Allocation to treatment
After the visit you will then be allocated randomly to either receive the psychological intervention or to continue to receive your usual treatment which is the control group. You will have a 50% chance of receiving the psychological intervention plus your usual care and a 50% chance of continuing to receive your usual care only. If you are in the control group you will not receive the

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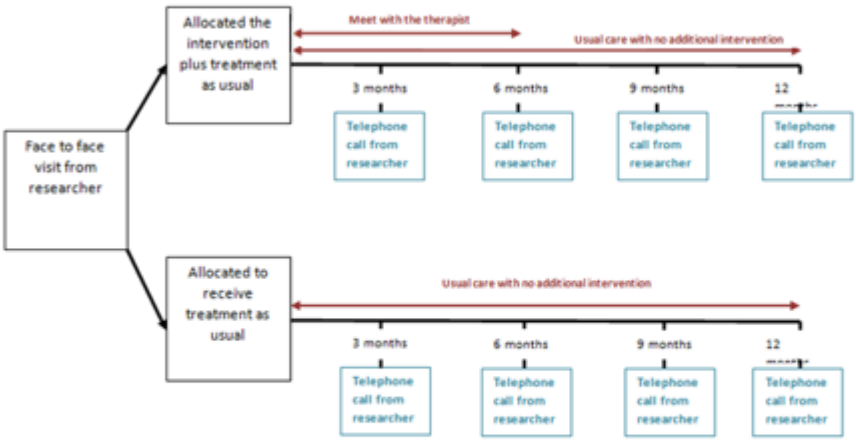
additional psychological intervention. You will continue with your treatment as usual from your care team but you will be asked to complete the assessments from the study team.

Assessments
Both those people who are allocated to the psychological intervention and those who continue to receive their usual care will receive either a telephone call from researcher every 3 months who will complete a similar interview and the same questionnaires with you until 12 months after your first visit. You will also be asked to complete an additional set of questionnaires at 6 and 12 months and these will be sent through the post or by email depending on your preference. During the time that you are taking part in the study your clinical notes may also be examined to assess for any changes.

Intervention
If you are allocated to receive the psychological intervention, this will involve meeting regularly with a therapist for a period of 6 months. The sessions can either take place at Lancaster University or in your own home. Each session will last approximately 45-60 minutes. In total you will have the opportunity to attend up to 14 sessions with the therapist.

We will ask for your consent to audiotape some of the assessments and therapy sessions. These recordings help us understand more about what happens in therapy and assessment. **You may decline permission for us to audio record assessment and therapy sessions at any time and still take part in the study**. The diagram below may help you understand what is involved in each type of treatment:



What are the alternatives for treatment?

You can access treatment in the usual way, via your care team, regardless of whether you take part in this research trial or not.

What are the possible benefits of taking part?

It is hoped that individuals may find receiving the psychological intervention beneficial in their recovery in bipolar disorder through helping people to manage the impact of a diagnosis of bipolar disorder on them, helping to identifying an individual's own triggers and early warning signs of a relapse, increasing people's coping skills and aid people in developing a 'recovery plan'. For those in the control group, there may not be any benefits. However we hope that the overall information that we gain from the study will help individuals living with bipolar disorder in later life in the future.

What are the possible risks or disadvantages of taking part?
Like with other psychological interventions, it is possible that people may find it distressing when talking about emotional topics. However, the nature of the psychological intervention means that any distress caused can be dealt with and worked on within the therapy itself.

What happens when the research study stops?
If you were one of the people who received the psychological intervention, when the study ends your therapist will discuss with your care team any relevant information that may help with your continuing care. You will no longer be able access the psychological intervention that you had in the research study, but you will continue to receive your usual care.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

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Participant Information Sheet
Part 2

What if relevant new information becomes available?
Sometimes we get new information about the treatment being studied. If this happens, a member of the research team will tell you about this new information and discuss whether you would like to continue in the study. If you decide not to carry on, arrangements will be made for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.

What will happen if I don't want to carry on with the study?
If you decide that you wish to withdraw from the study at any point you can do so without it affecting your care now or in the future. You may withdraw from the study completely or just withdraw from treatment and continue with follow up appointments.

If you withdraw from the study, we will destroy all your identifiable data, but we will need to use the clinical data collected up to your withdrawal.

What if there is a problem?

If you have any questions you are welcome to ask the researcher, whose contact details are listed at the end.

Complaints: If you wish to make a complaint you can contact:

Professor Steven Jones
Email: s.jones7@lancaster.ac.uk
Phone: 01524 593382.

If you would prefer to contact someone independent of the research with any concerns, please contact:

Professor Roger Pickup
Email: r.pickup@lancaster.ac.uk
Phone: 01524 593746

Harm: It is unlikely that you will be harmed by participating in this study. However, in the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Lancaster University but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?
All data recorded in this experiment will be completely confidential. All information about your identity will be stored separately from data gathered during the study. All participants will be

assigned an identification number which will be used to match responses. All data will be stored securely either on paper, or password protected databases. Personal data will not be kept any longer than 12 months, and will be destroyed by this time. Completely anonymous copies of people's responses may be retained for up to 10 years after the study.

If there are any particular concerns about you that are raised through your participation in this study, we may ask for your consent to refer these concerns to either your NHS management team, where applicable, or another suitable professional. Due to our duty of care to you, in extreme cases it may be necessary to breach the confidentiality of this study and inform your management team or a suitable professional of your responses. This would include cases where the specific intent to hurt yourself or others has been made clear.

Involvement of the General Practitioner/Family doctor (GP)

If you have been referred to us via your care co-ordinator in NHS mental health services, they will be kept informed of your involvement in the research trial. We will also write to your GP to inform them that you are involved in this research. If you have been referred through your GP and do not have a care co-ordinator in NHS mental health services, then your GP will be kept informed of your involvement in the research trial. If you have come to be involved in the study through voluntary organisations, your care -coordinator in NHS mental health services (or GP if you don't have a care co-ordinator in mental health services) will be kept informed of your involvement in the research trial

What will happen to the results of the research study?

It is intended for the results of the study to be published in an academic journal. If you are interested in receiving a copy of any publications from this study, please tell the research assistant at the interview.

Who is organising and funding the research?

The research has been funded by the National Institute for Health Research and is sponsored by Lancaster University.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The committee that has reviewed this application is the RES Committee North West - Preston.

Further information and contact details

If you require any further information you can contact Elizabeth Tyler on **07967837938**

Elizabeth Tyler
Spectrum Centre for Mental Health Research
Institute for Health Research
Lancaster University
LA1 4YT
e.tyler@lancaster.ac.uk

Appendix U

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CONSENT FORM

Recovery Focused Therapy for Older Adults with Bipolar Disorder

REC ref:

Name of Researcher: _____

Name of Participant: _____

Participant Number ☐☐☐☐☐☐

PART ONE

Please initial box

1. I confirm that I have read and understood the information sheet version number 2.0 dated 20/05/2015 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the analysis and publication of this study. ☐

3. I give my consent for the research team to contact my care co-ordinator and / or GP / other health professional in order to obtain risk-related information. ☐

4. I agree to my GP (and care co-ordinator where appropriate) being informed of my participation in this study and being informed should the research team be concerned about my mental health whilst taking part in this study. ☐

5. I agree to being contacted by the research team for a maximum of 12 months to complete interview and questionnaire assessments, in person, over the telephone and on-line, to find out how I am. ☐

6. I understand that my medical notes and records may be made available to responsible individuals from Lancaster University, your relevant North West NHS trust the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential and all data published will be anonymous. ☐

7. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (If different from Principal Investigator)	Date	Signature
_____	_____	_____
Name of Principal Investigator	Date	Signature

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