Medication adherence in bipolar disorder: Understanding patients' perspectives to inform intervention development

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A thesis submitted for the degree of Doctor of Philosophy

Declaration

I, Lindsay Allison MacDonald confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Abstract

Bipolar Disorder is primarily treated with medication which can be effective in reducing relapse risk, however, treatment is complex and adherence is sub-optimal. People can face significant challenges in self-managing the condition. The aim of this thesis was to better understand patients' perspectives of BD and its treatment. Then, to use both this knowledge and self-regulation and behaviour change theory to develop and test a novel intervention entitled *Improving information for people with Bipolar Disorder (IBiD)*. Intervention mapping, a stepwise process was followed to develop intervention content, delivery and evaluation.

A systematic review with meta-analysis (k=18) was conducted and revealed that interventions are effective in improving adherence, effects are durable and brief interventions may be more effective than longer programmes (Chapter 3). A qualitative study (Chapter 4) (n=12) revealed patients insights into the burden of illness, unmet information needs and also how to live well with BD. These findings informed the IBiD intervention, which was tested in a feasibility RCT in a sample of patients in an acute mental health setting (Chapters 5-7). The intervention can feasibly be delivered in this setting and was acceptable to patients. Aspects of the intervention and the study itself had self-reported positive outcomes, however a more targeted, longer intervention may be required to actually modify specific medication beliefs and adherence.

In order to explore additional factors raised during these studies a cross-sectional study (n=57) into the associations between perceptions, adherence and involvement in treatment decisions was conducted. Experiences of involvement and preferences for this were high. Involvement was significantly associated with satisfaction with information and illness perceptions. Associations between involvement and adherence were inconsistent.

The results of this research programme have important implications for both mental health services and the application of health and illness theory to mental health.

Table of Contents

Table of Appendices

Table of Figures

Table of Tables

Acknowledgements

I would like to thank my supervisory team, Professor Rob Horne, Dr Angel Chater and Dr Richard Bowskill for both the opportunity to undertake this PhD and for their support and advice.

I offer my sincere thanks to staff at Sussex Partnership NHS Foundation Trust for their support and assistance in recruiting and implementing the IBiD feasibility trial, in particular Kelly Humphryes, Sally Skipper and Philippa Case and Dr Mark Hayward. I would also like to thank the individuals who took part in the research and gave their time and shared their valuable and personal perspectives and experiences. In addition to Michel Syrett and Bipolar UK for their valuable contributions.

At UCL School of Pharmacy I would like to thank all my colleagues and fellow PhD students, in particular Dr Sarah Chapman and Penny Weller.

I also wish to thank Professor Rory O'Connor for his invaluable support and encouragement during my PhD and Health Psychology training.

Finally to my husband and family, I would like to thank them for their understanding, support and encouragement.

Publications and presentations from this thesis

Journal publications

MacDonald L., Chapman S., Syrett M., Bowskill R. & Horne R. (2016) Improving adherence in bipolar disorder; a systematic review and meta-analysis of 30 years of intervention trials. Journal of Affective Disorders. 194:202-21.

Manuscripts submitted for publication

MacDonald, L., Kapari, M., Bowskill, R., Hayward, M., Syrett, M., & Horne, R. (2014). Patients' common-sense understanding of bipolar disorder and its treatment: implications for supporting informed treatment choices. Manuscript submitted for publication to Psychology and Psychotherapy: Theory, Research and Practice.

Conference posters

L. MacDonald, S. Chapman & R. Horne. Improving adherence to medication in bipolar disorder: A systematic review of interventions. Division of Health Psychology Annual Conference September 2013, Brighton. Poster

MacDonald, L., Kapari, M., Bowskill, R., Syrett, M. & Horne, R. Exploring patients' experience of living with bipolar disorder and their perceptions of prescribed treatment. 26th Conference of the European Health Psychology Society; August 2012; Prague, Czech Republic. Poster

Abbreviations

AOT	Assertive Outreach Team
API	Autonomy Preference Index
ASRM	Altman Self-rating mania scale
ATAP	Atypical antipsychotics
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
BD	Bipolar Disorder
BDI	Beck Depression Inventory
BMQ	Beliefs about Medicine Questionnaire
CBT	Cognitive Behavioural Therapy
CCO	Care Coordinator
CG	Control group
CHRT	Crisis resolution and home treatment team
CMHT	Community Mental Health Team
COM-B	Capability Opportunity Motivation Behaviour
CONSORT	Consolidated Standards of Reporting Trials
COREQ	Consolidated criteria for Reporting Qualitative Research
CQC	Care Quality Commission
CSM	Common sense model
CSO	Clinical Studies Officer
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders 4th edition
ELM	Elaboration Likelihood Model
e-SRM	Extended self-regulation model
HCP	Healthcare Professional
IBiD	Improving Information in Bipolar Disorder
IG	Intervention group
II	Implementation Intentions
IM	Intervention Mapping
IPQ	Illness Perception Questionnaire
ISMI	Internalised stigma of mental illness
JCP	Joint Crisis Plan

MARS	Medication Adherence Report Scale
MDF	Manic Depressive Fellowship
MI	Motivational Interviewing
MPR	Medication possession ratio
MRC	Medical Research Council
NCF	Necessity Concerns Framework
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
OCD	Obsessive Compulsive Disorder
PAPA	Perceptions and Practicalities Approach
PIS	Participant Information Sheet
PMG	Project Management Group
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised Controlled Trial
SAQ	Symptoms Associated with Bipolar Questionnaire
SDM	Shared Decision Making
SIMS	Satisfaction with Information about Medication Scale
TAU	Treatment as usual
TDF	Theoretical domains framework
TES	Treatment Empowerment Scale
VAS	Visual Analogue Scale

Introduction

Bipolar disorder (BD) is a serious, long-term mood disorder which is characterised by episodes of mania, hypomania and depression. It is estimated that around 1.3% of the UK population have this condition (Smith et al., 2013). One of the main treatments for by BD is medication which aims to reduce relapse risk, however, treatment is complex and is not always effective for everyone. However the potential for treatment effectiveness can be helped by ensuring appropriate adherence to medication. People with a BD diagnosis can face multiple challenges in living with the condition, from accepting and understanding the diagnosis, managing treatment and dealing with the stigma of being given a mental health diagnosis.

Self-regulatory theories of illness focus on the dynamic relationships between external factors and personal schemas influencing perceptions of illness and treatment, coping responses and subsequent beliefs. Models of health and illness and health behaviour change have been widely applied to physical health, but are in their early stages in application to mental health conditions. It is hoped that by exploring patients' perceptions of BD and its treatment in the context of these models, it will lead to a greater understanding. By understanding perceptions and behaviour in this area, it will in turn inform development of the models. The nature of BD, as a potentially life-long, complex and fluctuating condition with treatment reflecting these characteristics, provides unique challenges for the application of health psychology models.

Given the challenges faced by many people with BD and the personal and societal costs associated with the condition, effective interventions which can be integrated into clinical care are needed. The overarching aim of the research is to utilise current understanding of illness perceptions, behaviour change theory and direct consultation with individuals with a BD diagnosis to develop an intervention which will help people to manage BD more effectively in a way which empowers them.

Thesis aims

The specific aims of this thesis were to:

- Understand patients' perceptions of the challenges in dealing with a diagnosis of BD and engaging in self-management. (Chapters 1, 4, 6, 7, 8)
- Uncover the unmet information and support needs of people with BD. (Chapters 4, 6, 7, 8)
- Investigate how current understanding of determinants of health behaviour and behaviour change theory can be applied to adherence and self-management. (Chapters 2, 5)

- Determine the effectiveness of existing interventions which exist to address adherence in BD. (Chapter 3)
- Develop a novel intervention to target adherence to medication through proximal determinants of perceptions, understanding, satisfaction with information and internalised stigma by using the step-wise method of Intervention Mapping (IM) involving behaviour change theory and service-user consultation. (Chapter 5)
- Test the feasibility and acceptability of conducting an RCT of the intervention in an acute adult mental health setting. (Chapters 6, 7)
- Investigate the extent to which patients with BD wish to be involved in treatment decisions, the extent to which they are involved, the association of these two factors with their illness and treatment perceptions and their adherence to medication. (Chapter 8)

Structure of the thesis

The opening chapter of this thesis provides the background to the empirical work included in the thesis. The nature of BD and its treatment are described as well as the costs and consequences which can be associated with the condition and, particularly with non-adherence to treatment. The challenges with defining and measuring adherence are outlined, before a summary of the research evidence on the demographic, clinical, social and perceptual factors associated with adherence behaviour in BD. **Chapter 1** also describes the difficulties many individuals face in living with BD, their understanding the nature of the condition, how to manage it, and the stigma associated with a mental health diagnosis.

In **Chapter 2**, the theoretical foundation of this programme of research is described, the Common Sense Model of self-regulation (CSM) (Leventhal, Nerenz, & Steele, 1984) , leading onto the Necessity-Concerns Framework (NCF) (Horne, 2003b) which encapsulates the perceptual determinants of adherence and the Perceptions and Practicalities Approach (PAPA) (Horne, 2001) which additionally incorporates practical barriers to adherence. Together with current evidence on behaviour change theory, in particular the use of Behaviour Change Techniques (BCTs), these frameworks provide the theoretical grounding for intervention development described in later chapters. **Chapter 2** also outlines the approach used to guide and structure the research in this thesis, the Medical Research Council (MRC) framework for the development of complex interventions in healthcare (Craig et al., 2008) from evidence synthesis and modelling to intervention development and testing.

Chapter 3 comprises a key part of evidence synthesis in a systematic review and meta-analysis of 30 years of interventions to improve adherence to medication in BD. The aim was to review

randomised-controlled trials of interventions incorporating medication adherence for people with a diagnosis of BD. Specifically to: describe the interventions characteristics using published guidelines, evaluate the quality of reporting and design, quantitatively synthesise evidence for effectiveness of interventions and identify moderating factors associated with intervention effectiveness. Twenty-four trials were included in the review, with 18 having sufficient data available for meta-analysis.

Having reviewed evidence on existing interventions, it was vital to generate rich data from patients' perspectives on being diagnosed with, living with, and taking medication for BD. Qualitative interviews were conducted with 12 adults with a BD diagnosis who had been prescribed medication for BD (**Chapter 4**). The interviews explored perceptions of BD and its treatment as well as providing data on unmet information and support needs and preferences for meeting these needs. Primary qualitative research is a key component of both research and policy development and is recommended by both the MRC, the NIHR as well as in local NHS Research policies (Craig et al., 2008; NIHR n.d.; Sussex Partnership NHS Foundation Trust, 2012).

These preceding chapters comprise the groundwork for the development of a novel intervention. **Chapter 5** describes the development process using an Intervention Mapping (IM) approach, which is a stepwise process for systematically developing the content, techniques, delivery and evaluation of an intervention (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011; Kok, Schaalma, Ruiter, Van Empelen, & Brug, 2004). This chapter draws together the findings from Chapters 1 to 4, and uses this to generate the intervention aims, behavioural and cognitive outcomes and the determinants of change to reach these outcomes. Appropriate theory-based methods and practical strategies were selected using theory and research evidence. The chapter also described the process of service-user and stakeholder consultation which was undertaken to ensure that the intervention was appropriate and adoptable. This process produced the *Improving Information for people with Bipolar Disorder* (IBiD) intervention (Appendix K). This comprises a written information resource tailored to individuals' perceptions of BD, its treatment and their information needs. The intervention aimed to target adherence to medication through proximal determinants of perceptions, understanding, satisfaction with information and internalised stigma.

Chapter 6 describes the 'Feasibility & Piloting' stage of the MRC process for the development of complex interventions (Craig et al., 2008). In this chapter, a feasibility RCT was designed and conducted with 30 individuals in an acute mental health setting which randomised participants (1:1) to receive the intervention or care as usual. Baseline and follow-up assessments at 8 weeks used validated and adapted measures of illness and treatment perceptions, adherence,

satisfaction, and internalised stigma. The study aimed to explore a number of feasibility objectives: the number of eligible patients in the population; recruitment and retention rates; acceptability of the RCT protocol, instruments and intervention; and intervention need. In addition, changes in the outcome measures were explored in both groups.

To provide additional insight on study acceptability from participants taking part in the feasibility RCT, a qualitative study was conducted with seven participants, from both the intervention and control group (**Chapter 7**). This aimed to explore the experience of participants taking part in the IBiD study including: participants' reflection on their decisions to enter the study, views on the questionnaires and practical arrangements, the acceptability and their use of the IBiD intervention and more generally their experience of information provision and support in mental health services.

It was clear from the findings of the empirical work and by reviewing current literature on adherence and self-management in BD that additional factors may be important to consider in both understanding individuals' perspectives on BD and its treatment and also for intervention development. In particular, factors around patient choice, empowerment and involvement in making informed decisions around treatment. To this end, a cross-sectional study was conducted (**Chapter 8**). The sample comprised 57 adults with BD who were prescribed medication. Validated measures of illness and treatment perceptions, adherence, satisfaction and experiences and preferences for shared-decision making (SDM) were completed. The aims of this study were to investigate the extent of SDM and preferences for this and the relationship between these variables with the hypothesis that greater involvement in medication decisions would be associated with more positive perceptions and increased adherence.

Chapter 9 concludes this thesis by summarising the key findings from each piece of research and examining these outcomes in the context of published studies. The strengths and contribution of these findings are discussed in relation to health psychology theory and mental health care. The chapter includes a discussion of the wider issues around mental health which were uncovered through the research process, including the application of current health psychology models to mental health and in terms of practical aspects, areas of mental health care which are currently not meeting the needs of people with a BD diagnosis. Limitations of the research in terms of areas of bias and threats to validity are highlighted and finally the theoretical implications and future research directions are discussed.

Chapter 1 Bipolar Disorder

1.1 Bipolar Disorder

1.1.1 Diagnosis & Epidemiology

Bipolar disorder (BD) is an often, long-term mood disorder which usually appears in early adulthood and is, for many people, characterised by episodes of mania, hypomania and depression. Although the specific nature and experience of the condition for each person varies widely. To meet current Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) criteria a person must have experienced an episode of mania during their lifetime (American Psychiatric Association, 2000).

A manic episode can be characterised by persistent elevated mood over a period of more than one week and symptoms may include grandiosity, decreased need for sleep, pressure of speech, racing thoughts and risk-taking. A depressive episode can be characterised by symptoms such as diminished interest or anhedonia, sleep and appetite disturbance, low self-esteem and suicide ideation. Some people experience 'mixed episodes' where aspects of mania may be experienced along with symptoms of depression (The British Psychological Society, 2010). Multiple recurrence of episodes is common (Pallaskorpi et al., 2015) and for most people, the period of time spent in depressive episodes is longer than that in manic episodes, with one study indicating that three times more days are spent depressed than in manic states (Kupka et al., 2007). Assessments of time spent in euthymic or normal mood indicate that this accounts of half of the time (Kupka et al., 2007; Pallaskorpi et al., 2015).

BD affects approximately one person in every hundred (Fajutrao, Locklear, Priaulx, & Heyes, 2009). However this may be an underestimation of the true prevalence due to difficulties with diagnosis (Fagiolini et al., 2013). There is a wide range in the presentation of BD, the course of illness and resulting impairment (Judd et al., 2002). Most people with BD will experience recurrent relapses, although some individuals will have few episodes and experience long periods in remission. De Dios and colleagues (2012) found that just under a quarter of people had at least one recurrence during a 12 month period. However, the remaining 76% remained free of recurrence for the 12 month follow-up.

Misdiagnosis or delay in diagnosis can occur in BD due to unreported or non-recognition of manic or hypomanic symptoms. Most often people present with a first episode of depression and therefore may receive a diagnosis of unipolar depression or major depressive episode (M. Berk et al., 2007; Morselli & Elgie, 2003). Indeed the large-scale, cross-cultural BRIDGE (Bipolar

Disorders: Improving Diagnosis, Guidance and Education) study identified that an additional 31% of patients diagnosed with a major depressive disorder met the criteria for bipolarity (Angst et al., 2011). As a result of misdiagnosis, inappropriate treatment decisions and prescriptions can be made, with antidepressants potentially leading to worsening of the condition. In the BRIDGE study almost a quarter of the sample had experienced episodes of elevated or irritable mood triggered by antidepressants (Angst et al., 2011). There may also be psychiatric co-morbidity such as substance misuse which can impact on reaching a diagnosis. The diagnosis of BD is often an ongoing process with multiple diagnoses and treatments along the way. The time taken from onset of illness to reaching a correct diagnosis is approximately six years (M. Berk et al., 2007; Drancourt et al., 2013; Morselli & Elgie, 2003).

1.1.2 Costs associated with BD

BD can result in significant physical, functional and cognitive impairment, having a severe impact on individuals' quality of life and the people around them (Conus, Macneil, & McGorry, 2013; J. Goldberg, Harrow, & Grossman, 1995). Participants reported the impacts which BD had for them in the GAMIAN-Europe/ BEAM survey (Global Alliance of Mental Illness Advocacy Networks-Europe/ Bipolar Education Awareness Materials). Over half reported problems with relationships within the family (53.9%) and over a quarter reported difficulties in obtaining (33.8%) or retaining (34.4%) employment (Morselli & Elgie, 2003). People with BD are also at a higher risk of suicide, 10-15% of those admitted to hospital will eventually die by suicide (Hawton, Sutton, Haw, Sinclair, & Harriss, 2005). A recent systematic review concluded that people with BD are at an elevated risk of mortality in all of the causes studied (Hayes, Miles, Walters, King, & Osborn, 2015). BD is also associated with drug and alcohol misuse, with approximately half of people with the diagnoses being dependent at some point in their lives (Cassidy, Ahearn, & Carroll, 2001). In addition, those with substance use problems do not benefit as much from available treatment compared to those without these problems (Salloum & Thase, 2000).

BD is also connected with significant economic costs and loss of productivity. Recent estimates of the annual cost of managing BD to the UK healthcare system at £342 million, with hospitalisations accounting for 60% of this (A. Young, Rigney, Shaw, Emmas, & Thompson, 2011).

1.1.3 Management

Recommendations by the National Institute for Clinical Excellence (NICE) for the management of BD include both psychological therapies and medication. In 2006, the emphasis was placed on medication stating the *'treatment of bipolar disorder is based primarily on psychotropic medication to reduce the severity of symptoms, stabilise mood and prevent relapse'* (2006: pg 20). The guidelines recommend specific treatment options for mania, hypomania, depressive episodes and for long-term maintenance (NICE, 2006). The place of psychological therapy was, however, acknowledged as having an important role. With the revision of the guidelines in 2014, there was a greater emphasis placed on psychological therapy with the recommendation that all people should be offered this, both in primary and secondary care as well as for longer-term management (NICE, 2014). Existing programmes include psychoeducation and Cognitive Behavioural Therapy. However, these are not routinely used in practice in the UK (Basco & Rush, 2005; Colom & Lam, 2005).

The importance of collaborative treatment planning and informed decision making is emphasised in both guidelines in accordance with recovery-focused care, *'treatment and care should take into account people's individual needs and preferences. People with bipolar disorder should have the opportunity to make informed decisions about their care and treatment'* and *'Written, evidence-based information about the condition and its treatment should also be provided. All information should be tailored to the needs of the individual patient'* (2006: pg 4) (NICE, 2006). Management, in line with the recovery model, is explicit in the 2014 guidelines with the recommendation that '*care must promote a positive recovery message from the point of diagnosis and throughout care'* and building supportive and empathic relationships is an essential part of care (2014: pg 14) (NICE, 2014). This reflects a movement within mental health policy towards care which focuses on helping patients to become empowered and being able to gain control, not solely managing symptoms but working together to build resilience and set personal goals (for more details on recovery see Section 1.2.6) (Jacob, 2015).

Psychological therapy can include lifestyle-focussed self-management which refers to activities which patients carry out separately from their healthcare professional (HCP) which aim to maintain wellness even in chronic conditions (Lorig & Holman, 2003). In BD this includes: regular and sufficient sleep, appropriate exercise and nutrition, monitoring mood and activity changes and understanding personal behavioural patterns and warning signs, creating and using informal or formal plans for dealing with episodes and maintaining social connections and seeking professional support (NICE, 2006; Suto, Murray, Hale, Amari, & Michalak, 2010). Carers can support people with BD by listening, providing affirmation, empowering people to

develop and use coping strategies and supporting them to detect early warning signs (Billsborough et al., 2014).

In the UK, individuals may be managed in primary care through their GP, secondary care through their psychiatrist and also through a care-coordinator from Community Mental Health Teams (CMHT). At times of crisis, individuals may be admitted to acute inpatient units, have their care managed through the Crisis Resolution and Home Treatment teams (CRHT) or by Assertive Outreach Teams (AOT) which work with people experiencing frequent relapse or social difficulties (NICE, 2006).

It is clear that maintaining wellness with a diagnosis of BD can be a complex and ongoing process. The challenges faced by many people with BD, include adhering to their medication, understanding and coming to terms with the diagnosis, accessing and understanding appropriate information and support and dealing with societal issues such as the experience of stigma. Adherence to medication is one key aspect of staying well.

1.2 Adherence

1.2.1 Rates and consequences of poor adherence

Like other long-term conditions, treatment non-adherence in BD is a concern as it affects the chances of medication being successful. A recent prospective study found that after 18 months, one-quarter of patients had discontinued medication and one-third were not using it regularly (Arvilommi et al., 2014). Research indicates that lithium is only maintained continuously for around 70 days (R. E. Johnson & McFarland, 1996) and Keck and colleagues found that after 1 year, half of patients were non-compliant with maintenance treatment (Keck, McElroy, Strakowski, Bourne, & West, 1997). Non-adherence is associated with substantial costs both financial and human including hospitalisation, suicide and loss of productivity (Baldessarini et al., 2006; Hong, Reed, Novick, Haro, & Aguado, 2011; Keck et al., 1996; Scott & Pope, 2002b).

1.2.2 Defining adherence

Adherence is defined as the extent to which a person's behaviour corresponds with agreed recommendations from a health care professional (World Health Organisation, 2003). Within a recovery model, this should be a care plan as agreed collaboratively between a patient and clinician, taking into account the patients preferences and goals (NICE, 2014). In order to adhere to a treatment plan, individuals must perceive some need for treatment, be able to

access it, understand and follow instructions on how and when to take the medication and remember to take it. Non-adherence can occur at any of these steps. Non-adherence can be both intentional by deciding not to take medication as prescribed and unintentional, by forgetting or not having the resources to take it (Arvilommi et al., 2014; Horne, Weinman, Barber, Elliott, & Morgan, 2005). Unintentional non-adherence may be a problem in BD particularly when becoming manic and also through confusion with regimen changes (Clatworthy, Bowskill, Rank, Parham, & Horne, 2007).

Different patterns of adherence have been observed, for example partial adherence by patients modifying their regimens without advice or irregularity ,for example, taking medication holidays or not taking them when using alcohol or drugs (L. Berk et al., 2010). Adherence is a dynamic process which can change through the course of illness. There is no consensus on what constitutes adequate adherence levels in BD. A level of 80% has been recommended (Velligan et al., 2009), but an actual level for positive clinical outcomes has not been determined.

1.2.3 Measuring adherence

The measurement of treatment adherence is complex and precise assessment is a challenge given the need to take account of full, partial, irregular and selective adherence. Measurements can be broadly classified into: objective, such as pill counts, serum level measurement and electronic monitoring or subjective such as self or clinician report (Sajatovic, Velligan, Weiden, Valenstein, & Ogedegbe, 2010).

1.2.3.1 Objective adherence measurement

Pill counts estimate the percentage of medications taken by determining how many pills are missing from a container and comparing this with the number which should have been taken within a specified time. Random, unscheduled visits serve to increase reliability, however, the problem remains that patients may not consume all medications removed from containers and the act of monitoring may undermine the therapeutic relationship if conducted by the patients clinical care team (Velligan et al., 2008). However, pill counts have been found to be correlated with other adherence measures in psychiatric populations (Velligan et al., 2006).

Measurement of the presence of medications taken in blood serum may be monitored as part of routine clinical care, such as in the case of monitoring Lithium levels to ensure correct dosing and data may therefore be more easily obtained. However, this does not apply to some

newer atypical antipsychotics and it would rely on patients attending for samples to be taken. Differences in medication half-life, metabolism and variability both within and between individuals' means that determining levels of medication or when medication was taken is difficult. Biological measurements may not fully capture partial adherence behaviour (Sajatovic et al., 2010).

Data from pharmacy records can be used to estimate adherence, for example, Medication Possession Ratios (MPR) i.e the number of days of medication supplied against the number of days prescribed. However, there are numerous problems with this method, including how to take account of clinical advice to change doses (but not with a corresponding prescription change) and like other methods, filled prescriptions will not necessarily mean medications are actually taken (Sajatovic et al., 2010).

Electronic monitoring involves the use of devices to record when pill containers are opened, this data is used to estimate the timing of medication doses and calculate adherence rates. Despite offering benefits such as being able to monitor remotely and monitoring multiple medications which patients may be prescribed, this method has a number of drawbacks. The method is expensive to purchase and a large amount of data cleaning is necessary prior to analysis. Patients may open containers to check how many doses are left or take more than one out at a time. Frequently in published reports using electronic monitoring, the detail of the data is reduced to percentage of doses taken, therefore the expense of this method may have been unnecessary (Sajatovic et al., 2010). In patients with schizophrenia, studies have shown that electronic monitoring was correlated with self-report and pill counts (Byerly, Nakonezny, & Rush, 2008; Velligan et al., 2006). However, these methods of measurements may over-estimate actual adherence levels as those taking part in these intensive studies might be more likely to be adherent.

1.2.3.2 Subjective adherence measurement

Self-report measures ask patients to estimate the number of doses taken or number of days where medication was taken as prescribed or they are asked to rate or endorse items relating to general medication taking behaviour, such as *I sometimes forget to take my medication*. Self-report is a frequently used measure of adherence. However, it may be subject to social desirability and recall bias. While reports of non-adherence may be accurate, adherence may be overestimated by patients (Sajatovic et al., 2010). However, there is evidence that self-report and serum levels are well correlated (Jónsdóttir et al., 2010; Lam et al., 2003; Scott & Pope, 2002b). Despite their limitations, self-report questionnaires provide more information

on how and why a patient is non-adherent, helping to identify types of non-adherence and providing information which can be used to try and improve adherence. In addition, people's representation of their own adherence can be a precursor to how they choose to act in the future. Asking people about their adherence may result in greater contemplation of the behaviour and influence subsequent decisions. This should be acknowledged when considering self-report data (McClatchley, Shorter & Chalmers, 2014).

Self-report measures of adherence used in BD research are described in detail in Chapter 6. These include the Medication Adherence Report Scale (MARS) (Horne & Weinman, 2002), the Morisky Adherence Scale (Morisky, Green, & Levine, 1986), the Brief Adherence Rating Scale (BARS) (Dolder et al., 2004), and the Tablets Routine Questionnaire (TRQ) (Scott & Pope, 2002b).

Self-report measures of adherence also use proximal factors such as attitudes to medication, barriers and insight into illness. These include the Beliefs about Medicine Questionnaire (BMQ) (Horne & Weinman, 1999), Rating of Medication Influences (ROMI) (Weiden et al., 1994), Medication Adherence Rating Scale (MARS) (K. Thompson, Kulkarni, & Sergejew, 2000) and the Drug Attitude Inventory (DAI) (Awad, 1993; Hogan, Awad, & Eastwood, 1983). They provide useful information on factors associated with adherence but a careful distinction is needed as attitudes may not translate into behaviour. However, an association has been demonstrated between attitudes and both self-report adherence and blood measures in BD and schizophrenia (Clatworthy et al., 2009; K. Thompson et al., 2000; Weiden et al., 1994).

A number of studies have used clinician estimated adherence levels, however these appear to be limited as clinicians could not reliably identify non-adherent patients (de las Cuevas, Peñate, & Sanz, 2013; Stephenson et al., 2012; Velligan et al., 2007). Velligan and colleagues (2007) highlight that this difficulty in clinicians identifying patients medication taking behaviour may have important consequences for patient care as there may be incorrect assumptions of patient response to prescriptions.

Informant report where patients caregivers or significant others provide an assessment of adherence have also been used. However, patients may not have someone who is able to provide this data as they may not have anyone who is involved in their care to that degree (Velligan et al., 2006). Also there has been poor compliance with completing these assessments in trials (Cochran, 1984).

1.2.3.3 Composite measures

Researchers have attempted to mitigate the limitations of single methods of adherence measures by using a combination of methods which may be examined separately or combined into a composite measure (Velligan et al., 2006) and this is recommended as the best way to measure adherence (Horne et al., 2005; Sajatovic et al., 2010; Velligan et al., 2009). Despite this, there are still challenges with deciding how to combine the measures, ascertaining what weight to give to each measure and defining what actually constitutes adequate adherence (Sajatovic et al., 2010).

1.2.4 Factors associated with non-adherence/ antecedents of adherence

Identifying the factors associated with non-adherence can help identify where risk is highest. A number of reviews have investigated these factors in BD (L. Berk et al., 2010; Busby & Sajatovic, 2010; Colom & Lam, 2005; Crowe, Wilson, & Inder, 2011; Leclerc, Mansur, & Brietzke, 2013). Factors can be grouped into demographic and clinical, attitudes, beliefs and knowledge and interpersonal (Figure 1.1).

1.2.4.1 Demographic & clinical factors

With regard to demographic factors, a recent review concluded there is mixed evidence for gender differences in adherence (Leclerc et al., 2013). The evidence is generally in favour of younger age being a risk factor for non-adherence. Two studies found the OR to be 1.03 for younger patients having poor adherence over older patients (Baldessarini, Perry, & Pike, 2008; Montes, Maurino, de Dios, & Medina, 2012) and evidence contributing to this comes from large, prospective studies so more likely reflects a true association. Other factors not found to be consistently linked in BD are relationship status and education (Colom & Lam, 2005).

One consistently reported clinical risk-factor for non-adherence is the presence of co-morbid substance use (Colom et al., 2000; Gonzalez-Pinto et al., 2010; Keck et al., 1997; Montes et al., 2012; Sajatovic et al., 2007). Where the magnitude of effect was reported, this was OR=1.98 (Montes et al., 2012) and OR=0.31 (Gonzalez-Pinto et al., 2010). With substance use, patients may use these in place of medication and may derive some symptom relief. In addition, it could be possible that use of substances may contribute to cognitive difficulties in remembering to take medication or having the motivation to do so. The evidence of the link between other co-morbidities and adherence is limited, but studies have found lower adherence linked with a comorbid diagnosis of obsessive compulsive disorder (OCD), OR=7.24

(Baldessarini et al., 2008) and personality disorders (Colom et al., 2000). It should be noted that patients with co-morbidities can also successfully manage BD and achieve personal goals of recovery.

Systematic reviews have found that disorder-related factors associated with poorer medication adherence specific to BD include elevated mood states (L. Berk et al., 2010; Busby & Sajatovic, 2010), mixed episodes or rapid cycling (Leclerc et al., 2013). The experience of psychotic symptoms has also been shown to be related to non-adherence, OR=0.91 (Gonzalez-Pinto et al., 2010), OR=0.523 (Moon et al., 2012) where the was a decreased odds in being adherent with the experience of psychotic symptoms. Other factors where there is inconclusive evidence are; age of illness onset and cognitive impairments (Jonsdottir et al., 2012; Leclerc et al., 2013).

1.2.4.2 Treatment-related factors

With regard to treatment-related factors, some studies find similar rates of non-adherence between different medications (Arvilommi et al., 2014; Baldessarini et al., 2008) and evidence from a large systematic review demonstrated that the introduction of new types does not appear to have affected adherence rates (Lingam & Scott, 2002). Keck and colleagues (1997) found that adherence to a combination of medications (a mood stabiliser, anti-convulsant and an antipsychotic) was higher over one year than to any of the monotherapies. The reasons are unclear but could be related to higher effectiveness of these combination therapies. However, other studies have not demonstrated a significant effect of the number of medications taken on adherence (de las Cuevas et al., 2013), and there is also inconsistent evidence on the effect of how long individuals had been taking mood stabilisers (Moon et al., 2012; Scott & Pope, 2002a).

Actual experience of side-effects has not been consistently related to non-adherence (Baldessarini et al., 2008; Sajatovic, Bauer, Kilbourne, Vertrees, & Williford, 2006). Fear of side-effects or subjective experience appears to be more important (Scott & Pope, 2002a). Despite this, in a large European survey, almost one-fifth of respondents said that side-effects were the main reason for discontinuation (Morselli, Elgie, & Cesana, 2004). However, participants may be adherent despite experiencing side-effects (Rosa et al., 2007) and those reporting side-effects as a reason for non-adherence also frequently report other reasons contributing to it (Arvilommi et al., 2014). It is clear that the relationship between fears and experience of side-effects is a complex one and warrants further exploration. Qualitative research is needed to

understand people's motivations and decision making around medication, weighing up costs and benefits.

1.2.4.3 Interpersonal & cognitive factors

The factors related to non-adherence described above relate to the condition and treatment itself. Individual psychological or interpersonal factors are also related to adherence and can be selected for interventions to target non-adherence.

1.2.4.3.1 Knowledge of illness and treatment

Knowledge about bipolar and treatment has been associated with adherence in a large review of the evidence (L. Berk et al., 2010). Although knowledge in itself is not necessarily the primary determinant of adherence (Horne et al., 2005), the importance of patients being informed about illness and treatment provides strong support for the recovery-model of mental illness which emphasises the importance of providing information (NICE, 2014). Knowledge has been identified as a tool for empowerment for mental health service-users by enabling them to act autonomously (Jacobson & Greenley, 2001).

1.2.4.3.2 Interpersonal factors

Relationships and interactions with family have been shown to have an association with adherence, for example caregiver's emotional over-involvement was associated with non-adherence (OR=0.24) (Perlick et al., 2004). Positive therapeutic alliance (a collaborative partnership between professional and patient) has been shown to be associated with adherence in a systematic review (L. Thompson & McCabe, 2012). This provides support for recovery-oriented care where patients are experts in the experience of their condition and relationships involve shared expertise (Davidson, 2005). However, it is important to recognise that, as much of the evidence comes from cross-sectional research, the direction of association is unknown. It may be that positive relationships result in good adherence or that by adhering to medication, and therefore remaining stable this may result in better relationships with caregivers and clinicians. This goes for much of the evidence around factors associated with adherence.

1.2.4.3.3 Beliefs about treatment

Non-adherence has been shown to be associated with people's beliefs about their illness and treatment. Doubts about the personal necessity of medication have been shown to be associated with poorer adherence (OR=0.5) (Clatworthy et al., 2009) (Devulapalli et al., 2010). These doubts may also relate to perceptions of the disorder, for example, that it is not controllable or is not a chronic condition (Clatworthy et al., 2007). Due to the fluctuating nature of the condition, it is clear as to why at times people may choose to stop their medication. Low perceived need has been shown to be a key barrier for seeking mental health treatment and reasons for dropping-out of treatment include patients wanting to handle problems themselves and perceived or actual treatment ineffectiveness (Andrade et al., 2014). Another study found that the main reasons for dropping-out of maintenance treatment were denial of therapeutic need during stable mood and perceptions of a lack of treatment efficacy during illness (Moon et al., 2012). This study did not take account of the different types of treatments participants were prescribed however, a strength of this study was that it included people no longer engaged with treatment therefore providing insights from a population who are often not assessed due to the fact that they have dropped out of treatment.

Patients with BD have reported concerns about dependency on medication and long-term side-effects (Morselli & Elgie, 2003). A qualitative investigation of treatment perceptions in individuals with BD revealed many perceived medication as providing mood-stabilising benefits, however, there were concerns about long-term adverse effects (Sajatovic, Ignacio, et al., 2009). Concerns about adverse effects have been associated with non-adherence in qualitative (Clatworthy et al., 2007) and quantitative research (OR=2.0, with stronger concerns being associated with poorer adherence) (Clatworthy et al., 2009). Linked with this, concerns about harm of medicine as opposed to worry about too many medicines impacts negatively on adherence (de las Cuevas et al., 2013). These concerns can be understood as they may reflect quite reasonable fears. The long-term effects of many medications have not been established and the documented side-effects in patient medication information could lead to people being very concerned about taking these treatments.

1.2.4.3.4 Beliefs about illness

Poor insight has been linked to poor adherence in a large prospective study, with good insight at the start of maintenance treatment being a protective factor (OR=1.98) (Gonzalez-Pinto et al., 2010). This was also found in an earlier review in BD (Látalová, 2011). Adams and Scott (2000) found that in patients with severe mental illness (schizophrenia and affective disorders)

there was a significant difference between high adherers and partial adherers in their perception of illness severity and their control over the disorder (high adherence being associated with a belief in external control of health), and concerns about further hospitalization. Partially adherent patients (as identified through a structured clinical interview) have been shown to have greater denial of severity of illness (Scott & Pope, 2002a). Stronger beliefs that their own behaviour controlled their health status were associated with adherence in BD in an interview-survey study with 100 patients (Darling, Olmstead, Lund, & Fairclough, 2008). Adherent participants in the same study also had more resources for coping with stress (Darling et al., 2008).

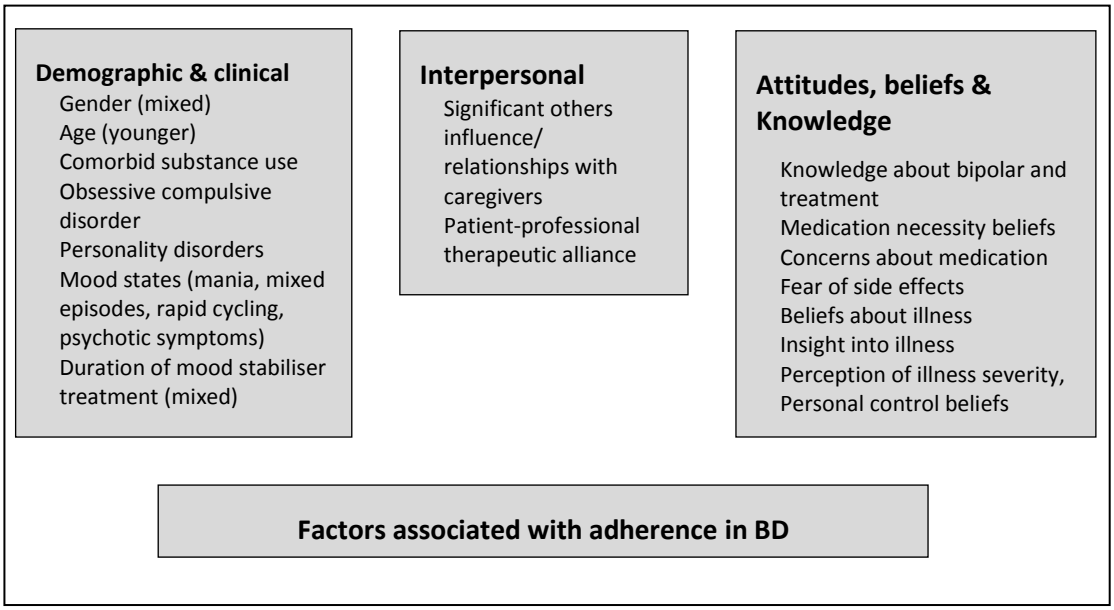


Figure 1.1: A summary of the factors associated with adherence in BD

1.2.5 Challenges associated with being diagnosed with and living with BD

It is clear that adherence is a major challenge in effective self-management, which is associated with a number of modifiable and non-modifiable factors. However, managing bipolar involves much more than adhering to medication, there are additional factors which affect individuals' ability to live well. These include the impact of receiving the diagnosis and associated stigma, accessing and understanding information about the condition and treatment and being actively involved in their own care.

1.2.5.1 Impact of receiving a BD diagnosis

Receiving a diagnosis for a mental health condition can have profound effects on an individual. Diagnosis, is for some, associated with reactions of shock and distress (Bilderbeck, Saunders, Price, & Goodwin, 2014; S. G. Goldberg, 2012) and a challenge to a person's identity or sense of self (Inder et al., 2008; Mansell, Powell, Pedley, Thomas, & Jones, 2010; Michalak et al., 2011; Proudfoot et al., 2009). Patients report feelings of internalised stigma from actual and perceived discrimination (Michalak et al., 2011). However, the diagnosis has also been reported as a useful way of explaining experiences and allowing individuals to separate their sense of self from the illness (Michalak, Yatham, Kolesar, & Lam, 2006; Proudfoot et al., 2009). The impact of bipolar itself may include the feeling of not being in control of moods or actions and this affects how people feel about the future (Crowe, Inder, et al., 2012; Lim, Nathan, O'Brien-Malone, & Williams, 2004). The studies about the impact of BD are often from small, qualitative studies, however the rich descriptions provided and the consensus across different pieces of research demonstrate how it actually is for people living with a BD diagnosis.

1.2.5.2 Understanding BD – Illness perceptions

In addition to their association with medication adherence, the relationship between both illness perceptions and treatment-seeking behaviour and subsequent outcomes has been investigated (Petrie, Broadbent, & Kydd, 2008). Illness beliefs have been demonstrated to have moderate to substantial stability over 12 months (Lobban, Solis-Trapala, et al., 2012). Using an illness cognitions measure (incorporating sick role, illness acceptance, dissatisfaction with treatment and support), Berk and colleagues (2013) investigated associations with outcomes (e.g. illness outcomes, functioning and self-esteem). More negative cognitions were associated with poorer outcomes. Lobban and colleagues (2012) investigated the impact of illness beliefs in BD, using a self-regulation model (described in Chapter 2) (Leventhal et al., 1984), on outcomes (mood and length of time before illness relapse). Stronger beliefs about the severity of the consequences of bipolar were associated with higher relapse risk and likelihood of becoming depressed. Stronger identity scores (more symptoms experienced) were associated with lower risk of relapse. Stronger beliefs in personal control were associated with lower risk of becoming depressed. This study followed up patients for 24 months, but did not investigate how beliefs may have changed over the course of illness. In addition to understanding how beliefs might change, a greater understanding of how beliefs originate and how they can be affected by care providers' views and what information they give to people with a BD diagnosis. A clinician using a disease-based model of mental health may not promote beliefs and feelings of personal control and help people towards a view of personal recovery and

living a fulfilled life despite the diagnosis. In patients with psychosis, illness perceptions (cognitive and emotional) have been found to mediate the relationship between illness course and quality of life (Gómez-de-Regil, Kwapil, & Barrantes-Vidal, 2014). In a South African sample, spiritual attribution of cause was associated with longer duration of untreated psychosis (Burns, Jhazbhay, & Emsley, 2011). Illness perceptions have also been shown to be related to negative expectations about returning to work in a population of mental health service users, specifically, more severe illness consequences, lower personal control over illness, greater illness identity and concern about their illness. (Løvvik, Øverland, Hysing, Broadbent, & Reme, 2014). Given the body of evidence, illness perceptions have been identified as an important area in developing interventions in mental health (Petrie et al., 2008).

1.2.5.3 Satisfaction with information & involvement in care

Dissatisfaction with information about medicines is commonplace and has been associated with poorer adherence (Bowskill, Clatworthy, Parham, Rank, & Horne, 2007). A number of studies have identified specific areas of dissatisfaction. Bowskill and colleagues (2007) found that the areas of information which participants with BD in a community sample were most dissatisfied with were 'the risks of getting side effects' and whether the medication would affect their sex lives. A large scale European survey of individuals with mood disorders identified the information which respondents would find helpful in dealing with BD were: managing the condition both day to day and in the long term, the range of treatments available and their efficacy and safety, the nature of the condition and where to obtain help (Morselli & Elgie, 2003). In a study by Perreault and colleagues (2006) the most endorsed items in terms of importance of information were confidentiality and access to medical information, followed by the type and side-effects of medication. However this was a small study (n=86) and did not include participants over 65 years of age. An online survey in Germany revealed that respondents searched for information about BD, in particular treatment options, because the information they received from their clinicians was insufficient (Liebherz, Tlach, Harter, & Dirmaier, 2015).

In the 2011 Care Quality Commission (CQC) survey of users of community mental health services in England over one-quarter of patients reported that they were not given information about possible side-effects of new medication and 15% were not provided with information in a way that they could understand (2011a). Findings for the inpatient setting have also indicated dissatisfaction in receiving explanations about medication (Care Quality Commission,

2009b). Almost half of patients reported that they were not provided with information on side-effects of medication in a way that they could understand (Care Quality Commission, 2009b).

As well as specific information needs, more general unanswered questions exist after patients receive a diagnosis of BD. Patients have reported uncertainty about what the diagnosis means for their future in terms of employment, relationships and family due to the chronic nature of the condition (Proudfoot et al., 2009). Participants have reported wanting practical help in managing their condition, not just explanations of it (Bilderbeck et al., 2014).

There is an increasing emphasis on involving patients in their own care in mental health and it has been recommended that information given in psychiatric care should enhance choice and reflect patients' values, this will promote informed decisions (Deegan & Drake, 2006; Hope, 2002). Shared decision making (SDM) involves patients actively in planning treatment and setting goals. It is important for both ethical reasons and for patient outcomes and has been addressed as part of the Toronto consensus statement for healthcare since 1991 (Simpson et al., 1991). A recent review found that having involvement in decisions, or receiving preferred treatment was associated with higher satisfaction with treatment, adherence and better clinical outcomes than where patient involvement or preference was not taken into account (Lindhiem, Bennett, Trentacosta, & McLear, 2014). The benefits of patient participation in medication choice are highlighted by Wilder and colleagues (2010) who found that patients were more likely to adhere to medications which they had requested in advance directives.

Patients wish to be informed about their diagnosis and involved in decisions about their treatment (Bilderbeck et al., 2014; de las Cuevas, Rivero-Santana, Perestelo-Perez, Perez-Ramos, & Serrano-Aguilar, 2012). However, in practice, national surveys conducted by the CQC have identified that there are a substantial proportion of patients who do not feel involved in decisions about their care and treatment. In the inpatient setting more than one-quarter (27%) of patient were not involved as much as they wanted to be (Care Quality Commission, 2009a). In terms of medication decisions in a community sample, only 13% did not feel their views were taken into account (Care Quality Commission, 2011a). However, in the local NHS trust in this programme of research, there was poor performance compared to national figures in patients' opinions of having their views taken into account during decisions and patients did not feel they had enough time to discuss their condition and treatment (Care Quality Commission, 2011b). The local figures for the inpatient setting show poor levels of satisfaction for being involved in care and treatment compared to those nationally (Care Quality Commission, 2009a). In the CQC Annual report of the provision of care for patients detained under the Mental Health Act, more than half of patients were not given a copy of their care

plan and one-third did not have their own views recorded on this (Care Quality Commission, 2013).

1.2.5.4 Stigma associated with mental illness

National surveys indicate movement towards increased understanding and tolerance of mental illness. However, in 2010, 87% of the public agreed that people with mental illness experience stigma and discrimination (TNS UK for the National Mental Health Development Unit, 2010). A large Europe-wide survey of people with BD and depression revealed 22% reported moderate or high levels of self-stigma (Brohan, Gauci, Sartorius, & Thornicroft, 2011). Many people with BD describe negative opinions and reactions from the public as well as people they are close to (Michalak et al., 2011; Michalak et al., 2006; Proudfoot et al., 2009; Todd, Jones, & Lobban, 2012). Stigma can serve as a barrier to accepting a mental illness diagnosis (Mizock, Russinova, & Millner, 2014).

A review of the factors associated with stigma in mental illness identified a number of psychosocial variables being negatively associated with internalised stigma, in particular, low levels of hope and empowerment, self-esteem, self-efficacy, quality of life, and social support. In terms of outcomes (from longitudinal studies) high levels of stigma were associated with a negative impact on self-esteem, coercion and experiencing symptoms of psychosis (Livingston & Boyd, 2010). A strong therapeutic alliance with HCPs had been shown to be associated with less negative feelings of stigma about BD (Strauss & Johnson, 2006).

1.2.6 Recovery, self-management and living well with BD

There are many definitions of recovery in mental health including syndrome recovery, i.e. no longer meeting the criteria for BD, symptomatic recovery i.e. the absence of symptoms and functional recovery in social, educational, occupational areas (P. Harvey, 2005). The absence of symptoms perspective represents a more traditional medical model of mental health, where recovery is externally defined according to criteria imposed by care providers/ organisations (Jacob, 2015). Recovery in mental health in the UK is moving towards a conceptualisation of living well with a chronic condition and staying in control of their life, as opposed to the complete absence of symptoms (Jacob, 2015). There has been policy shift towards making services more ‘recovery-orientated’ and encouraging personalisation of care and self-directed support (Perkins & Slade, 2012). Personal goals of recovery and staying well reported by participants included acknowledging the condition, having a good quality of life, being free from symptoms and being in control of their own lives (Michalak et al., 2006; S. Russell &

Browne, 2005; Todd et al., 2012). The most important consideration is that recovery must represent what is important to each individual (Davidson, 2005).

Reports from patients on what may have been helpful in reaching acceptance of the condition sooner included increased awareness in society, less stigmatisation, greater support from family and friends, more information and education immediately following the diagnosis and earlier access to treatment (Delmas, Proudfoot, Parker, & Manicavasagar, 2011).

In terms of what helps people move towards recovery or living well with BD, strategies for staying well identified by patients include being proactive and finding out information, maintaining and strengthening their support network, monitoring mood and behaviour and implementing strategies to counteract these, managing sleep and daily routines, engaging with treatment and creating and implementing wellness plans (Mansell et al., 2010; Michalak et al., 2006; Mizock et al., 2014; S. Russell & Browne, 2005; Todd et al., 2012; Van den Heuvel, Goossens, Terlouw, Van Achterberg, & Schoonhoven, 2015).

The process of monitoring personal warning signs, or prodromes, has been identified as a key aspect of self-management to reduce relapse risk and stay well (S. Russell & Browne, 2005). It had been demonstrated that patients are able to report prodromes reliably in a prospective study assessing relapse. Common prodromes for mania include reduced need for sleep and more goal directed behaviour and for depression, loss of interest in activity or people, worries and anxieties and interrupted sleep. The use of behavioural coping strategies for mania and depression prodromes reduced risk of relapse (Lam, Wong, & Sham, 2001).

In addition to the increasing literature on living well with BD, there has been a recent growing interest in looking at the positives the diagnosis can be associated with for people. A review identified that the diagnosis was associated with positive factors including spirituality, empathy, creativity, realism and resilience (Galvez, Thommi, & Ghaemi, 2011). Qualitative research identified positives associated with BD, including amplifying experiences like focus and creativity (not only associated with mania or hypomania by patients). Participants reported that BD gave them an increased range of feelings and experiences and the ability to learn from these (but with acknowledgement that with these positives come challenges and difficulties) (Lobban, Taylor, Murray, & Jones, 2012). Some patients have also reported that the diagnosis opened doors and allowed them to explore new opportunities such as different career paths and new social networks (Michalak et al., 2006).

Qualitative research by Russell and colleagues (2013) focussed on the differences between happiness and the highs of mania. Patients identified that happiness was more associated with acceptance and peace and mania was more chaotic and disruptive. Happiness was associated

with a sense of community and connecting with others whereas highs were associated with the disruption of social relationships. The authors conclude it is important a discussion is opened up where clinicians and patients are able to see that positive states aren't always a sign of 'illness' (L. Russell & Moss, 2013).

1.3 Conclusions

BD can be a chronic condition which is often associated with negative consequences for both the individual, their significant others and more widely in terms of economic and social costs. Medication can be effective in reducing the risk of relapse and potentially destructive consequences associated with this. However, medication is often not taken as prescribed or discontinued prematurely. Factors associated with non-adherence to prescribed treatment have been identified and include demographic and clinical characteristics as well as factors related to treatment. Psycho-social factors have also been identified including perceptions of both illness and treatment, satisfaction with information and interpersonal relationships with healthcare providers.

To manage BD, it is important for many to adjust to the diagnosis, be able to access information about their condition and treatment, feel involved in their care and work collaboratively with their HCPs, who in turn should acknowledge the patient's own unique, experiences. However, a number of issues exist which mean that staying well can be a challenge including unhelpful perceptions of treatment, practical barriers to taking medication, lack of support and understanding from healthcare providers, lack of access to information and public perceptions of mental illness.

Effective interventions are needed to address these issues in order to help people live well with BD. Chapter 2 first outlines the recommended process for development of interventions in health which is appropriate to use in developing an intervention to address outcomes for people with BD (Craig et al., 2008). A key first stage in this development process is to identify evidence to inform intervention development. This includes the evidence presented in this chapter concerning the identified areas of need for people with BD, the factors associated with adherence to treatment and the challenges for many people living with the diagnosis. Chapter 2 goes on to describe how current theories of behaviour and behaviour change relate to this area and can be used to inform an evidence-based intervention.

Chapter 2 Theoretical context

The evidence presented in Chapter 1 demonstrates that in bipolar disorder (BD) there are perceptual factors, such as beliefs about treatment, as well as practical factors, such as memory or physically being able to access treatment which are associated with adherence to medication and other self-management behaviours. In order to both understand and develop strategies to attempt to modify perceptions and behaviours, it is imperative to utilise an evidence-based theoretical framework.

In order to understand and modify behaviour, it is necessary to consider models and theories which attempt to describe relationships between, for example, cognitions and behaviours. These provide explanations as to why behaviours are enacted or not. It is also vital in developing strategies to modify these cognitions and behaviours to draw on the increasing evidence on theory-based behaviour change techniques. These are considered in this chapter in a context of how they can be applied to adherence and self-management in BD. The models are selected for their appropriateness to this programme of research. Specifically these are models which describe illness and treatment perceptions and the influence of these perceptions on health behaviours and outcomes. These are presented first to provide the context of the current theoretical framework, before leading into a discussion of how current models and research in health psychology and behavioural science uses the knowledge of determinants of behaviour and uses this to attempt to modify it.

Prior to describing these models and how they apply to the area of BD, the recommended process of developing complex interventions in this area is described (Craig et al., 2008). A first key stage of this process is to identify the theoretical basis on which to base the intervention development. Theories of behaviour and behaviour change are essential in designing and delivering an intervention to improve outcomes for people with BD. This chapter describes these processes as applied generally to health behaviour and healthcare interventions generally, Chapter 5 describes the detailed process of applying this framework and identifying the evidence-base for improving adherence and outcomes in BD.

2.1 Using the MRC Framework for the development of complex interventions

This programme of research applies the approach recommended by the MRC framework for the development of complex interventions in healthcare (Craig et al., 2008) (Figure 2.1). The aim of this guidance is to provide researchers with a systematic process for designing, testing,

evaluating and implementing interventions which are based on the best available evidence and tested using rigorous methods.

The process comprises four stages (which may or may not follow in a linear or cyclical sequence): development, feasibility/ piloting, evaluation, and dissemination. Firstly it outlines best practice in using evidence and theory for intervention development. Secondly it explains the process of establishing feasibility and undertakes piloting. Thirdly the effectiveness of the intervention is evaluated and finally, the intervention is implemented into practice. Despite being prescriptive, the authors acknowledge that intervention development must also be pragmatic. In practice, development is likely to take place under constraints, conditions or pre-existing service delivery, for example, the setting in which the intervention can practically take place is already specified and there may be time restrictions on delivery of an intervention. Each of these stages is described below in more detail.

Development phase: This comprises identifying the evidence base and involves systematic reviews and identifying or developing theory and potential mechanisms of behaviour change. This process should use published research as well as conducting new primary research. It aims to develop an intervention to the point where it could be expected, given the evidence available, that it would have the potential to have an effect. An intervention can then be developed and 'modelled' (more detail on how this process is conducted as applied to the BD intervention in this thesis is described in Chapter 5). This phase should also incorporate the selection and/ or development of outcome measures for the intervention evaluation. The development phase should also incorporate practical aspects such as considering how it might be possible to implement any future intervention, where, how and by whom this would be delivered. A recently developed checklist provides a framework on which to ensure that interventions are comprehensively described and replicable. The Template for Intervention Description and Replication (TIDieR) checklist comprises 12 items to fully describe the intervention; Brief name; Why (rationale, theory or goal); What (materials used); What (procedures used); Who provided; How (mode of delivery); Where (location); When and how much; Tailoring; Modifications; How well (planned); and How well (actual) (Hoffmann et al., 2014).

Feasibility/ piloting: This phase involves establishing the acceptability of the intervention and designing the processes to evaluate it. This may involve a number of stages, often involving both qualitative and quantitative methods and allows estimation of recruitment, retention, provides data on the fidelity of intervention delivery and methods to assess this. It also provides the opportunity to identify any other problems in order to anticipate and mitigate these prior to a full-scale trial. This is a crucial step to ensure that resources are not wasted in

the long-term (the distinction between pilot and feasibility studies are outlined in Chapter 6, Section 6.3). From feasibility and piloting studies, information can be gained to inform a sample size calculation and cautious estimation of the potential intervention effects.

Evaluation: After establishing that an intervention is feasible, it is then subject to a formal evaluation (and cost evaluation where possible) where an appropriate study design is chosen. This could be the individually randomised controlled trial, as the most robust option as it reduces elements of bias. However, there may be factors which mean that this is not appropriate or feasible to randomise. Other methods such as cluster trials, stepped-wedge, n of 1 design, quasi-experimental or non-experimental methods can be used. Important aspects of evaluation, as well as assessing outcomes, are in looking at process variables, or why interventions work, and what aspects might be most important or what factors the result is dependent upon or influenced by.

Dissemination: Once an intervention has been evaluated it is crucial to ensure that this learning is disseminated, used to inform further research or translated into clinical practice or policy. This could be using peer-reviewed journals, but importantly to disseminate to planners, policy makers and clinical teams to ensure translation into practice. The intervention evaluation may be short-term, however, it is important to follow-up outcomes of interventions in the longer-term and conduct surveillance to assess effects not covered in the evaluation.

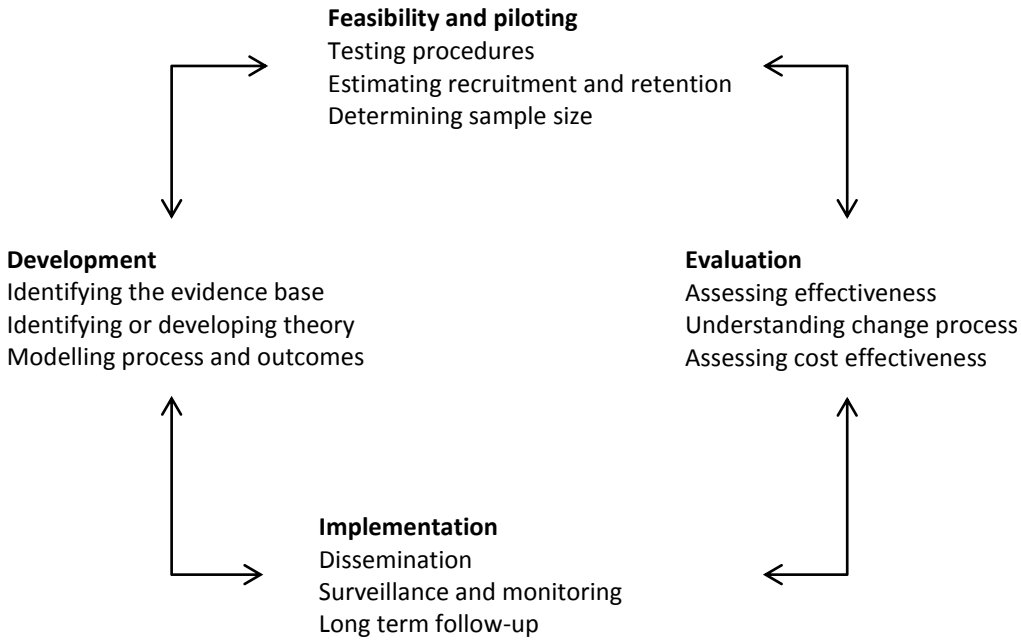


Figure 2.1: Medical Research Council framework for the development of complex interventions (Adapted from (Craig et al., 2008))

2.2 Understanding illness behaviour

Models, theories and frameworks of illness behaviour incorporate multiple and complex factors. These include individual factors as well as society and environmental influences. It is important to make the distinction between models and frameworks and theories. Frameworks serve to represent the structure of and potential relationships between relevant factors and behaviours. However, a theory takes this further by comprising empirically validated relationships between concepts and allowing testable hypotheses (Michie, West, & Spring, 2013). A good theory has been defined, in addition to these characteristics, as using clearly defined concepts that are parsimonious and coherent (Michie, West, et al., 2013).

Although some of the variance of illness behaviours such as adherence can be explained through disease characteristics, demographics and individual differences, these factors do not consistently account for behaviour. In addition, these factors are difficult to modify, thus their utility in attempting to change behaviour is severely limited. Individual, modifiable factors such as a person's beliefs about illness are an important factor in explaining health behaviour, including adherence, in both physical illness and in mental ill-health (Petrie et al., 2008). Research into physical illness has demonstrated the association between beliefs or perceptions, motivation and behaviour leading to the development of a number of theories, models and frameworks. One such model is the Common Sense Model of self-regulation of illness behaviour (CSM), described below (Leventhal et al., 1984).

2.2.1 Leventhal's Common Sense Model (CSM) of self-regulation of illness behaviour

The CSM provides a framework for understanding people's perceptions and responses to health threats and the cognitive proceses underlying them (Leventhal et al., 1984). The model is dynamic in that people's representations of threats are updated by actions and behaviours (Leventhal, Leventhal, & Breland, 2011). Central to the model are illness representations, which are beliefs or expectations about an illness or symptom. In the original CSM, illness represenations are comprised of five key components: 1. *identity*, beliefs associated with the label or name of the illness, diagnosis or symptoms, 2. *timeline*, beliefs concerning acute, cyclic or chronic, 3. *cause*, beliefs concerning the factors causing the illness, 4. *consequences*, beliefs concerning the expected effects of the illness, and 5. *control/cure*, beliefs associated with the extent to which treatment or behaviour can control or cure the illness.

The model describes the dynamic self-regulatory processing which takes place when symptoms are perceived or other stimuli are experienced, such as being informed of a diagnosis (particularly in asymptomatic conditions). Illness representations are activated

through symptoms perception by the individual themselves and also messages from society (including family and media, for example recommendation to seek help for a cough). The illness representations activated then motivate the individual to generate, select and utilise coping strategies, these can be behavioural and cognitive. Taking medication and engaging in other self-management strategies are examples of coping methods. The outcomes of coping strategies are appraised as either effective or ineffective. Outcome appraisals in turn lead to refinements of illness representation and subsequent selection of coping strategies. In conjunction with this cognitive processing, stimuli trigger emotional responses which result in the generation of emotion coping strategies which are appraised and processed (Leventhal, Diefenbach, & Leventhal, 1992).

The importance of illness representations on peoples' illness behaviour has been demonstrated in a number of studies over the previous 30 years (e.g. (Lobban, Solis-Trapala, et al., 2012; Løvvik et al., 2014; Petrie, Weinman, Sharpe, & Buckley, 1996)). For example, stronger beliefs that an illness could be controlled as associated with increased likelihood to attend a cardiac rehabilitation course (Petrie et al., 1996). A strength of this study was that patients were followed up over the course of six months so it is more likely that the direction of causality of cognitions and behaviour can be inferred. In mental health, even after adjusting for clinical and demographic differences, participants beliefs that their mental health problems had severe consequences was related to uncertain or negative return to work expectations. However there were limitations in measuring return to work expectations with a single item and this study was cross-sectional (Løvvik et al., 2014). In a prospective study in BD, illness beliefs (greater consequences, more symptoms, emotional concern) predicted illness relapse and symptom experience over 24 weeks. On the positive side, perceptions of personal effort to get well was associated with less symptom experience (Lobban, Solis-Trapala, et al., 2012). Overall a systematic review of the CSM as applied to mental illness concluded that illness perceptions are associated with a number of behavioural measures such as coping, help-seeking and treatment adherence. These in turn will be related to clinical outcomes (Baines & Wittkowski, 2013). However the review authors acknowledge that much of the research is cross-sectional.

The practical utility of the model is demonstrated by studies showing that changes to illness perceptions can improve disease outcomes, for example in increasing perceptions of the chronic nature of myocardial infarction, the severity of consequences as well as that the illness was controllable, was associated with return to work and symptom experience (Petrie, Broadbent, & Meechan, 2003; Petrie, Cameron, Ellis, Buick, & Weinman, 2002). However, this was a small trial with a limited follow-up time (3 months).

2.2.1.1 Operationalising the CSM

The original method used to elicit patient's illness representations were in-depth semi-structured interviews which focussed on their illness experiences. In order to provide a psychometrically verifiable method of assessing representations a theoretically derived questionnaire was developed which was based on patients own representations in a range of conditions. The original Illness Perception Questionnaire (IPQ) (Weinman, Petrie, Moss-Morris, & Horne, 1996) assessed the five key components of the CSM; identity, timeline, cause, consequences and control/cure, described above using 5 sub-scales. The 'identity' subscale comprises 12 core symptoms which can be tailored to specific illnesses. Patients rate the symptoms for frequency on a four point scale (all of the time, frequently, occasionally, never) and a sum score of those experienced at least occasionally is generated. Items in the additional four subscales are rated on a five point scale of levels of agreement and are scored according to guidelines (Weinman et al., 1996).

In 2002, a revision to the original IPQ was published (IPQ-R) (Moss-Morris et al., 2002) which due to problems with internal consistency added a cyclical timeline beliefs subscale in addition to the acute and chronic subscales of the timeline scale The control scale was split into two subscales of personal control and treatment control which accounted for growing evidence of outcome expectancies the importance of treatment beliefs (Horne, Weinman, & Hankins, 1999). The original IPQ did not include emotional representations which are a key part of the CSM, the IPQ-R includes a six item subscale assessing affective responses to illness. An illness coherence subscale was also added in order to assess whether an individuals' illness representations provide a coherent understanding of the illness (Moss-Morris et al., 2002).

On account of the length of the IPQ-R (over 80 items), in 2006, the Brief-IPQ was developed which contains only one-single item to measure each component (Broadbent, Petrie, Main, & Weinman, 2006). Both the IPQ-R and B-IPQ demonstrate good reliability and construct validity (Broadbent et al., 2006). However, some authors have identified problems with the content validity of the B-IPQ, for example respondents misinterpreting items about personal control and cause, therefore further validation is warranted (van Oort, Schröder, & French, 2011).

The utility of the use of illness perceptions in mental health has been advocated (Petrie et al., 2008) and recently the IPQ has been used or adapted for use in this area (Fortune, Barrowclough, & Lobban, 2004; Lobban, Solis-Trapala, et al., 2012; Witteman, Bolks, & Hutschemaekers, 2011).

2.2.2 An extended model of self-regulation (e-SRM) for treatment behaviours

In order to understand behaviour such as treatment adherence, it is important to have a detailed understanding of the coping procedures specific to the behaviour. Namely, 'how do representations of treatments relate to adherence?'. The orginal CSM was extended to explicitly incorporate treatment representations into the extended self-regulation model (e-SRM) (Horne, 2003b) (Figure 2.2). According to the model, perceptions of treatment are influenced by general beliefs about medications as well as by a persons experiences and perceptions of social norms. Clinician's input can also impact on these perceptions by providing or witholding information and their own viewpoint on the condition (ie. using a diseased-based model to understand and communicate to patients or a more recovery-focused model). Studies in physical illnesses have shown that negative perceptions of treatment are linked to perceptions of illness and the degree of 'fit' between patients belief about the problem (illness) and preferred solution (the treatment) (Horne & Weinman, 2002). A common-sense model in which an individual has a recognition of their condition, a perceived need for medication, and their concerns about the prescribed treatment have been acknowledged would be likely to lead to engagement in positive self-management, including adherence (Horne, 2003b). In the converse, conditions which are asymptomatic may result in a person doubting the need for treatment (Horne, 2003b).

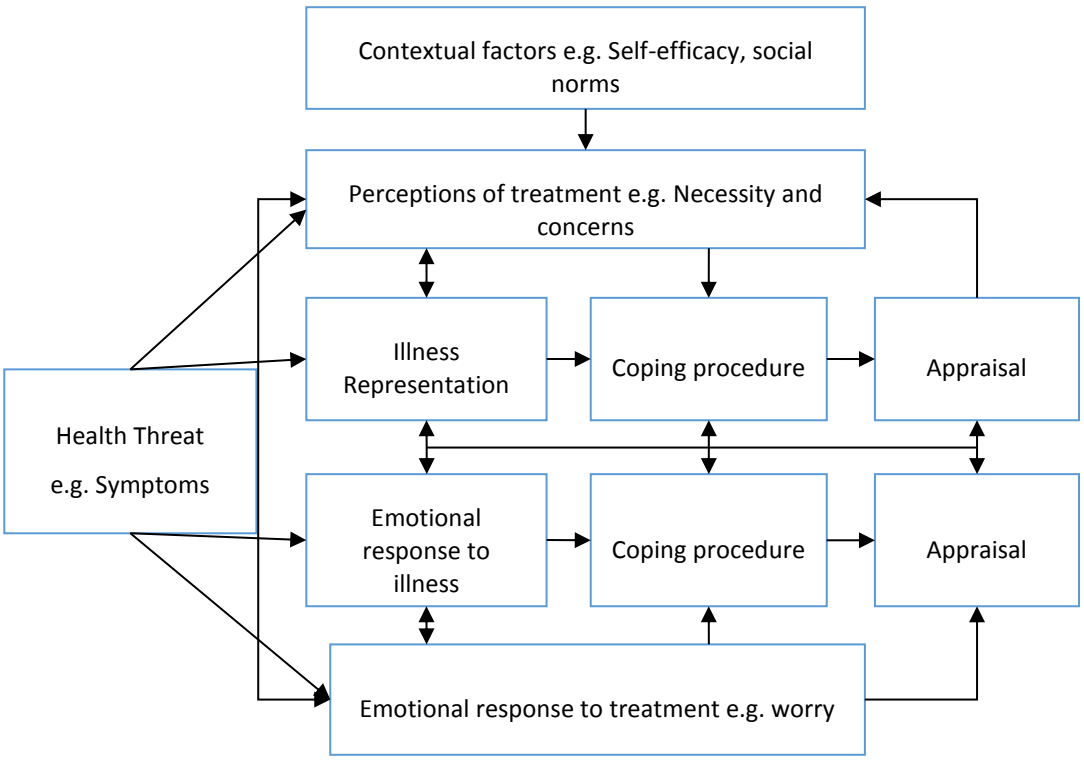


Figure 2.2: The extended model of self-regulation (adapted from (Horne, 2003b))

2.2.3 Necessity and Concerns Framework

Research has identified that treatment beliefs can be divided into beliefs about the personal necessity of treatment and individual's concerns about medication. People have higher-order beliefs about medication in general, i.e. pharmaceuticals as a specific class of treatment, these are influenced by more specific beliefs about particular medications. The Necessity and Concerns Framework (NCF) (Horne, 2003b) provides a model for understanding specific beliefs about medications. Necessity beliefs incorporate a person's perceptions of how much they feel they need a treatment, and related to this, their perception of a treatments efficacy. However a person could for example have high perceptions of a treatments necessity as it is the only option available, while not believing it is very effective. One limitation of the framework is that it is not clear exactly how necessity and efficacy beliefs interact. Concerns incorporate both cognitive and emotional representations and include the personal impact of treatment such as side-effects as well concerns about future effects and possible dependence on treatment.

These beliefs will influence a person's motivation to commence and continue with treatment. Beliefs about treatment necessity and concerns about potential negative consequences about taking it are often judged relatively to each other and subsequent behaviour will be a response to these judgements. There is a cost-benefit analysis where beliefs are weighed up against each other (Horne & Weinman, 1999). Individuals can also hold ambivalent or apparently contradictory beliefs about taking medication, for example they may feel that they need to take the medication to get better, however, they have strong concerns about the effects of taking the medication (Laakso, 2012). In this way, non-adherence to treatment can be regarded as a 'common-sense' response to weighing up these beliefs. There is a large body of evidence demonstrating the utility of the framework in explaining adherence. A meta-analysis of 94 studies demonstrated that better adherence was associated with stronger necessity beliefs and fewer concerns (Horne et al., 2013). A strength of this evidence is that the effect persisted when small, underpowered studies were excluded. Many studies were cross-sectional in design so the direction of causation cannot be implied, however, the association between beliefs and adherence remained when including only longitudinal and prospective studies. Further work is, however, needed to establish the relationship between beliefs and different ways of administering treatments other than oral medications, such as depot injections.

2.2.3.1 Operationalising the Necessity and Concerns Framework

The dimensions identified above have formed the content for a tool to assess treatment representations; the Beliefs about Medicines Questionnaire (BMQ) (Horne et al., 1999). The BMQ contains three scales, one relating to general beliefs about medicines which assesses the extent to which a person views medications as harmful and overused by doctors (General Harm and Overuse scale). The remaining two scales assess beliefs about specific medications and assess necessity beliefs (Specific Necessity scale) and concerns about that medication (Specific Concerns scale). An example of items on the necessity scale is 'My health at present depends on my medicines'. Concerns items relate to worries about side-effects, long-term effects, and worries about dependence, e.g. 'I sometimes worry about becoming too dependent on my medication' and 'Having to take this medication worries me'.

The BMQ has been widely used in physical health and more recently in mental health research, where it has shown utility in predicting adherence behaviour (Clatworthy et al., 2009; de las Cuevas, Peñate & Sanz, 2013; Horne & Weinman, 2002). Jonsdottir and colleagues (2009) measured adherence using both subjective self-report and objective serum levels in 285 psychiatric patients and demonstrated that high necessity and low concerns was associated with better adherence. However, the study was cross-sectional and there were high levels of adherence in the sample meaning that the size of the non-adherent group was very small.

2.2.4 Perceptions and Practicalities Approach (PAPA)

The frameworks outlined above describe clearly how adherence is influenced by volitional factors, and non-adherent behaviour can be described as 'intentional'. Non-volitional factors also account for non-adherence (Chambers et al., 2011; Clatworthy et al., 2007) and these are also influenced by illness and treatment representations. 'Unintentional' non-adherence occurs where a patient may wish to adhere but is prevented from doing so due to barriers in capacity and resources. These barriers can include financial costs, difficulties with recall and comprehension of instructions on how to take the treatment, and physical barriers to administering treatment. Volitional and non-volitional factors may overlap, for example patients might be highly motivated to take medication and therefore explore ways to overcome practical barriers (Horne & Clatworthy, 2010).

Unintentional and intentional non-adherence are incorporated in the Perceptions and Practicalities Approach (PAPA) (Horne, 2001) (Figure 2.3). The approach describes factors at an individual level which influence adherence, but also acknowledges that these individual factors are influenced by wider context, environmental and social factors. The perceptual barriers are

those specified in the NCF and the practical barriers are those capacity and resource barriers specified above. The two circles in Figure 2.3 overlap which represents the concept that perceptual factors may influence practical factors as specified above.

It is proposed that the PAPA can be used to provide a framework for the development of interventions (Horne & Clatworthy, 2010). The approach does not specify how interventions should be delivered beyond the fact that interventions need to be tailored to a person's specific barriers. However, a number of studies incorporate PAPA principles in interventions (Glattacker, Heyduck, & Meffert, 2012; O'Carroll, Dennis, Johnston, & Sudlow, 2010). Specifically, Glattacker and colleagues (2012) used these constructs to guide discussions with patients about lower back pain, these discussions were tailored to the patients individual illness and treatment beliefs and information needs. They found that those receiving this intervention perceived their pain as more controllable than those in a control group. However, the quasi-experimental, under-powered study also had a high dropout rate meaning that the intervention may not be effective in a real-world setting. The use of the principles of the PAPA approach in the development of the intervention in this thesis is described in Chapter 5 including how the actual methods of delivery was arrived at.

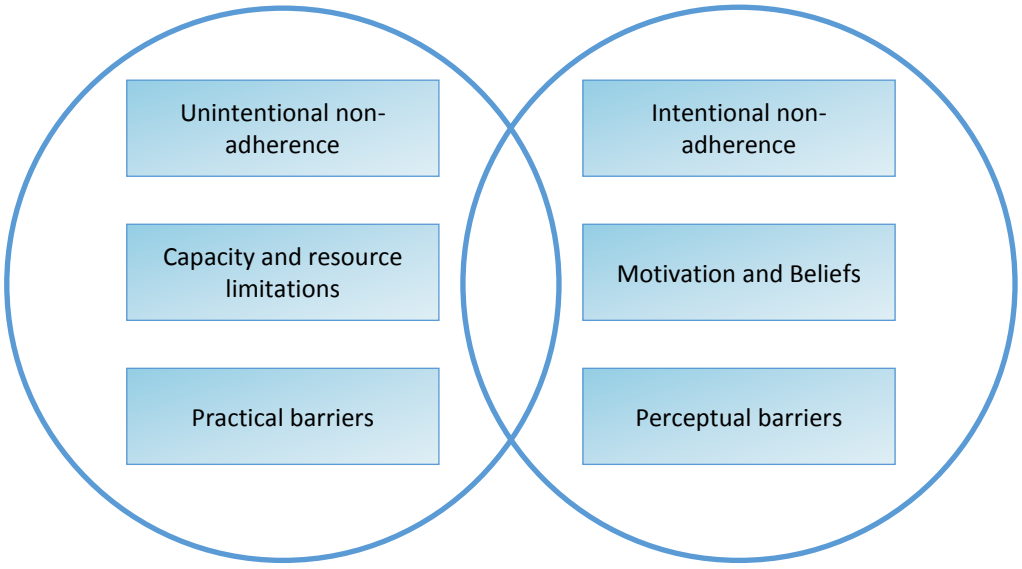


Figure 2.3: The Perceptions and Practicalities Approach (adapted from (Horne, 2001))

2.3 Behaviour change

The theories and frameworks described explain, predict and measure behaviours. In the development of theory-based interventions, they provide evidence-based causal pathways by which the mechanisms for behaviour change and behavioural determinants can be identified and targeted (Michie, Johnston, Francis, Hardeman, & Eccles, 2008). In order to develop

interventions to modify behaviour, it is necessary to map specific techniques and strategies onto these pathways. There is an increasing body of work devoted to the development of frameworks linking theory and evidence-based techniques for use in practice (Michie & Johnston, 2012). Connected with this is the creation of a taxonomy to ensure that the language used to describe active components of interventions is consistent and there is a common understanding of evidence-based techniques for modifying health behaviour (Michie, Johnston, Abraham, Francis, & Eccles, 2013).

2.3.1 Theories of behaviour

A range of constructs which influence behaviour have been identified and synthesised in a number of theories known collectively as social cognition models (SCM) which attempt to explain behaviour using predictors. The 'social' aspect of cognition refers to how people perceive the social environment as opposed how it might actually exist and it is those perceptions of reality which actually guide behaviour (Conner & Norman, 2005). Armitage and Connor (2000) provide an overview of these which include motivational models where the premise is that intentions predict behaviour including the Health Belief Model (Rosenstock, 1974), Social Cognitive Theory (Bandura, 1986), the Theory of Planned Behaviour (Ajzen & Madden, 1986). Behavioural enaction models include an action component between intentions and behaviour, for example Implementation Intentions (Gollwitzer, 1993) and finally multi-stage models which incorporate behaviour maintenance such as the Health Action Process Approach (HAPA) (Schwarzer, 1992).

In reviewing these theories it is apparent that many of the behavioural determinants they describe, overlap (French et al., 2012). Michie and colleagues identify problems with attempting to choose between the numerous theories of behaviour and instead it would be more useful if a definitive set of theoretical explanations of behaviour change were available and researchers had the means to identify those relevant to the context of their work (Michie, Johnston, et al., 2008). In addition, theories themselves do not provide guidance on intervening to improve health behaviours. By using one theory on its own, key determinants may be missed, particularly in complex health behaviours. Work conducted by Michie and colleagues (2005) draws together the key determinants of behaviour change into the Theoretical Domains Framework (TDF) which was subject to refinement and validation and has been widely used (Cane, O'Connor, & Michie, 2012; Francis, O'Connor, & Curran, 2012). In addition, an approach for using the TDF to actually develop an intervention has been developed (French et al., 2012), thus allowing researchers to meet the MRC guidelines and incorporate theory into the development phase of complex interventions (Craig et al., 2008).

As a further development to this work, Michie and colleagues (2011) have brought together, through expert consensus, the range of frameworks of behaviour change into the Behaviour Change Wheel (BCW). The 'hub' of the wheel comprises what the authors term the COM-B system (Capability, Motivation and Opportunity), this incorporates the physical, psychological and social elements of behaviour. Around the COM-B system, the BCW includes Intervention functions which can act on the COM-B elements, for example persuasion by using communication to increase motivation for a behaviour, and education by providing information to increase understanding. Finally, the BCW includes the policy context in which these functions would occur, for example published treatment guidelines for a condition and legislation. The BCW thus incorporates the environmental context in which behaviour change is attempted.

The COM-B elements of motivation and capability or capacity tie in with the Perception and Practicalities components of PAPA in that the elements they comprise refer to the same behavioural determinants. The *perceptual* factors are comparable to the *motivation* component which contains automatic and reflective processes, and the *practicality factors* compares to the capability components (psychological and physical). In addition, the Opportunity component of COM-B comprises the social and physical factors outside of the individual which allow behaviour to take place such as having a pharmacy in the local environment to be able to access medication. In the PAPA, these are comparable to practical barriers and resource limitations which comprise the *practicalities* factor. The BCW allows the systematic selection of intervention functions in order to develop an appropriate means of changing behaviour. This leads into the selection of the exact techniques which are likely to have an effect on the determinants of the behaviour.

2.3.2 Behaviour Change Techniques

The constructs and intervention functions which have been identified as influencing behaviour can be mapped on to specific behaviour change techniques (BCTs) in order to ensure that interventions are theory-based and evidence-driven (Michie, Atkins, & West, 2014). BCTs are the active, observable, irreducible components of an intervention (Michie, West, et al., 2013). A substantial body of work has been conducted in recent years by Michie and colleagues (2010; 2011) in order to provide a framework for this. This enables researchers to not only identify behavioural determinants to target, to select appropriate BCTs to use in interventions but also to use their research to further develop the theories themselves. In addition, it facilitates accurate replication of interventions as standardized definitions are available (Michie, Johnston, et al., 2013).

BCTs are numerous and have been listed by a number of pieces of work, with a taxonomy approach of these techniques still developing (Abraham & Michie, 2008; Dixon & Johnston, 2010). A recent example of which is the BCT Taxonomy (v1) which consists of 93 hierarchically clustered behaviour change techniques (Michie, Johnston, et al., 2013). Agreement on these were reached through a Delphi-type exercise involving experts in behaviour change and coding existing interventions using the taxonomy. The taxonomy has been applied to a range of health behaviours and also provides clear definitions of each BCT and examples of how this would translate to practical use. Research continues to apply the BCT taxonomy across different behaviours and populations including medication adherence (Bobrow et al., 2014; Dombrowski et al., 2012; Hartmann-Boyce, Johns, Jebb, & Aveyard, 2014). However, there has been criticism that the original purpose of BCT taxonomies was to describe the content of interventions, and use of the taxonomies to develop interventions should be cautioned (Kok et al, 2015). This is due to the fact that they do not list effective interventions or provide information on what parameters need to be in place for them to be applied.

2.3.2.1 Mapping BCTs to theory

In order to have a potential impact on behaviour, e.g. adherence, BCTs must be selected which relate to changing cognitions or emotions, or by addressing practical or environmental barriers connected with the relevant frameworks (e-SRM, NCF and PAPA). The exact selection of the methods used in the novel intervention developed in this thesis are specified in Chapter 5 (section 5.2.3) as part of the Intervention Mapping process. An example is included below to illustrate how BCTs can be mapped onto the frameworks and the constructs targeted by an intervention.

The NCF consists of concerns about taking treatment, for example fear of side-effects, worries about dependence and necessity beliefs such as needing the treatment to stay well and to avoid hospitalisation. These NCF constructs have been shown to be related to adherence as described in Section 2.2.3. The BCT Taxonomy (v1) (Michie, Johnston, et al., 2013) item 9.2 'Pros and cons' is relevant here as cost-benefit analysis is a method of helping patients consider making a behaviour change (Basco & Rush, 2005; Michie, Rumsey, et al., 2008; Rollnick, Mason, & Butler, 1999). Patients can weigh up the personal benefits and costs of both taking their medication and not taking it. Connected with this is that patients feelings of ambivalence towards treatment can be identified and addressed.

It is important to remember, as this research into BCTs is still very much in development, particularly in relation to adherence behaviour, there may not be an evidence-based technique

related exactly to the construct in the specified health area. Recently, researchers have discussed the application of COM-B to adherence, with a view to understanding how to change adherence (Jackson, Eliasson, Barber, & Weinman, 2014). The authors applied adherence behaviour determinants to the model then suggest the application of suitable BCTs to each component. BCTs, as applied to health behaviours such as smoking or engaging in physical activity can also be adapted and applied to adherence (Michie, Johnston, et al., 2008). This process of mapping determinants onto a model which then provides guidance on BCT selection is the process conducted in the development of then intervention in this thesis.

However, it has been noted that BCTs selected must target the specific beliefs in question, for example, not just personal control beliefs but specifically the technique needs to target perceptions of low personal control (Kok et al, 2015). The practical application of BCTs must be appropriate for the target population and the context in which they are being implemented. There may not be sufficient evidence to say with whom, where and when a BCT might expected to have a positive effect. Although by conducting qualitative research we can gain insights into the variability of the population and context.

2.4 Limitations of health behaviour theories and approaches

The models and approaches presented above provide useful evidence for understanding behaviour, relating constructs to behaviour and providing techniques in order to facilitate change. However, there are a number of limitations which apply to some or all of these.

Multiple terms for what is essentially the same construct have been identified in the range of theories in health psychology, for example, in a review, Skinner identifies over 100 ways of conceptualising perceived control (Skinner, 1996). In addition, outcome expectancies in social cognitive theory (Bandura, 1986) i.e. the expectation that a behaviour will lead to particular outcomes, overlap with the behavioural beliefs and attitudes in the Theory of Planned Behaviour (TPB) (Ajzen & Madden, 1986) and may also relate to Necessity beliefs in the NCF in that a patient will see a treatment as needed if they believe it to be effective, i.e. It is likely to result in a relief of symptoms. There is, therefore, much overlap between models. The synthesis of frameworks to define these constructs serves to move forward from relying on the range of theories in order to develop evidence based interventions (Michie et al., 2005). However, TDF serves as a descriptive framework but does not specify relationships between constructs. (Francis et al., 2012)

Some models focus on the motivational aspects of behaviour, through intentions to perform that behaviour, for example the TPB (Ajzen & Madden, 1986). However, intentions may not

translate into behaviour and indeed research has identified a considerable gap between prediction of intentions and subsequent behaviour, coined the intention-behaviour gap (Orbell & Sheeran, 1998; Sniehotta, Presseau, & Araújo-Soares, 2014). Models may lack an account of how the action actually occurs and specifically we need to understand volition in order to bring about behaviour change.

Some SCMs, such as the TPB do not include a specific role for emotions, thus ignoring the idea that factors such as anxiety or fear could influence behaviour, newer models do include these factors (McEachan, Conner, Taylor, & Lawton, 2011; Sniehotta et al., 2014). Models may not include the role of past behaviour and of wider influences on heath such as the perceptions and behaviours of health professionals, society and the environment. This is where newer frameworks do attempt to include not only the individual psychosocial determinants, but also those influencing an individual from the wider context such as the BCW incorporating COM-B (Michie et al., 2011) and the PAPA (Horne, 2001). These later frameworks however, still may need development, both in ensuring their comprehensiveness and in ensuring they are operationalised appropriately. With COM-B, a strength of the model is in its breadth in including wider influences on behaviour. However, some of the definition may be difficult to apply to the specific behaviour in question. Some aspects of illness models aren't clearer explicitly represented, such as symptom interpretation and that is where the e-SRM provides a useful model for this programme of research as symptom interpretation may impact on coping behaviours including adherence.

Social cognition models do not account for habitual behaviour, they focus on rational decisions based on considerations of the factors in the model and this is not appropriate for prediction of behaviours once they become habitual (Horne & Weinman, 1998; Jackson et al., 2014; Sheeran, Gollwitzer, & Bargh, 2013). However, the COM-B model and NCF both incorporate a role for automatic processes (Horne, 2003b; Michie et al., 2011). Initiation of a behaviour and maintenance might be influenced differently, so the dynamic, self-regulation models better account for behaviours which are not performed 'one-off', as in medication adherence (Horne, 2003a; Leventhal et al., 1984).

Recognising that the current testable models do not account for all of the necessary determinants of behaviour, the frameworks COM-B (Michie et al., 2011) and the PAPA (Horne, 2001) provide important tools for developing interventions. However, the next step might be to move back to conducting research to test the causal processes behind the constructs. This would aid in the development of interventions as a better understanding of the process of change could be gained, in accordance with MRC modelling process.

Further work is needed to ensure that validated tools are available to measure all of the constructs in order that empirical evidence can be obtained on the effectiveness of interventions which have been derived from theory. The original BMQ has undergone validation and further work on translations and extension to different conditions and treatment is underway (de las Cuevas et al., 2011; Komninis, Micheli, Roumeliotaki, & Horne, 2013). Validated tools to measure the practical barriers to adherence are needed, and there has been work to develop these (Jackson, 2011). However, as it currently stands the BMQ may be subject to limitations. Although it is acknowledged that necessity and efficacy beliefs may be different, it is not clear how they interact and it would be worthwhile to conduct analysis to determine this. The BMQ-specific is quite absolute in the way it is worded, e.g. 'Without this medicine I would be very ill'. In mental health, there are multiple factors contributing to staying well and the wording of the BMQ may not account for the perceptions of viewing a medication as one part of what helps someone to stay well. Side effect experience is measured but not fear of side effects which we know is an important factor in BD adherence. Also people might not interpret the wording of the side-effects item as including the effects on how they feel, they may just think of physical side effects and therefore miss a reason why people may not take their treatment. It is clear that adaptations are needed to make the BMQ relevant to mental health diagnosis.

Further research into the measurement of illness perception in mental health is warranted. There may be subjective judgements made by the wording of the IPQ, in that it characterises the mental health experiences people have as an illness or problem. People may not agree with the diagnosis, but agree that they experience difficulties and this doesn't seem to be fully accounted for in the way the SRM is operationalised. The emotional impact measurement is one single item and implies that all emotional consequences are negative. There may be a whole range of emotional impacts of the condition. In addition, the IPQ doesn't fully take into account the recovery model in that people may understand that the diagnosis may be chronic but they also forsee that they may recover and live a fulfilling life.

In relation to the area covered by this programme of research, there are still questions about whether or not these models as they currently stand are applicable to the area of mental health and in particular adherence to medication in mental health (Petrie et al., 2008). Do they include the constructs which may be relevant to this area, or miss key aspects of the influences particularly on behaviour in a mental health context? People's reports of their own BD experiences, perceptions of treatment and goals for recovery could lead to the development of these models and increase their applicability to mental health. These additional aspects could include perceptions of the medicalisation of mental health experiences, identity as being part

of or separate from the illness and hopes and fears around recovery. This thesis aims to identify and further understand some of these issues and contribute towards the development and application of the work of social cognition, self-regulation and behaviour change in mental health.

2.5 Chapter summary

In formulating an intervention to improve outcomes for people with BD, the MRC framework for complex intervention development is a systematic process which can be applied. As health behaviours, adherence and other activities such as self-monitoring are behaviours in themselves and as such, are covered by health behaviour theories such as social cognition models and theories of behaviour change such as COM-B. In addition, as this area relates to illness, treatment and coping, self-regulation theories including the e-SRM are most applicable. The NCF provides a way of conceptualising and understanding patients' perceptions about treatment and the PAPA approach allows us to formulate ways of intervening in adherence by understanding both the perceptual and practical barriers.

These frameworks and theories allow us to conceptualise and link the beliefs, cognitions and other factors which relate to the behaviours associated with managing treatment and living with the condition of BD. Additional models, frameworks and theories relating to mechanisms of behaviour change complement these and assist in selecting and using techniques to attempt to modify these perceptual and practical factors associated with the health behaviours in question. However, there are likely to be unknown limitations to applying the models in BD and therefore qualitative research is needed to explore this.

This chapter has outlined the selection of appropriate theories and techniques which the evidence suggests may be of use in taking forward for a novel intervention. This forms a crucial first stage in the MRC framework. The first stage also includes conducting a systematic review if no high quality, up to date review already exists in the area. Chapter 3 firstly describes an assessment of the availability of existing reviews, before then presenting a systematic review and meta-analysis of interventions to improve adherence in BD.

Chapter 3 Improving medication adherence in bipolar disorder: A systematic review and meta-analysis of 30 years of intervention trials.

3.1 Background

In assessing the need for a novel intervention, it is essential to review the existing literature on interventions in this field. From this, it is possible to identify whether high-quality, effective interventions have been conducted within the population in question. It can also identify which intervention content and delivery methods are worthwhile of development in order that previous work is built upon as opposed to developing new interventions from scratch each time (Campbell et al., 2000; Coyne, Thombs, & Hagedoorn, 2010; Liberati et al., 2009). In addition, important information can be obtained on how best to target interventions and whether there is evidence to suggest who might benefit most and who might be unlikely to respond.

Reviewing the existing evidence prior to developing an intervention is recommended by MRC guidelines for developing complex interventions (Craig et al., 2008) and the more detailed, Intervention Mapping (IM) process which is described in Chapter 5 (Bartholomew et al., 2011). This systematic review forms part of the first stage of the process of conducting a needs assessment to identify what methods have been used to attempt to improve outcomes, what has worked in terms of population samples and contexts, and what gaps need to be addressed by conducting new empirical research.

Systematic reviews should also provide an assessment of the quality of studies included, therefore whether the findings concerning the intervention effectiveness is likely to be subject to bias (Petticrew & Gilbody, 2004). In addition to assessing intervention effectiveness, it is crucial also to examine the reporting of interventions in order to identify whether potentially promising interventions could be replicated (Hoffmann et al., 2014).

In the same way that a novel intervention would not be conducted if an effective, appropriate high quality one existed, prior to conducting a review, it is necessary to conduct a scoping review in order to determine if a high-quality, up to date review had already been published. This identifies firstly if a review is necessary and secondly to identify areas which may not be covered either by the scope of previous reviews, specificity of inclusion criteria and whether an adequate assessment of intervention and study quality has been conducted.

3.1.1 Limitations of previous reviews

Systematic reviews of trials of programmes to improve outcomes in the area of severe mental health have been conducted however, they have limitations which reduce their use in identifying effective techniques to improve medication adherence. Some focussed only on psychoeducational or psychosocial interventions (Batista, Baes, & Juruena, 2011; L. Berk et al., 2010; Crowe, Porter, et al., 2012; C. Depp, Moore, Patterson, Lebowitz, & Jeste, 2008; Gaudiano, Weinstock, & Miller, 2008). Others did not examine adherence outcomes (Lolich, Vazquez, Alvarez, & Tamayo, 2012), provide only a narrative review (Busby & Sajatovic, 2010; Colom & Lam, 2005; Miklowitz, 2006), or were not specific to BD (Desplenter, Simoens, & Laekeman, 2006; Fernandez, Evans, Griffiths, & Mostacchi, 2006). Together these provide a limited picture of the adherence intervention literature in BD, as they do not systematically quantify the magnitude of intervention effects across studies, or test what components of study and intervention design may be most effective. The effects of inadequately powered studies may also be over-estimated in narrative reviews. Meta-analysis provides a quantification of effect and we can test whether particular components may significantly contribute to the effect. Reviews are also limited by the fact that they investigate what is ostensibly a single illness, but what is in reality a highly variable condition, with different ways of characterising the diagnosis and different experiences and beliefs held by participants. In the same way, they group together 'adherence' as a behaviour, which is in reality a highly variable behaviour, measured using different techniques and different cut-offs are applied.

3.1.2 Need for a comprehensive review in BD

It is important to systematically synthesise the evidence and conduct meta-analysis, where appropriate, to quantify the effect of interventions. In addition, this method can test whether particular components of the study design or intervention may significantly contribute to effects and whether effects depend on study quality, which is not possible in narrative reviews.

Interventions which are taken forward and used in clinical practice need to be clinically effective, but also cost and time efficient for providers and patients. As such, they should include only the necessary components and be delivered only for as long as needed. They need to be appropriately targeted to ensure they are delivered to participants who might benefit and not suffer unwanted effects. The intervention and study components tested in this review reflect current thinking of what may be useful in improving adherence and by conducting a meta-analysis, this allows for confident recommendations to be made on what makes for an effective intervention.

Certain interventions components may be important, for example; tailoring (L. Berk et al., 2010; Crowe, Porter, et al., 2012; Desplenter et al., 2006; Horne et al., 2005), content and delivery (ABC Project Team, 2013) specifically the focus given to adherence, the length of the programme (Batista et al., 2011; Gaudiano et al., 2008; Rouget & Aubry, 2007), whether it is educational, includes a focus on beliefs and cognitions (Desplenter et al., 2006; Fernandez et al., 2006; Gaudiano et al., 2008; Horne et al., 2005; Leclerc et al., 2013; Sajatovic, Davies, & Hrouda, 2004). Targeting and delivery variables which are explored include involving partners and family members (Gaudiano et al., 2008), stage of illness, whether patients were euthymic and also whether they were inpatients or outpatients (L. Berk et al., 2010; Lolich et al., 2012; Rouget & Aubry, 2007). In addition to content and delivery, certain process variables are key to assessing how interventions were implemented such as fidelity (Craig et al., 2008) and what comprises standard clinical care (de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009; Gaudiano et al., 2008).

3.1.3 Use of Systematic review, Intervention reporting and Quality assessment guidelines

This review follows the guidelines set out for reporting systematic reviews and meta-analysis of studies that evaluate healthcare interventions, the PRISMA statement (Preferred Reporting Items for Systematic reviews and Meta-analyses) (Moher, Liberati, Tetzlaff, & Altman, 2009). This ensures that it is transparent and complete in that it contains all of the details necessary for replication (see Appendix A for completed PRISMA checklist).

Published guidelines on reporting behavioural interventions were used to systematically describe content and delivery of the studies included in the review (Davidson et al., 2003) as well as guidance from the Consolidated Standards of Reporting Trials (CONSORT) (Boutron, Moher, Altman, Schulz, & Ravaud, 2008; Schulz, Altman, & Moher, 2010).

This review provides an assessment of the methodological quality and reporting of studies (Higgins et al., 2011). The problems of inconsistent and inadequate reporting have recently begun to be addressed. CONSORT guidelines state that interventions must be reported with 'sufficient details to allow replication, including how, and when they were actually administered' (Schulz et al., 2010). A recent study of intervention reporting in non-pharmacological trials concluded that 61% of interventions were reported inadequately (Hoffmann, Erueti, & Glasziou, 2013). To address this issue the Template for Intervention Description and Replication (TIDieR) checklist and guide has been published (Hoffmann et al., 2014). TIDieR is intended as a tool for study authors and systematic reviewers to describe interventions accurately and consistently, with enough detail to allow replication. In the

present review all interventions were assessed for the quality of intervention descriptions provided in published reports using TIDieR.

3.2 Aims and Objectives

3.2.1 Aim

To undertake a systematic review of randomised-controlled trials of interventions incorporating medication adherence for people with a diagnosis of BD.

3.2.2 Objectives

- To describe intervention design, delivery and study characteristics.
- To evaluate quality of reporting and trial design.
- To quantitatively synthesise evidence for the effectiveness of interventions relative to control conditions.
- To identify moderating factors associated with intervention effectiveness.
- To assess the likelihood of publication bias in the available literature.

3.3 Methods

We conducted a comprehensive search of published literature until the end of October 2012 through abstract databases, clinical trial registers, hand-searching of citations in previous reviews and included studies and by contacting researchers directly. In order to ensure the review was as up to date as possible, the original search criteria were re-run in August 2014 to identify additional studies.

3.3.1 Eligibility criteria

Type of studies: Randomised controlled trials of interventions incorporating medication adherence either directly or indirectly and comparing the intervention/s to an active or passive control (including trials where patients were described as being randomly allocated to condition).

Participants: Adults over 18 years of age with a diagnosis of bipolar disorder (all types), or with general psychiatric populations when subgroup analysis was provided for bipolar disorder.

Types of outcome measures: Medication adherence as either a primary, secondary outcome or mediator, measured by subjective or objective methods.

Excluded: Studies focussing exclusively on individuals with psychosis, schizoaffective disorders or a diagnosed substance misuse problem, or undergoing compulsory treatment.

3.3.2 Identification of studies

Studies were identified by searching the following databases; CINAHL, EMBASE, PsychInfo, PubMed, Sociological abstracts and Cochrane trials. No date or language restrictions were imposed and the search included studies added to the databases until end of October 2012, and updated to include studies published until the end of August 2014. Search strategies were designed and tested with the assistance of a research librarian.

Search terms to identify studies were as follows; Adheren*, complian*, medicat*, medicine, drug, clinical trial, random*, control*. For the Cochrane trials database the following terms were also included; **pharmacotherapy or regimen* or educat*. Consequently we combined this with s**earch terms; Bipolar disorder (MESH), Manic depressi* (Box 3.1). Subsequently the trials registers Clinicaltrials.gov and (Health Technology Assessments (HTA) were searched for trials including 'bipolar disorder'. The reference lists of previous reviews in the area and studies included in this review were examined for additional qualifying articles.

(patient compliance[MeSH Terms]) OR ("Medication Adherence"[Mesh])) OR (compliance OR adherence[Title/Abstract])) OR (complian* OR adheren*) OR ("treatment refusal") AND (drug therapy) OR (regimen[Text Word]) OR (medicat*[Text Word])) OR ("Drug Therapy"[Mesh]) AND (clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading]) AND (intervention[Title/Abstract])) OR ("Causality"[Mesh:noexp])) OR ("Outcome and Process Assessment (Health Care)"[Mesh]) OR "Health Services Research"[Mesh]) OR ("Treatment Outcome"[Mesh]) OR ("Outcome Assessment (Health Care)"[Mesh])) OR ("Intervention Studies"[Mesh]) AND (bipolar disorder[MeSH Terms]) OR (bipolar disorder) OR (manic depressi*)

Box 3.1: Example of search strategy from PubMed

3.3.3 Data collection

3.3.3.1 Selection of trials

The results of the search strategies were downloaded into Endnote x3 before removing duplicate studies and conducting and cross-checking the additional searches with the downloaded citations.

Two investigators (the author and SC) carried out title and abstract review on the 671 studies retrieved and excluded studies if they did not meet the inclusion criteria. Inter-rater agreement was high, with a kappa value of 0.986. Four potentially relevant papers, identified by SC were subsequently excluded after discussion (Colom, Vieta, Sanchez-Moreno, Goikolea, et al., 2009; Frank et al., 2008; G. Simon, Ludman, Bauer, Unutzer, & Operskalski, 2006; Valenstein et al., 2011). Papers for the remaining 116 studies were retrieved and the full texts of these articles were reviewed (Figure 3.1) (Moher et al., 2009). Twenty-three studies met the criteria for inclusion in the systematic review (Tables 3.8 and 3.9). Data was extracted from 26 papers as four studies reported methods and results across two papers each (accounting for where the number of references cited in the text is higher than the number of studies mentioned).

The search update in August 2014 retrieved an additional 125 studies which were reviewed by the same investigators and five potentially relevant articles were retrieved. One additional study was included in the systematic review (Javadpour, Hedayati, Dehbozorgi, & Azizi, 2013). The remaining four were excluded as they either comprised conference abstracts where the data was not available from authors or studies with mixed psychiatric sample for which sufficient detail for inclusion in the review was not available.

3.3.3.2 Data extraction and assessment of methodological quality

A data extraction template was designed and piloted before making refinements (Appendix B) and data was extracted on intervention design and delivery, study characteristics, quality of reporting and trial design and adherence outcomes.

Intervention content: The term ‘Psychoeducation’ was applied to heterogeneous interventions. Colom provides a broad definition; including empowering patients and give them the tools to manage, cope and live with bipolar disorder, involving adherence enhancement, early warning sign identification, lifestyle, crisis management and communication. It involves changing behaviour and attitudes in addition to simply providing information (Colom, 2011). We coded interventions in terms of whether they used the term

psychoeducation and whether the description of the programme included all of these elements of psychoeducation. Interventions were coded into whether adherence was the primary focus of the intervention, or whether the intervention was multi-focus.

Intervention tailoring: categorised ('yes', 'no' or 'unclear') according to inclusion of different forms of tailoring based on guidelines described by de Bruin and colleagues (2009) in the 'Coding manual for Behaviour change techniques': Individualization (content individualised to reflect participants' questions or individual progress), Macro-tailoring (intervention depends on pre-tested characteristics e.g. motivational stage or adherence level), Attention/Meso-tailoring (amount of intervention contacts depends on participant need), Micro-tailoring (intervention components are tailored to the participant e.g. specific action plans generated) and Participation (the participant is actively involved by providing input or making decisions) (de Bruin et al., 2009).

Intervention delivery: coded for provider, format (i.e. group, individual, family), delivery setting (e.g. specialist affective disorder/ bipolar clinic or unit, university), recipient, number of intervention contacts, total intervention contact time, duration of intervention delivery, intensity of intervention contacts. Guidelines on reporting behavioural intervention trials were used to summarise the descriptions of interventions (Davidson et al., 2003; Hoffmann et al., 2014). Where the number of intervention contacts, time or duration varied (as specified by protocol), we used the average. In coding intervention duration in months, one-contact interventions were classified as 0.03 months, in order that they had a quantifiable duration for computation of medians.

Control group: Due to differences in the intensity of standard care, treatment as usual (TAU) was coded as either 1. General care- outpatient psychiatry or GP appointments/ medication management usual (no specific education or psychological support mentioned) or 2. Intensive support- structured specialist support. Additional components were also coded as being included or not; additional GP training, additional education/ psychoeducation, additional sessions (not educational but attention matched) and receiving feedback on adherence.

Study and sample characteristics: date of publication, number of participants randomised (intervention and control groups), length of follow-up assessment (both from baseline and last intervention contact point), primary outcome (whether adherence was specified as a primary outcome or not), country of study, diagnostic assessment of bipolar (which assessment measure or criteria was used to determine the diagnosis), participants' illness state at the point of recruitment (depression, mania, euthymia or mixed), gender, ethnicity.

Adherence outcome: Primary outcome included adherence (Yes/ No). Mode of measurement - 1. subjective (self-report, physician report, informant report), 2. objective (e.g. electronic monitoring, pill counts), 3. biological (e.g. lithium serum levels) and 4. composite. Target medication– 1. Lithium only, 2. Multiple medications reported/analysed together, 3. Multiple medications – reported/analysed separately. Data was extracted on every reported adherence assessment at each time point. Eighteen studies provided sufficient data in the published report in order to compute standardised effect sizes for the meta-analysis. For six studies, authors were contacted for additional data and this was provided for one study (Eker & Harkin, 2012), data was unavailable for four (Frank et al., 2005; Frank et al., 1999; Gilbert, 2000; N. S. Harvey & Peet, 1991; Javadpour et al., 2013; Peet & Harvey, 1991) and in one study the data were medication continuation months (Bordbar, Soltanifar, & Talaei, 2009) which was not comparable with the other studies and was not included in the meta-analysis.

Intervention retention: the proportion of participants who took part in intervention sessions, completed the programme, or were classed as adhering to the protocol according to cut-offs specified in the study.

Fidelity: coded as formal assessment using coding systems by independent raters, informal assessment (where fidelity was reported to have been conducted, but formal scoring or rating was not used), or no evidence of fidelity assessment.

Quality of intervention reporting: coded using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014). This comprises 12 intervention items; Brief name; Why (rationale, theory or goal); What (materials used); What (procedures used); Who provided; How (mode of delivery); Where (location); When and how much; Tailoring; Modifications; How well (planned); and How well (actual). For each intervention, each item was coded as being either adequately reported, inadequately reported, not reported or not applicable to the intervention. Data was extracted for each study to demonstrate where in the paper the information could be found, or in the case of inadequate reporting, details on what information was lacking. As per TIDieR guidelines, details were sought from not only the published paper, but also papers referenced by the authors, available protocols and manuals, online supplementary material, and websites. Following independent coding, the two reviewers met to reach agreement on any coding discrepancies (seeking advice from a third reviewer where agreement could not be reached). To provide a simple assessment of quality for each study items were coded as adequately described, inadequately described, not reported or not applicable. This process was similar to that used by Hoffamn et al (2013) where items were rated as either clearly described, or not reported or not clearly described.

Quality of trial design: assessed using the Cochrane collaboration tool for assessing risk of bias in; selection, performance, detection, attrition and reporting (Higgins et al., 2011). Each study was classified into 'low risk of bias', 'high risk of bias' or 'unclear' for; Random sequence generation, Allocation concealment, Blinding of participants, Blinding of personnel, Blinding of adherence outcome assessments, Incomplete adherence outcome data, and Selective adherence outcome reporting. As studies frequently used more than one outcome measure, for the purposes of the narrative summary, the risk of bias in; blinding of outcome assessment, incomplete outcome data and selective reporting categorised studies according to the lowest risk of bias. For the meta-analysis, the risk of bias was assessed for the outcome measure and timepoint specified in each sub-analysis.

Data extraction for all studies was conducted by the author, with a second data extraction by two investigators (SC & another independent researcher). Inter-rater reliability was assessed for 15 items by calculating Cohens Kappa values. Kappa values were; target medications (k=0.91), intervention focus (k=0.66), setting (k=0.49), intervention tailoring (5 items, k= 0.11 to 0.78), control group (1 item, k=0.66) risk of bias (6 items, k=0.13 to 0.83). There was good agreement except for the TIDieR tailoring item (54%), for two items on intervention tailoring (Individualisation 38%, Micro-tailoring 50%) and for two risk of bias items (Personnel blinding 42%, Selective reporting 54%). Disagreements in coding were resolved through discussions between the three investigators.

3.4 Data analysis

Extracted data was organised and processed using IBM SPSS statistics (v21) and Comprehensive Meta Analysis (v2) software. Studies were included in the meta-analysis where it was possible to pool the adherence data and compute standardised effect sizes. Studies reported different statistics including t-tests, chi squares, ANOVAs, means, sd and p values. In order to compare data, standardised odds ratios with 95% confidence intervals were computed from the proportions of participants classified as adherent in the control and interventions groups at follow-up. A random effects model was selected as it is more conservative than a fixed effects model and should be used when analysing real world data (Field, 2003; Hunter & Schmidt, 2000).

Where data was reported on multiple outcome measures and time points, effect sizes were computed for each. The order of preference for selecting outcomes was, in descending order of priority; composite measure, serum lithium, self-report, informant report, based on papers

recommending that a combination is the most valid measure for adherence in psychiatric research (Sajatovic et al., 2010).

The chi-squared statistic (Q) was used to test for the presence of heterogeneity across studies with the level expressed using the I^2 statistic, describing the percentage of variation due to heterogeneity as opposed to by chance. Cochrane guidance provides cut-offs for interpretation of the magnitude of heterogeneity, where 30-60% represents potentially moderate heterogeneity, 50-90% represents substantial heterogeneity (Higgins et al., 2011).

Moderation analysis was conducted to assess if adherence outcome varied according to study characteristics (where possible i.e. where sub-categories contained two or more studies). This was conducted for the following categorical potential moderators; intervention focus (adherence primary vs Multi-focus interventions), content (all elements of psychoeducation vs other interventions), delivery setting (specialist clinic/ department vs other settings), delivery format (individual vs group), adherence as a primary outcome, adherence – what was measured (mixed medications assessed globally vs Lithium only) intervention tailoring, use of manual, assessment of fidelity, baseline illness state and study comparison group. Meta-regression analysis was conducted for the following continuous moderator variables: date of publication, intervention contacts (as per protocol) intervention duration (months), total intervention contact time, and follow-up duration, both from baseline and last intervention contact. Random effects models were used in this analysis as we have no reason to assume systematically different variance between groups of studies by moderator variable and there are a small number of studies within each category (Borenstein, Hedges, Higgins, & Rothstein, 2011).

Sensitivity analysis was performed to detect whether the overall effect was affected by the inclusion of; small studies, outliers, type of outcome and timepoint of follow-up, evidence quality and participant retention at follow-up. Studies with small sample sizes were excluded for the first sensitivity analysis (using a recommended cut-off of n<70 for either intervention or control group (Coyne et al., 2010)), resulting in the inclusion of only five studies (Colom et al., 2003; Eker & Harkin, 2012; Lenz, 2010; Reinares et al., 2008; Sajatovic, Davies, et al., 2009). For the second sensitivity analysis, one study was excluded due to its extremely large effect size (outlier) (Dogan & Sabanciogullari, 2003). Next, the longest follow-up outcome was selected for; serum levels, composite measures and self-report and computed effect sizes for each. Effect sizes were computed for study outcomes grouped into 1-3 months post-intervention, ~6 months and ~12 months. Then only those studies with satisfactory retention at follow-up using a slightly less stringent cut-off than in a previous review of adherence interventions (80%) (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008) of >75% in both intervention and control

groups were selected. Finally sensitivity analysis was conducted to detect if outcome was affected by evidence quality (including studies judged to have low risk of bias).

Risk of publication bias analysis was performed as it is possible that studies reporting a statistically significant result may be more likely to be published and therefore a meta-analysis may over-estimate the real effect of all studies conducted (published or unpublished) (Rothstein, Sutton, & Borenstein, 2006). A funnel plot was examined for symmetry which displays the effect size of the published studies against the variance; this would be asymmetrical if fewer studies with a large variance (typical of smaller studies) and large effect size were published, suggesting that small studies are more likely to be published if consistent with the intervention being effective. However, as funnel plots can be misleading, particularly when the number of studies is small or the studies are heterogeneous (Walker, Hernandez, & Kattan, 2008), a trim and fill method was applied (Duval & Tweedie, 2000), a classic fail safe analysis to compute the number of studies needed to produce a null result (Rosenthal, 1979) and Egger's test to measure funnel plot asymmetry (Egger, Smith, Schneider, & Minder, 1997).

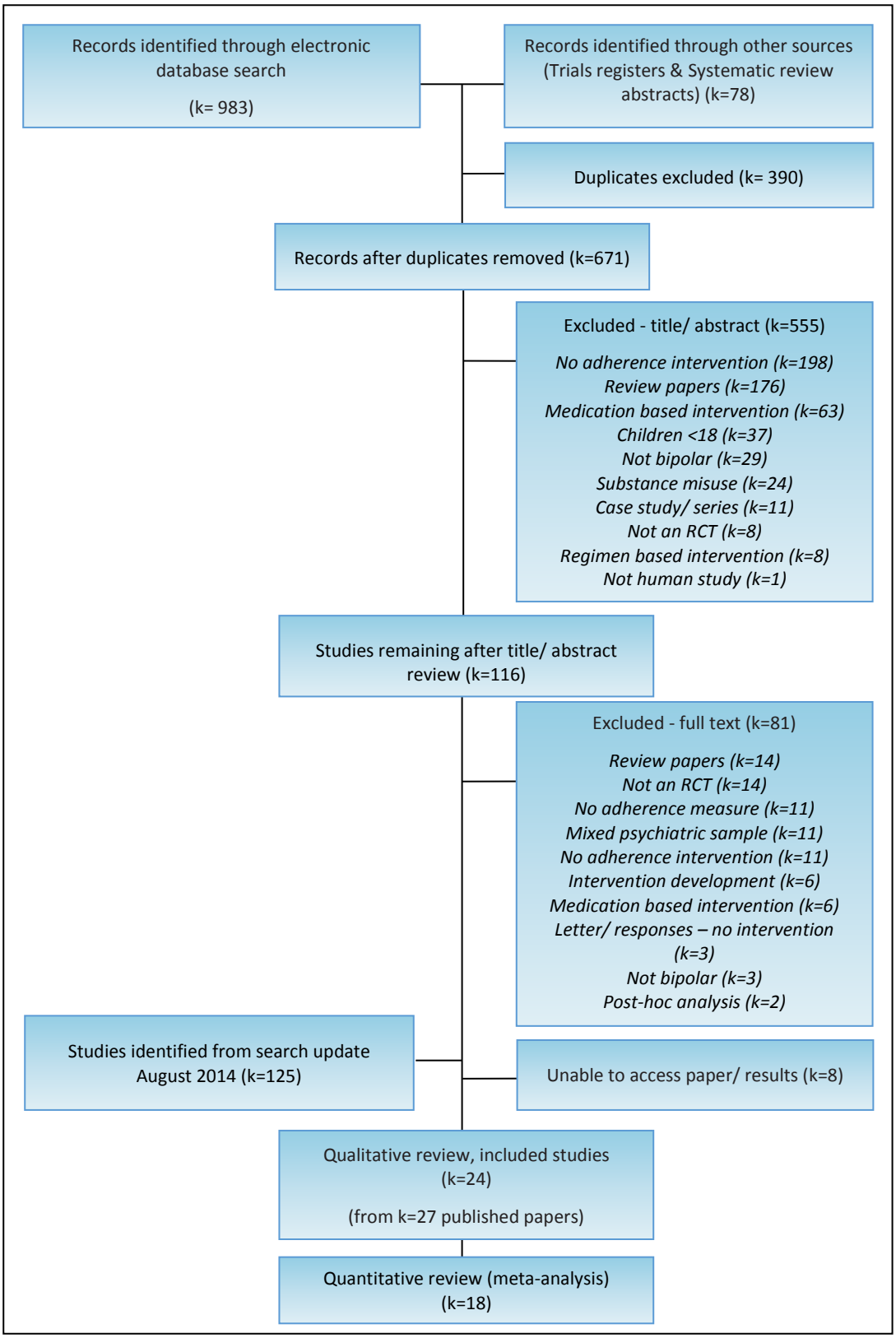


Figure 3.1: Flow of studies in the systematic review

3.5 Results

3.5.1 Description of studies

Studies are described in Tables 3.9 and 3.9 and intervention characteristics across all studies are summarised in Table 3.1 and Table 3.2.

3.5.1.1 Intervention content & tailoring

Five interventions had adherence as the primary focus of the intervention content (Cochran, 1984; Dogan & Sabanciogullari, 2003; Elixhauser, Eisen, Romeis, & Homan, 1990; N. S. Harvey & Peet, 1991; Peet & Harvey, 1991; Sajatovic, Davies, et al., 2009), 18 were multi-focus programmes, (Ball et al., 2006; D. Castle et al., 2007; Clarkin, Carpenter, Hull, Wilner, & Glick, 1998; Colom et al., 2003; D'Souza, Piskulic, & Sundram, 2010; Eker & Harkin, 2012; Frank et al., 2005; Frank et al., 1999; Gilbert, 2000; Javadpour et al., 2013; Lam et al., 2000; Lam, Hayward, Watkins, Wright, & Sham, 2005; Lam et al., 2003; Lenz, 2010; Miklowitz, George, Richards, Simoneau, & Suddath, 2003; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; van Gent & Zwart, 1991; Zaretsky, Lancee, Miller, Harris, & Parikh, 2008). We were unable to classify one study due to the limited information provided in the paper (Bordbar et al., 2009).

Fifteen interventions were described as being or including psychoeducation (Ball et al., 2006; Bordbar et al., 2009; Clarkin et al., 1998; Colom et al., 2003; D'Souza et al., 2010; Eker & Harkin, 2012; Gilbert, 2000; Javadpour et al., 2013; Lenz, 2010; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; Sajatovic, Davies, et al., 2009; van Gent & Zwart, 1991; Zaretsky et al., 2008). Five classified themselves as cognitive-behavioural therapy (CBT) or cognitive therapy (Ball et al., 2006; Cochran, 1984; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003; Zaretsky et al., 2008). When coding interventions based on the content described in the paper, 13 clearly included all elements of psychoeducation (Ball et al., 2006; D. Castle et al., 2007; Clarkin et al., 1998; Colom et al., 2003; D'Souza et al., 2010; Eker & Harkin, 2012; Gilbert, 2000; Javadpour et al., 2013; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003; Lenz, 2010; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003; Sajatovic, Davies, et al., 2009).

As described, four interventions appeared to be information provision only without a specific behavioural or psychosocial element (Bordbar et al., 2009; Dogan & Sabanciogullari, 2003; N. S. Harvey & Peet, 1991; Javadpour et al., 2013; Peet & Harvey, 1991). Three had a specific focus on family communication (Gilbert, 2000; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003). Elixhauser and colleagues (1990) used an electronic adherence monitoring device, adherence feedback and education.

Fifteen interventions included more than one type of tailoring. Sixteen interventions used micro-tailoring of components of the intervention such as action planning in relation to participants lifestyle and goals or information on risk tailored to individual characteristics or history (Ball et al., 2006; D. Castle et al., 2007; Cochran, 1984; Colom et al., 2003; D'Souza et al., 2010; Eker & Harkin, 2012; Frank et al., 1999; Gilbert, 2000; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; Sajatovic, Davies, et al., 2009; van Gent & Zwart, 1991; Zaretsky et al., 2008).

Sixteen studies involved participation where the participants had active input, for example own difficulties with adherence, deciding on strategies and evaluating the outcomes of strategies used (Ball et al., 2006; D. Castle et al., 2007; Cochran, 1984; Colom et al., 2003; D'Souza et al., 2010; Eker & Harkin, 2012; Frank et al., 1999; Gilbert, 2000; Javadpour et al., 2013; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; Sajatovic, Davies, et al., 2009; van Gent & Zwart, 1991; Zaretsky et al., 2008).

Six interventions used individualization, where the content of sessions was individualised in response to participants' needs, their questions or queries (Ball et al., 2006; Dogan & Sabanciogullari, 2003; Eker & Harkin, 2012; Gilbert, 2000; N. S. Harvey & Peet, 1991; Peet & Harvey, 1991; Rea et al., 2003).

Five interventions were tailored by varying the level of intervention contacts depending on participants' needs or preferences (Frank et al., 2005; Frank et al., 1999; Gilbert, 2000; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003) with the decisions either based on participant choice (k=1) (Gilbert, 2000), HCP/ clinical need (k=2) (Lam et al., 2000; Lam et al., 2003) or both patient and practitioner choice (k=2) (Frank et al., 2005; Frank et al., 1999).

One intervention used tailoring at a macro-level, i.e. determining the intervention to be received by pre-tested characteristics, in this case the levels of symptoms, where participants must be classed as asymptomatic before proceeding (Frank et al., 1999) and one tailored feedback according to a mid-point assessment of adherence (Elixhauser et al., 1990).

3.5.1.2 Delivery (provider, setting, target, duration, frequency of sessions)

A range of providers were involved in intervention delivery; most commonly psychologists (k=5) and psychiatrists (k=6), but also mental health nurses (k=3), social workers (k=3) and 'therapists' (k=3) (Table 3.1).

Five interventions were delivered through specialist affective, mood or bipolar disorder clinics (Cochran, 1984; Colom et al., 2003; Eker & Harkin, 2012; N. Harvey & Peet, 1991; Reinares et al., 2008). Other settings included hospital outpatient mental health departments and University psychology or psychiatry departments (not specifying specialism in affective disorders) (Table 3.1). In six cases, the exact location of delivery of the intervention was not specified (David Castle et al., 2010; Clarkin et al., 1998; D'Souza et al., 2010; Lenz, 2010; van Gent & Zwart, 1991; Zaretsky et al., 2008), however it might be assumed that they were conducted at the outpatient clinics or University departments where authors were based.

Most interventions targeted either the patient alone (k=11) or the patient and their family (k=10), three interventions targeted the family or patients significant others only (Bordbar et al., 2009; Reinares et al., 2008; van Gent & Zwart, 1991) (Table 3.1). Interventions were delivered to only groups (k=8), solely to individuals (k=9), or delivered to the patient and family members or as a couple (k=4).

The median number of intervention contacts as per protocol was 17 (range 1-56), with a mean contact time (estimated from data available for 16 studies) of 19.7 (sd 11.67) hours. The median duration of interventions was 6 months (IQR=0.5-12), ranging from a single intervention to 2 ½ years.

The spacing of intervention contacts was highly variable including, single-sessions (Bordbar et al., 2009) or two contacts (Elixhauser et al., 1990; Peet & Harvey, 1991), but most were delivered as a weekly programme for at least 6 sessions (k=17). Seven interventions started with regular weekly sessions, and before reducing the frequency. The family-focussed therapy programmes were conducted for 12 weekly sessions, reducing to bi-weekly, then 3 monthly (Miklowitz et al., 2000; Rea et al., 2003). Clarkin and colleagues (1998) psychoeducation for couples ran weekly for 10 sessions, then bi-monthly for remaining 15 sessions. Javadpour and colleagues (2013) conducted weekly face to face sessions for eight weeks then monthly telephone follow-up until 18 months. Booster sessions after the main intervention were a feature of three studies (Lam et al., 2000; Lam et al., 2003; Lenz, 2010).

3.5.1.3 Control group

Thirteen studies compared the intervention to TAU or standard care only (low or high intensity), eight compared standard care plus an additional component and four described the comparison group as another form of therapy. TAU was classified into low intensity general care or intensive support (structured specialist support).

The comparison group comprised only low intensity general care in six studies (Clarkin et al., 1998; Harvey & Peet, 1991; Javadpour et al., 2013; Lam et al., 2000; Lam et al., 2005; Lam et al., 2003; Peet & Harvey, 1991; Reinares et al., 2008) and only high intensity in three studies (Bordbar et al., 2009; D'Souza et al., 2010; Sajatovic, Davies, et al., 2009). Two studies did not provide detail on what TAU constituted (Dogan & Sabanciogullari, 2003; van Gent & Zwart, 1991).

Where the comparison group received additional components, these included additional clinician training (Ball et al., 2006), very brief medication training (Eker & Harkin, 2012) and attention matched group therapy sessions or phone calls to control for contact time (D. Castle et al., 2007; Cochran, 1984; Colom et al., 2003). Additional education or psychoeducation sessions were provided to control groups, for example seven sessions of psychoeducation (the IG received the same and the addition of 13 sessions of CBT) (Zaretsky et al., 2008), individual patient treatment sessions with a therapist and medication management sessions with a psychiatrist for a year (Rea et al., 2003), the provision of a self-help book and additional group sessions (Lenz, 2010).

The electronic monitoring device intervention provided by Elixhauser and colleagues (1990) was compared against TAU and individual compliance feedback based on lithium levels and suggestions for improving compliance.

For the four studies where the comparison group received an alternative intervention, this took the form of a programme of therapy differing in content or focus: Intensive Clinical Management (ICM), Interpersonal and Social Rhythm Therapy (IPSRT), 'Crisis management', Family Focussed Therapy and 'Individual patient management' (FFT) (Frank et al., 2005; Frank et al., 1999; Gilbert, 2000; Miklowitz et al., 2003; Miklowitz et al., 2000).

3.5.1.4 Study & sample characteristics

The median number of participants in the studies was n=66 (IQR=45-102) and participants randomised to intervention groups was n=31 (IQR=19-54). The length of time of follow-up varied across studies, participants were followed up for a median of 6 months (IQR=0.5-12) after last intervention contact (Table3.2).

Over one-third of studies (k=9) were based in the United States, three in the UK, three in Australia, two in Spain, two in Turkey and Iran and one each in Canada, Austria and the Netherlands (Tables 3.8 and 3.9). Data was available in 21 studies for the proportion of males and females recruited to the study. Overall there was a mean of 55.72% (sd=12.21) females in

the sample, ranging from 25% to 82%. Seventeen studies did not specify the ethnicity of participants.

To determine diagnosis eligibility different criteria were use; DSM (k=17); Research Diagnostic criteria (k=2); MINI (k=2); Schedule for Affective Disorders and Schizophrenia (SADS (k=2); unspecified (k=1). In 11 studies researchers recruited patients who were euthymic, 5 during episodes, 3 during manic episodes only, 1 recruited participants in all states, 4 studies did not report this (Table 3.2).

3.5.1.5 Adherence assessment and primary outcome

Thirteen studies reported the use of more than one assessment method, of which seven combined these into one adherence score or categorisation. Seven studies used a composite measure of adherence, combining a number of assessment methods which were then either rated for the level of adherence, or defined by pre-set criteria (Table 3.2). Subjective techniques included self-report (k=11), informant report (k=3) and physician report (k=4). Objective techniques (other than biological measures) were used in two studies (D'Souza et al., 2010; Elixhauser et al., 1990), nine studies used biological measures for example serum medication levels.

Seventeen studies either assessed and reported adherence overall for all medications participants were prescribed (Ball et al., 2006; Bordbar et al., 2009; D. Castle et al., 2007; Clarkin et al., 1998; D'Souza et al., 2010; Eker & Harkin, 2012; Gilbert, 2000; Javadpour et al., 2013; Lam et al., 2000; Lam et al., 2003; Lenz, 2010; Sajatovic, Davies, et al., 2009), or assessed them separately and then reported an overall adherence result (Frank et al., 2005; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; Zaretsky et al., 2008). Within these 17 studies, data was collected and reported for mood stabilisers only in four (Ball et al., 2006; Frank et al., 2005; Gilbert, 2000; Lenz, 2010), for mixed medications such as mood stabilisers, anti-depressants and benzodiazepines in nine studies (Bordbar et al., 2009; Clarkin et al., 1998; D'Souza et al., 2010; Lam et al., 2000; Lam et al., 2003; Miklowitz et al., 2000; Rea et al., 2003; Reinares et al., 2008; Zaretsky et al., 2008). Four studies did not report what medications were assessed (D. Castle et al., 2007; Eker & Harkin, 2012; Javadpour et al., 2013; Sajatovic, Davies, et al., 2009). Only one study measured and reported results individually for different mood stabilisers, and this was only at the two year follow-up paper (Colom et al., 2005). Six studies only reported on lithium prescriptions (Cochran, 1984; Dogan & Sabanciogullari, 2003; Elixhauser et al., 1990; Frank et al., 1999; N. S. Harvey & Peet, 1991; van Gent & Zwart, 1991).

The primary outcome included adherence (k=8) (three studies had adherence as the only primary outcome and five had multiple primary outcomes including adherence), relapse/ recurrence, symptoms (k=14), wellbeing/ functioning (k=7), coping with prodromes (k=1) and attitudes towards treatment (k=1), and was not specified for two studies (Clarkin et al., 1998; Lenz, 2010).

Table 3.1: Intervention components/ delivery

Intervention Component	Number of studies (k)
Content	
All elements of Psychoeducation	*13*
CBT/ CBT-type techniques	*9*
Social/ family therapy	*6*
Communication skills training	*4*
Education	*3*
Psychotherapy	*2*
Medication packaging technology	*1*
Tailoring	
Micro-tailoring	16
Participation	16
Individualisation	6
Attention tailoring	5
Macro-tailoring	1
Intervention focus	
Multi-focus	18
Adherence as primary focus	5
Unclear	1
Provider	
Psychologists	*5*
Psychiatrist	*6*
Mental health nurses	*3*
Social workers	*3*
'Therapists'	3
Other (research assistants/ trainees/ psychiatric counsellor)	4
Format	
Groups	*8*
Individual	*9*
Family/ couples-based	*4*
Group and individual	*1*
Electronic device, phone & mail	*1*
Group & telephone	*1*
Delivery setting	
Hospital outpatient psychology/ psychiatry department	5
Specialist affective disorder/ bipolar clinic/ unit	5
University psychology/ psychiatry department (not specialist BD)	5
Other	3
Actual delivery location unclear	6
Recipient	
Patient only	11
Family/significant others & patient	10
Family/significant others only	3

Table 3.2: Study design

Study Component	Number of studies (k)
Eligibility assessment	
DSM[a]	17
Research Diagnostic criteria	2
MINI[b]	2
SADS[c]	3
Not specified	1
Control/ Comparison group	
TAU[d] *only (general care)*	6
TAU only (intensive support)	3
TAU+ additional content (sessions or materials)	3
TAU+ attention matched sessions	3
TAU+ clinician training	1
TAU+ brief medication training	1
TAU+ compliance feedback	1
Alternative intervention	4
Unclear	2
Adherence assessment mode	
Self-report	11
Caregiver report	3
Physician report	4
Objective (pill counts/ MPR)	2
Biological measures	9
Composite measure	7
Adherence – medications analysed	
Mixed medications – reported globally	17
Lithium only	6
Mixed medications – reported separately	1
Primary outcome	
Relapse/ recurrence/	14
Symptoms	8
Adherence	7
Wellbeing/ functioning	1
Coping with prodromes	1
Attitudes towards treatment	2
Not specified	
n. participants, median (IQR)	66 (45-102)
n. participants IG, median (IQR)	31 (19-54)
Follow-up from last intervention contact, median (IQR) mths	6 (0.5--12)

[a] Diagnostic and Statistical Manual of Mental Disorders
[b] MINI International Neuropsychiatric Inventory
[c] Schedule for Affective Disorders and Schizophrenia
[d] Treatment as usual

3.5.1.6 Quality Indicators (Retention, Fidelity, Intervention description, Study design – risk of bias)

Many studies reported a good participant retention rate in multi-session programmes, for example, 76% completing the full programme of nine months of treatment (Rea et al., 2003), 73% of the intervention group adhering to the programme (missed no more than five out of 21 sessions) (Colom et al., 2003), 97% taking part in the two session intervention sessions (Harvey & Peet, 1991; Peet & Harvey, 1991), 89% participating in at least four psychoeducation sessions (average 7 sessions) (Javadpour et al., 2013). Sajatovic and colleagues (2009) found that 37% never participated in the sessions, 49% did complete at least four of the six sessions. This data was not reported for nine studies (Table 1). Where the programme was delivered to caregivers, a good retention rate was reported, for example, 100% of families agreeing to participate completing the intervention (Bordbar et al., 2009), 95% of caregivers attending at least eight out of 12 sessions (Reinares et al., 2008).

Eighteen studies specified that the intervention was manualised although only nine studies mentioned some form of fidelity assessment. For five studies this was formal assessment by independent raters using published or adapted coding systems or scales (Ball et al., 2006; Frank et al., 2005; Miklowitz et al., 2003; Miklowitz et al., 2000; Rea et al., 2003). The fidelity assessments reported good adherence to the manuals, compliance with the principles of the therapy and competent delivery. Fidelity assessments which were not formally scored or rated were used in four studies (Clarkin et al., 1998; Lam et al., 2000; Lam et al., 2003; Sajatovic, Davies, et al., 2009) for example, Sajatovic and colleagues (2009) reported that fidelity was assessed by the co-principle investigator delivering feedback at the end of each session.

Using the TIDieR checklist and guidelines, only two studies provided all detail required to allow replication (items 1-9) (Colom et al., 2003; Miklowitz et al., 2000). Adequate reporting was most common in; *Brief name* (100%), *Why* (rationale, theory or goal) (92%) and *What* (procedures used) (88%). Less well described items were *Where* (location) (54%), *When and how much* (58%) and *What* (materials used) (58%) (Figure 3.2). Reasons for coding items as 'inadequately described are reported in Table 3.3.

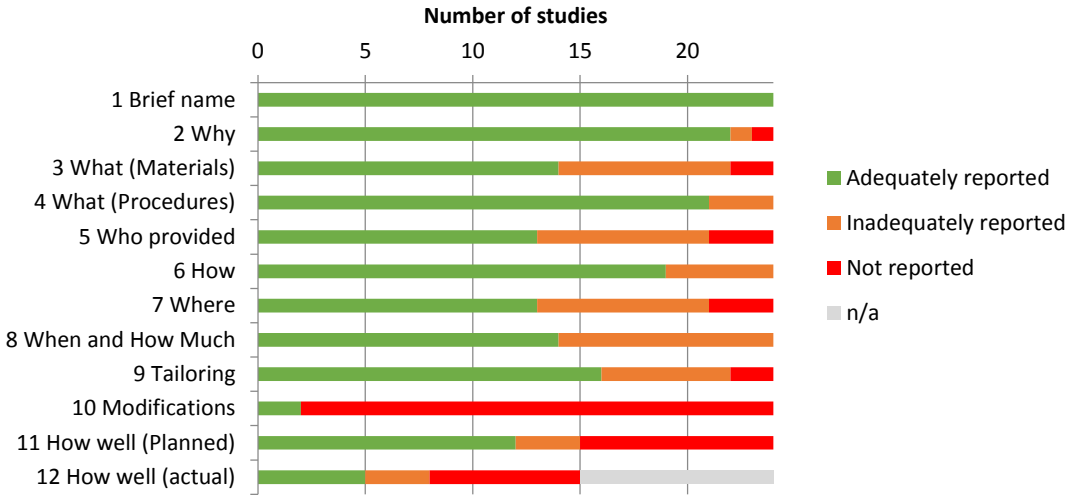


Figure 3.2: TiDier reporting

Table 3.3: Summary of reasons for inadequate reporting of interventions

TIDieR Item	Studies adequately reporting (%)	Example reasons for 'inadequate reporting' coding
1. Brief name	100.0	n/a
2. Why (rationale, theory or goal)	91.7	Paper doesn't link theory or rationale with actual intervention content or techniques.
3. What (materials used)	58.3	No information was provided on where or how to access intervention content or materials, or manuals not referenced.
4. What (procedures used)	87.5	Paper doesn't provide sufficient detail to replicate the procedure, key details on timing, or how to actually carry out the intervention is unclear.
5. Who provided	54.2	Information is required on who delivered the intervention, i.e. job role, training or expertise and background. Papers often reported only job title.
6. How (mode of delivery)	79.2	The descriptions provided did not report the size of the groups in group delivered interventions.
7. Where (location)	54.2	Either the context of the research (to provide information on the country and healthcare context) or the exact location of delivery of the intervention was not reported (for example in an outpatient clinic, hospital or research setting).
8. When and how much	58.3	The duration of intervention sessions or the spacing of contacts was not reported.
9. Tailoring	66.7	Tailoring techniques are mentioned as being part of the therapy, but unclear how they were used or personalised or whether there was a two-way dialogue.
10. Modifications	8.3	n/a
11. How well (planned)	50.0	The study was manualised but no actual assessment of fidelity, or sessions were recorded, but no mention of whether or not an assessment of recordings was conducted.
12. How well (actual)	20.8	The information provided was not specific, ie 'adherence to manual was high' or the outcome of any fidelity checks was not reported.

The method of randomisation was judged to have low risk of bias in nine studies, high risk in one study (Dogan & Sabanciogullari, 2003) but was inadequately described to make an assessment in 14 studies. Three studies demonstrated low risk of bias in allocation concealment, (Frank et al., 2005; Lam et al., 2003; Miklowitz et al., 2000), one demonstrated high risk of bias (Dogan & Sabanciogullari, 2003), in 20 studies and was judged to be unclear. Descriptions of blinding of study personnel was inadequately described to judge risk of bias in nine studies and in 14 studies there was high risk of bias. Studies were judged to have a high risk of bias in participant blinding in 10 cases. Only one study each were judged to have low risk of bias for personnel blinding (Castle et al., 2007) and participant blinding (Reinares et al., 2008) (Figure 3.3). In terms of adherence outcome assessment, 10 studies included an outcome measure with low risk of bias, however, 12 studies only included measures where there was a high risk of bias (for example self-report).

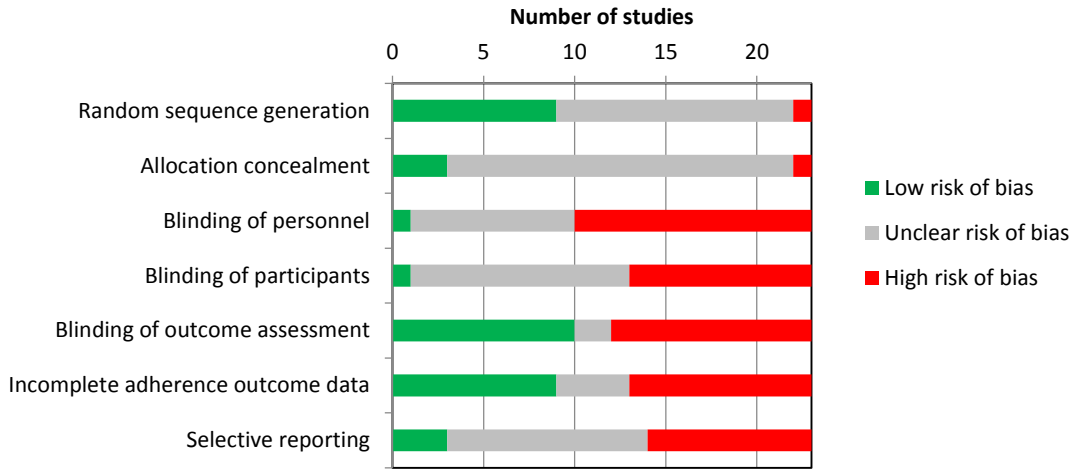


Figure 3.3: Risk of bias in included studies (k=23).

3.6 Meta-analysis results

3.6.1 Primary analysis

Across 18 studies, there was a significant effect of interventions versus control on adherence, OR 2.27, 95% CI [1.45, 3.56], p<0.001). Outcomes were better in the intervention group than the control group in 15 studies, as indicated by positive effect sizes, while in 3 studies adherence outcomes were not improved relative to control (Table 3.4, Figure 3.4). There was substantial heterogeneity between the studies Q(17)=36.96 (p=0.003) I^2=54.00.

Table 3.4: Primary meta-analysis

Comparison	k	OR	95% CI	p	I^2	Heterogeneity Q (df)	p
Composite measures> serum levels> self-report > informant report & longest follow-up assessment.	18	2.27	1.45,3.56	<0.001	54.00	36.96(17)	0.003

3.6.2 Moderation analysis

Moderation analysis was conducted to assess whether intervention and study characteristics (intervention focus, content, delivery, setting, tailoring, fidelity, primary outcome and target medication, baseline illness state, control group, publication year and follow-up time) contributed to the variability in effect sizes (Tables 3.5 & 3.6). Intervention contact time (hours) had a significant impact with increasing contact time being associated with a reduction in effect B=-0.08 (-0.14, 0.02); Q= 6.12 p=.013 (Tables 4 and 5). If TAU was supplemented with an additional component for the control group, the intervention effect was smaller (p=0.034) (Table 3.6). None of the other variables significantly moderated the intervention effect.

Figure 3.4: Forest plot of odds ratios of studies included in primary meta-analysis

Table 3.5: Moderation analysis - Intervention characteristics

Intervention characteristics	**k**	**OR (95%CI)**	**Heterogeneity (within group) Q(df), p, I^2**	**Heterogeneity (between group) Q(df), p**
Intervention focus				
Multi-focus	14	2.09 (1.23,3.54)	30.43(13), 0.004, 57.27%	0.50(1), 0.479
Adherence as primary focus	4	3.12 (1.18,8.25)	6.02(3), 0.111, 50.17%	
Content				
Psychoeducation – all elements	11	2.14 (1.18,3.89)	27.82(10), 0.002, 64.06%	0.25(1), 0.617
Other	4	3.03 (0.89,10.23)	5.59(3), 0.133, 46.35%	
Delivery setting				
Specialist	4	3.17 (1.09, 9.21)	9.28(3), 0.026, 67.66	1.12(1), 0.289
General	11	1.65 (0.94, 2.92)	18.80(10), 0.043, 46.79	
Delivered to partner/family only	2	1.31 (0.20,8.55)	0.73(1), 0.400, 0.00%	0.13(1), 0.719
Delivered to partner/family & pt	4	1.98 (0.57,6.93)	16.60(3), 0.001, 81.93%	
Individual and/or group only	12	2.66 (1.45,4.85)	17.89(11), 0.084, 38.49%	0.29(1) 0.588
Family/partner & pt involved	4	1.94(0.75,5.06)	16.60(3), 0.001, 81.93%	
Group & individual	2	1.75 (0.29,10.41)	3.99(1), 0.046, 74.95%	
Group only	4	2.77 (1.23,6.23)	8.13(3), 0.043, 63.12%	0.22(2) 0.896
Individual	6	2.69 (1.23,5.90)	4.98(5), 0.418, 0.00%	
Tailoring – Individualisation				
Yes	4	3.56 (1.84,6.89)	7.44(3), 0.059, 59.68%	1.06(1) 0.303
No/ Unclear	14	1.95 (1.41,2.69)	26.94(13), 0.013, 51.75%	
Tailoring – Attention (individual level)				
Yes	2	4.58 (1.43,14.66)	0.09(1), 0.763, 0.00%	0.89(1) 0.346
No/ Unclear	16	2.08 (1.54,2.81)	35.22(15), 0.002, 57.41%	
Tailoring – Micro (individual level)				
Yes	14	2.18 (1.57,3.01)	30.78(13), 0.004, 57.77%	0.14(1) 0.714
No/ Unclear	4	2.24 (1.17,4.30)	6.17(3), 0.104, 51.37%	
Tailoring – Participation				
Yes	13	1.97 (1.64,2.93)	27.44(12), 0.007, 56.27%	0.82(1) 0.365
No/ Unclear	5	2.89 (1.67, 5.00)	8.17(4), 0.086, 51.05%	
Manualised				
Yes	13	2.03 (1.21,3.42)	23.86(12), 0.021, 49.70%	0.76(1), 0.384
No	5	3.26 (1.29,8.27)	11.58(4), 0.021, 65.45%	
Intervention fidelity assessed				
Formal	3	0.98 (0.397,2.425)	4.80(2), 0.091, 58.32%	
Informal	4	4.25 (1.825,9.903)	0.82(3), 0.844, 0.00%	5.424(2), 0.066
No fidelity assessment reported	11	2.34 (1.372,3.976)	20.17(10), 0.028, 50.42%	
	k	**B, (95% CI)**	**Q; p**	
Intervention contacts (per protocol) Range 2- 27	18	-0.04 (-0.10,0.01)	2.21; 0.137	
Intervention duration (months) Range 1.4- 12	17	-0.11 (-0.24,0.02)	2.86; 0.091	
Intervention contact time (hours) Range 6- 31.5	12	-0.08 (-0.14,0.02)	6.12; 0.013	

Table 3.6: Moderation analysis – Study characteristics

Study characteristics	k	OR (95%CI)	Heterogeneity (within group) Q(df), p, I^2	Heterogeneity (between group) Q(df), p
Adherence a primary outcome				
No (including 'missing')	12	1.91 (1.12,3.27)	21.79(11), 0.026, 49.53%	1.29(1), 0.256
Yes	6	3.34 (1.40,7.45)	12.07(5), 0.034, 58.58%	
Target medication				
Mixed medication – reported/ assessed together	13	2.43 (1.45,4.01)	28.13(12), 0.005, 57.34%	0.002(1), 0.968
Lithium only	4	2.51 (0.65,9.63)	6.54(3), 0.008, 54.14%	
Baseline state				
Episodic included	5	2.05 (0.88,4.75)	15.95(4), 0.003, 74.93%	0.21(1), 0.649
Euthymia only	10	2.62 (1.38,4.96)	15.21(9), 0.085, 40.81%	
TAU type				
General care	11	2.46 (1.66,3.65)	17.82(10), 0.058, 43.87%	0.14(1) 0.710
Intensive care	5	2.02 (1.25,3.26)	17.42(4), 0.002, 77.03%	
TAU + education/ psychoeducation	4	0.92 (0.50,1.70)	4.42(3), 0.220, 32.11%	4.47(1) 0.034
Yes	14	2.81 (2.02,3.90)	22.75(13), 0.045, 42.86%	
No/ Unclear				
	K	**B, (95% CI);**	**Heterogeneity Q; p**	
Publication year	18	-39.88 (-160.74,80.98)	0.44, 0.509	
Follow-up duration (mths since last intervention contact) Range 0 to 60	18	-0.02 (-0.05,0.01)	1.66; 0.197	
Follow-up duration(mths from baseline (excluding van Gent) Range 1.4 to 65	17	-0.03 (-0.05,0.00)	3.06; 0.080	

3.6.3 Sensitivity analysis

The effect of interventions on adherence remained similar when small studies, studies with low retention and outliers were excluded, and across all follow-up points (Table 3.7). When only studies using serum levels were included there was no significant effect of intervention however the effect size was similar to the overall analysis. Highest OR were found by including those reporting outcomes from composite measures (2.50) followed by serum levels (1.91) and self-report (1.71). Significant heterogeneity was present when including ORs from studies using composite measures (Q(7)= 27.35, p<.001). Study ORs were not significantly heterogeneous within the serum level or self-report outcome measures.

The overall OR was reduced for those studies with low risk of bias in outcome measure blinding OR=1.49 (0.60,3.70) and selective reporting OR=1.66 (0.60,4.91). However, a higher effect was seen where studies had low risk of bias in incomplete outcome data OR=2.99 (1.44.6.21).

Table 3.7: Sensitivity analysis

Comparison	k	OR	95% CI	p	I^2	Heterogeneity Q (df)	p
Small studies excluded	5	2.57	1.31,5.06	0.006	53.72	8.64(4)	0.071
Outlier excluded	17	2.18	1.39,3.41	0.001	53.98	34.77(16)	0.004
Follow-up assessment retention < 75% excluded	9	3.16	1.67,5.96	<.001	50.78	16.25(8),	0.039
Adherence measure (final timepoint assessed is used)							
Serum levels	6	1.91	1.10,3.32	0.021	1.78	5.09(5)	0.405
Serum levels [a]	5	1.77	1.03,3.05	0.040	0.00	2.58(4)	0.631
Composite measures [a]	8	2.50	1.11,5.66	0.028	74.41	27.35(7)	<0.001
Self report [a]	9	1.71	1.05,2.14	0.033	40.43	13.43(8)	0.098
Timepoint assessed							
~1-3 mths	7	1.87	0.86,4.08	0.117	69.80	19.87(6)	0.003
~1-3 mths [a]	6	1.63	0.76,3.51	0.213	70.39	16.89(5)	0.005
~ 6 mths [a]	7	1.91	1.15,3.19	0.013	24.59	7.96(6)	0.241
~ 12 mths [a]	11	1.97	1.23,3.16	0.005	52.16	20.90(10)	0.022
Low risk of bias[b]							
Blinding of outcome measure	7	1.49	0.60,3.70	0.393	57.39	14.08(6)	0.029
Incomplete outcome data	9	2.99	1.44,6.21	0.003	54.82	17.71(8)	0.024
Selective reporting	2	1.66	0.56,4.91	0.362	25.60	1.34(1)	0.246

[a] Dogan et al (2003) excluded or not present in analysis (Dogan & Sabanciogullari, 2003)

[b] Risk of bias analysis for risk measures where at least 2 studies were in low risk category (where risk was unclear, studies were excluded)

3.6.4 Publication bias

The funnel plot was symmetrical suggesting the absence of publication bias (Figure 3.5). Duval and Tweedie's 'trim and fill' method suggested that one study would need to be added or removed for the funnel plot to be symmetrical. The imputed OR after this procedure was 2.181 (1.389, 3.422) i.e. very similar to our original estimate of the effect of interventions on adherence (Figure 4 for funnel plot with imputed study). Egger's test for asymmetry was not significant indicating no evidence for publication bias, the B0(bias) = 0.86213, 95% CI (-1.74167, 3.46594), with t=0.70191, df=16., p=0.24641. The fail-safe N was calculated and 117 studies would need to be included, i.e. 6.5 missing studies for every observed study, for the intervention effect to be nullified. The results of these tests indicate that publication bias does not present a threat to the results of this meta-analysis.

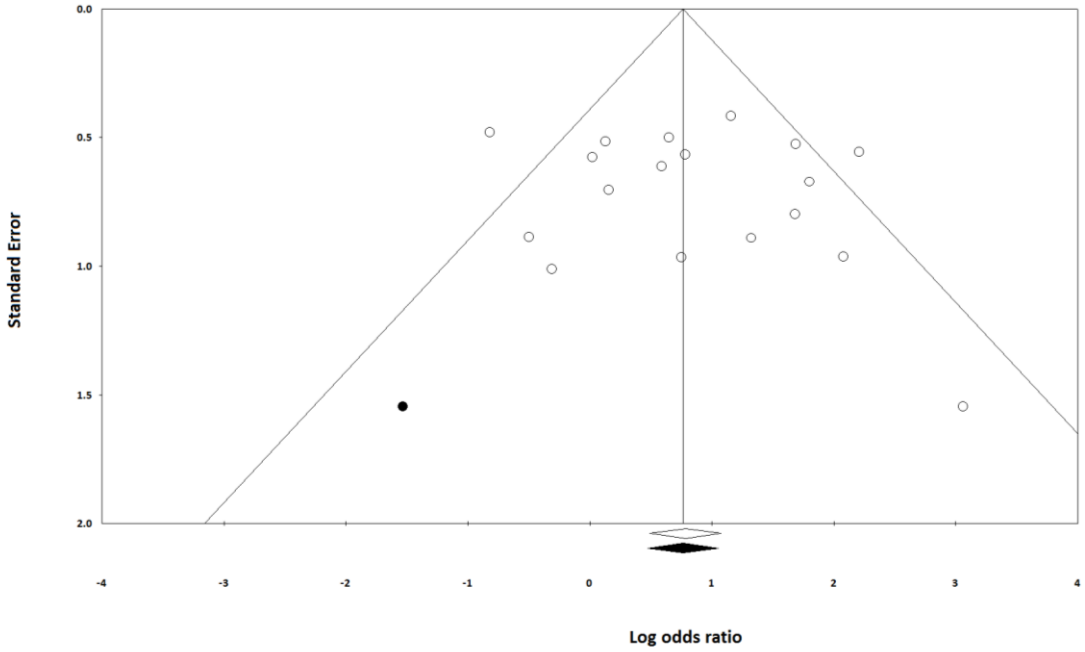


Figure 3.5: Funnel plot with one imputed study

3.7 Discussion

3.7.1 Intervention effects and moderators of effects

This review brings together the published literature on RCTs of interventions to enhance medication adherence in bipolar disorder. There is strong evidence that interventions can improve adherence. The pooled OR was 2.27 (95% CI 1.45, 3.56) equivalent to a two-fold increase in the odds of adherence in the intervention group relative to control. The effects appear to be durable, as there was no significant change in effect of the interventions when patients were followed up at longer post-intervention intervals. Studies with a two-year follow-up still reported positive effects on adherence.

Interventions which involved more contact were less effective than less intense interventions. Smaller intervention effects were found when the comparison group received additional therapy sessions compared to those receiving just TAU. When analysing only studies with low risk of bias, i.e. higher quality studies, interventions remained effective, indicating that effectiveness was not as a result of only poor quality studies. No other significant moderator variables were associated with intervention effectiveness. However, both intervention and study design were often poorly reported, limiting the extent of moderation and sensitivity analysis which could be conducted.

Most interventions involved psychoeducational techniques which appear to be effective; these take into account an individuals' knowledge, beliefs and attitudes. These are promising areas

of focus for interventions (Gaudiano et al., 2008; Leclerc et al., 2013; Sajatovic et al., 2004) and are included in recommendations for improving adherence in the UK National Health Service (Horne et al., 2005). Taking into account participants' own beliefs and opinions about bipolar and its treatment may foster better engagement (L. Berk et al., 2010; Clatworthy et al., 2009). However, additional evidence is needed to tease out the mechanisms behind how these interventions might have an effect because description of intervention content was often poor. The way psychoeducation or CBT were operationalised varied across studies, therefore accurate moderation analysis comparing intervention types is challenging. In this review the information provided on intervention content was scrutinised, rather than relying on the broad title or name given to each intervention.

Many of the interventions are complex and resource intensive and further identification of the active components, mechanisms of action and effective dose of intervention will be needed before they could be integrated into clinical care (Batista et al., 2011; Rouget & Aubry, 2007). It is recommended that future trials use published taxonomies of evidence-based BCTs in planning, delivery and reporting (Michie, Johnston, et al., 2013; Michie et al., 2011). Many studies used multiple methods to measure adherence conforming to the recommendation that studies should use more than one type of measure (Horne et al., 2005; Sajatovic et al., 2010). Sensitivity analysis demonstrated that a positive effect of the interventions was present regardless of type of measure used.

Smaller intervention effects were found when the comparison group received additional therapy sessions than when this group received only TAU. This confirms empirically the conclusion by Guadiano and colleagues (2008) that interventions compared to TAU, predominantly CBT and psychoeducation, had greater evidence for effectiveness than for those using an active control, which tended to be Family-focussed Therapy and Interpersonal and Social Rhythm Therapy interventions. Comparing groups receiving different 'active' interventions e.g. in factorial designs, is essential to identify the effective components of the intervention (Collins, Murphy, & Strecher, 2007) and if the intervention is effective beyond attentional 'Hawthorne' effects. However, TAU comparison groups are also extremely useful as, in practice, the content and attention participants' receive are components of the intervention and using TAU can establish whether the intervention can improve outcomes over and above current standard care (Freedland, Mohr, Davidson, & Schwartz, 2011).

Smaller effects on adherence were found in longer interventions. But these were typically multi-focused interventions that did not have adherence as the primary outcome and aimed to improve clinical outcomes through a range of determinants. Sessions may have focussed initially on medication, but then moved on to other aspects of self-management. The three

shortest interventions all had adherence as a primary outcome, the focus was firmly on adherence (Cochran, 1984; Eker & Harkin, 2012; Sajatovic, Davies, et al., 2009). These findings are consistent with Gaudiano and colleagues (2008) suggestion that making an intervention's primary focus adherence tends to increase effects on adherence, and suggests that resource intensive interventions may be unnecessary for adherence improvement. In clinical care, the briefest interventions may be more easily adopted. However, we recognise that many of the longer interventions also had impacts on adherence, and that these more complex interventions may address other determinants clinical outcomes in bipolar disorder not explored in this review.

There was a great deal of heterogeneity between the studies, in terms of setting, content, adherence outcome, follow-up and quality, concurring with previous narrative reviews (Crowe, Porter, et al., 2012; Desplenter et al., 2006; Leclerc et al., 2013; Reinares, Sánchez-Moreno, & Fountoulakis, 2014). We found no intervention, study design or delivery moderator variables except those mentioned above, significantly distinguished between the effectiveness of studies.

3.7.2 Limitations of studies included in the review

The conclusions which can be drawn from the review are limited by both the quality of the RCTs themselves and in the reporting of both the trials and the interventions tested. As stated, it was not possible to include a number of studies in the moderation analyses as data items were inadequately reported.

Although some intervention description items were consistently reported, overall only two out of 24 studies provided sufficient information for replication. Other assessments of inadequate reporting of trials have been conducted, although not using the TIDieR checklist. An assessment of reporting in National Institute of Health Research (NIHR) Health Technology Assessment (HTA) funded RCTs demonstrated that components necessary for replication were missing in 73% of published psychological interventions (Douet et al., 2014). Hoffman et al (2013) found that only 39% of non-pharmacological interventions published in 2009 had adequate reporting. Items poorly reported in the present review included Item 3 (Materials), concurring with previous studies (Glasziou et al., 2010; Hoffmann et al., 2013). However, in previous studies authors were able to increase the proportion of studies classed as having adequate information available by contacting authors for this information (not conducted in the present review). Item 7. Where (location) and Item 5 Who provided were also poorly reported, in specifying both the healthcare context and the actual delivery setting of the

intervention and in specifying the training and experience of staff members respectively. Hoffman and colleagues (2014) note that these details are important as they can affect the feasibility of replicating the intervention. If interventions were described consistently it would allow for more thorough moderation analysis to be conducted. It is recommended that authors make use of TIDieR guidelines to ensure consistency of reporting (Hoffmann et al., 2014).

The publication of reporting guidelines is relatively recent compared to the timescale of included studies in the review. The CONSORT extension for non-pharmacological interventions was published in 2008 (Boutron et al., 2008), however, in the present review eight studies were published in 2008 or later and the two studies reporting all items adequately were published prior to this. It is appreciated that due to journal restrictions it may be difficult to provide the necessary information succinctly. It is recommended that this information should be published in trial protocols, in supplementary journal information or linked to from trial register websites.

Study quality was assessed using published guidelines (Higgins et al., 2011) and sensitivity analysis was used to assess its impact on the conclusions. The quality of the studies varied and randomisation and allocation concealment methods were often not adequately reported to judge risk of bias. Blinding of personnel and participants may be difficult or impossible in the delivery of psychosocial interventions (Davidson et al., 2003). Blinding of outcome assessment of the studies in the meta-analysis was classified as having a high risk of bias in half of the studies as they included self-report. When we included only studies where the outcome assessments were blinded and where studies did not selectively report outcomes, the effectiveness of these interventions was lower than when all studies were included. This fits with the hypothesis that poor quality may inflate effects. However, interventions remained effective over control when only high quality studies were included. Researchers need to adopt consistent standards of reporting so that risk of bias can be reliably judged such as CONSORT statements (Boutron et al., 2008).

For the effect sizes selected for comparison, half (9/18) were based on results where over 25% of follow-up data was not available for one or both groups. Exclusion of these studies resulted in an increase in overall OR, indicating that studies with poorer follow-up rate were not biased to reporting better results. Sensitivity analysis also demonstrated that the effects did not arise purely from studies with small samples. However using a recommended cut-off of n<70 for either intervention or control group (Coyne et al., 2010), only five studies remained indicating that recruitment to these trials may be challenging. It is striking that many of the studies in this review were not sufficiently powered to detect moderate to large effects. The meta-analysis process, in pooling results, increases the statistical power overall (Petticrew & Gilbody, 2004;

Walker et al., 2008). However, the fact that the meta-analysis is based on a large proportion of small studies may affect the results as they may be more prone to methodological issues which may increase the risk of bias. These include that groups may be dissimilar at baseline, may be more influenced by outliers and recruitment may have stopped once statistically significant intervention effects are found (Coyne et al., 2010). Published protocols and clear sample size calculations are needed to assess the likelihood of this bias. It is clear that larger, more adequately powered trials are needed.

In terms of retention to the interventions themselves, data on this was not reported for nine studies so it is impossible to tell whether those assigned to receive it actually received did so or for researchers to conduct sensitivity analysis to detect whether effects were related to intervention exposure.

3.7.3 Strengths & Limitations of the review

There are a number of strengths to the present review which increase its validity and reliability. The review is reported in accordance with guidelines in the PRISMA statement (Moher et al., 2009). This helped minimise selection bias and ensure reporting transparency in order that the review could be replicated. Published guidelines for conducting reviews as well as assessing quality of studies and reporting of interventions were used (Boutron et al., 2008; Davidson et al., 2003; Higgins et al., 2011; Hoffmann et al., 2013; Schulz et al., 2010). An experienced librarian assisted with the design of the search strategy and search terms from a previous adherence review were incorporated (Haynes et al., 2008).

Registered trials, conference abstracts and published doctoral theses were included to reduce selection bias caused by including only studies published in peer-reviewed journals. Study selection was performed independently by two researchers to also minimise bias in selection. Two investigators coded and extracted data for each study, increasing reliability and disagreements were resolved through discussion and seeking input from a third researcher when needed.

Limitations of the published studies are reflected in the limitations of this review, i.e. poor reporting and quality limiting the conclusions which can be drawn. Included studies were not homogeneous, with regard to population, type of interventions and outcome measures, assessment timepoints and adherence definitions. It could be argued that studies which are too disparate cannot be compared. However, inclusion criteria were broad in order that the study characteristics could be examined using moderation analysis.

Lack of evidence on interventions for specific clinical groups limits our ability to establish what works for whom. The majority of the interventions in this and previous reviews have focussed on euthymic patients and are therefore not generalizable to those in acute phases (Colom & Lam, 2005; Crowe et al., 2010). Patients who have experienced greater number of bipolar episodes may be less likely to benefit from long duration CBT (Scott et al., 2006). In this review, data was not available on number of previous episodes for us to test this as a hypothesis. In addition, it is important to further investigate the effects on individuals who are inpatients, or who have comorbidities (L. Berk et al., 2010; Desplenter et al., 2006; Lolich et al., 2012; Rouget & Aubry, 2007).

The measurement of treatment adherence in psychiatry is complex (Sajatovic et al., 2010) and this review is affected by the heterogeneity of adherence outcomes. To compute an overall effect, odds ratios were used as most studies reported the proportion of participants who were classified as adherent/ non-adherent and this produced the most comparable results across studies, even though adherence cut-offs differed. There is no agreed clinical adherence level for BD and further research is needed to determine whether a clinically appropriate standard can be identified (Velligan et al., 2010). An improvement in adherence in one study may not equate to the same clinical outcome as the same magnitude of improvement in another. Sensitivity analysis demonstrated that a positive effect of the interventions was present regardless of type of measure used.

More broadly than the difficulties in measuring adherence, is the individual variability in BD itself, the symptom profile differs between individuals and within individuals over time. This means that it is challenging to draw conclusions about effectiveness of interventions, not just because of the different ways trialists might select participants, but also in the fact that the participants will have their own unique views and characteristics which may affect how they experience the intervention.

Using the TIDieR checklist interventions were coded from the published paper included in the review as well as any referenced protocols, papers and available manuals. Contacting authors for additional information as conducted by Hoffman et al (2013) was not carried out in this review which would be recommended for future reviews and intervention development. However, that the information is not readily available is itself an important finding as pursuing this extra information is time consuming and may not be feasible for clinicians looking to assess potential interventions. The checklist was only applied to the intervention group and not to the control or comparison group. In the present review the comparison group was coded using basic criteria for its content, however, a full assessment of reporting of all trial arms would add to the picture of reporting adequacy.

The present review is based on published data only. Registered trials were searched and investigators were contacted in order to obtain results of registered trials which were not found through the bibliographic database searches, but this did not yield additional results. In addition, the full text or sufficient results for meta-analysis were not available for eight studies despite numerous attempts to obtain these. However, we found no evidence of publication bias, and as adherence interventions are resource intensive, it would be unlikely that there would be the number of unpublished studies (k=117) needed to nullify the overall effect of interventions found in this review.

3.7.4 Other interventions of note

A number of relevant interventions were not included in the review due to either not utilising an RCT design or including a mixed psychiatric sample without sub analysis. It is worthwhile considering these briefly as they provide some useful points for consideration for the development of adherence interventions.

An adherence intervention for people with serious mental illness developed by Valenstein et al (2011) was tested in an RCT. Delivered by pharmacists or technicians, this comprised of 'unit of use packaging', an educational session about medication, refill reminders and clinician reminders in cases of failure to refill prescriptions. This intervention significantly increased adherence as assessed by medication possession ratios in comparison to the usual care group. This intervention is of note due to novel delivery by pharmacists. Additional research would be needed to establish its effectiveness in a statistically powered sample of patients with BD.

A pilot multi-component adherence intervention for older adults with BD, the Medication Adherence Skills Training for Bipolar Disorder (MAST-BD) used a quasi-experimental methodology (Depp, Lebowitz, Patterson, Lacro, & Jeste, 2007). The intervention comprised education, motivational training, medication management and symptom management and incorporated specific issues facing older adults, namely cognitive impairment and medical comorbidity and showed a decline in non-adherence. Feasibility and acceptability evaluation revealed that participants felt the intervention should be more individually tailored and future interventions should address this.

An intervention of psychiatric Advance Directives on adherence in people with severe mental illness comprised a guided discussion of choices for planning of mental healthcare to be received during future periods of illness and completion of advanced directives (Wilder et al., 2010). After 12 months, those who had requested a particular medication were more likely to be taking it and being prescribed at least one medication which had been requested in the

advance directive significantly predicted higher medication adherence. This study demonstrates the importance of involving participants in medication decisions.

Customised adherence enhancement (CAE) was designed to address the need for a short-term, lower intensity psychosocial intervention which focuses specifically on adherence and incorporates a 'needs-based approach' (Sajatovic et al., 2012). The intervention was delivered flexibly according to participant need and was tested in a prospective non-controlled trial with poorly adherent patients with bipolar disorder. The intervention was associated with improved adherence at three and six month follow-up, in addition, there was good attendance at intervention sessions. A larger, controlled study is needed to confirm the results from this study.

3.7.5 Conclusions & Implications for intervention development

This review quantitatively synthesises evidence for adherence interventions in BD, including psycho-educative approaches and other techniques and therapies. Strong evidence was found for the effectiveness of interventions to improve adherence. Brief adherence interventions should be incorporated in routine clinical practice as it would be likely to lead to improved and sustained adherence outcomes for patients. Adherence interventions could positively impact on outcomes for people with a diagnosis of BD through reducing relapse and risk of hospitalisation.

Identification of the active components, mechanisms of action and effective dose of intervention is needed to allow for easier integration into clinical care in that interventions only use the minimum resources necessary (Batista et al., 2011; Rouget & Aubry, 2007). It is recommended that future reviews and trials conducted make use of published taxonomies of evidence-based behaviour change techniques in planning and delivery as well as in reporting (Michie, Johnston, et al., 2013; Michie et al., 2011). However, we can be confident that prolonged, resource intensive interventions may not be necessary.

The capacity to draw conclusions about exactly what works and for whom is limited by the strength of reporting specifically the descriptions of the intervention content and delivery. The growing body of evidence and improved trial and intervention reporting will allow us to draw more conclusive recommendations as to whether these results can be generalised to more naturalistic clinical settings. However, with the evidence available, we can be confident that conducting a brief intervention incorporating psychoeducation or CBT skills can be effective in improving adherence outcomes in bipolar disorder.

Conducting this review comprises a crucial step in the process of developing a novel intervention (Craig et al., 2008) and forms part of the needs assessment stage of IM (Bartholomew et al., 2011). The results of the review therefore provide confirmation of the types of intervention which can be effective and has identified gaps where further research and deeper understanding of the specific needs of people is required. Chapter 4 comprises the next stage of this development process and needs assessment by exploring factors associated with adherence and self-management including illness and treatment perceptions and unmet information needs of people with BD. As well as seeking their perspectives on information and support to further inform intervention development.

Table 3.8: Summary of included studies –Adherence specific interventions

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
Cochran (1984).	US	Modified CBT delivered individually by Psychologists weekly for 6 weeks.	TAU (affective disorders clinic, inc. brief medication visits weekly or bimonthly)	86% participants completed full 6 weeks.	38 pts (IG=20, CG= 18) with current lithium prescription. Mean age 32, 61% female, 21% married.	6 mths	Yes	Author designed self report, informant report, and Physician report scales. Serum lithium levels. Compliance index	Self & Informant report: no sig. differences between IG and CG at post, 3 mths or 6 mths. Physician report: Sig. difference between IG and CG at post-intervention and 6 mths (n/s at 3 mths). Serum levels: n/s at post-intervention and 3 mths. Levels mostly unavailable at 6 mths. Compliance index: Sig. difference between IG and CG at post-intervention and 6 mths (n/s at 3 mths). IG less likely to have major compliance problems.
Dogan & Sabanciogullari (2003).	Turkey	Education sessions delivered individually by Psychiatric nurses for 2 sessions followed by one group session.	TAU (no details specified)	Not specified	32 pts (IG=14, CG=12) long-term lithium users. Mean age 38, 35% female, 73% married.	2 mths	Yes	Serum lithium levels	Sig. difference between IG and CG in baseline to 3 mth change in proportion of pts low to normal serum levels. Higher proportion in IG moving to 'normal' range levels than in CG.
Elixhauser et al. (1990).	US	Use of an electronic adherence monitoring device and feedback for individuals on adherence.	TAU (psychiatric outpatient clinic, usual mail refill of lithium prescriptions) +	Not specified	93 pts (IG=42, CG=51) with current lithium prescription. Mean age 49, gender	3 mths	Yes	Self-report (Morisky) Serum lithium levels. Prescription refills (% obtained).	Self report scale mean & % reporting no missed doses – n/s effect of intervention (monitoring or feedback).

		Provision of adherence education for non-adherent individuals by phone or mail.	Feedback on compliance (from lithium levels) and suggestions for improving compliance at visit 2.		breakdown not reported.			Medication taking patterns - Daily and period pill counts (% prescribed doses)	Serum lithium – n/s effect of intervention (monitoring or feedback). Prescription refills (%) – significant effect of monitoring with higher & refill in intervention group. n/s effect of feedback.
Harvey & Peet (1991). Peet & Harvey (1991)	UK	Educational video on lithium with illustrated transcript viewed by participants followed by individual home visit after 2 weeks for discussion with Psychiatrists.	TAU (not specified) + Educational intervention at 12 weeks.	97% attended IG sessions	60 pts (IG=30, CG=30) in remission attending lithium clinic. Mean age 55m 67% female.	5 mths	Yes	Red blood cell lithium levels during fixed-dose regimen. Estimate of missed doses/ days in each 6 week period, checked without warning with spouse or other.	Lithium RBC, serum levels and lithium ratio: No sig. difference between change scores for IG and CG. Lithium missed days: sig. difference in change scores with a greater reduction in missed doses in the IG compared to CG
Sajatovic et al. (2009).	US	Life Goals Program (LGP) – Group psychoeducation sessions delivered by a mental health nurse and 'psychiatric counsellor' in 6 weekly sessions. Followed by optional monthly unstructured group sessions.	TAU (community mental health centre care, typically medication management, psychosocial therapy, counselling, access to intensive assistance.	49% completed at least 4 sessions. 37% completed no sessions, less than 10% participated in optional sessions.	164 pts (IG=84, CG=80) in remission or episodic. Mean age 40, 68% female, 13% married.	10 ½ mths	Yes	Adherence behaviours SRTAB - self-report over past 30 days, 0%, 25%, 50%, 75% 100%.	SRTAB 3 months IG (n=62) 83.87(28.66), CG (n=61) 81.15(32.49) 6 months I (n=51) 90.20(22.40), C (n=55) 77.27(35.12) 12 months I (n=41) 95.73(11.04), C (n=39) 81.08(30.85) p=.41.

Table 3.9: Summary of included studies - Multi-focus interventions

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
Multi-focus interventions (Individual/ couples/ family)									
Ball et al. (2006).	Australia	Modular cognitive therapy programme incorporating Psychoeducation and CBT techniques. Delivered by Psychologists 20 weekly, individual sessions.	TAU (sessions as required with GP/ psychiatrist. + Clinicians provided with educational package on BD & mood monitoring.	Not specified	52 pts (IG=25, CG=27) with at least 1 bipolar episode in last 18mths. Mean age 42, 58% female.	12 mths	No	Serum concentration. Self-report (reporting occasions of missing medication)	Self-report; n/s between proportion with adequate compliance in IG and CG, either post-treatment or 12 mths. Serum levels not reported due to low attendance for measurement.
Clarkin et al. (1998).	US	Structured Psychoeducation intervention for patients and their spouses delivered by Social workers in 25 sessions, 11 months.	TAU (medication management as part of usual inpatient and outpatient care)	Not specified	42 pts (IG= 19, CG= 23) married or living with sig other > 6mths. Mean age 47, 46% female.	0 (post-intervention)	Not specified	Author developed adherence scale	Sig. difference between IG and CG in adherence scores at post-intervention follow-up. (nb missing data for 1/3 CG)
Frank et al (1999).	US	Interpersonal and social rhythm therapy (IPSRT) – Psychotherapy and psychoeducation with a focus on life events and social rhythms. Individually delivered with	Intensive clinical management (sessions focus on education, adherence & side-effects), delivered weekly for min 12 weeks, then monthly for 2 years.	Not reported for each treatment. 65% overall entered preventative phase.	82 pts (IG=60, CG=22) in at least 3rd discrete affective episode. Mean age 36, 66% female, 37% married.	0 (post-intervention)	No	Adherence – ratio of blood level to dose prescribed.	n/s difference between four different treatment strategies in blood levels and no effect of changing treatment strategy.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		ancillary family education sessions. IPSRT delivered by 'therapist' and physician weekly for min 12 weeks, then monthly for 2 years.							
Frank et al. (2005).	US	IPSRT delivered by non-physician clinician (social worker, nurse, or psychologist) and a psychiatrist. Sessions delivered weekly until stabilisation, every other week for 12 weeks (preventative phase) and monthly until the end of the 2-year (maintenance phase).	Intensive clinical management (sessions focus on education, adherence & side-effects), delivered weekly for min 12 weeks, then monthly for 2 years.	Not reported for each treatment. 70% retention rate at end of stabilisation. 53% of originally randomised completed 2 year maintenance.	175 pts (IG=132, CG=43) in at least 3rd discrete affective episode. Mean age 35, 57% female, 35% married.	0 (post-intervention)	No	Serum levels - coefficient of variation of mood stabilizer medication.	No significant difference between four different treatment strategies in coefficient of variation of mood stabilizer serum levels.
Gilbert (2000).	US	Family Focussed Therapy (FFT) involving psychoeducation, communication enhancement training and	Individual patient management (30 min sessions inc support, problem solving and education, 1-2 family education sessions &	Not specified	53 pts (IG=19, CG=18) with manic episodes with consenting family member. Mean age 25, 57%	12 mths	No	Adherence scale (7 point), psychiatrist rated for first 12 mths, then self report at 24 mths.	No significant effect of group for any time point. Study reported that there was lower adherence at 2 years than at 1 year follow-up.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		problem-solving skills training. Sessions delivered to families by therapists in 22 sessions delivered over 12 months Weekly for first 3 mths, bi-weekly for 3 mths, monthly for 3 mths.	crisis intervention as needed.		female, 14% married.				
Lam et al. (2000).	UK	Cognitive Therapy (CT) including Psychoeducation and CBT delivered by psychologists to individuals over 12-20 sessions over 6 months.	TAU (routine outpatient and appropriate MDT input judged by clinical team.)	Flexible number of sessions - average sessions 16.3(3.2). 92% completed at least 4 sessions.	25 pts (IG=13, CG=12) experiencing at least 2 episodes in previous 2 yrs, or 3 episodes in 5 yrs, but not currently episodic. Mean age 39, 52% female, 32% married/ cohabiting.	6 mths	No	Medication Compliance Questionnaire (MCQ) – self report over previous month. Never misses, missed once or twice, missed 3-7 times, missed more than 7, stopped altogether.	Sig. difference between mean scores over 12 mths with better adherence in IG.
Lam et al. (2003). Lam et al. (2005).	UK	Cognitive Therapy (CT) including Psychoeducation and CBT delivered to individuals by Psychologists over 12-18 sessions for	TAU (psychopharmacology & regular psychiatric outpatient appointments).	Flexible number of sessions. 84% retention rate to 6 sessions. Average sessions completed 13.9 (5.5).	103 pts (IG=51, CG=52) experiencing at least 2 episodes in previous 2 yrs, or 3 episodes in 5 yrs, but not	2 yrs	No	Medication Compliance Questionnaire (MCQ) Medication serum levels	Self report (MCQ): significant difference at 6 mths between IG and CG with higher proportion of IG categorised as having 'good compliance'.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		the first 6 months and 2 booster sessions in the second 6 months.			currently episodic. Mean age 44, 56% female.				Self report (MCQ mean): sig. difference between IG and CG at 24mths and 30 mths with IG group reporting better adherence (n/s difference at 18 mth follow-up). Serum levels: n/s difference between proportion classified as adequate in IG and CG at 6 mths (p= .06).
Javadpur et al. (2013)	Iran	Psychoeducation involving 8 individually delivered by psychiatrists in weekly sessions and follow-up phone calls for 18 months.	TAU (standard pharmacotherapy with own psychiatrist)	89% participated in at least 4 sessions. Average 7.3 sessions and 15.3 telephone sessions	108 pts (IG=54, CG=54) currently euthymic. Mean age not specified, 41% female, 20% married.	0 months (post final telephone follow-up)	Yes	Medication Adherence Rating Scale (MARS) (Thompson 2000) 10 items at 6, 12 and 18mths	Sig. difference between IG and CG over follow-up period (p=0.008) with higher adherence in the IG.
Miklowitz et al. (2000). Miklowitz et al. (2003).	US	Family Focussed Therapy (FFT) involving psychoeducation, communication enhancement training and problem-solving skills training. Sessions delivered at home to families by	Crisis management (2 x 1hr home-based family education sessions, crisis intervention as needed (9 months), relapse prevention and resolution of family conflicts, telephone support/ monitoring contact once per month.	10% of IG withdrew before 6 mths.	101 pts (IG=31, CG=70) with recent bipolar episode (within 3 mths). Mean age 36, 63% female, 60% married/ cohabiting.	15 mths	No	Patient reported compliance - Checked against physician and family report. Serum levels. Compliance (composite) 3 point rating from other	Compliance score - n/s group, time or interaction effects at 12 mths.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		therapists in 21 sessions delivered over 9 months 12 weekly, then bi-weekly, then 3 monthly.						reports; fully nonadherent, partially nonadherent, fully adherent.	
Rea et al. (2003).	US	Family Focussed Therapy (FFT) involving psychoeducation, communication enhancement training and problem-solving skills training. Sessions delivered to families by therapists in 21 sessions delivered over 9 months 12 weekly, then bi-weekly, then 3 monthly.	TAU (Weekly medication management sessions with psychiatrist for 1 year, then every two weeks then monthly. + Individual medication management sessions with psychiatrist for 1 year + Individually focussed patient treatment. 30 min sessions x 21 over 9 months.	79% of IG completed full 9 mths of treatment.	53 pts (IG=28, CG=25) recently hospitalised for mania episode. Mean age 26, 57% female, 15% married.	15 mths	No	Medication compliance - Psychiatrist rating using standardised form 7 point scale 1(full compliance 7(discontinued against medical advice). Composed of pt report, psychiatrist observation, medication blood levels.	Compliance score - n/s group, time or interaction effects at 12 mths. n/s difference between groups in mean compliance during post-treatment follow-up or any time points.
Zaretsky, et al. (2008).	Canada	Psychoeducation (7 sessions) followed by CBT (13 sessions) delivered individually by psychiatrists over a period of 20 weeks.	TAU (standard outpatient care usual pharmacotherapy, and naturalistic monitoring, no additional CBT) + 7 PE sessions.	72% of IG completed at least 6 sessions of psychoeducation and 9 sessions of CBT.	79 pts (IG=40, CG=39) currently euthymic. Mean age 41, gender breakdown not specified.	7 ½ mths	No	Number of missed doses per month (pt interview)	At follow-up there was high adherence in both the IG and CG, but no difference between groups.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
Multi-focus interventions (Group interventions)									
Study	**Country**	**Intervention**	**Control description**	**Intervention retention**	**Participants**	**Follow-up after last intervention contact**	**Adherence a primary outcome?**	**Adherence measurement**	**Adherence Results**
Bordbar et al (2009).	Iran	One session of group psychoeducation for family members prior to patient discharge.	TAU (routine psycho-education & pharmacotherapy for pts from own psychiatrist.	100% of families assigned to IG completed the intervention.	60 pts (IG30, CG=30) in acute manic episode, <5yrs onset. Mean age 30, 25% female, 42% married	12 mths	No	Mths using medication, questionnaire by blinded home visit team.	Sig. difference in time using medication at 6, 9 and 12 mths with IG continuing for longer.
Castle et al. (2007).	Australia	Psychoeducation and CBT-type group therapy delivered weekly for 12 weeks by Research Assistants. Personalised Collaborative Therapy Journal workbook, homework exercises and phone calls.	TAU (Own GP/ psychiatrist care) & weekly phone calls controlling for extra contact time.	90% retention.	20 pts (IG=10, CG=10) without current severe symptoms. Mean age 44, 82% female, 82% married/ with partner.	0 (post-intervention)	No	MARS	n/s difference between pre- and post intervention change scores.
Colom et al. (2003). Colom et al. (2009).	Spain	Group psychoeducation (Barcelona Bipolar Disorders Program) education, exercises and	TAU (4 weekly psychiatrist appointments with mood support, standard psychopharmacology. +	73% adhered to psychoeducation (did not miss more than 5 sessions).	120 pts (IG=60, CG=60) in remission. Mean age 34, 63% female.	5 yrs	No	Composite measure	Plasma lithium concentrations: Significant difference between IG and CG at 2 ys. Combined measure: Significant difference

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		discussion. Delivered by psychologists. 21 weekly sessions.	Weekly group meetings without instruction (control for supportive effects of group meetings)						between IG and CG at 5 yrs, fewer IG classified as poorly adherent.
Eker & Harkin (2012).	Turkey	Group psychoeducation delivered weekly over 6 weeks by mental health nurses.	TAU (outpatient mood disorders clinic) + 10-15 min medication training from doctor.	4 pts did not attend regularly (retention detail not provided)	71 pts (IG=36, CG=35) in remission. Mean age 36, 54% female, 49% married.	0 (post-intervention)	Yes	Composite. Medication Adherence Rating Scale (MARS). McEvoy treatment observation form.	Combined measure: significant difference in proportion of pts classified as adherent from baseline to 6 weeks, with greater proportion of IG pts classified as adherent at 6 weeks.
Lenz. (2010).	Austria	Cognitive Psychoeducative therapy (CPT) – psychoeducation and CBT-type techniques delivered in 14 weekly group sessions. 8 hours of group sessions with significant others, booster sessions 6 and 9 mths after baseline.	TAU (not specified) + Self-help book, 3 group sessions & booster sessions 6 and 9 mths.	Not specified	100 pts (IG=52, CG=48) with minimum 2 episodes in last 3 years or 3 episodes in last 5 years, but not currently episodic. Mean age 40, 59% female.	3 mths	Not specified	Medication Compliance Questionnaire (self-report)	Significant decrease after 12 months for control group in % reporting good compliance (no change in intervention group.
D'Souza et al. (2010).	Australia	Systematic Illness Management Skills Enhancement	TAU (community based case management; 45 min weekly review with	Not specified	58 pts (IG=27, CG=31) recently in remission. Mean	11 mths	No	Medication Adherence Scale (ARS) (pill count and	Significant difference in mean adherence scores with better adherence in IG at follow-up.

Study	Country	Intervention	Control description	Intervention retention	Participants	Follow-up after last intervention contact	Adherence a primary outcome?	Adherence measurement	Adherence Results
		Programme-Bipolar Disorder (SIMSEP-BD). Group psychoeducation sessions with companion-patient dyads delivered weekly over 12 sessions.	clinician & monthly medical review).		age 40, 52% female.			need for repeat prescription)	
Reinares et al. (2008).	Spain	Psychoeducation group delivered to caregivers (not patients) including communication skills. Delivered by psychologists in weekly over 12 weeks.	TAU (standard psychiatric care; outpatient follow-up, pharmacotherapy, advice to contact clinician as needed, no systematic psychotherapy.	95% attended at least 8 out of 12 sessions.	113 pts (IG=57, CG=56) euthymic for at least 3 mths. Mean age 34, 54% female, 40% married.	12 mths	No	Medication compliance - pt report, caregiver report, plasma concentrations (described in Colom 2000)	n/s within-group comparisons between the baseline and final assessment.
van Gent & Zwart (1991).	Netherlands	Group psychoeducation for partners delivered by a Psychiatrist and Social Worker over 5 sessions (unspecified duration).	TAU (not specified, but referred from university outpatient clinic.)	Not specified	39 pts (IG=19, CG=20) with a partner (no other criteria specified). Mean age 50, gender breakdown not specified.	6 mths	Yes	Serum lithium levels. Non compliance = difference between tests of more than 0.3 mmol/l	No significant difference between IG and CG in terms of proportion of patients categorised as non-adherent before and after the study.

Note: TAU=Treatment as usual, CBT= Cognitive Behaviour Therapy, IG= Intervention group, CG= Control group, RBC= Red blood count, SRTAB = Self-reported treatment adherence behaviours.

Chapter 4 Patients' common-sense understanding of bipolar disorder and its treatment: a qualitative study

4.1 Background

A key step in addressing the issues of poor adherence and difficulties in self-management through the development of an intervention, in accordance with the MRC framework, is conducting primary research (Craig et al., 2008). It is recommended that this research, where appropriate, consists of interviews with individuals who would be targeted by the intervention and who are involved in its development (Craig et al., 2008). The detailed process of Intervention Mapping, described in Chapter 5 includes as its first stage, a needs assessment. Conducting qualitative research contributes to this stage by identifying issues which may need addressing by an intervention and also factors associated with the intended outcomes (Bartholomew et al., 2011; Kok et al., 2004). In addition to providing evidence on which to base the intervention, this process constitutes stakeholder engagement and patient and public involvement. This is an integral part of research and policy development and is recommended by both the MRC, the NIHR as well as in local NHS Research policies (Craig et al., 2008; NIHR n.d; Sussex Partnership NHS Foundation Trust, 2012). The MRC advises that 'Qualitative research, as well as providing important insights into processes of change, can be a good way to involve users. It can complement user involvement in steering groups, and allows for a wider range of views to be canvassed and systematically incorporated into the design of an evaluation.' (Craig et al., 2008 p6) (Lewin, Glenton, & Oxman, 2009).

To this end, a series of semi-structured interviews were conducted with people with a diagnosis of BD recruited through Consultant Psychiatrists in Sussex Partnership NHS Foundation Trust. This study incorporates patient and public involvement through the input of a service-user representative who advised on research design and analysis and by seeking participants' views directly in the development of an intervention.

The study was undertaken to gain a greater understanding of the perceptual factors (e.g. beliefs about illness and treatment) and practical factors (capacity and resources) associated with taking medication for BD. In addition, it aimed to explore peoples' reactions to the diagnosis and experiences with their prescribed medication. In order to better understand levels of dissatisfaction with care and treatment reported locally in Care Quality Commission reports (2009b, 2011b), the research explored exactly what information needs were not being met and the impact of this on participants. By exploring these issues it was aimed that a greater understanding would help the subsequently developed intervention facilitate informed

choice and adherence to treatment. This study is reported following the guidelines set out for reporting qualitative research set out in the Consolidated criteria for Reporting Qualitative research (COREQ) checklist (Tong, Sainsbury, & Craig, 2007), this ensures that it is transparent and complete (see Appendix C for completed COREQ checklist).

4.2 Aims & Objectives

4.2.1 Aims

To explore the beliefs and lived-experience of people with BD in relation to their diagnosis and treatment.

4.2.2 Objectives

To explore participants'

- perceptions of BD, their reactions and adjustment to the diagnosis,
- perception of medication and how this relates to their perspectives of BD,
- unmet information and support needs,
- preferences in terms of content, delivery and context of sources of information and support.

4.3 Design

This research employed a qualitative design involving semi-structured interviews to investigate the beliefs and experiences of a group of individuals with BD. The choice of a research method should come from the particular research questions posed (Dootson, 1995). Qualitative methods are appropriate as the research question aimed to gain a greater understanding of the perspectives and lived-experiences of people with a common feature, in this case a diagnosis of BD (Elliott, Fischer, & Rennie, 1999). These methods allow us to take into account a person's own account and interpretation of their attitudes, motivations and behaviour (Hakim, 2000). As stated, qualitative methods are of use prior to testing interventions to explore the issues related to the research questions and inform intervention development (Lewin et al., 2009).

In designing a qualitative study a number of considerations are important, these include the method of data collection, participant sampling and data analysis techniques. In this study two data collection methods were considered; individual interviews and focus groups. A limitation

of focus groups is that when describing behaviour or attitudes, there may be a tendency for less typical views or experiences to be under reported (Bloor, Frankland, Thomas, Thomas, & Robson, 2001). Individual interviews were selected over focus group methods as we would be able to gain an in-depth perspective on an individuals' experience reducing the potential for under-reporting experiences. Due to the sensitive nature of the topic, participants may be less likely to share their thoughts and experiences with a group. In addition, it was practically easier to arrange interviews with participants as opposed to trying arrange a mutually convenient time and location for participants to attend a focus group. This was confirmed by advice from the service-user representative involved in the study who recommended that by using individual interviews participants would be more likely to share their experiences and we would gain a deeper perspective on an individuals' lived experience.

Conducting face-to-face interviews as opposed to over the telephone allows the researcher to pick up respondent's nonverbal cues, and they tend to provide a greater quantity of information (Holbrook, Green, & Krosnick, 2003). In addition, a rapport can be built up, helping the participant to feel open and comfortable with talking about their experiences.

A semi-structured interview schedule was used to guide the interviews (Appendix D). This was designed to explore participants' experience of diagnosis, their perceptions of BD and its treatment. In addition, participants were asked about their satisfaction with any information received and outstanding information needs about BD and treatment. An interview schedule allows for researchers to ensure that there is consistency in addressing subjects across all interviews and provide a framework for the interview. The sequence and emphasis of the questions can be altered according to each participant's experiences (Arthur & Nazroo, 2003). Open questions were used with probes being used to obtain greater clarity, detail or depth of understanding of participants' responses. The semi-structured nature of the interview allowed for sufficient flexibility to be adaptable to the issues pertinent to each individual. The design considerations related to participant sampling and data analysis techniques are described below.

4.4 Methods

4.4.1 Participants

Twelve people with a diagnosis of BD were recruited through their Consultant Psychiatrists in Sussex Partnership NHS Foundation Trust. All participants met the inclusion criteria of: having a diagnosis of BD according to ICD-10/ DSM-IV, having capacity to provide written, informed consent, currently being prescribed medication for BD and aged between 18 and 65 years.

Participants who suffered from organic brain syndrome or had active suicidal ideation were excluded from the study. Active suicidal ideation was assessed by researchers using the Beck Depression Inventory (A. Beck, Steer, & Carbin, 1988).

4.4.2 Sampling

Due to the focus of the study being an in-depth exploration of the experiences of individuals a small sample size is adequate. A large sample is unnecessary due to the fact that in qualitative methodology a phenomenon only needs to occur once to be of value and there is no requirement for statements about prevalence (Ritchie & Lewis, 2003). A process of sampling to thematic saturation was used, whereby new participants were recruited and interviewed until no new themes were identified. Purposive sampling by Psychiatrists was used to recruit from this potentially hard to reach population and to ensure there was variation in age, gender, degree of severity of BD, length of time since diagnosis and medication regimen complexity. Using a flexible, iterative approach, the number of participants required was assessed by transcribing and coding the interviews during the course of the study.

4.4.3 Ethics

Ethical approval for this study was granted by the Brighton & Sussex Research Ethics Committee (09/H1107/110) and by Sussex partnership NHS Foundation Trust Research & Development Department (CSP 25387) (Appendix E). In developing and conducting the study a number of ethical considerations were taken into account. Participants were ensured of the confidentiality of their disclosures and that their responses would not be shared with anyone outside the research team. It was important to give participants the confidence to discuss their thoughts and feelings about their diagnosis, to disclose their medication taking experience including non-adherence, as well as their opinions of care they have received. To ensure participants felt able to disclose personal information a non-judgemental interview approach was maintained. In the event of disclosure of information relating to severe risk of the health and safety of themselves and others, participants were informed that their care coordinators would be contacted. Participants were informed that they were free to withdraw at any time.

4.4.4 Recruitment

Potentially eligible participants were sent an information pack introducing the study (Appendix F). Participants were asked to contact the researchers if they were interested in participating.

The researchers responded to any questions potential participants had and if appropriate, arrangements were made for the interview to be conducted.

4.4.5 Procedure

Interviews were conducted, according to participants' preference either at a hospital or in their home and lasted between 45 and 90 minutes. Consent was obtained according to CGP guidelines (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996) (Appendix G). Interviews were audio-recorded with consent of the participants and transcribed verbatim. Two experienced PhD level, female, qualitative researchers (MK & GG) conducted the interviews.

Demographic information was obtained from participants to allow for description of the sample as although not intended to be representative it was important to understand the demographic and clinical characteristics of the sample. This consisted of participants' age, ethnicity, education, time since diagnosis and current medications.

4.4.6 Analysis

Thematic analysis was used to identify, analyse and report themes within the transcribed data (Braun & Clarke, 2006). All personal details such as names were removed from transcripts and replaced with generic text e.g. 'Dr name'. Transcripts were read a number of times to gain familiarity and understanding of each interview before coding individual portions of text which represented ideas, concepts or experiences. These codes were grouped into sub-themes representing common meanings in the data. The themes were then reviewed by a further two members of the research team. Following re-reading all coded extracts and returning to the original transcripts a number of refinements were made, these were then reviewed by one of the original coders. A constant comparison method was used, as new codes and themes emerged, earlier transcripts were subject to re-coding (Pope, Ziebland, & Mays, 2000). A consensus was reached between researchers on the hierarchy of sub-themes and super-ordinate themes.

The primary analysis conducted and presented first in the results (Section 4.5.2) focussed on lived-experience accounts of adjustment to diagnosis, perceptions of BD and treatment and a summary of unmet needs. As a second analysis, all interviews were re-read and coded by the author in order to identify specific features for the practical development of the intervention. The results of this analysis are presented in the second section of results (Section 4.5.3).

In undertaking qualitative research is it crucial that authors acknowledge their own experiences and theoretical orientations (Elliott et al., 1999). The theoretical perspective of the Necessity Concerns Framework (NCF) (Horne, 2003b) guided the design and analysis of this research; therefore it is acknowledged that the research did not take a grounded theory approach (Glaser, Strauss, & Strutzel, 1968). The research aimed to build on existing evidence, to further refine theories and inform intervention development (Bowskill et al., 2007; Clatworthy et al., 2009; Clatworthy et al., 2007). Key components of intervention development were used as a coding structure in the secondary analysis, specifically intervention content, delivery and context (Horne, 2012). The semi-structured nature of the interviews and multiple researchers coding and discussing themes ensured that where ideas and themes arose, there was the scope for inclusion of those which are not currently part of the original theoretical perspectives. The results were also scrutinised by the service-user representative involved in the study, a Consultant Psychiatrist and a Health Psychologist, independent from the data collection and analysis (AC) which added additional credibility checks (Elliott et al., 1999).

4.5 Results

4.5.1 Sample description

The sample consisted of 12 participants, nine were female and all were White British. The mean age was 43 years (range 24–55 years). In terms of clinical characteristics, the length of time since diagnosis ranged between three months and 26 years (mean 10 years). All were taking medication for BD, most commonly antipsychotics (n=10) (Table 4.1).

Table 4.1: Sample demographics and clinical information

Sample characteristic	
Gender	Female n=9
Mean age (sd) (range)	43 years (11.21) (24-55)
Ethnicity	White British (n=12)
Mean years since diagnosis (range)	10 (3 months-26 years)
Medications (n taking currently)	
Antipsychotic	10
Anticonvulsant	5
Antidepressants	5
Mood stabilisers	4
Hypnotics - Anti-anxiety Tranquillizers/ Sleeping pills	4
Beta blocker	1
Information not provided	1

4.5.2 Primary Thematic analysis

The data from the primary analysis of the interviews were organised into three superordinate themes, each subdivided into a number of subthemes as illustrated in the Table 4.2 with example coded text. The themes are described below and illustrated with verbatim quotes from participants.

Table 4.2: Themes and example codes from Primary Thematic analysis

Superordinate themes	**Subthemes**	**Example coded text**
The impact of illness and treatment on sense of self	Impact of the Illness	*the achievements what it would have been like if I hadn't been mentally ill*
	Stigma augmenting the negative impact of illness on sense of self	*The rejection from society*
	Medication as a symbol and reminder of illness identity	*I don't like what the medication represents*
	Concerns about treatment	*I just felt like a vegetable*
	A disconnect between the illness and the need for medication	*as soon as I start feeling well, I start thinking I can come off it*
Positive Interpretation of illness and treatment	Diagnosis as a helpful process	*I knew then I could get proper treatment*
	Medication as part of the solution	*Just being able to live normally*
	A gradual process of medication acceptance (involving trial and error)	*I've come to terms with that now and I'm happy to do that to stay well*
Unmet information and support needs and the impact on informed choice.	Information on the disorder	*When I first got diagnosed I had no information.*
	Information on action of medications, side-effects and long term effects	*you've got to know the side effects and the benefits of it*
	Information on finding the right treatment	*you're just one big experiment*
	Involvement in decisions about medication	*if the doctor said "Take this" I guess I would take it, don't really question it*

4.5.2.1 The impact of illness and treatment on sense of self

4.5.2.1.1 Impact of the Illness

Participants reflected on what the diagnosis of BD meant to them, how it had affected them and how they had adjusted to this diagnosis. Receiving a diagnosis was often associated with difficulties and challenges to their sense of self. Some participants chose not to identify with the label of BD, or perceive their condition in an alternative way, for example, not as an illness. This highlights aspects of the recovery model where people's own definitions of their experience should be acknowledged and supported as for some people this can be one part of gaining control and moving towards recovery.

P: "I hate, I can't bear saying, Manic Depression. I cringe whenever I hear it. I find it very, very difficult mostly to accept that I've got it. It's just something that other people have and I don't. I don't like admitting that I've got something wrong with me [...] I don't want to be in that sort of category that I was always ill." (P11: Female, 52yrs, 25yrs since diagnosis)

P: "since I've been diagnosed I've found that all I ever really get from organisations or where I work and that is sympathy. You don't need sympathy, I'm not [expletive] sick." (P2: Male, 36yrs, 4 mths since diagnosis)

An individual's sense of self can affect how they interact with the world. A diagnosis of BD was often regarded as a threat to fulfilment and therefore to an individual's achievement of a positive identity.

P: "It means that I've achieved a lot less than I've wanted to. I've lost a lot of confidence." (P9: Female, 33yrs, 10yrs since diagnosis)

Related to the challenges associated with the illness, some participants described that they could not control how they felt, they described having no control over the periods of highs and lows or their actions during these periods. Gaining a sense of personal control is an essential component of recovery and care that people are provided with should foster this sense of control which it is clear that some people feel they have lost.

P: "...bipolar for me is a lack of self control. There is this lack of self control. I can't control when I'm going to be sleepy. I can't control the suicidal thoughts..." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.2.1.2 Stigma augmenting the negative impact of illness on sense of self

Perceived stigma of BD compounded the burden that the illness had on participants' sense of self. Participants perceived negative reactions from others in society and, experienced the use of stigmatising language. The language used endorsed the stereotype of a distinction between mental illness and sanity or 'normality'.

P: "Just by not being in psychosis and not being paranoid and being able to function in the day and being similar to normal people..." (P5: Male, 47yrs, 8yrs since diagnosis)

P: "The rejection from society and you've got the embarrassment about your condition, especially if you were well before. You lose family that don't understand you [...] They think you are mad." (P8: Female, 30yrs, 10yrs since diagnosis)

This stigma was identified as a contributing factor to difficulties with accepting the diagnosis of BD. Participants' displayed a reluctance to label themselves as mentally ill.

P: "I didn't really accept the diagnosis until probably a couple of years ago... There is such a lot of stigma about giving yourself a label or mental illness in general that it's a hard thing to accept, really." (P9: Female, 33yrs, 10yrs since diagnosis)

Having disclosed a diagnosis, one participant felt that normal mood changes were interpreted as symptoms by people close to them. People's attitudes and the way they reacted to him were influenced by his diagnosis. He wanted his everyday experience of emotions to just be interpreted the same as others without a BD diagnosis.

P: "...what I found is that people tread softly around you. If you happen to get slightly emotional or angry about something you automatically get the feeling that "That's how he does things" kind of thing whereas you could be angry, you could be pissed off about something. So yes, attitudes have changed around me." (P2: Male, 36yrs, 4 mths since diagnosis)

4.5.2.1.3 Medication as a symbol and reminder of illness identity

Medication and what medication represents also had a negative impact on some participants' sense of self. In an illness with no apparent outward differences and from time to time, no symptoms, medication was a reminder and a symbol of this fundamental difference. The stigma which was associated with mental illness also related to participants readiness to accept medication. For some participants, taking medication reinforced the stigmatising label of mental illness.

P: "I don't like what the medication represents...It says, you know, you are taking that because you've got [that] and I hate that. I really hate that." (P11: Female, 52yrs, 25yrs since diagnosis)

P: "It's if I take these drugs I'm mentally ill, if I leave them then I'm fine you know, there's nothing wrong with me." (P1: Female, 54yrs, 26yrs since diagnosis)

4.5.2.1.4 Concerns about treatment

A number of concerns about treatment were described and how medication could have a negative impact on quality of life. These concerns included; the sedative effects of medication, reductions in positive emotions and enthusiasm as well as a reduction in daily functioning due to fatigue.

P: "...Lithium...it gave me more side effects than effects... blurred vision and tiredness and feeling dead and I just felt like a vegetable to be honest..." (P9: Female, 33yrs, 10yrs since diagnosis)

P: "...somewhat flat [...] it's just sort of less joy and less excitement and less colour in life [...] it's just not getting as much pleasure out of things and as much joy out of things than if I wasn't taking medication I think." (P3: Female, 55yrs, 4 ½yrs since diagnosis)

There were also concerns about the long-term effects of medication and participants expressed a feeling of dependence in that they would have to stay on the medication indefinitely for fear of experiencing another episode. These questions had not been answered by clinicians and therefore were the subject of fear and uncertainty.

P: "Will it cause Alzheimer's? Will it cause dementia? Will it cause short term memory loss and will it cause—it worries me that I don't know what the long term effects are and it appears that other people don't either. That frightens me." (P9: Female, 33yrs, 10yrs since diagnosis)

P: "It does scare me that I feel that I can't come off it or I can't miss three days without starting to feel more suicidal than I did before. That scares me. I find that frightening. What if I was in a position where I was somewhere in the world and I couldn't get that medication." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.2.1.5 A disconnect between the illness and the need for medication

For some participants there was a clear disconnect between their illness and the need for medication. The illness and the symptoms they experienced did not correspond to the treatment which they were prescribed. The implicit understanding of an illness is related to the experience of symptoms. It is therefore difficult to see that medication may be needed when participants are free of symptoms as the illness is episodic.

P: "...for whatever reason I need the medication and it makes me feel well. But the trouble is, as soon as I start feeling well, I start thinking I can come off it...It's about confidence, isn't it, because you think there is nothing wrong with me and I haven't got this label and I haven't got this condition and I'm not mentally ill. I was just going through a rough time." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.2.2 Positive Interpretation of illness and treatment

4.5.2.2.1 Diagnosis as a helpful process

When adjusting to the diagnosis, some participants made an effort to detach the diagnosis from their sense of self, perceived in this way, it no longer represented a threat.

P: "I may have a diagnosis of bipolar, but I'm [name] and I'm not my illness or the illness that I've been delivered from. And then I stopped introducing myself as [name] with bipolar, because I felt like this bipolar attached to me." (P8: Female, 30yrs, 10yrs since diagnosis)

For some, receiving a diagnosis helped them, by providing an explanation for their experiences. By having this diagnosis, they were able to move forward, take control and seek treatment.

> *P: "In a way, it was quite helpful. I don't know if I felt this at the time, but quite helpful because I knew then I could get proper treatment, whereas I'd been bumbling along and not been too great for years." (P7:* Female, 30yrs, 1 ½yrs since diagnosis)

4.5.2.2.2 Medication as part of the solution

Leading on from the observations above, that after a diagnosis, there was an inevitable need for medication. Medication was then not regarded as a threat but part of the solution of regaining control and maintaining a positive sense of self.

> *P: "I think that's something that I've realised since being given a diagnosis and then you think, okay, I'm someone that needs medication, as opposed to just being depressed when there is a very big question over whether or not you need medication, if you are bipolar then you need medication." (P7:* Female, 30yrs, 1 ½yrs since diagnosis)

> *P: "[I] had my own business and everything, and I realised that the only way I was going to maintain a life like that, and to live my life like that, was through drugs, through drug therapy…" (P1:* Female, 54yrs, 26yrs since diagnosis)

Some participants regarded their medicated 'self' as positive and normalised compared to their non-medicated 'self'. Medication helped provide a more stable future where otherwise BD could be associated with a loss of a positive view of the future. The medication served to control the symptoms and enable them to have a better quality of life.

> *P: "I'm much calmer, I'm less impulsive in terms of particularly around things like swearing [...] I have more control over my impulsivity [...] I'm quite confrontational, I've been quite confrontational with my boss, this is pre-medication, and that's only just begun to settle down so that's better [...] my quality of life has improved massively [...] life is much calmer..."* (P2: Male, 36yrs, 4 mths since diagnosis)

> *P: "At the moment, I've got a nine year old daughter and there is no way I could parent and not be on meds...I think the medication has probably saved me and my daughter's relationship as well...[medication is] vital at the moment..." (P9:* Female, 33yrs, 10yrs since diagnosis)

4.5.2.2.3 A gradual process of medication acceptance (involving trial and error)

Acceptance of the diagnosis and medication as part of an individual's life was achieved by participants, however, this level of acceptance could take years to achieve.

> *P: "I've accepted it and I've also accepted that the bipolar it will be for the rest of my life and I most certainly will have to take medication for the rest of my life and I've now come,*

it's taken me nearly 20 years or over 20 years, but I've come to terms with that now and I'm happy to do that to stay well." (P10: Female, 45yrs, 7yrs since diagnosis)

P: "It is vital [...] at some point I think I would have another period of being high and the last time I was ill I spent a lot of money and got myself into debt and it was quite scary when I came to reality and realised what I'd done and was dealing with the debt problem, so I would be quite terrified of getting ill again [...] yes so I've made the decision to stay on it for life." (P3: Female, 55yrs, 4 ½yrs since diagnosis)

The control of medication over their symptoms was learned through experience of either intentionally or unintentionally not taking their medication. These experiences gave those participants greater belief in the necessity of their treatment.

P: "...it was only in July I stopped taking one of my meds. I wouldn't stop taking my antidepressant, because I can see quite quickly that I became suicidal." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.2.3 Unmet information and support needs and the impact on informed choice.

Participants in the study were at differing stages in their adjustment to diagnosis and subsequent acceptance of treatment. However, there was a commonality in their dissatisfaction with information and support which they had been provided around diagnosis and treatment. Even for those who, over time had found a positive adjustment, there were unmet needs.

4.5.2.3.1 Information on the disorder

A lack of information about BD made it difficult for participants to accept the diagnosis and to know what it meant for themselves and their future. This deficit seemed to exist at the time of diagnosis but could persist for many years.

P: "When I first got diagnosed I had no information. No information whatsoever. It was pathetic. It was just, you know, what am I meant to do with this label? I had no idea." (P9: Female, 33yrs, 10yrs since diagnosis)

P: "I'd like to know more about it. I never ever remember somebody saying to me, well, you've got bipolar and you know you've got bipolar and here is some information on it." (P10: Female, 45yrs, 7yrs since diagnosis)

4.5.2.3.2 Information on action of medication, side-effects and long terms effects

There was a clear lack of satisfaction with information provided about medication with regard to; how they worked, what the side-effects were and any implications of taking them in the long term.

> *P: "...even when the psychiatrist has recommended the medication, in my experience it is not explained that well. What the medication does and why you are taking it etc." (P5:* Male, 47 yrs, 8yrs since diagnosis)
>
> *P: "One of the things that I think is vital is the side effects, knowing what the side effects are likely to be and if there is anything you can do about them I think." (P3:* Female, 55yrs, 4 ½yrs since diagnosis)

In order to make informed choices, participants felt that information about the benefits and positive effects of medication was also essential.

> *P: "The truth [...] you've got to know the side effects and the benefits of it, maybe you've got to take the side effects, like I had to do [...] the side effects outweigh them, they outweigh them with the good things..." (P1:* Female, 54yrs, 26yrs since diagnosis)

4.5.2.3.3 Information on finding the right treatment

The lack of understanding of both BD and prescribed medication was reflected in the lack of understanding of the process of finding the right treatment programme. Instead of understanding the need for individualisation of treatment, participants perceived changes to medication as a lack of correct management of their condition on the part of the health professional.

> *P: "I don't think they've got a clue what they're doing, some of the doctors, all they've got is what they see on paper and then you're just one big experiment." (P1:* Female, 54yrs, 26yrs since diagnosis)
>
> *P: "I think it's trial and error as well. So I've never seen a bipolar person and keep them on the same meds. I've seen it go on for years and years and years, it took all these years just to get me right. And they were just throwing stuff down me. They couldn't care." (P1:* Female, 54yrs, 26yrs since diagnosis)

4.5.2.3.4 Involvement in decisions about medication

A lack of specific information was compounded by participants feeling like they were not able to work in collaboration with their healthcare professionals and had very little input or knowledge of how they were being cared for. Their reflections on these issues seemed to indicate a lack of trust in the decisions about their care.

P: "I suppose it's almost a traditional doctor-patient relationship in some respects, the doctor says do this and, even though I've just said I haven't got much trust in them, I go ahead and do it anyway [...] if the doctor said "Take this" I guess I would take it, don't really question it." (P2: Male, 36yrs, 4 mths since diagnosis)

P: "So the collective medical profession missed the elephant in the room for what is probably all of my life. So I have a limited respect in some respects I would suggest, and therefore there is a natural scepticism I guess, particularly when it comes to any medication, because fundamentally when you chose, whether it was deliberate or not, you gave me something that made me worse." (P2: Male, 36yrs, 4 mths since diagnosis)

Collaboration and the importance of their relationships with health professionals was key and participants reported that they learned through experience that they did not need to passively accept treatment and could collaborate to find the most beneficial options.

P: "...I think maybe if the doctor had been able to say to me, even my GP had said, look, I will try you on this medication and it might not be suitable for you. I think a lot of people get thrown on medication like Citalopram, which makes a lot of people feel absolutely awful and then they try it and they think, I feel awful, but the doctor said I might feel awful and then they persevere with it, when, actually, when you find the right medication it's really helpful. I never really was given the information that it would take quite a long time to find a medication that suited me." (P9: Female, 33yrs, 10yrs since diagnosis)

P: "You go and see your GP and it's more useful if you kind of have a rough idea what's wrong with you and then you can talk it through and then you can explore it together. I don't think doctors necessarily have the definitive answer. They need your input. [...]. I'm an intelligent girl. I don't need to just blindly say, just do whatever you want to me. I know my mind. I know my brain. I know how I can feel and how I want to feel." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.3 Secondary Thematic analysis - IBiD Development

The data from the secondary thematic analysis of the interviews were organised into three themes which comprise key components identified for intervention development (Horne, 2012). These consist of recommendations for;

- Content - The specific information people diagnosed and prescribed treatment for BD should be provided with.
- Delivery - How the information should be provided, the mode or format of delivery including the providers of information or support.
- Context - Where and when information or support should be provided.

These components and the subthemes within them are illustrated in Table 4.3 with example coded text.

Table 4.3: Themes and example extracts from Primary Thematic analysis

Intervention component	Subthemes	Example coded text
Content	Information on bipolar, symptoms and positive reassurance	*When I first got diagnosed I had no information.* *if you take medications you can be controlled and you can live a healthy life*
	Information on medications, side-effects and medication choices	*I think maybe if the doctor had been able to say to me, even my GP had said, look, I will try you on this medication and it might not be suitable for you.* *One of the things that I think is vital is the side effects, knowing what the side effects are likely to be and if there is anything you can do about them I think*
	Sources of further information	*And also with a number to contact to speak to somebody if they had any other questions, speak to somebody knowledgeable.*
Delivery	Opinions of written information	*I think writing would actually be nice and I might consider speaking to maybe my support worker or even my key worker.* *I think that there should be almost like a booklet*
	Support groups	*It makes me think I have thought of going sometime ago and maybe it would be helpful to go and see what other people say.* *I found that they were more people who was really ill and I couldn't relate to them*
	Internet	*If I were looking on the internet then I would know that some sites, you can tell which sites are rubbish and which sites have good information. I would trust things like MIND and NHS websites.*
	Trusted sources of information	*I would go to the AOT for anything like that to the Outreach team. I'd use them rather than my own GP* *I do trust what psychiatrists tell me and what CPNs tell me*
Context	Readiness and desire to take in information can go up and down Information provision must be sensitive to illness state, but illness shouldn't preclude it	*at the moment I'm kind of on a holiday, I don't want to know anything more about it at the moment.* *later on, to know, later on is to know, the best thing to do is stabilise somebody first* *I mean I wouldn't take in a leaflet when I was in psychosis, so only afterwards.* *So even though I was high it was still good to be receiving information.*
	Tailoring to level of understanding and desire for detail	*Some people will be bright take it [information about medication] and automatically and they'll do what I done with.* *I think I feel that although I haven't been told much, I'm quite happy with that.*

4.5.3.1 Content

4.5.3.1.1 Information on bipolar, symptoms and positive reassurance

Some participants reported having received no information about the condition itself. It would have been useful to receive this information and participants reported needing more information even years after diagnosis.

P: "… if somebody was saying to me, you've got bipolar and this is a little bit about your illness. It's never come across to me as far as I can remember."
I: "Would it have been helpful to have…"
P: "Very. I'd like to know more about it." (P10: Female, 45yrs, 7yrs since diagnosis)

P: "I'd say I understand my illness, but I don't know if I know enough about it. Are there bits that I don't know? Are you with me?" (P10: Female, 45yrs, 7yrs since diagnosis)

The different signs and symptoms of episodes (the variety and not just typical signs) were crucial pieces of information allowing participants to begin to learn and recognise personal signs and symptoms.

P: "You get the classic people saying, you know, 'do you spend a lot?' and 'do you whatever?' and go through the questionnaire. 'Do you make rash decisions?' Yeah, yeah, yeah, definitely, definitely, definitely. It isn't, it doesn't really sum it up. […] I remember picking up after my recent manic episode, picking up my bipolar disorder survival guide and it said, what people are in mania they usually say, oh, I'm in control and I'm really confident at the moment. I found myself saying that exact phrase to my mate the week previous. It's with hindsight and experience that I can, it's almost like I need the information now but the information helps me to understand my past." (P9: Female, 33 yrs, 10yrs since diagnosis)

Information on the long-term nature of BD were seen as important for people to know, however, it was also important to emphasise positives for people diagnosed with BD, that they can live well, cope with the condition and lead a worthwhile life.

P: "And also realising it can go on for life as well. I can't see, I can't see them ever taking me off them." (P1: Female, 54yrs, 26yrs since diagnosis)

P: "I guess it was just the idea that erm, it's very difficult to predict what's going to happen, but that if you take medications you can be controlled and you can live a healthy life, as long as you take the medication, I guess." (P7: Female, 30yrs, 1 ½yrs since diagnosis)

4.5.3.1.2 Information on medications, side-effects and medication choices

Participants lacked information about their medication and recalled being prescribed treatment but not being informed fully about this or about different options which might be available.

P: "Obviously Dr [name] is my consultant Psychiatrist here and I do respect him and what he's doing is clearly having benefits kind of thing, but he hasn't directly told me a great deal about, we haven't sat down for example and had a conversation about '[name], you're on Seroxyl and Seroxyl does this and these are the biochemical implications and this is the' we haven't had that discussion. It's been very much kind of 'You'll go onto this medication'." (P2: Male, 36yrs, 4mths since diagnosis)

Specific information seen as essential was; possible side effects, the risk of these occurring, medications you can take to alleviate these and the possibility of trying different medications

to find those with the least side-effects. One participant noted that experiencing unexpected side-effects could lead to treatment non-adherence. However, some participants found that detailed side-effect information can be overwhelming, confusing or contradictory.

> *P: "Yeah, going back to the first medication that I tried. I would like to have known, like suddenly I felt quite dulled down and quite like flat, and no one sort of said to me, well there are alternatives, you shouldn't be feeling like this, you can try other things."* (P6: Female, 24yrs, 4yrs since diagnosis)

> *P: "What I didn't realise until my friend was a psychiatric nurse told me was that there is a drug that's available that you can use for the side effects. I didn't know that either. I feel like I'm learning all the time.* "(P9: Female, 33yrs, 10yrs since diagnosis)

> *P: "I didn't know about the weight gain with the Sodium Valproate until I went on the internet and I was like, why am I putting on so much weight."*
> *I: "If you'd had that sort of information, what difference would that have made?"*
> *P: "I wouldn't have gone on that one. I would have chosen something else. I wouldn't have gone on it. I'm sure I've got a bit of body dysmorphia so there is no way I would have gone on that one. As soon as I started putting on weight, the likelihood is I'm going to come off it and then I'm likely to go manic or depressed."* (P9: Female, 33yrs, 10yrs since diagnosis)

> *P: "I just find them [leaflets in the medication box] strange with possible side effects contradict each other, you know. They say it causes dizziness and another one says it doesn't. A lot of them are contradictory.*" (P1: Female, 54yrs, 26 yrs since diagnosis not reported)

Information should be straightforward, accurate and also realistic about the potential benefits of medication. Recognising that there were pros and cons of medication for BD was key in allowing people to make informed decisions around treatment.

> *P: "But maybe, side effects definitely. Especially life threatening and long term side effects. I'd like to know the good things. I really would like to know the good things [benefits of medication]." (P1: Female,* 54yrs, *26yrs since diagnosis)*

> *P: "That it does something very good for you if you take it and you can weigh up the side effects against the benefits."* (P8: Female, 30yrs, 10yrs since diagnosis)

Other information which participants thought was important included; reassurance that it could take time to find the right treatment, information about medication and alcohol; what the medications do and how to take them, drug interactions and instructions not to stop medication without advice.

> *P: "To actually tell someone that they will go through a period of time and they will go through and not they might, they will go through a time where they might—they will have to try different medications and find which one suits them."* (P9: Female, 33 yrs, 10yrs since diagnosis)

> *P: "I think it's a little bit ambitious with these products to say, do not drink alcohol. A lot of people will drink alcohol. I've learned that I can't drink wine. I can drink beer, but I can't drink wine. I can't drink too much."* (P9: Female, 33yrs, 10yrs since diagnosis)

I: "What was good about the booklet and the DVD [participant had previously received]."
P: "Informative. It explained everything about the drug and how to take it etc, etc.[..] it and what you've got to be careful of blah, blah." (P11: Female, 52 yrs, 25yrs since diagnosis)

P: "Maybe where to find out more, if you need. Other things you shouldn't take with it. That's about it, really." (P7: Female, 30yrs, 1 ½yrs since diagnosis)

P: "Not to just take themselves off medication and always ring this helpline or this number or whatever before you do it on that day." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.3.1.3 Sources of further information

Participants identified the importance of being signposted to sources of additional information or support so they are informed and empowered to find the information they need and also what to do in an emergency and where to go for help.

P: "…and also with a number to contact to speak to somebody if they had any other questions, speak to somebody knowledgeable." (P7: Female, 30yrs, 1 ½yrs since diagnosis)

P: "If you could have a bipolar survival pack from the hospital with numbers and sources that they thought were good and a way of recommending other sources back to them. That would be great." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.3.2 Delivery mode

4.5.3.2.1 Opinions of written information

Many participants were positive about written information either that they had received or that they thought would be useful to convey the information people might need. However, it was important that information was concise and presented in language that was easy to understand.

I: "Would it be something that you'd want in writing or would you want somebody to talk to you?"
P: "I don't know. I think writing would actually be nice and I might consider speaking to maybe my support worker or even my key worker." (P10: Female, 45yrs, 7yrs since diagnosis)

P: "I think that there should be almost like a booklet, not a pamphlet but a booklet where you just you know describing, basically the symptoms and the help group, Manic Depression Fellowship." (P11: Female, 52yrs, 25yrs since diagnosis)

P: "I'm not a genius but I've got a reasonable brain and frankly some of the information in the [medication] boxes baffles me. Why use long complicated words when you can just put stuff in plain English? And that frankly is where charities and stuff tend to be much more helpful in that they make the subject both understandable but relevant to the reader, or the audience, that they're targeting." (P2: Male, 36yrs, 4mths since diagnosis)

Participants reflected that it is useful to have a combination of written information and the opportunity to speak with someone and have questions answered. A personalised, tailored approach is important and when they are prescribed medication, it is important to be able to speak with someone about their treatment.

> *P: "I'd probably keep a copy. I'd read It [a leaflet], it would probably prompt some questions and I would go back to Dr [name] and I would ask him what his opinion and answers were kind of thing."* (P2: Male, 36yrs, 4mths since diagnosis)

> *P: "I read the leaflet whenever I'm given any new medication, so I read the leaflet, the pharmacy leaflet inside. I also talk to the psychiatrist, my GP, to the, I haven't got a care co-ordinator at the moment. My care co-ordinator left and they thought I'd be fine without one, so but I would have talked this over with the care co-ordinator."* (P3: Female, 55yrs, 4 ½yrs since diagnosis)

> *P: "I guess it would be written information that you are given, because you, if you are depressed you are not going to be keen to find out much or read at that time, but you would have it for a time when you could or when you are able to take in information. […] And also with a number to contact to speak to somebody if they had any other questions, speak to somebody knowledgeable."* (P7: Female, 30yrs, 1 ½yrs since diagnosis)

4.5.3.2.2 Support groups

Support groups were discussed by a number of participants and there were mixed opinions of these. Some participants found they could not relate to other members of the group or did not want to speak about their diagnosis. One participant had found sharing her experiences with a trusted group of people was useful and felt now that attending a support group might be something to consider.

> *P: "But then I found that I actually went to some MDF meetings and I found them awful. I hated it. I felt that I wasn't one of them. That was my problem and it wasn't theirs. They were lovely. I hated it. I was sitting in a room with a friend of mine who took me and I was listening to all these people and I just thought, I've got nothing in common with them, absolutely nothing."* (P11: Female, 52yrs, 25yrs since diagnosis)

> *P: "I've never gone along to the bipolar group. I know it exists and where to go but I've just, to begin with I never plucked up the courage and then since then I've sort of not felt the need but you saying it, it might be beneficial. I've got two or three friends now who also have mental health problems that I've met through the hospital being an in-patient or going to [community centre] which is one of the first help forums in the community and you know we can support each other and that's nice, so there are other people that I've met or who have problems. We've got a sort of mini little support group."*
> *I: "You share experiences."*
> *P: "Yes, as it were there. But I haven't joined formal support groups and you know you bringing it up it makes me think maybe I would like to go*." (P3: Female, 55yrs, 4 ½yrs since diagnosis)

4.5.3.2.3 Internet

Participants discussed their experience of and perceptions of the internet as a source of information about BD and medication. They were aware that caution was needed to identify trustworthy information sources. Participants had used the internet to find information about their medication and to share this with others. Personal stories featured on the internet had helped one participant as they were experiences he could relate to and found it reduced feelings of isolation. The advantage of information on the internet was that you could refer to it at any time and go back to useful information.

> *P: "In terms of the internet I think I really principally went on there because I had to try and explain to people at work what the hell was going on and I needed some background in terms of the medication. [..] But the internet was probably the most useful and immediate source and tool. Now, I think I ticked in there that I do trust it, which, am I that gullible? No, but generally I think I do. There are a number of sources on there, you've obviously got the NHS, as I recall there was some information on the NHS site about it. You can go to the, I think I went to the actual, some drug company information on it as well which, whilst I know that they're obviously very happy to sell their tablets and all that sort of stuff and they're private companies, the information on there was reasonably useful as I remember."* (P2: Male, 36yrs, 4mths since diagnosis)

> *P: "I found that useful [web videos about bipolar], yes, both in terms of people's experience of bipolar and how it affects them but also actually of the medication that they're on [..] But they are informative because they're human basically, and just listening to somebody, he asks her questions about what was life like beforehand and it's like the usual sort of shit, disorganised, confused, frustrated, describing and then he says "Explain to me what hypermania is like" and it's just like oh my God, I can completely relate to that, when your to-do list becomes longer than 24 hours in a day, it's like yes, it gets like that. And it's very informative because not only do you learn something about bipolar and you learn something about how the medication works but you also realise that you're not the only one who's thinking and feeling like that, which so often, more so at the depressive end of a manic episode than the hyper end, it's a very isolating, intensively individual experience*." (P2: Male, 36yrs, 4mths since diagnosis)

4.5.3.2.4 Trusted sources of information

When discussing trusted sources of information, participants frequently mentioned their own care team (specifically their mental health team) as being their point of contact. Health professionals were trusted sources of information as were mental health charities.

> *P: "You want to feel that someone has empathy and understands what it is, rather than just having the medical knowledge. [I] Trust psychiatrists, CPNs, I trust my psychotherapist because I think she's very experienced and my friend who has had experience of similar problems and is a psychiatrist herself."* (P7: Female, 30yrs, 1 ½yrs since diagnosis)

P: "I suppose a psychiatrist is a bit more objective where they have a feel for people's uncertainties, they are a bit more objective about it." (P6: Female, 24yrs, 4yrs since diagnosis)

P: "Basically they [MIND charity] went to their drawers and got the information and said, if there is anything that I want to talk about that I could sit and talk about it with them. […] MIND are absolutely out of this world." (P8: Female, 30yrs, 10yrs since diagnosis)

Other people with lived experience of BD were not consistently viewed as useful or trusted sources of information. Some found it reassuring to hear from the experiences of others, whereas some found it difficult to relate to other peoples' bipolar experiences.

I: "So what is it about speaking to other patients?"
P: "Well it is just refreshing that first of all I can relate to them and relate to their medications, but you know what funnily enough is a lot of people don't like talking about it and so it is quite frustrating from that point of view." (P5: Male, 47yrs, 8yrs since diagnosis)

P: "I am actually on a [online] forum. I joined that when I started kind of panicking really, just to meet other people with it really, because I had never met anyone in my real life who's ever had it, so it is not to feel alone, that is not very cheesy isn't it? You know it has really been just a source of information for chatting to other people, yeah, you know what they have experienced and things like that." (P6: Female, 24yrs, 4yrs since diagnosis)

P: "That is the frustrating thing about finding out information through others. It is that there's people who are really ill, I can't really, you can't, I can't relate to them and they can't relate to me and then the people in the middle, probably like me, don't really want to talk about it too much." (P5: Male, 47yrs, 8yrs since diagnosis)

4.5.3.3 Context

Issues surrounding the context of providing information and support have been described in above. These include the finding that beliefs about illness and the necessity of treatment may change during someone's experience from diagnosis onwards and these are highly individual. This demonstrates that information needs to be tailored. Participants may not feel involved in decisions around their care or feel confident or empowered to engage with health professionals and there may be a lack of understanding around decisions that are made. In addition, the wider societal context of stigma can affect acceptance of illness and engagement with treatment.

4.5.3.3.1 Readiness and desire to take in information can go up and down

The context of individuals' readiness to take in information is important to consider, and participants reflected that their desire to seek information themselves or be ready to hear about BD did change, going up and down.

P: "I went through phases when I sort of looked up things all about it. I suppose I sort of went into denial, really. I sort of got books about it and I read about it and I thought, no, that's not me. At times I went, yes, I suppose it is me." (P11: Female, 52yrs, 25yrs since diagnosis)

P: "I could about bipolar and ADD [attention deficit disorder] and at the moment I'm kind of on a holiday, I don't want to know anything more about it at the moment." (P2: Male, 36yrs, 4 mths since diagnosis)

P: "If it gets to a point where I start to get depressed again and suddenly think "I'm not really being able to cope with this very well" then I would probably go and look for sources of help from those kind of places." (P2: Male, 36yrs, 4 mths since diagnosis)

I: "Is it for example important that you could know what the side effects of a particular drug were or perhaps not."
P: "Yeah now, yeah now, I think in the early days I wasn't really interested. I just wanted to get well, but yeah, now."
I: "So that kind of links back to what you were saying about your information needs may be changing."
P: "Yeah." (P5: Male, 47yrs, 8yrs since diagnosis)

P: "I think generally I have started to get more information about medications, yeah, it has been a gradual process really."
I: "Has that come about because you sought more information or because it's been given to you."
P: "I think a bit of both really." (P6: Female, 24yrs, 4yrs since diagnosis)

4.5.3.3.2 Information provision must be sensitive to illness state, but illness shouldn't preclude it

Participants discussed when they thought were the most appropriate times to receive information during their illness and care. Some participants felt that it was important that any information provision should wait until the person is stabilised and so better able to take the information in.

P: "I mean I wouldn't take in a leaflet when I was in psychosis, so only afterwards, does that answer your question?" (P5: Male, 47yrs, 8yrs since diagnosis)

P: "It's got numbers to contact that you can speak to so that's very helpful. There is a lot to read [Rethink booklet]. I think if I was very depressed, I wouldn't..." (P7: Female, 30yrs,1 ½yrs since diagnosis)

P: "Yeah, I mean I remember when I was in psychosis and I was being sectioned and these two nurses came into the room and they said you are being sectioned and they gave me a form. I didn't even know what was on the form, I couldn't even read it. So it wouldn't make any difference. I mean I wouldn't take in a leaflet when I was in psychosis, so only afterwards." (P5: Male, 47yrs, 8yrs since diagnosis)

I: "...are you saying that there might be, it might be later on that information is more helpful?"
P: "Yeah, later on, to know, later on is to know, the best thing to do is stabilise somebody first and by that, that's quite nasty, people get the shakes."
I: "So once someone is stabilised then providing more information at that point would be helpful?"
P: "Yeah, even just stabilising them. Let them know what you're trying to do for them." (P1: Female, 54yrs, 26yrs since diagnosis)

P: "Yeah, I mean I remember when I was in psychosis and I was being sectioned and these two nurses came into the room and they said you are being sectioned and they gave me a form. I didn't even know what was on the form, I couldn't even read it. So it wouldn't make any difference. I mean I wouldn't take in a leaflet when I was in psychosis, so only afterwards." (P5: Male, 47yrs, 8yrs since diagnosis)

P: "I think I need to be stabilised on the drugs to be able to look back on things with hindsight to be able to understand my condition, because when you are in it you cannot understand it. It's only once stabilised I would say that you can then look back and go, do you know what, they are right." (P9: Female, 33yrs, 10yrs since diagnosis)

However, participants also felt that information should be provided from the start even if a person is not quite ready. They may be able to take some information from it, or feel that they are being involved in their care and they can return to it as and when they feel able or need more information. It is clear that in an illness like BD, information needs will be highly variable depending on a person's illness and also their level of acceptance at the time.

P: "Yes I found it quite helpful when in hospital, even though I might not be my normal self, I still find it helpful when I'm high to be told about what drugs I'm being put on and how they working and why they're working that way and what side effects I might be experiencing. I found that very helpful. When I was less ill I was here at [hospital name] and one of the nurses who tended to work nights was very, very helpful and he would look up things on the internet for me and give me, print it out and I found that very helpful. So even though I was high it was still good to be receiving information." (P3: Female, 55yrs, 4 ½yrs since diagnosis)

P: "I guess it would be written information that you are given, because you, if you are depressed you are not going to be keen to find out much or read at that time, but you would have it for a time when you could or when you are able to take in information." (P7: Female, 30yrs, 1 ½yrs since diagnosis)

I: "So the timing is about when people get the information is quite important."
P: "I would say. When I first got diagnosed I had no information. No information whatsoever. It was pathetic. It was just, you know, what am I meant to do with this label? I had no idea. I've ticked a few boxes and yes I've got bipolar and it really didn't do anything." (P9: Female, 33yrs, 10yrs since diagnosis)

4.5.3.3.3 Tailoring to level of understanding and desire for detail

Participants commented on how information needs to be provided in the context of peoples own level of understanding and intelligence.

> *P: "Medication. Depends how bright people are. Some people will be bright take it [information about medication] and automatically and they'll do what I done with."* (P1: Female, 54yrs, 26yrs since diagnosis)

> *P: "Exactly what I'm saying, you know. I need to be able to know what's right. I'm an intelligent girl. I don't need to just blindly say, just do whatever you want to me. I know my mind. I know my brain. I know how I can feel and how I want to feel. No-one can say that for me. I need the information out there."* (P9: Female, 33yrs, 10yrs since diagnosis)

> *P: "…what information do you really need? It comes back to the point I was saying earlier on, do I need a pharmalogical breakdown of all the chemicals? Well, actually, no, not unless I'm going off and doing a degree and then understand how those interact with me physiologically kind of thing."* (P2: Male, 36yrs, 4 mths since diagnosis)

> *P: "I think I feel that although I haven't been told much, I'm quite happy with that. I'm quite content with that."* (P7: Female, 30yrs, 1 ½yrs since diagnosis)

In participants' narratives there was the running theme that in what is by name, the same illness, individuals with this diagnosis may be very different and their illness and treatment experiences are unique to them. This has a bearing on information provision as it needs to be appropriately tailored.

> *P: "I do also know people that suffer with bipolar can be as different as anything even when they are ill by just by what others have told me how members of their family they've seen their members of their family and how they have been towards them and also been in hospital a lot of times when you see others with the same illness and condition and whatever and how they are."* (P10: Female, 45yrs, 7yrs since diagnosis)

> *P: "It does take a long time to sink in, only it just depends what sort of person to be able to deal with all, or was also uniquely individual."* (P1: Female, 54yrs, 26yrs since diagnosis)

4.6 Discussion

The findings from this study highlight the importance of the interplay between the burden of the illness, participants representations of illness and medication and their subsequent responses through engagement with the management of their condition. As well as providing insights on living with and managing BD, the study provides vital learning on the components necessary for intervention development, what the information should be included and how this should be framed or communicated (Content), how information and support could best be provided and by whom (Delivery vehicle) and the wider factors around receiving information including timing and locations of support (Context) (Horne, 2012).

Challenges associated with the diagnosis included threats to participants' sense of self and the impact on how they interacted with the world and felt about the future. These challenges were compounded by experience of stigma. The views and behaviour of people around them, including views consistent with the medical model, added to the burden of the illness. Participants reflected on changes in how others viewed them, for example, normal behaviour or emotions being seen as an indication of illness. This fear of being defined by the illness by others and the imposition of an illness identity is supported by previous research (Inder et al., 2008; Mansell et al., 2010; Michalak et al., 2011).

The lack of appropriate information on the disorder itself made it difficult for participants to accept the diagnosis, to understand what it meant and the implications for their future. Difficulty in making sense of the diagnosis has also been reported in more recent studies (Van den Heuvel et al., 2015). Unanswered questions after a diagnosis of BD have been shown to be related to uncertainty about the future in a qualitative study (Proudfoot et al., 2009). Individuals should be provided with information to meet these unmet needs to facilitate understanding and acceptance of BD.

Medication was a symbol of the illness which could provide an unwelcome reminder of the condition and an outward indication of fundamental difference from 'normality'. In this regard it compounded the impact of the illness on sense of self. Taking medication reinforced the stigma of mental illness. There was a strong desire for some to be 'drug-free' in the future as this would represent a return to normality. This concurs with descriptions in the recovery focussed literature (Mansell et al., 2010).

In the present study participants often described that medicated 'self' was a return to their true self, and a return to normality. This is in contrast to other work where participants reflected that when taking medication, they were not their true self. However participants in the study by Mansell and colleagues (2010) had remained relapse free for two years and so were more distant from acute episodes and how it felt to be on medication at this time and three of the participants were not currently taking medication.

The present research provides descriptions of how, for participants, medication was a tool for taking back control which enabled improved functioning and enhanced quality of life. The necessity of adherence to medication was reinforced by participants' experiences of the consequences of non-adherence.

This study confirms the links between views of treatment and beliefs about and experience of the illness (Horne, 2003b). Perceptions of treatment are linked to perceptions of illness and the degree of 'fit' between patients' belief about the problem (illness) and preferred solution

(the treatment) (Horne & Weinman, 2002). The episodic experience of the illness did not fit with a need for continuing maintenance treatment. When there were no symptoms, it was difficult for participants to see themselves as having an illness which necessitated treatment. People's beliefs about the necessity of medication have an impact on adherence, as do their concerns about medication (Horne, 2003b). Participants in the present study described their concerns about the medication. For many, medication was described as having a sedative effect, daily functioning was reduced and they reported getting less enjoyment out of life. There were also reports of feeling dependent on medication, including a fear of missing doses.

The medication concerns identified by participants and dissatisfaction with information on medications and side-effects resulted in many patients not effectively engaging with treatment. For example, knowing what to do in the event of side-effects occurring was a key unmet information need. Indeed, research with HCPs in the UK identified that professionals working with people with schizophrenia reported withholding information on side-effects for fear of providing too much information and fear of putting people off (E. Brown & Gray, 2015). Previous research identified widespread dissatisfaction with information about medication in BD and lower levels of satisfaction were associated with low adherence (Bowskill et al., 2007).

These findings concerning beliefs about illness and treatment and their impact on treatment engagement add further support to the importance of focusing on beliefs in mental health research and practice (Clatworthy et al., 2009; Clatworthy et al., 2007; Hou, Cleak, & Peveler, 2010; Jonsdottir et al., 2009; Lobban, Barrowclough, & Jones, 2003; Petrie et al., 2008).

This study provides important insights from individuals who have come to a positive resolution with their illness. It is critical to note, that this took time and experience to regain a positive sense of self where the diagnosis was acknowledged and treatment seen as part of the solution and was not without its challenges. Participants described re-evaluating and re-ascribing meaning to the diagnosis and treatment, separating their sense of self from their illness. For others, the diagnosis gave meaning to, explained and legitimised their experiences, and help them to regain control. This concurs with other qualitative research around adjustment and experiences with the BD diagnosis (Inder et al., 2008; Michalak et al., 2011; Proudfoot et al., 2009). Recent qualitative research also identified that being well enough to regain social roles and responsibilities such as looking after children was an important part of regaining autonomy and control (Van den Heuvel et al., 2015).

Challenges or difficulties associated with accepting a diagnosis of BD the need for medication may be tackled by providing information which is relevant for the individual's needs and beliefs and helps them with developing a helpful, common-sense understanding of their condition and treatment. Primarily this needs to focus on developing necessity beliefs and

addressing concerns about medication. However, the current research indicates, in addition, that successful engagement with treatment requires individuals to feel actively involved in their condition management.

Dissatisfaction with both information and care was compounded by a lack of participants' involvement in decisions about their own care and treatment and a sense that they were not working in collaboration with healthcare professionals. A key issue in the current study was a lack of understanding about the need for therapeutic individualisation through experiment. This was reflected in some participants' lack of confidence in HCPs. Other qualitative research in this area has also identified difficulties with relationships between patients and professionals, issues of trust relating to concerns about medication and frustration with trialling medications to find the right combination (Inder et al., 2010; Proudfoot et al., 2009). Shared-decision making which involves patients actively in their treatment has been addressed as part of the Toronto consensus statement for healthcare since 1991 (Simpson et al., 1991). However, it is clear that this not always achieved in psychiatric care.

It is encouraging that participants in the current study had learned to successfully engage with HCPs and collaborate to find treatments which suited them, minimising side-effects and providing the best effectiveness. This should be the goal for professionals and patients working together to manage BD. The importance of collaboration and encouraging medication alliance in adherence has been demonstrated in a large cross-sectional study (Zeber et al., 2008). Although a large sample (n=435), the cross-sectional nature of the study means that causation cannot be implied. However, an intervention study showed that clinician training to enhance therapeutic alliance can lead to increased adherence in mental health patients, suggesting that alliance does affect adherence (M. Byrne & Deane, 2011).

4.6.1 Limitations

Qualitative methods were appropriate to meet the aims of this study due to the need to explore participants' subjective beliefs and experiences and gain an understanding of the meaning of these and to provide participants recommendations for how to improve information and support. In addition, the study is reported in accordance with the COREQ guidelines this ensures that it is transparent and complete (Appendix C). However, the findings should be interpreted in the light of a number of limitations. This approach explores the experiences and views of this small sample and results should not be generalised to all people with a diagnosis of BD, however it provides an in-depth and rich description. All of the sample were of white British ethic origin so do not include insights from other cultures. However,

subsequent intervention development and trialling was conducted in the same geographical and healthcare context. The study being locally-based is advantageous and the MRC Framework recommends that primary research is conducted with those to be targeted by the intervention (Craig et al., 2008).

Recruitment methods comprised of purposive selection of participants by their psychiatrist, followed by self-selection. We cannot be sure that the findings from this study would be representative of those who have disengaged from formal care. However, participants did reflect on previous experiences of disengagement and non-adherence to medication.

A limitation of the interview method is that participants may not accurately report their experiences or behaviour, it relies on them being able to articulate their thoughts, and is dependent on memory. We aimed to mitigate this by the interviewers being non-medical staff, unconnected with participants' healthcare team or local NHS Trust and assuring participants of confidentiality. In addition, participants were not in an acute episode of illness where any deficits in cognitive functioning may be more severe (Quraishi & Frangou, 2002).

As with all qualitative research the themes generated are influenced by the experience and theoretical viewpoint of the researchers. However, the use of multiple researchers to analyse the data gives increased credibility to the analysis (Elliott et al., 1999).

4.6.2 Implications for intervention development

The findings from this research indicate the need for interventions to support patients through diagnosis and treatment management. Illness and treatment beliefs serve as a framework for people to make sense of information they receive, including that from healthcare professionals. To meet people's information needs it is imperative to link information to beliefs. The utility of illness and treatment beliefs in interventions has been discussed in a number of studies (Wearden & Peters, 2008). The findings have clear implications for informed choice in treatment as many participants have not received satisfactory information about their condition and medication, concurring with previous research (Bowskill et al., 2007). It has been recommended that information given in psychiatric care should enhance choice and reflect patients' values, this will promote informed decisions (Hope, 2002). It is clear that this had not happened in the experience of participants in this study.

A full description of how the intervention was developed based on the findings from the qualitative study and additional formulation work is presented in Chapter 5. The intervention content must include the most basic information about BD and treatment (due to reports of a complete lack of information). This information must address the necessity of ongoing

treatment especially during periods of euthymia. Concerns about medications should be elicited and addressed including information about medication switching, trialling treatment to find the most suitable and the alleviation of side-effects.

Written information is a valued delivery vehicle, however, participants need access to trusted sources of support to ask questions and these may be their own care team or mental health charities. This finding concurs with a review of the role and value of written information for patients where patients valued tailored information, however it should not be a substitute for information delivered verbally from their HCP (Grime, Blenkinsopp, Raynor, Pollock, & Knapp, 2007). Aspects of information delivery via the internet which were valued were the lived-experience of others with BD through forums or personal stories.

Information provision must take into account the context that participants can be impacted by stigma of the illness and the stigma around medication. It is crucial that information does not focus completely around negative aspects of illness and treatment, but provides a supportive and encouraging view of life with BD. The relationship with HCPs is important in feeling confident and able to engage in conversations about treatment. In terms of the temporal context of support, it appears to be important to allow someone to be stabilised after a severe mood episode. However, this should not preclude the provision of simple information about diagnosis and treatment. Van den Heuval and colleagues (2015) found that individuals with BD reported that information provided too early could be overwhelming when they were struggling to cope with the impact of BD. Difficulties in concentration also affected the ability to take on board information. Ongoing support and information is needed and participants must have this available to take up as and when needed. Participants' readiness to accept information and their desire for it increased and decreased during their illness. The finding that information needs vary over time is supported by a systematic review of patient information preferences (Grime et al., 2007). The individual context of someone's stage of acceptance and engagement as well as their level of understanding and desire for detail must be taken into account in any intervention or information provision.

These three components of interventions (content, delivery vehicle and context) all demonstrate the importance of tailoring information to both individual needs and to their stage of illness. The next chapter describes fully the process of developing an intervention to target illness and treatment perceptions with the aim of improving adherence and enhancing self-management. This takes into account the concepts and recommendations for this qualitative study, as well as the findings from the systematic review and meta-analysis in Chapter 3 and the research evidence presented in Chapters 1 and 2.

Chapter 5 Development of the IBiD intervention

5.1 Introduction to Intervention development

This chapter describes the development of the Improving Information for people with Bipolar Disorder (IBiD) intervention, specifically the content, delivery mechanism and context. As described in Chapter 2, the MRC Framework for the development and evaluation of complex interventions was applied (Craig et al., 2008). The framework specifies that both identifying and developing appropriate theory and modelling the processes and outcomes is a crucial stage. The processes of change are identified using existing theory and research evidence. However, the framework does not specify exactly how to undertake the process of using evidence and theory to model mechanisms for behaviour change (Hardeman et al., 2005).

Intervention mapping (IM) provides a detailed description of the systematic process and decisions behind intervention content, techniques and delivery (Bartholomew et al., 2011; Kok et al., 2004). The process has been used in a range of public health intervention trials including in adherence and in mental health (Balfour et al., 2006; Koekkoek, van Meijel, Schene, & Hutschemaekers, 2010; Lloyd, Logan, Greaves, & Wyatt, 2011; Pyne et al., 2014). IM provides a process for mapping objectives onto determinants or mediators of behaviour and selecting the techniques or strategies to attempt to modify these. It involves six steps (Bartholomew et al., 2011; Kok et al., 2004):

Step 1) Needs assessment -Defining the problem (including the behaviour and population at risk), the identification of outcomes and change objectives. Identify if previous interventions have worked and what the gaps are. This can involve systematic reviews as well as primary research.

Step 2) Generation of matrices of change objectives - Defining the aims of the intervention, the behavioural or cognitive outcomes and the determinants of change. The matrices link the outcomes and their determinants using previous research to generate hypotheses.

Step 3) Selection of theory based methods and practical strategies – Using appropriate theory and research evidence to select BCTs.

Step 4) The development of a programme plan - Ensuring that the intervention is fit for purpose i.e. correctly translates the BCTs, is deliverable and appealing to potential participants. This step involves creation of the intervention protocol and materials.

Step 5) Generation of adoption and implementation plan – Involving potential stakeholders to ensure that the intervention is designed for potential future

adoption. Considerations include potential adopters, capacity and ability to deliver, and required resources.

Step 6) Generation of an evaluation plan – Producing an evaluation protocol specifying appropriate study design, comparison group, outcome measures, analysis plan, process evaluation and fidelity assessment.

This chapter summarises the evidence and primary research contributing to intervention development (described in Chapters 1-4). It describes evidence-based decisions which determined the design, content and delivery of IBID. The chapter describes the detailed process of developing matrices and specifying methods and practical strategies selected for IBiD. This chapter also describes the process of development and subsequent refinement of IBiD through stakeholder and service-user consultation. Figure 5.1 illustrates the processes undertaken to produce the intervention. The chapter concludes with a description of the final intervention which is tested in a feasibility RCT (Chapter 6-7).

5.2 Developing the IBiD Intervention - Intervention mapping

The intervention was developed from the psycho-social constructs identified in Chapters 1-4 related to adherence and self-management in bipolar and retrospectively mapped onto techniques from the, then unpublished, BCT Taxonomy (v1) of 93 techniques (described in Chapter 2) (Michie, Johnston, et al., 2013). The processes informing the intervention development were; a review of behaviour change theory and techniques (Chapter 2), a systematic review of adherence interventions in BD (Chapter 3), the qualitative study with people with a bipolar diagnosis (Chapter 4), development work by the Project Management group (PMG), a review of existing resources and manuals, a review of illness and treatment beliefs in severe mental illness and consultation with service-user representatives. This process is illustrated in Figure 5.1.

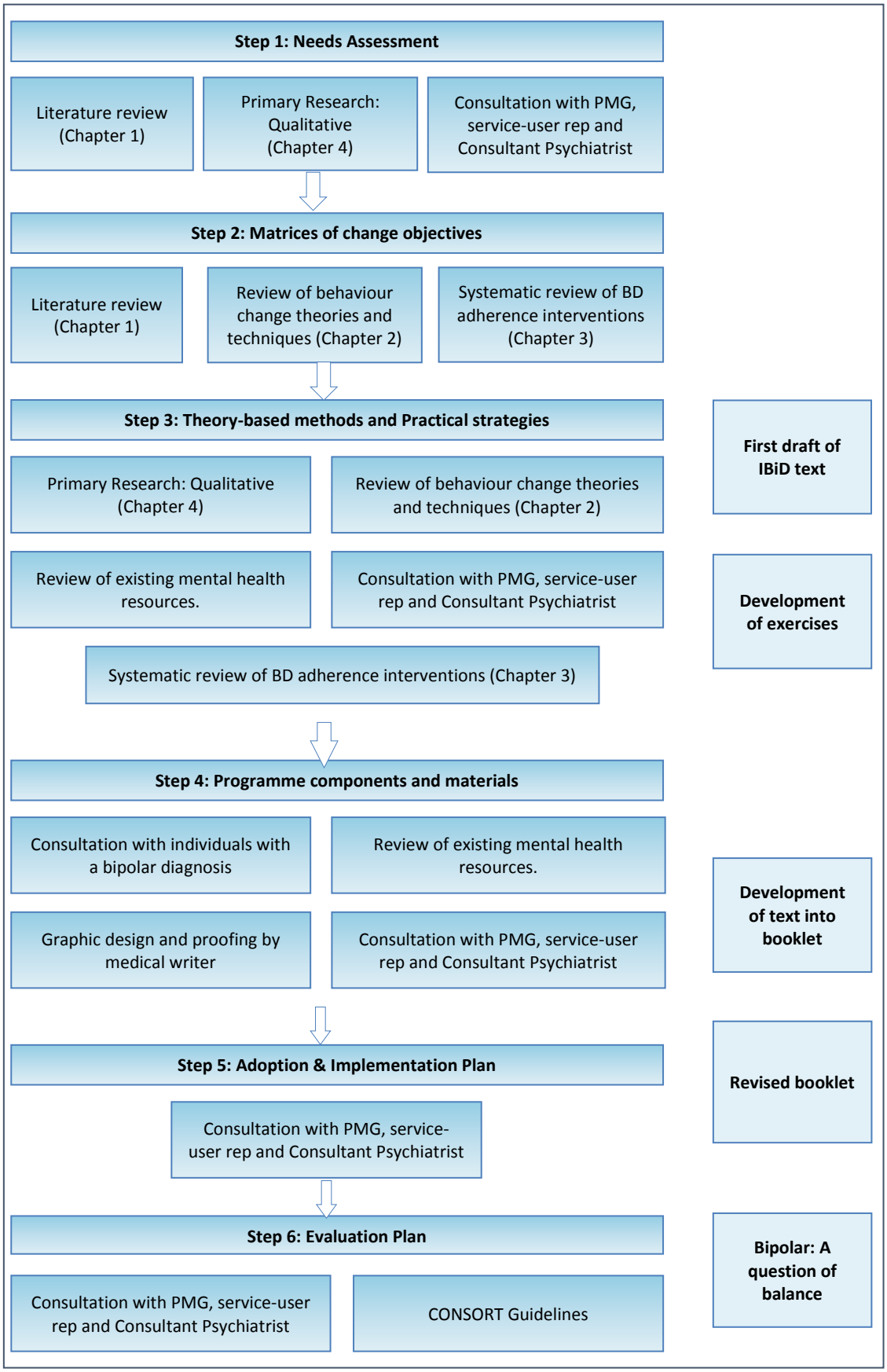


Figure 5.1: Illustration of the development of IBiD (Intervention mapping)

5.2.1 Step 1: Needs assessment

The needs assessment step ties in with the MRC's *development* phase comprising the identification of the evidence base using published research and new primary research (Bartholomew et al., 2011; Craig et al., 2008). The aim is to understand the population concerned, the extent or risk of potential problems and to identify the capacity for conducting an intervention. This was conducted by systematically evaluating the literature, theories and models and by conducting primary qualitative research.

A needs assessment can involve the use of the PRECEDE model (Green, 1974), the principles of this approach informed the IBiD development process. PRECEDE involves the identification of the determinants (both personal and environmental) of the behaviour or problem in question, this helps to focus the areas to be targeted through intervention. This can be equated to the establishment of a medical diagnosis before developing a treatment plan. Factors include predisposing factors (e.g. knowledge and beliefs), reinforcing factors (e.g. social support, economic reward), and enabling factors (e.g. skills, availability of resources). The model became the PRECEDE-PROCEED model in the 1990's in order to incorporate health determinants of policy and environmental factors (Green & Kreuter, 1999).

The needs assessment identified the problem to be addressed, namely non-adherence and potential consequences of this as well as dissatisfaction with information about BD and treatment and lack of involvement in decisions about care (Arvilommi et al., 2014; Baldessarini et al., 2006; Bowskill et al., 2007; Care Quality Commission, 2009b, 2011b; Clatworthy et al., 2009; Clatworthy et al., 2007; Hong et al., 2011; MacDonald et al., 2014; Morselli & Elgie, 2003) (covered in Chapters 1 & 4). An intervention was required to address these issues and the factors associated with non-adherence informed the intervention content.

A needs assessment also investigates 'community capacity' (Bartholomew et al., 2011). The establishment of a Project Management Group (PMG) is key in collaborative planning. In this programme of research the PMG comprised local HCPs, research and development staff and a service-user representative. Consultation with PMG members contributed to the assessment of need and in understanding the population and setting.

5.2.2 Step 2: Proximal Programme Objective Matrices

The evidence outlined in Chapter 1, 3 and 4 identified determinants of non-adherence which could potentially be amenable to change and were therefore of interest for intervention development. Programme objectives were selected in consultation with the PMG to ensure that they were valid, and would be potentially useable targets for future intervention delivery.

The target behaviour of adherence was tackled through a focus on the selected, potentially modifiable determinants; illness and treatment perceptions, satisfaction with information and feelings of stigma. Using IM terminology, these comprise performance objectives, i.e. the targets which the intervention aims to change (Bartholomew et al., 2011).

The behavioural outcome was identified as adherence to medication. However, for this feasibility study, the focus for outcome measurement was on cognitive outcomes as they are proximal to adherence and illness outcomes. In addition, needs assessment and consultation with stakeholders and patients demonstrated that it was important to consider the broader aspects of staying well with BD, and not just adherence. The intervention content therefore targeted self-management strategies previously identified by research with people with BD (Mansell et al., 2010; Michalak et al., 2006; Mizock et al., 2014; S. J. Russell & Browne, 2005; Suto et al., 2010; Todd et al., 2012). The effective management of BD requires, not just adherence to prescribed medications, but also appropriate dose adjustments and changes to different types of medication as agreed with patients' health professionals, therefore content included advice on finding the right treatment.

Table 5.1 comprises a Change Matrix specifying the performance objectives to improve behavioural and cognitive outcomes and their determinants. As described in Chapter 2, self-regulation theories of health behaviour are applicable, specifically the CSM (for understanding illness perceptions and coping strategies) (Leventhal et al., 1984), the e-SRM (incorporating treatment perceptions and the PAPA (understanding medication taking behaviour) (Horne, 2003b). Indeed, Bartholomew and colleagues (2011) recommend that in the self-management of chronic illness, self-regulatory processes are important to consider when selecting programme objectives and designing the intervention.

As illness and treatment perceptions and practical barriers to adherence are specific to each individual, it was important that the intervention reflected this. The process of self-managing chronic illness also includes the importance of taking into account the skills or knowledge of the individual, and tailoring intervention to these (Lorig & Holman, 2003). Hoffmann and colleagues (Hoffmann et al., 2014) highlight the importance of accurate reporting when individual participants do not all receive the same intervention. This can involve different doses, or the rules on which participant assessments affect the formulation of the intervention for each person. In IBiD, baseline assessments were used to ensure that the information presented to participants was adapted to their particular concerns and needs. The exact methods and rules of tailoring for IBiD are specified in Section 5.3.

The intervention development work also identified that it was important to address other concepts and factors associated with acceptance and engagement with treatment and ongoing

management of BD, these included the need for medication trial and error, lifestyle self-management and stigma and discrimination (Identified in Chapters 1 & 4).

The process of selecting programme objectives informs Step 6, the evaluation, in particular, the operationalization of the outcomes. Objectives need to be measurable and therefore consideration is given to the selection of outcomes where valid, reliable measures exist or a plan is put in place to develop novel measurement, this is covered in Chapter 6, Section 6.3.

In the IM process, environmental conditions are important considerations for full intervention development, these comprise social and physical including organisational and community conditions which impact the health problem (Bartholomew et al., 2011). However, in the present intervention, the research focused on psycho-behavioural aspects.

Table 5.1: Change Matrix of Behavioural and cognitive outcome and determinants.

Performance (behavioural) Objective	Determinants/ Proximal objectives	Model framework/ construct
Intentional Medication adherence – Take medication as agreed with HCP	**Medication concerns** Long term effects concerns Dependence concerns Side-effects concerns	NCF – Concerns
	Necessity beliefs Adherence and risk of relapse Long-term necessity of medication	NCF – necessity beliefs
	Satisfaction with medication information	PAPA Practicalities e-SRM (appraisal of coping strategy, Contextual factors)
	Feelings of stigma Medication related Disorder related	e-SRM (affective emotional response to illness and treatment) COM-B (motivation)
	Therapeutic alliance Effective communication with HCPs	COM-B (all components) e-SRM (contextual factors)
	Illness beliefs Acceptance of BD diagnosis Stronger bipolar identity Severity perception Timeline beliefs (BD as a long-term condition) Control perception	e-SRM (illness representations)
	Symptom monitoring Personal triggers of episodes Prodrome recognition Self-management in response to changes	e-SRM (illness representations - identity)
	Therapeutic alliance Effective communication with HCPs	COM-B (all components)
Unintentional Medication adherence	**Practical barriers** Medication understanding Forgetting, dealing with routine changes etc	PAPA & COM-B (opportunity & capability)

5.2.3 Step 3: Theory-based methods and practical strategies

Theory-based methods are the processes which are anticipated to have an effect on the behavioural determinants specified in Step 2. In addition, practical strategies are required in order to actually deliver the methods in the intervention (Bartholomew et al., 2011). A useful way of explaining this is provided by Bartholomew and colleagues (2011) *'Models and practical applications form a continuum that extends from abstract theoretical methods through practical applications to organised programs with specified scope, sequence and support materials'* (p.310).

In order to ensure that the techniques used in IBiD are specified and described using the most up to date and comprehensive taxonomy, and a 'common language', the intervention content and delivery has been mapped onto BCTs from the Taxonomy (v1) of 93 techniques (described in Chapter 2) (Michie, Johnston, et al., 2013). This taxonomy had not been published when the intervention was being developed. Previously published resources were used in order to select BCTs and practical strategies (content and delivery) to operationalise these. These included Abraham and Michie's taxonomy of 26 BCTs (2008), a framework of health behaviour change competencies (Dixon & Johnston, 2010), existing therapeutic manuals for BD (Basco & Rush, 2005; Colom & Vieta, 2006) and CBT guides and workbooks (Centre for Clinical Interventions, 2008). Table 5.2 specifies how each determinant was addressed by specific intervention content and which BCTs this maps onto.

The concept of self-management in chronic illness also aids the formulation of IBiD. Five components of self-management have been defined and inform the application of BCTs to the intervention; problem solving, decision making, resource utilisation, forming of a patient/health care provider partnership, and taking action (Lorig & Holman, 2003).

There is growing evidence for specific techniques in improving medication adherence, for example, Implementation Intentions (I. Brown, Sheeran, & Reuber, 2009), eliciting and targeting beliefs about illness and medication and practical barriers (O'Carroll, Chambers, Dennis, Sudlow, & Johnston, 2013) and in improving outcomes in BD (Lolich et al., 2012).It has also been recommended that BCTs applied to other health behaviours such as smoking or engaging in physical activity can be adapted and applied to adherence (Michie, Rumsey, et al., 2008).

A number of techniques were used in the overall intervention delivery, for example, Motivational Interviewing (MI) (Miller & Rollnick, 1991). MI is classified as one BCT in the Taxonomy (under BCT code 3.3 Social support, emotional) (Michie, Johnston, et al., 2013), however the approach encompasses a variety of techniques for motivating change (Hagger &

Hardcastle, 2014), most frequently involving goal setting, provision of social support and feedback and comparing possible outcomes using a pros and cons discussion (Morton et al., 2014). In IBiD, as well as these specific techniques, the client-centered focus of MI guided how the intervention was delivered. Participants were encouraged to make choices which were appropriate for them, to feel in control of these decisions and feel they have the ability to carry out any changes. The approach used was non-judgemental, made use of open questions, affirmations and reflective listening. In the face to face discussions with participants they were provided with encouragement that they could successfully manage their medication and condition. This corresponds to the BCT Verbal persuasion about capacity (code 15.1). The discussions also covered past successes in adherence and self-management, and therefore covered 'Focus on past successes' (code 15.3).

This ethos of MI ties in with self-management as opposed to more traditional patient education, whereby patients are active participants tailoring and applying the skills and knowledge gained to their particular needs and circumstances (Lorig & Holman, 2003). Tailoring was a key aspect of the intervention and this is described fully in Section 5.3. In brief, information was presented to participants reflecting their individual beliefs and concerns about BD and treatment.

Therapeutic models have been applied to BD for example, Cognitive Behaviour Therapy (CBT) e.g. (Basco & Rush, 2005) and Psychoeducation e.g.(Colom & Lam, 2005) (see Chapter 3). Psycho-education, in the context of BD refers to a therapeutic model focussing on adherence enhancement, early identification of prodromes (personal early warning signs preceding episodes), the importance of lifestyle regularity, exploring individuals' health beliefs and illness-awareness, and enabling the individual to understand the relationship between symptoms, personality, interpersonal environment, and medication side-effects.(Colom & Lam, 2005). CBT as a therapy aims to identify and challenge negative thoughts and emotions. In mental health the aims include managing symptoms and preventing relapse and learning effective coping techniques for managing stress and mood and dealing with negative thoughts (J. S. Beck, 1995).

In the Taxonomy (Michie, Johnston, et al., 2013), the authors specify that encouraging adherence to medication in order to facilitate behaviour change (BCT code 11.1 *Pharmacological support*) is a technique in itself. However this related to, for example, using nicotine replacement therapy to aid smoking cessation. In the case of IBiD, the behavioural objective is adherence so therefore this is not a specific technique used in this intervention. If the measured behaviour outcome was illness relapse then the intervention would be using this technique to encourage adherence.

The remainder of this section describes the process of targeting specific determinants and proximal objectives through the development of practical strategies including the intervention content. Table 5.2 summarises each determinant from the matrix above and the practical strategy, IBiD section and relevant BCTs which this maps onto.

Table 5.2: Matrix of Determinants/ Proximal objectives, implementation in the IBiD intervention and BCTs these mapped onto.

Determinants/ Proximal objectives	**Implementation strategies in IBiD**	**IBiD section/ exercise**	**BCTs (Michie, Johnston, et al., 2013)**
Medication concerns	Prompt participant to identify and compare reasons for adherence and non-adherence (medication concerns), then prompt them to weigh up the concerns vs the benefits of medication.	Balancing pros and cons – information and decisional balance exercise	9. Comparison of outcomes - 9.2 Pros and cons
Medication concerns - Side-effects	Provide information to allow participant to identify which physical symptoms are side-effects. Prompt them to generate or select strategies to help manage these, minimise the impact, or find alternative treatments. Advise participant to seek practical support from HCPs on managing side-effects and finding the right medications.	I'm worried about the side effects from these medications Common side effects and strategies to manage them Taking this medication affects my daily life 'What should I do if I am having problems..' I dislike the way these medications make me feel Medications prescribed for bipolar disorder Sussex Partnership NHS Trust leaflets Link to Choice and Medication website	1. Goals and Planning - 1.2 Problem solving 3. Social support - 3.2 Social support (practical) 5. Natural consequences - 5.6 Information about emotional consequences 9. Comparison of outcomes - 9.1 Credible source
Medication concerns – Dependence	Provide information on dependence, what constitutes addiction and withdrawal symptoms. Acknowledge concerns about dependence.	'I sometimes worry that I might become addicted to or dependent on the medication I'm taking'	5. Natural consequences - 5.1, Information about health consequences
Medication concerns - Long term effects	Provide information on risk of long-term effects and how to reduce risks. Prompt participant to identify and compare reasons for adherence and non-adherence (long-term effects concerns), then prompt them to weigh up the risk of long-term effects vs the benefits of medication.	'I sometimes worry whether there might be long-term effects...' Link to Choice and Medication website Balancing pros and cons – information and decisional balance exercise	5. Natural consequences - 5.1, Information about health consequences 9. Comparison of outcomes - 9.1 Credible source, 9.2 Pros and cons

Determinants/ Proximal objectives	Implementation strategies in IBiD	IBiD section/ exercise	BCTs (Michie, Johnston, et al., 2013)
Necessity beliefs - Adherence and risk of relapse	Provide information about non-adherence and relapse risk. Prompt participant to imagine and compare the outcomes of adherence and non-adherence for them in the future and the pros and cons of adherence and non-adherence (relapse risk). Provide information about the challenges with managing bipolar and factors which precipitate non-adherence (antecedents). Emphasise the emotional, social and environmental consequences of adherence and non-adherence and the specific impact which these could have on participants' lives (relapse/ hospitalisation/ employment etc). Prompt participants reflect on the consequences of previous adherence/ non-adherence. Provide information to stimulate future regret about non-adherence (based on previous experience). Provide ways in which others have viewed BD and taking medication more positively.	Your thoughts and feelings about taking medication Exercise - What does taking medication for bipolar mean to you? Taking control: 3 steps to effective management - Challenges exercise Balancing pros and cons – info and exercise (taking and not taking medication) Exercise – impact of stopping or taking medication differently Making sense of the diagnosis: Does taking medication mean I have to accept I am ill?	13. Identity- 13.2 Framing/reframing 4. Shaping knowledge - 4.2 Information about antecedents 5. Natural consequences - 5.1 Information about health consequences, 5.2 Salience of consequences, 5.3 Information about social and environmental consequences, 5.4 Monitoring of emotional consequences, 5.5 Anticipated regret 9. Comparison of outcomes - 9.2 Pros and cons, 9.3 Comparative imagining of future outcomes
Necessity beliefs - Long-term necessity of medication (health in the future depends on medication)	Provide information that medication is a preventative treatment to reduce relapse risk and framing BD as a long-term condition with ongoing susceptibility to episodes.	I don't feel ill so why should I continue to take my medication? Will I always have bipolar?	13. Identity - 13.2 Framing/reframing
Satisfaction with medication information	Provide information on medications for BD and the specific medications participants are prescribed. Provide links to where to access additional information from credible sources.	Medications prescribed for bipolar disorder Sussex Partnership NHS Trust leaflets Link to Choice and Medication website Useful resources.	9. Comparison of outcomes - 9.1 Credible source
Feelings of stigma - medication related	Provide information (quotes from people with lived experience) on positive ways to perceive medication. Encourage participant to build a positive identity of having a BD diagnosis and taking medication.	Taking medication is an unwelcome reminder of my condition (quotes) 'I tend to hide the fact that I am taking these medications...'	9. Comparison of outcomes - 9.1 Credible source 13. Identity - 13.5 Identity associated with changed behaviour
Feelings of stigma - disorder related	Provide information on public perceptions of mental health (national survey) and prompt participant to compare with their own perceptions to attempt order to change cognitions about stigma.	There's such a lot of stigma about giving yourself a label – Information & exercise Public views about mental illness	9. Comparison of outcomes - 9.1 Credible source 13. Identity - 13.2 Framing/reframing

Determinants/ Proximal objectives	Implementation strategies in IBiD	IBiD section/ exercise	BCTs (Michie, Johnston, et al., 2013)
Therapeutic alliance Effective communication with HCPs	Advise participant to seek support and practical advice from HCP on adherence and managing BD. Provide suggestions on how to communicate effectively with HCP and get the most benefit from consultations.	Taking control: 3 steps to effective management Challenges exercise (advice to use with HCP) 'What should I do if I am having problems..' Getting the most from your consultations	3. Social support - 3.1 Social support (unspecified), 3.2 Social support (practical)
Illness beliefs - Bipolar identity (acceptance of BD diagnosis)	Encourage participant to build a positive identity of having a BD diagnosis and taking medication. Recommendation of where to seek more information on BD from credible sources.	Making sense of the diagnosis: Does taking medication mean I have to accept I am ill? Exercise – What does bipolar mean to you? Useful resources	13. Identity - 13.5 Identity associated with changed behaviour 9. Comparison of outcomes - 9.1 Credible source
Illness beliefs - Severity perception	Provide information on the consequences of mood episodes and why bipolar is treated as an illness	Understanding bipolar, Highs & Lows (Q&A)	9. Comparison of outcomes - 9.1 Credible source
Illness beliefs – Timeline beliefs (BD as a long-term condition)	Framing BD as a long-term condition with ongoing susceptibility to episodes. Encourage participant to build a positive identity of having a BD diagnosis and taking medication.	Will I always have bipolar?	13. Identity - 13.2 Framing/reframing, 13.5 Identity associated with changed behaviour
Illness beliefs - Control perception	Provide information that medication and self-management can help control BD.	Taking control: 3 steps to effective management	13. Identity - 13.2 Framing/reframing
Practical barriers - Forgetting, dealing with routine changes etc.	Prompt participant to identify own practical barriers to adherence then generate or select strategies to help overcome barriers. Suggest environmental or social stimulus which prompt medication taking, advise participant of ways of minimising demands on mental resources (e.g. use of alarms, reminders, linking medication with another activity, requesting assistance from friends/ family), advise to change the physical environment to facilitate adherence (e.g. dosette boxes, location of medication storage), prompt detailed planning of daily medication taking (e.g. context, frequency, duration, intensity), advise to seek support from friends/ family and let them know their treatment plan and to contact HCPs for practical support on difficulties with medication.	Sometimes I find it difficult to take my medication 'What should I do if I am having problems..' Implementation Intentions exercise	1. Goals and Planning - 1.2 Problem solving, 1.4 Action Planning 3. Social support - 3.2 Social support (practical) 7. Associations - 7.1 Prompts/cues 11. Regulation - 11.3 Conserving mental resources 12. Antecedents - 12.1 Restructuring the physical environment

Determinants/ Proximal objectives	Implementation strategies in IBiD	IBiD section/ exercise	BCTs (Michie, Johnston, et al., 2013)
Practical barriers - Understanding how to get and take medication, and how and why changes may be needed.	Presentation of information on specific medications prescribed to each participant. Provide advice to participant to seek practical support from HCPs on finding the right medications.	Medications prescribed for bipolar disorder Sussex Partnership NHS Trust leaflets Link to Choice and Medication website Useful resources I've been on the same medication for years, do I need to change? Why does the medication I am given keep changing?	3. Social support - 3.2 Social support (practical) 9. Comparison of outcomes - 9.1 Credible source
Symptom monitoring - Identifying personal triggers of episodes.	Provide information on potential triggers and prompt participant to identify previous triggers to enable identification of future ones (i.e. define stimulus which cue self-management).	Is there a cause of bipolar (triggers information & exercise)	7. Associations - 7.1 Prompts/cues
Symptom monitoring Prodrome recognition	Provide advice to participant to identify personal prodromes of episodes. Prompt participant to track triggers (e.g. life events) prodromes (e.g. sleep, spending), behaviour (including adherence) and outcomes.	Monitoring your symptoms and looking after yourself Completing your own mood chart Taking control: 3 steps to effective management	1. Goals and Planning - 1.2 Problem solving 2. Feedback and monitoring - 2.3 Self-monitoring of behaviour, 2.4 Self-monitoring of outcome(s) of behaviour
Symptom monitoring Self-management in response to changes	Prompt participant to identify barriers to effective self-management. Presentation of information on practical strategies to try in the event of mood changes. Prompt participant to generate or select strategies to put into place in the event of noticing prodromes. Advise participant to work with HCP to help generate or select strategies. Instruct and advise participant to use mood charting exercise to monitor prodromes, behaviour and outcomes and advise to use this with HCP to problem solve.	Taking control: 3 steps to effective management – Challenges exercise Monitoring your symptoms and looking after yourself Completing your own mood chart	1. Goals and Planning - 1.2 Problem solving 2. Feedback and monitoring - 2.3 Self-monitoring of behaviour, 2.4 Self-monitoring of outcome(s) of behaviour

5.2.3.1 Treatment perceptions – Necessity & Concerns beliefs

As previously discussed, medication perceptions have been linked to adherence in BD (Clatworthy et al., 2009). Therefore the intervention needed to use techniques to attempt to help participants come to a view of medication that is consistent with adherent behaviour i.e. reduce concerns and increase perceptions of need.

Persuasive communication involves guiding people towards an attitude or behaviour using persuasive arguments. A theoretical model of persuasive communication is the Elaboration Likelihood Model (ELM) (Petty & Cacioppo, 1986). The ELM involves two processing routines for persuasion; central and peripheral. In the central route, an individual takes the relevant information and scrutinises this, and is conducted on a conscious level. This is relevant in the IBiD intervention as the aim is to involve participants in the active process of making informed choices about treatment. The peripheral route relies on affective associations and perceived credibility of the information. Persuasive communication is part of a number of BCTs and therefore these were used in order to target beliefs, some examples of which are provided here.

Participants' perceptions of the necessity of treatment were targeted by emphasising the consequences of adherence and non-adherence for them as an individual. This involved the use of an exercise to determine what the outcomes were of non-adherence for them in the past (mapped to BCT code 5.2: *Salience of consequences)* (Figure 5.3). This technique is used in psychoeducation programmes for BD (Colom & Vieta, 2006). A mood charting exercise provided by Bipolar UK allowed participants to track their moods and their medication taking behaviour thus allowing them to visualise the relationship between their mood and adherence (Appendix K).

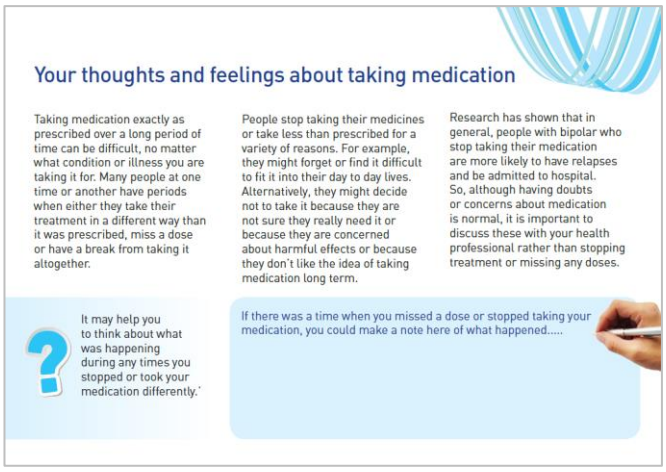


Figure 5.2: Your thoughts and feelings about taking medication

Cognitive restructuring (*BCT code 13.2 Framing/ reframing*) is used in CBT and aims to encourage participants to identify and re-evaluate their beliefs (Basco & Rush, 2005). The rationale being that behaviour is influenced by cognitions and mood and therefore modifying dysfunctional cognitions and moods will have an effect on behaviour (J. S. Beck, 1995). In IBiD, persuasive communication was used to frame medication-taking as a way to help participants to reduce the risk of problems associated with BD as opposed to changing who they are.

To target necessity beliefs and concerns about medication, a decisional balance exercise, as used in CBT interventions, was included (Basco & Rush, 2005). This prompts participants to weigh up the reasons for adherence versus non-adherence (Figure 5.3). This maps to the BCT *Pros and cons* (*BCT code 9.2*) (Michie, Johnston, et al., 2013). Problem solving and decision making are identified as a skill required for self-management. In chronic conditions such as BD, people must make decisions on a day to day basis with regard to changes in mood, side-effects or dealing with environmental changes or life events (Lorig & Holman, 2003). This incorporates the principles of MI where people are more likely to make changes if the individual themselves identifies the potential benefits of change as they are most salient (Miller & Rollnick, 1991).

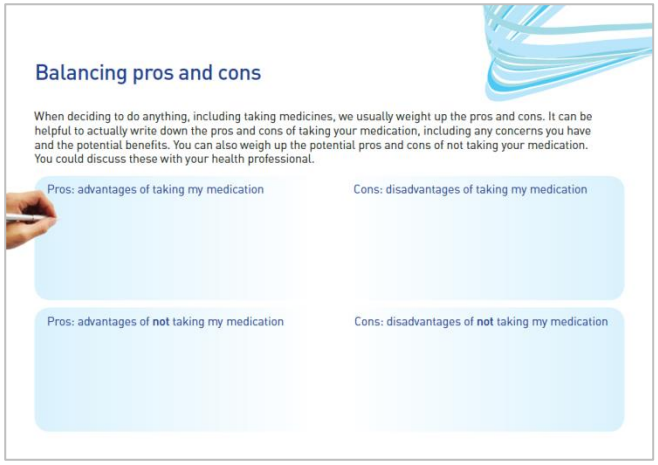


Figure 5.3: Pros and cons of taking medication exercise

Information was provided so participants could have sufficient knowledge on which to weigh up their concerns. This was framed around the BMQ concerns items (e.g. side effects, long-term effects, fears of dependence). IBiD presents information about common side-effects to give participants knowledge to decide how to deal with them. Lorig and Holman (2003) recommend that patients with chronic conditions are given information which enables them to determine if symptoms are an indication of a problem which needs to be addressed and how urgent this need is. Participants were also advised to seek additional information and support from their HCP and medication information websites. The provision of knowledge about

treatment is a key objective of psychoeducation programmes (Colom & Vieta, 2006) and is identified as a prerequisite to be able to make informed decisions (Lorig & Holman, 2003).

An additional topic in relation to medication raised by participants in the qualitative study in Chapter 4 was the importance of understanding the need to find treatments which are right for them individually. Text was included to explain the need for therapeutic experimentation and the importance of participants own involvement in trialling medication and doses to find the most effective treatment whilst minimising side-effects. This section of IBiD also highlights the importance of communication with HCPs and forming an effective partnership which is a part of self-management (Lorig & Holman, 2003) and therapeutic alliance has been identified as an important determinant of adherence and symptom experience (Strauss & Johnson, 2006; L. Thompson & McCabe, 2012).

5.2.3.2 Illness perceptions & symptom monitoring

Illness perceptions which may be associated with effectively managing BD, include perception of illness severity and perceived control over BD (Adams & Scott, 2000; Scott & Pope, 2002a). Information was included in IBiD on BD including the consequences of relapse, the chronic nature of the condition using persuasive communication in order to increase severity perceptions. In addition, information on taking control in BD was included in order to increase perception of personal control.

Self-management requires ongoing symptom and behaviour monitoring and selecting and using coping procedures such as seeking information and help and making lifestyle changes (Mizock et al., 2014; S. Russell & Browne, 2005; Todd et al., 2012). Recognising the prodromes or early warning signs of BD episodes is the crux of self-management in BD (Lam et al., 2001; S. Russell & Browne, 2005).

IBiD included a section on symptom monitoring, using a number of techniques including relapse prevention, decision making and problem solving (Figure 5.4). Psychoeducation programmes which have demonstrated effectiveness (e.g. (Colom, Vieta, Sanchez-Moreno, Palomino-Otiniano, et al., 2009)) recommend creating and using lists of symptoms, warning signs and self-management strategies which need to be put in place when these symptoms are identified (Colom & Vieta, 2006). The mood charting exercise allowed participants to track their moods and make notes on self-management used. This is a technique which has been used in CBT for BD (Basco & Rush, 2005).

Decision making and problem solving skills are followed by 'taking action' where patients must have the skills necessary to carry out the behaviours chosen to help manage mood episodes (Lorig & Holman, 2003). Practical actions are included and participants are advised to seek support from significant others and from HCPs in implementing strategies.

In reviewing the BCT taxonomy (v1) (Michie, Johnston, et al., 2013), these strategies were mapped onto *Problem solving (BCT code 1.2), Self-monitoring of behaviour and Self-monitoring of outcome(s) of behaviour* (BCT codes 2.3 and 2.4).

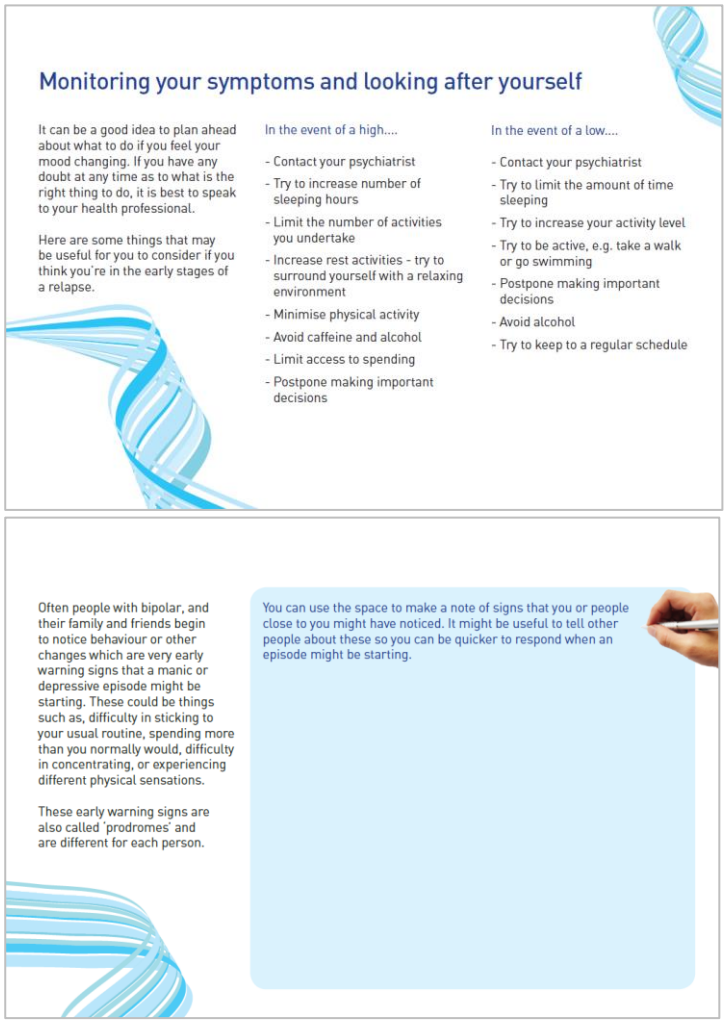


Figure 5.4: Symptom monitoring information and exercise

5.2.3.3 Satisfaction with information

Satisfaction with information has been demonstrated to be related to adherence in BD (Bowskill et al., 2007). In order to improve satisfaction with medication information, general and specific information on medications which participants were prescribed was provided. This comprised Patient Information Leaflets from Sussex Partnership NHS Foundation Trust (Appendix X) and links to the Choice and medication website (Bazire, 2013). Providing

information tailored to participants needs has been shown to be effective in improving satisfaction in chronic pain (Glattacker et al., 2012). Expert communication comprises the BCT *Credible source* (BCT code 9.1) (Michie, Johnston, et al., 2013). Providing information with a credible source encompasses the peripheral route of the ELM (Petty & Cacioppo, 1986). Lorig and Holman (Lorig & Holman, 2003) specify that finding and using resources is a key self-management skill. However, simply signposting to resources may not be enough if people do not know how to use them. In the intervention delivery, it was checked that participants were able to access online information and a description of how to use the websites was provided.

5.2.3.4 Practical barriers to adherence

To target practical barriers to non-adherence including unintentional non-adherence an Implementation Intentions exercise was included (Gollwitzer, 1993). Implementation Intentions (IIs) are behaviour goals which are set with the intention of motivating behaviour and but crucially also include how and when this is to be achieved. Previous research demonstrates the effectiveness of IIs in a range of health areas (Gollwitzer & Sheeran, 2006) including mental health (Toli, Webb, & Hardy, 2015). They have also been used effectively in medication adherence in Epilepsy (I. Brown et al., 2009). 'If-Then' planning statements are used to operationalise the II and in IBiD participants are encouraged to create their own statement. 'If' comprises the anticipated situation (e.g. brushing teeth in the bathroom) and 'Then' comprises the anticipated outcome 'taking medication' (Figure 5.5). IIs are included in the BCT *Action Planning* (BCT code 1.4) (Michie, Johnston, et al., 2013).

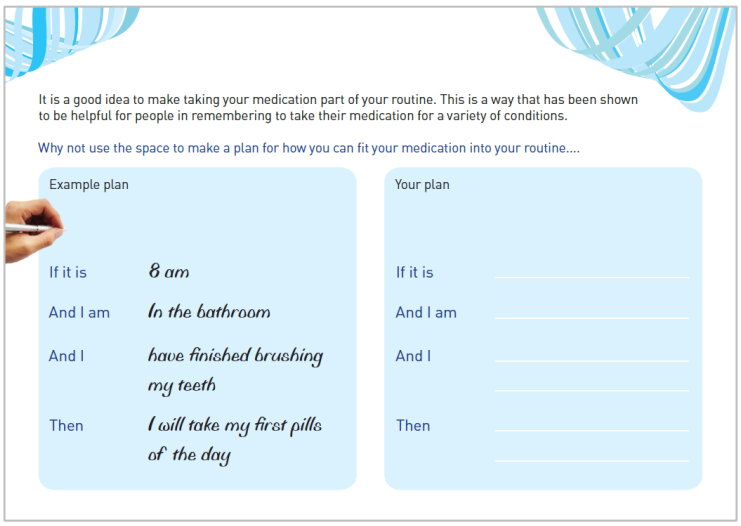


Figure 5.5: IBiD Implementations Intentions exercise

A key self-management strategy in Psychoeducation and CBT is problem solving (Basco & Rush, 2005; Colom & Vieta, 2006) (mapped onto BCT code 1.2), which involves defining the problem, generating possible solutions, implementation of solutions and evaluation of success (Lorig & Holman, 2003). In problem solving, patients must take an active role in generating possible solutions rather than just having them imposed on them. IBiD incorporates problem solving in addressing practical barriers to adherence by asking participants to write-down ideas which they feel would be useful and they would be able to carry out for remembering to take their medication. This technique was also used in relation to dealing with side-effects of medication.

The BCT *Prompts/cues* from earlier taxonomies (Abraham & Michie, 2008) and mapped onto BCT code 7.1 (Michie, Johnston, et al., 2013) was used to encourage participants to introduce cues in their physical or social environment to prompt medication taking. This is also used as an exercise in (Colom & Vieta, 2006). In IBiD a range of potential solutions to the problem of remembering to take medication is provided including advising on use of reminders or alarms and dosette boxes or the location of medication storage. Participants can then select appropriate solutions which fit with their practical barriers and they feel they have the self-efficacy to carry out (Figure 5.6). These strategies map onto the BCTs; *Conserving mental resources (BCT code 11.3)* and *Restructuring the physical environment* (BCT code 12.1).

Figure 5.6: 'Sometimes I find it difficult to take my medication' – Practical adherence solutions

5.2.3.5 Improving effective communication with HCPs

Lorig and Holman (2003) identify that helping people to form partnerships with their health care providers is a key self-management skill. As identified in Chapter 1, better relationships with providers where there is a collaborative partnership between professional and patient appears to be associated with better treatment adherence (L. Thompson & McCabe, 2012;

Zeber et al., 2008). Effective communications and a good partnership brings together self-management strategies in that individuals can bring their skills and knowledge to the consultations and can work in partnership to inform treatment decisions. This is an important aspect of recovery-oriented care where patients are experts in the experience of their condition and relationships involve shared expertise (Davidson, 2005).

IBiD targeted the therapeutic relationship by providing advice to raise side effects, practical problems, feelings about medication and changes in symptoms with HCPs. The text included a reminder that it is important to work in collaboration with HCPs due to the nature of BD (Figure 5.7). These techniques map onto the BCTs *Social support (unspecified), Social Support (practical)* (BCT codes 3.1 and 3.2). The intervention included advice on how to get the most from consultations with HCPs. This acknowledged that it can be difficult to raise questions and to remember to ask them. Suggestions of possible questions and the space to write additional questions was provided.

Figure 5.7: Getting the most from your consultations

5.2.4 Step 4: Programme plan

The practical strategy used to implement the intervention needs to be fit for use, deliverable and appealing to potential participants. The materials and delivery strategy must adequately translate the BCTs and implementation strategies described above to ensure that the programme objectives can be met (Bartholomew et al., 2011). A key part of this step of IM is to ensure that the programme is appropriate for the population and context (Bartholomew et al., 2011).

The process of selection of a written information resource supported by a face to face session is described below. Producing the IBiD intervention involved a number of stages (Figure 5.1). The stages are described with detail on what components of the intervention these contributed to. In section 5.3, the final IBiD intervention is described in terms of the key components identified for intervention development; Content, Context and Delivery vehicle (Horne, 2012).

Briefly, the booklet format of the intervention was determined through discussion in the project management group using previous research. Written information was viewed as a valued way of receiving information by participants in the primary qualitative research but it was important to also have the opportunity to speak face to face and to be signposted to additional information (Chapter 4). This concurs with a review of the role of written patient information where it was found that tailored information was valued, however it should not be a substitute for interactions with HCPs (Grime et al., 2007). In a large European study it was determined that easily readable booklets were viewed as more helpful whereas internet and CD-roms were perceived as not helpful (Morselli & Elgie, 2003). Written material is a valid method for delivering persuasive communication messages and the exercises developed are consistent with those used in Psychoeducation, CBT and MI interventions (Basco & Rush, 2005; Colom & Vieta, 2006) (see Section 5.2.4.2 below).

The development process was iterative in that the intervention content underwent a process of drafting and redrafting at each stage with ongoing communication with stakeholders and service-user representatives.

5.2.4.1 Project Management Group (PMG) development meetings

During PMG meetings, the intervention design and content was discussed and contributions from NHS Trust staff ensured that the intervention would be appropriate and implementable within the context of adult mental health services (Bartholomew et al., 2011). Initial ideas for

intervention content were provided by group members, taking into consideration the preliminary development work and this were then used to develop the first working draft of IBiD. This was consistent with methods recommended by Bartholomew and colleagues (Bartholomew et al., 2011) where the creativity of group members contributes towards designing the intervention. A key member of the PMG was a service-user representative from Bipolar UK who contributed to the text of the resource. Stakeholder consultation is a key component of intervention developments (Craig et al., 2008; NIHR; Sussex Partnership NHS Foundation Trust, 2012).

5.2.4.2 Review of existing health information resources, intervention and therapy manuals and guidelines

In developing the content of IBiD, existing resources produced by voluntary, statutory and professional organisations were reviewed (The British Psychological Society, 2010; Bipolar UK, 2012; Rethink Mental Illness, 2010; Scotland, 2011). It is recommended that intervention planners utilise existing materials or parts of these (although these must also be pre-tested with potential service users) (Bartholomew et al., 2011). Existing therapeutic manuals for BD were consulted (Basco & Rush, 2005; Colom & Vieta, 2006) as well as more general CBT techniques (Centre for Clinical Interventions, 2008). The content on identifying individual signs, symptoms and triggers preceding episodes was developed using the techniques identified in these published manuals. Reviewing these manuals also served to increase the knowledge and skills of the researcher in delivering a face to face session with participants.

5.2.4.3 Consultation with individuals with a diagnosis of BD

Consulting with potential intervention users is crucial in ensuring that it has face validity, that the programme messages are clearly communicated and the delivery vehicle is credible. This is a key component recommended by the MRC, NIHR as well as in local NHS Research policies (Bartholomew et al., 2011; Craig et al., 2008; Lewin et al., 2009; NIHR; Sussex Partnership NHS Foundation Trust, 2012). This process in IM is referred to as formative or preproduction research (Bartholomew et al., 2011). Patient information needs to be reflective of actual patient needs, which many are not, being too centered around information which is important to health professionals, but not to patients themselves. When preparing patient information, issues are likely to be raised which were not considered initially by intervention developers (Grime & Pollock, 2004).

Once the first working draft of the complete intervention resource had been developed, a process of review with people with a diagnosis of bipolar was conducted. The PMG service-user representative sought out a number of individuals with a diagnosis of BD to request their assistance in reviewing the resource. Five people expressed an interest and four subsequently agreed to provide feedback on the resource.

The resource was emailed or posted to each individual and they were provided with a set of prompts to consider when reviewing the resource. Reviewers were asked for their feedback on the wording, design, layout, images and exercises. The feedback received from the reviewers is summarised in Table 5.3 and detailed in Appendix H. All reviewers felt that the resource would be helpful and that the exercises were relevant and useful. The reviewers' comments were synthesised and through a process of discussion with PMG members the comments were incorporated.

Table 5.3: Summary of service-user feedback on draft IBiD resource

Content & clarity
Additional information and clarification
Include physical and cognitive aspects of bipolar, not just mood changes (e.g. physical early warning signs and changes in ability to concentrate).
Provide examples for challenges in successfully managing bipolar.
Clearer instructions on completing exercises (e.g. change 'Is there anything that worries you about taking your medication in the long term?' to 'Use this space to write down any worries you may have about taking your medication in the long term').
Additional information on importance of regular blood tests when taking Lithium.
Increase amount of information on sexual dysfunction side-effects of medication and strategies to manage this.
Clarity
Wording changes to improve clarity and removal of definitive statements ('can' and 'usually' as opposed to 'is').
Remove the term 'informed choice' and change to more user-friendly language.
Change wording of causes of BD to improve clarity on interaction of multiple causes.
Reword information on scientific definition of addiction and reword into simpler language.
Add suggestion to 'write down questions for HCPs in between appointments as you think of them'.
Additional text/ content comments
Positive feedback on Stigma section.
The mood chart at the end is a really great idea.
'Very accessible and straightforward'
'Like all the headings and subheadings'
Visual appearance
Layout
'Very well set out, layout very accessible and straightforward'

No need to repeat titles on the next page of the same section (confusing). Include icons to indicate exercises to be completed on each section. Colours 'Lovely peaceful pale blue colouring' Images 'No mountains' 'I think photos/cartoons of people are counterproductive. People with bipolar insert own images when reading and those deserve to be explored. Any you insert could cause blockages and lead to a sense of frustration or of being controlled/ contained.' 'I am not sure whether other pictures are really needed. I don't like these photos that often accompany articles on bipolar of close-ups of pills or of people with their head in their hands '
Additional comments
'I wish I had had this resource when I was diagnosed! It would have saved so much loneliness and thrashing about in the dark until I found my way to the Bipolar UK website and online forum and got myself a psychotherapist.' 'The exercises follow a logical and helpful order, and lead the 'service user' (horrid term) gently and in the right direction. I think that if it were me using it, I would come to the end wanting to move forward and feeling reassured.' 'I think on the whole this booklet is really good and I wish I had been given something like this when I was first diagnosed' 'Overall, I think this booklet is clearly written and easy to understand. I like fact that there's a focus on using real experiences of people with bipolar rather than just asking HCPs'

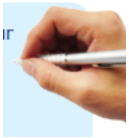
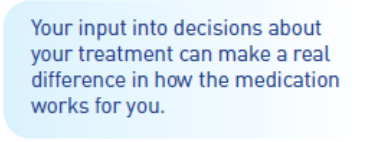
'Hand writing' icons and light blue coloured boxes to indicate where participants can write their responses.	
'Question mark' icons to indicate where there is something for participants to think about.	
'Speech bubble' icons to indicate where participants are reminded that they could talk to their health professional.	
Boxes to highlight key points on the page.	

Figure 5.8: Visual cues

5.2.5 Step 5: Adoption & Implementation Plan

The fifth stage of IM is planning for the adoption and implementation of the intervention (Bartholomew et al., 2011). This is an important part of the process when developing new

interventions as the adoption and implementation focuses on how the intervention would be tested for efficacy.

It is crucial to design the intervention in such a way that it has the potential for adoption by service-providers. This includes who might adopt and implement it as well as the capacity and resources required. The intervention should be designed so it can be delivered by persons not involved in developing the intervention initially. A crucial aspect of this is in documenting the intervention procedure comprehensively to ensure that future replication or implementation was possible. The TIDieR guidelines provide a method for reporting complex interventions (Hoffmann et al., 2014) and a checklist of these items for the IBiD intervention can be found in Appendix I.

As the intervention was tested in a feasibility study, it was necessary to consider how it was to be implemented at this stage. The delivery of IBiD is described in detail in Section 6.4. The plan for implementation in the feasibility testing phase was pragmatic to fit with the care procedures in place in the acute adult mental health setting in which IBiD was tested in.

Discussions in the PMG meetings led to the decision of conducting the intervention in the acute setting for a number of reasons; the identified need and dissatisfaction with information during this phase (see Chapters 1 & 4); the availability of eligible participants and the potential for this to be a salient time for providing information about medication due to difficulties with self-management and medication adherence likely to precede inpatient admission or participants being newly diagnosed. It was also decided to include the Crisis Response and Home Treatment teams (CRHT) as they form part of acute services.

With the aid of hospital discharge data for the preceding 12 months, an assessment of the potential number of eligible participants was estimated. As well as informing the recruitment plan for the IBiD feasibility study, this data also provides information on how many patients would be likely to be able to receive the intervention, aiding plans for future adoption.

Following these discussions there was consultation with ward and team managers on implementation of the study. These meetings served to better understand the running of each ward (which differed) and how IBiD could fit in with the least inconvenience to staff and patients. This also relates to the evaluation of 'community capacity' which forms part of the needs assessment stage (Bartholomew et al., 2011).

Consideration was given during the planning stage about potential future adoption within the setting. There are severe pressures on mental health services (BBC, 2014) and it is well documented that there may be little capacity for information provision or discussions with staff (Rose, Evans, Laker, & Wykes, 2013; Stenhouse, 2011; Walsh & Boyle, 2009). It was

therefore necessary that the intervention be brief and resource efficient for implementing the trial and to ensure potential for future adoption.

5.2.6 Step 6: Evaluation Plan

The stages of IM described above in developing the IBiD intervention all inform the plan for evaluating the intervention. Steps 2 and 3 in producing the programme objectives inform the evaluation objectives and the selection or design of outcome measures. The process evaluation objectives are informed in part by Step 5 (Adoption and Implementation) as these relate to how the intervention is delivered (Bartholomew et al., 2011).

The evaluation model was developed in order to determine, in the first instance, the feasibility of conducting a full RCT of the IBiD intervention. The evaluation is described fully in Chapter 6 and also includes a discussion of the various decisions which must be made including choice of study design, outcome measures and comparison groups.

As well as quantitatively assessing the feasibility of the intervention and trial, the evaluation plan included a qualitative evaluation to seek in-depth feedback from participants as well as the study team member conducting recruitment.

In developing the evaluation plan, the input of the PMG was crucial in order to determine participant eligibility criteria, recruitment strategies and facilitate access to staff and patients in the research sites.

Although the primary objectives of the RCT are on the feasibility of both recruiting to and conducting an intervention in this setting and on how the intervention itself is received, it is important to ensure that the evaluation plan would be applicable to a definitive trial. An evaluation of an intervention should comprise both an assessment of the effect (i.e. the outcome or impact) and process (i.e. factors related to the implementation of the intervention and interpretation of the findings).

The evaluation model follows the CONSORT Statement for reporting RCTs of non-pharmacologic treatments (NPT) (Boutron et al., 2008). In following these guidelines, the evaluation of the IBiD intervention is reported transparently and comprehensively. This addresses inadequacies in reporting of trials and interventions identified in Chapter 3. (See Appendix J for a checklist detailing the CONSORT items and where these are described in this thesis).

5.3 Description of the IBiD intervention

The intervention is a tailored written resource presented by the author to adults who have received a diagnosis of BD in an individual session. The resource is designed to be taken away by participants and follow-up contact with the author via telephone or email was available. The description below summarises the content and delivery of IBiD and follows recommendations for reporting complex interventions (TIDieR) (Hoffmann et al., 2014).

5.3.1 Content of the intervention

The final intervention for use in the feasibility RCT comprises evidence-based content on BD and its treatment including medication and self-management (see Appendix K for full intervention content). The content of the intervention is framed and structured around the components of the extended self-regulation model and PAPA with a focus on the NCF (Horne, 2001, 2003b). The intervention covers the identity of BD, causes and triggers, episodic timeline, consequences as well as information about the need for medication and specific concerns related to medication for BD. The content and exercises are informed by the BCTs identified in Sections 5.2 above.

The intervention also contains information which was specifically highlighted in the qualitative study (Chapter 4) and published research evidence (Bowskill et al., 2007; Morselli & Elgie, 2003; Perreault et al., 2006) as being valuable for inclusion in a resource; specifically, information on stigma, bipolar and alcohol use, and working in partnership with professionals.

The content of the intervention comprises of the following;

- An introduction to the resource
- Information about BD –framed around extended SRM
- Stigma and mental health conditions
- Information about specific medications
- Information about medications –framed around e-SRM and NCF
- Practical barriers to taking medication – framed around the PAPA
- Self-management – monitoring prodromes
- Getting the most out of consultations with health professionals
- Additional resources
- Bipolar UK Mood charting tool

5.3.2 Intervention tailoring

IBiD was designed to be easily tailored to participants needs based on their baseline beliefs and concerns. Tailoring interventions to individuals needs has been recommended by a previous review in BD (L. Berk et al., 2010) as well as by the qualitative research in Chapter 4 and other published studies in mental health (Hatonen, Suhonen, Warro, Pitkanen, & Valimaki, 2010).

Sections of the resource were designed to target individual perceptual barriers to acceptance of the illness and engagement with treatment and practical barriers in accordance with the PAPA approach (Horne, 2001, 2003b). The procedure for tailoring is detailed in Table 5.4. In summary, participants baseline responses to items on the IPQ, BMQ (specific), BMQ (practical), SAQ, SIMS and ISMI dictated whether or not they received the relevant sections of the resource, for example, if participants endorsed the BMQ item 'I sometimes worry about whether there might be long-term effects of taking these medicines', their tailored resource included the section which addressed this concern.

Table 5.4: IBiD tailoring pages and guidelines (from baseline assessments)

Tailored pages	**Theory-based tailoring**	**Detail from baseline assessment – who receives the section?**
Will I always have bipolar?	e-SRM - Acute beliefs	Acute beliefs - IPQ item 2 <7 (0=acute 10=chronic)
'There's such a lot of stigma about giving yourself a label' (2 pages)	Internalised stigma	ISMI score >2.0 for any overall score or subscale (2.01-4.0=mild to severe stigma)
I'm worried about the side-effects from these medicines (3 pages)	NCF - Side-effect concerns	BMQ item C6 Strongly agree, Agree or Uncertain for any medication prescribed And/ or SAQ any items endorsed with medications as attributed cause
I sometimes worry about whether there might be long-term effects of taking these medicines.	NCF - LT effects concern	BMQ item C2 Strongly agree, Agree or Uncertain for any medication prescribed
Taking medication is an unwelcome reminder of my condition	NCF - Reminder concerns	BMQ items C9 Strongly agree, Agree or Uncertain for any medication prescribed
I tend to hide the fact that I am taking these medicines from other people	NCF - Medication stigma concern	BMQ item C7 Strongly agree, Agree or Uncertain for any medication prescribed
I don't feel ill, so why should I continue to take my medication?	NCF - Necessity beliefs e-SRM - Illness identity	BMQ items N1, N2, N3, N4, N5, N7 Strongly disagree, Disagree or Uncertain for any medication prescribed And/ or IPQ item 5 <4 (0=no symptoms, 10=many symptoms)

Tailored pages	Theory-based tailoring	Detail from baseline assessment – who receives the section?
I don't feel like the medication is working	e-SRM – treatment control Necessity beliefs	BMQ items N1, N2, N3, N4, N5, N7 Strongly disagree, Disagree or Uncertain for any medication prescribed And/ or IPQ item 4 <6 (low treatment control)
I dislike the way these medicines make me feel	NCF –feelings concern	BMQ item C10, C11 Strongly agree, Agree or Uncertain for either item for any medication prescribed
Taking these medicines affects my daily life	Disruption Concerns/ all	BMQ item C4 Strongly agree, Agree or Uncertain for any medication prescribed
I sometimes worry that I might become addicted to or dependent on the medicines I'm taking.	NCF - Dependence concern	BMQ items C5 and C8 Strongly agree, Agree or Uncertain for either item for any medication prescribed
Alcohol, bipolar and your medication	Satisfaction with Information	SIMS item 12 = 'too little'/ 'none received'
Sometimes I find it difficult to take my medication	PAPA – Practical barriers	BMQ – practical barriers & MARS forgetting Any barriers or forgetting

5.3.3 Intervention delivery

The detail of the procedure used in delivering IBiD is described in Chapter 6. The face to face delivery with the opportunity to ask questions was selected based on findings from the qualitative study (Chapter 4). The approach taken incorporated the principles of MI by promoting autonomy as decisions and goals set by the participant are more likely to be carried out than those imposed on them (Ryan & Deci, 2000). The delivery left scope to explore the most important issues for each individual. After a general introduction, the topics selected for discussion during the face to face session were flexible to participants' priorities.

5.4 Summary and conclusions

This chapter described the development of the IBiD intervention using an adapted Intervention Mapping (IM) process (Bartholomew et al., 2011). Development of the IBiD intervention involved a detailed process of needs assessment, primary research, evaluation of evidence theory and behaviour change as well as consultation with service-users and professionals. By following this process, the intervention should meet an identified need, contain appropriate content and be in a format acceptable to patients as well as being based around techniques which are evidence-based for changing behaviour. However, IM has been criticised as being complex and time consuming and in practice, intervention development often takes place in conditions where there are time and financial constraints. In this programme of research,

steps needed to be undertaken concurrently in order to achieve the development and feasibility assessment within the time available. An additional criticism of IM is that it may be difficult to select the appropriate behavioural determinants and in this case and many studies do not conduct this stage adequately (Godin, Gagnon, Alary, Levy, & Otis, 2007). In the present research this process did present a number of challenges. Through the IM process, researchers specify the exact content of the intervention and how it is delivered. But it must be relevant for the population and context, for example techniques to enhance self-efficacy in smoking cessation may be very different in enhancing self-efficacy to take medication. Also what might work for people with a physical condition might be different for people with a BD diagnosis. Also within this group, people are very different with their own beliefs, hopes and fears so may respond to the same technique quite differently. There is limited evidence available on BCTs as applied specifically to the programme objectives in the context of mental health. Therefore knowledge from other health areas was extrapolated, consistent with recommendations (Michie, Johnston, et al., 2008).

The practical application of techniques must be appropriate for the target population and the context in which they are being implemented. There isn't sufficient evidence to say who, where and when a BCT might expected to have a positive effect. Although by conducting qualitative research we can gain insights into the variability of the population and context and find out people's preferences and situations. How each technique is operationalised could potentially have a big impact on whether or not it is effective. The format of delivery had been called a key 'active ingredient' (Dombrowski, O'Carroll, & Williams, 2016). Although we may not have evidence as to which form of delivery is most effective in delivering a specific BCT, qualitative research allows us to be confident that that it will be an acceptable form for participants. This is an important part of the feasibility assessment of any novel intervention. In addition, the actual application of the technique is difficult to control and there are a lot of related variables, such as how the practitioner's beliefs impact on the delivery of a technique, how the participant understands, perceives and responds the technique. People's responses will be affected not just by the intervention but a range of intra and interpersonal and external factors.

In developing the content of IBiD it was important to ensure that sufficient information was covered, however, the resource needed not to become too long as this would have made implementation too resource intensive. A balance was needed, ensuring that the focus was not just on medication concerns, but also on BD so as to provide context to the information on treatment. The issues covered were determined in part by the qualitative research (Chapter 4).

However, it was not possible or appropriate to include all suggestions from service-users for the sake of brevity and in keeping the resource focussed on the programme objectives.

As described in the review in Chapter 3, many interventions are multi-component and conducted over a period of weeks or months. However, this intervention was designed with minimal resources available and keeping in mind the potential for future adoption. In terms of producing an intervention which could realistically be conducted, and not to over-burden patients or staff, a one session intervention was used with the resource designed as a self-management tool which could be used by participants on their own and with their HCP.

The intervention developed focusses on change at an individual behaviour level. However, the development work in Phase 1 and the evaluation of the intervention as part of the feasibility RCT informs more environmental, or system level factors which may also act as determinants for adherence and positive outcomes in BD, this will include recommendations for practice.

The following chapter described the testing of the intervention in a feasibility RCT in line with the MRC recommendations for developing complex interventions (Craig et al., 2008). This incorporates Step 6 of Intervention mapping, 'Planning for evaluation', where the decisions on design, comparison group, selection of outcome measures is described.

Chapter 6 Evaluation of the Improving Information for people with Bipolar Disorder (IBiD) intervention: A feasibility RCT.

6.1 Introduction

This chapter presents a trial to assess the feasibility of conducting an RCT to evaluate the novel intervention, Improving Information for Bipolar Disorder (IBiD). This chapter describes, the development of the design and selection of appropriate outcome measures. This comprises Stage 6 of the IM procedure of *'Planning for evaluation'* (Bartholomew et al., 2011). It then details the methods and procedures used in the feasibility trial. Finally the results of the feasibility RCT are described. This study comprises the 'Feasibility & Piloting' stage of the MRC process for the development of complex interventions (Craig et al., 2008). Section 6.3 describes the importance of this stage during intervention development and evaluation to ensure that future evaluations are not beset with problems associated with the study protocol, materials and delivery. The evaluation description follows the CONSORT Statement for reporting RCTs of non-pharmacologic treatments (NPT) (Boutron et al., 2008) (see Appendix J for completed CONSORT checklist).

6.1.1 Challenges with designing and conducting RCTs in mental health settings.

Prior to developing the feasibility RCT protocol, it was important to consider the potential challenges and ethical considerations in conducting trials within a mental health setting. Consideration of these in a feasibility trial is a crucial part of the pre-trial phase.

A criticism of RCTs, is that they may apply stringent inclusion criteria, such that the population included in the trial is not generalizable to the clinical population (Hotopf, 2002). It is important to ensure that trial results are applicable to real clinical situations in which an intervention might be taken forward (see Section 6.3 below) (J. Green, 2006).

With a relatively diverse clinical sample, and a complex intervention, there will be significant individualisation needed in the content and delivery of the intervention. In alignment with the recovery model of mental health, any intervention must take into account individuals beliefs, needs and preferences and foster their own goals (Jacobson & Greenley, 2001; NICE, 2014). Davidson (2005) states that in mental health care there should be *'An emphasis on individual, rather than collective solutions'* (pg 26). The pre-trial phase allows the exploration of the range of individual needs and to test the procedures and responding to them. Future protocols developed will then have procedures built in to respond to this complexity (J. Green, 2006).

As well as more practical considerations, there are a number of ethical issues specific to research in this setting (Graor & Knapik, 2013). There is a careful balance which must be maintained with recruiting potentially vulnerable groups to research. On one hand, it is important to ensure that people are not excluded from participating in research simply on the basis of having a diagnosis for a severe mental health problem. However, it is critical people are not put under pressure to participate and informed consent is maintained throughout. Challenges with staff acting as gatekeepers had been identified as a barrier to recruitment in mental health settings (J. Green, 2006). In the present study a number of steps were taken to ensure that those who were eligible to participate would be invited to do so. Ward visits and regular communication and discussion with staff on suitability of patients to participate took place. In accordance with the Mental Capacity Act (HMSO, 2005), ability to consent was assessed throughout. If patients were deemed unable to provide informed consent at one time point, this was assessed up to the point of discharge; if they became well enough, they were given the opportunity to consider participation. Conversely, if patients were deemed eligible and able to consent, but later became unwell, they were informed that their care team would be able to judge whether it was appropriate to continue with the study.

To help ensure that unnecessary 'gatekeeping', preventing participants from being invited to participate did not limit recruitment, staff were shown the patient study materials and explained the process in order that they could see the minimal burden being placed upon participants and see the potential for improving information and service provision for future patients. In addition, minimal burden was placed on staff who were working in wards involved in recruitment. Ward meetings ensured that staff knew they would have to not do anything in addition to identifying patients who were eligible. They did not have to approach or explain study if they did not wish to as this was carried out by Clinical Studies Officers (CSOs.) Regular emails were sent to remind staff of the study inclusion criteria and study information materials delivered regularly and to each ward.

The process of obtaining informed consent is described in Section 6.4.7. Ensuring informed consent within the mental healthcare setting presents challenges. Patients with BD may have difficulties with concentration and executive functioning (Quraishi & Frangou, 2002) and particularly at this time coming out of an acute episode. In addition, there may be a power balance in favour of researchers and staff, as patients are receiving healthcare within this service and are reliant on staff. Patients need to feel informed and empowered to make decisions about participating and understand they are free to withdraw. It needs to be clear that the research and the researchers are separate from the care they are receiving and a decision to participate or not will not have an impact on their care. The protocol in the

feasibility trial and the approach taken aimed to ensure fully informed consent. Consultation with service-users and seeking advice from Consultant Psychiatrists, Clinical Psychologists, mental health nurses and CSOs when designing the protocol all served to ensure this.

Despite these challenges with planning and conducting research in this setting there is strong evidence that people participating in research in a mental health context have very positive experiences (Jorm, Kelly, & Morgan, 2007; Taylor et al., 2010). Positive experiences can include participation having a cathartic effect, result in a sense of empowerment and sense of purpose and lead to greater self-awareness. Only a small minority (less than 10%) experience distress in research participation based on a review in psychiatric research (Jorm et al., 2007).

6.2 Aims & Objectives

6.2.1 Aim

To determine the feasibility and acceptability of an RCT of a novel, tailored intervention to address adherence and unmet needs in BD.

6.2.2 Objectives

This feasibility RCT was designed to explore the following objectives:

- Number of eligible patients in the population
- Recruitment and retention rates
- Acceptability of recruitment, randomisation, questionnaires and the intervention.
- Resource usage in terms of staff time and participant time in completing study components and intervention delivery.
- Need for the intervention in terms of baseline illness and treatment perceptions, satisfaction with information and feelings of internalised stigma.
- The potential effects of participating in the intervention and control group through quantitative and qualitative (Chapter 7) methods.

6.3 Development of the feasibility RCT

6.3.1 Design considerations

6.3.1.1 Pilot and feasibility trials

Prior to conducting a large-scale definitive RCT to establish the effectiveness of a novel intervention it is imperative to conduct smaller scale studies to determine the feasibility of conducting a larger scale trial as well the acceptability of both the trial and the intervention (Craig et al., 2008). Problems which may beset trials such as lack of eligible participants, recruitment difficulties and poor retention can be anticipated and procedures to ameliorate these issues (Craig et al., 2008). Indeed, Clinical Trial Unit Directors identified that research into methods to boost recruitment in trials was of the highest priority followed by methods to minimise attrition (Tudur Smith, Hickey, Clarke, Blazeby, & Williamson, 2014).

The terms pilot and feasibility study are often used interchangeably. The National Institute for Health Research (NIHR) state that *'Feasibility Studies are pieces of research done before a main study in order to answer the question "Can this study be done?". They are used to estimate important parameters that are needed to design the main study.' (NIHR).*

However, the NIHR also state that pilot studies test whether components of a definitive trial can all work together (NIHR). The current study therefore does incorporate elements of both the definitions of feasibility and pilot studies, however the parameters investigated aim to address areas of uncertainty. The parameters reflect the recommendations for feasibility studies from NIHR and are; number of eligible patients in the population, recruitment and retention rates, acceptability of the trial, intervention and outcome measures to patients and staff. In addition the study aims to gather information on outcome data, in terms of standard deviations to inform a sample size calculation for a larger trial (see 6.2 above) (NIHR).. NIHR also advise that '*the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision' (NIHR)*. It is important in the conduct of a preliminary study to cautiously interpret any outcomes in terms of statistical significance due to limited sample size (Thabane et al., 2010).

It is important to define criteria for success of feasibility. In this study the following criteria are used;

- To estimate that it would be possible to recruit sufficient participants for a full trial within a reasonable period expected for conducting a definitive trial (12 months).
- Retention rates should be comparable with published trials within this setting.

- Protocols should be acceptable to patients and staff with no undue burden placed upon them.
- The intervention should be acceptable to patients and have the potential to have a positive impact on patients.

6.3.1.2 Pragmatic design considerations

To ensure that feasibility evaluation is based on the population and setting that a definitive trial would take place in, a number of pragmatic considerations were taken into account. Although a highly controlled, narrowly designed RCT has good internal validity, it can result in an intervention which is detached from clinical practice and the actual patient group which the intervention aims to target, therefore reducing its external validity (Hotopf, 2002; J. Green, 2006). The following aspects of this study relate to pragmatic design considerations;

- Participant selection – exclusion criteria kept to a minimum i.e. inclusion of comorbid physical conditions, not just newly diagnosed participants, both those who have been admitted for manic and depressive episodes and participants who have experienced psychosis.
- Blinding and allocation concealment – It was impossible to blind participants to their allocated group in this study, as ethical requirements specified that participants were informed of the two study arms and after randomisation were informed of their allocation. However, measures were taken to try to ensure that members of the study team assessing outcomes remained blind to allocation. Minimisation by the researcher who was not involved in recruitment ensured that recruitment to the study remained independent from treatment allocation processes. Participants were requested at follow-up, not to disclose their treatment allocation until after the questionnaires had been completed. Questionnaire outcome measures also serve to reduce the possibility of observer bias.

6.3.1.3 Selection of a Control group

With a pragmatic trial it is important to compare a new treatment with what is currently practiced as it offers the potential to answer the question of whether the treatment gives benefit over what patients currently receive (Freedland et al., 2011; J. Green, 2006). It is difficult to determine whether any effect observed is due to the intervention or to other non-

specific effects such as therapist time. However, the content and attention participants received are both components of the intervention and a TAU comparison is appropriate.

6.3.1.4 Unit of randomisation: Individual vs Cluster RCTs

In designing an RCT the unit of randomisation must be decided upon, whether this is at the level of the individual or at the level of the site or unit in which the intervention is delivered. A summary of these considerations in relation to the IBiD intervention is presented in Table 6.1. When interventions are delivered in settings such as hospital sites, consideration must be given as to whether there is any possibility of clustering effects i.e. will those in each cluster be independent of one another. When designing a trial where randomisation occurs at the level of clusters, a large number of clusters are required as participants within one cluster are not independent of one another (intra-cluster correlation) and this must be taken into account in the computation of statistic power (Elley, Kerse, & Chondros, 2004). A number of steps were taken to ensure that any cross-contamination between participants allocated to TAU was minimised. Specifically, the intervention resource was not provided to staff during the course of the study so could not be shared with other patients. It was ensured as much as possible that the intervention was conducted as close to the point of discharge as possible so the resource would not be shared between patients.

6.3.1.5 Process evaluation

In trials, consideration must be given to variables which might act to either 'mediate' i.e. change or occur during treatment and have a significant effect on the study outcome or to 'moderate' i.e. exist at baseline and interacts with the intervention to have an effect on the outcome (Kraemer, Wilson, Fairburn, & Agras, 2002).

Exploring process variables helps to systematically describe aspects of the intervention which occur during delivery of the intervention and provide a description of what constitutes treatment as usual which may not be otherwise systematically recorded. Identifying potential moderating factors provides information for future definitive trials in this setting, helping to either targeting the intervention or for in stratification for randomisation. Identifying potential mediators could lead to the development of the intervention to maximise change in particular variable (J. Green, 2006). The feasibility study cannot statistically investigate these factors influence on outcomes due to not being powered to investigate these variables. However, data can be obtained on the variance of potential mediators and the feasibility of collecting data on these.

Table 6.1: Advantages and Disadvantages of Parallel group and Cluster research designs for IBiD

Design	Explanation	Advantages	Disadvantages	Possible solutions
Parallel groups	Each participant is randomly assigned to a group (intervention or TAU).	Strong research design. Reduction of potential bias. Tends to produce comparable groups.	Possibility of contamination between groups. Participants within wards may share the written resource. Potential of confounding from other variables if randomisation not conducted properly. Generalisability - Participants may not be representative of patient group due to 'volunteer effects' and exclusion criteria. Administrative complexity.	Intervention would be individually tailored, therefore control group might have accessed written material but would not have received the tailored element (potentially limiting contamination). Delivery of intervention close to discharge may minimise contamination.
Cluster	Wards or sites randomised to receive either intervention or TAU. Need to account for clustering in the design and analysis. Clusters would be based on Wards (n=13).	Provides protection against contamination when participants are managed within the same setting and cannot be assumed to act independently. Administratively convenient. Economic evaluation is facilitated as unit of randomisation is unit of healthcare service.	A lack of independence leads to a loss of power. To achieve the equivalent power of a parallel groups the sample size needs to be inflated. Longer fieldwork period needed to achieve required sample. Ethical issues of consent at individual level. Potential of individual and whole-cluster drop-outs.	Sample size needs to be inflated by a factor 1+ (n-1) p n= average cluster size p = an estimation of the ICC 'intracluster correlation coefficient' i.e. the degree of similarity among responses within a cluster. The ICC is estimated from previous research. Adjustments needed to statistical tests to account for clustering effects. Multi-level modelling can take account of clustering effects from degree of personal interaction between members of cluster.

6.3.2 Selection of outcome measures

Selection of the outcome measures took into account a number of factors to ensure their reliability and validity for the study. The outcome and clinical measures selected are summarised in Table 6.2 and the following sections provide details of why these measures were selected.

- Content validity - Must be relevant to the target population and intervention.
- Construct validity
- Reliability as assessed by Cronbach's alpha.
- Sensitive to change.
- Minimise burden on participants.

6.3.2.1 Selecting an adherence measure

The challenges and complexity associated with adherence measurement, particularly within psychiatry have been discussed in Chapter 1. For the present study, it was unfeasible to use objective measures of adherence for a number of reasons; the administration of medications changes at the point of discharge from hospital pharmacy supply to prescribing by patients GPs. Furthermore, changes in medication are likely and it would be impractical to follow these up. Participants may be on a range of medications and it would not be possible to objectively measure each of these. Administration of medications can be in tablet, liquid or depot injection, further complicating objective measurement.

Self-report measures were selected for the present study in preference to clinician administered scales in order that the questionnaire could be completed by participants with minimal assistance and without the need for a mental health professional. A number of self-report measures have been used in psychiatry (Sajatovic et al., 2010).

The Medication Adherence Report Scale (MARS) (Horne & Weinman, 2002), a 5 item self-report measure, was selected. This is a widely used scale (Clatworthy et al., 2009; Jónsdóttir et al., 2010; L. Williams, O'Connor, Grubb, & O'Carroll, 2011), only measures behaviour as opposed to attitudes and has been used previously in research with people with BD (Bowskill et al., 2007). Due to the nature of psychopharmacology for BD, participants were likely to be taking a number of different medications and as such it was necessary to select a brief measure which could be quickly completed for each medication. Sajatovic and colleagues (2010) recommended that adherence is assessed for each medication separately to take into account differing adherence to different medications.

Other self-report scales were considered but rejected, such as the Medication Adherence Rating Scale, used in schizophrenia and psychosis, which includes items assessing medication attitudes, not solely adherence behaviour (K. Thompson et al., 2000). Participants may be reluctant to admit instances of non-adherence, therefore questionnaire item wording needs to reduce any sense of 'judgement' of the behaviour. The Morisky scale, consisting of four items with yes/ no response categories, uses the word 'careless' in reference to non-adherence which may reduce accurate self-reporting. In addition, some items contain double questions such as 'If you felt worse when you took your medication, did you sometimes stop taking your medication?' which may be difficult for participants to interpret (Morisky et al., 1986).

To provide additional self-report information on adherence, a visual analogue scale (VAS) was included. Participants are asked to mark on a scale of 0-100%, the approximate percentage of medication they think they take. The VAS has been shown to be significantly correlated with

blood serum levels of medication in participants with schizophrenia and bipolar disorder (Jonsdottir et al., 2009).

6.3.2.2 Selecting a medication attitude measure

A number of scales exist to measure attitudes towards treatment. The Beliefs about Medicine Questionnaire (BMQ) was previously described in Chapter 2 (Horne et al., 1999). Other measures used in psychiatric populations including BD were rejected, for reasons including; mixing constructs i.e. combining items relating to both behaviour and attitudes in the Brief Evaluation of Medication Influences and Beliefs scale (BEMIB) (Dolder et al., 2004), measuring attitudes towards illness in addition to treatment in the Treatment Attitudes Questionnaire (Johnson & Fulford, 2008) and combining practical and perceptual barriers without separate subscales such as the Lithium Attitudes Questionnaire (Harvey & Peet, 1991) and Brief Medication Questionnaire (Svarstad, Chewning, Sleath, & Claesson, 1999).

The BMQ has been widely used in physical health and more recently in mental health including BD, where it has shown utility in predicting adherence (Clatworthy et al., 2009; Horne & Weinman, 2002; Jonsdottir et al., 2009). The BMQ- Specific version used in this study comprised six 'Necessity' items and 11 'Concerns' items. Participants completed this measure for all medications they were currently prescribed for BD. Participants specified the mode of administration of each medication (tablet, liquid or injection). Participants also completed the BMQ-General (described in Chapter 2).

Practical barriers to taking medications for bipolar were assessed by participants rating a number of statements which were compiled from previous studies (Clatworthy et al., 2007) and the qualitative research presented in Chapter 4.

6.3.3 Final outcome measures

A copy of the final outcome measures formatted into the baseline and follow-up questionnaire booklet can be found in Appendix L.

6.3.3.1 The Satisfaction with Information about Medication Scale (SIMS)

The Satisfaction with Information about Medication Scale (SIMS) is a 17 item measure which has been validated with a range of health conditions (Horne, Hankins, & Jenkins, 2001). The items in the SIMS are derived from Association of the British Pharmaceutical Industry (ABPI)

recommendations for the type of information patients require to facilitate safe self-management of medication. Participants rate each item as either 'too much', 'about right', 'too little', 'none received', or 'none needed'. A total satisfaction rating (0-17) is obtained by summing the number of positive scores (about right or none needed) with higher scores indicating a greater degree of satisfaction. SIMS comprises two subscales; satisfaction with information about the 'action and usage of medication' and the 'potential problems of medication'. The scale has shown good internal reliability (0.81 to 0.91) and satisfactory test-retest reliability (> 0.6) (Horne et al., 2001). SIMS has been previously used in a cross-sectional study investigating perceptions of information received by people with a bipolar disorder diagnosis (Bowskill et al., 2007).

6.3.3.2 The Brief Illness Perceptions Questionnaire (Brief-IPQ)

The Brief Illness Perceptions Questionnaire (Brief-IPQ) is a short-form of the Revised Illness Perceptions Questionnaire (IPQ-R) in which each dimension of illness perception is represented by a single item (Broadbent et al., 2006). The Brief-IPQ has been described in Chapter 2. The brief-IPQ as adapted for previous bipolar research was used in this study (Clatworthy et al., 2009; Lobban, no date). The word "illness" in the questionnaire was replaced by "bipolar". In this 9-item version, five items assess cognitive illness representations of illness: consequences, timeline, personal control, treatment control, and identity (symptom experience). Two items assess emotional representations: concern about bipolar, and emotional effects. One item assesses how much participants agree with their diagnosis. Each item is rated by participants on an 11 point scale (0-10) with higher scores reflecting perceptions of more serious consequences, a chronic timeline, greater personal control, greater treatment control, many/severe symptoms, high concerns about illness and high negative emotional responses to illness. The B-IPQ demonstrates good reliability and construct validity (Broadbent et al., 2006) (Table 6.2).

6.3.3.3 Illness Perceptions additional sections on Identity & Causes

In order to provide more detailed information on participants perceptions of their illness, but without the use of the full IPQ-R (Moss-Morris et al., 2002), additional sections on causes and illness identity (acknowledging that participants may have received differing mental health diagnoses prior to their current diagnosis and may hold alternative explanations for their mental health issues).

Participants were presented with a list of mental health terms and asked to confirm if these had been used to describe their mental health problems. They were given space to also add in other terms which may have been used. For each term which has been used, they were asked to rate on a 5 point scale their level of agreement that the term described the experiences they have had. To gain a perspective on their current views about their mental health problems, there was an open-response box asking participants to write what term or label they felt best describes their mental health problems.

To assess perceptions of causes, participants were asked to rate their level of agreement on a 5 point scale (from strongly agree to strongly disagree) to 19 possible causes of bipolar. They were asked for their own views on possible causes rather than what health professionals, family or friends may have suggested. Participants were then asked to write the three most important causes of their mental health problems and were able to include other causes in addition to the pre-specified list. They were also asked to write three possible factors which in their view were responsible for maintaining their mental health problems.

6.3.3.4 Symptoms associated with bipolar questionnaire (SAQ)

In order to capture information on the type and severity of symptoms and side-effects participants were experiencing, the SAQ was included. This asks participants to endorse 'yes' or 'no' for whether they are currently experiencing a list of symptoms and side-effects associated with bipolar disorder. The list was compiled through consultations with the Consultant Psychiatrist in the research team as well as including items from the Glasgow Antipsychotic Side-effect Scale (GASS) (Waddell & Taylor, 2008). Space was also left for participants to add any additional symptoms they were experiencing. For items participants endorsed, they were asked to rate its severity on a 5 point scale from 'Mild' to 'Very severe' and then to select whether they thought the cause of the symptom was 'Bipolar', 'Medication', 'Both', 'Neither' or 'Unsure'.

6.3.3.5 Internalized Stigma of Mental Illness Inventory (ISMI)

The Internalized Stigma of Mental Illness Inventory (ISMI) is a 29 item measure with five subscales; Alienation, Stereotype Endorsement, Discrimination Experience, Social Withdrawal and Stigma Resistance. The scale has been validated in mental health outpatient populations (Boyd Ritsher, Otilingam, & Grajales, 2003). A review identified that this measure was commonly used and had the highest internal consistency of a range of measures identified,

with the average being 0.85 (Livingston & Boyd, 2010). The ISMI has been used within a large scale European survey of people with BD or depression (Brohan et al., 2011).

The scale is scored by summing the answered items and dividing by the number of answered items, stigma-resistance items are reverse-coded. Higher scores indicate less internalised stigma and range from 1-4. Cut-offs have been defined in the literature for 4 categories (Lysaker, Roe, & Yanos, 2007) and 2 categories (Boyd Ritsher et al., 2003). ISMI has been demonstrated to have high internal consistency (r=0.90) and test-retest reliability (*r*=0.92) (Boyd Ritsher et al., 2003).

6.3.3.6 Clinical measures (Beck Depression Inventory (BDI-II) & Altman Self-Rating Mania Scale (ASRM))

The Beck Depression Inventory (BDI-II) (A. Beck, Steer, Ball, & Ranieri, 1996) is a 21 item scale for the measurement of depression severity which can be self administered and has shown good internal consistency (0.92) (A. Beck et al., 1988). The BDI-II has been recommended for its utility in measuring depression in people with a diagnosis of BD and distinguishing between depressive, manic and mixed episodes (Kumar, Rissmiller, Steer, & Beck, 2006). Each item is scored from 0-3 and scores are summed to produce a total score ranging from 0 to 63 with higher scores indicating more severe depression. Cut-offs have been defined as 0 -13 - minimal range; 14-19 - mild depression; 20-28 -moderate depression; and 29-63 - severe depression (Smarr & Keefer, 2011).

The ASRM is a 5 item scale measuring the presence and severity of manic symptoms and is compatible with DSM-IV criteria. ASRM is shorter than the alternatives; Young Mania Rating Scale (YMRS) (R. Young, Biggs, Ziegler, & Meyer, 1978), or the Clinician- Administered Rating Scale for Mania (CARS-M) (E. Altman, Hedeker, Janicak, Peterson, & Davis, 1994) and unlike these it is designed to enable self-administration, but correlates significantly with these other measures (E. Altman, Hedeker, Peterson, & Davis, 1997). Due to its good reliability (r = .86) and validity, ease of administration and imposing the least burden also in consultation with the Consultant Psychiatrist in the research team, this measure was selected. Each ASRM item is scored from 0 to 4, with total scores ranging from 0-16 with higher scores indicating higher probability of mania. Cut-offs have been defined as a score of 6 or higher indicating possible manic state (E. Altman et al., 1997).

Table 6.2: List of validated and adapted measures used in IBiD study

Type	Measure	Items/ Scoring	Cronbach's alpha (published)
Clinical	The Beck Depression Inventory (BDI-II) (A. T. Beck et al., 1996)	21 items 4 point scale - 0-3 (summed) 0–13: minimal depression 14–19: mild depression 20–28: moderate depression 29–63: severe depression	0.91
	Altman Self-Rating Mania Scale (E. G. Altman et al., 1997)	5 items 5 point scale - 0-4 (summed) 0-5: no indication of mania 6-20: possible manic state indicated	0.79
Treatment beliefs	The Beliefs about Medicine Questionnaire Specific (BMQ Specific) (Horne et al., 1999) adapted for BD	17 items 2 factor structure; Necessity, Concerns 5 point scale, Strongly agree – Strongly disagree (Mean score)	0.63-0.74[a]
	The Beliefs about Medicine Questionnaire General (BMQ General) (Horne et al., 1999)	8 items 2 factor structure; Overuse, Harm 5 point scale, Strongly agree – Strongly disagree (Mean score)	0.63-0.74[a]
Illness beliefs	The brief Illness Perception Questionnaire (Broadbent et al., 2006)	8 items (+1 additional for BD) 10 point scale	
Adherence	Medication Adherence Report Scale (MARS) (Horne & Weinman, 2004)	5 items 5 point scale - Always to never (summed)	0.67–0.90
Satisfaction	The Satisfaction with Information about Medication Scale (SIMS) (Horne et al., 2001)	17 items 2 subscales 'Action and Usage', 'Potential Problems' Response categories – too much (0), about right (1), too little (0), none received (0), none needed (1) (summed)	0.81 - 0.91
Stigma	Internalised Stigma of Mental Illness (ISMI) (Boyd Ritsher et al., 2003)	29 items 4-point scale, Strongly agree – Strongly disagree 5 subscales - Alienation, Stereotype Endorsement, Discrimination Experience, Social Withdrawal, Stigma Resistance. Cut offs - 4-category method 1.00-2.00: minimal to no internalized stigma 2.01-2.50: mild internalized stigma 2.51-3.00: moderate internalized stigma 3.01-4.00: severe internalized stigma 2-category 1.00-2.50: does not report high internalized stigma 2.51-4.00: reports high internalized stigma	0.90

[a] Cronbach's alpha for psychiatric sample across specific and general subscales.
[b] Cronbach's alpha ranges across subscales.

6.3.3.7 Clinical and demographic data

Information was collected on clinical factors relating to participants diagnosis and previous psychiatric history, this is detailed in Table 6.3. These variables were selected, as potentially important moderating variables and were refined through consultation with the Consultant Psychiatrist in the research team. The following demographic information was collected; date of birth, gender, ethnic origin, marital status and highest level of education.

Table 6.3: List of clinical information collected at baseline

Variable	Description
Diagnosis received	Current diagnosis at recruitment
Diagnosis before admission	Previous psychiatric diagnosis (if applicable)
Age of bipolar diagnosis	Age of first bipolar disorder diagnosis
Current hospital admission	Was this admission voluntary or involuntary/detained?
Reason for current admission	Participant's view & information from notes.
Date of admission	Date on which current admission commenced
Anticipated date of discharge	Anticipated date of discharge (if known)
Number of previous psychiatric admissions	Number of previous admissions (estimated by participant & checked in notes by CSO)
Any voluntary admissions	Yes/ No
Any involuntary/ detained admissions	Yes/ No
Number of previous manic episodes	Estimated number of episodes of mania
Number of previous episodes of depression	Estimated number of episodes of depression
Any current psychotic symptoms?	Yes/ No
Family history of bipolar	Yes/ No/ Unknown
Physical health conditions	Details of any co morbid health conditions

6.3.3.8 Acceptability of baseline questionnaire

In order to gather data on the acceptability of the baseline questionnaire a number of questions were included at the end of the questionnaire (see Appendix L). In addition, CSOs kept a note of any problems encountered during questionnaire completion and the researcher kept a record of any additional notes made by participants on their questionnaire.

6.4 Methods & Procedure

Figure 6.1 represents the procedure for the IBiD feasibility study from recruitment to follow-up.

6.4.1 Setting

The study was conducted in Adult Mental Health Services across Sussex Partnership NHS Foundation Trust including acute in-patient wards and Crisis Response and Home Treatment teams (CRHT). In total five hospital sites (including 16 wards and 5 CRHTs) were involved in the study.

6.4.2 Ethical approvals

Favourable NHS Research Ethics Committee approval for this study was granted in November 2012 (REC Ref 12/LO/1615) (Appendix M). Local NHS Research and Development approval from Sussex Partnership NHS Foundation Trust (Ref number CSP 87823) was granted in November 2012 (Appendix N). A minor amendment was submitted and approved in June 2013 in order to remove the upper age inclusion criteria for participants as the wards moved from having separate services for adults and older adults to being an 'ageless' service. A Letter of Access from Sussex Partnership NHS Foundation Trust allowing the author access to study sites and patients (Appendix O).

6.4.3 Pre-recruitment site visits & staff updates

Between May and July 2013, the research team undertook pre-recruitment visits to introduce the study to staff at each site, deliver study materials and arrange to commence the study. These visits included presentations at Governance meetings, care manager meetings, Business meetings and meetings arranged specifically to introduce the study. All wards and teams received a study pack which contained copies of the following; study protocol, staff information sheets, Patient Information Sheet (PIS), and posters advertising the study for display in staff areas (Appendix P).

To ensure ongoing awareness and enthusiasm for the study, email updates to ward and team staff were sent on a monthly basis. These updates informed staff of current recruitment figures, targets, any changes to study team members and provided a reminder for staff about how to receive additional copies of study materials (Appendix Q).

6.4.4 Eligibility Criteria

Patients were eligible to participate in the study if they were aged over 18 years, had a diagnosis of BD (as assessed during their current inpatient stay or referral to the CRHT), were being prescribed medication for this and were able to provide written, informed consent.

Exclusions were limited to; patients with organic brain syndrome (including brain injury and degenerative disorders), active suicidal ideation as assessed by ward care team, a primary diagnosis of substance misuse and patients considered as presenting a risk to others.

When conducting pre-recruitment site meetings, clinical staff advised that it would not be appropriate to include patients with a duel diagnosis of personality disorder and BD.

6.4.5 Risk

Initial eligibility screening with patients' care teams ensured that those assessed as posing a risk to themselves or others were not approached. When ward visits were undertaken, risk was checked with the on-duty team and if recommended a personal alarm was provided. For home visits the CSO followed Sussex Partnership NHS Foundation Trust's lone worker policy. The researcher informed participants Care Coordinator (CCO) of the date and time of the appointment and left the participants and CCO details with a colleague at UCL School of Pharmacy.

6.4.6 Recruitment & Baseline assessments

Potentially eligible patients were initially identified in two ways. CSOs used the electronic Patient Information Management System (PIMS) to identity patients at each site with a diagnosis of BD. Concurrently, ward staff identified patients in their care who were eligible and at an appropriate stage to participate. Liaison between ward staff and CSOs was maintained during the study to ensure that potentially eligible patients were not missed.

Eligible patients were provided with a copy of the PIS from ward staff and informed that if they were interested in finding out more, a CSO would visit with them in the next couple of days. CSOs visited eligible patients who had expressed an interest in participating, confirmed understanding of the study and if appropriate took consent and conducted baseline assessments. These appointments took place in private locations on the wards or in participants' homes or community mental health centres. Following the administration of the baseline assessments, CSO sent a scanned copy of the completed questionnaire to the researcher to enable the tailored IBiD resource to be assembled. All researchers involved in

recruiting to and delivery of the study completed Good Clinical Practice (GCP) training prior to starting recruitment.

6.4.7 Informed consent

Informed, written consent (Appendix R) obtained from participants by the CSO was taken in accordance with Trust procedures, the Mental Capacity Act 2005 (HMSO, 2005) and International Conference on Harmonisation-Good Clinical Practice (ICHGCP) (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996). The PIS and the CSO when taking consent emphasised that participants were free to withdraw from the study at any time and that this would not affect their care.

6.4.8 Sample size

As this study formed a feasibility assessment of the RCT, a formal sample size calculation was not appropriate. However, a sample of 30 participants was determined to be sufficient to provide feasibility and acceptability data. Sample sizes recommended as necessary for feasibility studies range from 24 to 50 (Julious, 2005; Lancaster, Dodd, & Williamson, 2004). Approximate numbers of eligible participants was estimated from previous discharge data from the Trust (number of patients discharged from inpatient stays in 12 months with a diagnosis of BD =328). We estimated that 164 patients might be discharged in the fieldwork period of six months, however, not all may meet the eligibility criteria. Estimates of recruitment and retention rates in published studies were used to assess the likely rates. Refusal rates range between 15% and 31% and attrition between 16% and 25% (Castle et al., 2010; Kemp, Hayward, Applewhaite, Everitt, & David, 1996; Sajatovic, Davies, et al., 2009; Scott et al., 2006). Recruitment of 30 participants was estimated to take six months, and by conducting this study we would be able to ascertain recruitment and retention to an RCT within this specific population.

6.4.9 Randomisation

After completion of baseline assessments, participants were randomised to the intervention (IG) or treatment as usual (TAU) condition independently by the researcher, under the guidance of a statistician. CSOs passed the identifiable participant details (name, contact details of both the participant and their care coordinator) to the researcher by telephone. These were then stored on a password protected Excel file where unique participant ID

numbers were linked with the personal details which was only accessible by the researcher to ensure confidentiality.

The first 10 participants were randomised using a random number table (Kirkwood, 1988). Following this, minimisation was used in order to minimise the difference between the IG and TAU with regard to gender and age (D. Altman & Bland, 2005). These criteria were selected in consultation with the Consultant Psychiatrist. Each subsequent participant was allocated on the basis of minimising the imbalance between groups (Appendix S). Where both groups were equal during the process, simple randomisation by means of a coin toss was used to allocate the next participant. Minimisation is an acceptable approach where a balance is required between prognostic factors in small trials where other methods such as blocking and stratification are not appropriate (D. Altman & Bland, 2005).

6.4.10 Allocation concealment

The CSO remained blinded to participants' allocation. They did not have access to the random number table or minimisation procedure so therefore could not be aware of forthcoming allocations when recruiting or influence randomisation. This is a critically important procedure to ensure that recruiters are blinded from knowledge of upcoming treatment assignments (Schulz & Grimes, 2002). Once participants were allocated to a treatment group, the researcher contacted the participants care team, either on the ward, with the CHRT or through the community care coordinators (CCOs) as appropriate. Participants CCOs were sent an email informing them of their clients' participation (Appendix T). Both the care team and the participant were informed of their treatment allocation. They were asked not to feed this back to the CSO when they were contacted for the follow-up assessments. Incidences where unblinding occurred were recorded and details of these can be found in Section 6.6.3 Where cases did occur prior to follow-up, arrangements were made for a different CSO to conduct the follow-up assessments.

6.4.11 Treatment as usual procedure

Participants allocated to TAU received a letter informing them of their allocation, reminding them of the follow-up assessments and notifying them that they could contact the researcher if they required any additional information (Appendix U) for TAU notification letter.

6.4.12 Intervention group procedure

The procedure for participants allocated to IG varied according to their discharge status. For those still admitted as inpatients, the researcher arranged with ward staff and the participant a convenient time to visit to conduct the intervention (arranged to fit around participant ward-leave, mealtimes, activities and psychiatrists ward-rounds). The interventions took place in one of the private quiet rooms on the ward. In the cases where participants had been discharged, their CCO was contacted to notify them of the allocation and to seek their advice on whether home visits were appropriate. The researcher (LM) contacted the participant to arrange a convenient time to conduct the intervention either in their home or at a local community mental health centre. Prior to meeting the participant, the researcher compiled the tailored IBiD booklet to participants' baseline questionnaires. Tailoring details for each participant can be found in Appendix V. Booklets also contained Patient Information Sheets for each medication participants were prescribed (Appendix W).

To ensure competency to deliver the intervention, the researcher held a Masters degree in Health Psychology and was undergoing training for Chartered Health psychology status. They had undertaken training in MI, Mental health and wellbeing, Health Behaviour Change as well as studying Psychoeducation and CBT manuals for BD. Supervision by a Consultant Psychiatrist allowed ongoing support during intervention delivery.

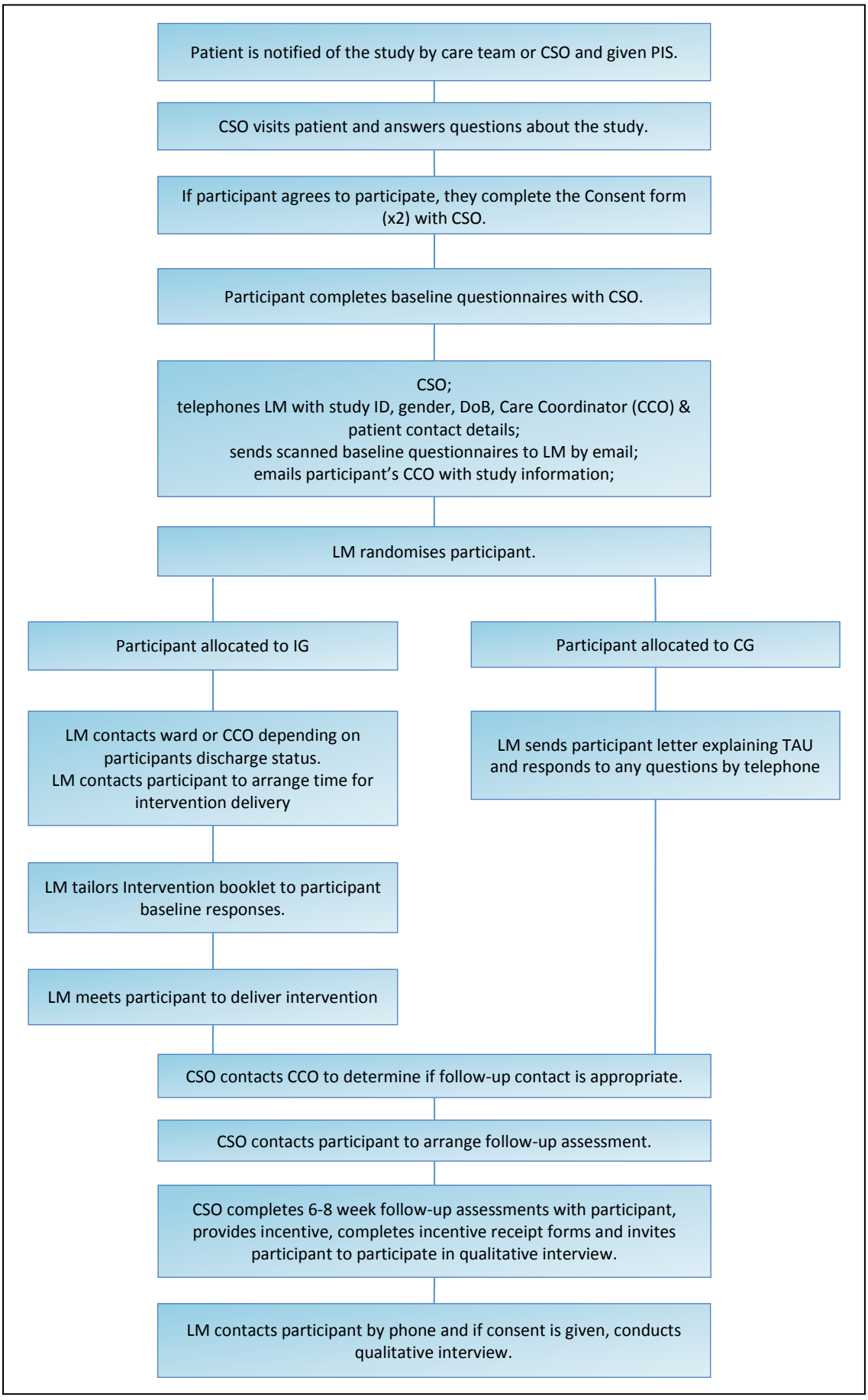


Figure 6.1: IBiD procedure

6.4.13 Fidelity assessment

It was deemed inappropriate to audio-record the intervention delivery. In consultation with mental health professionals and service-user representatives it was judged that participants may have been unwilling to disclose their thoughts, feelings and behaviour surrounding their condition, treatment and interactions with health care professionals if the interactions were recorded. Therefore steps were taken to capture information on fidelity to intervention. Each intervention booklet was tailored according to specific tailoring syntax using IBM SPSS Statistics 21 (described in Chapter 5). This ensured that all tailoring was conducted consistently. After each appointment, detailed field notes were made which described the researchers general impressions of the session, the sections covered and not covered, any issues discussed which are not covered by the resource and participants engagement with the intervention. These reflections are, however, subject to memory effects and bias on the part of the researcher.

6.4.14 Follow-up procedure

After 6 weeks, CCOs were contacted to ensure that it was appropriate to contact the participant. Appointments were made with participants at a suitable location to conduct the assessments, either participants' homes or community mental health centres. Completion of the follow-up assessment followed the same procedure as the baseline assessments. On completion of the follow-up assessments participants received £20 as a thank-you for their participation in the study. Participants were asked if they wished to receive a copy of the results of the study when they became available and this information was recorded.

6.4.15 Interview with Clinical Studies Officer

After the last participants had completed follow-up assessments, a face to face interview with the CSO who was most involved with the IBiD study was conducted in order to gain qualitative data on the study process. The interview was not audio-recorded as such no verbatim quotes are available. Notes taken during the interview were checked by the CSO as being an accurate reflection of the conversation and additional points were added where necessary. The interview covered the following areas, but was flexible in or to allow for any additional pertinent issues to be raised;

- Study set-up
- Recruitment, challenges and positives

- Usefulness of study materials
- Contacts and communication with ward staff, care coordinators and study staff.
- Conducting baseline assessments – challenges and positives
- Follow-up assessments, challenges and positives
- Overall reflections on the study
- Suggestions for improving IBiD

6.5 Data processing and quantitative analysis

Questionnaire data was organised and analysed using SPSS version 21. Descriptive statistics were used to determine recruitment and retention rates, to describe the demographic and clinical characteristics of the sample and determine the need for an intervention by examining baseline assessments for the whole sample.

Although the present study focussed on feasibility outcomes, exploratory analysis was conducted on the outcome measures, however, with the understanding that the study is underpowered to detect significant effects. Paired-sample t-tests were used to examine changes between assessment points for the IG and TAU separately. In addition, to explore differences between groups at follow-up, controlling for baseline measure, ANCOVA were performed. In powered-trial conditions in a definitive trial, the data would need to be tested for the following assumptions; normality using histograms and measures of skewness and kutosis, multicollinearity, homogeneity of variance and homogeneity of regression slopes. As appropriate, non-parametric tests would be selected where available.

6.6 Results

The results section comprises four subsections; a description of the characteristics of the sample recruited; an assessment of the need for intervention from baseline measures; quantitative data on the feasibility and acceptability of the RCT protocol and IBiD intervention, qualitative data from the CSO interview; an exploratory assessment of the baseline and follow-up assessments in order to test the data analysis protocol.

6.6.1 Sample characteristics

6.6.1.1 Demographic characteristics

Between June 2013 and January 2014, 30 participants were recruited (sample characteristics in Tables 6.4 & 6.5 for the 29 participants who completed baseline assessments). Participants mean age in the IG was 51.7 (10.93) years and 51.4 (11.81) years in the TAU, the majority were female and of White British ethnicity. There were no significant differences between groups in terms of their baseline demographic characteristics.

6.6.1.2 Clinical characteristics

Participants had been diagnosed with bipolar on average for six and a half (IG) or seven (TAU) years. In terms of recentness of diagnosis, only six participants were diagnosed less than a year previously. The only significant difference between IG and TAU was in their history of voluntary admissions with a higher proportion of IG participants having had voluntary admissions, χ^2 (1, n=29) = 5.66, p=.017. With regards to measures of current affective state, both scales demonstrated good reliability (ASRM α=.801, BDI-II α=.926). In total, 40% of participants had indications of a possible manic state at baseline and 42% showed signs of a moderate to severe depressive state.

Table 6.4: Sample socio-demographic characteristics

	Total (n=29)	**IG (n=14) n (%)**	**TAU (n=15) n (%)**	**p**
Age at baseline				
Mean (sd)	52 (11.0)	51.71 (10.93)	51.40 (11.81)	.941
Median (IQR)	52 (44-61)	52 (43-59)	54 (44-64)	
Gender				
Female	20 (69.0)	10 (71.4)	10 (66.7)	.782
Ethnicity				
White British	22 (75.9)	11 (78.6)	11 (73.3)	.538
White Irish	1 (3.4)	-	1 (6.7)	
White other	5 (17.2)	3 (21.4)	2 (13.3)	
Mixed ethnicity	1 (3.4)	-	1 (6.7)	
Relationship status				
Single	12 (41.4)	5 (35.7)	7 (46.7)	.276
Married/ Civil partnership/Cohabiting	7 (24.1)	4 (28.6)	3 (20.0)	
Divorced/ Separated	6 (20.7)	2 (14.4	4 (26.7)	
Widowed	3 (10.3)	3 (21.4)	-	
Other	1 (3.4)		1 (6.7)	
Highest level of education				
No qualifications	2 (6.9)	2 (14.3)	-	.124
O levels/CSEs/GSCEs	6 (20.7)	4 (28.6)	2 (13.3)	
Vocational education	5 (17.2)	3 (21.4)	2 (13.3)	
Degree	7 (24.1)	4 (28.6)	3 (20.0)	
Higher degree	6 (20.7)	1 (7.1)	5 (33.3)	
Professional qualifications	3 (10.3)	-	3 (20.0)	

Table 6.5: Sample Clinical characteristics

	Total (n=29)	**IG (n=14) n (%)**	**TAU (n=15) n (%)**	**p**
Age of BD diagnosis (approx)				
Mean (sd)	41.41 (13.26)	39.50 (12.16)	43.07 (14.35)	.488
Median (IPQ)	37 (31.5-51.5)	37.00 (33.5-48)	38.00 (31-56)	
Number of years since first bipolar diagnosis (approx)				
Mean (sd)	9.89 (10.79)	11.55 (12.64)	8.46 (9.11)	.461
Median (IPQ)	6.5 (2-14)	7.00 (2.5-15)	6.00 (2-13)	
Current admission				
Voluntary	13 (44.8)	6 (42.9)	7 (46.7)	.837
Involuntary/ Detained	16 (55.2)	8 (57.1)	8 (53.3)	
Current psychotic symptoms (yes)	11 (37.9)	6 (42.9)	5 (33.3)	.581
N psychiatric medications				
Mean (sd)	3 (1)	3 (1)	3 (1)	.708
Median, range	3 (2-3)	3 (2-4)	3 (2-3)	
Previous admissions				
Voluntary admissions (yes)	21 (72.4)	13 (92.9)	8 (53.3	.017*
Involuntary/ Detained admissions (yes)	23 (79.3)	12 (85.7)	11 (73.3)	.411
N previous manic episodes				
1-2	7 (24.1)	3 (21.4))	4 (26.7)	.775
3-4	12 (41.4)	7 (50.0)	5 (33.3)	
5-6	2 (6.9)	1 (7.1)	1 (6.7)	
7+	6 (20.7)	2 (14.3)	4 (26.7)	
Not reported	2 (6.9)	1 (7.1)	1 (6.7)	
N previous episodes depression				
0	6 (20.7)	4 (28.6)	2 (13.3)	.106
1-2	4 (13.8)	3 (21.4)	1 (6.7)	
3-4	6 (20.7)	-	6 (40.0)	
5-6	5 (17.2)	2 (14.3)	3 (20.0)	
7+	6 (20.7)	3 (21.4)	3 (20.0)	
Not reported	2 (6.9)	2 (14.3)	-	
Family history of bipolar				
Yes	14 (48.3)	6 (42.9)	8 (53.3)	.632
No	12 (41.4)	7 (50.0)	5 (33.3)	
Unknown	3 (10.3)	1 (7.1)	2 (13.3)	
ASRM Scale				
Mean (sd)	5.62 (4.71)	7.14 (4.91)	4.20 (4.18)	.093
Median IQR	5 (2-9)	8.00 (4-10)	3.00 (1-6)	
No indication of mania	17 (58.6)	6 (42.9)	11 (73.3)	.096
Possible manic state indicated	12 (41.4)	8 (57.1)	4 (26.7)	
*BDI-II **				
Mean (sd)	17.35 (12.62)	15.17 (10.74)	19.21 (14.15)	.426
Median (IQR)	15 (7-25)	14.50 (6.5-23)	17.00 (7-28)	
Minimal depression	13 (50.0)	6 (50.0)	7 (50.0)	
Mild depression	2 (7.7)	2 (16.7)	-	.379
Moderate depression	7 (26.9)	3 (25.0)	4 (28.6)	
Severe depression	4 (15.4)	1 (8.3)	3 (21.4)	

*n=26 as unable to compute total scores due to missing items (prorated scores not recommended)

6.6.2 Need for the intervention – an assessment of baseline measures

The baseline measures for the whole sample (n=29) on information dissatisfaction, treatment and illness perceptions and internalised stigma provide an assessment of the need for an intervention.

6.6.2.1 Beliefs about illness

6.6.2.1.1 Brief IPQ

Table 6.6 presents the results from the Brief IPQ, and it can be seen that beliefs in personal control over BD were low (Mdn=4, IQR=3-7). BD had a severe effect on participants lives (Mdn=8, IQR=7-10) and strong emotional consequences (Mdn=7, IQR=5-9).

The proportion of participants who reported higher or lower beliefs in the Brief IPQ items was calculated to provide an indication of how many participants might have beliefs not conducive to adherence. 62% reported low personal control, 62% experience higher levels of symptoms, 69% reported higher feelings of emotional affect due to bipolar and 59% reported higher levels of concern. 31% were judged to have acute timeline beliefs, 31% reported low treatment control and 31% report lower levels of understanding. Twenty-one percent reported low agreement with their diagnosis.

Table 6.6: Brief-IPQ descriptive statistics (n=29)

IPQ item	Mean (sd)	Median (IQR)	<6 n (%)	>5 n (%)
Consequences - How much does bipolar affect your life?	7.53 (2.76)	8.00 (7-10)	5 (17.2)	24 (82.8)
Timeline - How long do you think your bipolar will continue?	7.45 (3.09)	8.00 (5-10)	9 (31.0)	20 (69.0)
Personal control - How much control do you feel you have over your bipolar?	4.53 (3.10)	4.00 (3-7)	18 (62.1)	11 (37.9)
Treatment control - How much do you think your treatment can help your bipolar?	6.97 (2.67)	7.00 (5-9)	9 (31.0)	20 (69.0)
Identity - How much do you experience symptoms from bipolar?	6.07 (3.32)	7.00 (4-9)	11 (37.9)	18 (62.1)
Concern - How concerned are you about your bipolar?	6.26 (3.24)	6.00 (5-9)	12 (41.4)	17 (58.6)
Understanding - How well do you understand your bipolar?	6.62 (3.35)	7.00 (4-10)	9 (31.0)	20 (69.0)
Emotional response - How much does your bipolar affect you emotionally? (e.g. does it make you angry, scared, upset?)	6.59 (3.16)	7.00 (5-9)	9 (31.0)	20 (69.0)
Identity - How much do you agree with your diagnosis?	7.39 (3.31)	8.00 (7-10)	6 (21.4)	22 (78.6)

6.6.2.1.2 Illness Identity

In terms of BD identity, almost all (93%) participants reported that the term Bipolar Disorder had been used to describe their mental health problems. The terms used are presented in Table 6.7 and the number of terms used to describe participants mental health problems ranged between 2 and 7, most participants had four or five terms applied (n=8 for both four and five terms).

Participants generally agreed with the terms applied to their mental health problems. Only five out of 27 disagreed or were uncertain about whether the term Bipolar Disorder applied to them. Seven participants (out of 19) who had had the term Mania applied to them disagreed or were uncertain about this. Six (out of 16) who had had the term Psychosis applied to them disagreed or were uncertain about this. In terms of participants own definitions of their mental health problems, 19 participants stated 'Bipolar'/ 'Bipolar Disorder'/ 'Manic Depression', three stated 'Depression'. Other non-diagnostic terms used included; 'physical ailments – no mental health problems', 'Vulnerable', 'Extra sensory perception' and 'Grieving issues' (all n=1).

Table 6.7: Terms used by HCPs to describe participants mental health problems (n=29)

Term	**n (%)**
Bipolar disorder	27 (93.1)
Depression	20 (69.0)
Anxiety	20 (69.0)
Mania	19 (65.5)
Psychosis	16 (55.2)
Manic Depression	13 (44.8)
Schizoaffective	4 (13.8)
Other [a]	11 (*37.9)*

[a] Borderline personality disorder, 'Traits' only, High, Hypomania, Mental illness, Paranoia, Religious mania, Schizoidpremature child, Schizophrenia - past diagnosis, Obsessive Compulsive disorder, Stress (n=2).

6.6.2.1.3 Perceived cause of BD

The most frequently endorsed prompted causes of participants BD (Table 6.8) were stress or worry (n=27) and family problems or worries (n=24). Participants identified the most important causes of bipolar for them (up to three), the most common were; Stress/ anxiety/ worry (n=16), Family/ relationship issues (n=9), Emotional state (n-9). The most important maintaining factors were Stress/ worry (n=11), Poor healthcare/ support from professionals (n=8), Stopping/ remembering medication (n=5) and Negative thinking/ over thinking (n=5).

Table 6.8: Participants agreement with causes of their BD

	Agree n (%)	Uncertain n (%)	Disagree n (%)
Stress or worry	27 (93.1)	2 (6.9)	-
Family problems or worries	24 (82.8)	1 (3.4)	4 (13.8)
My emotional state e.g. feeling down, lonely, anxious	20 (69.0)	1 (3.4)	8 (27.6)
Hereditary it runs in my family	18 (62.1)	4 (13.8)	7 (24.1)
Overwork	18 (62.1)	2 (6.9)	9 (31.0)
My personality	17 (58.6)	4 (13.8)	8 (27.6)
Chemical Imbalance	16 (55.2)	10 (34.5)	3 (10.3)
My mental attitude e.g. thinking about life negatively	12 (41.4)	3 (10.3)	14 (48.3)
My own behaviour	11 (37.9)	5 (17.2)	13 (44.8)
Chance or bad luck	9 (32.1)	1 (3.6)	18 (64.3)
Pollution in the environment	8 (27.6)	2 (6.9)	19 (65.5)
Ageing	7 (24.1)	4 (13.8)	18 (62.1)
Alcohol	6 (21.4)	2 (7.1)	20 (71.4)
Diet or eating habits	5 (17.2)	2 (6.9)	22 (75.9)
Accident or injury	5 (17.2)	4 (13.8)	20 (69.0)
Recreational drugs e.g. cannabis, cocaine, ecstasy	4 (13.8)	4 (13.8)	21 (72.4)
Poor medical care in my past	3 (10.3)	4 (13.8)	22 (75.9)
Smoking	2 (6.9)	3 (10.3)	24 (82.8)
A Germ or virus	1 (3.4)	3 (10.3)	25 (86.2)

Table 6.9: Medications prescribed at baseline

	n (%)
Atypical anti-psychotics	25 (86.2)
Mood stabilisers	20 (69.0)
Benzodiazepines	10 (34.5)
Sleeping tablets	6 (20.7)
Typical anti-psychotics	4 (13.8)
Anti-depressants	4 (13.8)
Other medications	2 (6.9)
SSRI	1 (3.4)
SNRI	1 (3.4)

6.6.2.2 Medications prescribed at baseline

Participants were prescribed, a median of three medications at baseline (IQR=2-3). The most commonly prescribed medications were two atypical anti-psychotics (ATAP) Quetiapine and Olanzapine (n=11 for both). Twenty-five participants were prescribed ATAPs and 20 were

prescribed mood stabilisers (most commonly Valproate, n=10) (Table 6.9). Some participants were prescribed more than one type in any one class of medication For example two ATAP, mood stabilisers or two or more Benzodiazapines.

6.6.2.3 Beliefs about treatment

6.6.2.3.1 General beliefs about medication

The BMQ general scales demonstrated adequate reliability in this sample at baseline (Overuse scale α=.70, Harm scale α=.68). Participants' general beliefs about medication at baseline demonstrated high levels of Overuse beliefs, 23 (79%) reported high beliefs about the overuse of medicines and the mean score was 3.75 (SD 0.98) out of a maximum score of 5. Levels of general harm beliefs about medication were lower, only seven (24%) participants reported high harm beliefs the mean score was 2.64 (SD 0.75) out of a maximum score of 5.

6.6.2.3.2 Practical barriers to taking medication

Almost all participants reported at least one practical obstacle to taking medication (n=27). Twelve participants reported experiencing four or more obstacles, the most common were; to get the best from their care team (52% always, often or sometimes find it difficult), and to remember to take their medication when their daily routine changes (48% sometimes or often find it difficult) (Table 6.10).

6.6.2.3.3 Specific beliefs about medication prescribed for BD

Due to the variability in medication regimens and the fact that participants were often taking more than one medication within a particular class, BMQ necessity and concerns scores for the most commonly prescribed medications are presented (Table 6.11).

Twenty-three (79.3%) participants had low necessity beliefs about at least one medication they were prescribed, 19 (65.5%) had high concerns about at least one medication. The average number of medications with high concerns was 2 (IQR=0-3) and with low necessity was 2 (IQR=0.5-3). 38% of participants had high concerns and the same proportion had low necessity beliefs about all of the medications they were prescribed.

Table 6.10: BMQ Practical barriers n (%)

	Always n (%)	Often n (%)	Sometimes n (%)	Rarely n (%)	Never n (%)
I find it difficult to remember to take my medication when my daily routine changes	-	1 (3.7)	12 (44.4)	2 (7.4)	12 (44.4)
I find it difficult to remember to take my medication when my regimen (treatment plan) changes	-	1 (3.7)	6 (22.2)	8 (29.6)	12 (44.4)
I find it difficult to keep track of when I need to take each medicine	-	1 (3.6)	6 (21.4)	6 (21.4)	15 (53.6)
I find it difficult to remember to take my medicines every day	-	-	3 (10.7)	7 (25.0)	18 (64.3)
I find it difficult to cope with the costs of medicines	2 (6.9)	2 (6.9)	1 (3.4)	3 (10.3)	21 (72.4)
I find it difficult to know when to get a further supply when my prescription runs out	-	2 (7.7)	5 (19.2)	3 (11.5)	16 (61.5)
I find it difficult to travel or go on holidays	4 (14.3)	2 (7.1)	4 (14.3)	2 (7.1)	16 (57.1)
I find it difficult to swallow my tablets	3 (10.3)	1 (3.4)	3 (10.3)	4 (13.8)	19 (62.1)
I find it difficult to get the best from my care team	3 (10.3)	4 (13.8)	8 (27.6)	5 (17.2)	9 (31.0)
I find it difficult to get information about my medicines	2 (6.9)	3 (10.3)	5 (17.2)	5 (17.2)	14 (48.3)

Table 6.11: BMQ necessity and Concerns beliefs for the most commonly prescribed medications

	High necessity n (%)	Low necessity n (%)	High concerns n (%)	Low concerns n (%)	Total n
Valproate	5 (45.45)	6 (54.55)	3 (27.27)	8 (72.73)	11
Quetiapine	7 (63.64)	4 (36.36)	5 (45.45)	6 (54.55)	11
Olanzapine	5 (45.45)	6 (54.55)	6 (54.55)	5 (45.45)	11
Lithium	7 (87.50)	1 (12.50)	1 (12.50)	7 (87.50)	8
Sleeping tablets	2 (33.33)	4 (66.67)	2 (33.33)	4 (66.67)	6
Risperidone	5 (100.00)	0 (0.00)	1 (20.00)	4 (80.00)	5
Lorazepam/ Diazepam/ Valium	3 60.00 ()	2 (40.00)	4 (80.00)	1 (20.00)	5

6.6.2.4 Adherence to medication (VAS & MARS)

The median percentage of medications taken (VAS) ranged between 90-100% (IQR=80-100) (See Table 6.12 for average MARS scores). The MARS data for the most commonly prescribed medications (prescribed to ten or more participants),showed that 60% of participants were classified as having high adherence (a score of 23 or more) to Benzodiazepines, 64% to Valproate, and 71% to Lithium. Thirteen participants had low MARS adherence scores for at least one medication they were prescribed. Two participants had low adherence for three medications.

Table 6.12: MARS median scores for most common medications prescribed

	n	Mdn (IQR)
Valproate	11	24 (21-25)
Quetiapine	11	25 (25-25)
Olanzapine	11	25 (23-25)
Lithium	7	24 (22-25)
Sleeping tablets	6	25 (21-25)

6.6.2.5 Symptoms and side-effects experienced

Commonly experienced symptoms or side-effects included restlessness (n=25), difficulty concentrating (n=23), feeling apprehensive, fearful or anxious (n=22), dry mouth (n=21), and tiredness (n=21) (Table 6.13). Participants reported experiencing a median of 15 symptoms (IQR=10-19), and a median of 12 at a moderate to severe level (IQR=6-15). In terms of symptom attribution more symptoms were attributed to medication (median 8, IQR=3-12), than to BD (median 5, IQR=1-7). Common symptoms attributed to medication experienced at a moderate to severe level were dry mouth (n=10), tiredness (n=10) and sedation (n=10).

Table 6.13: Symptom reporting

	Median (IQR)
Total number of symptoms reported	15 (10-19)
Total number of symptoms reported (Moderate to very severe)	12 (6-15)
Total number of symptoms attributed to BD	5 (1-7)
Total number of symptoms attributed to medication for BD	8 (3-12)
Total number of symptoms with unknown attribution	0 (0-1)

6.6.2.6 Satisfaction with information about medication

Both SIMS subscales demonstrated good reliability (Action and Usage α=.868, Potential problems of medication α=.809). Median SIMS scores were 7 (IQR=2-12) out of a possible 17 (higher scores indicating greater degree of satisfaction). For the Action and Usage subscale the median was 4 (IQR=2-8) and for the Potential Problems was 3 (IQR=1-5) (Table 6.14). Overall 59% (n=17) of participants were satisfied with less than 9 items and 72% (n=21) were satisfied with less than five of the Potential Problems items.

Looking at individual SIMS items, highest levels of dissatisfaction were reported in 'Whether the medicine will interfere with other medicines' (n=23), 'Whether the medication will affect your sex life' (n=21) (Table 6.15).

Table 6.14: Mean and median SIMS scores

	Mean (sd)	Median (IQR)
SIMS Score	7 (5)	7 (2-12)
SIMS Action & Usage scale	4 (3)	4 (2-8)
SIMS Potential problems of medication scale	3 (2)	3 (1-5)

Table 6.15: Proportion of participants satisfied and dissatisfied with SIMS scale items

	Dissatisfied n (%)	Satisfied n (%)
Whether the medicine will interfere with other medicines	23 (79.3)	6 (20.7)
Whether the medication will affect your sex life	21 (72.4)	8 (27.6)
How long you need to be on the medicine	20 (69.0)	9 (31.0)
Whether the medicine will have any unwanted effects (side effects)	20 (69.0)	9 (31.0)
How you can tell if they are working	19 (65.5)	10 (34.5)
What are the risks of you getting side effects	19 (65.5)	10 (34.5)
What you should do if you experience unwanted side effects	19 (65.5)	10 (34.5)
How long they take to act	18 (62.1)	11 (37.9)
What these medicines are for	17 (58.6)	12 (41.4)
How they work	17 (58.6)	12 (41.4)
What you should do if you forget to take a dose	16 (55.2)	13 (44.8)
Whether the medication will make you feel drowsy	15 (51.7)	14 (48.3)
If you can drink alcohol whilst taking this medicine	13 (44.8)	16 (55.2)
What they do	12 (41.4)	17 (58.6)
What the medicines are called	10 (34.5)	19 (65.5)
How to use them	10 (34.5)	19 (65.5)
How to get a further supply	9 (31.0)	20 (69.0)

6.6.2.7 Internalised stigma (ISMI)

The ISMI scale and subscales demonstrated adequate to good reliability (ISMI 29 items α=.865, ISMI 24 items excluding Stigma Resistance α= 929, ISMI Alienation α=.892, ISMI Stereotype Endorsement α=.851, ISMI Discrimination Experience α=.745, ISMI Social Withdrawal α=.829, ISMI Stigma Resistance α=.698). Only around one quarter of participants reported at least moderate internalised stigma (using the 24 item scale) (n=8). However, for the subscales, 45% reported moderate or severe 'Alienation', 48% moderate or severe 'Discrimination Experience' (Table 6.16).

Table 6.16: Responses to the ISMI scale – levels of internalised stigma

	Minimal to none n (%)	Mild n (%)	Moderate n (%)	Severe n (%)
ISMI score	10 (34.5)	12 (41.4)	7 (24.1)	-
ISMI score (excluding Stigma resistance subscale)	9 (31.0)	12 (41.4)	7 (24.1)	1 (3.4)
ISMI Alienation	10 (34.5)	6 (20.7)	11 (37.9)	2 (6.9)
ISMI Stereotype Endorsement	22 (75.9)	6 (20.7)	1 (3.4)	-
ISMI Discrimination Experience	6 (20.7)	9 (31.0)	10 (34.5)	4 (13.8)
ISMI Social Withdrawal	12 (41.4)	8 (27.6)	9 (31.0)	-
ISMI Stigma Resistance	20 (69.0)	7 (24.1)	2 (6.9)	-

6.6.3 Feasibility of the IBiD RCT

6.6.3.1 Recruitment

Out of the eligible 145 patients, 44.8% (n=65) were approached. The main reasons for not approaching those eligible were that they were discharged before it was possible to visit the ward (n=55), or that they were too unwell (n=24) (Figure 6.2). Of the 65 approached, 46.2% agreed to participate (n=30). The main reasons why participants were not recruited after being initially approached were; unable to make contact once they were discharged (n=16) and not being interested in the study (n=10).

6.6.3.2 Retention

The overall follow-up rate at 6-8 weeks was 72% (n=21), (IG=67%, TAU=73%). The main reason for withdrawal was illness relapse (n=4) (Figure 6.2). One participant consented to participate, was allocated to the IG, subsequently was withdrawn as during completion of the baseline assessments (over two sessions), they suffered a relapse.

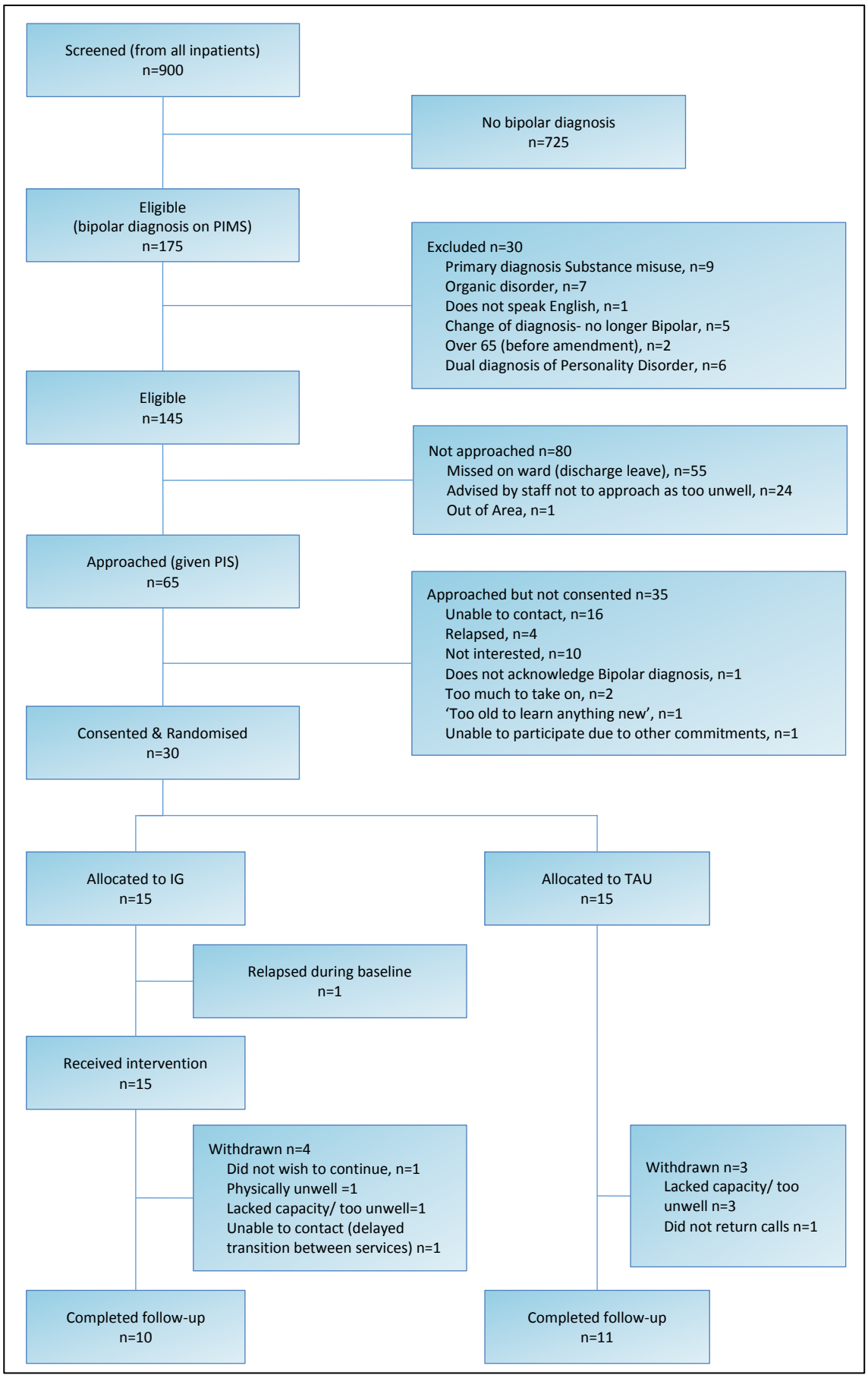


Figure 6.2: Flow diagram of screening, recruitment and retention

6.6.3.3 Allocation concealment & Blinding

The CSO who was recruiting participants did not have access to the minimisation criteria or the allocation of prior participants. Therefore they would be concealed from being able to determine the allocation of subsequent participants. There were four instances of unbinding which may have had an impact on the results, all in the IG. Participants either brought their booklet to the follow-up assessment or mentioned it to the CSO. Two additional participants' allocation became revealed, however, they did not complete follow-up assessments due to illness relapse so unblinding was not an issue.

6.6.3.4 Protocol deviations - Time between baseline and intervention

It was intended that interventions would be completed within the shortest possible time frame after baseline assessment. In practice, a number of factors resulted in a delay for some participants (Table 6.17). The median number of days between baseline and intervention was six (range 2-20).

Table 6.17: Reasons for delays in conducting Interventions

	Delay (working days)	Reason
EA01	6 days	Participant on day leave and we were advised to call back after ward rounds later in the week.
EB09	4 weeks	Seen on ward then found out was RSO after discharge so sought advice about appropriateness for inclusion in terms of risk and meeting in community. Negotiated with CCO, pt was transferred between different temporary accommodation so advised to contact when settled. Took time to book room in community setting.
CO10	4 weeks	Participant went on holiday shortly after discharge. CCO advised to contact once back and settled.
WM12	8 days	Pt on leave and arranged to see on ward when coming in for other appointment as most convenient for pt.
HC15	9 days	Pt seen at home for baseline and intervention. Appointment arranged at convenience of pt.
WM25	9 days	Discharged from ward just after baseline and moved area and no continuity with CCO. Tried to sort out CCO issue before seeing. Then arranged with pt to see in Community at a time they were going to be at location. Unsuitable for home visit.
HC26	7 days	Arranged at home at convenience of pt.
WL27	7 days	Pt on extended overnight leave. Not appropriate to visit at home. Appointment re-arranged to fit in with returning to ward.

6.6.3.5 Process – Timing and location of assessments

The majority of baseline assessments were completed in one session (n=23), five participants completed them over two sessions and one over three sessions due to fatigue. All follow-up assessments took one session to complete. At baseline the majority of assessments took place on the ward (n=22), five took place in participants homes and two took place in Community Mental Health centres on the advice of CCOs. At follow-up, the majority of assessments took place in participants homes (n=17), three in Community mental health centres and one on the ward as this participant was still awaiting housing.

6.6.3.6 Acceptability of baseline questionnaires

The questionnaire appeared to be acceptable to participants, almost all agreed it was interesting to complete (93%) and helped them to reflect on bipolar (82%). However, 14% agreed that it was difficult to understand and 18% that it made them upset. In terms of questionnaire length, 78% agreed that the amount of questions was about right, however, 21% felt it took too long to complete (Table 6.18).

Table 6.18: Opinions on completing the baseline assessments, n (%) (Shaded statements=negatively phrased questions)

	Strongly Disagree n (%)	**Disagree n (%)**	**Uncertain n (%)**	**Agree n (%)**	**Strongly Agree n (%)**
The questionnaire was interesting to complete	1 (3.6)	-	1 (3.6)	14 (50.0)	12 (42.9)
The questionnaire helped me to reflect on bipolar	2 (7.1)	3 (10.7)	-	13 (46.4)	10 (35.7)
The questionnaire made me upset	9 (32.1)	11 (39.3)	3 (10.7)	3 (10.7)	2 (7.1)
The questionnaire was difficult to understand	6 (21.4)	15 (53.6)	3 (10.7)	4 (14.3)	-
The amount of questions was about right	-	4 (14.8)	2 (7.4)	15 (55.6)	6 (22.2)
The questionnaire was not relevant to me	12 (42.9)	14 (50.0)	1 (3.6)	-	1 (3.6)
The questionnaire was easy to understand	-	3 (10.7)	2 (7.1)	16 (57.1)	7 (25.0)
I would recommend the questionnaire to others	-	-	2 (7.1)	19 (67.9)	7 (25.0)
The questionnaire took too long to complete	5 (17.9)	15 (53.6)	2 (7.1)	4 (14.3)	2 (7.1)

6.6.3.7 Intervention process

Intervention sessions lasted on average for just over one hour (67 mins, range 40-90 minutes). Eight participants were seen on the ward, four were seen at home and two in a Community mental health centre.

6.6.3.8 Interview with CSO – feedback on IBiD set-up, recruitment and assessments

Results from the interview with the CSO are summarised in Table 6.19. Challenges were presented by the ward environment including changing staff shift patterns, ward incidents and covering the large geographical area. Facilitators for study delivery, recruitment and retention included engaging all staff through existing team meetings, identifying a key individual within wards, maintaining good communication with CCOs from the outset, and having the flexibility to conduct assessments at participants' homes.

Table 6.19: CSO feedback on IBiD

Setting up IBiD in the study sites
• It was sometimes challenging to ensure that the study information was communicated to all staff due to shift-patterns. It was difficult to ensure that information we left was distributed to the whole team. • The most effective way to communicate was by attending team meetings, this worked well and staff were interested in the study and knew what their role would be.
Recruitment
• It was often challenging to actually get onto the wards due to incidents (e.g. violence or harm) meaning all staff were busy dealing with this. • Wards are extremely busy and it was often difficult to speak with members of staff. • Different teams had differing levels of involvement with IBiD, some would identify eligible patients and introduce the CSO to facilitate recruitment. Others were happy for her to approach patients directly without much involvement. • Some wards had almost no-one with a bipolar diagnosis on the ward at the time of the study. Some staff reflected that this was just unlucky as at other times they would have had eligible patients. • Recruiting patients once they had been discharged was challenging. Patients expressed interest on the ward and then were discharged quickly with very little notice before CSO could meet them. At this point it was difficult to try and negotiate recruitment through crisis teams and CCOs. • Recruitment on the wards and notifying the CCO in the community was the best strategy. • Overall challenges with the study were covering all the sites as this took a lot of time. There were often wasted journeys if it was not possible to actually get on the ward at the time of visiting.
Assessing eligibility
• When assessing eligibility and ability of patients to participate in the study, ward staff assessed their ability to make informed consent and assessed that patients were significantly improved in terms of their wellness from when they were admitted. However, this did not always

correspond to whether they were well enough to complete the study assessments. When the CSO went to try and recruit some patients, assessed as able to consent, it was clear they would have struggled with the assessments.
Communication with ward staff
• The amount and quality of contacts with ward staff was variable depending on how much time they had or were interested in research. • Most successful recruitment was from sites where a particular member of staff such as the ward manager, or a consultant psychiatrist was really engaged.
Communication with community care teams
• Informing the CCOs that a patient under their care was participating in the study (by email or letter) was a good strategy and kept them informed and included. This was really appreciated by CCOs as it is not often done in other studies. This set up good communication and facilitated making follow-up contact with participants.
The research process
• Control group participants – when contacting for follow-up weren't always sure of their treatment allocation or couldn't remember being told what would happen next. It could be that they didn't read the letters that we sent, or that in sending them c/o the CCO, they might have got lost in transit. • CSO blinding – despite the CSO asking participants not to disclose when she contacted them, some participants still brought their booklets to the meeting, or had them visible in the home. • One risk incident occurred where the CSO was not informed about one participant being on the Sex Offenders Register. As such this was only discovered once the participant had been recruited. Communication with the care coordinator ensured that risk was managed and the participant was met only at Community Mental Health premises. • Patients were frequently given leave at short notice and so were not on the wards at arranged times. Also they were discharged with very short notice making it challenging to meet with them.
Conducting baseline assessments
• Only a couple of participants reported to the CSO that it was too long. • There was sometimes not an option for participants to give a response which meant most to them. What they wanted to say did not fall into the options available. • Participants would have liked more qualitative space to give their thoughts. • Things which the participants felt were missing from the questionnaire were 'lifestyle' and views on other 'treatments' or therapies in bipolar not just medication. • Participants found completing the questionnaire interesting and for some it was the first time they had really talked about bipolar.
Conducting follow-up assessments
• Follow-up assessments were generally straightforward to arrange. Often CCOs wanted to check with participants themselves before agreeing that the CSO could contact them. This seemed to work ok and the response rate was good. • The CSO found follow-up assessments easier to complete as participants were in their homes and were more stable.

6.6.4 Exploratory analysis of IBiD outcome measures

6.6.4.1 Medications prescribed

Data was collected for each medication prescribed at baseline and follow up. A descriptive assessment of medications prescribed at baseline and follow-up revealed that in the TAU

group 3/11 and in the IG 5/10 stayed on the same medications at each time point. The medication changes are summarised in Table 6.20 for participants who were retained at follow-up. Medication changes were common at this time of discharge from acute services to community teams. Data was not collected on reasons for medication changes.

6.6.4.2 Medication beliefs & adherence to medication

Detailed statistical analysis of the BMQ, MARS and VAS data for individual medications is beyond the scope of this feasibility study as it was not powered to detect changes. In addition heterogeneity in medication regimens mean that there were very small numbers prescribed each type of medication at both assessment points, and participants were prescribed more than one medication in a particular class. Instead, data on medication perceptions and adherence at each time point is reported descriptively and summarised in Tables 6.21 and 6.22. This demonstrates the complex nature of assessing and analysing medication perceptions and adherence at this time.

Table 6.20: Medication changes between baseline and follow-up

TAU participants	**Medication changes**
HC03	Stopped Rispeidone & Halperidol Started Promethazine & Palipiridone (depot)
WM13	Stopped Diazepam Started Olanzapine
MR17	Started Quetiapine
CO18	Stopped Chlorpromazine & Simvastatin (cholersterol)
HM20	Stopped Mirtazapine
HC22	Started Lamotrigine
EB23	Started Aripiprizol
HC28	Started Quetiapine Stopped Haoperidol, Zopiclone, Promethazine, Clonazepam
IG participants	**Medication changes**
EB09	Stopped Olanzapine Started Valproate & Sertraline
CO10	Stopped Clonazepam
HC24	Stopped Olanzepine, Zopiclone. Started Paliperidone (depot)
HC26	Started Diazepam. Stopped Haloperidol, Clonazepam
WR27	Stopped Lorazepam, Zolpidem

Table 6.21: Intervention group treatment beliefs and adherence data (B=baseline, FU= follow-up, h=high, l=low) (MS= mood stabilisers, ATAP= Atypical antipsychotic, SSRI= Selective serotonin uptake inhibitors)

Pt	**Medications (B=baseline) (FU=follow-up)**	**BMQ Necessity (baseline-follow-up)**	**BMQ Concerns (baseline-follow-up)**	**MARS (baseline-follow-up)**	**VAS (baseline-follow-up)**	**Summary of changes**
EB09	Olanzapine B	h	l	h	100	Retained positive MS perceptions, but decreased adherence. Discontinued ATAP. Started SSRIs with positive perceptions.
	Valproate – Depakote B&FU	h-h	l-l	h-l	100-90	
	Sertraline FU	h	l	h	90	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
CO10	Valproate – new B &FU	h-l	l-l	h-l	100-90	Reduced necessity and adherence for MS. Reduced positive perceptions for ATAP.
	Olanzapine B &FU	h-l	l-h	h-h	100-90	
	Clonazepam B	l	l	h	100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
WM12	Lithium B &FU	h-h	l-l	h-h	100-100	Retained positive MS and ATAP (x2) perceptions and adherence. Retained poor benzo perceptions and adherence.
	Quetiapine B &FU	h-h	l-l	h-h	100-100	
	Diazepam B &FU	h-l	h-h	l-l	35-50	
	Amisulpiride B &FU	h-h	l-l	h-h	100-100	
	Pramipectal – (side effects) B &FU	h-??	L - ??	n/a	n/a	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC15	Valproate new B & FU	l-l	l-h	h-h	100-95	Reduced and retained positive perceptions of MS and ATAP.
	Quetiapine –new B & FU	h-l	h-h	h-h	100-100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC16	Olanzapine B & FU	l-h	l-l	h-h	100-100	Increased necessity for ATAP. Retained adherence.
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
CO21	Lithium B & FU	h-h	l-l	h-h	100-100	Retained positive perceptions and adherence of MS, ATAP & antidepressant.
	Risperidone B & FU	h-h	l-l	h-h	100-100	
	Mirtazepine (new) B & FU	h-h	l-l	h-h	100-100	

Pt	Medications (B=baseline) (FU=follow-up)	BMQ Necessity (baseline-follow-up)	BMQ Concerns (baseline-follow-up)	MARS (baseline-follow-up)	VAS (baseline-follow-up)	Summary of changes
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC24	Olanzepine B	l	h	H	100	Discontinued ATAP with negative perceptions.
	Zopiclone B	l	l	H	100	Started ATAP with negative perceptions.
	Paliperidone FU	l	h	h	100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC26	Epilim Chronol (valproate) B & FU	l-l	l-l	l-h	80-100	Retained low necessity for MS.
	Risperidone B & FU	h-l	l-l	h-h	100-100	Retained low concerns and improved adherence for MS. Decreased N for ATAP, but retained low concerns and high adherence.
	Haloperidol B	L	l	h	100	
	Zolpidem B & FU	h-h	l-l	L-h	80-????	Changed benzo.
	Clonazepam B	h	l	l	100-100	
	Diazepam FU	h	l	h	100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
WR27	Lithium B & FU	h-h	l-l	??-h	??-100	Retained positive MS and ATAP perceptions.
	Quetiapine B & FU	h-h	l-l	l-h	70-70	Increased ATAP adherence.
	Lorazepam B	h	h	h	100	Retained high N and C and adherence for benzo.
	Zolpidem B	H	L	h	100	
	Clonazepam B & FU	h-h	h-h	h-h	100-100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC30	Olanzepine B & FU	h-l	l-l	l-h	95-90	Reduced N, but increased adherence for ATAP and SNRI.
	Venlafaxine B & FU	h-l	l-l	l-h	95-90	
	Mirtazepine B & FU	l-l	h-l	l-l	95-70	Reduced C for antidepressants, but low adherence.

Table 6.22: Control group treatment beliefs and adherence data (B=baseline, FU= follow-up, h=high, l=low) (MS= mood stabilisers, ATAP= Atypical antipsychotic, SSRI= Selective serotonin uptake inhibitors)

Pt	**Medications (B=baseline) (FU=follow-up)**	**BMQ Necessity (baseline-follow-up)**	**BMQ Concerns (baseline-follow-up)**	**MARS (baseline-follow-up)**	**VAS (baseline-follow-up)**	**Summary of changes**
HC03	Oxycarbamazapine B &FU	h-h	l-l	h-h	100-100	Retained positive perceptions for MS. Decreased C for ATAP. Discontinued ATAPs. Started depot ATAP.
	Quetiapine B &FU	h-h	h-l	h-h	100-100	
	Rispeidone – new B	h	L	h	100	
	Halperidol – new B	h	H	H	100	
	Zolpidem - new PRN B	l	L	H	80	
	Promethazine FU	l	L	H		
	Palipiridone (at depot clinic) FU	h	L	h	100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC04	Lithium B &FU	h-h	l-l	h-h	100-100	Retained positive perceptions and adherence for MS. Increased N for MS.
	Lamotrigine – new B &FU	l-h	l-l	h-h	90-100	
	Diazepam PRN B	l	h	L - n/a	n/a	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HM05	Lithium B &FU	h-h	l-l	h-h	100-100	Retained positive perceptions and adherence for MS. Retained low N and C and high adherence for ATAP and antidepressant.
	Quetiapine – new B &FU	l-l	l-l	h-h	100-100	
	Mirtazapine B &FU	l-l	l-l	h-h	100-100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC07	Olanzapine B &FU	l-l	h-h	h-l	95-80	Retained negative perceptions and reduced adherence for ATAP.
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
WM13	Lithium B & FU	l-h	h-h	l-l	95-95	Increased N for MS, retained high C and low adherence. Started ATAP with negative perceptions. Discontinued benzo.
	Diazepam (1 week) B	h	h	h	95	
	Pregabalin (1 week for anxiety) B & FU	h-h	l-l	h-h	95-95	

Pt	Medications (B=baseline) (FU=follow-up)	BMQ Necessity (baseline-follow-up)	BMQ Concerns (baseline-follow-up)	MARS (baseline-follow-up)	VAS (baseline-follow-up)	Summary of changes
	Olanzapine - cutting down dose at present FU	l	h	H	95	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
MR17	Risperidone B & FU	h-h	l-l	h-l	100-70	Retains positive beliefs, but decreased adherence for ATAP. Started ATAP with low necessity and adherence.
	Quetiapine FU	l	l	l	50	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
CO18	Valproate (Depakote) new B & FU	h-h	h-h	h-h	100-100	Retains high N, C and adherence for MS and ATAP.
	Quetiapine B & FU	h-h	h-h	h-h	100-100	
	Chlorpromazine B	missing	missing	missing	Missing	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HM20	Valproate – new B & FU	l-h	l-l	h-h	100-99	Increased N, and maintained low N and high adherence for MS. Maintained high N and C and increased adherence for ATAP.
	Quetiapine B & FU	h-h	h-h	l-h	90-99	
	Mirtazapine – new B	missing	missing	missing	missing	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
HC22	Valproate B & FU	l-l	h-h	h-l	100-100	Negative beliefs and reduced adherence for MS and ATAP. Started new MS with negative perceptions.
	Olanzepine B & FU	l-l	h-h	h-l	100-50	
	Lamotrigine FU	l	h	h	99	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	
EB23	Epilim Chronol (valproate) B & FU	h-h	l-l	l-h	90-100	Positive perceptions and increased adherence for MS. SSRI retained positive perceptions, increased adherence. Discontinued high C AP.
	Citalopram B & FU	h-h	l-l	l-h	100-100	
	Propanylol B & FU	h-h	l-l	h-h	100-100	
	Aripiprizol FU	h	h	h	100	
Pt	**Med**	**BMQ**		**MARS**	**VAS**	

Pt	Medications (B=baseline) (FU=follow-up)	BMQ Necessity (baseline-follow-up)	BMQ Concerns (baseline-follow-up)	MARS (baseline-follow-up)	VAS (baseline-follow-up)	Summary of changes
HC28	Valproate B & FU	h-h	l-l	l-h	50-100	Positive perceptions and increased adherence for MS. ATAP maintained high N, high C and adherence. ATAP started high C, high N, and adherence.
	Olanzepine B & FU	h-h	h-h	h-h	100-100	
	Haloperidol B	h	h	H	100	
	Zopiclone & Promethazine B	h	h	H	100	
	Clonazepam B	l	h	h	100	
	Quetiapine FU	h	h	H	100	

6.6.4.3 Changes in other outcome measures

Paired-sample t-tests were used to compute changes in each group between assessments (Table 6.23). No significant differences were detected between baseline and follow-up for either the IG or TAU for any of the brief IPQ items. However, as a feasibility study, it was not powered to detect changes. For the ISMI scale, only a significant difference was detected for the control group with a reduction in stigma scores. Adjusted means at baseline and follow-up and the results of exploratory ANCOVA are also presented (Tables 6.24 and 6.25). The ANCOVA revealed no significant effects of the intervention relative to TAU controlling for baseline scores (Table 6.25).

Table 6.23: Results of paired-sample t-tests for Brief-IPQ, SIMS and ISMI

	Group	Mean diff (sd)	t (df)	p
Brief IPQ				
How much does your bipolar affect your life? (Consequences)	IG	.30 (2.31)	.41(9)	.691
	TAU	.77(2.60)	.99(10)	.348
How long do you think your bipolar will continue? (Timeline)	IG	.20(1.75)	.36(9)	.726
	TAU	-.55(2.70)	-.67(10)	.518
How much control do you feel you have over your bipolar? (Personal Control)	IG	-.80(2.66)	-.95(9)	.366
	TAU	-.86(3.18)	-.90(10)	.389
How much do you think your treatment can help your bipolar? (Treatment control)	IG	-.30(2.16)	-.44(9)	.671
	TAU	1.18(2.60)	1.51(10)	.163
How much do you experience symptoms from bipolar? (Identity)	IG	1.40(5.17)	.86(9)	.414
	TAU	-.18(4.14)	-.15(10)	.887
How concerned are you about your bipolar? (Concern)	IG	-.90(3.07)	-.93(9)	.378
	TAU	.68(2.76)	.82(10)	.432
How well do you understand your bipolar? (Coherence)	IG	-.50(3.7)	-.44(9)	.668
	TAU	-.09(1.87)	-.16(10)	.875
How much does your bipolar affect you emotionally? (Emotion component)	IG	-1.30(2.91)	-1.41(9)	.191
	TAU	1.09(2.66)	1.36(10)	.204
How much do you agree with your diagnosis of bipolar?	IG	.77(2.11)	1.11(8)	.301
	TAU	-.73(2.24)	-1.08(10)	.307
SIMS				
SIMS total score	IG	-1.80(4.29)	-1.32(9)	.217
	TAU	-2.18(3.37)	-2.14(10)	.057
SIMS Action & Usage scale	IG	-.30(2.87)	-.33(9)	.748
	TAU	-.36(1.63)	-.74(10)	.476
SIMS Potential problems of medication scale	IG	-1.50(2.42)	-1.96(9)	.081
	TAU	-1.82(2.23)	-2.71(10)	.022
ISMI				
ISMI (29 items)	IG	-.01 (.57)	-.08(9)	.937
	TAU	.15 (.36)	1.35(10)	.208
ISMI (24 items – Excluding Stigma resistance subscale)	IG	.04 (.65)	.21(9)	.842
	TAU	.21()	2.32(10)	.043

Table 6.24: Unadjusted means for IG and TAU at baseline and follow-up

	IG Mean (sd)		TAU Mean (sd)	
	Baseline	**Follow-up**	**Baseline**	**Follow-up**
Brief IPQ				
How much does your bipolar affect your life?	7.90(2.33)	7.60(1.90)	8.50(1.50)	7.72(2.10)
How long do you think your bipolar will continue?	9.40(1.35)	9.20(1.40)	7.09(2.21)	7.63(3.07)
How much control do you feel you have over your bipolar?	5.90(2.92)	6.70(1.16)	2.86(2.51)	3.72(2.90)
How much do you think your treatment can help your bipolar?	7.80(2.48)	8.10(1.52)	6.63(2.33)	5.45(2.33)
How much do you experience symptoms from bipolar?	7.20(3.32)	5.80(2.69)	6.45(3.32)	6.63(2.06)
How concerned are you about your bipolar?	5.80(3.73)	6.70(3.09)	8.23(2.22)	7.54(2.11)
How well do you understand your bipolar?	7.30(3.23)	7.80(1.98)	6.09(3.61)	6.18(2.48)
How much does your bipolar affect you emotionally?	6.20(3.76)	7.50(2.06)	8.00(2.56)	6.90(1.81)
How much do you agree with your diagnosis of bipolar?	9.33(1.00)	8.56(1.94)	7.09(2.70)	7.81(1.88)
SIMS				
SIMS score	10.00(5.33)	11.80(3.91)	4.82(3.40)	7.00(4.05)
SIMS Action & Usage scale	5.70(3.16)	6.00(2.74)	3.36(1.96)	3.73(1.84)
SIMS Potential problems of medication scale	4.30(2.54)	5.80(1.87)	1.45(1.57)	3.27(2.37)
ISMI				
ISMI (29 items)	1.88(.52)	1.90(.31)	2.42(.26)	2.28(.14)
ISMI (24 items – Excluding Stigma resistance subscale)	1.94(.62)	1.90(.32)	2.50(.22)	2.29(.16)

Table 6.25: ANCOVA of follow-up scores by group (adjusted for baseline score)

	Group	**Estimated Marginal mean**	**95% CI**	**F**	**p**	**ETA**
Brief IPQ						
How much does your bipolar affect your life?	IG	7.417[a]	5.650, 9.183	.490	.544	.165
	TAU	7.858[a]	6.043, 9.673			
How long do you think your bipolar will continue?	IG	9.083[a]	6.636, 11.531	.111	.795	.100
	TAU	7.475[a]	5.680, 9.270			
How much control do you feel you have over your bipolar?	IG	6.688[a]	5.145, 8.230	2.152	.237	.412
	TAU	3.625[a]	1.960, 5.290			
How much do you think your treatment can help your bipolar?	IG	7.806[a]	6.608, 9.003	2.049	.216	.308
	TAU	6.321[a]	5.139, 7.504			

	Group	Estimated Marginal mean	95% CI	F	p	ETA
How much do you experience symptoms from bipolar?	IG	6.333[a]	4.466, 8.201	.250	.705	.200
	TAU	7.167[a]	5.324, 9.009			
How concerned are you about your bipolar?	IG	6.310[a]	4.566, 8.053	.189	.692	.056
	TAU	7.743[a]	5.945, 9.540			
How well do you understand your bipolar?	IG	7.690[a]	5.746, 9.635	3.319	.115	.341
	TAU	5.292[a]	3.450, 7.133			
How much does your bipolar affect you emotionally?	IG	6.952[a]	5.450, 8.454	4.053	.099	.441
	TAU	6.733[a]	5.311, 8.155			
How much do you agree with your diagnosis of bipolar?	IG	8.500[a]	7.058, 9.942	.344	.735	
	TAU	7.600	6.268, 8.932			
SIMS PP	IG	5.786[a]	4.367, 7.205	.753	.448	.197
	TAU	4.250[a]	2.806, 5.694			
SIMS AU	IG	6.000[a]	4.343, 7.657	1.043	.411	.333
	TAU	4.095[a]	2.579, 5.612			
SIMS score	IG	11.500[a]	9.637, 13.363	.399	.572	.116
	TAU	7.625[a]	5.830, 9.420			
ISMI (29 items)*	IG	1.897[a]	1.693, 2.100			
	TAU	2.272[a]	2.075, 2.469			
ISMI (24 items – Excluding Stigma resistance subscale)*	IG	1.875[a]	1.747, 2.003			
	TAU	2.314[a]	2.190, 2.438			

* Cannot compute the appropriate error term due to small mean squares.

6.7 Discussion & Conclusions

6.7.1 Feasibility of the RCT protocol

6.7.1.1 Number of eligible patients in the population

Over the course of the six month study period, 145 patients were eligible to be approached to participate, approximately 20 per month. Only 24 patients were not approached due to being too unwell as judged by ward staff. These results indicate that there is a sufficient population of eligible patients in this setting to undertake a definitive trial. Only a few patients (under ten in each case) were excluded due to having clinical diagnoses rendering them ineligible for the study (Organic disorder, Personality Disorder, substance misuse as a primary diagnosis). Informal feedback from staff on wards who had almost no eligible patients during the recruitment period, was that this was unlucky and they would have expected more patients with a BD diagnosis.

6.7.1.2 Recruitment and retention

Overall the recruitment rate of those patients actually approached to participate and provided with the PIS was 46%. The main reason for not recruiting patients was that they were discharged during the time period stipulated to allow participants to consider the research before approaching them for consent (48 hours). The number approached also was restricted by the fact that they were discharged or on leave after the initial approach was made. This was, in part due to the rapid discharge times and compounded by the limited number of recruiting staff available for this small feasibility study and the large geographical area they were required to cover. It was sometimes difficult to get on to the wards at certain times due to risk situations. The pressures on space within mental health units is well documented (BBC, 2014) and patients are discharged quickly.

In a larger trial a number of steps could be taken to overcome these challenges; more recruiting staff who are based geographically closer to sites and ethics permission to contact eligible patients through their CCOs after discharge from hospital.

Positive aspects of recruitment were that staff were engaged by attending team meetings. This provided an effective and efficient way to inform and enthuse teams about the study. Providing regular updates kept staff informed and establishing a key member of staff at each site who was interested in the research as a point of contact facilitated recruitment. This concurs with the results of a survey of CSOs working across mental health research in the UK. Having an identified member of staff to facilitate recruitment, clinician attitudes to research, having a senior member of the study team visit sites and providing structured updates about recruitment progress were key in enhancing access to participants (Borschmann, Patterson, Poovendran, Wilson, & Weaver, 2014).

Retention in the study was good (72%) and comparable to other research in this area (David Castle et al., 2010; Kemp et al., 1996; Sajatovic, Davies, et al., 2009; Scott et al., 2006). Reasons for this good rate include ongoing communication between research staff and CCOs. Informal feedback from sites was that in other studies in this setting, CCOs are not always kept informed when participants are recruited on the ward. The main reason for withdrawal was illness relapse which is not unexpected given the variable nature of the condition and the high risk of relapse. This time of transition can be a difficult period for patients. Treatment decisions may be made quickly and there may not be time to address the social needs facing patients after discharge (Glick, Sharfstein, & Schwartz, 2011). Patients have reported that they struggle with transitions between teams following discharge and communication gaps between providers exist. In addition, after the structure provided during inpatient stays, patients find it difficult to cope with living independently (I. Jones et al., 2009). In this feasibility study, the

follow-up time point was 6-8 weeks post baseline. This was kept flexible to make allowances for the changing health status and social circumstances of participants. Retaining almost three quarters of participants over a period of transition between services and care teams is an encouraging finding in terms of the feasibility of conducting a larger trial.

Randomisation appeared to be acceptable to participants as no-one withdrew due to their allocation. However, one patient, when invited for follow-up, reported having found the baseline assessments too tiring and difficult. However, overall feedback on the questionnaire was positive with participants finding it interesting and that it helped them reflect on BD. There were difficulties however, in comprehending the questionnaire for a minority of participants and one-fifth felt it took too long to complete. For a definitive trial, future work on reducing questionnaire burden should be explored. Qualitative feedback from participants including their perspectives on recruitment, the study itself and the IBiD intervention is covered in Chapter 7.

In terms of completion of individual parts of the questionnaires, the procedure used, meant that there were very few missing responses as participants were encouraged to complete each item, responding 'not applicable' where necessary. Feedback from the CSO about difficulties with item completion, or additional notes made on the questionnaires were collated as part of this feasibility stage and can be used to inform refinement of measures as is recommended as part of the feasibility assessment process (NIHR).

6.7.1.3 Resource usage in terms of staff time and participant time in completing study components, intervention delivery

During the recruitment and follow-up period, three CSOs were working on the study. However all three were also involved in recruiting to other studies during this period. Baseline and follow-up assessments, for the most part were completed in one session and intervention sessions lasted on average for just over one hour. Most baseline sessions were completed on the ward and there was always a suitable location available to meet with participants, either in quiet rooms or activity rooms. Participants' homes were also used frequently for assessments or intervention delivery with the level of risk being judged by CCOs. No problems were encountered during the study with home visits. At baseline, intervention and follow-up it was sometimes necessary to book rooms at Community Mental Health centres due to the unsuitability of participants living arrangements. No difficulties were experienced booking rooms for the purposes of the study.

6.7.1.4 Methodological quality/ protocol deviations

As part of the feasibility study, components of RCT methodological quality were assessed (Higgins et al., 2011). Randomisation was conducted as per protocol, using minimisation criteria of age and gender and coin toss where groups were balanced (Appendix S). Allocations were concealed to CSOs conducting assessments and held in electronic files at UCL which could not be accessed by CSOs.

Unblinding did occur on four occasions in the intervention group and therefore in a definitive trial, it should be emphasised more strongly to participants that they should not reveal their allocation to the CSO and if they have an intervention booklet, they should ensure this is not on display until follow-up assessments have been completed.

In practice, the study deviated from the protocol in terms of completing interventions as soon as possible after baseline assessments were conducted.

As we are unsure as to the stability of treatment perceptions, we cannot determine from this study if this deviation was an issue in terms of intervention delivery. However, when conducting the intervention sessions, no participants had had a change in prescribed medications since the baseline assessments. As flexibility to participants' needs and circumstances is important, pragmatically allowing these deviations was essential.

6.7.1.5 Intervention need

The feasibility study allows an assessment of the need for an intervention within this particular population and setting. The evidence covered in Chapter 1 and Chapter 4 identified that patients with BD have unmet information and support needs in relation to their diagnosis and treatment and in addition, hold perceptions of treatment which may not be consistent with adhering to medication. The baseline measures in this sample demonstrate that in terms of illness perceptions; perceptions of personal control over BD were low and participants reported experiencing severe symptoms and negative consequences on their lives and emotions. Fewer participants reported disagreeing with the diagnosis, and many had a good understanding of BD. These findings offer a mixed picture of recovery-oriented care, it is encouraging that many had a good understanding of BD, but low levels of personal control may mean that they have not been supported to be involved in their treatment plans and take some ownership of this. These results concur with results from a UK community mental health sample which also found that higher consequences and more symptoms experienced predicted higher rates of relapse (Lobban, Solis-Trapala, et al., 2012).

Perceptions of causes corresponded to the diathesis-stress model (Salomon & Jin, 2013) with a predisposition or vulnerability to suffering from psychological distress, with the exposure to stress increasing the likelihood that problems will manifest. Common cause perceptions were; stress and family problems and overwork and also vulnerability from hereditariness and a biological chemical imbalance. This concurs with previous qualitative research (Clatworthy et al., 2007). Participants report of factors responsible for maintaining mental health problems were potentially amenable to intervention. These included; stress and worry, poor healthcare or support from professionals, not taking medication and negative thought patterns. Contextual factors like low social support and difficulties with the health service have been identified as barriers to recovery in BD as well as dysfunctional attitudes held by the patient, however significant others and HCPs are also seen as facilitators of recovery (Sanchez-Moreno et al., 2010).

In terms of treatment perceptions, general beliefs about medication indicated strong perceptions that medications are overused. The majority of participants had negative treatment perceptions for at least one medication they were prescribed, eight out of ten had low perceived need and two-thirds had high concerns. Previous research presenting average BMQ data across multiple medications for a community sample of individuals with BD demonstrated high perceptions of medication necessity and concerns on average were not high (Clatworthy et al., 2009). High concerns and low necessity were associated with poorer adherence. The results from the feasibility trial therefore suggest that this inpatient group hold views inconsistent with good medication adherence for at least one of the medications they are prescribed.

In terms of self-reported adherence, even in the inpatient setting where medications are administered by nursing staff and patients do not take responsibility for this, almost half of participants were classified as low adherers for at least one of their medications.

The most common practical barriers to taking medication were getting the best from their own care team, consistent with other research where barriers to effective communication included changes to the care team and lack of communication between teams (I. Jones et al., 2009). Coping with the changes to daily routine and the impact this has on remembering to take medication was also an issue for approximately half the sample. Around one-third of participants at baseline found it difficult to get information about their medication.

Participants experienced a high number of symptoms, many of which they attributed to medication including dry mouth, tiredness and sedation. Sedation was a reported side-effect in qualitative studies (Clatworthy et al., 2007; Morrison, Meehan, & Stomski, 2015).

Low levels of satisfaction with information about medication were observed at baseline, both in terms of being informed of what they do and how to use them (Action and Usage) and in terms of the side-effects and drug interactions (Potential problems). This concurs with a community survey of individuals with BD which demonstrated low levels of satisfaction using the same scale (Bowskill et al., 2007). It can be inferred then that being admitted as an inpatient does not mean that there is any better information provision in terms of medications which are prescribed, this is supported by data collected by the Care Quality Commission (2009a) and more recent qualitative research (Hatonen et al., 2010).

In terms of feelings of internalised stigma, overall for the sample levels were low. However, half of participants reported stigma in terms of feelings of being different and a worse person (Alienation) and experiencing discriminatory treatment from others (Discrimination Experience) (Boyd Ritsher et al., 2003). A large European study, however, found that the discrimination experience was the least reported form of stigma reported (Brohan et al., 2011). Feelings of internalised stigma have been shown to be associated with reduced adherence (Livingston & Boyd, 2010).

6.7.2 Changes in outcome measures

As a feasibility study, the sample was not powered to detect changes in the outcome measures. As such, drawing conclusions about intervention effects was not the aim of this study. However, exploratory analysis was conducted to test the data analysis protocol and to explore any changes between baseline and follow-up.

Medication data (treatment perceptions and adherence) was complex as participants were on average prescribed three medications at baseline, in addition, they were often taking more than one of a particular class of medication, such as a combination of two ATAPs. A chart-review study found rates of complex polypharmacy (four or more medications) was 36% (Weinstock et al., 2014), so many of the sample in this study were receiving a complex treatment regimen.

There have been mixed results in studies which aim to target illness and treatment perceptions. O'Carroll and colleagues (2013) conducted a beliefs-based adherence intervention in anti-hypertensive medication. Mixed results were observed, with significant reductions in concerns and an increase in adherence, but no effect on necessity beliefs or illness perceptions. The authors posit that necessity beliefs were high at baseline as they were not new medications. In addition, this study pre-screened participants for low adherence. This was a small pilot study, which was not powered to detect changes. A short face to face

intervention for patients with chronic pain was effective in changing illness perceptions, but not treatment perceptions (Glattacker et al., 2012). This study, however, used a quasi-experimental design and was underpowered to detect small changes.

Zwikker and colleagues (2014) conducted a trial of an intervention designed to target necessity and concerns about medication and adherence in Rheumatoid Arthritis which was not successful in changing beliefs or behaviour. This study was powered to detect BMQ changes. They hypothesise that it could be more difficult to modify established beliefs in those with a long-standing diagnosis rather than helping participants form adaptive beliefs when newly diagnosed.

Potential reasons for no intervention effects include, firstly, that the intervention was not successful in changing beliefs or adherence. The challenges in actually selecting techniques were due in part due to the lack of evidence of what is actually effective. Even if useful techniques can be identified, they may not be effective for the specific population or context in which they are applied. Secondly, changes in the control group could occur. There may be an active component of completing the assessments, prompting participants to think about their condition and treatment in a different way, perhaps prompting information seeking. In addition, asking about adherence may, in turn serve to enhance it, though the mere measurement effect (Sherman, 1980). However, this could only be overcome by observational measurement of adherence without patients' knowledge, which poses ethical issues in informed consent. Other possible reasons include, baseline group differences, ceiling effects, limitations of the outcome measures, heterogeneity of participants (mixed new diagnosis and long-standing diagnosis) and high symptom burden.

High symptom burden may be a potential problem in this study, and people with BD have reported that when dealing with the effects of an acute episode of illness, it is difficult to take on board much information (Van den Heuvel et al., 2015).

More generally, with measurement of perceptions, Siemonsma and colleagues (2010) state that although the IPQ-R and BMQ do measure changes in illness and treatment perceptions, they may not detect changes in the specific content of the perceptions and they recommend that qualitative methods are used to assess these. In addition, the limitations of both measured outlined in Chapter 2, Section 2.4 may contribute to difficulties in establishing whether there are positive changes for participants. Key constructs may be missed such as the whether there are changes in beliefs about the efficacy of treatments, and views about psychological side-effects. People may have been supported to have a more recovery-oriented model of their BD experiences, but this may not be captured by the Brief IPQ which does take a more medical model.

6.7.3 Limitations

There are a number of limitations to the feasibility RCT which it is important to take into account and also use to inform future research. The sample size was small, however, as a feasibility study it allowed the capture of important data to establish the acceptability of the study protocol and intervention. Due to limited resources (staff and time), the number of participants who could be engaged was restricted.

In terms of sample bias, there were few newly diagnosed participants, with the average number of years since first diagnosis of BD being around nine years, as such the findings may not be as applicable to a sample where more individuals are newly diagnosed. The sample may include participants who are highly engaged and therefore not generalizable to people with a BD diagnosis who do not engage with formal healthcare. However, by recruiting from hospital it is hoped the sample is more representative of people who face challenges with managing their condition and therefore may be in more need of support and information. Keck and colleagues (1996) reported that 60% of patients admitted to hospital with acute mania had not taken their medication as prescribed in the previous month.

Although participants had been stabilised and were judged to be able to consent to the research, they were still often being affected by mania and depression symptoms. Just over 40% had a possible manic state indicated, and approximately the same proportion were indicated to be experiencing moderate to severe depressive symptoms. These experiences may have affected the cognitive abilities of participants, in particular in concentration and retaining information. A large RCT in BD found that greater severity of illness was a significant predictor of recruitment (Busch, He, Zelevinsky, & O'Malley, 2015). It is likely that there may be an increased perception of intervention need when people are struggling most with the symptoms of BD. The challenge in future studies would be to recruit individuals who are euthymic and may perceive less immediate need (although are still susceptible to future non-adherence and relapse).

With regards to both providing medication information and in assessing BMQ and MARS outcomes, these are both confounded by changes to medications between the two assessment times. This is a limitation of these measures as they don’t provide instructions for use in changing medication regimens or take account of polypharmacy and how perceptions and adherence to different medications taken concurrently may interact. Future studies should track medication use more regularly and assess reasons for discontinuation or starting new treatment, as this may be on clinician advice. Research should explore correlation between treatment beliefs and adherence to see if combined measures could be used, but this was beyond the scope of this study.

The control group in this study was treatment as usual, and therefore with this design, the effects of therapists contact time are not controlled for. However, this was chosen as it does compare the intervention to current service provision and the fact that both the content and attention participants' receive are components of the intervention (Freedland et al., 2011; J. Green, 2006). Factorial designs where comparison groups receive different 'active' interventions could be conducted to identify the effective components of the intervention (Collins et al., 2007) and if the intervention is effective beyond attentional 'Hawthorne' effects.

In a small sample, randomisation did not produce groups which were evenly matched at baseline with regard to outcome measures. Although controlling for baseline score can be conducted during analysis (adding baseline score as a covariate in ANCOVA), stratification could be used to ensure more evenly matched groups. In addition, ceiling effects were a possibility, where positive beliefs in at baseline had less scope for improvement. Zwikker and colleagues (2014) conducted an RCT of a beliefs based intervention (also using the BMQ), which did not find a significant effect on beliefs and adherence, and the authors propose that a potential reason was the lack of scope for improvement.

The intervention follow-up assessment was only conducted at eight weeks, this limits the conclusions that can be drawn about both the feasibility of retaining participants beyond this point and about the potential changes to treatments which occur beyond this point. . However, participants were successfully retained during a difficult transition phase between care providers, from acute to community care. Other studies have followed-up participants for a year or more, however, these are often programmes as part of routine clinical practice so easier to follow-up patients (Colom, Vieta, Sanchez-Moreno, Goikolea, Popova, Bonnin et al., 2009; Miklowitz, Simoneau, George, Richards, Kalbag, Sachs-Ericsson et al., 2000).

During the intervention planning process, it was recommended that follow-up assessments were kept to a minimum to reduce participant burden. Intervention follow-up was also, in the end, restricted by funder restrictions on project completion timing. However, conducting immediate assessments of illness and treatment beliefs as well as perceptions of internalised stigma would have allowed for assessment of any immediate impact of the intervention. In addition a full RCT should follow-up participants for longer than 8 weeks as previous research on medication adherence indicates that lithium is only maintained continuously for around 70 days (R. Johnson & McFarland, 1996). Although this may not generalise to continuation rates for other medications one study found that adherence to benzodiazepines and antipsychotics was lower after 1 year than to mood stabilisers (Keck et al., 1997). At this time in participants' treatment journey, adherence for many medications was quite high, as at baseline participants

were provided with their medications as inpatients and at follow-up many were prescribed new medications and may start off with high adherence.

Finally, although measures were in place to blind CSOs to participants' treatment assignment, their care teams were informed of their assignment. This was necessary to arrange communication with participants and attending the wards to conduct the intervention. However, occasions occurred when staff expressed disappointment to their patients being assigned to TAU. This could potentially lead to them being provided with extra information on BD or medication, however, we have no evidence of this actually taking place. This also raises the issue of clinician's understanding of clinical equipoise. As this was a trial of a novel intervention, there was no evidence of its superiority over care as usual. In future trials it would be important to ensure that clinical staff understood this.

6.7.4 Conclusions & Implications

This feasibility trial demonstrated that an RCT of a psychosocial intervention could feasibly be delivered in the acute mental health setting but with some important resourcing considerations and modifications. Important lessons were learnt in this trial, including to ensure efficient recruitment, sufficient staff are required to cover study sites which are geographically spread out and where multiple visits are required to complete the recruitment process. However, in a larger trial this would have substantial cost implications.

Due to rapid discharge times, recruitment could be extended to community recruitment with the assistance of CCOs. Building relationships with acute community staff was a significant strength of this project and in future studies this is recommended and would also facilitate ongoing recruitment in the community.

Baseline assessments indicate that there was a need for intervention in this group, particularly in being provided with information on the risk of experiencing side effects and what to do in the event of these occurring, and in low levels of personal control participants felt they had over BD. By taking a recovery-focussed approach, an intervention needs to meet information needs so participants can be empowered to make decisions and set goals. Their beliefs and fears need to be acknowledged and taken into consideration when planning treatment in a collaborative partnership. Helping to foster greater involvement and ownership of care would be anticipated to lead to better recovery-focussed outcomes which are important to an individual (Jacobson & Greenley, 2001; NICE, 2014).

Medication changes during the transition period resulted in challenges in analysis and confounding the outcome measurement in terms of adherence, treatment perceptions and

satisfaction with information. Future studies should track treatment perceptions and adherence more frequently and record reasons for medication changes. In terms of intervention delivery, information should also be provided on newly prescribed medications after the point of discharge to address concerns. This would result in an intervention with greater contact as opposed to a one off, however, from the evidence on retention and understanding that in this patient group flexibility is key, this may result in an improved, more tailored intervention which better responds to a patient's treatment journey.

The evidence of changes to medications from the quantitative evaluation implies that access to information on the ward is key as patients are prescribed medications they have concerns about and lack information on, but also people may need more long-term support to help with changes to medication and adherence once discharged from hospital. However, the IBiD intervention was designed to be very brief to test an intervention which would have greater capacity for use in clinical practice. In addition, the meta-analysis in Chapter 3 revealed that brief interventions can be highly efficacious in improving adherence. However to achieve belief change, a more intensive or longer-lasting intervention may be needed.

Chapter 7 IBiD qualitative evaluation

7.1 Rationale

In order to capture information on the acceptability of the study procedures, materials and intervention, a concurrent qualitative study with participants from the IBiD feasibility RCT was conducted. This study is reported following the guidelines set out for reporting qualitative research set out in the Consolidated criteria for Reporting Qualitative research (COREQ) checklist (Tong, Sainsbury, & Craig, 2007), this ensures that it is transparent and complete (see Appendix X for completed COREQ checklist).

7.1.1 Aims

To explore the experience of participants taking part in the IBiD study to provide data on the feasibility of the study design and intervention.

7.1.2 Objectives

To explore;

- acceptability of the study protocol, i.e. participants' reflection on their decisions to enter the study, questionnaire completion and practical arrangements,
- acceptability and use of the IBiD intervention and participants' recommendations for its improvement,
- participants' experiences of information provision and support in mental health services.

7.2 Methods

Ethical permissions were granted by the local REC through the approval of a substantial amendment to the original application (12/LO/1615: Amendment 1) (Appendix Y). Participants were invited to take part in the qualitative evaluation of IBiD at the end of the follow-up assessment. They were provided with a PIS (Appendix Z) by the CSO and if consent was given (Appendix AA) they were contacted by the author (LM) to arrange a suitable time to conduct the interview. Both IG and TAU participants were invited to participate. It was deemed not appropriate to contact those who had withdrawn from the study or those who were too ill to complete the follow-up assessments.

Participants completed the interviews over the phone or in-person at hospital in one case as this participant was still waiting for accommodation to be arranged. Interviews were audio-recorded with participants' consent.

The interviews followed a semi-structured interview guide (Appendix BB) which was preceded by the researcher explaining the purpose of the study and reiterating the confidential nature of the interviews. The interview schedule covered the following topics;

- Initial decisions to take part in the study and reflections on participating,
- Opinions on completing the baseline and follow-up questionnaires,
- Views on the timing and management of the research process,
- Views on the IBID booklet and one to one meeting (IG only),
- Views on the communication of and assignment to TAU allocation (TAU only),
- Views on other information received about BD and medication,
- Recommendations for improving information or support.

The interview schedule was used to start and facilitate discussion, but additional points which arose spontaneously were explored by the researcher. The process was iterative, whereby the interview schedule was adapted by exploring issues raised in previous interviews.

7.3 Data analysis

Interviews were transcribed verbatim from audio-recordings before being transferred to NVivo 10. All personally identifiable information was removed, for example participants and healthcare professionals' names, wards and other identifiable locations. Each transcript was read and re-read by the researcher to gain familiarity with the content. Thematic analysis was used to explore themes within the data (previously described in Chapter 4). Codes identifying discrete parts of the transcripts were assigned, before reviewing these codes and grouping these into common themes (Braun & Clarke, 2006). A process of constant comparison was used whereby previously coded data were re-coded with the generation of new themes and research questions throughout the research process (Pope et al., 2000). The themes and extracts were discussed with an independent researcher and refined following this process.

7.4 Results

Seven participants consented and took part in an individual semi-structured interview (IG n=4; TAU n=3). Reasons for non-participation were, participants were too unwell, had withdrawn from the study, wanted time to think about participating, but then declined. Ethics approval

for the qualitative evaluation was delayed resulting in not being able to invite all earlier participants to take part. Interviews lasted, on average for 25 minutes, (range 16 to 39 minutes).

7.4.1 Sample characteristics

Four IG and three TAU participants were interviewed, six were female and one was male, with a mean age of 50 (sd 11.84) reflecting the characteristics of the whole sample participating in the feasibility study. In terms of clinical characteristics, the mean length of diagnosis was 4.80 (sd 5.22) years and participants were taking a mode of three medications at follow-up (range 1-4). Two had been admitted on a voluntary basis and five had been detained under a Section (Table 7.1).

Table 7.1: Demographic and clinical characterises of sample participating in qualitative interviews

ID	IBiD group	Gender	Age	Marital status	Education	Length of diagnosis	N. medications at follow-up	Admission type	N. previous admissions	Family history
P1	TAU	M	48	Single	Vocational	6 mths	2	Voluntary	0	Unsure
P2	IG	F	66	Widowed	None	6 mths	3	Voluntary	4	No
P3	TAU	F	65	Single	Professional	7 yrs	3	Involuntary/ Detained	2	No
P4	IG	F	36	Married	Degree	2.5 yrs	1	Involuntary/ Detained	3	No
P5	IG	F	39	Single	Vocational	10 yrs	4	Involuntary/ Detained	10	Yes
P6	TAU	F	44	Single	Higher degree	13 yrs	3	Involuntary/ Detained	3	Yes
P7	IG	F	52	Single	Degree	1 mth	3	Involuntary/ Detained	1	No

7.4.2 Thematic analysis

The themes are structured in a way to address feasibility and acceptability of IBiD, the participants' reflections on each part of the process (Figure 7.1). This is followed by wider mental health themes generated in the data, relating to their experiences of care received, information they have been provided and their reflections on their condition and views of their treatment (Figure 7.2).

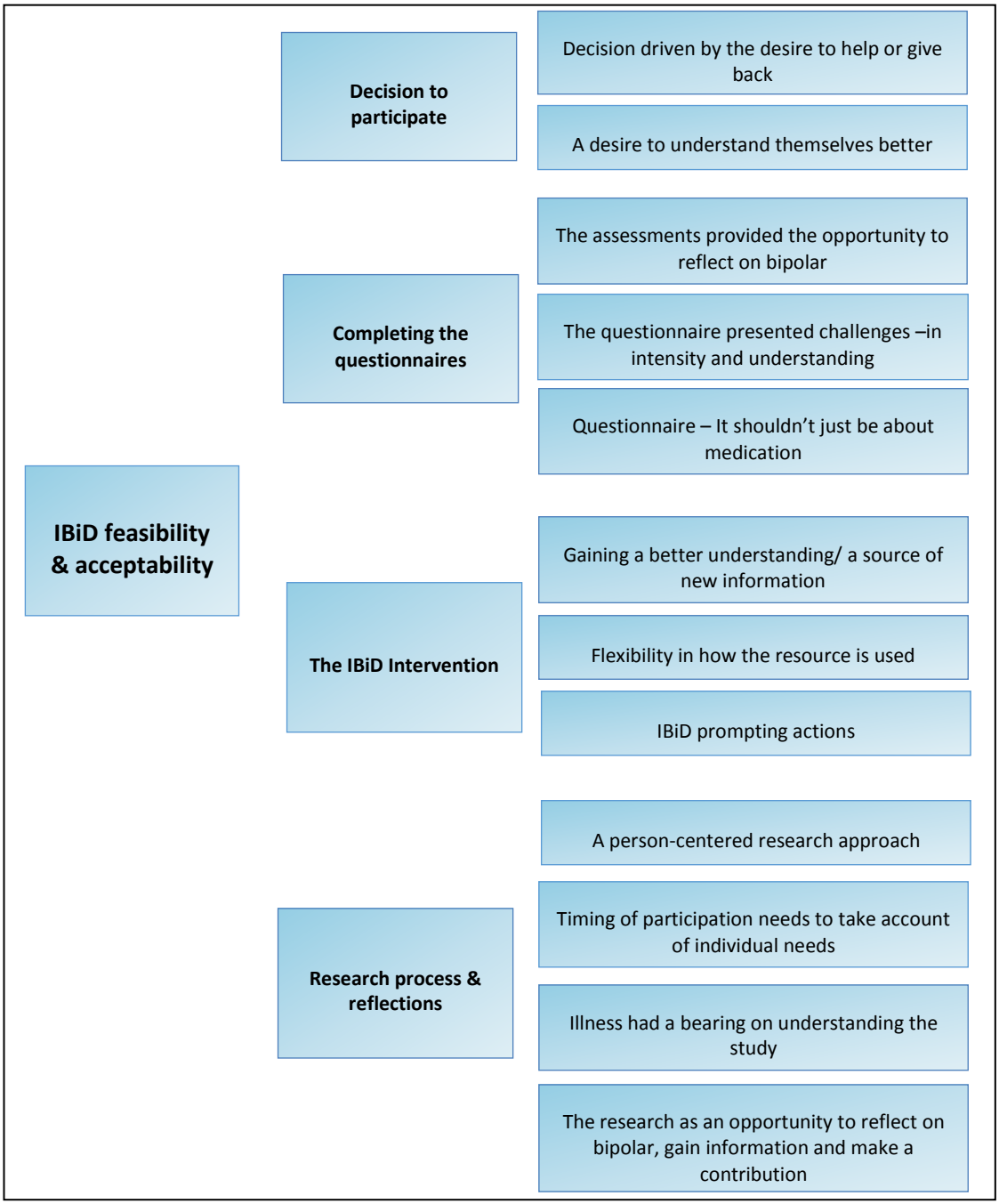


Figure 7.1: IBiD Feasibility & acceptability – Themes and subthemes

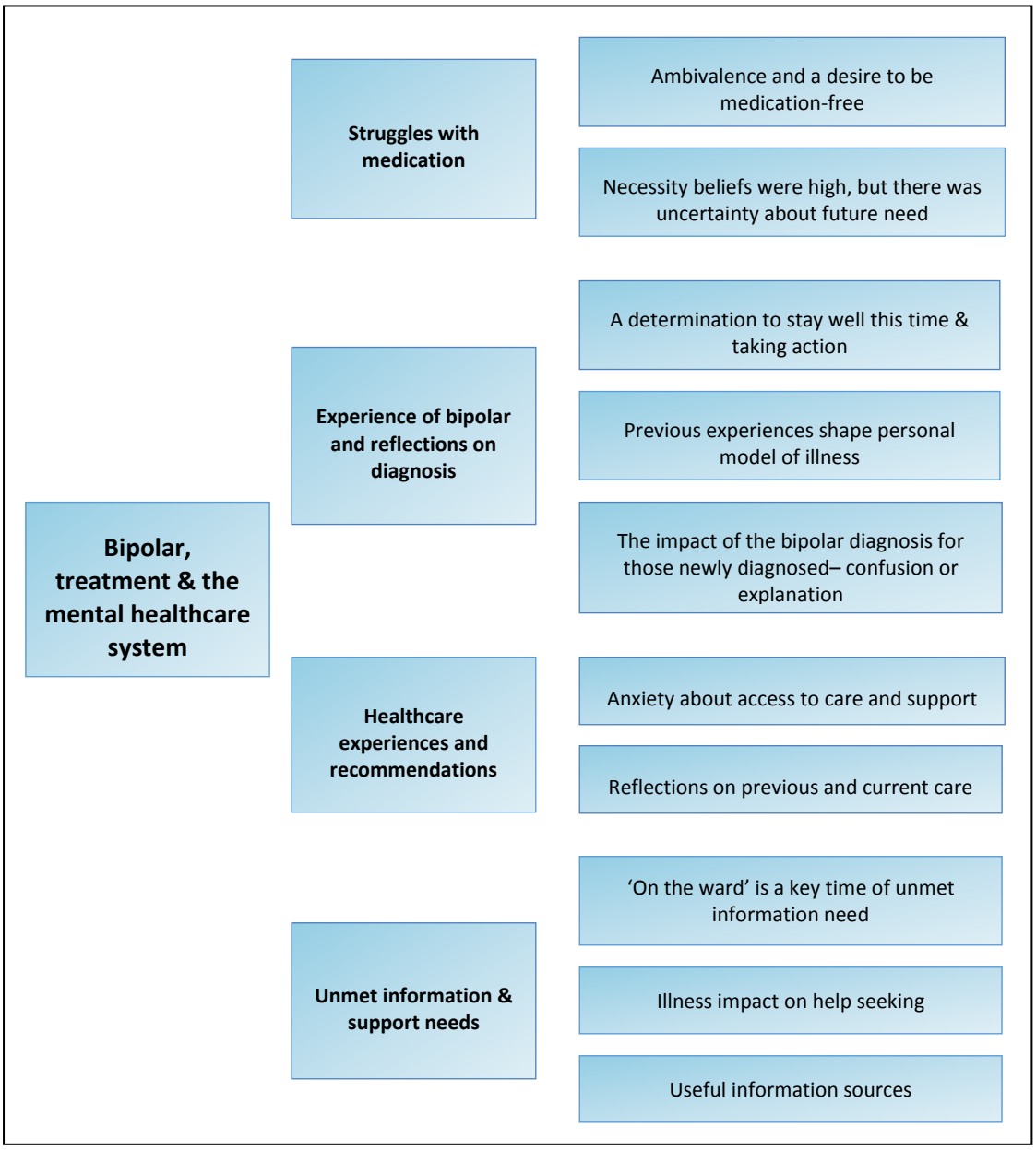


Figure 7.2: Bipolar, treatment & the mental healthcare system - Themes and subthemes

7.4.2.1 IBiD feasibility & acceptability

7.4.2.1.1 Decision to participate

Participants reported different factors influencing their decision to take part in IBiD: wanting to help or contribute to research, a hope to understand their condition better and a general interest in mental health.

Decision driven by the desire to help or give back

Participants hoped that by participating in research this would go some way to improving mental health care, contribute to knowledge and help to tackle public stigma around mental

health. One participant particularly wanted to 'give back' in return for the NHS care he had received.

P: "I think the more research and the more insight people get and the more about any type of mental health would be brought out to the public in general and then maybe the stigma will be reduced you know." (P3: TAU, Female, 7 yrs since diagnosis)

I: "What made you decide you wanted to take part?"
P: "Erm, reason being because, because I've got mental health problems myself and I've also got members of my family with mental health problems. I've seen the mental health hospitals since back in the 80's and anything to improve the mental health system I'm kind of willing to do, so that's why I decided that it would be a good idea to take part." (P5: IG, Female, 10 yrs since diagnosis)

I: "I get the impression you like to be involved with different things, so this research fits in with that?"
P: "Yes, absolutely, and the NHS have been wonderful and I've got to give back, absolutely." (P1: TAU, Male, 6 mths since diagnosis)

A desire to understand themselves better

Participants commented that they thought it would be helpful to take part in the study and it was a way to get more information about their condition and understand themselves better. Two participants commented that it was a way to access information which had otherwise been lacking.

P: "I just, well it's a new diagnosis for me, I don't know very much about it, it's a way of getting more information." (P7: IG, Female, 1 mth since diagnosis)

P: "Well I was happy to try and find out anything and everything about what's going on and I thought I could get some clear view, maybe helping."
I: "Was the study an opportunity, a way for you to explore that, the bipolar?"
P: "Indeed yes, I was happy to do it, to see if there was anything else I could learn about where my heads been and is." (P1: TAU, Male, 6 mths since diagnosis)

For one participant, the invitation to take part came at a time where she was starting to reach an acceptance of her diagnosis and therefore it fitted into this process of acceptance, she was willing to discuss her diagnosis and was receptive to the study. This demonstrates the recovery journey which is unique to each individual.

I: "When you were first asked to take part in the study, what made you make the decision to take part?"
P: "I think because as I say I was diagnosed about 7 years ago and I've always resisted the diagnosis, this time my admission was so bad and also a beloved dog of mine got killed on the road and therefore I suppose I've more or less accepted it. [….] what I am saying is that I received better treatment this time and the consultants were more a two way process, you know.."
I: "It seemed to be the right time for you."
P: "Exactly yeah" (P3: TAU, Female, 7 yrs since diagnosis)

7.4.2.1.2 Completing the questionnaires

The assessments provided the opportunity to reflect on bipolar

Participants reflected positively on actually completing the questionnaires, For many it was the first time they had been asked for their thoughts on their diagnosis, their experiences living with BD and the treatment they had been prescribed. They reported finding it helpful and interesting, giving them more insight into BD. The questions and their own reflections on their answers prompted them to consider aspects of the condition they had not previously considered.

> *P: "Yes, the questionnaire certainly helped me yeah definitely it gave me more insight into bipolar" (P3: TAU, Female, 7 yrs since diagnosis)*
>
> *P: "Interested to learn about the questions. Some of the questions I had never really thought about before and they cropped up and I thought 'what this?', you know?"*
> *I: "It was something quite new..."*
> *P: "Yeah. I had not discussed my illness before, not with anyone, no." (P2: IG, Female, 6 mths since diagnosis)*
>
> *I: "About the questionnaires can you remember back to what you thought about the type of questions?"*
> *P: "Yeah, I thought they were quite helpful, things about taking my drugs and how I felt stigmatised, being seen as somebody is mentally ill. Yeah, I thought they were all quite interesting questions really." (P6: TAU, Female, 13 yrs since diagnosis)*
>
> *P: "A lot of them were things were things I hadn't thought about before, in fact when I was an inpatient I think, although the consultant was very good, she was about the only one because I asked her something about bipolar. The nurses on the wards, I have to say you got no, no information at all, there was very little between the nurses with the patients and in fact the auxiliaries were more helpful in a way than the trained staff so the actual research that you did, the answers and that taught me quite a bit about bipolar." (P3: TAU, Female, 7 yrs since diagnosis)*

The questionnaire presented challenges – both in intensity and understanding

Despite finding the questionnaires interesting and helpful to complete, participants also reported challenges. These related to two areas, firstly the experience of completing the questionnaire in terms of the intensity and understanding the meaning, and secondly the actual content of the questions and the relevance to them.

Participants sometimes found it hard to articulate their experience of completing the questionnaire. Their difficulties focussed on the intensity or taxing experience of completing it, 6/29 of the whole sample had to complete it over more than one session. However, two participants specifically commented that it was not too long (confirmed by the quantitative data reported in Section 6.6.3).

I: "Completing those questionnaires, how did you find that?"
P: "Alright, a bit, not tiring, but a bit, wearing, a bit."
I: "Because they were long?"
P: "Because of the questions themselves, you know, what they were."
I: "A bit tiring to think about? Was there one particular part?"
P: "No, just bits and pieces. Not tiring really, but a bit, made you think. Had to think hard for the questions, and as it went on you had to think harder." (P2: IG, Female, 6 mths since diagnosis)

P: "I think you have to have it in that format to get any kind of answers from it but it can be a bit taxing as I say you know 'when is this going to stop' you know." (P3: TAU, Female, 7 yrs since diagnosis)

P: "…and it was a little intense here and there, but I'm happy to bite the bullet and do it [...]It was ok, you know we had to break for a drink and it was a little exhaustive, but all right, you know. It was good, very good." (P1: TAU, Male, 6 mths since diagnosis)

Participants commented on how sometimes it was difficult to understand the questions, or that the wording or language used was confusing. Sometimes they connected this with how they were feeling at the time in terms of their ability to concentrate. But sometimes it related to the way the questions were phrased.

P: "Some of the questions I didn't really understand, because they contradicted themselves if you know what I mean? Some of them [were quite difficult]." (P2: IG, Female, 6 mths since diagnosis)

P: "I found them quite taxing, you have to have your wits about you but that was the good thing, if you got a bit confused she was quite good at explaining it again." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I found it, difficult isn't the word, I found it confusing is the word." (P5: IG, Female, 10 yrs since diagnosis)

P: "I don't recall there being any major problems with it. I think some of the questions on both occasions were a bit strange and I wasn't quite sure about answering them, but that was the questions themselves rather than the actual process. […] some that were just I don't know, just the way they were phrased, just quite bizarre, so it was difficult to answer them." (P4: IG, Female, 2.5 yrs since diagnosis)

I: "The type of the questions themselves were they straightforward?"
P: "Yeah, pretty much, yeah, some of the language you had to look at twice, yeah, like a political statement sometimes when you look at it." (P1: TAU, Male, 6 mths since diagnosis)

There were a couple of factors which influenced questionnaire completion. Firstly, having the CSO there to help through the questions was vital for some participants with being able to understand and get through the questionnaire.

P: "I found them quite taxing, you have to have your wits about you but that was the good thing, if you got a bit confused she [the CSO] was quite good at explaining it again." (P3: TAU, Female, 7 yrs since diagnosis)

I: "Can I just check that it was having [CSO] going through it with you made the process..."

P: "Oh yes, a lot easier. You know where it says 'fair', 'moderate' or 'very often', or not etc etc, there's like say 5 answers, multiple choice, maybe it's me well lately I seem to be having difficulty finding words, but you kind of forget what the five answers were. She was very good in giving you any help you needed you know without telling you the answers or imposing the answers on you." (P3: TAU, Female, 7 yrs since diagnosis)

Secondly, the impact of bipolar and how participants were currently feeling influenced how they engaged with the questionnaire. For one participant she was feeling better at the second appointment and found it easier to engage with the questionnaire. For the second participant she was feeling sluggish because of the effects of medications she was taking and found it more taxing the second time around.

I: "Can I go back, [CSO] came to see you again to complete the questionnaires a couple of weeks ago. Can I ask how you found filling in the questionnaires themselves?"
P: "Because I was in a pretty well state, pretty straightforward, fine."
I: "This time it was a bit easier?"
P: "It was easier. The first time round, my head was quite muffled. I found it, difficult isn't the word, I found it confusing is the word. But when [CSO] came round and my head was in a better state and I was quite straightforward with it so I found it easy."
I: "It was depending on how you felt at the time,"
P: "Well really yeah, so yeah" (P5: IG, Female, 10 yrs since diagnosis)

I: "Can I go back to completing the questionnaires again. [CSO] came and met with you. How did you find completing them then?"
P: "A little bit tricky really, now I'm out of hospital and being that I'm a little bit sluggish. Just a little bit, so, yeah. I'm a bit slower so everything takes a bit longer at the moment."
I: "Was that thinking though the questions?"
P: "Yeah, being a bit more thinking through I think."
I: "How you felt about completing it depended on how you felt at the time."
P: "Yeah." (P6: TAU, Female, 13 yrs since diagnosis)

Questionnaire – It shouldn't just be about medication

Participants commented on sections of the questionnaire and their relevance to their situation. Specifically completing the BMQ and MARS for each medication they were taking was repetitive for some and gave a large focus on medications. They also sometimes felt there was not always the option to fully account for their own experiences. Some parts they felt were not relevant, or the response categories did not fit with how they wanted to respond.

P: "Most of it was fine, the bit on medicines was a bit repetitive I thought. Going through every single medication and answering the same set of questions I found a little bit laborious. Yeah."
I: "Did you feel you had a different opinion about the different medications?"
P: "Erm, no, I felt that the questionnaire itself was very much the medical model and there wasn't really room for anything else. […]"
I: "[Summarising] Competing the questionnaires themselves, it didn't incorporate all your experiences and it was a little bit tedious to fill out?"

P: "Yes, (laughs) because my answers were more or less the same for all the medications. I mean, there were slight variations, but nothing." (P7: IG, Female, 1 mth since diagnosis)

I: "Were there any questions which were not relevant?"
P: "I can't remember. I think a lot of them didn't refer to me really. The way I felt." (P2: IG, Female, 6 mths since diagnosis)

I: "About the questionnaire were there things you felt weren't relevant to you?"
P: "Erm, yeah, but it's difficult because of my background [nursing]. I think they were relevant to anybody who has been an inpatient and suffered from bipolar yeah. I mean some of the questions, maybe about medication 'do you forget to take it', do you do this that or the other, some of them were a wee bit, my responses might have been based on myself and my career if you like. Other people wouldn't have found the same kind of thoughts about it." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I didn't think it was too long, just that some of them were awkward to answer, just sometimes end up giving, not incorrect answers, but answers to fill out, rather than ones that didn't apply."
I: "There wasn't an option there that applied to you?"
P: "Yeah." (P4: IG, Female, 2.5 yrs since diagnosis)

7.4.2.1.3 Research process & reflections

A person-centered research approach

Participants were given an information sheet before having time to consider whether or not they wished to participate. This process was straightforward and everyone interviewed reported that they had the information and time necessary to make the decision. Participants also commented positively on the approach of researchers and the way the study was conducted. No problems with the practical arrangements of the study were raised, with participants commenting on how it was straightforward to arrange the appointments and find appropriate locations for each stage of the process.

I: "Did you think you had enough time to decide?"
P: "Yes, I think so. This is in the beginning, yes I did really, I was quite keen to do it. It was all explained. It was explained all right." (P2: IG, Female, 6 mths since diagnosis)

I: "Then [CSO] contacted you to do the follow-ups can I ask about arranging that process?"
P: "And very considerate, and making appointments that were convenient to me and very considerate and polite and respecting you in your own home." (P3: TAU, Female, 7 yrs since diagnosis)

I: "And it was ok in terms of arranging coming to meet you?"
P: "Yes, I think it feels nice that it is in my home, that you're making an effort you know and it doesn't feel so clinical so that's nice." (P7: IG, Female, 1 mth since diagnosis)

Timing of participation needs to take account of individual needs

Discussions arose about the timing of the research in terms of being invited whilst participants were in hospital and also the appropriateness of completing the study stages whilst in hospital

or once discharged and how this related to how participants were feeling. The timing of being approached whilst in hospital was felt to be appropriate by participants but they did reflect how there would have been an inappropriate time for them, or that other people may not have been able to cope with or understand the research in hospital.

I: "The timing of the study for you in hospital, is it an ok time to approach people to take part in research?"
P: "I think so, I think if you leave it until they are discharged a certain amount of them won't be bothered because you get out and its all passed by you are on medication and you are involved then in your life and some might not want to be reminded having been an inpatient." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I think you've got to be a bit, careful who you select, you know that some people would be, depends on their stage of recovery." (P3: TAU, Female, 7 yrs since diagnosis)

Some commented that their time in hospital was a positive time to participate in research and they did not have other things going on for them at the time and it gave them focus or purpose. For one participant, it was convenient as she was then in a position where she was able to make enquires about her treatment whilst still on the ward.

I: "In terms of the timing of the study, was it ok being approached when you were in hospital?"
P: "Yes. Break the tedium (laughs) it's very boring on the ward." (P7: IG, Female, 1 mth since diagnosis)

I: "The timing of it, you were approached when you were in hospital."
P: "I mean it was ideal in a way, I was going to say 'sitting audience' I don't really know what I mean by that, I was available. If it had been any earlier... I mean I was on the road to recovery at that point which is good, but if it had been any earlier I probably wouldn't have been in the right space to be able to make the decision about whether to get involved in the study or not, well not a very informed decision anyway." (P4: IG, Female, 2.5 yrs since diagnosis)

P: "I think it was really good in hospital, I felt like it gave me a purpose" (P6: TAU, Female, 13 yrs since diagnosis)

I: "In terms of the timing for me coming down to provide the information, was that ok in hospital or better when you were discharged."
P: "No it was fine actually I think it was a good time as it led to me making enquiries about medication and things which I might not have done otherwise. I think it was probably good that it was whilst I was in hospital." (P4: IG, Female, 2.5 yrs since diagnosis)

For one participant she felt that being asked to participate whilst in hospital was fine, but actually completing the questionnaires and intervention was better conducted once she was at home.

I: "The timing of the study, you were asked whilst you were in hospital, is that an ok time?"

P: "I'm talking for me personally that's absolutely fine. I imagine there would be patients in there that wouldn't but for me personally it wouldn't have mattered whether I was in hospital or not."
[…]
P: "For me personally, I don't know I saw a few other people doing the first part on the ward. Other people might be able to concentrate, but not me personally. My head was all over the place, I could not concentrate and that was only asking me a few questions." (P5: IG, Female, 10yrs since diagnosis)

Another participant initially felt unable to participate when first approached, but then as she felt better she was interested in taking part, and in the end waited until she was discharged which suited her better.

P: "I think she probably did approach me and I said not at the moment or something. And then she came back. Because I was very unwell. So I wasn't getting involved in anything at all for a long time. I was in there for 10 weeks."
I: "There would have been a time where it wasn't appropriate."
P: "Yeah, but I felt able to say, I didn't feel pressurised." (P7: IG, Female, 1 mth since diagnosis)

Illness had a bearing on understanding the study

Most participants felt that the process was well explained and they knew what each step of the process was, however the exact details about what they were told were hard to recall at the time of interview.

I: "Then the next stage, was me phoning you and bringing down the information pack. Did you understand about, how you may or may not receive the information pack?"
P: "Erm , yes I think [CSO] explained that 50% of people would and 50% wouldn't and she didn't know who that would be."
I: "But you were still happy to take part in the study regardless of whether you were going to receive or not."
P:" Yes, but I guess I was hoping I would get the information (laughs). Which I did. It would be slightly frustrating I think to know that there's an information pack out there and not get it." (P7: IG, Female, 1 mth since diagnosis)

I: "Can I take you back to the study when [CSO] left after doing those first questionnaires, what were you told about what would happen next?"
P: "Yeah I was told, I can't remember exactly. I was told everything yes definitely."
I: "That was communicated ok?"
P: "Yes definitely from the start what the set up was." (P3: TAU, Female, 7 yrs since diagnosis)

Participants did comment on how it was difficult to remember and absorb the details of what the study would involve at the time of recruitment due to how they felt. However, they felt the ongoing parts of the study were communicated appropriately and they felt informed.

I: "Can you tell me a bit about what you understood about the study and what it would involve?"
P: "Not much actually to be honest, just literally, where I was in hospital at the time I wasn't at my wellest, yeah, obviously one of the nurses, was like 'its just answering questions basically about the mental health system'. I didn't remember much at all apart from answering questions."
I: "Maybe it could have been explained better?"
P: "It could have been yeah, it could have been explained better definitely." (P5: IG, Female, 10yrs since diagnosis)

I: "Did you have a clear idea about what would be involved?"
P: "Erm, I don't know at the time I was probably a bit elated really, because I was in hospital."
I: "Then after [CSO] left, did she explain the next stage of the study?"
P: "Erm, she must have done, but I can't quite remember." (P6: TAU, Female, 13 yrs since diagnosis)

Reflecting on the research as an opportunity to reflect on bipolar, gain information and make a contribution

Participants reflected on what they had gained from the experience of participating in IBiD. This included, IG participants reflecting on having obtained new information about bipolar. TAU participants also got something out of having the opportunity to speak about their condition and having people listen to them. Having the opportunity to speak about BD was new to some participants (both IG and TAU), having never spoken to anyone about it before. In addition, as mentioned previously, being given a sense of purpose whilst on the hospital ward was felt to be valuable.

P: "I'm glad I did as I have got some information from it all." (P2: IG, Female, 6 mths since diagnosis)

I: "How you felt about the study and being involved overall?"
P: "Erm, I was pleased about the study and I found the information quite useful" (P4: IG, Female, 2.5 yrs since diagnosis)

P: "I thought it felt quite relaxed and not pressurised into doing it and quite interested to do it for my own self. I kind of welcome, the more information the better." (P7: IG, Female, 1 mth since diagnosis)

P: "I thought it was really good idea, yeah, really good idea that I was involved, it was like taking part in something, like you say that was outside of the hospital and was quite nice seeing somebody, (not) a staff member and would like time to talk through something, things that are relevant to people with bipolar really." (P6: TAU, Female, 13 yrs since diagnosis)

Both IG and TAU participants reflected that it was worthwhile participating in the research as it contributes to knowledge and potentially to improvements in mental healthcare in the future, reflecting their feedback on why they wanted to participate in the research originally.

P: "I felt very pleased to be in it and I think it's wonderful that you are doing this kind of thing, really do." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I felt pleased really. There's not, I've never known about anyone who's wanting to change the system. I've never spoke to anyone who's wanted to change the system, I've never been part of anything like that so I was interested really." (P5: IG, Female, 10 yrs since diagnosis)

7.4.2.1.4 The IBiD Intervention

Gaining a better understanding/ A source of new information

Participants commented on what they had got out of receiving the IBiD resource, this included gaining a better understanding of BD. They also commented on how it addressed concerns they had and the information was reassuring. This reflects the feedback provided during the consultation phase during the development of the resource (Section 5.2.4.3) where the service-users said that they would have found it very useful when they were diagnosed and reflected how it would have reassured them.

P: "Well I understand more about the illness and why it starts really. If that's possible. The reason for it." (P2: IG, Female, 6 mths since diagnosis)

P: "I remember it [the booklet] being useful and reassuring at the time and I've still got it." (P4: IG, Female, 2.5 yrs since diagnosis)

New information to participants contained in the booklet varied for each individual and included the information on medication, side-effects, BD and its symptoms and causes or triggers. The quotes from people with a bipolar diagnosis, the mood charts and information about specific medications and side-effects were mentioned as being particularly useful or reassuring. This also reflects the feedback provided during the development of the resource (Section 5.2.4.3) where the service-users particularly liked the mood charts and the inclusion of experiences of real people with a BD diagnosis.

P: "It was quite interesting to read about bipolar generally and all sorts of material I had never had access to before." (P4: IG, Female, 2.5 yrs since diagnosis)

I: "Can I ask about coming to that understanding, what you have learnt fits in with your experiences and that information has come from the information we went through and the book?"

P: "Yeah, I think, because I'd never thought of myself as bipolar because I've never had great periods of elation, I have more of the depression so I've always thought I was depressed and well and not depressed and well and elated and well. I didn't see that so I could identify with some of the mania, not all of it." (P7: IG, Female, 1 mth since diagnosis)

I: "Was that new to you the information about the medication?"
P: "It was really because no one ever discussed medication with me." (P2: IG, Female, 6 mths since diagnosis)

P: "It had everything that I needed to know. I'm not getting kind of like, terrible side effects off any of the medications, so it's not like I need to say. But it did answer a few of the symptoms that I've been getting. Yeah." (P5: IG, Female, 10yrs since diagnosis)

P: "And I was intrigued to find that it is genetic or hereditary and looking back through my family, I'm not sure I could think of anyone who would fit the bill." (P7: IG, Female, 1 mth since diagnosis)

P: "I remember that there were some sections where people, sort of anecdotes from people saying their experiences which is always quite reassuring when you hear that other people are experiencing similar things."
I: "You particularly liked the section with other peoples experiences, it was the most useful?"
P: "Yeah, or kind of, not useful, but reassuring" (P4: IG, Female, 2.5 yrs since diagnosis)

P: "The mood chart was very useful and what was particularly helpful, the mood charts, and the bits where you gave me, the medication and all the side effects of the medications."
I: "The leaflets?"
P: "That was really helpful. Those were the two particular bits." (P5: IG, Female, 10yrs since diagnosis)

P: "That was another thing that was handy on your bipolar booklet."
I: "The information about other resources?"
P: "Yeah that's right yeah, to sort of find out information about the [charity], so I'm sure if I did need more information, I'm sure the [charity] would provide me with that." (P5: IG, Female, 10yrs since diagnosis)

I: "[…] there was some information at the back about identifying early warning signs and triggers which I think we spoke about briefly."
P: "I think that's very helpful. I think each individual probably knows or has thought about what the triggers are. Yeah, I guess that would be a useful thing to actually write down in the booklet, reminders for yourself." (P7: IG, Female, 1 mth since diagnosis)

P: "There's also, the stigma is covered isn't it within the booklet. I think that's really important" (P7: IG, Female, 1 mth since diagnosis)

A couple of participants commented on content of the resource which was a repetition of information they were already aware of, this related to medications and practical barriers (information on unintentional non-adherence). Leading on from this one of these participants felt that it would have been useful to include more information on lifestyle and an alternative health approach to managing BD and also issues related to employment and mental health.

P: "There were bits which for me personally which I thought didn't find useful, like how to take your medication and remembering to take the medication." (P5: IG, Female, 10yrs since diagnosis)

P: "I suppose I had already had a lot of the information about medication, that was a repetition of what I already knew." (P7: IG, Female, 1 mth since diagnosis)

P: "I think, more about a kind of holistic package would be much more welcome, what you can do for yourself apart from pop pills." (P7: IG, Female, 1 mth since diagnosis)

P: "Erm, might be useful to know about mental health and work actually, that's another question in my mind. How much do you disclose if you are going for a job for example, what are your rights, that side of it would be really useful to know." (P7: IG, Female, 1 mth since diagnosis)

IBiD prompting actions

Participants commented on actions that they had taken as a result of receiving IBiD. One participant was prompted to find out about different medications available to her which led to changing to a monthly injection which she felt was a better alternative for her. Two participants used the mood charting exercises and found this useful to visualise their moods. The information on charity organisations/ other resources was planned to be or had been used by two participants, with one also sharing this with a peer support worker.

P: "I was prompted by it to go and find out about the different medications out there and yeah, just some enquiries with the pharmacist."
I: "Did you get the opportunity to talk to the pharmacist in hospital about your medications?"
P: "Yeah, I discussed the medication I was prescribed at the time and the options for when I was going to be leaving hospital."
[…]
I: "Has that helped, the information [booklet] help with managing to take it and any doubts or worries?"
P: "A little bit, I've still got concerns about taking it at all, but it's led me to a new medication which I wasn't aware of before which is the, I'm currently taking a monthly injection. Rather than tablets so that wasn't something I was aware of at all that I discussed with the pharmacists and looked at the pros and cons of taking that instead."
I: "You found something that could be a better alternative for you?"
P: "Yes.2 (P4: IG, Female, 2.5 yrs since diagnosis)

P: "I do now with that mood chart, I used that. Before that bipolar research study I'd write a daily diary of my moods anyway, but sometimes I can't explain my moods, that chart kind of and the colours have kind of helped me see where my head is. Writing down wise, the mood chart was really, really helpful."
I: "It was useful to visualise your moods?"
P: "Yeah that's right to visualise my moods as have someone else, put my moods on paper was really, really handy."
I: "Did you share that with anyone?"
P: "Yeah, the only people I've seen since you have been the transition team and I told the transition team about it." (P5: IG, Female, 10yrs since diagnosis)

P: "I'm thinking, something that I will definitely will do, is joining the [charity] which is in [town]. I've never actually been to a meeting. That was another thing that was handy on your bipolar booklet."
I: "The information about other resources?"
P: "Yeah that's right yeah, to sort of find out information about the [charity], so I'm sure if I did need more information, I'm sure the [charity] would provide me with that." (P5: IG, Female, 10yrs since diagnosis)

P: "And also there's a guy here who comes in, he was a patient, and he works here now and he takes people for walks and things like that and does board games and that sort of thing and he is bipolar and he was looking for somewhere where he could go near where he lived and I got the information from the booklet of Bipolar and everything."
I: "The charities?"
P: "The charities and the three books I wrote out for him and he found it very interesting as he had not seen them before so that was something really. Pass it on." (P2: IG, Female, 6 mths since diagnosis)

Flexibility in how the resource is used

Participants used the resource in a way which suited them, they described how they used the booklet as a resource to return to or as something which they used once.

P: "I read through the folder, that was quite interesting and I shall probably go back to it and read it again, because I don't always take in everything all at once. I'll have to go back and read over."
I: "There was a lot of information to read, and you have had a look afterwards. You like to dip in and out?"
P: "Yeah." (P2: IG, Female, 6 mths since diagnosis)

P: "Yes, I did look at it and then I left it for a bit and then I read a bit more, kind of went to the bits that appealed to me most." (P7: IG, Female, 1 mth since diagnosis)

I: "Did you use it since that day?"
P: "I read through the whole thing and no, I haven't looked back at it since then, but I did find it quite interesting and informative at the time." (P4: IG, Female, 2.5 yrs since diagnosis)

One participant reflected that she found it useful to go through the information during the session as there was a large amount of information. For another, she found it useful to go through the information in her own time.

P: "For me it was useful to have the guided session to start with to be honest as far as I can tell I would have been a bit daunted by the amount of information." […] "I found the pack really useful, but I don't know, as I say it was really useful initially to have someone else to go through some of it beforehand rather than just being left to read it on my own." (P4: IG, Female, 2.5 yrs since diagnosis)
P: "I remember you came round and I had that cold. I found it useful more after you left as I was able to spend a bit of time going through the book myself you know. So yeah, at the point you came round I really wasn't feeling particularly well. But I did find it useful as I was able to go through it myself." (P5: IG, Female, 10yrs since diagnosis)

Only one participant interviewed completed the exercises themselves, this was not the way the resource appeared to be used by others.

I: "There were spaces to write your own responses in there, did you get to use that?"
P: "Yeah a couple of times I did, not all the time, a couple of times I was filling those out yeah." (P4: IG, Female, 2.5 yrs since diagnosis)

I: "There were spaces to write your own notes..."
P: "I didn't fill any of them in I must admit. But I will do because I shall go back and read it over and over and then make my comments. When it's more in my mind, because there was so much going on recently and I only found out yesterday lunchtime that I had got a flat." (P2: IG, Female, 6 mths since diagnosis)

7.4.2.2 Bipolar, treatment & the mental healthcare system

Alongside discussions about the study, participants frequently reflected on their experience with their diagnosis, treatment and the mental healthcare system. These important insights provide context around their IBiD participation and recommendations more generally for how better to support people with a bipolar diagnosis.

7.4.2.2.1 Struggles with medication

Necessity beliefs were high, but there was uncertainty about future need

Participants expressed an acceptance of the necessity of medication for them to get well and therefore be able to be discharged from hospital. However, doubt or uncertainty was reported in the ongoing need for medication. They judged the success of medication on how they were feeling, but also then expressed doubt for its need when symptoms were not present.

One participant described how she felt her medication was working well for her at the moment. She appeared to have found a balance with a medication which was keeping her moods stable and she was feeling well.

> *P: "Overall I am very happy, because I feel well, I don't feel manic, even slightly manic, I don't feel depressed I feel quite level. I don't either feel like I've been numbed to the world. I feel quite in touch as well, so I imagine I am experiencing the world the way most people experience the world if they haven't got bipolar. So the proof is in the pudding isn't it so for me that's my gauge, and if I stop feeling like that then I will go to my GP." (P7: IG, Female, 1 mth since diagnosis)*

However, she later reported finding it confusing that she still needed an 'antipsychotic' as she was not experiencing psychotic symptoms. In a way, the names of the medications did not correspond to what she felt she needed at the time and did not have a common-sense fit with her symptoms. She questioned the ongoing need for medication in the long term.

> *P: "And Olanzapine is an anti-psychotic and I'm not psychotic so is it appropriate now? Now it was while I was in hospital, but I'm not. So she's reduced the dose of that down to 5 mg with a view to getting off it completely which would be good." (P7: IG, Female, 1 mth since diagnosis)*
>
> *P: "Do you get to a point where you don't need to take it anymore, that I don't get. It would be quite useful to know, interesting to know." (P7: IG, Female, 1 mth since diagnosis)*

Participants commented about the uncertainties around how medicines work and how medication-related decisions are taken in mental health, they acknowledged that it was not an exact science, however, it may not have been presented as such by healthcare professionals. This also ties in with the quote above and the final quote below around confusion about medication types and changes needed.

P: "The other thing I don't understand is, are you on this medication for life. Surely if it's a chemical imbalance you put these drugs into your body, I mean do they disappear, I don't understand. Do you get to a point where you don't need to take it anymore, that I don't get. It would be quite useful to know, interesting to know."
I: "It's quite a mystery?"
P: "My take on psychiatric medication is that it is an experiment every time because everyone is unique and they go with their gut feeling everyone and then they tweak it. And if it doesn't suit you they take you off it and try a different one. There's no exact science to it, but it's presented as an exact science." (P7: IG, Female, 1 mth since diagnosis)

P: "I mean I'll take, you see, with bipolar or with a lot of mental health illnesses there is no thing, you can't take a blood test and therefore the medication is hit and miss, sometimes you are afraid to not take it but you don't know if it's doing you good or whether you just feel a bit better. I think that is the difficulty with mental health with regard in contrast with physical." (P3: TAU, Female, 7 yrs since diagnosis)

I: "In terms of changing medication, have you changed since you left hospital?"
P: "Yes I mean when I saw this consultant he has changed a lot and I don't know where I am at the moment, the Chemist has made a few mistakes saying its ready and it's not. Some of the medications that I was on is being got rid of, kind of like a sliding scale to complete it and then the other medication is to come in, it's could be a bit confusing really."
I: "Knowing what you have to take now..."
P: "Yes exactly and when one finishes and the other takes over, the other one is going to be increased, and I think that is a bit difficult." (P3: TAU, Female, 7 yrs since diagnosis)

Ambivalence and a desire to be medication-free

Despite appearing to accept the diagnosis and the need for medication participants still expressed concerns about taking medication generally and a desire to not be taking it, there was an ambivalence with understanding the need for medication, but a wish to be medication free. One participant commented that after the intervention she still had concerns about medication, these did not go away, but she was able to find a medication where the advantages for her outweighed the disadvantages.

P: "There was a GP on it [TV programme] who controlled it with diet, so I wish I could do that because I don't like medication, I mean anybody I think if you can cut down on medication its good. There are things that are vital that you have to take. (P3: TAU, Female, 7 yrs since diagnosis)"

I: "Has that helped, the information [IBiD booklet] help with managing to take it and any doubts or worries?"
P: "A little bit, I've still got concerns about taking it at all, but it's led me to a new medication which I wasn't aware of before which is the, I'm currently taking a monthly injection" (P4: IG, Female, 2.5 yrs since diagnosis)

P: "For me, well I don't like to be on medication, I was very anti-medication prior to having very severe clinical depression and I don't think it is the single determinant of recovery, but it's played out in the hospital as if that's the only thing to get you better really. That you must take your medication and that's the bottom line and although its voluntary if you are not sectioned, there is a very strong pressure to take the medication and you know, you are considered an idiot if you don't take it (laughs)." (P7: IG, Female, 1 mth since diagnosis)

Participants experienced side-effects, but the degree to which these bothered them varied, and it also varied as whether they took action to address the side-effects.

P: "I'm not getting kind of like, terrible side effects off any of the medications, so it's not like I need to say [report them to their care team]." (P5: IG, Female, 10 yrs since diagnosis)

P: "Yeah, unfortunately I've come, my medication has come, he's introduced a new medication that I used to be on and, erm, a new one that was introduced in hospital and its kind of slowed me down quite a lot. So I feel like I'm going down a bit at the moment, so I'm a bit sluggish, a bit opposite to what I was in hospital really." (P6: TAU, Female, 13 yrs since diagnosis)

P: "I've been to my doctor and said I've been putting on loads of weight, I think that's the Olanazapine and I've said I want to look at something else and she suggested reducing." (P7: IG, Female, 1 mth since diagnosis)

7.4.2.2.2 Experience of bipolar and reflections on diagnosis

A determination to stay well this time & taking action

Participants reflected on how their illness had improved, there appeared to be a determination after their most recent admission, not to return to hospital. Participants described new opportunities and activities they have engaged with since being discharged from hospital this time, these all feed into their determination to stay well. The recovery model highlights the importance of setting personal goals and how the definition of what recovery means to a person is unique.

P: "Yes, it's all been full on, moved to this fantastic place with fantastic staff. I'm determined not to go back [to the ward]. I saw people come and go and I thought, no I can't live like that." (P1: TAU, Male, 6 mths since diagnosis)

P: "Well, I've just starting a new group called a recovery education group and that's coming up and I think with my primary worker there were are going to be talking about episodes of bipolar, so that is something new." (P6: TAU, Female, 13 yrs since diagnosis)

I: "Things have been going well since you left [hospital]?"
P: "Yes, absolutely, I go back a couple of times a week for my art class and chat, the book lady, there's a lot going on."
I: "They are still keeping in touch.."
P: "Yeah." (P1: TAU, Male, 6 mths since diagnosis)

P: "I've done, outside of hospital, with my care coordinator, I did a WRAP [wellness recovery action plan], you know where you look at all your triggers, and you make an action plan of what should happen, what help you need, who can step in." (P7: IG, Female, 1 mth since diagnosis)

P: "Eventually I would like to do voluntary work in the mental health system, because it is a bit shoddy, its just the way the mental health system is." (P5: IG, Female, 10 yrs since diagnosis)

Participants discussed and reflected on their diagnosis, in particular that this was a time when they had come to terms with and accepted it. This was prompted by their experiences surrounding their most recent admission.

P: "I just sort of accept it every day and get on with it. I didn't sort of dive into it and analyse it and think shall I do this, shall I do that. I just take each day as it comes and hope for the best [laughs]." (P2: IG, Female, 6 mths since diagnosis)

P: "I think because as I say I was diagnosed about 7 years ago and I've always resisted the diagnosis, this time my admission was so bad and also a beloved dog of mine got killed on the road and therefore I suppose I've more or less accepted it and also the, when I was an inpatient the Psychiatrist I had whose name was [name], was quite good, so it was easier to accept it you know and the consequences of me being ill were so, well nearly horrific, and I never want it to happen again. "(P3: TAU, Female, 7 yrs since diagnosis)

P: "I've just been diagnosed with bipolar, I think I've had it since I was a teenager, actually it's, I might not like a label, but it's good to know cos now I know what I am dealing with and I feel more optimistic about the future because I've got different medication and hopefully I won't have these great lows where I go into hospital'. So for me it feels a very positive thing to have the diagnosis, or the correct diagnosis." (P7: IG, Female, 1 mth since diagnosis)

P: "I guess I have been manic and I think back to me and it does describe me I suppose and then a big part of it is acceptance. I've had to accept being in hospital in the first place." (P1: TAU, Male, 6 mths since diagnosis)

The impact of the bipolar diagnosis for those newly diagnosed– confusion or explanation

Two participants interviewed were newly diagnosed having had a previous diagnosis respectively of schizophrenia and severe depression. For one, she felt no different to how she had felt before and so having a different label did not make sense for her. For the other, having the bipolar diagnosis helped to explain her experiences both to herself and her family and had a positive impact in terms of her relationship with her family.

P: "I don't feel any different to how I felt when I was schizophrenic. I don't feel any different now I am bipolar. They are telling me I am bipolar, which was a bit confusing at first." (P2: IG, Female, 6 mths since diagnosis)

I: "Can I ask, was that since the diagnosis of bipolar, had things changed?"
P: "I think my family suspected it before it was diagnosed, and they saw me when I was well and the hospital didn't so for them it was confirmation or validation and so I think it has been quite positive in that respect." (P7: IG, Female, 1 mth since diagnosis)

I: "Your family are trying to make sense of the new diagnosis."
P: "It probably makes them more compassionate, because some of my behaviour's been a bit off the wall. Now they've got an understanding of why that might have happened." (P7: IG, Female, 1 mth since diagnosis)

I: "So in that way the diagnosis itself has been of some help."
P: "Yeah. You know it's that kind of 'ah-ha! oh God, that's why that happened, that's why I haven't managed to keep down a job or have a successful relationship, or whatever', because I've had these periods of severe episodes, which I wasn't hospitalised for but maybe I should have been (laughs). So it kind of makes sense of a lot of my journey, if you

like, so for me that is quite empowering, rather than disempowering." (P7: IG, Female, 1 mth since diagnosis)

She also reflected on the consequences of her illness in terms of her employment history, she now understood why she had been unable to work at particular periods which she had attributed to stress, but now understands this was periods of severe depression.

P: "My mental health is why I am self-employed. I kept becoming unwell and losing jobs and I felt like being self-employed was the answer as I could work when I was well and take time out when I wasn't but not really understanding that it was anything more than stress. I thought it was just stress." (P7: IG, Female, 1 mth since diagnosis)

Previous experiences shape personal model of illness

Learning from the IBiD intervention about the different ways that mania can be characterised was a revelation to one participant. Her personal model of bipolar, was that highs were always periods of elation with consequences such as spending large amounts of money. She did not characterise the times when she was working constantly and being very confident as signs of mania, but just as a return to normality. For the second participant, she had a model of bipolar based on her mother who has the diagnosis so she was able to relate her experiences to those of her mothers and the diagnosis made more sense for her.

P: "I'd never thought of myself as bipolar because I've never had great periods of elation, I have more of the depression so I've always thought I was depressed and well and not depressed and well and elated and well. I didn't see that so I could identify with some of the mania, not all of it, I don't think I have it in the extreme form. And I think that's why it's been so difficult to diagnose. Because I've just thought of it as 'oh I'm back on top of it, I can get things done'. But actually I was like overdoing things and taking on far too much. I would have described it more as over confident and no confidence whatsoever. Fluctuating between those two places and they are self-sabotaging because I would start a project in the confident place and then become unwell as think what the hell am I doing, I can't do this!"
I: "Some of those classic signs of mania, actually there are a wide range of symptoms of highs."
P: "Well I've been asked before, do I go out and spend lots of money, well no I don't because I don't have it. Perhaps if I had it I would, but that's never been an issue for me."
I: "Being able to identify some of the other experiences you had been having.."
P: "Yeah and just being over busy and filling every second and talking far too quickly and getting excited and passionate about things. But I didn't ever see that as anything anybody else wouldn't do. It just felt like a return to being not depressed." (P7: IG, Female, 1 mth since diagnosis)

P: "Right, well the first time I was diagnosed was probably when I was 19, it was with depression and elation. They didn't really say 'you've got bipolar'. I don't know really if it was that clear, that that was definitely what I had. And my mum has manic depression, or bipolar as well. So I had a little bit of an idea of what happens when you do and when you go high or a bit low, because I'd seen her going into hospital."
I: "In your experience, it didn't come completely out of the blue?"
P: "No." (P6: TAU, Female, 13 yrs since diagnosis)

7.4.2.2.3 Unmet information & support needs

'On the ward' is a key time of unmet information need

The ward was seen as a key time to provide information and support. Information is not routinely provided in participants experience and this could leave them feeling unsupported and uninformed when they were discharged. These unmet needs included information about medication but also about BD itself. Even those who reported receiving information reported that it was insufficient, or that they would have liked the opportunity to discuss the information with a health professional.

I: "Can I ask about the information you received about medication?"
P: "I don't think it was that brilliant to be honest."
I: "Did you get given anything?"
P: "No flyers, leaflets that were inside the tabs really."
I: "Just the standard information?"
P: "Yeah." (P6: TAU, Female, 13 yrs since diagnosis)

I: "You hadn't got much on the wards."
P: "No, no, I never have done when I've been on the wards, unless, unless I'm in a well enough state to ask. But yes, I've never had any information about medications on the wards."
I: "It's not routinely provided?"
P: "Yes, (not) for me personally." (P5: IG, Female, 10 yrs since diagnosis)

P: "I'm sorry, you don't really receive much information in hospital, certainly I hadn't until that point." (IG, Female, 2.5 yrs since diagnosis)

P: "Yeah I mean that's one of the things that is lacking as an inpatient [information about medication], let's leave that aside [during discussion about IBiD]." (P3: TAU, Female, 7 yrs since diagnosis)

I: "Were you given new medication this time in hospital?"
P: "Yes, I was."
I: "In terms of getting information about those new medications?"
P: "Dr [name] actually gave me a sheet with the medication listed and possible side effects etc etc, but nobody actually went through it with me." (P3: TAU, Female, 7 yrs since diagnosis)

I: "Would it have been useful to have information when you are on the wards?
P: "Erm, yeah actually it would. Because the only information I got was about the medication and a two-page thing about bipolar disorder and the different types." (P7: IG, Female, 1 mth since diagnosis)

I: "Did you ever get information about your medications from the hospital?"
P: "The stuff written down on bits of paper, on sodium whatever, but overall there was like blank bit missing with the whole subject [the subject of bipolar itself]." (P1: TAU, Male, 6 mths since diagnosis)

Following on from these areas where information was felt to be lacking, participants recommended that more information should be provided on bipolar, medication including

side-effects and different doses, disclosure of mental health diagnosis in the workplace. It was also recommended that more psychological support should be provided on the ward.

P: "Probably just a little bit more information about bipolar, I think there were some leaflets on the ward, could be better I think." (P6: TAU, Female, 13 yrs since diagnosis)

P: "No one seems to know what this thing is, what this monster."
I: "You were given information about medication, but not about what bipolar is or what it means..?"
P: "Pretty much yeah, it's the new manic depression, I suppose that's enough to know. I don't know." (P1: TAU, Male, 6 mths since diagnosis)

P: "But if I was applying to go back into the labour market and I was filling out an application form, what do I disclose, that's still a question for me." (P7: IG, Female, 1 mth since diagnosis)

P: "I don't know, for example what the alternatives are to Mirtazepine, that would be quite useful for me to know, to make an informed choice. And what the side effects of each of those are. And also short term effects compared to potential long term effects."
I: "Side effects that you might expect when first taking medication versus if you are on medication for some time. That's not been 100% clear?"
P: "No, I don't feel that has been clear, and it was all very new and I trusted the doctor and they've put me on this and I don't know what the alternatives are and I also don't understand about the dosage and you know, how they decide what dosage you are going to be on." (P7: IG, Female, 1 mth since diagnosis)

P: "Yeah, I always thought it would be good to have some sort of information or therapy during the time when you are on the wards really. Or some sort of counselling. Because you are sort of left and then you get out into the community you just kind of left a little bit without... […]"
I: "It might be time on the wards that would be a good opportunity to provide some support?"
P: "Yeah." (P6: TAU, Female, 13 yrs since diagnosis)

P: "I mean when it's supposed to be a psychiatric ward and yet you don't have any psychological support when you are actually in there. It is a shame and the only time, well it depends on the nurse, is when you are getting your medication. You've any chance to ask anything. I don't know what they are doing with these computers, it would be much better if they were interacting with the patient." (P3: TAU, Female, 7 yrs since diagnosis)

Participants' recommendations on when information should be provided demonstrate that it is important to receive information when on the ward, to have someone take the time to explain bipolar, symptoms and treatments as illustrated by the following narrative.

I: "If you were going to recommend what would have been useful in terms of information or anything you still feel you could receive more information on about bipolar or medication?"
P: "I think it would help in the ward when you are admitted, unless you are a long term bipolar patient, I mean I was never ill until 7 years ago. If someone would, trained staff, or somebody would sit you down and even after the acute stage when you come in and explain exactly what has happened, why it has happened, I mean to a degree, they may not know but the contributing factors and have a chat and explain exactly what bipolar is I think that would definitely be. I think also to say to people 'well what help can we gave to

you?'. You know, we are here for you to talk to etc. I think staffing issues but it would be great if they had the time or the inclination to do that. Because I think you are totally ignorant as to what exactly it is. Unless you have had it for years and years."
I: "That's crucial to get that information."
P: "When you have come out of that acute stage, you are with it, well as with it as you can be. It would be very, it doesn't have to be the whole thing in one session but if that was continued until both parties were happy with it, it would be great. Because otherwise you are going in, you are given the knockout pills and then you get better than then you come home." (P3: TAU, Female, 7 yrs since diagnosis)

However, one participant felt that information should be provided once you are at home and able to concentrate better.

I: "Being provided with information when you are in hospital. When is the best time?"
P: "I think it is best back at home. Better able to concentrate really.[…] For me personally, when you are on a one to one, in your own space where it's a bit quieter."
I: "It's important to be in your own space."
P: "Yeah, yeah." (P5: IG, Female, 10 yrs since diagnosis)

Waiting until discharge might be more practical in terms of when to provide information as participants were aware of how quickly discharge occurs after you show signs of illness improvement.

P: "GPs might be a point where that information could be given as well, because discharge is very quick as you know, as soon as you show the slightest signs of recovery you are out! Because they haven't got the beds so care is handed back to the GP." (P7: IG, Female, 1 mth since diagnosis)

Illness impact on help seeking

A couple of participants acknowledged that the nature of their illness itself has an impact on if and how they might seek information or support for bipolar.

P: "Trouble is that sometimes depending on what way it goes and you get ill you are reluctant to seek help and I think for me personally if you become aware of it, because you are not always aware of it. But after this particular incident I have kind of identified the triggers and seek help as quick as you can." (P3: TAU, Female, 7 yrs since diagnosis)

P: "[…] one thing with me is that I find it really difficult to speak, to communicate when I am unwell. When I am in the depths of severe depression or anxiety state and can barely get my words out." (P7: IG, Female, 1 mth since diagnosis)

Useful information sources

Information sources which people have used or feel confident in knowing they could provide the information needed included participants Community Psychiatric Nurse (CPN), Psychiatrist and books.

P: "I would turn to my support worker." (P5: IG, Female, 10 yrs since diagnosis)

P: "Yeah, my CPNs have downloaded information and printed it out and given it to me before." (P6: TAU, Female, 13 yrs since diagnosis)

P: "Well, I usually ask my psychiatrist, I feel like, he could tell me that really."
I: "So if you had any concerns you could discuss it with your psychiatrist?"
P: "Yeah, I can discuss it with him or I can discuss it with the social worker that I see." (P6: TAU, Female, 13 yrs since diagnosis)

P: "I'm just going to read that book [Bipolar survival guide] and then there was another one with quite similar title that people have recommended, I think it might be recommended in your information booklet. I might get that as well." (P7: IG, Female, 1 mth since diagnosis)

7.4.2.2.4 Healthcare experiences and recommendations

Anxiety about access to care and support

Participants described the care they had been receiving since being discharged from hospital. Although they were able to describe the support they were currently receiving, when they reflected on this, there was a sense of anxiety about getting access to the support they might need. One participant felt there was a pressure to be discharged quickly which she was not ready for.

P: "I think the difficulty arises then of getting an appointment. My appointment with him is for 3-4 months later and it was at half nine and I'm not good at getting up early. It was said to me if I didn't take that appointment it would be a long time before I could get one again. I think the system is if it is an urgent appointment it can be got. That's the best way in terms of doing it. I think the CPN, if mine is off, there is a duty CPN." (P3: TAU, Female, 7 yrs since diagnosis)

P: "Yes and probably to a degree trying to get it [support] , and against that, it sounds a contradiction, when I mean, they are restricted budget wise and time wise, like the CPN is. But I think the level of support would be great if you could get more of it, it's not their fault, it's the system if you want to call it that." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I mean, I feel like my doctor, there is a sort of slight, lack of clarity about who is prescribing the medication and when it gets formally handed back to your GP if you like. I felt a slight hesitance with my GP as to whether she might be stepping on the Psychiatrists toes if she changes the medication. So that's a slightly grey area really." (P7: IG, Female, 1 mth since diagnosis)

I: "And then once you were well, you were discharged."
P: "Yeah, exactly (laughs) as soon as you show any signs of recovery you are out the door. I had to insist that they didn't discharge me for a week and they said 'oh we are going to discharge you' and I said 'that's ridiculous, I haven't even been home', so I refused to be discharged, and made them wait a week until I was ok at home before I was formally discharged." (P7: IG, Female, 1 mth since diagnosis)

Reflections on previous and current care

Participants described a range of difficulties they had experienced with care received both previously and in relation to their most recent admission. For one participant she described a number of difficulties experienced, including prescribed inappropriate medication, staff not having the time to focus on her care and a lack of support.

P: "And, for example, last time as an outpatient, Dr [name] was one of the psychiatrists, overprescribed lithium for me and I ended up in a coma in the general hospital, so I've had bad and good." (P3: TAU, Female, 7 yrs since diagnosis)

P: "There was an office, you had to knock on the door and wait, you had people going by all the time so you were lucky even if you got to the door to, it should have been in private, but you had to ask in an open corridor and I was in for quite a long time and I heard a patient say to one of the auxiliaries, 'oh can I have a chat with you later?'. And I thought 'oh my goodness you can do that!' I hadn't realised you could do that.. "
I: "You weren't told."
P: "No, and apart from the odd trained staff it was more medication time or something, you might have a question. But I really did, any information, on bipolar or that was very scant it was even worse than 7 years ago." (P3: TAU, Female, 7 yrs since diagnosis)

P: "I mean when it's supposed to be a psychiatric ward and yet you don't have any psychological support when you are actually in there." (P3: TAU, Female, 7 yrs since diagnosis)

Two participants described the status of the Consultant Psychiatrist on the wards and how they were detached from the actual patients and their time spent understanding the individual patient was limited.

P: "But I do feel that it runs from the Psychiatrists down and the Consultant Psychiatrist is God and these poor front line staff who know you better than anyone, although they keep copious notes, does the Psychiatrist actually read them, they don't have time!" (P7: IG, Female, 1 mth since diagnosis)

P: "I don't know if you are aware of the ward rounds. It's it was built up to such a thing as if God was coming round, and in that process when you are actually in with the consultant, they don't have the time to go into a lot of what is wrong." (P3: TAU, Female, 7 yrs since diagnosis)

Despite some poor experiences, participants commented positively on their involvement in their own care now, compared to previous experiences, for one the experience after discharge, and for the other the experience in hospital.

I: "You mentioned you being involved in the decisions, has this got better?"
P: "On Friday the psychiatrist I saw, it was a lot better than what it had been 7 years ago, there was more give and take, definitely, more explanations given." (P3: TAU, Female, 7 yrs since diagnosis)

I: "How does that feel? Does it feel you are an active part?"
P: "Yes it did actually to be fair to the hospital, they're looking for feedback all the time,

how you are doing, and they do change it. What do they call them, the rounds they have every week. They do ask for lots of feedback and they do make adjustments." (P7: IG, Female, 1 mth since diagnosis)

However, one participant reflected on how medication is seen as the one way to stay well and so although you may be involved in care and treatment is voluntary, you are still under pressure to take medication.

P: "it's played out in the hospital as if that's the only thing to get you better really. That you must take your medication and that's the bottom line and although its voluntary if you are not sectioned, there is a very strong pressure to take the medication and you know, you are considered an idiot if you don't take it (laughs)." (P7: IG, Female, 1 mth since diagnosis)

7.5 Discussion

7.5.1 Overview of findings

The findings from this qualitative evaluation identified themes related to research participation, both in acceptability of the IBiD intervention and RCT protocol and in wider aspects of mental health, namely understanding illness and treatments and reflections on mental health care. There are a number of themes which link and corroborate the findings from Chapter 4 from participants who were recruited from a community-based treatment population as opposed to those in acute treatment in the IBiD study.

Unmet information and support needs were a key theme in this evaluation, motivating participation in the study. These relate to finding out more for themselves but helping others in the future to have better access to information. In terms of timing of provision, the inpatient time was a challenging but equally important time to be allowed to participate in research and receive information. Participants identified benefits to taking part in the study, having the opportunity to talk and being prompted by the intervention to take actions and to better understand the experiences they have as part of their illness.

Wider issues raised in the interviews were that participants found it hard to accept the need for long-term medication. They reflected on challenges with the inpatient environment in getting information they needed and being involved in decisions. The findings indicate that care is not always provided in accordance to recovery-focussed care. Factors which support recovery include developing good relationships with care providers, being listened to and having their beliefs respected and having the opportunity for personal growth (Jacob, 2015). It was clear that people felt that their beliefs were not always acknowledged during their care.

The research gave them the opportunity to speak and have their views valued. In order that people have the full opportunity to be involved and empowered to participate in their care, they need their information needs to be met (NICE, 2014) and this was not always the case for these participants. The intervention helped to meet this unmet need.

7.5.2 Research participation

Participants' decisions to take part were based on both a desire to improve services and give back for care received and also desire to get more information about their diagnosis and treatment. This emphasises the unmet information needs of people with BD in the acute mental health setting, reflecting the findings from the community-based research in Chapter 4. People do not appear to have the opportunity to learn about and explore their diagnosis, which is not consistent with recovery-focussed care.

In terms of decisions to take part in research, these findings concur with previous studies in mental health. Zullino and colleagues (2003), found that three-quarters of patients in an acute mental health setting would hypothetically be willing to participate in a study which would involve follow-up after discharge, their desire to participate was led by a desire to progress science and help other patients. These desires have also been reported in real trials as opposed to hypothetical participation studies (Woodall, Howard, & Morgan, 2011). The present evaluation included participants who had both declined and agreed to take part in the trial. The finding in the study by Woodall and colleagues that the research gave them a sense of purpose and something to get up for agrees with the findings in the IBiD evaluation (Woodall et al., 2011). Given the potential positives of and the enthusiasm for research participation it is important that people have the opportunity to take part in trials. However, a survey by the NIHR Clinical Research Network found that only 21% of people surveyed would feel confident in asking about asking their clinician about research opportunities. As a response to this, the 'OK to ask' campaign encouraged patients and carers to ask about research opportunities (NIHR, 2015). Initiatives like this should mean that the enthusiasm for research participation is translated into greater numbers of people being involved.

We found that recruitment in hospitals was an acceptable time for patients, but flexibility must be allowed for completion of baseline and interventions both in their location and timing. This concurs with findings from Zullino and colleagues (2003) described above about hypothetical participation in a study which would involve follow-up after discharge. In the present study, this time appeared to be appropriate for participants who reported that it was a time of information need, relevant due to their recent admission, they had the time to take part in the

research and were potentially able to explore treatment options for after discharge. However, recruitment in this setting needs to be carefully judged as potential participants may still be too ill, or they may be more comfortable participating in their own home environment and some may like the detachment from the hospital/ healthcare system. This reflects findings in Chapter 4 that having an acute episode should not preclude the option to receive information about what is going on for them and what treatments they are taking, however this needs to be carefully judged. Due to the speed that discharge can occur once participants' illness improves, although recruitment is practical in the ward, after discharge may be better to provide information as there is more time to do this. Short hospital stays are increasingly common with the aim of inpatient treatment being crisis management and ensuring patient safety (BBC, 2014; Glick et al., 2011). Woodall and colleagues qualitative research around participation in a psychosis trial also revealed that timing of approach is important and may act as a barrier to participation if it is inappropriate (Woodall et al., 2011).

7.5.3 Positives of taking part – both in IG & TAU

The actual research process appeared to confer some self-reported benefits for participants, which was not anticipated. Participants found the process of completing the questionnaires interesting and it helped them to reflect on BD and this was the case in both groups. This concurs with other research where completing the questionnaires normalised mental health issues for participants (R. Byrne & Morrison, 2014). The questionnaires covered topics they had not been asked about before and revealed potential symptoms and side-effects which they had not been told about. Despite some having a long standing diagnosis, participants report not having received information on their condition. This could have significant implications for people, for example not being able to recognise early signs of illness episodes and not having information on potential medication side-effects, and what to do in the eventuality that they experience them. This concurs with previous research identifying unmet information needs in the mental health setting (Bowskill et al., 2007; Care Quality Commission, 2009a, 2011a; Morselli & Elgie, 2003).

Benefits from research participation alone have been reported in a number of studies in mental health. A qualitative study alongside an early intervention in psychosis trial reported that participants found having the opportunity to open up and for some it was the only opportunity they had to actually speak about their experiences and concerns (R. Byrne & Morrison, 2014). Woodall and colleagues (Woodall et al., 2011) found that some participants reported that speaking to a researcher was beneficial and different to discussing problems with a clinician. The researcher may be seen to be more interested in the participants' beliefs

and experiences and see value in them. Clinicians may be viewed as interpreting their experiences in the medical model of illness. Perhaps participants felt there may be consequences for their own care in disclosing beliefs and behaviours not consistent with the clinician expectations.

The helpful and potentially therapeutic effects of completing the questionnaires themselves should be explored as it could provide a quick, efficient way to raise important issues for patients in clinical practice which could be shared with care teams. This was also noted in qualitative research by Pollack and Aponte (2001) who found that interviews served to raise new issues for patients to consider and allowed then to speak openly about them. The authors also point out that this method would be useful for raising issues which would be of value for discussion with their care team.

7.5.4 Challenges with understanding - completing the questionnaire & the research process

Feedback from participants revealed important insights into how the study was communicated and the acceptability of the questionnaire. Some participants reported that the questionnaire at times could be confusing or the language used was not clear. Participants did not always feel there was a space for them to write exactly how they felt in the questionnaire and questions at the baseline were not always appropriate to the inpatient setting. Cognitive interviewing or think-aloud studies could be used to identify the specific problems with understanding and where participants would want to add additional views or response items, and to ensure that they are fully valid in a mental health context (van Oort et al., 2011).

Participants' ability to concentrate and engage with the research was affected by their mood state and side-effects affecting their cognition. The flexibility of completing the questionnaire over two sessions allowed participants who would have been unable to concentrate for long periods the opportunity to take part. In addition, having support from the CSO was seen as vital for some, they reported finding completing the BMQ and MARS repetitive for each of their medications so the assistance helped them get through it. Research has shown cognitive deficits including verbal memory, attention and executive function can occur during symptomatic periods of illness (Quraishi & Frangou, 2002). This concurs with an evaluation of a psychoeducation programme where participants reported that their mood affected their ability to engage with the course by affecting their concentration, enthusiasm and ability to focus (Poole, Simpson, & Smith, 2015).

In future studies it would be important to ensure that the process of the research was effectively communicated to participants. TAU participants who, as they received fewer

contacts, were not always sure of the process and when their next contact with the research team would be. Although being assessed as having the ability to consent at each time point by their care team, this does not preclude the chance that their memory for specific details may lapse and need to be refreshed.

7.5.5 Acceptability of the study – practical arrangements

Practically the study was acceptable to participants, for example, arranging appointments and suitable locations to meet. Overall, there was positive feedback on the process of taking part. Participants commented positively on the approach of researchers including the flexibility and respectful attitudes, this appears to be a key part in maintaining participants' engagement. The research team are viewed positively where they maintain empathy, informality and professional understanding around the personal and potentially difficult disclosures involved in mental health research (R. Byrne & Morrison, 2014). Lessons can be learned from this as to what is valued by patients in mental healthcare. Recovery-focussed care which values patients' perspectives and is flexible to acknowledge and respond to their fears, needs and goals would clearly be viewed positively by patients (Jacob, 2014).

7.5.6 The IBiD intervention

The intervention was commented on positively in the qualitative interviews and participants were able to benefit from it depending on their needs and priorities (information, reassurance, prompting into finding out more, tracking moods etc.) and used it in different ways. Having written information was a good way to receive information and having the flexibility to speak about it, reflect in their own time or raise issues with their care team confirm that this delivery method was acceptable. The ward environment is a time of information need, but people are often not given information at this time. In Chapter 4, participants described how they did not receive information when they needed it.

Self-reported actions taken after the intervention were; investigating different medication options, finding out more about BD and monitoring mood. Participants also reported feeling reassured by the information about symptoms and side effects. One participant felt that the information about the different ways that mania can be characterised was extremely useful and helped her to identify her own personal prodromes of mania. These outcomes reflect those reported in a qualitative evaluation of a group psychoeducation programme in the UK, where participants reported that mood diaries were useful and the content of the programme helped participants to better understand the symptoms of BD and provided information on

medication which they felt was lacking from their care (Poole et al., 2015). A pilot study of a web-based intervention in BD found self-reported impacts on insight into illness, health behaviour, personal routines and positive attitudes towards medication (Poole, Simpson, & Smith, 2012).

The self-completion exercises had only been used by one participant interviewed, another remarking that she planned to go back and look at them. It could be that an additional appointment in person or over the telephone with the researcher might prompt use of these exercises. The mood charting exercise was commented on positively, with a couple of participants finding this useful for visualising their moods.

7.5.7 Broader aspects of mental health raised in the interviews

The interviews raised additional issues which participants wished to discuss about their views and experiences about the diagnosis and treatment and the care they have received.

For some participants there was still some confusion and difficulties with accepting the long-term need for medication, for example the need for an 'anti-psychotic' when not actively psychotic. This reflects the challenges reported in Chapter 4 by participants in agreeing with the need for medication when they were not acutely ill. This adds weight to the premise of the extended model of self-regulation (Horne & Weinman, 2002), whereby the identity of the medication did not have a common-sense fit with symptoms. There was a lack of understanding that this medication was prescribed to help prevent mood episodes as opposed to just treating periods of psychotic symptoms. Participants' narratives also supported the idea of personal models of their illness, part of the CSM (Leventhal, Brissette, & Leventhal, 2003). One participant described how her model of mental illness was formed by witnessing her family history of illness, others' models were influenced prior diagnoses of schizophrenia and severe depression.

Ambivalence was clear in the narratives of participants. The messages in the IBiD intervention may not have fully addressed medication concerns for individuals. There appeared to be a strong desire in two of the individuals interviewed in the qualitative evaluation to be medication free in the long-term although understanding the need for it to get well during and after a hospital admission. Participants in an adherence therapy for psychosis study also acknowledged benefits of medication in stabilising them and therefore having a positive effect on their lives. However, they still felt that there was an over-emphasis on medication and participants still had concerns about taking it (E. Brown, Gray, Jones, & Whitfield, 2013). These beliefs are important personal views of medication and clinicians need to acknowledge and

work with them rather than against them. Indeed, one participant still had concerns about medication but had been prompted to find out about a medication which, for her, had on balance, more advantages than disadvantages. This provides support for the recovery model and the importance of being actively involved in treatment decisions as recommended by NICE guidelines for BD (NICE, 2014). Participants in Chapter 4 also described the need for trialling different medication to find the right treatment, but report that this process was not always well communicated or straightforward.

Participants' narratives included their experiences with mental health services and provide a narrative on the extent to which the recovery-model is implemented in current care and therefore a number of implications for service provision. Participants expressed their difficulties with the transition period between services and how any medication changes were decided upon and arranged. This difficulty between changing from the care of mental health services to primary care was reported in a qualitative study by Gale and colleagues (2012). In addition, Jones and colleagues (2009) found that people found transitions confusing, they disliked the difficulties presented in building relationships with providers due to changes and found that communication gaps meant that personal or care changes were not always communicated. Participants in the IBiD evaluation had mixed reports of moving medication prescribing from psychiatrists to GPs. Challenges faced were when GPs did not get the information that medication or dose changes were needed, or GPs were reluctant to interfere. Participants commented about their uncertainties around how medication-related decisions are taken in mental health. They felt that HCPs had not fully informed them of the uncertainties around medication decisions and the need for trialling different options, this also reflects the reports of participants interviewed in Chapter 4 who reported feeling like an experiment and that medications were just tried out without a real strategy. Participants in this evaluation also expressed anxiety about ongoing access to care and where and how to get the support they might need. This demonstrates clearly that there is a long way to go in ensuring everyone receives recovery-focussed care. A key aspect of care in line with the recovery model is empowering people to be active and informed partners in their treatment (Davidson, 2005). If patients feel like an experiment, it is clear that they have not had an active role in decisions.

We found some support for the inpatient setting being an appropriate time to start to provide information. There were unmet information needs, as for some they were newly diagnosed and needed information about BD and new medications were prescribed. Even when information had been provided, participants reflected that they would have appreciated the opportunity to discuss it. Time with their Consultant Psychiatrist was particularly limited, with

participants describing the ward rounds and the hierarchy of clinicians. This hierarchy was also described by Happell and colleagues (2004) that in inpatient settings the psychiatrists were not approachable even by the nurses. Sweeney and colleagues (2014) also report on how the inpatient time is difficult for developing therapeutic relationships, in part due to the loss of liberty.

Satisfaction with 'care information' as an inpatient has been shown to be associated with participation in treatment after discharge from hospital (Bowersox, Bohnert, Ganoczy, & Pfeiffer, 2013). Care information included involving patients in decisions about their care. The authors hypothesise *providing more information and opportunities for involvement in care decisions during an inpatient stay may reduce the risk of nonadherence to subsequent outpatient appointments'* (pg 561).

Previous research has revealed individuals felt some medication information was deliberately withheld by doctors, for example side-effects. When not informed, they were then not prepared when side-effects occurred, did not know how to manage them and this resulted in patients making dose changes without informing their clinicians. If participants felt better informed, they were more inclined to ask questions, voice concerns and thus felt more involved in their treatment (Happell et al., 2004). Patients interviewed by Duxbury and colleagues (2010) also reported information they were provided with about medication tended to mostly be about the therapeutic effects and not the possible side-effects.

A review of inpatient care found that patients accepted the need for medication as part of their treatment, but had not been provided with education about medication or side-effects and there was a lack of involvement in treatment planning. Discharge planning involvement was another common theme of research included in the review. Patients wished to be involved in planning, informed about arrangements and needed better continuity of care between inpatient and outpatient providers. Early discharge was a factor in difficulties experienced after discharge (Hopkins, Loeb, & Fick, 2009).

Patients' need for information is likely to extend beyond the inpatient setting. This may be due to changes to medication after discharge, moving from treatment to stabilise someone after an acute episode of illness, changing to prophylactic treatment. In line with the recovery model, patient's own perceptions of treatment, their priorities and goals may change and along with this, information provision and support should continue after discharge. As mentioned, more work is required to determine if concerns about medication can be assuaged, or whether actually finding the medication with least concerns and providing accurate information about side-effects may be more effective.

7.5.8 Limitations

This qualitative evaluation provides important insights on the RCT protocol and intervention, however, the findings must be interpreted in light of some limitations.

The qualitative study was limited by only including seven participants, due to delays in processing the ethics submission it was not possible to return to participants who had participated early on in the study. The results from these participants may then not fully generalise to those recruited at the outset of the study. We cannot be sure more themes would not have emerged, had we interviewed more participants. However, the reflections and feedback provided from each participant provide valuable lessons for assessing the feasibility and acceptability of the study.

The results are also only from participants who were retained at follow-up. However, the reasons for withdrawal were frequently due to illness relapse (Chapter 6), therefore it was not appropriate to contact those who had withdrawn to invite them to participate in the qualitative interviews.

Participants often found it difficult to recall specifics about the questionnaires or the interventions to provide more detailed feedback. Byrne and colleagues (2014) reported participants in their qualitative evaluation of an early intervention trial also found it hard to recall details of the study, however, they could describe aspects which were helpful to them. This recall difficulty could be addressed by providing participants with copies of the materials during the interview to prompt their memory.

The interviews took place up to a couple of months after participants had been recruited to the study, therefore are subject not only to recall effects, but also to participants reflecting back on the process. Participants' reflections on decisions, for example, may not accurately represent how they felt at the time, but may be affected by subsequent experiences.

Finally, participants may have been unwilling to give negative feedback on the study due to the researcher conducting the intervention sessions also interviewing the participants. Participants were encouraged to provide frank and honest feedback as this was a feasibility study with the aim of making improvements. However, they may have been unwilling to do so.

7.5.9 Conclusions

The qualitative evaluation indicated the IBiD RCT was acceptable to patients. There was a clear need for information, with participants expressing that the decision to participate was led, in part, by the desire for information about BD and treatment. Some had a recent diagnosis and

they needed information, and others felt that they had the time to explore medication options. It was acceptable to participants to approach them whilst in hospital, but only once their mood had stabilised and to allow for flexibility in how the different stages of the research are conducted, in timing and location.

Valuable aspects of research participation were reported by both those receiving IBiD and those assigned to TAU. The research provided both an opportunity for reflection about the diagnosis and their experiences and to speak about these with the research team. In addition, even the questionnaire provided insights into symptoms and side-effects, helping to explain some of the experiences they had been having. This potentially therapeutic effect of assisted questionnaire completion could have implications for clinical care, opening up communication between patient and clinician which could have an influence on treatment decisions.

The questionnaires used in this study could potentially be modified through cognitive interviewing or think-aloud studies. This evaluation revealed participants could be confused by the response categories and felt it did not always incorporate the full range of their views and experiences. This would ensure outcome assessment for future studies evaluating an intervention of this kind would have higher levels of validity to BD. The importance of allowing flexibility in questionnaire completion and in having the CSO to help with both motivation and concentration was clear.

The IBiD resource itself was used flexibly according to participant need and priorities, they reported using the information on medication and symptoms of BD, mood monitoring exercise and sources of additional help. One participant found it useful to have the facilitated session and one preferred to read it through on her own. The resource prompted one participant to change to a medication which better fitted with her needs and preferences. In the future the intervention could benefit from having additional follow-up sessions and assistance in working through the exercises as there was not time to cover these in the single session.

By including participants in both groups in the qualitative evaluation the potential therapeutic effects of research participation and how the randomisation process was accepted can be assessed. Both groups reflected positively on the process of the study, particularly in how arrangements were made which were sensitive to participants needs and the assessments and intervention contacts were conducted respectfully. Maintaining these positive relationships may have been the key factor in maintaining participants' engagement with the study. This has implications also for engagement with treatment. Care providers developing and maintaining good relationships with patients could help to facilitate engagement with treatment including adherence.

As well as providing important feedback on the feasibility RCT, participants' reflections provide insight into the application of models of illness and adherence in mental health as well as reflections on the care process itself. It is clear that the transition period between acute services and community-teams can be associated with not only medication changes, but potential confusion with the care pathway. It may be that this time may not be the most appropriate for an intervention which aims to target perceptions about prescribed medications, but perhaps this could be incorporated at a later follow-up once maintenance medication is initiated.

For some, medication is still associated with symptom perception and personal models of illness are influenced by prior experiences and social factors. The common-sense model of illness and extended self-regulation model is supported. There was strong medication ambivalence for participants. Although there was a need for it in hospital, this appeared to taper off once symptoms improved and there was a strong desire to be medication-free. The IBiD intervention is not sufficient to challenge medication perceptions over this short time frame at this particular time point. Instead, helping people to find a treatment which fits better with their beliefs and practical needs, but which is still efficacious may be a more realistic goal.

Chapter 8 Treatment perceptions and Shared Decision Making in bipolar disorder: A cross-sectional study

8.1 Introduction

Service-user involvement in planning care and making decisions about treatment, referred to as Shared Decision Making (SDM) is increasingly important in mental health care policy under a more recovery-focussed care model (Coulter, Edwards, Elwyn, & Thomson, 2011; Jacob, 2015). This reflects a move away from paternalistic care where decisions are made by clinicians based on their perception of what is best for the patient (Farrelly et al., 2015).

Before describing SDM in mental health and the factors associated with patient experiences and preferences it is important to consider how it has been defined and operationalised. SDM is a process where patients receive evidence-based information about treatment options including areas of uncertainty as well as a process of counselling to reach a decision and the recording of patients' preferences (Coulter et al., 2011). Charles et al (1999) identify four features of SDM: both the clinician and patient are involved in the process, sharing of information is bi-directional, both parties can express treatment preferences and the decision is based on an agreement between the two. A challenge is presented by the fact that various measures exist to assess SDM preferences and experiences and they have often been developed for particular healthcare contexts. It has been recommended that modifications are often needed to ensure they are context and language appropriate (Fischer, 2006). Scholl and colleagues (2011) conducted a review of SDM instruments. Most are self-report of the patients' perspectives on the decision making process. But other aspects included role preferences, evaluating the decision outcomes or patients' reflections on the process. The psychometric properties of existing scales is generally good in terms of reliability, but validity has often not been fully investigated (Scholl et al., 2011). Barr and Elwyn (2015) found two main threats to validity in SDM measures, specifically that patients may not be aware of what and where the decision making points are and the measures don't take account of the number of decisions involved in consultations.

Returning to SDM in mental healthcare, the momentum is shifting towards the view that information provided to patients in psychiatric care should enhance choice and reflect their values (Deegan & Drake, 2006; Hope, 2002). This acknowledges that patients themselves have valuable expertise on their condition, how they respond to treatment and their hopes and wishes for outcomes. Mental health patients' generally prefer to be informed and involved in their care and treatment (Bilderbeck et al., 2014; de las Cuevas et al., 2012; Hill & Laugharne,

2006; Sajatovic et al., 2005). A recent online study conducted in Germany including people with a BD diagnosis found that 65% preferred an SDM role (Liebherz et al., 2015). There are, however, a range of preferences expressed. Eliacin and colleagues (2015) report preferences from full engagement in decision making to no input at all.

As described in Chapter 1, Section 1.2.5, where patient preference and involvement is used, outcomes are improved (adherence and clinical) and patients are more satisfied with treatment (Lindhiem et al., 2014; Wilder et al., 2010). In a qualitative study, patients viewed SDM as an important part of recovery (Eliacin et al., 2015). Medication changes driven by patient choice have been found to be associated with better treatment engagement, adherence and in medication attitudes (Sajatovic et al., 2014). The authors posit that these improvements were related to feeling more actively involved in treatment. Conversely, patients have reported that they change medication dosages in response to side-effects without consultation with health professional as they found it difficult to communicate with them (Happell et al., 2004).

Despite the policy shift towards SDM, UK surveys reveal that in practice, patients are not always involved to the extent they wish to be (Care Quality Commission, 2009a, 2011a, 2013). Analysis of psychiatric consultations showed a minimal attempt to involve patients in decisions (Goss et al., 2008). Liebherz and colleagues (2015) found that 55% of people with BD reported that, in their most recent consultation, decisions were shared. However, half reported finding it difficult to make decisions around taking a different treatment or changing dose. Patients have also reported that a lack of knowledge and worry about making an incorrect decision was a barrier to involvement in decisions (Eliacin et al., 2015). This highlights that information on medication choices is a key unmet need, concurring with previous work (Bowskill et al., 2007; Morselli & Elgie, 2003). Unmet needs appear to affect patients' perceived control over their medication management, with a lack of knowledge about how long they would have to take medication for affecting perceptions of their control (Happell et al., 2004).

In a UK study on anti-psychotic prescribing, around 40% of patients with a diagnosis of schizophrenia felt they had not been given enough information about their medication. However, half of these said they did not want more information as they trusted their doctors' decisions. This still means that these patients may then not be familiar with potential side-effects or how to take the treatment (Paton & Esop, 2005).

Recent research explored barriers to implementing SDM in a UK mental health setting (Farrelly et al., 2015). Implementation of SDM was affected by the power differential between patients and psychiatrists. Clinicians had concerns that patients may not choose what they saw as the most suitable options or that they might choose treatments which were not available. Patients

described feeling disempowered and having little influence on their own care and feeling unsure about trusting their own decisions (Farrelly et al., 2015). This concurs with findings reported in Chapter 7, where participants were acutely aware of the Consultant Psychiatrists status and reported difficulties in communicating with them. They also reported that there was rarely time to speak to other care staff on the ward. This emphasises the importance of patients being fully informed about options and feeling that they can discuss their care openly.

A qualitative study with UK psychiatrists indicated that they desired a concordant relationship characterised by shared decision making, making choices that reflect the patient's wishes, negotiated agreements and a sense of partnership, with patients. They reported sometimes withholding information about adverse effects of medication as it was perceived that this may discourage acceptance of treatment (Seale, Chaplin, Lelliott, & Quirk, 2006). This reflects findings from the current programme of research where patients reported that they were not fully informed about how treatment decisions are made and the different alternative medications available (Chapter 4 & Chapter 7). As Charles and colleagues point out, for SDM to occur both clinician and the patient must perceive that there are choices available (Charles et al., 1999).

The barriers to SDM reported by mental health nurses reflect the barriers reported by psychiatrists. In addition, mental health nurses also identified that a lack of resources inhibited involving patients more in their care planning. Lack of time, staffing levels and greater priorities on the ward meant that patient involvement did not take precedence (Anthony & Crawford, 2000). The qualitative evaluation of the IBiD intervention (Chapter 7) also found that there was little opportunity for participants to ask questions about their diagnosis or the medication they were prescribed which is a key aspect of SDM. Satisfaction with care as an inpatient has been shown to be associated with participation in treatment after discharge from hospital (Bowersox et al., 2013). However, in this study respondents with higher satisfaction may be overrepresented in those responding to the survey at discharge and satisfaction with inpatient care may be subject to recall bias influenced by experiences after discharge. It is, however, possible that having a negative experience in hospital may result in disengagement once discharged. Despite this, other factors may mitigate against this such as having a strong belief in the necessity of treatment to avoid readmission. Nurses have also reported that some patients were not motivated to be involved in care planning and see it as the professionals' role. The authors highlight that traditional expectations of the 'patient role' could come across as a lack of motivation to be involved in their care, however, this does not necessarily indicate a lack of desire or interest (Anthony & Crawford, 2000). Indeed, patients have reported fearing that trying to be involved in decision making crosses the boundary of normal patient and

clinician roles and that any disagreements could result in a difficult ongoing relationship (Eliacin et al., 2015). The results of the qualitative study in Chapter 4 also highlighted some patients do still experience the 'traditional' relationship where they follow instructions without having input. However, participants did discuss how the better way to manage their illness was collaboratively with both parties offering their expertise. This is encouraging that participants are in agreement that a recovery model which, as Davidson (2005) states includes patients as the experts in their own experience.

Concurring with the perspectives from nurses and psychiatrists, mental health service users reported that being included in the decision making process depended in part on their ability to articulate themselves or how much their provider perceived they could understand (Gale et al., 2012). Participants have also reported having a mental health diagnosis affected the perceived credibility of their input to health professionals, they felt their views and input was dismissed as being symptomatic of their illness (Happell et al., 2004). Patients have also reported struggling to be perceived as competent and having an equal role in their own care, in direct contravention of the recovery model (Dahlqvist-Jönsson, Schön, Rosenberg, Sandlund, & Svedberg, 2015). In mental health, treatment choices may sometimes be limited, however, patients' fears and values must be acknowledged and respected. Psychiatrists may assume patients are not able to deal with information and choice so they may not be asked to participate in decision making (Samele, Lawton-Smith, Warner, & Mariathasan, 2007).

There is little evidence on factors associated with SDM preferences. A qualitative US study identified the relationship with the clinician was a factor in patients involvement in decisions, particularly the level of trust they felt. Involvement and preferences for SDM fluctuate according to condition stage and previous experiences (Eliacin et al., 2015; Sajatovic et al., 2005). The patient having adequate knowledge and a sense of empowerment were two main facilitators of SDM in a large review across health conditions (Joseph-Williams, Elwyn, & Edwards, 2014). The combination is key, as knowledge is not useful without a sense of being able to or having the opportunity to voice opinion.

A cross-sectional survey involving people with serious mental illness on involvement in decisions found that older age was associated with stronger preferences for involvement in decisions. However, in terms of previous experiences, older adults were more likely to have been in a passive role (O'Neal et al., 2008). This study had a number of limitations, firstly a small sample size (n=65), secondly a quarter of the older adults were recruited from a residential facility so do not represent a community-living population and finally there were few participants from the upper and lower ends of the age spectrum. Hill and colleagues (2006) found that younger age and being employed were associated with a greater desire to

be involved in decision making in patients from a much larger mixed psychiatric sample (n=160).

Despite barriers to SDM, resources exist to empower patients in decisions over their treatment, in order that care has a recovery-focus (Jacob, 2015). Advance statements are written statements which allow an individual to set out their preferences for future care such as where and how they wish to be cared for and how practical arrangements will be made such as childcare in the event of the person losing the capacity to make decisions (Rethink Mental Illness, 2013). Advanced Directives are a type of advance statement and are documents which are drawn up in accordance with the Mental Capacity Act (HMSO, 2005) which gives individuals a legal right to refuse certain medical treatments in the future. The content of user-created advance directives has been shown to be feasible, useful and consistent with clinical standards (Srebnik et al., 2005). Completing an advance directive can lead to greater therapeutic alliance and patients report receiving mental health services consistent with their wishes (Swanson et al., 2006). Wilder and colleagues (Wilder et al., 2010) found that patients whose advance directives contained requests for particular medications were more likely to be prescribed these treatments at 1 year follow-up and if they were prescribed any of their requested medications they had higher overall adherence. However, the authors also point out that in their sample completing an advance directive doesn't guarantee that it will be adhered to. Joint Crisis Plans (JCPs) are statements which are negotiated by patient and provider together covering treatment preferences in the event of a psychiatric emergency. The content of crisis plans show that requests are reasonable and consistent with current treatment guidelines (Farrelly et al., 2014). However an RCT indicated that JCPs may not be implemented consistently and did not always fully incorporate patient preferences (Thornicroft et al., 2013). Wellness Recovery Action Planning (WRAP) was developed in the US and is a tool to plan strategies to maintain wellness including identification of triggers and warning signs of relapse and action plans to deal with these including crisis planning (Copeland, 1997). It involves self-management, education, healthy lifestyle promotion and peer support. WRAP training has been associated with improvements in self-management and detecting early warning signs of illness (Cook et al., 2010) as well as feelings of hope (Fukui, 2011). An RCT demonstrated significant improvements in both symptoms, recovery scores as well as personal confidence and goal orientation (Cook et al, 2012). The WRAP approach may promote volitional motivation for changing behaviour, as it is highly individualised, incorporating the values and goals of each person. In turn, these goals may be more likely to be enacted and maintained, with the support of a peer network.

The literature above and findings from the primary research in this thesis demonstrates a number of barriers inhibiting patient involvement in mental health care and treatment decisions; some of these appear more relevant to mental health, for example paternalism and the power differential between clinician and patient, potential lack of insight or competence to understand information and make decisions during illness phases and a lack of access to accurate and comprehensible information about a patient's condition and treatment options.

There appears to be a lack of evidence as to the psychological factors associated with SDM preferences and experience. It is hypothesised that factors such as illness and treatment perceptions and satisfaction with information received might contribute to this. A better understanding these factors might be utilised in developing ways to improve involvement, concordance with medication and informed decision making.

During the course of the IBiD feasibility trial (Chapters 6-7) broader contextual factors around bipolar and medication emerged from both the qualitative study and from field-notes during intervention delivery. These related to how people feel about and engage with their treatment including a lack of opportunity to find out information about medication, or discuss this with their healthcare professional. This did not allow people to fully understand and manage their treatment when discharged from hospital. It appeared that for some participants the motivation to take treatment was extrinsic, i.e. to keep their clinician happy, because they were detained under a section, to avoid compulsory treatment or to stay out of hospital once discharged.

However, autonomous regulation where an individual is acting out of volition due to the personal importance of the behaviour and their level of perceived autonomy has been found to be associated with increased adherence (G. Williams, Rodin, Ryan, Grolnick, & Deci, 1998). It follows patients involved in SDM might have increased autonomous regulation and may be more inclined to be adherent to medication as it has personal importance to them. The authors posit that supporting patients' autonomy might help improve adherence and meet their needs (G. Williams et al., 1998). A meta-analysis revealed across a range of areas, choice has a positive effect on intrinsic motivation (Patall, Cooper, & Robinson, 2008).

The factors influencing whether a person wishes to be involved in their treatment decisions is not well understood. Fischer (2006) identifies in a commentary around SDM in mental health that there is a paucity of knowledge about the 'extent, variability, and correlates of shared decision-making in mental healthcare, especially in care for individuals with severe mental illness (SMI)' (pg 108). Specifically the links between SDM and treatment perceptions are not understood. This study was conducted in order to address these outstanding questions. Specifically to explore whether greater involvement in care and planning (shared decision

making) is associated with more positive treatment perceptions and is SDM associated with adherence. It is hoped that by exploring these links, it may be possible to begin to extend existing models of treatment perceptions, cognitions and adherence within mental health to include potentially important aspects of SDM.

8.1.1 Aims & Objectives

8.1.1.1 Aim

To describe SDM experiences in BD and explore whether a stronger desire for SDM is associated with more positive illness and treatment perceptions and adherence to medication.

8.1.1.2 Objectives

To investigate;

- experiences with and the extent of SDM in people with BD in a community population,
- the relationship between psychological factors experience and preferences for SDM, to explore whether more positive perceptions are associated with stronger preferences for SDM, specifically
    - treatment perceptions
    - perceptions of illness
    - satisfaction with information about medication
- the relationship between SDM preferences and experience and adherence to medication to explore if SDM is associated with higher adherence.

8.2 Methods

8.2.1 Design

This study comprised a cross-sectional survey, using validated questionnaires, conducted online using Qualtrics software. Ethical approval for the study was granted by UCL Research Ethics Committee (Reference 6811/001).

8.2.2 Inclusion criteria

Participants were eligible for the study if they self-reported a diagnosis of bipolar disorder and reported being currently prescribed medication for this, were over 18 years of age and living in the UK.

8.2.3 Recruitment

Recruitment was conducted via online advertisements, through twitter, Facebook groups and established links with charity organisations (Bipolar UK and the Scottish Association for Mental Health). (See Appendix CC for advertisements/ tweets).

8.2.4 Procedure

Individuals interested in the survey were directed, via a Qualtrics survey link, to a Participant Information Sheet contacting information about the study and contact details for the research team if they had any questions (Appendix DD). If they wished to proceed, they were directed to an online consent form, and once completed, were directed to the survey. They were assured of their right to withdraw and confidentiality. The survey took approximately 15-20 minutes to complete.

8.2.5 Measures

8.2.5.1 Treatment and illness perceptions, adherence and satisfaction

The questionnaire comprised the measures summarised in Table 8.1. For consistency with previous surveys (Bowskill et al., 2007; Clatworthy et al., 2009) and with the feasibility RCT data (Chapters 6-7), treatment and illness perceptions, adherence and satisfaction with information about medication were measured using the Beliefs about Medicine Questionnaire Specific & General (BMQ) (Horne & Weinman, 1999), the Brief Illness Perception Questionnaire (Broadbent et al., 2006), the Medication Adherence Report Scale (MARS) (Horne & Weinman, 2004), adherence Visual Analogue Scale (VAS) and the Satisfaction with Information about Medicines Scale (SIMS) (Horne et al., 2001) (Described in detail in Chapter 6 Section 3).

8.2.5.2 Shared decision making and treatment empowerment

As described in Section 8.1, SDM has been operationalised in different ways. To measure preferences for SDM in this study, two scales were selected for conciseness and reliability, the Treatment Empowerment Scale (TES) (10 items) (D. Webb, Horne, & Pinching, 2001) and the Autonomy Preference Index (API) (Ende, Kazis, Ash, & Moskowitz, 1989).

The TES is a concise, 10 item scale designed to assess control over the choice and use of medications incorporating communication, treatment choice, decision-making and

satisfaction. It uses a 5 point scale (5=very often, 4=often, 3=sometimes, 2=rarely and 1=never) and items are summed to produce a total score with higher values indicating a greater degree of treatment empowerment. This measure has been used with HIV patients (D. Webb et al., 2001) and has demonstrated acceptable reliability (Cronbach's alpha 0.85).

The API (Ende et al., 1989) consists of two scales; decision making preference (6 items) and information seeking preference (8 items). Clinical vignettes used in the original scale were not included. The scale is scored on a five point Likert scale (Strongly agree to Strongly disagree) and each scale is summed (reversing items as necessary). The API demonstrated good internal consistency in psychiatric samples (Cronbach's alpha 0.79) (Hamann et al., 2007; Hill & Laugharne, 2006).

To measure SDM experience for each medication participants were prescribed they were asked to indicate their perceived level of involvement in starting the medication and in continuing with the medication on a scale of 1 (not involved at all in the decision) to 5 (completely involved in the decision). In addition, participants were asked if they had ever completed advance requests or directives or joint crisis plans and to describe their experience with this.

8.2.5.3 Demographic and clinical data

Two validated clinical measures were included to assess levels of depression and mania. The Patient Health Questionnaire - Nine Item (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) and the Altman Self-Rating Mania Scale (E. G. Altman et al., 1997). Demographic and clinical data was collected at the end of the survey, this comprised; age, gender, ethnic origin, marital status and highest level of education, age of bipolar diagnosis, history of inpatient admissions, and timing of most recent admission.

Table 8.1: List of validated and adapted measures used in IBiD study

Type	Measure	Items/ Scoring	Cronbach's alpha (published)
Treatment beliefs	The Beliefs about Medicine Questionnaire Specific (BMQ Specific) (Horne et al., 1999) adapted for BD	17 items 2 factor structure; Necessity, Concerns 5 point scale, Strongly agree – Strongly disagree (Mean score)	0.63-0.74[a]
	The Beliefs about Medicine Questionnaire General (BMQ General) (Horne et al., 1999)	8 items 2 factor structure; Overuse, Harm 5 point scale, Strongly agree – Strongly disagree (Mean score)	0.63-0.74[a]
Illness beliefs	The brief Illness Perception Questionnaire (Broadbent et al., 2006)	8 items (+1 additional for BD) 10 point scale	
Adherence	Medication Adherence Report Scale (MARS) (Horne & Weinman, 2004)	5 items 5 point scale - Always to never (summed)	0.67–0.90
Satisfaction	The Satisfaction with Information about Medication Scale (SIMS) (Horne et al., 2001)	17 items 2 subscales 'Action and Usage', 'Potential Problems' Response categories – too much (0), about right (1), too little (0), none received (0), none needed (1) (summed)	0.81 - 0.91
SDM	Treatment Empowerment Scale (TES) (D. G. Webb et al., 2001)	10 items 5 point scale - Very often to never (summed)	0.85
	The Autonomy preference scale	14 items 2 subscales 'Decision making preference' and 'Information seeking preference' 5 point scale, Strongly agree – Strongly disagree (summed)	0.82
Clinical	Patient Health Questionnaire (PHQ) (Kroenke et al., 2001)	9 items Not at all (0), Several days (1), More than half the days (2), Nearly every day (3) (Summed) 0-4 None, 5-9 Mild, 10-14 Moderate, 15-19 Moderately Severe, 20-27 Severe	0.89
	Altman Self-Rating Mania Scale (E. G. Altman et al., 1997)	5 items 5 point scale - 0-4 (summed) 0-5: no indication of mania 6-20: possible manic state indicated	0.79

[a] Cronbach's alpha for psychiatric sample across specific and general subscales.
[b] Cronbach's alpha ranges across subscales.

8.2.6 Data analysis

Data was analysed using SPSS Statistics 22, all scales were scored according to published guidelines. MARS data was dichotomised into low (≤ 21) and high (>21) adherence for consistency with published studies (Bowskill et al., 2007; Clatworthy et al., 2009).

Medications were grouped into classes; mood stabilisers, atypical anti-psychotics (ATAPs), typical anti-psychotics, antidepressants, benzodiazepines and sleeping tablets. When more

than one medication was prescribed within a class of medication, an average of BMQ, MARS and VAS scores was calculated for that participant. Analysis was subsequently run for the most common classes of medication, mood stabilisers, atypical anti-psychotics and antidepressants due to small numbers of participants prescribed the other medication classes.

Descriptive statistics were used to describe the samples scores for each scale and reliability statistics were conducted (Cronbach's alpha). Scale distributions were assessed for normality in order to run parametric analysis. MARS and VAS data were not normally distributed, therefore for continuous outcomes, non-parametric tests were selected. Spearman's Rho were performed to investigate the relationship between SDM experience and preferences and demographic, clinical, illness and treatment perceptions and adherence.

8.3 Results

8.3.1 Response rate, sample demographic & clinical characteristics

Ninety-four individuals accessed the survey and reached the participant information sheet. Fifty-seven (61%) participants proceeded to complete the information on their prescribed medications (valid psychiatric medications). Demographic and clinical data was completed by 51 participants (Tables 8.2 and 8.3). The mean age of the sample was 44 (SD 14.42) years, 65% of the sample were female, the majority were of White British ethnicity (82%), there was a mix of relationship status and educational levels. This is a similar demographic profile to the community sample in Chapter 4, and broadly similar to the participants recruited to the feasibility RCT with the exception of that sample being on average slightly older.

The mean age of receiving a BD diagnosis was 32 (SD=9.79) years, and participants were prescribed a median of 2 (IQR 2-3) medications for BD. 17% of participants had been an inpatient within the last 12 months. Eighty percent of participants described their mental health problems as 'Bipolar Disorder', others characterised it as manic depression, schizoaffective disorder or depression. In terms of current episodic state, the ASRM scores indicated on average low mania scores, but 43% had scores indicating a possible manic state. Average PHQ-9 scores indicated that the sample generally had moderate levels of depression, however, there was a spread of the number of people in different depression status categories (none through to severe) (Table 8.3).

Medications prescribed are described in Table 8.4, mood stabilisers were the most commonly prescribed class of medication (81%), followed by atypical anti-psychotics (58%). Over one-third of the sample (39%) were prescribed anti-depressants. All medications were taken by tablet except two participants who took their typical anti-psychotic by injection.

Table 8.2: Sample socio-demographic characteristics

	Total (n)
Age at baseline	
Mean (sd)	43.67 (14.42)
Median (IQR)	41 (32-53)
Gender	
Female	64.7 (33)
Ethnicity	
White British	82.0 (41)
White Irish	2.0 (1)
White other	10.0(5)
Indian	2.0 (1)
Chinese	4.0 (2)
Relationship status	
Single	31.4 (16)
Married/ Civil partnership/Cohabiting	47.1 (24)
Divorced/ Separated	13.7 (7)
Other	3.9 (2)
Highest level of education	
O levels/CSEs/GSCEs	13.7 (7)
A levels / AS levels	7.8 (4)
Vocational education	3.9 (2)
Degree	35.3 (18)
Higher degree	21.6 (11)
Professional qualifications	17.6 (9)

Table 8.3: Sample clinical characteristics

	Total % (n)
Term best describing own mental health issues	
Bipolar Disorder	80.4 (41)
Manic depression	11.8 (6)
Schizoaffective Disorder	5.9 (3)
Depression	2.0 (1)
Age of BD diagnosis (approx)	
Mean (sd)	32.31 (9.79)
Median (IPQ)	30 (24-39.75)
N psychiatric medications	
Mean (sd)	2.23 (0.95)
Median, range	2 (2-3)
Previous admissions	
Voluntary admissions (yes)	53.1 (26)
Involuntary/ Detained admissions (yes)	41.3 (19)
Timing of most recent admission	
4-12 months ago	17.2 (5)
More than 12 months ago	82.8 (24)
ASRM Scale (Cronbach's alpha = 0.78)	
Mean (sd)	4.75 (3.92)
Median IQR	4 (1-8)
No indication of mania	56.9 (29)
Possible manic state indicated	43.1 (22)
PHQ-9(Cronbach's alpha = 0.93)	
Mean (sd)	10.10 (8.21)
Median (IQR)	7 (3-17)
None	37.3 (19)
Mild	19.6 (10)
Moderate	9.8 (5)
Moderately severe	11.8 (6)
Severe	21.6 (11)

Table 8.4: Medications prescribed (base n=57)

	Percentage [a] (n)
Mood stabilisers	80.7 (46)
Lithium	31.6 (18)
Lamotrigine	31.6 (18)
Valproate	24.6 (14)
Carbamazepine	5.3 (3)
Atypical anti-psychotics	57.9 (33)
Quetiapine	22.8 (13)
Aripiprazole	15.8 (9)
Olanzapine	8.8 (5)
Risperidone	7.0 (4)
Amisulpride	1.8 (1)
Lurasidone	1.8 (1)
Typical anti-psychotics	7.0 (4)
Flupentixol	3.5 (2)
Chlorpromazine	1.8 (1)
Zuclopenthixol	1.8 (1)
Antidepressants	38.6 (22)
Venlafaxine	15.8 (9)
Citalopram	8.8 (5)
Duloxetine	3.5 (2)
Mirtazapine	3.5 (2)
Escitalopram	1.8 (1)
Fluoxetine	1.8 (1)
Sertraline	1.8 (1)
Phenelzine	1.8 (1)
Agomelatine	1.8 (1)
Bupropion	1.8 (1)
Trazodone	1.8 (1)
Benzodiazepines	10.5 (6)
Diazepam	5.3 (3)
Clonazepam	5.3 (3)
Sleeping tablets	7.0 (4)
Zolpidem	3.5 (2)
Promethazine	1.8 (1)
Zopiclone	1.8 (1)
Other psychiatric medications	3.5 (2)
Propanolol (beta blocker)	1.8 (1)
Pregabalin (anticonvulsant)	1.8 (1)

[a] Participants may take more than one medication in each class accounting for where total number for class is less than the total of each medication within that class.

8.3.2 Experience of and preferences for SDM – Descriptive statistics

In general, participants appear to be involved in decisions to start and continue treatments, Table 8.5 shows that for most classes of medication there was high average levels of involvement in both starting and continuing medications, with the exception of benzodiazepines. However, a significant minority have had no involvement i.e. a quarter of those prescribed mood stabilisers (Table 8.5).

Descriptive statistics for each SDM scale are summarised in Table 8.6. The cronbach's alpha for TES was acceptable, however, for the API Information seeking scale, the item *'As you become more unwell you should be told more and more about your illness'* reduced the overall scale alpha slightly from 0.69 to 0.65, and this item was removed from the scale as it was deemed to be less appropriate for mental illness which can result in cognitive difficulties in worsening of illness episode. Treatment empowerment was high in the sample as was information seeking, reflecting a strong preference for receiving information about BD and its treatment. Preferences for decision making tended towards the desire for personal over physician control.

Eight (15%) participants had completed advance requests or directives about their mental health care, 7 (14%) had completed joint crisis plans, overall 14 (26%) participants had completed one or the other. Participants provided details about this experience, these are summarised in Table 8.7. Positive and negative experiences of completing plans were reported, with some participants finding it a simple process that they completed with help and support from their care providers. They found it reassuring to have the knowledge that this was in place even though they had not had reason to use it. However some commented on experiences or fear of plans not being honoured and others did not feel that they were fully involved in the process of completing the plans.

Table 8.5: Involvement in starting and continuing prescribed medications

Medication (n)	Starting medication		Continuing medication	
	Mdn (IQR)[a]	Little or no involvement % (n)[b]	Mdn (IQR)[a]	No involvement at all % (n)
Mood stabilisers (43)	4 (2-4)	25.7 (10)	5 (3-5)	21.4 (9)
Atypical anti-psychotics (27)	4 (2-5)	29.1 (7)	5 (3-5)	11.1 (3)
Antidepressants (21)	4 (3-5)	15.0 (3)	4.5 (3-5)	5.6 (1)
Benzodiazepines (2)	2.5 (1-)	50.0 (1)	3.5 (2-)	50.0 (1)
Typical anti-psychotics (4)	3 (1-)	50.0 (2)	5 (2-5)	25 (1)
Sleeping tablets (2)	5 (4-)	-	5 (5-5)	-

[a] 5 point scale, 1=no involvement, 5=completely involved
[b] Participants selecting 1 or 2

Table 8.6: Descriptive and reliability statistics for validated scales

	Mean (sd)	Min-max	Cronbach's alpha
Treatment Empowerment Scale (TES) [a]	35.15 (9.70)	10-50	.93
API Decision making [b]	16.04 (3.76)	6-30	.63
API Information seeking (7 items) [c]	31.86 (2.43)	7-35	.69

[a] TES – higher scores indicating greater degree of empowerment
[b] API Decision making – higher scores indicate a greater desire for physician involvement
[c] API Information seeking - higher scores indicating a greater desire for information.

Table 8.7: Participants experience of advanced directives and JCPs

Theme	Example text
Description of plan	*The joint crisis plan was written with a GP trainee to complete a government document-it says contact GP and ask them to contact crisis equivalent team, which is adequate as I live with my husband.*
	Daughters have power of attorney for both health and property. This is only to be used if I am incapable of making my own decisions and hasn't been used yet.
Process of completing plan (positive)	*Hi process was very simple, I did this with my care coordinator a long time ago but I no longer have any contact with them.*
	The doctor asked if I would be ok with him [friend] making a medical decision for me if I was unable to do so due to mental health issues. I told the doctor that if my mental health deteriorated to that point, I had instructed my friend to drag me to the doctor - kicking and screaming if necessary - and to do whatever was necessary to get me back on track. As my condition is bipolar II, and very well managed with medication, I don't foresee this ever being an issue, but it's good to have a plan, and I was glad my doctor thought to bring it up
	My JCP was completed after I had passed the low point of my crisis/breakdown so thankfully never had to fully put the plan into action. I think it is a good idea though, knowing you have a backup plan if it all goes pear shaped again.
	Work based for disability adjustments not CMHT. Straightforward
Process of completing plan (negative)	*When I moved to [location] two years ago, I was told I would only get care if in crisis so I was not able to establish an advance directive. They have recently engaged with me and I have started this process but progress is slow as their mental health resources are stretched.*
Lack of involvement	*I made an advance request to use Thioridazine next time (in the days it was available. They ignored the request making my hospital stay longer than it needed to be.*
	I was very ill when the JCP was written up. So a psychiatric nurse at the hospital where I was being assessed wrote it up. They did explain everything to me, but I don't feel I was very involved in the plan.
Plan not adhered to/ worry about lack of adherence	*It seemed to be a useful process at the time but when I needed it to be used no one was aware that it existed or able to find it.*
	Useful to write advance request but feel it would never be honoured.

8.3.3 Treatment perceptions & adherence - Descriptive statistics

Adherence to medications was generally high (Table 8.8). However around one quarter of those prescribed mood stabilisers, atypical anti-psychotics and antidepressants were categorised as having low adherence. Around half of participants had high concerns about their medication and between half and three-quarters of participants had low necessity beliefs, this was true for each medication class (Table 8.9).

8.3.4 General medication beliefs, satisfaction with information about medication and illness perceptions – Descriptive statistics

Descriptive statistics for each scale are summarised in Table 8.10. Cronbach alphas for the BMQ-General and SIMS scales were acceptable. Overall there were high beliefs about the overuse of medications, but lower than midpoint average beliefs about the general harm of medication. There were low levels of satisfaction with information about medications particularly in receiving sufficient information on the potential problems of medication (this includes the risks of side-effects and what to do in the event of these occurring). In comparison to the sample recruited to the feasibility RCT, this sample had higher levels of satisfaction with information, however, this was still not at an acceptable level, demonstrating that in both settings, people have unmet information needs.

In terms of illness perceptions, on average participants held beliefs consistent with severe illness consequences, a chronic timeline, high levels of concerns and emotional responses but a clear understanding of illness and strong agreement with the diagnosis. Perceptions of treatment and personal control as well as symptom experience were around the scale midpoint. With the exception of the two control items, the other illness perceptions were consistent with those found in the group of participants recruited to the feasibility RCT. This community sample had higher levels of personal control and lower levels of treatment control. Perhaps this may be due to experiences of managing BD themselves and potentially using other ways, besides medication to stay well, whereas in the inpatient sample their feeling of personal control may have been reduced by the fact that they had experienced an acute illness episode, and treatment control may be higher as they felt this had been an effective way to improve their symptoms.

Table 8.8: Medication adherence data (MARS & VAS)[a]

Medication (n)	**MARS**		**VAS**
	Mdn (IQR)	**Low adherence % (n)**	**Mdn (IQR)**
Mood stabilisers (43)	24.00 (21-25)	25.6 (11)	99.00 (81-100)
Atypical anti-psychotics (27)	24.00 (21-25)	25.9 (7)	98.50 (91.25-100)
Antidepressants (21)	23.00 (21-24)	23.8 (5)	92.50 (61.75-100)
Benzodiazepines (2)	24.00 (23-25)	-	100.00 (100-100)
Typical anti-psychotics (4)	24.00 (11-24.75)	25 (1)	100.00 (99-100)
Sleeping tablets (2)	23.00 (21-25)	50 (1)	54.00 (8-100)

[a] MARS and VAS data were not normally distributed, therefore Mdn and IQR are presented

Table 8.9: BMQ Specific necessity and Concerns scales

	BMQ Concerns[a]		BMQ Necessity [b]	
Medication (n)	**Mean (sd)**	**High concerns % (n)**	**Mean (sd)**	**Low necessity % (n)**
Mood stabilisers (43)	3.00 (0.71)	45.2 (19)	2.82 (1.08)	67.40 (29)
Atypical anti-psychotics (27)	2.97 (0.87)	48.1 (13)	2.75 (1.14)	58.60 (17)
Antidepressants (21)	2.95 (0.71)	55.0 (11)	2.74 (0.84)	77.80 (14)
Benzodiazepines (2)	2.58 (1.24)	50.0 (1)	3.50 (0.71)	50.0 (1)
Typical anti-psychotics (4)	2.75 (0.64)	50.0 (2)	3.46 (1.02)	25.00 (1)
Sleeping tablets (2)	2.45 (0.99)	33.30 (1)	2.83 (0.60)	66.70 (2)

[a] Scores range from 1-5 with higher scores indicating higher levels of concerns
[b] Scores range from 1-5 with lower scores indicating greater doubt about the necessity of medication

Table 8.10: Descriptive and reliability statistics for validated scales

	Mean (sd)	**Median (IQR)**	**Min-max**	**Cronbach's alpha**
BMQ General Overuse [a]	3.29 (1.02)		1-5	.84
BMQ General Harm [a]	2.29 (0.88)		1-5	.86
SIMS scale [b]	10.39 (4.84)		0-17	.89
SIMS Action and Usage	6.31 (2.66)		0-9	.83
SIMS Potential problems	4.08 (2.70)		0-8	.83
Brief IPQ [c]			0-10 for all	n/a
Consequences - How much does bipolar affect your life?	7.06 (2.60)	8.00 (6-10)		
Timeline - How long do you think your bipolar will continue?	9.24 (1.77)	10 (9-10)		
Personal control - How much control do you feel you have over your bipolar?	5.02 (2.40)	5 (3-7)		
Treatment control - How much do you think your treatment can help your bipolar?	6.39 (2.15)	6 (5-8)		
Identity - How much do you experience symptoms from bipolar?	5.96 (2.10)	6 (4-8)		
Concern - How concerned are you about your bipolar?	7.16 (2.69)	8.00 (6-10)		
Understanding - How well do you understand your bipolar?	7.84 (1.99)	8.00 (6-10)		
Emotional response - How much does your bipolar affect you emotionally? (e.g. does it make you angry, scared, upset?)	7.39 (2.60)	8 (6-10)		
Identity - How much do you agree with your diagnosis?	8.33 (2.21)	9 (8-10)		

[a] BMQ General – higher scores indicate greater perceptions of overuse and harm
[b] SIMS – higher scores indicate greater degree of satisfaction
[c] Brief IPQ – higher scores indicate; greater severity, chronic timeline, greater personal and treatment control, experience of symptoms, greater concern, better understanding, greater emotional impact and greater level of agreement.

8.3.5 Associations between SDM and other measures

Spearman's rank order correlations were run to explore relationships between variables. As expected, a significant positive correlation was present between MARS and VAS scores for mood stabilisers (r_s = .53, p<.001), ATAPs (r_s =.50 , p=.015) and antidepressants (r_s =.54, p=.031). There were no age or gender differences for any of the SDM variables.

8.3.5.1 Involvement in the decision to start and continue prescribed medications

There was a significant positive correlation between involvement in the decision to start and to continue medication for mood stabilisers (r_s =.43, p=.007). Involvement in the decision to start mood stabilisers was significantly correlated with overall SIMS (r_s =.42, p=.011), and both subscales (Action and usage r_s =.36, p=.034) (Potential problems r_s =.42, p=.010). Involvement in the decision to continue mood stabilisers was significantly correlated with overall SIMS (r_s =.33, p=.037), and the Action and usage subscale (r_s =.35, p=.028) as well as with agreement with the BD diagnosis (r_s =.45, p=.003). Involvement in the decision to start ATAPs was significantly correlated with overall SIMS (r_s =.49, p=.019), and the Potential problems subscale (r_s =.50, p=.016). Involvement in the decision to start antidepressants was significantly correlated with overall SIMS (r_s =.46, p=.046), and the Action and usage subscale (r_s =.57, p=.010). It was also significantly positively correlated with personal control (r_s =.47, p=.042), and negatively correlated with symptom experience (r_s =-.54, p=.018), concern about BD (r_s =-.52, p=.022) and agreement with diagnosis (r_s =-.47, p=.042). Involvement in the decision to continue ATAPs was significantly correlated with three Brief IPQ items, personal control (r_s = .40, p=.044), treatment control (r_s = .61, p=.001) and agreement with diagnosis (r_s = .45, p=.022).

For ATAPs, there was a significant negative correlation between VAS adherence and involvement in the decision to continue treatment (r_s =.44, p=.035), but not to start treatment and also not between involvement and MARS adherence. For antidepressants there was a positive correlation between VAS adherence and involvement in the decision to continue antidepressants (r_s = .60, p=.031). There was no association between involvement and adherence for mood stabilisers. There was also no association between involvement and necessity and concerns beliefs for mood stabilisers, ATAPs, or antidepressants. There was a negative correlation between BMQ General Harm score and involvement in the decision to continue antidepressants (r_s = -.52, p=.033).

8.3.5.2 Treatment Empowerment

For the TES, there were positive correlations with satisfaction (r_s = .62, p<.001), and for the two subscales, Action and Usage (r_s = .56, p<.001), and Potential problems (r_s = .56, p<.001). There was also a positive correlation between TES and two Brief IPQ items, treatment control (r_s = .39, p=.004), and agreement with diagnosis (r_s = .36, p=.009).

No association was found between TES score and adherence to mood stabilisers, ATAPs or antidepressants or to necessity or concerns beliefs. There was also no association between TES and either Information seeking or decision making preferences.

8.3.5.3 Autonomy Preference – decision making and information seeking

For mood stabilisers, positive correlations were found between MARS score and API information seeking (r_s =.36, p=.025). There was no association for either ATAPs or antidepressants.

For ATAPs, a negative correlation was found between BMQ necessity beliefs and API Decision making (r_s = -.44, p=.020), and a positive correlation with API information seeking preferences (r_s = .47, p=.012).

There were significant negative correlations between information seeking preferences and overall satisfaction (r_s = -.28, p=.049) and for the Potential Problems subscale of the SIMS (r_s = -.29, p=.043). There was a positive correlation between information seeking preferences and two Brief IPQ items, impact of bipolar (r_s = .29, p=.037), and understanding of bipolar (r_s = .37, p=.007).

8.3.5.4 Other associations

Additional post-hoc analysis was conducted to explore relationships between the treatment and illness perceptions and adherence. For mood stabilisers, positive correlations were found between BMQ General Harm score and length of time on mood stabilisers (r_s = 41, p=.015). There was a negative correlation between BMQ General Overuse beliefs and VAS adherence (r_s = -.64, p=.010), and for BMQ General Harm score and VAS (r_s = -.65, p=.009) and MARS score (r_s = -.74, p<.001). There were no significant differences between those who had created an advance directive or JCP for any of the SDM variables.

T-tests explored differences between adherence groups (high or low) and illness and treatment perceptions, satisfaction and SDM preferences and experience. For mood stabilisers, there was a significant difference in the number of prescribed medications, with

low adherers (M=1.91, SD=0.54) being prescribed significantly fewer medications than high adherers (M=2.59, SD=0.945); t(31)=-2.94 , p= .006. For ATAPs, there was a significant difference between groups and BMQ General harm scores with low adherers (M=2.83, SD=0.89) having significantly higher perceptions of medication harm than high adherers (M= 2.00, SD=0.81); t(24)=, p= .033. For antidepressants, there was a significant difference between groups for the API information seeking scale with low adherers having a greater desire for information (M=29.40, SD=2.19) than high adherers (M=32.53, SD=1.92): t(18)=-3.06, p=.007. In addition, the level of understanding of bipolar (from the Brief IPQ) was significantly lower in low adherers (M=5.60, SD=2.61) than high adherers (M=8.27, SD=1.58); t(18)=-2.78, p=.012. No significant differences were observed between adherence group and BMQ concerns or necessity for mood stabilisers, ATAPs or antidepressants.

8.3.6 Participants' additional comments

At the end of the survey, participants were given the opportunity to provide additional comments on the topics covered (Table 8.11). Participants raised issues relating to mixed feelings about medication, the lack of support and information, problems with medication and experiences with adherence and non-adherence. The ambivalent feelings about medication reflect those reported by participants in Chapter 4 and Chapter 7, having strong concerns about their medications but taking it as it is the tool to help them to function. Participants' experiences of non-adherence confirmed the necessity of medication. The findings on lack of information and support and experiences with side-effects also reflect those findings from the smaller samples in the qualitative studies in Chapters 4 and 7.

Table 8.11: Participant additional information provided

Theme	Example text
Mixed feelings about medication	*I feel like taking Lamictal [Lamotrigine] has taken away some of my creativity, and I don't feel as smart as I used to. I don't have a great memory anymore, and I feel like Lamictal is the reason I haven't done as well in my academic and professional life as I should have. That said, I don't know if I'd be able to function without it.*
	I was recently strongly advised to resume Lamotrigine after a relapse and was told I could not work until I had complied with the doctor's instructions. I was quite upset as I felt that my choice/freedom had been restricted but at the same time I am now gad to be back on the medication as I am feeling much better and able to function ok.
	I think lithium has helped me the most. I just miss my energy and creativity.
Lack of support and information	*A major issue is GPs not informing patients about side effects. The NHS does not help with the consequences, e.g. side effects and withdrawal syndrome, of psychotropic medications they have prescribed.*
	I also feel psychiatrists don't care about awful side effects so long as your mood is under control. When I was prescribed olanzapine my weight shot up, I went from being clinically underweight to overweight in a year. More attention needs to be paid to the person as a whole so they understand when a side effect is having a really bad effect on your life.
Problems with medication	*Going through repeated med changes. Lamotrigine isn't fully tackling my symptoms but all the antipsychotics I've tried cause horrendous side effects at lowest dose.*
	The thing about having been on medication so long is that I don't know who I am without it. I couldn't tell you if I'm an introvert or an extrovert, because my behaviour was first ruled by my illness, and then by my medications.
Adherence to treatment	*All I know is that the time I tried to come off my medications did not go well, and I have no desire to try again*
	I've recently quit all my meds for bipolar because they had made me gain weight. I am discovering I do need the meds for my mental health, and plan to restart them this week.
	In 2013 I had my Depixol [Flupentixol] reduced by half which transformed me from a zombie into a fully functioning individual and therefore made me medicine compliant.
	Your questions tackled the heart of the issues, I have no wish to take any medication but I'm too afraid to stop as when I do, within 10 days I'm not sleeping, over thinking and very anxious. if I could ascertain how long this would go on for I would be prepared to continue..

8.4 Discussion

This study aimed to describe SDM experiences and preferences in BD as well as explore whether psychological factors of illness and treatment perceptions and satisfaction with information are associated with SDM. In addition, to explore whether SDM was associated with higher adherence to medication. In terms of experience of SDM, the majority of participants were involved in the decisions about starting and continuing the medications they were currently prescribed. There was also a high degree of treatment empowerment in this sample with individuals feeling that they have control over the choice and use of medications. However, a significant minority felt they had no involvement and only one quarter had completed statements or plans to specify future care or treatment in the event of crisis or lack of capacity. There was a significant correlation between being involved in starting and continuing mood stabiliser. This indicates that if SDM can be instigated at the start of treatment, it may then be extended to ongoing involvement. In terms of preferences (measured using the API scale), scores on the Decision Making subscale indicate that there is a general preference for more personal and less physician involvement in making decisions about their care. In terms of information seeking there was a strong preference for being informed about their care and treatment.

With regard to associations between the SDM measures and psychological factors, higher levels of satisfaction with information about medication was associated with increased involvement in decisions about individual medications and with treatment empowerment, i.e. overall experience in being involved in treatment.

In terms of the relationship between adherence, treatment beliefs and both involvement in specific medication decisions and overall treatment empowerment, there were no consistent associations. For antidepressants there was a significant association for the VAS adherence measure and involvement in the decision to continue this medication. There was a significant positive association between adherence to mood stabilisers and a greater preference for being informed about treatment. Stronger belief in the necessity of treatment of ATAPs was significantly related to both a stronger preference for personal involvement in decision making and for being informed about illness and treatment. Lower preferences for information about illness and treatment were associated with higher levels of satisfaction with information about medication. Higher satisfaction levels can reflect a lack of desire for information as individuals may perceive that they do not need any, and this is part of the SIMS measure, this may account for this result.

It is encouraging to note the high level of treatment empowerment, as the perceived power differential between patient and clinician had been reported as a significant barrier to patients having an influence on their own care in the UK (Farrelly et al., 2015). The power differential which was reported qualitatively by participants in the IBiD evaluation (Chapter 7) in the acute setting, is perhaps less of an issue in community mental health care. Empowerment has been shown to be a facilitator of SDM in a large review across health conditions (Joseph-Williams et al., 2014) so the high empowerment seen in this population in encouraging, patients undergoing mental health treatment are likely to be involved in their care decisions.

The finding that a higher degree of satisfaction with information about medication was associated with increased involvement in decisions and with treatment empowerment concurs with the results of a review in psychiatric care. This found that a lack of information about treatments and choices was a barrier to involvement in care planning (Bee, Price, Baker, & Lovell, 2015). Another barrier which has been reported is worry about making an incorrect decision (Eliacin et al., 2015). Therefore, being provided with appropriate information about medications, may enhance potential for involvement, or indeed those who are more empowered to be involved may also be more likely to seek out information about treatments.

The lack of associations found between SDM measures and adherence and treatment perceptions is surprising, as other studies have indicated that there may be an association as medication driven by patient choice was associated with improved attitudes and adherence (Sajatovic et al., 2014) and between levels of autonomy and adherence (G. C. Williams et al., 1998). However the study by Sajatovic and colleagues (2014) had a small sample size (n=29) and an uncontrolled design therefore switching medication at all, whether informed by patient choice could have improved adherence. A meta-analysis of 32 studies in mental health found that those receiving preferred treatment or who were involved in SDM had higher treatment satisfaction (Lindhiem et al., 2014). The present study hypothesised involvement in decisions would be associated with more positive treatment perceptions, however this was not found. The limitations discussed below may account for this and there may be other factors, not included in this study which account for differences in treatment perceptions.

The investigation of illness perceptions and SDM, has to our knowledge, not been reported to date in BD. It was found that increased involvement in decisions was associated with greater perceptions of personal and treatment control over BD. Being involved may enhance self-efficacy to manage BD through having positive experiences of involvement, thus improving people's perceptions of how they can affect their own outcomes or receiving affirmation from HCPs on how their input in their own care is important. Or perhaps, having a more positive view of how BD can be controlled by medication may lead to feeling empowered to get

involved. However, associations do not imply causation and the direction of causation may be the other way around. Being involved in decisions could potentially lead to greater views about the effectiveness of treatment as participants may be taking a treatment which works better for them as they were involved. Involvement and treatment empowerment was also associated with greater levels of agreement with the diagnosis, again this ties in with effectively self-managing the condition which has shown to be associated with insight and acceptance of the diagnosis (Gonzalez-Pinto et al., 2010; Látalová, 2011). A qualitative study with patients with depression also showed that insight into severity of depression affected engagement in decision making (D. Simon, Loh, Wills, & Härter, 2007).

The findings from this study relating to whether people wish to be involved in decisions, i.e. their SDM preferences, indicated a general preference for more personal and less physician involvement and strong preferences for being informed about care and treatment. This concurs with previous research in mental health where patients report that they wish to be involved in their care (Bilderbeck et al., 2014; de las Cuevas et al., 2012; Hill & Laugharne, 2006; Sajatovic et al., 2005). Woltmann and Whitley (2010) elaborate on what shared decision making means to patients from the results of a small qualitative study with people with severe mental illness. Participants descriptions of what they meant by 'shared' was that they wish to have an autonomous role in the first instance only to defer to clinician judgement if necessary. This does differ from the definitions of SDM where the whole process is collaborative in that information is shared and discussed and the decision is reached together.

We did not find an association between SDM and whether participants had actually created a treatment or care plan, although the numbers actually having done this was small. As relatively few make these formal, written decisions, it appears that more informal SDM is occurring as many reported they are involved in the decisions. Previous research in a trial of completing advanced directives has shown that being helped to complete these was associated with greater likelihood of receiving desired treatment than those given no assistance in completing a directive (Swanson et al., 2006; Wilder et al., 2010). However, participants' feedback, although only from a small number, indicated experience and fears that plans would not be enacted, concurring with an RCT showing that implementation of JCPs was not consistent (Thornicroft et al., 2013). Further work is needed to establish whether plans were followed and the outcomes of this in terms of adherence and perceptions of treatment.

We found no age or gender differences for any of the SDM measurements, this ties in with the mixed evidence in this area, demographic differences do not seem to be consistently associated with SDM. However these studies include different populations recruited from

different settings and so are not directly comparable (Hill & Laugharne, 2006; O'Neal et al., 2008).

Although not the primary hypothesis of this study, analysis revealed no associations between adherence and either necessity beliefs or concerns about medication for any of the classes of medication prescribed. However, beliefs about the general harm of medication were associated with poorer adherence for antidepressants and mood stabilisers, and a belief that medications are overused and poorer adherence for mood stabilisers only.

8.4.1 Limitations

This cross-sectional study is limited by the small sample size, this was compounded by the need to analyse different classes of medication separately. It was important to acknowledge the differences between medications and not create composite measures which mask differences. Different results were observed for different classes of medication participants were prescribed, this emphasises the importance of measuring behaviours and beliefs separately instead of, as other studies have done, asking participants to generalise across their medications. However, by doing this, the power for this analysis is reduced. However, a major limitation is that the aspects of SDM measured using scales may actually be different for different classes of medication. It may be possible that participants prefer to be involved in decisions about some classes of medication they have more experience and / or more information about and might wish for a more paternalistic approach for new treatments. This would need to be investigated with further research.

The study only achieved a small sample and it was found that recruitment through social media was challenging. It was not possible to recruit through some channels which initially had been proposed as potential sources of participants. With more resources, linking with community mental health teams would enhance recruitment. However, a strength of this research is that the recruitment strategy aimed to recruit participants who do not necessarily engage with specialist mental health services, just with primary care to give a more representative sample of people with BD. By using social media to recruit participants, we cannot be sure that there are only UK respondents, however, UK based social media users and groups were contacted to minimise the chance of responders from outside the UK.

The cross-sectional design only allows us to investigate the relationship between factors, and not direction of causation. Further longitudinal research would be needed to investigate how SDM might actually alter perceptions and behaviours. In addition, it would be possible, with a

larger sample to analyse whether SDM preferences change over time and are affected by illness stage for example.

This study explored the different measures of SDM as well as multiple possible related variables. Corrections for multiple testing were not performed as the analysis was exploratory in nature and the study was not powered to do so.

Participants' diagnosis was unconfirmed by diagnostic interview, although as all participants reported psychotropic medications, this goes some way to verifying that they had received a diagnosis. One participant was excluded from the analysis as their medications were reported as 'drug a', 'drug b'.

There may be a number of factors not explored in this study which may contribute to experience of SDM and medication adherence, for example therapeutic alliance as there is evidence for this from qualitative research (Eliacin et al., 2015).

This study only focussed on decisions around medication, however we acknowledge that mental healthcare includes a number of other decisions which are made in an individual's care. For example, referral for psychological treatment, hospital admission and discharge and provision of acute or primary care as an outpatient. Therefore it doesn't cover the full spectrum of decision making which might occur for individuals.

8.4.2 Conclusions

People with a BD diagnosis in this sample appear to generally be involved in their treatment decisions and express a preference for this. This is reassuring given concerns in mental health, issues of a history of containment and compulsory treatment may present a significant barrier to involvement (Bee et al., 2015). However, the fact that there were participants who were not involved demonstrates that there is clearly work still to be done to achieve the aims to make sure that all psychiatric patients have the opportunity to be involved in their care (Coulter et al., 2011). This concurs with national surveys of community and acute patients which show that not all are involved in their care (Care Quality Commission, 2009a, 2011a, 2013).

This study goes some way to addressing the paucity of knowledge about the *'extent, variability, and correlates of shared decision-making in mental healthcare, especially in care for individuals with severe mental illness'* which was previously identified (pg 108) (Fischer, 2006). Our study was the first to investigate illness perceptions and SDM and found the importance of personal and treatment control beliefs as well as agreement with the diagnosis in involvement in treatment decisions.

The importance of having sufficient and appropriate information about treatment and BD itself was emphasised in this research with a preference for receiving information being expressed and the association between satisfaction with information and involvement in treatment decisions. Having accurate and sufficient information as well as feelings of empowerment are important aspects involved in SDM.

Although we did not find consistent associations between adherence and treatment beliefs and SDM experience, we did find some evidence for adherence being associated with a preference for being informed and greater perceived necessity of treatment being associated with stronger preference for personal involvement in decision making and for being informed about illness and treatment. It is unclear from this study why SDM preferences as opposed to actual experience demonstrated these associations.

Chapter 9 General Discussion

9.1 Overview

The final chapter of the thesis provides an overall discussion of the key findings, summarising how the results addressed the research aims and places the findings in the context of published research. It discusses the main limitations, theoretical and clinical implications and areas for future research.

This thesis sought to:

- Understand patients' perceptions of the challenges in dealing with a diagnosis of BD and engaging in self-management.
- Uncover the unmet information and support needs of people with BD.
- Investigate how current understanding of the determinants of health behaviour and behaviour change theory can be applied to adherence and self-management.
- Determine the effectiveness of existing interventions to address adherence in BD.

Following this the thesis sought to:

- Develop a novel intervention to target adherence to medication through proximal determinants of perceptions, understanding, satisfaction with information and internalised stigma by using the step-wise method of Intervention mapping (IM) involving behaviour change theory and service-user consultation.
- Test the feasibility and acceptability of conducting an RCT of the intervention in an acute adult mental health setting.
- Investigate the extent to which patients with BD wish to be involved in treatment decisions, the extent to which they are involved, the association of these two factors with their illness and treatment perceptions and their adherence to medication.
- Investigate the level of involvement in treatment decisions, preferences for this and association with illness and treatment perceptions and adherence in a population of people with BD.

9.2 Summary of research

In **Chapter 1** the unique challenges presented by BD for many individuals, HCPs and service planners were identified. Staying well with BD can be dependent on; acknowledging and understanding the condition, holding beliefs consistent with adherence, receiving and understanding information on medication, effective relationships with HCPs and effective self-management such as monitoring mood and behaviour for early warning signs of relapse. It can

be affected by personal factors such as people's hopes, fears and how they view their experiences as well as contextual factors, the environment around them and the care they receive. Potential barriers to staying well and factors associated with medication adherence are clear. From these, potentially modifiable determinants of adherence were identified. The next stage was to select appropriate techniques to modify these determinants to improve outcomes for people with BD and devise a trial to evaluate the effects of an intervention.

Chapter 2 discussed how current theory and research in health psychology and behavioural medicine contributes towards understanding how people with BD view their condition and how this can contribute to improving outcomes. Self-regulation theories, specifically the CSM (Leventhal et al., 1984) and e-SRM (Horne, 2003b), which address patients' common sense understanding of their condition and treatment are of value, as they allow us to understand how people see their condition, their treatment, and how this affects their selection and appraisal of coping strategies.

Chapter 3 formed a key stage in the process of developing an evidence-based intervention. By conducting a systematic review, we can see if there are current effective interventions which could be utilised, and by conducting moderation analysis we can see what may be promising content to improve adherence as well as ways of targeting and delivering an intervention. This was the first systematic review of adherence-focussed interventions in BD which used meta-analysis to quantify the magnitude of effect. The review of 30 years of interventions demonstrated that they are generally effective in improving adherence relative to control groups and the effects appear to be durable.

A key part of the MRC framework and IM process for the development of a novel intervention is conducting primary research to inform the intervention. It is particularly important to draw from the population and if possible, context where an intervention would be implemented. **Chapter 4** comprised primary qualitative research which supports and elaborates on findings from CQC reports of the extent of unmet information and support needs in mental health care (Care Quality Commission, 2009a, 2013). The research identified crucial, specific insights into people's own perceptions of their condition, their medication and information they have received and would wish to receive. The qualitative research provided detailed and specific service-user perspectives on which to develop the intervention, specifically to inform the content, delivery vehicle and context (Horne, 2012).

The findings from the literature review, meta-analysis and primary qualitative research contributed to the development of a novel intervention described in **Chapter 5** using IM. The Improving Information for People with Bipolar disorder (IBiD) intervention comprised a tailored, written booklet framed around the NCF and PAPA. The booklet, *Bipolar Disorder: A*

question of balance, was developed in consultation with individuals with a diagnosis of BD and a carer. The intervention aimed to improve adherence through the proximal measures of illness and treatment beliefs and satisfaction with information. BCTs were selected based on research evidence into potentially effective techniques to modify beliefs and behaviour. These included comparisons of pros and cons of taking medication, providing information from credible sources, promoting social support and problem solving.

Once developed, IBiD was tested in a feasibility RCT within an acute adult mental health setting (**Chapter 6-7**). In terms of recruitment and retention, it was determined that there would be a sufficient population of eligible patients in this setting for a large trial. The study identified key aspects of good practice in recruitment in this setting, namely engaging staff well in advance of the study and maintaining communication throughout. Retention rates were good and again this can be attributed to the relationships built at recruitment stage and good ongoing communication between research staff, care-coordinators and participants.

It was clear from the IBiD feasibility trial that more development work is required for a brief psychosocial intervention to address adherence and illness and treatment perceptions and meet other information and support needs which would help people to recovery and manage their condition. Particularly in dealing with some of the issues particularly pertinent to mental health treatment, namely, lack of involvement in treatment decisions, power differentials between clinician and patient and ongoing need for support in the context of fluctuating illness state and associated changing treatment. To this end a cross-sectional study of Shared Decision Making (SDM) was conducted (**Chapter 8**) to explore how both experiences and preferences around treatment decisions relate to illness and treatment perceptions and adherence. Participants had experience in being involved in decisions about their care and treatment and a preference for being involved. They reported feeling a high degree of control over their choice and use of medications. Overall the results of this study emphasised the importance of both receiving accurate and sufficient information about treatment and feeling empowered to be involved in care. However, there is still some way to go to ensure that all individuals with BD have the resources and capability to be involved.

9.3 Strengths and contribution of this research

9.3.1 Patients' perceptions of BD, engaging in self-management and their information and support needs.

This programme of research aimed to better understand patients' experiences in being diagnosed with BD, and how they have found managing their condition. Alongside this it

sought to understand the information and support needs they had in relation to both the diagnosis and treatment.

A review of published literature revealed that elements of self-management in BD included, receiving and understanding information on the condition and medication, building effective relationships with HCPs and using tools such as monitoring mood and behaviour for early warning signs of relapse (Chapter 1). In addition to this review, the primary qualitative research (Chapter 4) identified crucial, specific insights into people's own perceptions of their condition, their medication and information they have received and would wish to receive. This was a vital step in developing a novel intervention and forms a key part of the MRC framework and IM process. Illness could be a burden to participants, in dealing with symptoms, challenges to sense of self and wider stigma. However, we heard how participants came to an understanding of BD and medication which allowed them to recover their sense of self and live well with the condition. This provides support for the recovery model, in that despite the fact that they may still experience symptoms, they were able to achieve recovery in the sense of living a life which fulfilled their goals and wishes.

With regard to the effect of the diagnosis and treatment on individuals' sense of self, taking medication was seen as either a return to the true sense of self or taking this away. By investigating both perceptions of peoples' perceptions of mood modifying medications, and how these impact on their feelings about themselves, this study adds greater insight into the area. It was illuminating to discover that for people with ostensibly the same diagnosis, their experiences and reactions to the diagnosis and treatment varied considerably and also how much it could change through their lives. Stevenson and Knudsen (2008) also found that the fact that medication has been prescribed meant that individuals were able to understand that the problems they were experiencing were more than sadness and were depression. For some people, taking medication can represent acceptance of the diagnosis so there was ambivalence with a feeling that they should be able to come to a solution that is not reliant on medications, but that this was in many cases the only way to live a normal life. Chang and colleagues (2015) investigated the links between attitudes to medication and social factors in people prescribed mood stabilisers. More favourable medication beliefs were associated with higher levels of social support and a belief that others (family and clinicians) can influence their health. However, those taking part in IBiD often did not have support, were isolated and depended on care coordinators as opposed to family and friends.

Despite the fact that individuals expressed that medication is helpful, some expressed a desire to be medication free, to reach a stage where they could manage mood episodes with lifestyle changes. This area has not received a great deal of research attention. We do know from

adherence rates a high proportion of patients will stop taking their prophylactic medication (Arvilommi et al., 2014; Cavanagh, Smyth, & Goodwin, 2004). Research conducted by Cappleman and colleagues (2015) adds to the knowledge of reasons which people might not wish to take medication (adding to insight, necessity beliefs and concerns about medications). Individuals carried out their own cost-benefit analysis in deciding whether to stop. Costs included side-effects and how these affected them as individuals, for example their ability to work. Those experiencing episodes whilst taking medication had reduction in perceived effectiveness. They searched for alternatives to medication, managing lifestyle, exercise, trying to change how they think about things in trying to keep mood stable. But experienced difficulties in recognising these changes and having an incentive to bring mood down. We also observed this in this programme of research. Participants in the IBiD qualitative evaluation (Chapter 7) wished to find other ways to manage their BD. This was perhaps why the mood monitoring exercise included in the IBiD intervention was viewed positively as it may have served as a way for participants to feel more informed and empowered, in alignment with the recovery model. It was clear throughout the development of IBiD, that instead of simply developing an intervention just focussing on adherence to medication, it needed to address their wider needs and acknowledge that people want ways to stay well and help them set and meet personal goals.

Cappleman and colleagues (2015) found people conducted cost-benefit analysis to evaluate the outcomes of their self-management strategies, in the same way that medication is evaluated. This fits with self-regulation theory of choosing coping behaviours which fit with the symptoms and schema of illness. If they judged medication had not been effective an alternative strategy was selected and tried. In IBiD, this technique was used in the form of an exercise and during discussions, participants were able to identify these costs and benefits for themselves. A participant in the qualitative evaluation reported finding a new medication which she felt had more benefits and therefore was happier to take it. This was an extremely encouraging finding and an example of the recovery model in action. She was empowered to seek out information and make an informed decision. It is vital that patients are told about medication alternatives, not just alternatives to medication and that their fears are acknowledged and addressed. The cross sectional study identified a strong desire to be informed about different types of treatments and to be given accurate information about side-effects. A decision to stop taking medication may for a patient represent the outcome of their own cost benefit analysis and this must be acknowledged. This idea supports the movement towards SDM. The cross-sectional research showed that people generally have been involved in decisions about their treatments. Previous research indicated that treatments involving

shared decisions are more likely to be adhered to and effective (Sajatovic et al., 2014; Wilder et al., 2010). However, the small cross-sectional study was not able to corroborate these findings.

The empirical research identified stigma as a significant issue for some people with BD. In the qualitative study, the stigma of mental illness made it difficult to accept the diagnosis and be labelled as mentally ill. They felt they were treated differently because of their condition. In the feasibility RCT, although rates of overall internalised stigma were not high, half of participants reported feelings of being different and a worse person (Alienation) and experiencing discrimination (Discrimination Experience). Participants in the qualitative study also reported concerns about disclosure, particularly in the workplace. In a similar vein, findings from Healthwatch England found that people with a mental health condition were treated differently from others by health professionals because of their diagnosis (Healthwatch England, 2015). In particular, as with participants in the qualitative study in Chapter 4, people felt that physical health problems were overlooked as professionals took physical symptom reporting as a part of the mental health condition. This is a significant issue as people with a mental health diagnosis have an increased risk of physical illnesses (Hert et al., 2011). Stigma has been shown to be associated with reduced help seeking for mental health problems (Clement et al., 2015). At present stigma is included only in one item of the BMQ 'I tend to hide the fact that I am taking this medicine from other people' and it is not covered in the brief IPQ. The addition of stigma, particularly experience of discrimination would be important to investigate and potentially adding explicitly to treatment and illness models to increase their relevance for mental health.

The dissatisfaction of information about side-effects found in this programme of research in both the qualitative and quantitative studies within community and the acute setting is reflected in the published literature. Indeed, patient reports are corroborated by professionals who report concerns about giving too much information about side effects so information was withheld, they did not always inform patients that medication was needed in the long-term as they had a fear of putting people off (E. Brown & Gray, 2015). Clinicians own views about medication and adherence are likely to be an important consideration for future interventions to help patients adhere and to promote informed decisions. Mental health staff have reported regarding side-effects as an inevitable consequence which must be accepted or ignored, and some community mental health staff appear to also lack knowledge of medications (Morrison, Meehan, & Stomski, 2015).

In acute wards in the UK, patients have reported accepting the need for medication administration, but were troubled by side-effects and reported that these were not routinely

monitored (Duxbury et al., 2010). This finding was also reported by participants in this programme of research. Patients wanted more information and some of their anxieties were associated with a limited understanding of their treatment. However the nature of medication administration on the wards means that this may not be an appropriate time for information exchange due to time pressures and a lack of opportunity for confidential discussions (Duxbury et al., 2010). On the ward, there is a key need for information provision to ensure informed consent and facilitate a good therapeutic relationship, but the time and place for this requires consideration. In addition, this programme of research found that on the wards, patients wished to spend more time with staff and engage in therapeutic activities. A review of how inpatient mental healthcare provision meets the needs of users (Hopkins et al., 2009) found that they expect to form relationships with staff, but administration responsibilities mean there is little contact time. It has been found that there is decreasing amounts of time on wards for social interaction or activities and nurses time spent with patients has decreased and little of this time is actually spent in therapeutic intervention (Sharac et al., 2010). We know that the length of inpatient psychiatric stays has decreased and the focus is on ensuring safety and stabilising patients after a mental health crisis (Glick et al., 2011). Participants in the current research also identified that discharge was sometimes too quick and they didn't feel all their needs were met. It may indeed be difficult to rationalise the needs of patients with the practicalities of the inpatient setting. Interventions need to have flexibility in how they are delivered. The IBiD intervention comprised a resource which could be used in the inpatient setting and also following discharge. Comparing the findings from this programme of research and current mental health policy in the UK, gives clear indication that there is a considerable way to go to meeting targets. The 2011 mental health strategy sets out that more people with mental health problems will recover, have greater ability to manage their own lives and have a positive experience of care and support (HM G, 2011). It also states that people should have access to interventions which give people choice and control over their lives. Participants in this programme of research often reported experiences of care, particularly in the inpatient setting which were not positive. However, the fact that many in the cross-sectional study had been involved in treatment decisions and felt high levels of personal control implies that the government targets could be met with effective, understanding care and adequate resources.

9.3.2 The application of frameworks for understanding health behaviour and behaviour change theory to adherence and self-management in BD

This programme of research identified and applied appropriate models and frameworks which aim to explain health behaviours and also drew on the behaviour change evidence and apply

this to adherence and self-management in BD. The CSM (Leventhal et al., 1984) and e-SRM (Horne, 2003b) incorporate patients' common sense understanding of their condition and treatment. The programme of research conducted aimed to better understanding how people see their condition and treatment so add to the applicability of the models to BD. The models cover the relationship between people's beliefs to their selection and appraisal of coping strategies, one of which is adherence to medication. The findings from the research in this thesis support the dynamic nature of the models as illness and treatment perceptions may change, particularly in an episodic condition such as BD. It was clear during the research that there are aspects of mental health conditions which mean that some further development of the models are needed to ensure they apply adequately to these conditions. These implications and future research directions are addressed in Section 9.5, but include a more detailed emotion component (not solely anxiety, fear etc.), perceived discrimination, relationships with care providers and involvement in and preferences for decision making.

Linked in with developing the frameworks to increase applicability to mental health, is the corresponding need to ensure that the measures used to operationalise the frameworks contain all the relevant constructs. This was explored in Chapter 2, section 2.4 and the findings from this programme of research provide insights into how measures of illness and treatment perceptions might be adapted. These include taking into account that individuals may view medication as one of the factors which help them to stay well or manage BD and the wording of the BMQ should acknowledge this. For the influence of side-effects on an individual's beliefs, the side-effects item needs to acknowledge that people experience both physical effects and effects on how they feel. With regards to illness perceptions, as mentioned above, the measurement of the emotional impact of the condition in the brief IPQ should be expanded and not just include negative emotions. The measure does not take a recovery-model approach as people may understand that the diagnosis may be chronic but they also forsee that they may recover and live a fulfilling life so the single item does not provide any understanding of how people view their ongoing life with BD. As discussed below in 1.4.1, findings from the IBiD qualitative evaluation and cross-sectional study indicate that further development is required to improve the applicability of the measures for people with BD>

Returning to the support for self-regulatory models, findings from this programme of research support the concept that adjustment and agreement with the diagnosis may be a facilitating factors in better engagement with treatment, being involved in decisions and accepting medication. A large European study found that improvements in insight and improvements in therapeutic relationship were associated with improvements in adherence and clinical outcomes. Relationships between these variables may be bidirectional (Novick et al., 2015).

Interventions targeted particularly at those with low levels of insight might be worthwhile to improve adherence.

9.3.3 The effectiveness of existing interventions to improve adherence in BD

Through a systematic review and meta-analysis, the effectiveness of existing interventions for adherence in BD was explored. This is a key part of developing any evidence-based intervention as key moderating variables of effectiveness can be identified. The systematic review was reported in accordance with PRISMA guidelines (Liberati et al., 2009), ensuring that the review was transparent and replicable.

The review identified that interventions are generally effective in improving adherence relative to control groups and the effects appear to persist. Moderation analysis revealed that even brief interventions were effective and the effects were robust when sensitivity analysis was conducted to include only high quality studies. However, many interventions were inadequately reported, both in terms of what the intervention comprised and how it was delivered. Reporting of trial design and procedure was also frequently inadequate, meaning that the risk of bias was impossible to judge accurately. It was not possible, from the published evidence to specifically identify what would work for a particular patient group, in a particular context. However, within the context of the development of a novel intervention for this programme of research, the review demonstrated that a brief intervention would have the potential to improve adherence. CBT and psychoeducation techniques should be selected due to the findings indicating that these would be valuable components of an effective intervention where adherence was the primary target. It wasn't possible to identify a specific intervention which was brief, well described in sufficient detail to be implemented and appropriate for the needs for this particular group of patients. In order to ensure that an intervention would be appropriate for and acceptable to the target population, additional development work was conducted to design a novel intervention.

9.3.4 The development and feasibility assessment of a novel intervention to target adherence to medication in BD

A novel intervention (IBiD) was developed which aimed to target adherence through the proximal determinants of perceptions, understanding, satisfaction with information and internalised stigma. IBiD was tested in a feasibility RCT to establish the viability and acceptability of the intervention in an acute adult mental health setting. Development of the IBiD intervention was conducted using MRC guidelines (Craig et al., 2008) and the IM process

(Bartholomew et al., 2011) to ensure methodological rigour and that the interventions were based on, not only up to date research evidence on behavioural determinants and behaviour change theory, but also were relevant and applicable to the actual target population. Published guidelines were used to report the feasibility RCT, the CONSORT Statement for reporting RCTs of non-pharmacologic treatments (NPT) (Boutron et al., 2008) and the TIDieR guidelines to guide reporting of the intervention description (Hoffmann et al., 2014). This ensured that the study was reported transparently, it would be replicable and the descriptions are comprehensive.

Patient information must reflect actual patient need, which current written information may not (Grime & Pollock, 2004). A strength of the current intervention was that it was written using insights gained through the primary research with patients (Chapter 4) as well as the content and wording being developed in consultation with service-users. The qualitative research provided detailed and specific service-user perspectives on which to develop the intervention, specifically to inform the content, delivery vehicle and context (Horne, 2012). Namely, that medication can help regain self-identify, was a means to living well and that patients valued being given written information and having the opportunity to discuss this. The content needs to cover information on illness and treatment, in particular, side-effects, but also acknowledge people's varied beliefs, experiences and needs. The appropriate time to provide this was found to be both at the acute stage of illness and when not experiencing an episode. The IBiD intervention has a number of features which add strength to its design. The intervention uses personal pronouns which have been shown to be related to greater satisfaction with explanation about medication side-effects than non-personal language (Berry, Michas, & Bersellini, 2003). BCTs were selected based on research evidence into potentially effective techniques to modify beliefs and behaviour. These included comparisons of pros and cons of taking medication, providing information from credible sources, promoting social support and problem solving.

In keeping with the aims of a feasibility study, the IBiD intervention study provided valuable data on available participants in an acute setting, recruitment, retention & acceptability. In terms of recruitment and retention, it was determined that there would be a sufficient population of eligible patients in this setting for a large trial. However, by extending the recruitment to patients after discharge a greater number of eligible patients who were initially approached on the ward and expressed interest in taking part but were discharged rapidly would be able to be followed up once in community treatment. This would potentially increase the recruitment rate.

The protocol provides an example of good practice in conducting research in this area and the study set-up, recruitment and retention strategies concur with recommendations for successful conduct of studies in mental health (Borschmann et al., 2014). In particular, engaging healthcare providers at the beginning, ensuring the study is relevant for the setting and maintaining respect and ongoing communication are vital. Borschmann and colleagues (2014) also conclude that robust feasibility studies are crucial to the success of studies. The feasibility RCT research process ensured that there was a strong focus on ethical considerations of conducting research in the mental health setting. It was vital to ensure that there was appropriate access for people with mental health difficulties to participate in research (Graor & Knapik, 2013; Lakeman, McAndrew, MacGabhann, & Warne, 2013). Gatekeeping can be an issue in recruiting to studies in this area (Borschmann et al., 2014). A severe mental illness diagnosis shouldn't be a reason for not being able to participate in research and many patients wish to take part. Potentially the focus on protecting vulnerable participants can have the unintended effect of removing their autonomy which is unethical in itself. However, it is crucial to be aware that participants may be experiencing difficulties with cognitive and executive functioning (Quraishi & Frangou, 2002). The study protocol for the RCT was also flexible to the illness fluctuations and practical needs around the discharge period such as getting housing issues arranged.

Retention rates were good and again this can be attributed to the relationships built at recruitment stage and good ongoing communication between research staff, care-coordinators and participants. This study provides important learning for recruitment in this complex time of transition between inpatient and community mental healthcare. Randomisation was found to be acceptable to participants and they reported finding it interesting to take part in the study itself and complete the assessments. However it was important to remain flexible to the needs of individual participants, illness fluctuations and symptoms and side-effects associated with BD and medication throughout the whole study and intervention process.

There was clearly a need for an intervention demonstrated by baseline illness and treatment perceptions, feelings of stigma and lack of satisfaction with information. The intervention was well received and self-reported actions included mood-charting and investigating different medication options. The IBiD feasibility trial provided benefits from participation in the study. In particular having the opportunity to open up about BD and to complete the questionnaires was reported by participants as helping them with their own insight into their condition. This supports published studies and reviews in mental health which has also shown benefits of research participation (Biddle et al., 2013; R. Byrne & Morrison, 2014; Jorm et al., 2007; Pollack

& Aponte, 2001). Lakeman and colleagues (2013) discuss a number of potential benefits for research participants, including the knowledge that their participation may help people in the future, potentially by altering how individuals viewed themselves as a valuable contributor rather than a service-user. Often vulnerable people may see themselves as powerless and research participation can give them a voice (Holloway & Freshwater, 2007). Participants may benefit by telling their story as it helps to frame and find meaning in their experiences (Lakeman et al., 2013).

The complexities of medication regimens and the changes to treatment during the transition period presented challenges in how to measure outcomes for the trial and challenges for intervention delivery in how to take account of these changes. Future studies should conduct more regular assessments and track reasons for medication changes. Additional aspects of perceptions and behaviour around medication should be incorporated into questionnaires and some aspects are not appropriate for inpatient care. Questionnaires need to take account of the fact that some barriers may not be present in the inpatient setting, such as forgetting medication, and there may be other factors affecting adherence such as taking medication to satisfy clinicians and to be discharged. Current measures do not include these aspects. Future studies should also include a measure of motivations to take treatment as this also provides a useful discussion point for any adherence intervention and was not measured in this study.

It was clear from the IBiD feasibility trial that more development work is required for a brief psychosocial intervention to address adherence and illness and treatment perceptions. Particularly in dealing with some of the issues particularly pertinent to mental health treatment, namely, lack of involvement in treatment decisions, power differentials between clinician and patient and ongoing need for support in the context of fluctuating illness state and associated changing treatment.

9.3.5 Patients' experiences and preferences for involvement in treatment decisions in BD

The final aims of this programme of research were to explore peoples' involvement in decisions about treatment. Specifically, how much people with BD have been involved, their preferences and how these relate to both illness and treatment perceptions as well as adherence to medication. The cross-sectional study of Shared Decision Making (SDM) explored these aims (Chapter 8) and was among the first to quantitatively explore SDM in a UK sample of individuals with BD. It contributes to addressing the paucity of knowledge in this area (Fischer, 2006).

Overall participants expressed both having experience in being involved in decisions about their care and treatment and a preference for being involved. Participants expressed feeling a high degree of control over their choice and use of medications. Being involved in starting a mood stabiliser was associated with involvement in continuing to take it, demonstrating that if SDM can be instigated at the start of treatment, it extends to ongoing involvement. This provides reassurance that there appears to be a move towards SDM in mental health with many people feeling empowered to be involved and make decisions about their care. However, there is still some way to go as a minority who wish to be involved are not and few have the opportunity to make advanced plans about their treatment.

To date, illness and treatment perceptions and their association with SDM in BD had not been investigated. This study highlighted three key factors related to how involved people were in their treatment decisions, firstly perceptions of personal control over BD, secondly perceptions of how effective treatment is in controlling BD and finally agreement with the diagnosis. Greater satisfaction with the information they have received about medication was related to more involvement and preference for SDM. By identifying and implementing BCTs which enhance perceptions of control and also by providing sufficient and appropriate information about treatment, there is evidence that this may enhance SDM.

In terms of outcomes, no consistent association between SDM experience and adherence was found. Larger studies, powered to detect changes in adherence in the same medications are needed to investigate this further. Overall the results of this study emphasise the importance of both receiving accurate and sufficient information about treatment and feeling empowered to be involved in care. However, there is still some way to go to ensure that all individuals with BD have the resources and capability to be involved.

Dissatisfaction with a number of areas of current mental health care, information provision and support was uncovered through this thesis. Since this programme of research was conducted, the most recent CQC community mental health report continues to identify some dissatisfaction with involvement in care, although the Trust involved in this programme of research performed to an equivalent level to other NHS Foundation Trusts. Not all patients felt involved in their care and treatment decisions or given medications information (Care Quality Commission, 2014). In addition, generally Trusts performed poorly in supporting people in areas such as finance, housing and signposting to other services (Questions changed between 2010-2013 surveys and 2014 so results are not able to be directly compared). The cross-sectional research in this thesis found that generally people feel empowered to be involved in their treatment and there was a preference for personal involvement and receiving information. However, in practice, few had made advanced requests about their care and

there were low levels of satisfaction with information about medications particularly on the potential problems like side-effects of medication. This concurs with the CQC surveys indicating that unmet needs are still very much an issue in mental healthcare. Further research is needed to investigate how both SDM preferences, and specific information needs might differ across illness fluctuations and over the care journey from pre-diagnosis to the longer term. Psychiatrists often cannot predict patients' preferences for SDM (Hamann et al., 2010). It is therefore important that as well as encouraging involvement right from the start of treatment, clinicians check with patients regularly about their experience and preferences towards their treatment. SDM training of five sessions demonstrated encouraging results in a pilot study where an increase in preferences for participation and desire for greater responsibility. However, a decrease in trust in clinicians and increased scepticism toward psychiatric treatment was also observed (Hamann et al., 2011). It is key that any SDM intervention is combined also with psychoeducation on illness and treatment and also that clinicians are also aware of the importance of SDM and how to effectively communicate around treatment decisions.

A qualitative investigation with mental health service-users in the UK identified both positive and negative experiences of mental healthcare, consistent with the studies in this thesis. It was highly individual whether people felt they had been involved in their care. There was strong dissatisfaction between the continuity of care between services, and also inconsistency regarding messages about medication (Gale et al., 2012). This concurs with our findings that after discharge there was a lack of clarity as to what care was provided, who it was provided by and who was responsible for medication prescription. Previous research identified that changes in care providers were a concern for patients who also felt that there was a lack of ongoing support for preventing mental health crisis, and care was focussed on crisis periods, during periods of stability, they felt 'invisible' (I. R. Jones et al., 2009).

A recent inquiry by Healthwatch England (2005) regarding support after hospital discharge raised a number of issues which reflect the findings from this thesis. One issue was a lack of coordination between services meaning that individuals were unsure who was to provide their care. Also, people are often discharged without the knowledge, skills and support to manage BD. However, in the Healthwatch enquiry as with the qualitative findings in Chapter 4 and the IBiD evaluation (Chapter 7), positive stories of good relationships with care providers were reported. We know good therapeutic relationships are associated with better adherence and outcomes (M. Byrne & Deane, 2011; Zeber et al., 2008). Healthwatch England (2005) also found that people did not feel involved in hospital discharge planning and did not feel that their concerns were acknowledged.

9.4 Limitations

This programme of research extends knowledge in the field of BD and informs the future development of interventions to improve adherence and self-management in BD. However, the research programme is subject to a number of limitations. These limitations relate to the following areas;

- Introduction of potential bias and threats to validity in the research
- Limitations of the scope and scale of the studies

9.4.1 Bias, validity and generalisability

Research studies are often subject to a number of threats to validity. Bias can be introduced by different systematic, unintended errors such as selection and information bias which threaten internal validity, namely, whether results are true or as a result of how the study was conducted. In addition, external validity or generalizability refers to the extent to which results apply in other settings or populations (Kukull & Ganguli, 2012). This section describes how these limitations apply to the research in this thesis.

9.4.1.1 Selection bias

Within the systematic review the specific limitations of both the studies included and in the review methodology are detailed in Chapter 3. Potential bias may have been introduced by the selection of data for computation of effect sizes. Included studies were not homogeneous, therefore decisions were made by the researchers on how to best select the most comparable data. The outcome measures subject to lowest risk of bias (starting with serum medication levels) were chosen in preference to minimise bias introduced by self-report. Potential selection bias may have also been caused by the inclusion of published data only, however, no evidence of publication bias was observed in the meta-analysis. Moderation analysis may be affected by bias, in that the necessary data was not provided in published papers in order to include some studies in each analysis. In addition, the issues in participant retention in many of the studies introduce bias.

Selection bias may have impacted on the findings from the qualitative and empirical studies in this thesis. The qualitative study in Chapter 4 did not include those who had disengaged with formal care. However, the objective was to include those who are prescribed medication and as such, recruiting from those engaged with psychiatrists was appropriate. The IBiD feasibility

study may be subject to selection bias as staff advised on participants who it was felt not appropriate to approach. This was for risk purposes to ensure that only participants well enough to provide consent were approached. Those who were eligible but we were unable to contact or were not interested in participating may differ from those recruited. However, the data is not available on which to make an assessment of this.

Random sequence generation aims to mitigate against selection bias. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials allows an assessment of the risk of bias in the feasibility RCT (Higgins et al., 2011). The random sequence generation to allocate participants (described in Chapter 6, section 6.4) used minimisation, which is an acceptable approach where a balance is required between prognostic factors in small trials where other methods such as blocking and stratification are not appropriate (D. Altman & Bland, 2005). Minimisation ensured that groups were balanced on age and gender and the method was judged to have low risk of bias. Although this is a small, feasibility study and ensuring balanced groups was not necessary, it was noted that groups were not equivalent on key outcome measures at baseline. A baseline imbalance is an additional potential source of bias for a definitive trial, and either this should be included as a minimisation criteria or controlled for in the analysis if an imbalance is present.

Selection bias may also be present in the cross-sectional study (Chapter 8). Participants were self-selected based on their willingness to complete measures relating to treatment and illness perceptions. The findings may not represent those who have a neutral view of treatment. In addition, in this study, the diagnosis of BD was not verified by clinical interview, however, participants all reported being prescribed medication consistent with the management of BD which provides validity to their self-report.

9.4.1.2 External validity

In the systematic review, a threat to external validity was that studies mostly included community samples where patients were euthymic. The applicability to an acute population may be limited, however, the dearth of research in this population meant that it was not possible to select according to this. Further studies in this area will help address this, as long as they are well described and high quality and future reviews could account for illness stage in the moderation analysis.

Limitations in the generalizability of the qualitative research in Chapter 4 have already been described. The small sample were all of white British ethic origin, however, there was a mixture of genders, ages and length of BD diagnosis. Results generalise to the target

population for the intervention, this may be sufficient for the purpose for which the study was conducted. Indeed, generalizability is not always a target of qualitative research. It is more important to achieve sample adequacy to address the research questions (O'Reilly & Parker, 2013). It is recommended that primary research for intervention development is conducted with the intended population (Craig et al., 2008). In terms of wider generalisation to other populations the results may not be as applicable. It is possible, for different ethnic groups, there may be key differences in illness and treatment perceptions, such as the cause of the illness, personal control and the necessity of medication. Further qualitative research and additional service-user testing with more diverse groups would add insight here.

In terms of the external validity of the IBiD feasibility RCT, the small sample was majority female and aged on average 52 years. This compares with UK hospital admissions for affective disorders, with more females than males admitted in 2013/2014 and a mean age of 50 years (HSCIC, 2015). Participants had an average length of diagnosis of nine years with the majority having had previous hospital admissions and multiple episodes of mania and depression. Results may not generalise to newly diagnosed patients. However, within this population, the total number of patients who were eligible is small.

9.4.1.3 Ascertainment bias

Results of a trial may be influenced by knowledge of participants' treatment allocation, this is referred to as ascertainment bias (Jadad & Enkin, 2007). Inadequate allocation concealment may result in exaggerated intervention effect sizes (Pildal et al., 2007). Allocation concealment was ensured by conducting the allocation separately from the CSOs involved in recruitment. They did not have knowledge or access to either the minimisation criteria, or previous allocations. Allocation concealment was judged to have low risk of bias.

In terms of blinding, participants could not be blinded to the intervention as the comparison was TAU and we were upfront to participants about the two groups and their allocation. Blinding of personnel delivering the intervention was not possible, nor was blinding the care team of participants for pragmatic reasons, however, blinding of personnel conducting assessments was attempted. This was, in the most part, successful with six instances of unblinding and only four in those followed-up, which could therefore have impacted on the results. It is recognised that blinding of personnel and participants may be difficult or impossible in the delivery of psychosocial interventions and in these cases, blinding of outcome assessment reduces potential bias (Davidson et al., 2003).

Assessments based on non-blinded assessors results in a more beneficial intervention effect compared to blinded assessors (Hróbjartsson et al., 2013). Outcome assessments were conducted by blinded assessors and used validated tools. However, as outcomes were self-report data, they cannot be regarded as blinded. There is therefore the potential for high risk of bias in the outcome assessments.

9.4.1.4 Measurement bias

There is the potential for self-presentation bias in the use of self-report measures. Participants may be fearful of admitting non-adherence in the hospital setting for fear of being held under section or subject to community treatment order. However the fact that the research team were separate from the care team and participants were reassured of confidentiality to reduce the potential of self-presentation bias. The wording of questionnaires also normalises and gives permission to report negative attitudes to treatment and instances of non-adherence. In the cross-sectional study, responses were anonymous in order to attempt to reduce the risk of self-presentation bias.

Incomplete outcome data refers to either missed data from attrition or non-completion of questionnaire items and exclusions by investigators (Borenstein et al., 2011). The questionnaires were completed without missing data, potentially due to the CSOs going through the questionnaires with participants encouraging them to complete items and the questionnaire contained space for participants to indicate they were 'unsure' or the question was 'not applicable'. In terms of attrition, follow-up data was not available for seven participants, however attrition numbers were comparable in the two groups.

The outcome measures selected may have issues around validity of the results. There is the potential that the questionnaires may not have face validity. The IBiD evaluation and SDM study used validated questionnaires. However, it would be of value to conduct research to find out what outcomes are of value to patients. A review of existing outcome measures in mental health revealed that service-users felt that there was too much emphasis on the negative, that what was considered a 'good' outcome according to the scales, didn't always reflect what participants felt was a positive outcome for them (Crawford et al., 2011).

Indeed, participants in the IBiD qualitative evaluation and feedback from the cross-sectional study highlighted that there was not always a response category which they felt best fitted with their views and they wished to have more opportunity to add their own words. By conducting additional development work on both the validated measures and including outcomes pertinent to patients, the assessments would have greater validity. A fine balance is

needed between measures which are comprehensive enough to capture patients' experiences, but brief enough not to cause fatigue and exacerbate any problems with concentration and comprehension which people might be experiencing as a result of a BD episode or side-effects.

Regarding the BMQ specifically, there may be value in adding additional components or revising existing items in order to generate a BD specific version, this would acknowledge the differences and complexity of medication in this area as well as specific perceptions in mental health, for example the threats to sense of self reported in the qualitative study in chapter 4. The BMQ also doesn't include a measurement of perceived efficacy of treatment and a separate efficacy subscale may be warranted (Horne, 2003b).

Both the IBiD feasibility study and the cross-sectional study presented the challenge of the complex and changing medication regimens in BD. The medication outcome measures were confounded by changes between timepoints. Other studies have dealt with the issue of multiple medications by selecting one medication to measure, or asked patient to give their global feedback. For example, Levin and colleagues (Levin, Sams, Tatsuoka, Cassidy, & Sajatovic, 2015) computed an average self-report score when multiple medications were taken, but using electronic adherence monitoring for the medication taken most frequently. This removes the nuances of treatment beliefs and adherence whereby an individual patient may have different views on their mood stabilisers compared to their benzodiazepines for example. We found that differences were observed in adherence and perceptions between different medications in the cross-sectional study and therefore asking about individual treatments is important to capture this variability. This observed variation may be a result of the small sample, further studies are needed to investigate whether there are real variations between adherence and treatment perceptions within individuals.

Data from the qualitative studies and IBiD evaluation indicate that other behaviours, aside from adhering to medication are important in maintaining wellness and preventing relapse, for example sleep management and monitoring prodromes. A new measure of self-management could be developed and used to assess changes in using self-management techniques. Research has identified techniques which patients find useful (S. Jones, Deville, Mayes, & Lobban, 2011; Suto et al., 2010; Todd et al., 2012). In fact this may represent a useful patient reported outcome measure to capture, not recovery from illness, but having the skills and empowerment to manage the condition well. Early work on the development of the Mental Health Self-Management Questionnaire (MHSQ) may provide a promising tool to measure this and should be integrated into future work on adherence and self-management (Coulombe et al., 2015). This scale incorporates active involvement in accessing information and treatment

decisions, monitoring for signs of illness and engaging in healthy lifestyle activities in addition to taking medication and engaging with mental healthcare.

9.4.1.5 Selective outcome reporting

Selective outcome reporting occurs where only a selection of the original outcomes are included in publication. It might be the case that after analysis, non-significant results are not reported. In the IBiD feasibility trial, the aims were, not to determine, statistically the intervention effectiveness and the trial was not powered to do so. As is demonstrated by the inclusion of the study questionnaire as Appendix L it can be seen that all original outcomes are presented in this thesis. The study therefore has a low risk of bias with regard to selective outcome reporting.

9.4.2 Scope and scale of the research

The research programme here forms the necessary preliminary work prior to a definitive trial. As such it is limited in its scope and scale. We did not have the capacity to quantitatively draw conclusions on the efficacy of the intervention. Exploratory analysis did not reveal any indications of superiority of the intervention over the control group, and the potential reasons for this were outlined in Chapter 6, section 6.7.2. The scope to assess outcomes was limited by the measures used. The fact that this was a feasibility trial does allow us to gather data on potential what other factors might be important to collect and which might provide data on potential confounders. It was clear that the follow-up assessments need to incorporate the collection of more information on medication changes between the time points including reasons for the changes.

The feasibility study could be viewed as being limited in that the comparison group was TAU, rather than an existing intervention or attention-matched control. However, as this was the trial of a novel intervention with no evidence of superiority over usual care (clinical equipoise) it was a valid comparison group. As discussed in Chapter 6, Section 6.3.1, it was also necessary for pragmatic reasons and provides a valid comparison as it compares to current service provision. Definitive trials of a psychosocial intervention might investigate comparing an intervention against both TAU or an attention matched control, as well as possibly comparing the self-management written resource on its own and with support from a therapist. The follow-up period in this study was limited to 6-8 weeks, so we are unable to draw conclusions about the feasibility of retention over a longer period. In addition, we were unable to assess

the immediate effects by conducting an assessment immediately post-intervention due to HCP concerns about participant burden.

The scope of the IBiD intervention itself was also limited. Partly by the desire to keep it brief to enhance the potential use in clinical practice and also by the lack of available evidence on effective BCTs and how exactly to implement them, both within this context and for this patient group. The use of BCTs in intervention development has been challenged for the fact that in order to be successful, certain conditions are necessary, including that the selection of techniques should carefully match the behavioural determinants and that the determinants do in fact predict the behaviour (Kok et al., 2015). There is good evidence within this programme of research that the second condition was met. However, the lack of evidence to draw upon for matching specific methods to implement techniques means that the intervention development drew on the best available evidence from mental health and adherence research in physical health and the qualitative research from people with BD. As such, it is possible that these techniques may not work in practice to affect behaviour or with this particular group. Modelling work where intervention messages are tested in an experimental setting would be a useful avenue for further developing the intervention content.

The cross-sectional study was also limited by its scope and scale. A cross-sectional design does not allow for analysis to determine causation, as such the conclusions drawn only infer the association. However, from these associations, hypotheses can be made which could further be tested using a longitudinal design. For example, are illness perceptions of treatment and personal control a cause of SDM preferences and experience, or do perceptions change as a result of experiences with care. The cross-sectional study was also limited by the small sample size. Larger samples would allow for determining the predictive value of other variables on SDM or for more detailed analysis of different medication classes. However, recruitment to research in mental health clinical populations is challenging and a strength of this research is that recruitment was not restricted to people who are engaged with mental healthcare and recruited through their clinicians and may not have previously been given a voice to participate in research.

9.5 Theoretical implications & future research directions

Overall the findings from this thesis support the components of self-regulation models of illness and treatment (Horne, 2003b; Leventhal et al., 1984). Beliefs about illness and treatment appear to be related to adherence and engage in self-management (Chapter 4 and Chapter 7). There is support for the parallel processesing of emotions and cognitions, the

emotional impact of the diagnosis, taking medication and the life experiences people had had due to BD was a strong theme for paricipants narratives. The impact of emotional aspects should be investigated further in terms of the relationship with treatment engagement. The utility of illness perceptions in relating to how people are involved in care adds support to the utility of the CSM in mental health and in being associated with outcomes.

However, conducting this research has provided the opportunity to add insight into how BD research could inform future development of these models. Future research in this area should incorporate measuring other moderators of behaviour (Sniehotta, 2009; T. Webb & Sheeran, 2006). These could include volitional control as people may not actually have the control over performing the behaviour and habitual control, which may be particularly important in adherence due to the behaviour being repeated within the same context (T. Webb & Sheeran, 2006). Additional factors which would be useful to add into current models of adherence for further testing are stigma, in particular, perceived discrimination, therapeutic alliance, involvement in and preferences for decision making and perceived coercion or enforced treatment. The wider determinants of adherence should also be incorporated, including these social and interpersonal factors.

Longitudinal research is needed to determine the stability of illness and treatment beliefs as well as decision making preferences during both episodes of mania, depression and euthymia and also from first diagnosis to later in the illness journey. In addition, this would help to determine the relationship between perceptions, behaviour and clinical outcomes.

A further issue, specific to BD is that individuals may not perceive some components of their illness as a problem (during periods of mania), therefore these may not be included in their perceptions of symptoms or challenges with BD. Illness perceptions during periods of hypomania may be rated with less severity. The findings from Chapter 4 which showed the differences between how people distinguish between themselves and their illness compound the difficulties with measurement of illness perceptions in mental health, this is backed up by research in schizophrenia (Kinderman, Setzu, Lobban, & Salmon, 2006). The component of identity in the CSM (Leventhal et al., 1984) warrants further exporation. Given this future research, along with service-user led development, outcome measures which have greater validity for use in BD could be developed.

This research highlighted and emphasised the importance of comprehensive and accurate reporting of studies and interventions. The implication from this research is that high quality frameworks for describing studies and interventions exist and should be utilised. By using the TIDieR framework in assessing studies for systematic review, this process extends the original aim of this guidance. The outcomes of this assessment demonstrate that researchers need to

be clearer about their interventions, in particular, the materials used, who delivered the intervention and their training, the healthcare context of delivery, dosage and whether the intervention was modified or delivered differently than intended.

With regards to intervention delivery, further research is warranted to better understand how to best target and deliver an intervention. Whether baseline assessments should be used to target interventions towards those most at risk of adherence should be investigated. However, longitudinal work on the stability of these variables, as mentioned above may mean that vulnerability to non-adherence and relapse may be difficult to predict based on baseline scores. Additional work is needed to determine the effectiveness of the intervention in a fully-powered study and whether it should be delivered in multiple stages or with follow-ups to address additional concerns and information needs as they arise.

9.6 Clinical and policy implications

The unmet information and support needs for people with BD was confirmed by all studies in this thesis. Participants were not routinely provided with information on their condition, and frequently also on the treatments they were prescribed and the potential problems associated with taking treatment. The impact of this was that it was difficult for people to accept and move forward with managing their condition. An important point also raised was that people were not given sufficient information about side-effects or what could be done to alleviate these or change to alternative medications. This ties in with research with HCPs in the UK, where professionals working with people with schizophrenia reported withholding information on side-effects for fear of providing too much information and fear of putting people off (E. Brown & Gray, 2015). Illness should not be a factor which precludes information provision and therefore in line with SDM principles, an open, honest discussion should take place around medication where the side-effects and any uncertainties around effectiveness are included. Clinicians should be trained in having these conversations.

Personal control perceptions within BD are an area in which intervention is warranted, concurring with previous research in illness perceptions in mental health (Baines & Wittkowski, 2013). The IBiD intervention did not explicitly target this and it is worthwhile investigating specific techniques which could target personal control and self-efficacy.

This programme of research indicates that the use of questionnaires in themselves may be useful clinical intervention. They give patients the opportunity to consider symptoms and side-effects they may not have been told about. It is, however, imperative that they have the opportunity to complete these with a staff member so that issues can be raised. The

questionnaire could provide a way for them to raise issues which they may not feel empowered to do so otherwise.

There are challenges with introducing clinical interventions within the mental health setting with pressures on mental health services (BBC, 2014) and there may be little capacity for information provision or discussions with staff (Rose et al., 2013; Stenhouse, 2011; Walsh & Boyle, 2009). In addition, increasing patient choice and responsibility will change the way that services are delivered. However, this programme of research indicates that there may be ways to integrate information provision and prompting discussion between patient and HCPs in order to empower patients within existing clinical encounters.

9.7 Summary conclusions & recommendations

This programme of research adds to the field of understanding, both of how it is to live with a diagnosis of BD and how we can start to assist people to better understanding and more effective management of the condition. Specifically this research has extended the evidence in a number of key areas outlined below.

The challenges faced to living well by many people with BD are more complex than simply managing medication. There is a complex interplay between acceptance of the diagnosis, perceptions of treatment and ongoing management. These processes are also variable within and between individuals. The evidence from this thesis adds further support to the extended-SRM, NCF and PAPA and in particular investigates these theories and frameworks within the context of long term mental health problems as opposed to physical illnesses. This further extends the applicability of these models to different health areas.

It is recommended that further research, particularly longitudinal studies are conducted into applying illness and treatment perception models in mental health. This should include additional factors which this thesis has shown may impact on adherence and illness outcomes including stigma, the emotional aspect of receiving and living with a mental health diagnosis and its impact on self-identity, interpersonal factors such as therapeutic alliance and family relationships, shared decision making and the impact of enforced treatment and coercion. This will give a clearer picture of the determinants of adherence and outcomes in BD.

Effective adherence interventions exist for people in BD and brief interventions can have durable effects. Focusing on knowledge, beliefs and attitudes can be an effective strategy to improve adherence. However, studies are generally poorly described, therefore the potential to replicate successful interventions accurately is limited. It is recommended that fully powered, adherence trials are conducted using theory-based behaviour change techniques

and these are described using published guidelines to ensure that findings can be replicated and interventions built upon and accurately targeted to appropriate populations.

The feasibility RCT allowed assessment of illness and treatment perceptions in an under-researched population. For patients in the setting of acute mental health services, personal control over illness was low and they felt negative consequences from their condition, both on their lives and emotions. They experienced many moderate or severe symptoms and side-effects. Most participants held treatment inconsistent with good adherence (low necessity/ high concerns) for at least one of the medications they are prescribed. There were low levels of satisfaction with information about medication. It is recommended that the IBiD intervention provides a starting point to address these needs but should be adapted and tested as described above. Opportunities for people with BD to find out information and explore their diagnosis and treatment are severely limited. There may be some merit in the intervention in terms of prompting information seeking, mood monitoring and providing reassurance. Completing questionnaires about BD and treatment may be associated with a therapeutic benefit.

The findings from the feasibility study should be used in developing protocols for research in mental health acute settings. It was demonstrated that with sufficient staffing resources, it is feasible to recruit and retain patients with BD to an RCT during the transition between acute inpatient and community adult mental health services. Good practice in conducting research in this area was identified and this should be adhered to in future studies: building relationships with teams, reducing burden on HCP staff, maintaining contacts with staff and patients.

Many people in both acute and community services are still facing significant unmet information and support needs. However, providing honest and sufficient information on BD and its treatment as well as empowering patients to make decisions and seek information is of vital importance for effective mental healthcare. This thesis has provided important insights into the challenges faced by many people living with BD and how to begin to address some of these challenges through better understanding of what the areas of unmet need are and also how to meet these needs.

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Appendices

Appendix A. **PRISMA checklist**

Section/topic	#	Checklist item	Reported in Chapter, section #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Chapter 3,
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	n/a
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3.1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3.2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3.3.1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	3.3.2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	3.3.2, Box 3.1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3.3.3.1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3.3.3.2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3.3.3.2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3.3.3.2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	3.3.3.2
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	3.4
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	3.3.3.2 & 3.4
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which	3.4

Section/topic	#	Checklist item	Reported in Chapter, section #
		were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3.3.3.1 & Figure 3.1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Tables 3.8 & 3.9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Figure 3.3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Figure 3.4
Synthesis of results	21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency	3.6.1 & Table 3.4
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	3.5.5.1.6
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	3.6.2, 3.6.3, 3.6.4
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	3.7.1
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	3.7.2 & 3.7.3
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	3.7.4 & 3.7.5
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	n/a

Appendix B. **Data extraction template**

Review of the effectiveness and methodological quality of interventions designed to improve medication adherence in bipolar disorder.

Source

Study ID	
Citation	

Participants

Total number randomised	Total	Intervention	Control

Intervention

Number of intervention groups			Number of control groups		
Content/ elements Description of intervention/s What was the content of the intervention?	Psychoeducation (all elements) ☐ Education ☐ Social/ family therapy ☐ Other _____ _____ _____		CBT/ CBT type ☐ Psychotherapy ☐ Device/ packaging ☐		
Intervention focus (tick one option)	Adherence is primary focus ☐ Multi-focus intervention ☐ Unclear – insufficient information to judge ☐				
Provider Intervention delivered by.. (tick all that apply)	Psychologist ☐ Nurse (mental health) ☐ Other health professional ☐ Social worker ☐ Other _____ Not specified ☐		Psychiatrist ☐ Trainee/ student ☐ _____		
Format Method(s) of intervention administration (tick all that apply)	Face-to-face (individual) ☐ Online ☐ Device/ Packaging ☐ Other _____ Not specified ☐		Face-to-face (group) ☐ Telephone ☐		
Setting (intervention delivery)	Hospital outpatient psychology/ psychiatry department ☐ Specialist affective disorder/ bipolar clinic/ unit ☐ University psychology/ psychiatry dept (not specialist BD) ☐ Other ☐ _____ _____ _____ Actual delivery location unclear ☐				

<table>
<tr><td>Recipient

Intervention delivered to</td><td>Patient ☐ Practitioner ☐
Family/ partner and Patient ☐ Family/ partner (only) ☐
Other _____</td></tr>
<tr><td rowspan="2">Intensity</td><td>Number of different patient contacts (or range and average)</td><td></td></tr>
<tr><td>Total contact time involved (or range and average)</td><td></td></tr>
<tr><td rowspan="2">Duration</td><td>Time period of intervention contact

Months/ years</td><td></td></tr>
<tr><td>Spacing of intervention contact e.g. Weekly/ Biweekly/ monthly</td><td></td></tr>
<tr><td>Tailoring</td><td>http://www.marijndebruin.eu/sites/default/files/Coding%20Manual%20&%20Taxonomy.pdf
<table><tr><td></td><td>Yes</td><td>No</td><td>Unclear</td></tr><tr><td>1. Individualization</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>2.a) Macro-tailoring (group level)</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>b) Attention-tailoring (individual level)</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>c) Micro-tailoring (individual level)</td><td>☐</td><td>☐</td><td>☐</td></tr><tr><td>3. Participation</td><td>☐</td><td>☐</td><td>☐</td></tr></table></td></tr>
<tr><td>Intervention retention

% completing parts of intervention</td><td></td></tr>
<tr><td>Control group</td><td>Code actual TAU described....

1. General care – outpatient psych or GP appointments/ medication management usual – no specific education or psychological support mentioned.

2. Intensive support – structured specialist support, i.e more than general psychiatric appointments

TAU care (tick one) General care ☐ Intensive support ☐

Code all additional components in addition to above care for Control group

Sessions (attention matched) ☐
Education ☐ Psychoeducation ☐
Compliance feedback ☐ GP training ☐
Other ☐ _____</td></tr>
<tr><td>Fidelity

Intervention delivered as intended? How was this monitored and measured?</td><td>Formal assessment ☐ Informal assessment ☐
No reported assessment ☐
Details _____
_____</td></tr>
</table>

TIDieR – Intervention description assessment

Use primary citation & papers referenced by the authors, available protocols and manuals, online supplementary material, and websites.

	Adequately described	Inadequately described	Not reported	Not applicable to intervention	Description
1. Brief name					
2. Why (rationale, theory or goal)					
3. What (materials used)					
4. What (procedures used)					
5. Who provided					
6. How (mode of delivery)					
7. Where (location)					
8. When and how much					
9. Tailoring					
10. Modifications					
11. How well (planned)					
12. How well (actual)					

Adherence Outcomes – every measure listed as a separate outcome

Primary outcome Adherence ☐ Other ☐ Not specified ☐

	Description of measure (inc. units of measurement – Include medications analysed	Time points assessed	Sample size analysed	Result
Self-report				
Physician report				
Informant report				
Biological (lithium/ serum level)				
Pill counts/ prescription refill				
Chart review				
Composite measure				
Other				

Methodological quality - Risk of bias – See Cochrane guidelines for instructions on assessing risk of bias

	Risk of bias			
	Low	High	Unclear	Description
Random sequence generation	☐	☐	☐	
Allocation concealment	☐	☐	☐	
Blinding of participants	☐	☐	☐	
Blinding of personnel	☐	☐	☐	
Please specify risk for all outcome measures used.				
Blinding of adherence outcome assessment	☐	☐	☐	
Incomplete adherence outcome data	☐	☐	☐	
Selective adherence reporting	☐	☐	☐	
Blinding of adherence outcome assessment	☐	☐	☐	
Incomplete adherence outcome data	☐	☐	☐	
Selective adherence reporting	☐	☐	☐	
Other bias	☐	☐	☐	

Other Comments

Appendix C. **COREQ Checklist for Chapter 4**

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	4.4.5
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	4.4.5
Occupation	3	What was their occupation at the time of the study?	4.4.5
Gender	4	Was the researcher male or female?	4.4.5
Experience and training	5	What experience or training did the researcher have?	4.4.5
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	4.4.4
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	4.4.4
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	4.4.6
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	4.4.6
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4.4.2
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	4.4.1
Sample size	12	How many participants were in the study?	4.4.1
Non-participation	13	How many people refused to participate or dropped out? Reasons?	n/a
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	4.4.5
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	n/a
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	4.5.1
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix D
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	n/a
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	4.4.5
Field notes	20	Were field notes made during and/or after the inter view or focus group?	n/a
Duration	21	What was the duration of the inter views or focus group?	4.4.5
Data saturation	22	Was data saturation discussed?	4.4.2
Transcripts returned	23	Were transcripts returned to participants for comment and/or	n/a

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	4.4.6
Description of the coding tree	25	Did authors provide a description of the coding tree?	Table 4.2 & 4.3
Derivation of themes	26	Were themes identified in advance or derived from the data?	4.4.6
Software	27	What software, if applicable, was used to manage the data?	n/a
Participant checking	28	Did participants provide feedback on the findings?	n/a
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	4.5
Data and findings consistent	30	Was there consistency between the data presented and the findings?	4.5
Clarity of major themes	31	Were major themes clearly presented in the findings?	4.5
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	4.5

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Appendix D. **Phase 1 research- Semi-structured interview schedule**

A study examining patients' satisfaction with information about medicines prescribed for bipolar disorder

Qualitative research – Interview schedule

Introduction

Many thanks for agreeing to participate in this study.

First we will ask you to fill in a questionnaire about how you have been feeling recently.

This will be followed by a second questionnaire that will help us explore your information needs and any concerns you may have about your prescribed medication.

Finally, we will ask you to tell us a bit more about your answers to the questionnaires and we will also show you examples of existing information about medicines for bipolar disorder and ask you to tell us what you think of these.

Reiterate confidentiality & No right or wrong answers, interested in your personal views.

Part 1: Clinical assessments

We will now ask you to complete a questionnaire (**Beck Depression Inventory)** about how you have been feeling recently. Could you also tell us what medicines you have been prescribed?

Part 2: Questionnaire Completion (Beliefs about Medicines Questionnaire (BMQ), Satisfaction with Information about Medicines Scale (SIMS) and Sources of Information Questionnaire (SIQ))

We would like you to complete another questionnaire that explores people's beliefs about their medicines for bipolar disorder and also their satisfaction with the information they have received about these medicines. We will score your questionnaire as soon as you complete it and we will ask you to talk a bit more about your answers.

Part 3: Interview & evaluation of existing information

Section 1: Identified concerns about the prescribed medication
First, we would like to explore your answers to the questionnaires in a bit more detail. Prompts: What concerns, if any, do you have about your medicines? How do you feel about the long-term use of your medication? To what extent do the medicines affect how you feel? Does medication affect your ability to work, your relationships or your social life? What concerns, if any, do you have about side effects?
Section 2: Satisfaction with information received about the prescribed medication
Prompts: What do you think about the information you received regarding the potentially beneficial effects of your prescribed medication? What do you think about the information you received regarding the potential side effects of your prescribed medication?
Section 3: Sources of Information
We would like to explore in a bit more detail your answers to the Sources of Information Questionnaire (SIQ). <u>Most trusted sources</u> Would you mind telling us a bit more about the sources you say you trust the most?

Prompts: Why is this?

Least trusted sources Would you mind telling us a bit more about the sources you have say you trust the least?

Prompts:

Why is this?

Ease of getting information?

Timing when information was received?

Section 4: Evaluation of existing information about medicines for bipolar disorder

We are really interested to hear your views on existing information about medicines prescribed for bipolar disorder.

These have been written by the Sussex Partnership NHS Foundation Trust and a charity.

(NB: interviewers to present information leaflets during the interview)

There are no right or wrong answers; we are interested in your personal views.

(NB: Interviewer to go through questions/prompts for each information leaflet separately)

Familiarity with information

Have you seen written information about medicines prescribed for bipolar disorder before?

Have you seen these NHS leaflets and/or this booklet before?

Evaluation of information

What do you think about the information presented in this booklet/leaflet?

Usefulness of information

Prompt:

Do you find this information useful?

Does this leaflet/booklet address any concerns you may have about your medication?

(NB: Interviewer to ask this if specific concerns were reported in the questionnaire)

Adequacy of information

Prompt:

Is there anything that you would like to know about your prescribed medication that is not included here? If yes, what?

Is there any information you have been given about your medicines that you wish you hadn't?

Comprehension / Clarity

Prompt: Is the information presented in a clear way? Is it understandable?

Presentation / design

Prompt:

What do you think about the size of the letters and the illustrations included in this booklet/leaflet?

Do you find the information in this booklet/leaflet is presented attractively?

Preferred format/medium of information

So, to summarize what is your preferred format of information?

What is the best way of getting information?

Have you obtained information in any different way that you might wish to share with us?

Appendix E. **Confirmation of ethical approval for Phase 1 qualitative research**

NHS

National Research Ethics Service

Brighton East Research Ethics Committee

NHS Brighton & Hove
1st Floor, Prestamex House
171-173 Preston Road
Brighton
East Sussex
BN1 6AG

Telephone: 01273 545373
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15 February 2010

Professor Rob Horne
Head of Department of Practice & Policy, Director of Centre for Behavioural Medicine, The School of Pharmacy, University of London
The School of Pharmacy, University of London
School of Pharmacy, Mezzanine Floor
BMA House, Tavistock Square
London
WC1H 9JP

Dear Professor Horne

Study Title:	**Improving satisfaction with information about medicines prescribed for bipolar disorder**
REC reference number:	**09/H1107/110**
Protocol number:	**2**

Thank you for your letter of 21 February 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair who chaired the meting when the study was reviewed.

Confirmation of ethical opinion

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

Ethical review of research sites

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

Conditions of the favourable opinion

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

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

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisations in accordance with NHS research

governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

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

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

Approved documents

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

Document	*Version*	*Date*
Covering Letter		30 November 2009
Investigator CV		
Summary of protocol	1	30 October 2009
Research contract document (letter from Obi Onyian)		19 May 2009
Rethink booklet		
Leaflet on Lithium		
Leaflet on Valproate		
REC application		03 November 2009
Protocol	2	20 January 2010
Response to Request for Further Information		21 February 2010

Statement of compliance

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

After ethical review

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

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

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

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

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

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

09/H1107/110	**Please quote this number on all correspondence**

Yours sincerely

Dr Paul Seddon
Chair

Email: nischinth.cherodian@bhcpct.nhs.uk

Appendix F. **Participant Information pack**

Sussex Partnership NHS
NHS Foundation Trust

Dear

A study examining patients' satisfaction with information about medicines prescribed for bipolar disorder

I am writing to inform you about a research study that is being carried out by researchers at the Centre for Behavioural Medicine, School of Pharmacy, University of London.

The purpose of the research is to find out what people think about the information they receive in relation to their prescribed medication for bipolar disorder. The findings of this study will aim to improve the information about prescribed medications that patients receive in the future.

Please read the enclosed information sheet to find out more about the study. If you would like to participate in the study, please contact Dr Marcia Kapari at the Centre for Behavioural Medicine.

If you decide that you do not want to participate in the study, the care that you receive will not be affected in any way.

If you would like any further information about the study, please telephone **Dr Marcia Kapari** on **020 7874 1287**.

Yours sincerely,

Dr ……
Consultant Psychiatrist

A study examining patients' satisfaction with information about medicines prescribed for bipolar disorder

Participant Information Sheet

You are being invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may wish to discuss it with others. If there is anything that is not clear or if you would like more information, please contact **Dr Marcia Kapari** on **020 7874 1287**.

What is the purpose of the study?

The purpose of this study is to find out what people think about the information they receive in relation to their prescribed medication for bipolar disorder.

Why have I been chosen?

You have been chosen because you have been prescribed medication for bipolar disorder from a mental health professional within the Sussex Partnership NHS Foundation Trust. It is hoped that forty people will decide to take part in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision not to take part, or a decision to withdraw at any time, will not affect the standard of care that you receive.

What will happen to me if I take part?

If you decide to take part, please contact Dr Marcia Kapari, a researcher at the Centre for Behavioural Medicine, School of Pharmacy, to arrange a one-off appointment which will take place at the Mill View Hospital in Hove. Two researchers will be present at the appointment, which is expected to last one and a half hours. The appointment will have four parts:

1. You will be asked to answer some questions about how you have been feeling recently.
2. You will be invited to complete a short "writing task" in response to how you felt about first taking your medication for bipolar disorder.
3. We will ask you to fill in a questionnaire which explores peoples' beliefs about their medicines for bipolar disorder and also their satisfaction with the information they have received about these medicines.
4. We will ask you to talk a bit more about your answers to the questionnaire. We will show you examples of existing information about these medicines and ask you to tell us what you think of these.

Will I be paid for my participation?

You will not be paid for participating to the study but your travel expenses to and from the Sussex Education Centre, Hove, will be reimbursed. We will also offer you refreshments during the interview.

What are the possible benefits of taking part?

You may not benefit personally from taking part. However, we hope that findings from this study will help to address patients' information needs about prescribed medications for bipolar disorder and improve their overall quality of care in the future.

Will my taking part in this study be kept confidential?

Everything that you say during the interview or write during the writing task and on the questionnaire will be kept strictly confidential and will not be fed back to those caring for you, unless the researchers feel that the health and safety of you or others is at severe risk. In this unlikely event, you will be informed that your care coordinator will be contacted.

All information you provide (e.g. during the audio-recording of the interview, the written task and the questionnaire) will be stored securely. Any sections of the interview that is typed out will not include your name (a participant number will be used instead) so it will not be possible for people to match any information to you personally.

What will happen to the results of the research study?

If the results of this study are published, your identity will not be revealed. If you wish to obtain a copy of the published results, please tell one of the researchers and they will happily supply you with one.

Who is organising and funding this study?

This study is being organised by researchers at the Centre for Behavioural Medicine, Department of Practice and Policy, School of Pharmacy, University of London and is being funded by the National Institute for Health Research, Patient Benefit Programme.

Who has reviewed the study?

The study has been reviewed by the Brighton East Research Ethics Committee (Ref 09/H1107/110).

What should I do now?

If you would like to participate in this study, please contact Dr Marcia Kapari (her details are listed below) in the next two weeks to arrange a date to meet with her.

Contact for the study: Dr Marcia Kapari, Research Fellow

Centre for Behavioural Medicine, Department of Practice and Policy, The School of Pharmacy, University of London, BMA House, Mezzanine Floor, Tavistock Square, London WC1H 9JP

Phone: **020 7874 1287** Email: marcia.kapari@pharmacy.ac.uk

Appendix G. **Consent form**

Patients' satisfaction with information about medicines prescribed for bipolar disorder.

CONSENT FORM

Contact Researcher: Dr Marcia Kapari

Please initial box

1. I confirm that I have read and understand the participant information sheet dated … for the above study and have had the opportunity to contact Dr Marcia Kapari 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, without my medical care or legal rights being affected. ☐

3. I understand that the interview will be audio-taped and that sections of it (with my name removed) may be used in published articles and conference presentations. ☐

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

5. I understand that the research data collected during this study may be looked at by other individuals from the research team, sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. ☐

……..	……	…….
Name of participant	Date	Signature
……	……	…….
Name of researcher	Date	Signature

Appendix H. **Feedback from service-users on IBiD content and design**

Bipolar: A question of balance - Intervention content feedback

Page		Feedback
How we hope this booklet can help you	SO	Suggested change: 'Throughout this booklet we have LEFT space' not we have made space. Final box - replace 'We hope you find the information useful' with 'Turn to page XXX for a list of other resources you might find useful' - I think the current sentence isn't really saying anything
	LM	This booklet aims to help to answer your questions about bipolar and its treatment. We have drawn on the ~~real~~ experiences of people with bipolar and from research looking at what helps people ~~need to~~ get the best from their treatment. Our ~~We are a~~ team includes ~~of~~ people with bipolar, ~~researchers in~~ health communication researchers, NHS psychiatrists~~, and~~ pharmacists and representatives from Bipolar UK. This ~~Our~~ project is funded by the the NHS through the National Institute for Health Research ~~(NIHR), the research division of the NHS~~. Everyone's experience of bipolar is different~~unique~~. Throughout the booklet we have made space for you to make notes to help you to manage your treatment and work with your health professionals. We do ~~are~~ not expect~~ting~~ this booklet to be the only information you ~~will ever~~ need. We have included a list of other resources you might find helpful at the end. We hope ~~that~~ it ~~will~~ answers some of the ~~main~~ questions you have and points the way to where~~how~~ you can get ~~any~~ extra if help you need to.
Understanding bipolar (2 pages)	JT	Need to acknowledge physical and cognitive aspects of bipolar - not just mood changes. Physical early warning signs (e.g. the 'someone just tipped cold water over me, I'm shivering!' symptom). Brain fluctuating in its ability to think and function.
	AMB	Mention rapid cycling bipolar. Highs and lows don't necessarily last for weeks or months. 'Bipolar is part of who I am and I embrace it. I would not even call it an "illness". I think perhaps you could mention this' (Think this is covered in 'making sense of the diagnosis') Many creative people in the past had bipolar, e.g. Tchaikovsky, Beethoven etc. Make people see bipolar in a positive way.
	SO	p3. Suggest rewording this: Bipolar does not fit with the common idea of a disease as something which you get and then it goes away when you find the right treatment (like a chest infection or headache). This sentence suggests that people aren't familiar with chronic conditions that can be managed, such as diabetes, but I think they are. Could reword to something simple like: Bipolar is not a condition that goes away when you find the right treatment (like a chest infection or a headache). p4. Need to be careful here that statements aren't definitive ie. need to say People with bipolar CAN experience intense highs. Depression IS USUALLY a big part of bipolar. Don't know why 'out of control' is in inverted commas - suggest removing them. Suggest rewording the Q&A to: A: Bipolar is treated as an illness because it can cause moods to go out of control, often leading to distress and suffering. It can be effectively treated, though, to restore balance and stability over time.
	LM	W~~As human beings w~~e all experience a variety of emotions and moods. S~~However, s~~ome people experience larger swings in their mood with extreme ~~from~~ highs and~~to~~ lows. ~~For some people, t~~These ~~x~~treme mood swings don't necessarily have a big impact on someone's~~n their~~ life~~,. especially if most of the time, they Some~~ manage to keep~~how~~ things ~~stay more or less under control in balance~~. For others people, mood swings can make life very difficult, causing ~~, it can cause~~ huge problems for them and those around them. Extreme m~~M~~ood swings may be labelled as bipolar disorder when they affect a person's ability to live a normal life. I~~So i~~n some ways, bipolar is ~~simply~~ a label ~~that is~~ applied when mood swings stop someone being able to ~~interfere with a person's ability to~~ function in their every day ~~day to day~~ life or interfere with their relationships with other people~~s~~. The aim of treatment is not to cure the condition. Bipolar does not fit with the common idea of a disease as something which you get and then it goes away when you find the right treatment (like a chest infection or a headache). The aim of treatment is to help people ~~the person to~~ restore and then maintain balance in their moods so that the highs and lows have less impact on their lives. People with bipolar can experience intense high energy moods~~s.~~ In everyday life. At the time, this can make them outgoing, energetic. They can often feel ~~and they are often~~ very creative, or be seen as the "life and soul of the party".

		However these intense high energy moods can become ~~At other times these highs can tip into~~ something which is much more of a problem, especially if the mood goes on for too long.~~.~~ The person may find their high energy mood makes their behaviour difficult or even impossible to control and this causes ~~y may experience times when things go too far and highs become "out of control", their behaviour then causes~~ problems for~~to~~ themselves and for their families. For example, s~~S~~omeone ~~people~~ might spend money recklessly, be extremely irritable or get involved in sexual behaviour that is out of character. Depression is a big part of bipolar. Periods of high energy ~~Highs~~ can be followed by crushing periods of low energy~~s~~ and often feelings of despair. Sometimes p~~P~~eople ~~often~~ feel that their mood and energy plummets for no particular reason. This low can also happen after a period of fairly even mood. You might recognise some of the signs of depression as sadness, thinking negatively and ~~a~~ difficulty concentrating. People with bipolar often find their periods of low mood or energy also mean they lose interest in doing things they might usually enjoy and notice more ~~include other signs such as a lack of energy, loss of interest in activities and~~ physical aches and pains. Q: If it is just an extension of normal moods, why is bipolar treated as an illness? A: A person's moods~~It~~ can get~~o~~ out of control and cause distress and suffering. Treatment aims over time, to help a person's moods become more ~~, but it can also be effectively treated, restoring~~
Mood mapping	SO	p5. In the para explaining the second chart, delete the word ALSO: These periods can [ALSO] have a negative impact on a person's life. In the box below the charts, can we relate/link the text to the second chart? Also, these three points could be annotated into three separate points rather than lumped together as one sentence - would read clearer. In box mentioning tools to create own mood chart, is it possible to add a page number so it's more useful?
Is there a cause of bipolar? (2 pages)	AMB	"biological changes in the brain" and a "chemical imbalance" - these ideas have only ever been theories, should not really be presented as facts, only ideas. 2nd page - "Episodes of bipolar" don't really exist, only episodes of euphoria or mania, and episodes of depression. Bipolar itself is not episodic but usually a lifelong condition.
	SO	p6-7. I'm not quite sure what this sentence means: This is one of the mysteries of science that our minds are linked to our biological and physical nature. Usually the complex interplay between our minds and body reacts to maintain a balance. Saying that scientists haven't yet agreed on the cause of bipolar suggests that one day they might agree on the cause. My understanding is that they currently do agree that there isn't a single cause and isn't ever likely to be! So I think this needs to be reworded. Suggesting that scientists don't agree isn't helpful.
	LM	Science cannot explain how ~~This is one of the mysteries of science that~~ our minds ~~are~~ link ~~ed~~ to our biological and physical nature. However there is a ~~Usually the~~ complex interaction~~play~~ between our mind~~s~~ and body and they inter~~re~~act to give moods, emotions and thoughts~~s to maintain a balance~~. Naturally there are many ways in which these interactions balance themselves. Bipolar can run in ~~tends to run through~~ families, may ~~it can~~ be passed on from parent to child. But it does not mean that everyone who has a parent with bipolar will go on to develop it or that it will definitely be passed on to children, it just means that there is an increased chance of this happening. Research has also shown that people who experience more stressful life experiences seem to be more at risk of the development of bipolar. The cause of someone's bipolar may be different from those things that trigger ~~What may have caused the development of bipolar, and what might trigger~~ a recurrence of symptoms or relapse.~~may be different,~~ For example, ~~this means that even though~~ a stressful relationship, problems or change in job might trigger a depressive or manic episode, but it does not mean that this is the ~~these are not~~ cause~~s~~ of the disorder.
A long journey to diagnosis Making sense of the diagnosis: Does taking medication mean I have to accept I am ill? (2 pages)	AMB	Mentioning that it is not easy to diagnose, and sometimes GPs or consultant psychiatrists can get it wrong.
	SO	p8. Final sentence: Should this read 'why they have been experiencing so many CHALLENGING symptoms' rather than so many changing symptoms? p9. In time, most people with bipolar learn to understand and accept etc etc. Is this true? Suggest change to: In time, MANY people with bipolar etc etc Need a full-stop after final sentence.
	LM	This can mean that some people have mixed feelings about the condition. For example, their relief at finding out what the problem is~~,~~ mixed with resentment at having had to wait so long for a diagnosis or resenting being given a~~the idea of having a~~ mental health diagnosis. Some people are upset by the diagnosis of ~~Getting a diagnosis of~~ bipolar ~~can be very upsetting for many people~~. ~~Apart from the symptoms of the condition, l~~it can feel as though~~like~~ an important part of a person's character, things about themselves which seem to~~can make~~ make them ~~them~~ attractive to other people, are now seen as part of a medical condition requiring treatment. They~~People~~ may find it confusing that parts of their personality (such as being extremely creative and joyous) are being described as part of an illness. Successful treatment of bipolar does not change your personality but aims to reduce the problems associated with the more extreme mood swings.

		For other ~~some~~ people, receiving a diagnosis can come as a relief as it helps them understand why they have been experiencing so many changing symptoms.
Will I always have bipolar?	SO	p10. Change 'were' to: It is much better to see it as a process WHERE people become 'ill' Can we add page number to final box - ie. on page XX
	LM	As bipolar disorder is a tendency that someone has to experience extreme mood swings, rather than an illness with a known cure, the susceptibility may never fully go~~es~~ away, even if you don't experience the symptoms anymore.
'There's such a lot of stigma about giving yourself a label'	AMB	Liked the section which points out how people are not so negative about sufferers of mental health problems as you might think.
	LM	Many people with bipolar feel stigmatised. B~~b~~ecause of their diagnosis. they may be ~~This can mean feeling~~ discriminated against in work, personal life or~~and~~ when using healthcare. Experiencing ~~feelings of~~ stigma can make people feel less hopeful about their recovery.
Taking control	SO	p12. Add page number and full-stop after final sentence.
	LM	Many things can make it difficult for people to be able to successfully manage bipolar. It might be useful to try and think of some things which make it difficult for you to manage your condition. This might be something to do with your work, or someone who you have to be in contact with, such as a relative who is not happy with your diagnosis. You can use these next time you see your health professional to try and work out strategies to deal with them together.
Medications prescribed for bipolar	AMB	Should read "in bipolar, there is scientific evidence which shows that pathways in the brain which regulate mood ARE not functioning in the normal way".
	SO	Suggesting rewording first sentence of Q&A answer to: In PEOPLE WITH bipolar, there is scientific evidence which shows that pathways in the brain which regulate mood DO NOT FUNCTION in the usual way.
Making an Informed choice about medications prescribed for bipolar	SO	Suggest rewording first sentence to: It is important to be able to access the information you need about the DIFFERENT medications available SO YOU CAN make an informed choice. I think it's a bit confusing that the heading refers to 'mood stabilisers and antipsychotics' and then the text goes on to talk about 'This type of medication' as if they're one and the same... Need to clarify.
	LM	It is important to be able to find ~~access the~~ information you need about different~~the range of~~ medications so as to be able to choose which medication might help you the most, whilst causing the fewest side effects ~~available to make sure you are able to make an informed choice.~~ Making decisions about medications is not easy. Getting all the information you need and weighing up the pros and cons of differen~~a~~ treatment~~s can~~ help~~s~~.
Medication sheets	LM	Essential to have blood tests to check lithium levels, kidney function and thyroid function every six months Important long term side effect of lithium – getting up in the night to pass urine, this may mean your kidneys are affected by the lithium, making it difficult to concentrate urine overnight, so your bladder fills up and you need to get up to pass urine. It is important to discuss this symptom with your doctor.
Your thoughts and feelings about taking medication (3 pages)	SO	p17. Taking medication appropriately in the long term can be difficult, no matter what condition or illness you are taking IT for. Many people at one time or another have periods [of time DELETE] when either they take their treatment in a different way than it was prescribed, miss a dose or have a break from taking IT ALTOGETHER. p19. Repetition - the second half of point 3 and all of point 4 are saying the same thing. Suggest rephrasing point three to: It means relapses are likely to last a shorter time.
I'm worried about the side-effects from these medicines (3 pages)	AMB	The most important information people need to know about medication is what side-effects there are. GPs very often do not know about even well-known side-effects. People can be having side-effects which they do no attribute to the drug because it is not listed.
	SO	p20. Throughout - sometimes side effects, sometimes side-effects? Needs to be consistent with or without hyphen. p21. Suggest rewording sentence: Now, think about what might HELP to manage these side-effects. p22. The box about sexual dysfunction is so short and unhelpful compared to the other boxes, it almost seems like an after-thought/dismissive. Is there any way to edit down the other boxes a bit to make room to expand this/add some advice?
	LM	• Take regular exercise Finding it hard to have an orgasm or having ~~.~~n~~N~~o desire for sex. Discuss with your doctor.
I sometimes worry about whether there might be long-term	AMB	Some drugs are really difficult to come off. Withdrawal symptoms can mimic the symptoms of the problem they are designed to treat. People should always have the option to try going med-free if they want to. I don't think advocating permanent drug therapy is such a good idea. ()

effects of taking these medicines.	SO	p23. Reword this sentence to: Is there anything that worries you about taking your medication in the long term? to USE THIS SPACE TO WRITE DOWN ANY WORRIES YOU MAY HAVE about taking your medication in the long term Reword this sentence to: Lithium can increase the risk OF HAVING an underactive thyroid. Some medications, SUCH AS XXXX, increase the likelihood etc etc Suggest deleting this sentence: [Having this information means you can be more informed about possible long-term effects.] because it's repeating the sentence above the link Will the person reading the booklet know how the research team referred to in this sentence is? If you don't have access to the internet, one of the research team can the information printed off for you.
	LM	TWorries about the possible risk of possible long-term effects of any medication need to be balanced alongside the positive aspects of effective treatment and the risks of a relapse. With medications for bipolar there are some increased risks of long-term effects. It doesn't mean they will definitely happen after taking medication in the long term, just that there is an increased risk of it happening. Lithium can affect theincrease the risk of underactive kidneys and thyroid gland. Regular blood tests ensure that problems are recognised and treated early. Some medications increase the likelihood of weight gain which can increase the risk of diabetes.
Taking medication is an unwelcome reminder of my condition	SO	George's quote doesn't read well....
I tend to hide the fact that I am taking these medicines from other people	SO	I don't like the idea of advising people to challenge negative opinions about them taking medication. I think it makes more sense to talk about responding / ignoring / dealing with but NOT challenging. Suggesting that they challenge someone seems unhelpful and unnecessarily inflammatory.
	LM	It is a personal issue about who you decide to tell about your condition and treatment. You do not have to tell your employer that you have bipolar disorder, only that you have a long term health condition. Your employer can then refer to Occupational Health who can ensure that you have appropriate adjustments to your work to reduce the likelihood of further episodes, for example, keeping a regular shift pattern so you get regular sleep. Some people find it helps to explain to people the biological/ chemical reasons for psychiatric medication.
I don't feel ill, so why should I continue to take my medication?	SO	Suggest deleting second sentence in title box as follows: [Taking medication when I feel well doesn't make sense to me]
I don't feel like the medication is working	SO	Suggest rewording to: Some people will remain free of symptoms WHILST taking mood stabilisers; [for] others [they] may experience episodes of depression or mania during [this] treatment, but for most these will be fewer and less severe.
Medication changes: Why does the medication I am given keep changing?	SO	Delete first two words of title [Medication changes:] Why does the medication I am given keep changing? Suggest rewording to: For your health professional, it is difficult to know in advance which treatments will help you [personally], SO [this is why] you may need to try different medications, doses or combinations. Adjustments and changes are very common.
I sometimes worry that I might become addicted to or dependent on the medicines I'm taking.	SO	I don't think the explanation about whether drugs prescribed for mental health conditions are addictive or not is very clear - needs rewording so it's more reassuring. eg. In scientific terms, drugs which are actually addictive cause tolerance, produce artificial reward or euphoria and cause cravings for the drug. What does 'cause tolerance' mean? What does 'produce artificial reward' mean?
Alcohol, bipolar and your medication	AMB	Good idea to advise people to steer clear of alcohol altogether. Mention that marijuana and other street drugs are known to make bipolar worse.
	LM	The problem with this is that even legal substances like alcohol can worsen psychiatric symptoms such as depression and anxiety. It is 's really important to talk to your health professional about any worries you have about alcohol or any other drugs and bipolar.
'Sometimes I find it difficult to take my medication' (3 pages)	AMB	Suggestion to remove Implementations intention exercise as can be seen as patronising as 'makes it sound as though you think bipolar folk need help to do this, which they don't'. Could just say "take your meds with your morning cup of tea" or something.
	SO	p36. It might be a good idea to stick a little 'eg' in the box with the example to make it clear that it's an example...
What should I do if I am having any problems	SO	Is this the right heading for this page? This isn't really about having problems, but more about being prepared/having support lined up for when you need it... Suggest changing title to something like: Organising your support network for when you need it

and who should I contact in an emergency?	LM	You can write this information in the space below. Include a space for medication
Monitoring your symptoms and looking after yourself (2 pages)	JT	Mention some people have physical early warning signs (e.g. the 'someone just tipped cold water over me, I'm shivering!'). Symptom - Brain fluctuating in its ability to think and function, and therefore need to map my daily activities to current capability.
	AMB	Advice about what to do if you are "high" or "low" is not really practical. If you are "high" it is simply not physically possible to get more sleep, and when you are "low" you cannot stop yourself sleeping too much. These are symptoms and not behaviour. It's like telling someone not to experience pain when they have a heart attack.
	SO	p38. Suggest rewording to: Some things which may be useful for you to consider if you think YOU'RE IN THE EARLY STAGES OF a relapse.
Getting the most from your consultations (2 pages)	SO	p40. Suggest rewording to: MENTION TO your health professional any concerns you may have about your medicines and any side effects you may be experiencing. Suggest rewording to: It CAN BE difficult to remember to or feel like we can ask all the questions we want to ASK. Think we need to add a sentence above the three bits of advice here / could also annotate or number then? - something like: You might find it helpful to: 1. Ask your doctor to clarify etc; 2. Talk about your concerns. 3. Do not worry etc p41. Suggest rewording second question to: FOR how long will I have to take this medication?
	LM	It is ~~really~~ important to ~~make sure you always~~ keep your health professional informed about how you are feeling and what effect ~~how~~ your medication has on how you feel ~~is working for you~~. It is difficult to remember to ~~or feel like we can~~ ask all the questions we want to. Between appointments, write down the questions you want to ask as you think of them.
Completing your own mood chart (4 pages)	AMB	The mood chart at the end is a really great idea.
	SO	p43. Suggest rewording to: You can then use this when you meet with your health professionals to discuss how things have been going, SO you have [a] more reliable information to help you both decide on the best course of action. Suggest adding: USING THE CHART PROVIDED ON THE NEXT PAGE, each day etc

Wording & Text

Very accessible and straightforward. Like all the headings and subheadings. (JT)

In the title boxes, I think it makes sense for all the 'I' statements to be in quotations marks - ie. add to headings on pages 10, 20, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32 and 37.

I think there are too many boxes throughout prompting people to turn the page to find out more (ie. on page 6 'Find out more about bipolar causes and triggers over the page') - I think they are unnecessary and get in the way. I prefer the idea of encouraging the reader to concentrate on the page they're on rather than to think ahead. (SO)

Like the font. (JT)

Layout

Very well set out, layout very accessible and straightforward. (JT)

I think the blue title boxes work really well - the headings are simple and bold. What I find confusing though is that on some pages the titles are big and bold while on others the titles are smaller (ie. p17 & 18). I realise that you're differentiating between the first and second page of the same subject, but I don't think it's obvious that it's a continuation - it simply looks like a new subject heading (just with a smaller font size). On some of the second pages of the same topic you haven't used a heading at all, you've just continued with text (ie. p6 & 7). I think this works much better, plus it gives you more space / a cleaner, less cluttered feel.

Colours/ Images

Lovely peaceful pale blue colouring with birds - just what people need to focus their eyes on when trying to shut out so much 'noise' from within and without! I'd stick to pale blue. Maybe small and gentle waves coming onto a beach with pretty pebbles. No mountains. (JT)

I like the graphics of the bird in flight and the blue background. (AMB)

I think photos/cartoons of people are counterproductive. People with bipolar insert own images when reading and those deserve to be explored. Any you insert could cause blockages and lead to a sense of frustration or of being controlled/ contained. (JT)

I am not sure whether other pictures are really needed. I don't like these photos that often accompany articles on bipolar of close-ups of pills or of people with their head in their hands. (AMB)

Mental imagery in bipolar people is incredibly strong, which is actually one reason why suicidal ideation often leads to carrying out an attempt, because the whole process is more or less instantaneously visualised. (JT)

Next to some of the exercise boxes there's a blue 'EXERCISE' circle (with or without a little pen!) to flag up the fact that there's a space to write in, yet this is missing on many of the pages. I think it works really well to help the reader clearly see which bits they're meant to fill in. Is it possible to add it throughout? (SO)

Suggested additions

Advance statement proforma (or link to PDF of one online). (JT)

Debt and mental health evidence form. (JT)

Comorbidity. It's well-known that as soon as people focus on mental health, physical health conditions/symptoms get ignored. So a warning somewhere to keep checking breasts, testicles etc. (JT)

'engaging in meaningful social activity', good nutrition, fresh air - things people can do to be more well. (JT)

Mention in the text all the ways to combat bipolar, either with or without drug therapy. For example, CBT, mindfulness meditation, mind mapping, regular exercise, and owning a pet. (AMB)

Something brief on the kind of stupid things others might say to you when they find out/you tell them, and some quick, appropriate answers.
E.g. 'Oh well everyone gets down sometimes - that's normal'
Answer: 'Sorry but this is of a different order. Would you like to know more or shall we change the subject?'

Appropriate ways of dealing with environmental difficulties and social injustice; staying at home, rehearsing things to say and do in a crisis, joining online campaigns rather than being confrontational. (JT)

Other

'I wish I had had this resource when I was diagnosed! It would have saved so much loneliness and thrashing about in the dark until I found my way to the Bipolar UK website and online forum and got myself a psychotherapist.' (JT) 'I love the idea that you work through it with a professional.' (JT)

'The exercises follow a logical and helpful order, and lead the 'service user' (horrid term) gently and in the right direction. I think that if it were me using it, I would come to the end wanting to move forward and feeling reassured.' (JT)

'I think on the whole this booklet is really good and I wish I had been given something like this when I was first diagnosed' (AMB) 'On the whole I think it is great and full of really good advice' (AMB)

Overall, I think this booklet is clearly written and easy to understand. I like fact that there's a focus on using real experiences of people with bipolar rather than just asking hcps to give a more detached/expert view - there's a personal, 'inclusive' feel right from the intro. (SO)

I would think that the exercises are very useful. (SO)

Appendix I. **TIDieR checklist for IBiD**

TIDieR Template for Intervention Description and Replication

Checklist*: Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	**5.1**	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	**Chapter 2 & 5**	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	**5.3 & Appendix J**	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**5.3**	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	**6.4.12**	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	**5.3 & 6.4.12**	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	**6.4.1**	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	**6.4.12**	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	**5.3.2, 6.4.12 & Appendix J**	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	**n/a**	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	**6.4.13**	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	**6.6.3.8**	_____

Appendix J. **CONSORT checklist for IBiD study**

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported in section no.
Title and abstract			
	1a	Identification as a randomised trial in the title	6.1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	n/a
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Chapters 2 & 5
	2b	Specific objectives or hypotheses	6.2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6.3, 6.4.9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	6.4.2
Participants	4a	Eligibility criteria for participants	6.4.4
	4b	Settings and locations where the data were collected	6.4.1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6.4.11 & 6.4.12
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6.3.3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	6.4.8
	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	6.4.9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6.4.9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6.4.9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6.4.9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6.4.10
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6.5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	6.6.3
	13b	For each group, losses and exclusions after randomisation, together with reasons	6.6.3.2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6.4
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6.6
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	6.6

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	6.6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	6.6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6.7.3
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	6.7.3
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6.7
Other information			
Registration	23	Registration number and name of trial registry	n/a
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	n/a

Appendix K. **IBiD intervention and Bipolar UK mood charting exercise**

Bipolar: a question of balance

Understanding bipolar and its treatment

Improving Information for people with a diagnosis of bipolar

Sussex Partnership NHS

National Institute for Health Research

UCL

How we hope this booklet can help you

This booklet aims to help to answer your questions about bipolar and its treatment.

We have drawn on the experiences of people with bipolar and from research looking at what helps people get the best from their treatment.

Everyone's experience of bipolar is different.

Throughout the booklet we have left space for you to make notes to help you to manage your treatment and work with your health professionals.

We do not expect this booklet to be the only information you need. We have included a list of other resources you might find helpful at the end.

We hope it answers some of the questions you have and points the way to where you can get extra help if you need to.

We hope you find the information useful.

Our team includes people with bipolar, NHS psychiatrists, psychologists, pharmacists, health communication researchers and representatives from Bipolar UK.

This project is funded by the NHS through the National Institute for Health Research.

Understanding bipolar

We all experience a variety of emotions and moods. Some people experience larger swings in their mood with extreme highs and lows.

Mood swings don't necessarily have a big impact on someone's life. Somehow things stay in balance. For others, mood swings can make life very difficult, causing huge problems for them and those around them.

Extreme mood swings may be labelled as bipolar disorder when they affect a person's ability to live a normal life.

So in some ways, bipolar is a label applied when mood swings interfere with a person's ability to function in their day to day life or their relationships with others.

The aim of treatment is not to cure the condition. This is because bipolar does not fit with the common idea of a disease as something which you get and then it goes away when you find the right treatment (like a chest infection or a headache).

The aim of treatment is to help people to restore and then maintain balance in their moods so that the highs and lows have less impact on their lives.

Bipolar is a common condition, affecting between 1-2% of adults in the UK. To put this number into context, if Wembley Stadium was full to capacity, between one and two thousand people in there would have bipolar.

Highs

People with bipolar can experience intense highs. In everyday life this can make them outgoing, energetic and they are often very creative or seen as the "life and soul of the party".

At other times these highs can tip into something which is much more of a problem especially if the high continues for too long. They may experience times when things go too far and highs become out of control, their behaviour then causes problems to themselves and their families. Some people might spend money recklessly, be extremely irritable or get involved in sexual behaviour that is out of character.

Lows

Depression is usually a big part of bipolar. Highs can be followed by crushing lows and often feelings of despair. Sometimes people feel that their mood and energy plummets for no particular reason. This low can also happen after a period of fairly even mood. You might recognise some of the signs of depression as sadness, thinking negatively, feeling tired and difficulty concentrating.

People with bipolar often find their periods of low mood or energy also mean they lose interest in doing things they might usually enjoy and notice more physical aches and pains.

Q&A

If it is just an extension of normal moods, why is bipolar treated as an illness?

Bipolar is treated as an illness because it can cause moods to go out of control, making it difficult for a person to manage day to day life and causing distress for themselves and others. Treatment aims over time to help a person's moods become more balanced and stable.

You can find out more about what it means to be given a diagnosis of bipolar in the next section.

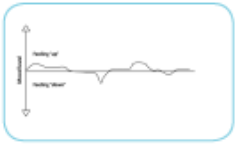
Mood charting

These two diagrams are called mood charts and they might help in understanding how there is a difference between extreme moods and normal mood swings that everyone experiences.

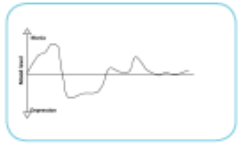
In the first chart, over time a person experiences the ups and downs of normal mood changes often triggered by events in their life.

In the second chart, the intensity of the highs and lows is much greater. These periods can have a negative impact on the person's life.

Non-bipolar mood swings



Bipolar mood swings



People do not necessarily swing from one extreme to another, it is not inevitable that a period of high will crash into low mood. There are also periods of relatively more stable moods.

There are tools at the end of this booklet for you to create your own mood chart.

'Is there a cause of bipolar?'

What, if anything, do you think might have caused bipolar for you? You can write your ideas in the box below.

There is no single explanation about the cause of bipolar and different factors may act together to increase the risk of developing the condition.

Like all our moods, the mood changes in bipolar are linked to biological changes in the brain. They are not the fault of the person experiencing them.

Science cannot fully explain how our minds link with our biological and physical nature. However, there is a complex interaction between our mind and body that creates our moods, emotions and thoughts. Naturally, there are numerous ways in which these interactions balance themselves.

Although there is no single cause, much progress has been made in understanding and managing the condition and in helping people to achieve a better balance in their moods.

Find out more about bipolar causes and 'triggers' over the page.

People may be born with the possibility of developing bipolar (biological cause).

Bipolar can run in families, it may be passed on. But it does not mean that everyone who has a parent with bipolar will go on to develop it or that it will definitely be passed on to children, it just means that there is an increased chance of this happening.

Research has also shown that people who experience more stressful life experiences seem to be more at risk of the development of bipolar.

The cause of someone's bipolar may be different from those things that trigger a recurrence of symptoms or relapse. For example, a stressful relationship, problems or change in job might trigger a depressive or manic episode, but it does not mean that this is the cause of the disorder.

In your experience, what do you think has 'triggered' manic or depressive episodes for you in the past. You can write your ideas in the box.

A long journey to diagnosis

Many people with bipolar say that they have experienced a long journey to diagnosis. They might have received different medical explanations for the problems they are experiencing and different opinions on what treatment might help.

This can mean that some people have mixed feelings about the condition. For example, their relief at finding out what the problem is, mixed with resentment at having to wait so long for a diagnosis or concerns about being given a mental health diagnosis.

Making sense of the diagnosis: 'Does taking medication mean I have to accept I am ill?'

Getting a diagnosis of bipolar can be upsetting for some people. Apart from the symptoms of the condition, it can feel as though an important part of a person's character, things about themselves which seem to make them attractive to other people, are now seen as part of a medical condition requiring treatment.

They may find it confusing that parts of their personality (such as being extremely creative and joyous) are being described as part of an illness.

Successful treatment of bipolar does not change your personality but aims to reduce the problems associated with the more extreme mood swings.

For other people, receiving a diagnosis can come as a relief as it helps them understand why they have been experiencing so many changing symptoms.

Not everyone finds it useful to think of the experiences of bipolar as an illness. Some prefer to think of it as an aspect of themselves which can have both positive and negative effects on their lives.

So, rather than thinking of it as a mental illness that has to be 'cured', they view it as a tendency to experience intense moods and accept it as being part of who they are. Being aware of their moods and using medication and other methods can help them to maintain a balance.

Coming to terms with the diagnosis, in a way that makes sense for you, is the crucial first step towards finding the treatment which is best for you.

In time, many people with bipolar learn to understand and accept the challenges involved with the condition.

The diagnosis and problems associated with bipolar may be part of your life, but they do not need to be your whole life.

What does bipolar mean to you? Try writing down your thoughts and feelings about your diagnosis in the box.

'Will I always have bipolar?'

It may be helpful to think of bipolar as a tendency to experience extremes of mood rather than as an illness with a known cure. People with bipolar experience periods without symptoms when the condition fades into the background for a time. However, the susceptibility may never fully go away, even if you don't experience the symptoms anymore.

People often think about mental health in boxes, for example either being 'normal' or having a 'mental illness'. However the reality of bipolar goes beyond these old ideas.

It is much more helpful to see it as a process where people become "ill" when things get out of balance (e.g. their moods go too high, they are too energised, or they get too low and it becomes difficult to cope with daily living).

It might sometimes feel hard to accept that bipolar cannot be cured so that it goes away forever and therefore life-long treatment may be needed. This is balanced by the good news is that it can be managed.

You can find out more about the medications prescribed for bipolar later in the booklet.

Many people with bipolar are able to lead happy and productive lives because they have found a way of managing their condition and achieving a balance in their moods.

'There's such a lot of stigma about giving yourself a label'

Quote from a woman, aged 33 with bipolar

Getting a diagnosis for any mental health condition can make people feel different about themselves and about how other people see them.

Many people with bipolar feel stigmatised. Because of their diagnosis they may feel they will be discriminated against in work, personal life or when using healthcare.

Many people are worried about telling people about their mental health condition as they are worried about what people might think.

How do you think the general public view mental illness?

Public views about mental illness may be different to what you might think

You can compare your impressions of what people think about mental health problems with the results of a large survey of public attitudes to mental illness.

Attitudes to mental illness 2006 research report, National Mental Health Development Unit, Department of Health. (Survey of almost 2000 people in England)

I would not want to live next door to someone who has been mentally ill.
Less than 1 in 10 people agreed

One of the main causes of mental illness is a lack of self-discipline and will-power.
Less than 2 out of 10 people agreed

Virtually anyone can become mentally ill.
9 out of 10 people agreed

Mental illness is an illness like any other.
8 out of 10 people agreed

Do these results fit with your views of how the public thinks about mental illness?

Experiencing stigma can make people feel less hopeful about their recovery. Feeling stigmatised can also get in the way of coming to terms with a diagnosis and managing treatment.

Some people with a diagnosis of bipolar have told us that it is important not to stigmatise yourself, they told us;

'Bipolar is something you have, not who you are'.

It is an individual's decision about whether to tell people about their diagnosis of bipolar and who to tell. It might be best to start off by telling someone you trust and feel closest to. You could recommend the links to other resources at the end of this booklet to family or friends.

Taking control: 3 steps to effective management

Successfully managing bipolar depends on a combination of:

1. Taking medications
2. monitoring how you are thinking and feeling and taking action
3. maintaining a healthy lifestyle

It is key that you feel you have the confidence to take charge of the management of bipolar.

Many things can make it difficult for people to be able to successfully manage bipolar. It might be useful to try and think of some things which make it difficult for you to manage your condition. These may be related to your thoughts, feelings, people or situations. You can use these next time you see your health professional to try and work out strategies to deal with them together.

Find out more about making the most of your time with health professionals later in the booklet.

Challenges I face with managing bipolar.....

Medications prescribed for bipolar

Many different types of medication can be helpful in managing bipolar. On the next few pages are some of the more commonly used medications, although people may be prescribed a variety of different ones.

Some people like to find out a lot of information about their medications and it is important that the information you find is up to date and reliable.

On the other hand some people can feel a bit overwhelmed by the amount of information, so it's important to discuss your information needs about the medications you are prescribed with your health professional.

As there are a wide variety of medications prescribed for bipolar, we have not included details about them all here. You can find more detailed information by going to the website; www.choiceandmedication.org/sussex/ or the other links listed at the end of this booklet.

Some people don't like the idea of taking medication because they see them as chemical substances that interfere with the mind and the body in an unnatural way. This puts them off taking the treatment which could help them control their bipolar. Bipolar medications actually work with the body's natural mechanisms for maintaining balance in moods.

Q&A How do these medications work?

In people with bipolar, there is scientific evidence which shows that pathways in the brain which regulate mood are not functioning as they should.

Medications are thought to work by rebalancing the natural chemical messages within the brain that are affected by bipolar, restoring the natural balance of the pathways.

You can find out more about specific medications over the next few pages.

Making an informed choice about medication prescribed for bipolar

It is important to be able to find information you need about different medications so as to be able to choose which medication might help you the most, whilst causing the fewest side effects.

Making decisions about medication is not easy. Getting all the information you need and weighing up the pros and cons of different treatment can help.

Mood stabilisers and antipsychotics

Why are they prescribed?
These types of medications help depressive and manic phases and also work as maintenance therapy to help prevent episodes. They can also reduce the severity of episodes which do occur.

What are the common medications?
- Lithium
- Valproate
- Lamotrigine
- Quetiapine
- Olanzapine

Antidepressants

Why are they prescribed?
Antidepressants are used to treat depressive episodes (in combination with mood stabilisers).

What are the common medications?
- Citalopram
- Sertraline

You can find more detailed information about the medications you have been prescribed over the next few pages.

Your thoughts and feelings about taking medication

Taking medication exactly as prescribed over a long period of time can be difficult, no matter what condition or illness you are taking it for. Many people at one time or another have periods when either they take their treatment in a different way than it was prescribed, miss a dose or have a break from taking it altogether.

People stop taking their medicines or take less than prescribed for a variety of reasons. For example, they might forget or find it difficult to fit it into their day to day lives. Alternatively, they might decide not to take it because they are not sure they really need it or because they are concerned about harmful effects or because they don't like the idea of taking medication long term.

Research has shown that in general, people with bipolar who stop taking their medication are more likely to have relapses and be admitted to hospital. So, although having doubts or concerns about medication is normal, it is important to discuss these with your health professional rather than stopping treatment or missing any doses.

It may help you to think about what was happening during any times you stopped or took your medication differently.

If there was a time when you missed a dose or stopped taking your medication, you could make a note here of what happened.....

Mixed feelings about medication

Many people have mixed feelings about taking medication for bipolar. On one hand they can see that it might help them through an episode. On the other hand they don't like the idea of having to take it in the long term. They may see the medication as something which is imposed on them, some people talk about this as a form of control.

Other people with bipolar have found a way of coming to terms with bipolar and its treatment as see the medication in a different way. Rather than being something that controls them, they see medication as a tool that they can use to control bipolar. This view of medication is illustrated by a poem written by a woman with bipolar.

Friend or Foe?

Lithium, I wonder, are you friend or foe?
Sometimes I'm sure I know
And I've nearly always felt "FOE!"
For you are the chains that bind me,
The suppressor that controls me
The drug that limits my level of experience.
You clip my wings when I try to
Soar to (great of) new heights.

Family and friends ask with good intention
"Are you still taking your pills?"
And the anger rises in me at those words
- Fast like a mountain stream flowing downhill
- Fast like the sap in a springtime tree rising –
And I reply resentfully and with exasperation
"YES, I am!"

I resent their monitoring of my behaviour!
I resent the label the medics have given me!
The doctors haven't listened to my words,
They haven't understood the struggles I have endured
I want to shout –
"How dare you label me 'manic depressive'!"
I want to prove to them how strong I now am.
They don't understand that at eighteen
When I should have been blooming
I felt like an empty shell
So fragile and so damaged.
They don't understand that
When I first tried to kill myself
I was in the 'pit' of depression
Not realising that deep down

I was picking up the pieces,
Repairing my shell
And re-building my shattered, scattered
Foundations.
"You can't build your life on sand"
Is the title of the book
I one day might write
When I feel brave enough,
When I get to the right point in my life.
But for now
I have come to recognise
That maybe you can
Be a friend to me, Lithium.
For I can take control of you.
I can use you to help keep me 'well'
Just as I use dance, singing, yoga,
Friendships and love to heal and enhance
Me – and the planet.
For my belief holds firm
That positive attracts positive
And negative, negative
And that if you can erase
With care and respect
Those with whom you come into contact
Whether they be a close friend
Or the 'man in the street'
And can make of that connection
A positive outcome – without undermining
Yourself,
Then indeed you are helping
To heal yourself, those around you,
And ultimately, the planet.

Julie Jackson

Mixed feelings about medication

What taking medication for bipolar mean to you? If you like, you could write your thoughts and feelings about this in the box below.

Balancing pros and cons

When deciding to do anything, including taking medicines, we usually weight up the pros and cons. It can be helpful to actually write down the pros and cons of taking your medication, including any concerns you have and the potential benefits. You can also weigh up the potential pros and cons of not taking your medication. You could discuss these with your health professional.

Pros: advantages of taking my medication	Cons: disadvantages of taking my medication
Pros: advantages of **not** taking my medication	Cons: disadvantages of **not** taking my medication

Pros and cons of taking medication for bipolar

Some of the advantages and disadvantages people with bipolar and health professionals have given about taking medication are shown below.

Advantages

- Taking medication reduces the chance of relapses and the need to go into hospital
- Medication can reduce the severity and consequences of future episodes
- It means if relapses happen, they are likely to last a shorter time
- It can help people feel more able to take control of their lives

Disadvantages

- Medication can often cause side effects
- It can be associated with a dampening of mood
- Taking medication affects how some people see themselves and possibly how other people see them
- Some people dislike the idea of being on medication
- Concerns about possible effects of medication in the long-term

'I'm worried about the side effects from these medications.'

Side effects are the unwanted effects of medications. It can be hard to be sure if something you are experiencing is a side effect from medication or something else entirely.

If you think you might be experiencing a side effect, ask your health professional for help.

The side effects from medications vary from one form of medication to another and also will be individual to each person. Not everyone will necessarily get side-effects and it is difficult to be certain in advance what, if any, side effects you might experience.

While there is no doubt that side effects do occur and that these can be unpleasant, it is worth considering the following....

- The side effects may not last. The most common side effects often reduce over time as your body adjusts itself to the medication
- There may be things you can do to lessen the impact of any side effects you might experience (see information over the next few pages).
- There is often alternative medication. If you experience unpleasant side effects, you can discuss with your health professional what alternatives might be appropriate

Some people report that when they weigh up the side effects against the benefits they get from taking the medication, they are able to tolerate some level of side effects. Also, when comparing the side effects to the severity of the symptoms they experience as part of bipolar, the side effects may be easier to tolerate.

It is important to balance any risks of medication against the benefits so you can make an informed choice. The benefits should outweigh the risks.

You can find more information about side effects of each of your medications on the individual information leaflets.

Side effects & strategies to manage them

What side effects have you experienced or are you worried you might experience from your medications?

Now, think about what might help to manage these side effects.

If I experience....	Then I can try...

Read on to see some common side effects and ways that you might deal with them

Common side effects & strategies to manage them

Weight gain

Try and make some changes to your diet. This is easier said than done. You can start with a few simple changes:

- Increase the amount of fruit and vegetables you eat
- Reduce foods that have high sugar or fat content
- Drink water instead of soft drinks
- Increase the amount of exercise you take. If you have been unable to take any exercise then start exercising very slowly. Give yourself small achievable goals and build these up.

You might find this charity website helpful www.weightconcern.org.uk
Occasionally it may be necessary to change your medication because of weight gain. You can discuss this with your doctor.

Sexual dysfunction

This is quite common and can involve difficulties in achieving orgasm or a reduced desire for sex. This is more likely to occur with some medications than with others. Being open and discussing it with your partner is important as well as talking it thought with your health professional.

Constipation

This usually wears off in a few weeks. To help, try to eat enough fibre, bran or fruit. Make sure you are drinking enough fluid.

Keep active and think about how you can increase your exercise. If this does not help, ask your doctor or pharmacist for a mild laxative.

Feeling or being sick and having diarrhoea

With anti-depressants, this effect tends to wear off after a few days or a week or so. If it is mild, see your pharmacist. If you feel sick, it might help to take your medication with or after food. If you are sick for more than a day, contact your doctor. If you have diarrhoea drink plenty of water. If it lasts for more than a day or so, contact your doctor.

'I sometimes worry whether there might be long-term effects of taking these medications'

Use this space to write down any worries you may have about taking your medication in the long term?

The possible risk of long-term effects of any medication need to be balanced alongside the positive effects of taking it and the risk of relapse if you don't take it.

With medications for bipolar there are some risks of long-term effects. Lithium can affect the kidneys and thyroid gland. Regular blood tests ensure that problems are recognised and treated early. Some medications (e.g. Olanzapine, Lithium and Valproate) increase the likelihood of weight gain which can increase the risk of diabetes.

It doesn't mean they will definitely happen after taking medication in the long term, just that there is an increased risk of it happening.

It is important to remember that the risks of developing long-term effects can be reduced by:

- regular monitoring of your health to identify and prevent any problems early on
- maintaining a healthy lifestyle to minimise any weight gain

You can read more about the evidence for long-terms effects on the website www.choiceandmedication.org/sussex/.
Having this information means you can be more informed about possible long-term effects.
If you don't have access to the internet, one of the research team can print the information for you.

'Taking medication is an unwelcome reminder of my condition'

For many people it is a big step to decide to take medication.

Taking medication can feel like reinforcing the idea that you are unwell, as it is a daily reminder of the condition. However, there are different ways of thinking about taking medication, some of which might be helpful for you. On the right are examples of what the people we spoke to said.

Bipolar is linked to an imbalance in chemical messages within the brain. Taking medication can help restore the balance and help protect you from severe mood swings and so reduce vulnerability to the effect of stress on mood.

Some people have told us that they see their medication as a tool to help regain control over their lives.

"I think that's something that I've realised since being given a diagnosis and then you think, okay, I'm someone that needs medication, as opposed to just being depressed when there is a very big question over whether or not you need medication, if you are bipolar then you need medication."

(George, 30)

"At the moment, I've got a nine year old daughter and there is no way I could parent and not be on meds...I think the medication has probably saved me and my daughter's relationship as well...medication is vital at the moment..."

(Jan, 33)

Names have been changed to protect identities.

'I tend to hide the fact that I am taking these medications from other people'

Some people are worried about the reaction of other people in response to finding out they are taking psychiatric medication. You may have even experienced some of these negative reactions first-hand.

It is a personal issue about who you decide to tell about your condition and treatment.

Some people find it helps to explain to people the biological and chemical reasons for your medication. You could explain that medications are thought to work by rebalancing the chemical messages in the brain that are affected by bipolar, restoring the natural balance of the pathways responsible for regulating mood.

You do not have to tell your employer that you have bipolar disorder, only that you have a long term health condition. Your employer can then refer you to Occupational Health who can ensure that you have appropriate adjustments to your work to reduce the likelihood of further episodes, for example, keeping a regular shift pattern so you get regular sleep.

You might find it helpful to think of some negative opinions that you have heard or are worried about. Then think of ways to respond to these opinions.

Negative opinions	Responses

'I don't feel ill, so why should I continue to take my medication?'

With bipolar, particularly when it is treated effectively, there will be times when you don't experience any negative symptoms from the condition.

Bipolar most often requires people to continue taking medications, even if they are symptom free.

This is because medication can act in a preventative way, helping people to avoid relapses and helping to keep their moods in balance.

Because mood stabilisers are used to prevent episodes, taking them only when you start to feel symptoms cannot prevent a relapse because it takes a while for them to start working.

If appropriate, you could remind yourself what happened if you have ever missed a dose or stopped taking your medication, by turning back to the exercise on 'Your thoughts and feelings about taking medication' which you might have completed earlier.

'I don't feel like the medication is working'

When taking a new medication or a new dose it is important to allow time for the medication to have an effect. Some mood stabilisers and anti depressants may take a number of weeks before you experience the benefits. This is perfectly normal and common.

It is important to monitor how you are feeling whenever you start or have a change in medication, try and keep a note of how you feel and any side effects you experience. This will help when you review your treatment with your health professional.

If you have been on a medication for a few weeks and you don't think it is working, it is important to speak to your health professional and you might together agree a change in the type of medication or dose.

Some people will remain free of symptoms whilst taking mood stabilisers, others may experience episodes of depression or mania during treatment, but for most these will be fewer and less severe.

If you have experienced relapses whilst taking medication, you might feel discouraged by this. However, the success of preventative treatments like this should be assessed in the long-term. It is important to give it time.

'Why does the medication I am given keep changing?'

People who have been diagnosed with bipolar often feel frustrated with the length of time it takes to find treatments which work for them.

You are affected by bipolar in a way that is individual to you and so your treatment will also be specific to you. The best treatment for you may also change over time.

Finding the right treatment is like going shopping for a new outfit. We don't know whether something will fit us until we try it on. Even if it fits someone else it might not work for us.

For your health professional, it is difficult to know in advance which treatments will work for you, so you may need to try different medications, doses or combinations. Adjustments and changes are very common.

It may be helpful to think of adjustments to your medication as a routine part of your treatment. It is difficult to know beforehand how long it will take before you feel the medication is working. Being patient when starting a new medication will help you and your health professional decide whether that treatment will work for you.

Reviewing your medication regularly with your health professional will help to make sure you are on the right dose and to any minimise side effects.

Your input into decisions about your treatment can make a real difference in how the medication works for you.

Find out more about making the most of your time with health professionals later in the booklet.

'I've been on the same medication for years, do I need to change?'

The best treatment for you as an individual can change over time. Your individual responses to a medication can change as well as changes in your needs for different medications. There are also new drugs being developed for bipolar all the time.

This is why it's important to review your medication with your health professional regularly. This can help you get the most out of your treatment and help to minimise any side effects you might experience.

However, you might not need to change. Stable medication can mean that your treatment is effective and right for you.

Even if your medication does not need to change, you will still need to see your health professional to monitor your physical health. This includes blood tests to check the levels of medication in your blood as well as monitoring your weight and blood pressure.

'I dislike the way these medications make me feel'

Our feelings and moods are an essential part of who we are. Successful treatment does not aim to change your personality but aims to reduce the problems associated with more significant mood swings.

Some medications can make people feel flat or dulled down, however, there may be alternative medications which might suit you better.

These feelings can indicate an unwanted side effect so it is important to talk to your health professional about the possibility of adjusting your medication.

It's very important you don't stop taking mood stabilisers suddenly so it's always important to discuss any concerns or problems you are having with your health professional.

By being open and working closely with your health professional he or she can help you find a treatment that can make you feel more like yourself.

'Taking this medication affects my daily life'

What kind of impact has taking medication for bipolar had on your day to day life?

If you find that the side effects of medication are having a negative impact on your daily life, it's important to discuss these issues with your health professional.

On the plus side, when people find a treatment which works for them, they often find it allows them to take greater control over their lives and return to work and socialising.

'I sometimes worry that I might become addicted to or dependent on the medication I'm taking'

Many people who are taking mental health medication worry that these may be addictive.

To become physically addicted to a medication or a drug it needs to make the body want it more and more, without giving the same effects it originally gave. This is called building up tolerance.

Some medications for mental health conditions can produce withdrawal symptoms when they are stopped, but they are not addictive as the body is not physically dependent and they do not cause cravings.

Although medications prescribed for bipolar are not addictive, it's understandable why people might worry about this:

- They may have experienced reactions when suddenly stopping medication
- These drugs have an effect on the brain, so it's necessary to have a period of adjustment by gradually stopping medication
- Some people also feel addicted because they know that they will need to use their medication in the long term

Alcohol, drug use, bipolar and your medication

Some people with a diagnosis of bipolar wish to know about drinking alcohol or drug use and how this may affect their condition and treatment.

Sometimes, people with a diagnosis of bipolar may use alcohol or other drugs to seek relief from some of their symptoms.

The problem with this is that even legal substances like alcohol worsen psychiatric symptoms such as depression and anxiety.

Advice about medication and alcohol or is specific to each medication. For information on this see each individual resource for the medications you have been prescribed.

It's important to talk to your health professional about any worries you have about alcohol or any other drugs and bipolar.

'Sometimes I find it difficult to take my medication'

People don't always take their medication exactly as prescribed for a whole range of reasons. Busy lives, complicated prescriptions and how you are feeling can mean that it is sometimes hard to remember.

There are practical things which can help...

- Link taking medication to another activity such as brushing your teeth or before having a cup of tea/coffee or at dinner?
- Keep your medications somewhere you will see them, this could be near your toothbrush, or in the kitchen
- Set an alarm on your phone or watch to remind you when it is time to take your medication
- If you use your computer regularly, you could set up a reminder to appear on your screen
- Find a place to put a reminder note (i.e. on the bathroom mirror, fridge or television)
- Ask for help from friends, family and flatmates – let them know your treatment plan
- Planning ahead, for example if you are going out or away, making sure you have enough medication
- Writing down the essential details of your treatment, and carrying it with you as a quick reminder
- Store your pills in a dosette box which organises them into compartments by time and day. Dosette boxes are available at chemists or online
- It is sometimes possible to simplify your prescriptions. Ask your health professional about the possibility of simplifying how you take your tablets
- Put a note on the back of your front door to remind you to take your medication with you when you are going out

On the next page you can create your own list of strategies or techniques

It is important that you find strategies and techniques for taking your medication which suit you and your lifestyle.

Why not use this space to write some of your own ideas for remembering to take your medication....

It is a good idea to make taking your medication part of your routine. This is a way that has been shown to be helpful for people in remembering to take their medication for a variety of conditions.

Why not use the space to make a plan for how you can fit your medication into your routine....

Example plan		Your plan	
If it is	*8 am*	If it is	
And I am	*In the bathroom*	And I am	
And I	*have finished brushing my teeth*	And I	
Then	*I will take my first pills of the day*	Then	

'What should I do if I am having problems and who should I contact in an emergency?'

If you have questions about how you are feeling or concerns about the medication you are taking, it is important to contact your health professional.

Making a note of the names and contact numbers of people to contact in the event of any problems or an emergency may be helpful to you. Some people make up a card with the information below which they can carry around in their purse or wallet.

You could write this information in the spaces provided.

In an emergency.....

Psychiatrist

GP

Nurse

Support people (e.g., friends or family members)

Medications I am currently prescribed

In the event of a high

In the event of a low

Monitoring your symptoms and looking after yourself

It can be a good idea to plan ahead about what to do if you feel your mood changing. If you have any doubt at any time as to what is the right thing to do, it is best to speak to your health professional.

Here are some things that may be useful for you to consider if you think you're in the early stages of a relapse.

In the event of a high....

- Contact your psychiatrist
- Try to increase number of sleeping hours
- Limit the number of activities you undertake
- Increase rest activities - try to surround yourself with a relaxing environment
- Minimise physical activity
- Avoid caffeine and alcohol
- Limit access to spending
- Postpone making important decisions

In the event of a low....

- Contact your psychiatrist
- Try to limit the amount of time sleeping
- Try to increase your activity level
- Try to be active, e.g. take a walk or go swimming
- Postpone making important decisions
- Avoid alcohol
- Try to keep to a regular schedule

Often people with bipolar, and their family and friends begin to notice behaviour or other changes which are very early warning signs that a manic or depressive episode might be starting. These could be things such as, difficulty in sticking to your usual routine, spending more than you normally would, difficulty in concentrating, or experiencing different physical sensations.

These early warning signs are also called 'prodromes' and are different for each person.

You can use the space to make a note of signs that you or people close to you might have noticed. It might be useful to tell other people about these so you can be quicker to respond when an episode might be starting.

Getting the most from your consultations

It is important to keep your health professional informed about how you are feeling and what effect your medication has on how you feel.

Mention to your health professional any concerns you may have about your medication and any side effects you may be experiencing.

It is important to remember that you are the expert when it comes to how you are feeling and how you have responded to your treatment.

Sometimes people find that when they go to an appointment with their health professional they don't always get the most out of the consultation and sometimes feel unsatisfied.

It can be difficult to remember to or feel like we can ask all the questions we want to.

Do not worry about expressing your doubts about treatment, due to the nature of bipolar and medication, it's important you engage in an active role in your treatment.

You might find it helpful to:

- Write down any questions you want to ask between appointments as you think of them
- Ask your doctor to clarify and explain anything that you do not understand.
- Talk about your concerns

Some questions you might want to ask during your consultations....

- How will I know if my medication is working?
- How long will I have to take this medication?
- What should I do if my medication doesn't work or makes me feel worse?
- What are the common side effects of my medication and what can be done to manage these effects?
- Will it affect my daily life (family, work, relationships, sex life)?
- Are there services available locally to help me manage my condition?

You might like to use this space to write down other questions you think of.

Useful resources

Websites providing information on bipolar, medication and other mental health issues.

Bipolar UK
A UK charity working to support people affected by Bipolar
www.bipolaruk.org.uk
020 7931 6480

Rethink Mental Illness
A charity supporting people with mental illness across England
www.rethink.org

Choice and Medication
Information from Sussex Partnership NHS Foundation Trust Pharmacy service on medications.
www.choiceandmedication.org/sussex/

Mental Healthcare
Information from the Institute of Psychiatry at King's College London and South London and Maudsley NHS Foundation Trust on medication and mental health diagnoses including bipolar and schizophrenia
www.mentalhealthcare.org.uk/home

Books

Dr Liz Miller, Mood Mapping: Plot your way to emotional health and happiness.

Sarah Owen, Bipolar Disorder - The Ultimate Guide

Kay Redfield Jamison, An Unquiet Mind: A memoir of moods and madness

Feel free to use the space below to make a note of your own useful resources

Completing your own mood chart

When you meet with your health professionals it can be difficult to remember your symptoms over the past weeks, especially if you are feeling unwell.

It might help to create your own monthly mood chart by tracking your daily mood ratings, your medication, your sleep and things which happen in your day to day life.

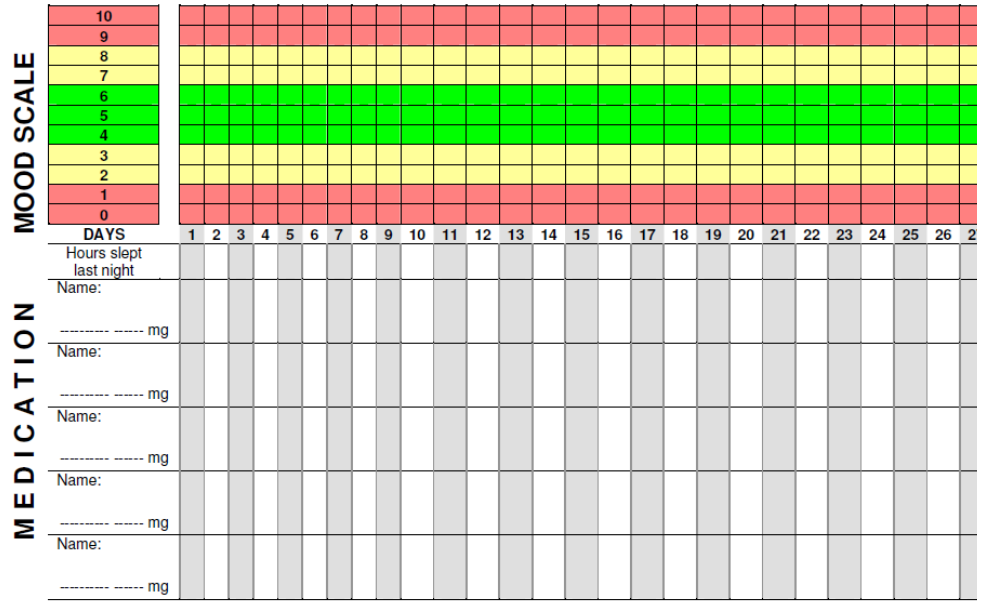
You can then use this when you meet with your health professionals to discuss how things have been going, so you then have more reliable information to help you both decide on the best course of action.

Instructions

1. Using the chart provided each day, choose the number which best describes how you have felt during that day (use the mood scale provided to choose a number from 0 to 10).
2. Mark this number on the appropriate day on the Mood Diary.
3. Complete the information on the number of hours you slept and the medication you have taken that day.
4. Use the daily notes page to make a note of other things which may have happened that day, such as stressful events, different behaviour you or those around you have noticed.

MONTHLY MOOD DIARY **ID No:** _____

Bipolar UK **MONTH / YEAR:** _____



Mood Scale

This scale is not meant to be definitive but is an indicator of possible behaviours

Mania	10	Total loss of judgement, exorbitant spending, religious delusions and hallucinations.
	9	Lost touch with reality, incoherent, no sleep, paranoid and vindictive, reckless behaviour.
Hypomania	8	Inflated self-esteem, rapid thoughts and speech, counter-productive simultaneous tasks.
	7	Very productive, everything to excess (phone calls, writing, smoking, tea), charming and talkative.
Balanced Mood	6	Self-esteem good, optimistic, sociable and articulate, good decisions and get work done.
	5	Mood in balance, no symptoms of depression or mania. Life is going well and the outlook is good.
	4	Slight withdrawal from social situations, concentration less than usual, slight agitation.
Mild to Moderate Depression	3	Feelings of panic and anxiety, concentration difficult and memory poor, some comfort in routine.
	2	Slow thinking, no appetite, need to be alone, sleep excessive or difficult, everything a struggle.
Severe Depression	1	Feelings of hopelessness and guilt, thoughts of suicide, little movement, impossible to do anything.
	0	Endless suicidal thoughts, no way out, no movement, everything is bleak and it will always be like this.

Bipolar UK

Call us on 020 7931 6480 info@bipolaruk.org.uk www.bipolaruk.org.uk

11 Belgrave Rd, London, SW1V 1RB

Appendix L. **IBiD Questionnaire booklet**

Improving Information for people with a diagnosis of bipolar
Participant Baseline Questionnaire booklet

What this questionnaire is about

This questionnaire is the first part of the study looking at different ways of providing information to people who have received a diagnosis of bipolar disorder.
The questions in this booklet will ask; how you have been feeling lately, how you feel about taking medication, your opinions about your diagnosis and how satisfied you are with any information you might have received, it will also ask about your experience of living with a mental health diagnosis.

How to fill out the questionnaire

The survey should around 35 minutes to complete.

- Please answer the questions as completely and honestly as possible.
- Answer each of the questions in turn.
- Please don't feel that you have to spend a long time over each question. Often the first answer that comes to you is the best.
- Please answer every question.
- Most of the questions can be answered by ticking the box.

This questionnaire is completely confidential

Use of your responses

- Your responses will be seen only by the research team.
- Your responses will not be seen by any of your healthcare team
- Reports or publications based on information provided will be based on everyone's responses brought together. Individual responses will not be identifiable.

If there is anything that is not clear, please ask the researcher who will be able to help you completing this questionnaire.

MEDICINES PRESCRIBED FOR YOUR BIPOLAR

- We would like to ask you about the medicines you are prescribed for bipolar.
- We know that you may be taking several different medicines for bipolar and that you may have different views about each one.
- We would therefore like to ask you about your medicines separately.
- Please look at the list of medicines below and draw a circle around any that are being prescribed for you at the moment.

	Medicines
1.	**Lithium** (Priadel, Camcolit)
2.	**Valproate** (Valproic Acid, Depakote, Epilim Chrono)
3.	**Carbamazepine** (Tegretol)
4.	**Lamotrigine** (Lamictal)
5.	**Quetiapine** (Seroquel)
6.	**Olanzapine** (Zyprexa)
7.	**Risperidone** (Risperdal)
8.	**Haloperidol, Chlorpromazine, Stelazine**
9.	**Modecate, Depixol, Haldol, Piportil, Clopixol**
10.	**SSRI antidepressants** (Fluoxetine (Prozac), Citalopram (Cipramil), Sertraline (Lustral), Paroxetine (Seroxat), Escitalopram (Lexapro, Cipralex)
11.	**Venlafaxine** (Effexor) **Duloxetine**
12.	**Tricyclic antidepressants** (Dothiepine, Dosulepin, Prothiadine, Amitriptyline, Clomipramine, Anafranil)
13.	**Mirtazapine** (Zispin)
14.	**Lorazepam, Diazepam, Valium**
15.	**Sleeping tablets** (Temazepam, Zopiclone, Zolpidem, Nitrazepam, Oxazepam, Promethazine)
16.	Other (please specify)

To tell us how you feel about each of the bipolar medicines prescribed for you, please would you fill out a separate copy of the next two pages of the questionnaire for each medicine? We are sorry to ask you the same questions about each medicine but we are interested in your views about each one.

Your views about medicines
PRESCRIBED FOR YOUR BIPOLAR

Please choose one of the medicines that you are prescribed and you circled on the table on the previous page. Write its name in this box.

How do you take this medicine? (please tick) Tablet ☐
Injection ☐

We would like to ask you about your personal views about this medicine.
In the table are statements that other people have made about their medicines.
Please show how much you agree or disagree with them by ticking one box for each statement.
There are no right or wrong answers. We are interested in your personal views

	Views about this medicine	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
N1	My health, at present, depends on this medicine					
C1	Having to take this medicine worries me					
N2	My life would be impossible without this medicine					
C2	I sometimes worry about long-term effects of this medicine					
N3	Without this medicine I would be very ill					
C3	This medicine is a mystery to me					
N4	My health in the future will depend on this medicine					
C4	This medicine disrupts my life					
C5	I sometimes worry about becoming too dependent on this medicine					
N5	This medicine protects me from becoming worse					
C6	This medicine gives me unpleasant side effects					
C7	I tend to hide the fact that I am I am taking this medicine from other people					
C8	I sometimes worry about becoming addicted to this medicine					
C9	Having to use this medicine is an unpleasant reminder of my condition					
C10	This medicine makes me feel 'flat'					
C11	I dislike the way this medicine makes me feel					
N7	I need to take this medicine to prevent going into hospital					

Using your medicines for bipolar

Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

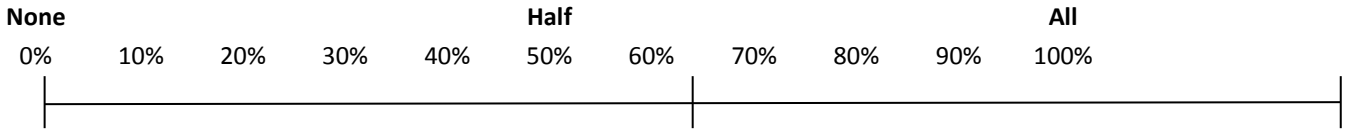
We would like to ask you a few questions about how you use this medicine.

Here are some ways in which people have said that they use their medicines.

For each of the statements, please tick the box which best applies to you.

	Your way of using this medicine:	Always	Often	Sometimes	Rarely	Never
M1	I **forget** to take them					
M2	I **alter** the dose					
M3	I **stop** taking them for a while					
M4	I decide to **miss** out a dose					
M5	I take **less** than instructed					

Approximately what percentage of this medication do you think you take? Please make a cross on the line to show this. (For example, if you think you take about half of your medication, put a cross at 50%)



If you are prescribed any other medicines for bipolar disorder, please continue on the extra pages.

Your views about medicines in general

These are statements that other people have made about medicines in general.
Please show how much you agree or disagree with them by ticking the appropriate box.
There are no right or wrong answers; we are just interested in your views.

	Your views about medicines in general	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
BG1	Doctors use too many medicines					
BG2	People who take medicines should stop their treatment for a while every now and again					
BG3	Most medicines are addictive					
BG4	Natural remedies are safer than medicines					
BG5	Medicines do more harm than good					
BG6	All medicines are poisons					
BG7	Doctors place too much trust on medicines					
BG8	If doctors had more time with patients they would prescribe fewer medicines					

Using your medicines for bipolar

These are statements that other people have made about the obstacles that prevent them from taking their medication as it was prescribed by their doctors.

For each of the statements, please tick the box which best applies to you.

	I find it difficult to:	Always	Often	Sometimes	Rarely	Never
P1	Remember to take my medication when my daily routine changes					
P2	Remember to take my medication when my regimen (treatment plan) changes					
P3	Keep track of when I need to take each medicine					
P4	Remember to take my medicines every day					
P5	Cope with the costs of medicines					
P6	Know when to get a further supply when my prescription runs out					
P7	Travel or go on holidays					
P8	Swallow my tablets					
P9	Get the best from my care team					
P10	Get information about my medicines					

Information about Medicines

We would like to ask you about the information you have received about your medications prescribed for bipolar disorder.

Please rate the information you have received about each of the following aspects of medication. There are also options to tell us if you did not receive or did not need the information.
There are no right or wrong answers. We are interested in your personal views.

	Have you received enough information about...	Amount of Information Received				
		Too much	About right	Too little	None received	None needed
S1	What the medicines are called					
S2	What these medicines are for					
S3	What they do					
S4	How they work					
S5	How long they take to act					
S6	How you can tell if they are working					
S7	How to use them					
S8	How long you need to be on the medicine					
S9	Whether the medicine will have any unwanted effects (side effects)					
S10	What are the risks of you getting side effects					
S11	What you should do if you experience unwanted side effects					
S12	If you can drink alcohol whilst taking this medicine					
S13	Whether the medicine will interfere with other medicines					
S14	Whether the medication will make you feel drowsy					
S15	Whether the medication will affect your sex life					
S16	What you should do if you forget to take a dose					
S17	How to get a further supply					

Your views about your mental health

Please tick any of the following terms that have been used to describe your mental health problems, and add any other terms that may have been used.

For each term, please indicate the extent to which you would agree that this label describes the experiences you have had.

	Label/ term	Tick if been used to describe your mental health problem	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
I1	Bipolar Disorder	☐					
I2	Manic Depression	☐					
I3	Mania	☐					
I4	Psychosis	☐					
I5	Depression	☐					
I6	Schizoaffective	☐					
I7	Anxiety	☐					
I8	Other _____	☐					
I9	Other _____	☐					
I10	Other _____	☐					

Please write in the box below, the term or label that you feel best describes your mental health problems.

Your views about the causes of your bipolar

We are interested in what you consider may have been the initial causes of your mental health problems. As people are very different, there is no correct answer for this question. We are most interested in your own views rather than what others including doctors or family may have suggested to you.

Please tell how much you agree or disagree that the items below were causes of your bipolar disorder by ticking the appropriate box.

	Possible causes	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
C1	Stress or worry					
C2	Hereditary - it runs in my family					
C3	A Germ or virus					
C4	Diet or eating habits					
C5	Chance or bad luck					
C6	Poor medical care in my past					
C7	Pollution in the environment					
C8	My own behaviour					
C9	My mental attitude e.g. thinking about life negatively					
C10	Family problems or worries					
C11	Overwork					

	Possible causes	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
C12	My emotional state e.g. feeling down, lonely, anxious					
C13	Ageing					
C14	Alcohol					
C15	Smoking					
C16	Accident or injury					
C17	My personality					
C18	Chemical Imbalance					
C19	Recreational drugs (e.g. cannabis, cocaine, ecstasy)					

Your views about the causes of your bipolar

In the spaces below, please write down what you think are three most important causes for the start of your mental health problems. You may use any of the items from the box on the last page, or you may have additional ideas of your own.

	Possible causes
C20	
C21	
C22	

We are also interested in what factors you think may be MAINTAINING your mental health problems i.e. preventing you from getting better.

In the spaces below, please write down what you think are possible factors that are maintaining your mental health problems.

	Possible Maintaining factors
C23	
C24	
C25	

Your views about your mental health problems

We would like to ask you about your personal views about bipolar disorder.

Please answer the following questions by circling the number which best describes your views about how you feel at the moment.

1. How much does your bipolar affect your life?

No affect at all										Severely affects my life
0	1	2	3	4	5	6	7	8	9	10

2. How long do you think your bipolar will continue?

A very short time										Forever
0	1	2	3	4	5	6	7	8	9	10

3. How much control do you feel you have over your bipolar?

Absolutely no control										Total control
0	1	2	3	4	5	6	7	8	9	10

4. How much do you think your treatment can help your bipolar?

Not at all										Extremely helpful
0	1	2	3	4	5	6	7	8	9	10

5. How much do you experience symptoms from bipolar?

No symptoms at all										Many severe symptoms
0	1	2	3	4	5	6	7	8	9	10

6. How concerned are you about your bipolar?

Not at all concerned										Extremely concerned
0	1	2	3	4	5	6	7	8	9	10

7. How well do you understand your bipolar?

Don't understand at all										Understand very clearly
0	1	2	3	4	5	6	7	8	9	10

8. How much does your bipolar affect you emotionally? (e.g. does it make you angry, scared, upset?)

Not at all affected emotionally										Extremely affected emotionally
0	1	2	3	4	5	6	7	8	9	10

9. How much do you agree with your diagnosis of bipolar?

Don't agree at all										Totally agree
0	1	2	3	4	5	6	7	8	9	10

Symptoms and side effects you have experienced

Listed below are a number of experiences that you may or may not have had since your mental health problems began.

Please indicate by ticking Yes or No whether or not you have had each of these experiences.

Next, please rate the severity of any symptoms you are currently experiencing by circling the appropriate number on the scale, where 1 indicates very mild and 5 indicates very severe.

		Are you currently experiencing this symptom		If yes, please circle the symptom's severity					Tick box to indicate what you think caused the symptom				
		Yes	No	Very mild	Mild	Moderate	Severe	Very severe	Bipolar	Medication	Both	Neither	Unsure
SS1	Tremor/ shaky			1	2	3	4	5					
SS2	Weight gain			1	2	3	4	5					
SS3	Restlessness			1	2	3	4	5					
SS4	Constipation			1	2	3	4	5					
SS5	Dry mouth			1	2	3	4	5					
SS6	Tiredness			1	2	3	4	5					
SS7	Dizziness			1	2	3	4	5					
SS8	Sexual problems			1	2	3	4	5					
SS9	Sedation			1	2	3	4	5					
SS10	Nausea			1	2	3	4	5					
SS11	Stiffness			1	2	3	4	5					
		Are you currently experiencing this symptom		If yes, please circle the symptom's severity					Tick box to indicate what you think caused the symptom				
		Yes	No	Very mild	Mild	Moderate	Severe	Very severe	Bipolar	Medication	Both	Neither	Unsure

SS12	Sore eyes				1	2	3	4	5						
SS13	Headaches				1	2	3	4	5						
SS14	Upset stomach				1	2	3	4	5						
SS15	Sleep difficulties				1	2	3	4	5						
SS16	Loss of strength				1	2	3	4	5						
SS17	Speech Problems				1	2	3	4	5						
SS18	Slowed thinking				1	2	3	4	5						
SS19	Hearing voices				1	2	3	4	5						
SS20	Depressed mood (feelings of sadness, hopeless, worthless)				1	2	3	4	5						
SS21	Mood swings				1	2	3	4	5						
SS22	Feeling apprehensive, fearful or anxious				1	2	3	4	5						
SS23	Difficulty concentrating				1	2	3	4	5						
SS24	Involuntary muscle movements				1	2	3	4	5						
SS25	Loss of interest in hobbies or work				1	2	3	4	5						

If you have experienced any other symptoms recently, please write them in the spaces below.

		Are you currently experiencing this symptom			**If yes, please circle the symptom's severity**						**Tick box to indicate what you think caused the symptom**				
		Yes	**No**		**Very mild**	**Mild**	**Moderate**	**Severe**	**Very severe**		**Bipolar**	**Medication**	**Both**	**Neither**	**Unsure**
SS26					1	2	3	4	5						

Stigma of mental illness

We are going to use the term 'mental illness' in this question, but please think of it as whatever you feel is the best term for it.
For each statement, please tick whether you strongly disagree, disagree, agree or strongly agree.

		Strongly Agree	Agree	Disagree	Strongly Disagree
IS1	I feel out of place in the world because I have a mental illness.				
IS2	Mentally ill people tend to be violent.				
IS3	People discriminate against me because I have a mental illness.				
IS4	I avoid getting close to people who don't have a mental illness to avoid rejection.				
IS5	I am embarrassed or ashamed that I have a mental illness.				
IS6	Mentally ill people shouldn't get married.				
IS7	People with mental illness make important contributions to society.				
IS8	I feel inferior to others who don't have a mental illness.				
IS9	I don't socialize as much as I used to because my mental illness might make me look or behave "weird."				
IS10	People with mental illness cannot live a good, rewarding life.				
IS11	I don't talk about myself much because I don't want to burden others with my mental illness.				
IS12	Negative stereotypes about mental illness keep me isolated from the "normal" world.				
IS13	Being around people who don't have a mental illness makes me feel out of place or inadequate.				
IS14	I feel comfortable being seen in public with an obviously mentally ill person.				
IS15	People often patronize me, or treat me like a child, just because I have a mental illness.				
IS16	I am disappointed in myself for having a mental illness.				
IS17	Having a mental illness has spoiled my life.				
IS18	People can tell that I have a mental illness by the way I look.				
IS19	Because I have a mental illness, I need others to make most decisions for me.				

		Strongly Agree	Agree	Disagree	Strongly Disagree
IS20	I stay away from social situations in order to protect my family or friends from embarrassment.				
IS21	People without mental illness could not possibly understand me.				
IS22	People ignore me or take me less seriously just because I have a mental illness.				
IS23	I can't contribute anything to society because I have a mental illness.				
IS24	Living with mental illness has made me a tough survivor.				
IS25	Nobody would be interested in getting close to me because I have a mental illness.				
IS26	In general, I am able to live my life the way I want to.				
IS27	I can have a good, fulfilling life, despite my mental illness.				
IS28	Others think that I can't achieve much in life because I have a mental illness.				
IS29	Stereotypes about the mentally ill apply to me.				

Questions about how you feel

Choose the one statement in each group that best describes the way you have been feeling for the past week. Please note that on this page the word; "occasionally" means once or twice; “often” means several times or more; "frequently" means most of the time.

Circle the number next to the statement you picked.

0	I do not feel happier or more cheerful than usual.
1	I occasionally feel happier or more cheerful than usual.
2	I often feel happier or more cheerful than usual.
3	I feel happier or more cheerful than usual most of the time.
4	I feel happier or more cheerful than usual all of the time.

0	I do not feel more self-confident than usual.
1	I occasionally feel more self-confident than usual.
2	I often feel more self-confident than usual.
3	I feel more self-confident than usual most of the time.
4	I feel extremely self-confident all of the time.

0	I do not need less sleep than usual.
1	I occasionally need less sleep than usual.
2	I often need less sleep than usual.
3	I frequently need less sleep than usual.
4	I can go all day or night without any sleep and still not feel tired.

0	I do not talk more than usual.
1	I occasionally talk more than usual.
2	I often talk more than usual.
3	I frequently talk more than usual.
4	I talk constantly and cannot be interrupted.

0	I have not been more active (either socially, sexually, at work, home or school) than usual.
1	I have occasionally been more active than usual.
2	I have often been more active than usual.
3	I have frequently been more active than usual.
4	I am constantly active or on the go all the time.

Clinical Information

Diagnosis received	
Diagnosis before admission (if different)	
Age of bipolar disorder diagnosis	
Current hospital admission	Voluntary ☐ Involuntary/ Detained ☐ Other (details below) ☐ _____
Reason for current admission	
Date of admission	
Approximate date of discharge	
Number of previous psychiatric hospital admissions	
Any Voluntary admissions?	Yes ☐ No ☐
Any Involuntary/ Detained admissions?	Yes ☐ No ☐
Number of previous manic episodes	
Number of previous episodes of depression	
Any current psychotic symptoms?	Yes ☐ No ☐
Family history of bipolar	Yes ☐ No ☐ Unknown ☐
Physical health conditions	

Demographic information

Date of Birth	
Gender	Male ☐ Female ☐
Ethnic Origin	White British ☐ Black Caribbean ☐ White Irish ☐ Black British ☐ White Other ☐ Black African ☐ Black Other ☐ Indian ☐ Pakistani ☐ Mixed ethnicity ☐ Bangladeshi ☐ Chinese ☐ Asian Other ☐
Marital Status	Single ☐ Married/ Civil partnership/Cohabiting/ ☐ Divorced/ Separated ☐ Widowed ☐ Other(please state) _____
Highest level of Education	No qualifications ☐ O levels/CSEs/GSCEs ☐ Vocational education NVQ/GNVQ/ HNC/ HND ☐ A levels/AS levels ☐ Degree ☐ Higher degree ☐ Professional qualifications (e.g. nursing, accountancy) ☐

Your views of this Questionnaire

Thanks-you for completing this questionnaire.
We are interested to find out your opinions of the questionnaire and how you found completing it.
For each statement, please tick whether you strongly disagree, disagree, agree or strongly agree.

		Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Q1	The questionnaire was interesting to complete					
Q2	The questionnaire helped me to reflect on bipolar					
Q3	The questionnaire made me upset					
Q4	The questionnaire was difficult to understand					
Q5	The amount of questions was about right					
Q6	The questionnaire was not relevant to me					
Q7	The questionnaire was easy to understand					
Q8	I would recommend the questionnaire to others					
Q9	The questionnaire took too long to complete					

Please use the space below to tell us anything else about completing the questionnaire

Thank-you for taking the time to complete this questionnaire. Your response is greatly appreciated.
All the responses you have given are completely confidential and will not be seen by anyone involved in your care.

About your recent care

We would like to ask you some questions about your experiences and your care since you completed the first questionnaire in this study.

Please tell us how many appointments or visits with the following health professionals you have had since you completed the first questionnaire in this study.
Please tell us if these were planned (for example, appointments or meetings which were routine as part of your usual care), or if they were unplanned (for example, for unexpected or emergency situations). If you have not had any, please write 0 in the spaces provided.

		Number of planned appointments/ visits	Number of unplanned appointments/ visits
	Your GP for mental health problems		
	Community Mental Health Team		
	Crisis Resolution and Home Treatment Team (CRHT)		
	Your Psychiatrist		
	A Pharmacist		
	Any other health professionals (please tell us who in the boxes below)		

Please tell us if you have had any contact with mental health support groups or charities since you completed the first questionnaire in this study.

Yes ☐ **No** ☐

If yes, please tell us about this in the space below ...

To what extent have the following things had a positive or negative effect on your mental health problems. Please tell us by ticking the appropriate box.

		Made my mental health a lot worse	Made my mental health a bit worse	No effect on my mental health	Made my mental health a bit better	Made my mental health a lot better
	Physical health problems					
	Family/ people around you					
	Finance/ money issues					
	Housing/ where I live					

Please use the space below to tell us about anything else you think might have had an effect on your mental health since you completed the first questionnaire in this study.

Thank-you for taking the time to complete this questionnaire and for your involvement in the study. Your responses are greatly appreciated.
All the responses you have given are completely confidential and will not be seen by anyone involved in your care.

Appendix M. **Confirmation of ethical approval for pilot RCT**

NHS
Health Research Authority

NRES Committee London - Queen Square
HRA Head Office
Skipton House
80 London Road
London, SE1 6LH

Telephone: 020 7972 2556

30 November 2012

Professor Rob Horne
Head of Department of Practice & Policy, Director of Centre for Behavioral Medicine
UCL School of Pharmacy
UCL School of Pharmacy, Mezzanine Floor
BMA House, Tavistock Square
London, WC1H 9JP

Dear Professor Horne

Study title: **A pilot randomised controlled trial of a theory-based, tailored intervention designed to address perceptions of illness and treatment, for people prescribed medication for Bipolar Disorder.**
REC reference: **12/LO/1615**

Thank you for your letter of 21 November 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mr Thomas McQuillan, thomas.mcquillan@nhs.net.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

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

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

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

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

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

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

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

Approved documents

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

Document	*Version*	*Date*
Covering Letter		12 September 2012
Investigator CV	Prof Rob Horne	
Other: CV: Lindsay Allison MacDonald		
Other: CV: Dr Mark Hayward		
Other: CV: Sally Skipper		
Other: CV: Michel Syrett		

Other: CV: Dr Richard James Bowskill		
Other: Sussex Partnership NHS Foundation Trust: Lone Worker Policy		
Other: Control Participant Leaflet		
Participant Consent Form	2	06 November 2012
Participant Information Sheet: Staff	1	18 April 2012
Participant Information Sheet: RCT	2	06 November 2012
Protocol	1	29 May 2012
Questionnaire: Altman Self Rating Mania Scale		
Questionnaire: The Beck Depression Inventory		
Questionnaire: The Beliefs about Medicine Questionnaire		
Questionnaire: The Illness Perception Questionnaire		
Questionnaire: Medication Adherence Report Scale		
Questionnaire: The Satisfaction with Information about Medication Scale		
Questionnaire: Internalised Stigma of Mental Illness		
REC application	87823/362954/1/868	12 September 2012
Referees or other scientific critique report		
Response to Request for Further Information		21 November 2012

Statement of compliance

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

After ethical review

Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

Feedback

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

Further information is available at National Research Ethics Service website > After Review

12/LO/1615	**Please quote this number on all correspondence**

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

Yours sincerely

pp
Dr Yogi Amin
Chair
Email:NRESCommittee.London-QueenSquare@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Ms Tanya Telling, Sussex Partnership NHS Foundation Trust*

Appendix N. **Confirmation of R&D approval for pilot RCT**

Sussex Partnership NHS
NHS Foundation Trust

Research and Development
Sussex Education Centre
Mill View Hospital
Nevill Avenue
Hove BN3 7HZ

Tel: 01273 265928
Fax: 01273 242182

www.sussexpartnership.nhs.uk

30th November 2012

Professor Rob Horne
Head of Department of Practice & Policy,
Director of Centre for Behavioral Medicine
UCL School of Pharmacy, Mezzanine Floor
BMA House, Tavistock Square
London
WC1H 9JP

Dear Rob,

Study title: A pilot randomised controlled trial of a theory-based, tailored intervention designed to address perceptions of illness and treatment, for people prescribed medication for Bipolar Disorder.

Ref: CSP 87823

Thank you for your application to Sussex Partnership Trust for research governance approval of the above named study.

I am pleased to inform you that you have all the necessary internal and external regulatory approvals to proceed. Details of your research project and any associated supporting documentation will be stored on an electronic database administered by the R&D Department.

This approval is valid in the following sites:

- Sussex Partnership in patient wards

The documents reviewed for this approval were:

Document	Version	Date
R&D Form, locked and signed	87823/374170/14/692	04/09/2012
SSI form, locked and signed	87823/378817/6/ 331/181274/257381	31/10/2012
NRES Committee London Queen Square Favourable opinion letter		30/11/2012
Investigator CV Prof Rob Horne		
CV Lindsay Allison MacDonald		
CV Dr Mark Hayward		
CV Sally Skipper		
CV Dr Richard Bowskill		
CV Michel Syrett		
Participant Consent Form	2	06/11/12
Participant Information Sheet	2	06/11/12
Participant Information Sheet: Staff	1	18/04/12
Participant Information Sheet: Controls		

Sussex Partnership NHS
NHS Foundation Trust

Protocol	1	29/05/12
Questionnaire: Altman Self Rating Mania Scale		
Questionnaire: The Beck Depression Inventory		
Questionnaire: The Beliefs about Medicine Questionnaire		
Questionnaire: The Illness Perception Questionnaire		
Questionnaire: Medication Adherence Report Scale		
Questionnaire: The Satisfaction with Information about Medication Scale		
Questionnaire: Internalised Stigma of Mental Illness		

Conditions of approval

- **Lindsay MacDonald requires a Research Passport before commencing work in Sussex.**

The approval covers the period stated in the Research Ethics Committee (REC) application and will be extended in line with any amendments agreed by the REC. Research must commence within 12 months of the issue date of this letter. Any delay beyond this may require a new review of the project resources.

Please alert the Research and Development Office if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.

Please ensure that you comply fully with the Department of Health Research Governance Framework, in particular that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.

Please ensure that all information regarding patients or staff remains secure and strictly confidential at all times. Ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Amendments

Project amendment details dated after the issue of this approval letter should be emailed to the Research and Development Office for formal approval.

NIHR Adoption

This project has been adopted by the NIHR and as Principal Investigator for this site you are responsible for ensuring accrual numbers are submitted to the co-ordinating centre for study. If you need any support to manage this please contact me.

Appendix O. **Letter of access for research**

A teaching trust of Brighton and Sussex Medical School

Sussex Partnership NHS
NHS Foundation Trust

Research and Development
Sussex Education Centre
Mill View Hospital
Nevill Avenue
Hove BN3 7HZ

Tel: 01273 265896
www.sussexpartnership.nhs.uk

2nd April 2013

Lindsay MacDonald
Flat 4
40 Shoot Up Hill
London
NW2 3QB

Dear Lindsay

Letter of access for research
R&D Ref: CSP 87823
Study Title: IBID

This letter confirms your right of access to conduct research through Sussex Partnership NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on 02/04/2013 and ends on 02/04/2015 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at Sussex Partnership NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Sussex Partnership NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Sussex Partnership NHS Foundation Trust, you will remain accountable to your employer University College London but you are required to follow the reasonable instructions of Mark Hayward in this NHS organisation or those given on his behalf in relation to the terms of this right of access.

A teaching trust of Brighton and Sussex Medical School

Sussex Partnership NHS
NHS Foundation Trust

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Sussex Partnership NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Sussex Partnership NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Sussex Partnership NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

A teaching trust of Brighton and Sussex Medical School

Sussex Partnership NHS
NHS Foundation Trust

Sussex Partnership NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely,

Tanya Telling
R&D Manager
Sussex Partnership NHS Foundation Trust

Please sign and date this letter and return one copy. Do not detach this lower section from the letter.

I confirm my acceptance of this standard letter of confidentiality and the associated terms.

SIGNATURE .....

NAME (in block capitals) ...LINDSAY MACDONALD.....

DATE .....2/4/13.....

Appendix P. **IBiD study pack for staff**

Improving Information for people with Bipolar Disorder:

a randomised controlled trial

Study Protocol

Chief Investigator **Professor Rob Horne**
Sponsor **Sussex Partnership NHS Foundation Trust**
Funders **NIHR RfPB**

1.0 Introduction & Background

Bipolar disorder is a serious, long-term mood disorder affecting approximately one person in every hundred (Fajutrao *et al*., 2009). It is characterised by episodes of mania and depression, which can severely impair the quality of life of those affected and the people around them (Goldberg *et al*., 1995). Recent estimates of the annual cost of managing bipolar disorder to the UK healthcare system at £342 million, with hospitalisations accounting for 60% of this (Young *et al*, 2011).

Medication is recommended as a key part of the treatment of manic and depressive phases as well as prophylaxis preventing recurrence (National Institute for Health and Clinical Excellence, 2006). Adherence to maintenance treatment medication is associated with, reduced relapse rates (Hong *et al*., 2011), fewer hospital admissions (Scott & Pope, 2002), a reduced risk of suicide and attempted suicide (Baldessarini *et al*., 2006), and significantly lower healthcare costs (Hong, *et al*., 2011). However, many patient do not adhere to medication prescribed for bipolar disorder; a review by Lingam and Scott (2002) estimated a non-adherence rate of 41% to long-term prophylactic medication (Lingam & Scott, 2002).

Research has found that many people prescribed medication for bipolar disorder are concerned about their medicines and do not feel they have been given enough information about them. In order to decide to take medication, an individual must first perceive that they have a condition, and this condition warrants treatment. Studies in physical illnesses have shown that negative perceptions of treatment are linked to perceptions of illness and the degree of 'fit' between patients belief about the problem (illness) and preferred solution (the treatment) (Horne & Weinman, 2002). Individuals formulate a commonsense understanding of their condition and the subsequent treatment they have been prescribed. A commonsense model in which an individual has a recognition of their condition, a perceived need for medication, and their concerns about the prescribed treatment have been acknowledged would be likely to lead to engagement in positive self-management strategies, including adherence to medication (Horne, 2003).

Non-adherence to medication for bipolar disorder has been shown to be associated with people's beliefs about their illness and treatment, in particular their doubts about the need for treatment and concerns about adverse effects (Clatworthy *et al*., 2009; Clatworthy *et al*., 2007). A person's individual beliefs and concerns will be associated with the information they may choose to seek and their unanswered questions surrounding their diagnosis and treatment.

In terms of information, knowledge about bipolar and its treatment has been associated with adherence (Berk *et al*., 2010). Yet dissatisfaction with information about medicines among service users is commonplace (Bowskill *et al*., 2007) (Morselli & Elgie, 2003) (National Schizophrenia Fellowship, 2000). In the 2011 Care Quality Commission survey of users of community mental health services, Sussex Partnership NHS Trust showed scope for improvement in terms of provision of information about medicines and patients' opinions of having their views taken into account during medication decisions. In addition, there was scope for improvement with regard to whether patients felt they had enough time to discuss their condition and treatment (Care Quality Commission, 2011). Findings for the inpatient setting have also indicated patient dissatisfaction in receiving explanations about medication and being involved in their own care and treatment (Care Quality Commission, 2009).

To inform the development of the current study, a qualitative study was carried out with adults currently prescribed medication for bipolar disorder. Themes which emerged from the analysis concurred with findings from previous research, with regard to necessity beliefs and concerns held by patients. Insights from the qualitative study, in particular; the importance of internalized stigma; necessity and concern beliefs; unmet information needs and the importance of individual needs, will be used to inform this intervention (Unpublished data).

There is a clear need to improve information provision regarding bipolar disorder and medicines prescribed for its treatment in the Trust. There is a need individuals' information requirements to be

elicited and addressed, in order to facilitate informed choice and adherence to treatment (Bowskill, *et al*., 2007). However, rather than healthcare professionals providing generic information, it is important that patients are allowed to discover and understand information which is relevant to them and helps to build accurate, common sense models of their illness.

In addition to the above research and qualitative work carried out by our research group, informing the development of the current pilot intervention, an exploration of the literature on improving adherence in mental health has contributed to the development phase. In terms of improving medication adherence, a review by Sajatovic and colleagues (2004) concluded that for bipolar disorder, effective therapies occur in the context of long-term management of illness that incorporates a good understanding of medications and their risks and benefits as well as education about illness awareness and self-management. The majority of effective therapies feature an interactional component between patients and their care providers or therapists (Sajatovic *et al*., 2004). We have as a result incorporated these findings in the design of our intervention. A review by Berk and colleagues concluded that 'a person centred approach that considers risk factors for non-adherence and barriers to other health behaviours may assist with the development of more targeted briefer interventions' (Berk, *et al*., 2010). In addition to the recommendations from reviews of mental health interventions, the most recent Cochrane review of adherence interventions for chronic health problems acknowledged the lack of evidence for effective adherence interventions and recommended that 'High priority should be given to fundamental and applied research concerning innovations to assist patients to follow medication prescriptions for long-term medical disorders' (Haynes *et al*., 2008).

The evidence related to non-adherence in bipolar disorder clearly indicates that interventions are needed to facilitate informed choice and support optimal adherence to appropriately prescribed treatment.

The intervention will take a novel approach informed by theories of self-regulation of illness and commonsense representations of illness and treatment. The content of the intervention will be tailored to meet individual need. This will be achieved by identifying, for each individual, the salient perceptual factors (e.g. beliefs about illness and treatment) and practical factors (e.g. capacity and resources) influencing the motivation and ability to engage with treatment and use it to best effect.

1.1 Development of the present study – Using the MRC Framework for the development of complex interventions

This programme of research has been funded by a grant from the National Institute for Health Research (NIHR) and applies the approach recommended by the Medical Research Council (MRC) framework for the development of complex interventions (Craig *et al*., 2008). The qualitative research was preceded by a preclinical/ theoretical phase which explored existing evidence and identified the theoretical framework, the extended self-regulation model (Horne, 2003). This phase will pilot the intervention to allow for a larger, more definitive trial.

This broader research programme comprises the following sub-studies:

Phase 1 (09/H1107/110): Identifying the components of the intervention

- A qualitative study identified unmet information needs and evaluated existing information from a service-user perspective (completed). Results confirmed previously identified beliefs and concerns of patients with bipolar disorder. Identified information needs included; information about diagnosis, side effects of treatments and a desire to be informed about and contribute to their care plan (unpublished data).

Phase 2: Pilot Randomised Controlled Trial.

- Development, implementation and pilot study of the intervention as an RCT.

1.2 Intervention Aim

- To facilitate informed choice and support optimal adherence to appropriately prescribed treatment through the delivery of an information resource with tailored individual support which addresses participants' personal information needs and concerns about treatment.

1.3 Intervention Development

1.3.1 Content

The intervention is informed by theories of self-regulation of illness and commonsense representations of illness and treatment. As stated in section 1.0 above, research has shown that adherence behaviour is associated with people's beliefs about their illness, their beliefs about the necessity of treatment and concerns about adverse effects of treatment.

The perceptions and practicalities approach (PAPA) (Horne, 2001) provides a framework to guide the development of the intervention itself as it operationalises both intentional and non-intentional non-adherence.
For each individual, the content of the written material used to guide the session will be tailored to meet individual need. This will be achieved by identifying, for each individual, the salient perceptual factors (e.g. beliefs about illness and treatment) and practical factors (e.g. capacity and resources) influencing the motivation and ability to engage with treatment and use it to best effect. This is described in section 4.2 below.
Written material will be prepared to address beliefs and perceptual and practical barriers related to engagement with treatment:

- Beliefs about illness, operationalised by the Illness Perception Questionnaire constructs; identity, cause, timeline, consequences, personal control, treatment control, illness coherence, and emotional representation.
- Perceptions of medication, operationalised by the sub-scales of the Beliefs about Medication Questionnaire, i.e. perceived need and concerns about medication.
- Practical factors to address non-intentional non-adherence, e.g. capacity and resources.

Only those relevant to participants' individual responses will be included in their tailored intervention.

1.3.2 Delivery vehicle

The intervention will consist of tailored written material delivered in a face-to-face session with the researcher. In addition, as this material will be provided for participants to take away, they will be able to refer back to this and seek additional support from the researcher in the follow-up telephone contact. This method was suggested during the Phase 1 qualitative work with service users.

1.3.3 Context

The intervention will be delivered in the in-patient setting when participants are close to discharge. Phase 1 qualitative work and the care Quality Commission survey identified that this is a time where patients may not receive information they require about their diagnosis and treatment. By delivering the intervention close to discharge this will minimise the impact of, for example, cognitive difficulties during a manic or depressive episode.

1.3.4 Content development – consultation with service users

The draft content and delivery mechanism will be discussed with service-users in a consultation exercise. Refinements will be made following this consultation before the final intervention is developed.

2.0 Research Aims

2.1 Principle research aim

- To determine the effect of a theory-based intervention on participants perceptions of bipolar disorder and its treatment.

2.2 Secondary research aims

- To determine the effect of the intervention on the secondary outcome measures; satisfaction with information about medication prescribed for bipolar disorder, adherence to treatment, and self-stigmatisation.
- To determine the effect size of the intervention versus treatment as usual (TAU) to inform the power calculation for a definitive RCT.
- To conduct a process evaluation to gather information on the acceptability and feasibility of the intervention in terms of recruitment and retention.

3.0 Methods

3.1 Design

A pilot RCT will allocate patients to receive either the intervention plus treatment as usual (I + TAU) or to the control group (TAU) and investigate changes to the identified outcome measures.

3.2 Participants

Participants (aged over 18) with a diagnosis of bipolar disorder will be recruited from inpatient Psychiatric services across Sussex Partnership NHS Foundation Trust. It is estimated that a potential pool of approximately 320 patients will be eligible over a period of 12 months (based on previous 12 months discharge data).

3.2.1 Inclusion Criteria

- Receiving care as an inpatient within Sussex Partnership NHS Foundation Trust

- Received a diagnosis of bipolar disorder
- Currently prescribed medication for bipolar disorder
- Ability to give written informed consent
- Aged over 18 years

3.2.2 Exclusion Criteria

- Organic brain syndrome
- Active suicide ideation
- Primary diagnosis of substance misuse

3.3 Recruitment

Participants will be recruited from inpatient wards across 12 wards within Sussex Partnership NHS Foundation Trust. Identification of patients meeting the inclusion criteria will be carried out by their direct care team on the wards. These staff will identify whether potential participants are able to provide consent and are at a stage in their care where it is appropriate for them to take part.
Staff will be provided with Information sheets, a copy of the Protocol and Patient Information Sheets. This will provide them with inclusion and exclusion criteria and the procedure for identification and recruitment of participants. Eligible patients will be provided with a Participant Information Sheet (PIS). Participants will be informed that it is their decision whether or not to participate and agreeing or declining will not affect their care in any way. For further information participants will be able to contact the Clinical Studies Officer or Researcher.
Recruitment will be carried out by the Clinical Studies Officer (CSO) who will arrange to meet with eligible patients before taking them through the content of the PIS to ensure informed consent is able to given for those wishing to participate. At this point an appointment will be made for them to give consent and complete the baseline assessments.

3.3.1 Consent

Fully informed consent will be ensured by the direct care team identifying that informed consent can be provided, and by the CSO explaining the information in the PIS and confirming understanding with participants. The CSO has GCP and Informed Consent Training as well as previous experience of consenting in other Mental Health research studies.

3.3.2 Site information

12 wards will be included for participant recruitment across 6 units.

- Woodlands Centre, East Sussex (Woodlands)
- Department of Psychiatry, General Hospital, Eastbourne (Amberley, Bodiam)
- Centurion Mental Health Centre, Chichester (Orion)
- Langley Green Hospital, Crawley (Jade, Coral, Opal)
- Meadowfield Hospital, Worthing (Maple, Rowan)
- Mill View Hospital, Hove (Meridian, Regency, Caburn)

3.4 Randomisation

Participants will be randomly allocated to the intervention or treatment as usual (TAU) condition. Randomisation will be carried out independently by Kings College London Clinical Trials Unit using an online randomisation system. The Researcher will coordinate this and receive email confirmations of allocation.

3.4.1 Treatment allocation & Allocation concealment

Following participants providing consent, this information will be passed to the Researcher. Patients will be allocated to either the intervention or control group. Participants assigned to the control group will be notified of their allocation by letter. The CSO will remain blinded to participants allocation to ensure allocation concealment. The Attrition rate at this point will be recorded for inclusion in the assessment of feasibility for a larger trial.

3.5 Sample & sample size

Participants (aged over 18) with a diagnosis of bipolar disorder will be recruited consecutively from in-patient Psychiatric services across Sussex Partnership NHS Foundation Trust. The number of participants the study is estimated to be able to recruit during the fieldwork period allowed for the study (12 months) has been estimated from previous 12 month discharge diagnosis data.
In a 12 month period 328 patients were discharged with a diagnosis indicating bipolar disorder from 12 eligible wards (adult in-patient mental health services, excluding intensive care). A sample of 30 participants was determined to be sufficient to provide feasibility and acceptability data.

3.6 Outcome measures

Validated questionnaires and modified measures will be used to investigate time and treatment effects following the delivery of the intervention in the primary and secondary outcome measures; beliefs (illness and treatment), adherence, satisfaction with information and self-stigmatisation. These measures will be taken at baseline, and repeated 6-8 weeks post-intervention delivery. Demographic, diagnosis and treatment related information will also be recorded including mental health service-utilisation. Clinical measures will be administered in order to control for current state in analysis.

3.6.1 Piloting questionnaires

The questionnaires will be presented to a small group of service users to obtain their feedback on the wording and format of the questionnaires. Following this process the questionnaire booklet will be refined, minor adaptations to wording will be made and the format will be finalised.

Table 1: List of measures to be used

Clinical	The Beck Depression Inventory (BDI)
	Altman Self-Rating Mania Scale
Treatment beliefs	The Beliefs about Medicine Questionnaire (BMQ) The BMQ consists of two scales assessing patients' beliefs about the necessity of prescribed medication for controlling their disease and their concerns about potential adverse consequences of taking it.
Illness beliefs	The Illness Perception Questionnaire (IPQ Bipolar adaptation) The IPQ assesses the cognitive and emotional representations of illness. This has been adapted for use with patients with Bipolar Disorder.
Adherence	Medication Adherence Report Scale (MARS)
Satisfaction	The Satisfaction with Information about Medication Scale (SIMS)
Stigma	Internalised Stigma of Mental Illness (ISMI)

4.0 Procedure

4.1 Baseline assessment

Prior to randomisation and delivery of the intervention, participants will be asked to complete baseline assessments, through an interview with the CSO. These baseline assessments will consist of the measures outlined above in section 3.6. The interviews will take place at the inpatient setting at a time convenient to the participant. Baseline data will also be collected on participants' demographic information, diagnosis and treatment data.

4.2 Intervention delivery

Participants responses to the baseline BMQ and IPQ-BD measures will be used to tailor written information to address the specific concerns about bipolar disorder and its treatment. For each individual, the salient perceptual factors (e.g. beliefs about illness and treatment) and practical factors (e.g. capacity and resources) influencing the motivation and ability to engage with treatment and use it to best effect will be identified.

Participants will then have a one-to-one appointment with the Researcher to work together through the intervention material, address concerns raised at this stage and advise on self-help aspects of the resource. The information gathered from scoring the BMQ and IPQ measures collected at baseline will also provide a starting point for discussion about these issues. Participants will also receive existing material produced by Sussex Partnership NHS Foundation Trust on specific medications which they have been prescribed. These sessions will take place in a private location in the inpatient setting. The Researcher will contact each participant by telephone on one occasion to follow-up on any additional concerns.

4.3 Control group

Those participants allocated to the control group will be notified of their allocation by letter and will be able to have any questions answered by the unblinded Researcher. They will continue to have treatment as usual with their healthcare professionals. They will be asked to complete the same follow-up measures as participants in the intervention group.

4.4 Follow-up

The baseline assessment measures will be repeated in order to assess any changes 6 weeks post-intervention, or 6-8 weeks post discharge for the control group participants. In addition, data will be collected on possible confounders such as participants' contacts with mental health professionals and prescribers at any point between baseline and follow-up, and changes to their medication regimen. These interviews will be carried out by the Clinical Studies Officer in a location convenient for the participant, either at home, at the hospital or in a community mental health setting. If necessary, this can also be carried out by telephone. Participants will be requested not to disclose their treatment allocation to the CSO.

4.4.1 Qualitative follow-up

At the follow-up appointment with the CSO, all participants will be invited to take part in a semi-structured interview with the Researcher to assess the feasibility and acceptability of the study. This interview will take place over the telephone and will be audio-taped with the participants permission.

4.5 Incentives

Participants will receive an incentive of £20 for their participation in the study. An incentive is offered in order to maximise the retention rate at follow-up. Participants will be reimbursed for any travel expenses incurred and will be offered refreshments during their appointments and interviews.

5.0 Data analysis

The validated questionnaire measures will be scored as per published guidelines. BMQ data will be analysed using and intention to treat protocol with a repeated measure design with two groups and two time points. Interaction effects will be explored. This will be repeated for the secondary outcome measures. The pattern of missing data will be examined and appropriate methods to account for this will be applied.

Qualitative data from the follow-up interviews will be subject to Thematic analysis in order to elicit themes and provide recommendations for a definitive RCT.

6.0 Anticipated outputs of the study

The expected outcomes of the study will be the development of an intervention designed to improve satisfaction with information about medications for bipolar disorder and address service-users concerns about their condition and treatment. If the intervention is successful, we anticipate that by increasing satisfaction with information, this will enhance informed and collaborative decision making. By encouraging individuals to address personal concerns, the intervention will aid with personalised care planning.

6.1 Dissemination plan

- Conference presentations.
- Publication in peer-review journal.
- Publication through service-user magazine (Pendulum, the Bipolar UK journal)

7.0 Core research team

Professor Rob Horne (Chief Investigator, Academic Lead, UCL School of Pharmacy)
Dr Richard Bowskill (Clinical Lead, Sussex Partnership NHS Foundation Trust)
Dr Mark Hayward (Director of R&D, Sussex Partnership NHS Foundation Trust)
Lindsay MacDonald (Researcher/ PhD student, UCL School of Pharmacy)
Sally Skipper (Clinical Studies Officer, Sussex Partnership NHS Foundation Trust)
Mr Michel Syrett (Service User Representative, Bipolar UK)
Additional Clinical Studies Officers (Kelly Humphreys & Philippa Case, Sussex Partnership NHS Foundation Trust)

Sussex Partnership NHS
NHS Foundation Trust

Improving Information for people with Bipolar Disorder (IBiD)
Participant Information Sheet

Invitation
We would like to invite you to take part in our research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You may wish to discuss it with others. A member of our team will go through the information with you and answer any questions you may have.

What is the purpose of the study?
Often people with a diagnosis of bipolar disorder do not have access to the information they need and this can make understanding their diagnosis and treatment they have been prescribed more difficult. It is important however, rather than healthcare professionals providing generic information, patients are allowed to discover and understand information which is relevant to them.
This study aims to find out whether providing information which is tailored or personalised to people's individual needs is more helpful than the information that is currently available within Adult mental health services. This type of study is called a 'randomised controlled trial'.

What is a randomised controlled trial?
A randomised controlled trial (RCT) is the best type of research to test new approach when we don't know which option is best. To find out we need to compare different approaches. We put people into groups and give each group a different approach. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group at random (by chance).

Why have I been chosen?
You have been chosen because you are receiving care from health professionals in Sussex Partnership NHS Foundation Trust and have been prescribed medication for bipolar disorder. In total approximately 90 people will participate in the study. Half of these will be offered the additional information and half will continue with their usual care.
Your care team have agreed that it would be ok/ appropriate for you to take part in this study if you wanted to. The research team will keep in touch with your care team throughout the study to make sure that everything is still ok.
Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to change your mind at any time and without giving a reason. A decision not to take part, or a decision to withdraw at any time, will not affect the care that you receive.

What will happen to me if I take part?
If you are interested in taking part after reading this Information Sheet please let your care team know and they will pass your contact details on to a member of the research team. They will make direct contact with you and arrange a meeting within the next couple of days.
When you meet, the researcher will go through this Information Sheet with you, make sure you understand everything about the research and answer any questions you might have about the research. If you wish to participate you will be asked by an experienced research nurse to sign an Informed Consent form. You may still choose not to take part in the research at this stage, without giving a reason and with no detriment to you. You can also ask for more time to consider whether or not to take part.
If you proceed with the study we will ask you to complete a questionnaire. The questionnaire will include five sections. These will ask; how you have been feeling lately, how you feel about taking medication, your opinions about your diagnosis and how satisfied you are with any information you

might have received, it will also ask about your experience of living with a mental health issue. This will take between 40 – 60 minutes and will take place in a private place in the hospital.
After this meeting someone independent to the study and without knowing your name or details will allocate you at random to either the group where the information you receive will be tailored specifically for you or to continue with your usual care. Half of the people in the study will be allocated to a therapy group and the other half will not be allocated to a therapy group.
If you are allocated to receive the new approach, you will be invited to meet with the Researcher on a one-to-one basis to informally talk about your thoughts and opinions about your diagnosis and medications. You will be provided with written information tailored for you and you will also have the opportunity to discuss this with the Researcher after the meeting via telephone or email. This appointment will last between one hour and one and a half hours and will also take place in a private place at (insert hospital). If you are allocated to this group, you will also continue to receive standard care from your care team.
If you are allocated to the usual care group, you will continue to receive the standard care and information from your care team. You will receive a letter letting you know that you have been allocated to the usual care group. Participating in the study will not interfere with your usual care.
Everyone in both groups will be asked to complete a second questionnaire about 2 months after their previous appointment with the researcher. This should take no longer than about 30 minutes and will take place in a location convenient for your, for example in your home or where your care team work.
You will receive £20 to compensate for your time in taking part in the study.

Will my taking part in this study be kept confidential?
Yes. All the information you give during the study will be confidential and only the research team will have access to your responses. All information you provide will be stored securely. The questionnaires you complete will not have your name on them, (a number will be used instead) so it will not be possible for people to match any information to you personally. The study complies with data protection laws. No NHS staff involved in your care will be able to see your individual responses. In the unlikely event that the researchers feel that the health and safety of you or others is at severe risk, you will be informed that your care coordinator will be contacted.

What are the possible benefits of taking part?
This study is testing a new approach, for this reason we do not know whether or not it will be effective. By taking part in the study you will help us learn if this approach is helpful and this will in the future help mental health services to provide information for people using these services.
You may find that receiving information and having the opportunity to talk about your medication and diagnosis is helpful and rewarding for you.

What are the possible disadvantages of taking part?
It is unlikely that there are any risks or disadvantages of taking part.
If you are allocated to receive the new approach, taking part in the study will involve talking to a researcher about the diagnosis you received and symptoms and side-effects you may have experienced. For some it may be difficult to consider these feelings and experiences. You do not have to discuss anything that you find difficult to talk about. If difficult issues come up during the interview you are free to stop the session at any point to take a break, reschedule or finish the session, or withdraw from the study, again with no detriment to yourself or the service you receive. In discussion with you the researcher can make arrangements for you to receive support from an appropriate person. Either you or the Researcher, with your permission, can seek support from members of your care team in the event that you might need this.

What will happen to the results of the research study?
The results of the study will be written up for publication in a journal. No-one will be identified in any part of the write-up or article. If you would like to obtain a copy of the published results of the study, please tell one of the researchers and they will happily supply you with one when they become available.

Who is organising and funding this study?
This study is being led by Professor Rob Horne, Professor of Behavioural Medicine at UCL School of Pharmacy in collaboration with Sussex Partnership NHS Foundation Trust. The research is being funded

by the Research for Patient Benefit Programme, National Institute for Health Research. The study is part of a PhD being undertaken by Miss Lindsay MacDonald. Funding is available for the duration of the study.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the London Queen Square Research Ethics Committee (Ref No: 12/LO/1615) as well as by the Research and Development Department within your local NHS trust.
Contact details of the London Queen Square Research Ethics Committee: **Health Research Authority,** HRA Head Office, Skipton House, 80 London Road, London SE1 6LH. Phone: 020 7972 2584

What should I do now?
If you are interested in taking part after reading this Information Sheet please let your care team know and they will pass your contact details on to a member of the research team.
For further information about the study please contact:
Lindsay MacDonald (Researcher), UCL School of Pharmacy.
Phone: 020 7874 1297
Email: l.macdonald@ucl.ac.uk

Kelly Humphryes (Clinical Studies Officer)
Phone: 01273 265921
Email: kelly.humphryes@sussexpartnership.nhs.uk

Philippa Case (Clinical Studies Officer)
Phone 01273 265921
Email: philippa.case@sussexpartnership.nhs.uk

Thank-you for taking the time to read this information.

Improving Information for people with Bipolar Disorder (IBiD)

Staff Information

This study is being carried out by Researchers from the Centre for Behavioural Medicine, at UCL School of Pharmacy in partnership with Sussex Partnership NHS Foundation Trust. The research is being funded by the Research for Patient Benefit Programme, NIHR (Grant number: PB-PG-1207-15248).

What is the purpose of the study?

We are recruiting patients from wards across the Trust to take part in a trial aiming to address some of the outstanding information needs of patients with Bipolar Disorder. The study will run from June 2013 until December 2013.

The aim is find out whether providing information which is tailored or personalised to people's individual needs is more helpful for people than usual care. By conducting a randomised controlled trial (RCT) we will be able to find out whether this approach results in any changes about how people feel about their diagnosis and treatment.

A copy of the research protocol is available if you would like further information about the study.

What will happen to participants who take part in the study?

Everyone who agrees to take part will complete a questionnaire with a member of the research team. The questionnaire includes how they feel about taking medication, their satisfaction with information about medication and their opinions about their diagnosis. This will take approximately 45 minutes and will take place in a private place within the hospital environment.

Randomisation will then be carried out independently from the Research Team or care staff.

Those who have been randomised to receive the additional information will meet with the researcher to informally talk about their thoughts and opinions about their diagnosis and medications and receive written, tailored information. This appointment will last between one hour and one and a half hours and will also take place in a private place within the hospital environment.

Everyone will be asked to complete a second questionnaire about 2 months after their previous appointment with a member of the research team.

Participants will receive a payment of £20 to compensate them for their time.

Who is eligible to take part?

Inclusion Criteria	**Exclusion Criteria**
Able to provide written informed consent	Organic Brain Syndrome
Diagnosis of bipolar disorder	Active suicidal ideation
Currently prescribed medication for bipolar disorder	Primary diagnosis of substance misuse
Age over 18 years	Patients considered as presenting as risk to others.

How can you help?

Recruitment to the study will be carried out by Clinical Studies Officers (CSO), employed by Sussex Partnership NHS Foundation Trust, based in the R&D Department.

We are asking ward staff to identify patients who meet the eligibility criteria outlined above. Patients identified as meeting the eligibility criteria should be provided with a Participant Information Sheet (your ward will be provided with a supply of these).

Those patients expressing a verbal interest will be approached, if appropriate, within 48 hours by the CSO.

The CSO will go through the information sheet with potential participants and answer any questions they may have.

The researchers involved in the study will visit with you prior to the start of the study to discuss how to make sure that we keep any disruption to a minimum.

Who has reviewed the study?

This study has been reviewed and approved by London Queen Square Research Ethics Committee (Ref No: 12/LO/1615) as well as by the R&D Department within Sussex Partnership NHS Foundation Trust (Ref: CSP 87823).

Who can I contact for further information?

If you would like more information, please contact **the relevant individual listed below.**

Lindsay MacDonald, Researcher Centre for Behavioural Medicine, UCL School of Pharmacy, **020 7874 1297** l.macdonald@ucl.ac.uk	**Sally Skipper**, MHRN Clinical Studies Officer, Sussex Education Centre, **01273 265921** sally.skipper@sussexpartnership.nhs.uk
Kelly Humphryes MHRN Clinical Studies Officer, Sussex Education Centre, **01273 265921** kelly.humphryes@sussexpartnership.nhs.uk	**Philippa Case** MHRN Clinical Studies Officer, Sussex Education Centre, **01273 265921** philippa.case@sussexpartnership.nhs.uk

Thank-you for taking the time to read this information sheet.

Sussex Partnership NHS
NHS Foundation Trust

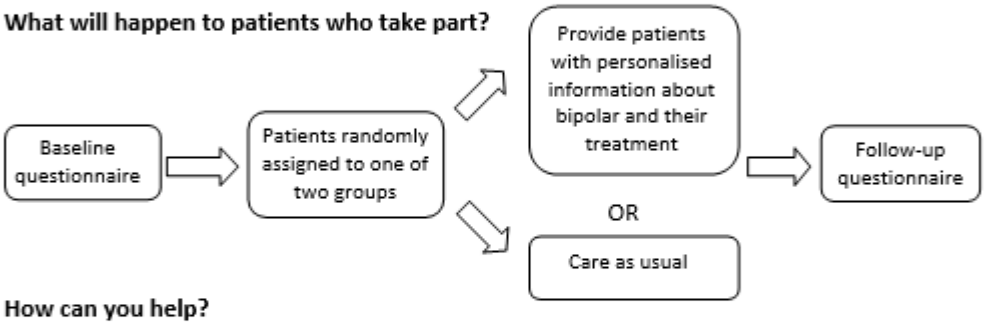
Improving Information for people with Bipolar Disorder (IBiD)

We are currently recruiting adults with bipolar disorder to a new study looking at the effects of providing people with personalised information.

Who?
Patients with bipolar disorder from wards and from the Crisis teams across the Trust.

When?
We are recruiting from June until December 2013.

What will happen to patients who take part?



How can you help?
We are asking ward staff to help identify eligible patients and provide them with an information sheet.

Who can I contact for further information?
If you would like more information, or you have identified a patient who may be interested in taking part please contact us.

Lindsay MacDonald, Researcher, UCL School of Pharmacy,
020 7874 1297 l.macdonald@ucl.ac.uk

Sally Skipper, MHRN Clinical Studies Officer, Sussex Education Centre,
01273 265921 sally.skipper@sussexpartnership.nhs.uk

Kelly Humphryes, MHRN Clinical Studies Officer, Sussex Education Centre,
01273 265921 kelly.humphryes@sussexpartnership.nhs.uk

Philippa Case, MHRN Clinical Studies Officer, Sussex Education Centre,
01273 265921 philippa.case@sussexpartnership.nhs.uk

Study details
NIHR grant number: PB-PG-1207-15248
Research Ethics Ref No: 12/LO/1615
Research & Development Ref: CSP 87823

NHS National Institute for Health Research

UCL

Appendix Q. **Example email to ward staff to update on progress of the study**

Improving Information for people with Bipolar Disorder (IBiD)

Dear colleagues,
This is just a quick email to update you about the IBiD study currently recruiting patients with bipolar disorder across the Trust.
Thank-you to all those already involved for your support and for starting to refer patients to the study.
If we have not yet met as part of our visits to the sites, I hope we can arrange to speak soon and I can tell you about the study.

Recruitment
We have so far recruited 8 participants to the study, but just to remind you we are recruiting until December 2013.
We aim to recruit at least 30 people with a bipolar diagnosis before the end of the year.

An update on our team
Just to update you, Sally Skipper has moved to a different role, so your points of contact now for any potential recruits are Kelly, Philippa (cc'd into email) and myself.

Any new staff members in your teams?
Please let me know if it would be useful for us to come and meet with any new members of staff who may have joined your teams since we started the study. I will be pleased to come and meet with them to discuss the study.

Study documents
Please also let me know if you would like any more copies of either the Participant Information sheets or Staff information sheets and I will bring or send copies to you.

Please feel free to forward this email around your teams as you feel appropriate.

Once again, many thanks for helping us with this study.
Please do not hesitate to get in touch with us about anything relating to the IBiD study or if you have any patients who might be interested in participating.

Best wishes,

Lindsay
(IBiD study coordinator)
(on behalf of the IBiD team; Lindsay MacDonald, Kelly Humphryes & Philippa Case)

Lindsay MacDonald
Follow CBM on twitter @CBM_UCLSoP
Centre for Behavioural Medicine,
UCL School of Pharmacy, Mezzanine Floor, BMA House,
Tavistock Square, London WC1H 9JP
Direct line: + 44 (0) 207 874 1297

Appendix R. **IBiD study consent form**

Participant Consent Form, Version 3, 12/06/13,
REC 12/LO/1615

Sussex Partnership NHS
NHS Foundation Trust

Centre number:
Participant Identification Number:

Improving Information for people with Bipolar Disorder

CONSENT FORM

Name of Researcher leading the study: Professor Rob Horne

Contact Researcher: Lindsay MacDonald

	Please initial box
1. I confirm that I have read and understand the participant information sheet dated, 05/06/13 (Version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3. I understand that if I choose to withdraw, any questionnaires I have already completed will be kept by the research team.	☐
4. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
5. I understand that in the event that I disclose information which may indicate new risk to myself or others, the researcher will be obliged to follow Trust risk procedures that may require release of my personal data.	☐
6. I agree to take part in the above study.	☐

.....	.....	.....
Name of participant	Date	Signature
.....	.....	.....
Name of researcher	Date	Signature

Appendix S. **IBiD randomisation process**

First 10 participants are allocated using a random number table (Kirkwood, Medical Statistics; pg 485, Column 6, first 10 rows).

Coin toss used to allocate even numbers (Heads) for IG and odd numbers (Tails) for CG.

After first 10 participants, use minimisation to balance by age group and gender (Ref Clinical trials A practical guide to design, analysis and reporting).

Pt ID	Gender	DoB	Age	Treatment allocation
	F	**Removed**	59	IG
	F		74	IG
	F		31	CG
	F		34	CG
	M		56	CG
	F		45	CG
	F		37	CG
	M		61	IG
	M		55	IG
	M		39	IG

Participant F 62		IG	CG		IG=6 CG=5 **=CG**
	M F	3 2	1 4	10	
	18-30 31-45 46+	0 1 4	0 4 1	10	
Participant F 47		IG	CG		IG=6 CG=7 **=IG**
	M F	3 2	1 5	11	
	18-30 31-45 46+	0 1 4	0 4 2	11	
Participant M 54		IG	CG		IG=8 CG=3 **=CG**
	M F	3 3	1 5	12	
	18-30 31-45 46+	0 1 5	0 4 2	12	
Participant F 64		IG	CG		IG=8, CG=8 Balanced groups, simple randomisation to determine allocation (coin toss). Heads (IG) Tails (CG) Tails **=CG**
	M F	3 3	2 5	13	
	18-30 31-45 46+	0 1 5	0 4 3	13	
Participant F 47		IG	CG		IG=8 CG=10 **=IG**
	M F	3 3	2 6	14	
	18-30 31-45 46+	0 1 5	0 4 4	14	

Participant F 55		IG	CG	IG=10, CG=10 Balanced groups, simple randomisation to determine allocation (coin toss). Heads (IG) Tails (CG) Heads **=IG**
	M F	3 4	2 6	15
	18-30 31-45 46+	0 1 6	0 4 4	15
Participant F 46		IG	CG	IG=12 CG=10 **=CG**
	M F	3 5	2 6	16
	18-30 31-45 46+	0 1 7	0 4 4	16
Participant F 65		IG	CG	IG=12, CG=12 Balanced groups, simple randomisation to determine allocation (coin toss). Heads (IG) Tails (CG) Tails **=CG**
	M F	3 5	2 7	17
	18-30 31-45 46+	0 1 7	0 4 5	17
Participant F 54		IG	CG	IC=12 CG=14 **=IG**
	M F	3 5	2 8	18
	18-30 31-45 46+	0 1 7	0 4 6	18
Participant M 48		IG	CG	IC=11 CG=8 **=CG**
	M F	3 6	2 8	19
	18-30 31-45 46+	0 1 8	0 4 6	19
Participant F 66		IG	CG	IG=14 CG=15 **=IG**
	M F	3 6	3 8	20
	18-30 31-45 46+	0 1 8	0 4 7	20
Participant F 65		IG	CG	IG=16 CG=15 **=CG**
	M F	3 7	3 8	21
	18-30 31-45 46+	0 1 9	0 4 7	21
Participant M 54		IG	CG	IG=12 CG=11 **=CG**
	M F	3 7	3 9	22
	18-30 31-45 46+	0 1 9	0 4 8	22
Participant F 36		IG	CG	IG=8 CG=13 **=IG**
	M F	3 7	4 9	23
	18-30 31-45 46+	0 1 9	0 4 9	23

Participant M 51		IG	CG	
	M F	3 8	4 9	24
	18-30 31-45 46+	0 2 9	0 4 9	24
Participant F 39		IG	CG	
	M F	4 8	4 9	25
	18-30 31-45 46+	0 2 10	0 4 9	25
Participant F 43		IG	CG	
	M F	4 9	4 9	26
	18-30 31-45 46+	0 3 10	0 4 9	26
Participant HC28 F 44		IG	CG	
	M F	4 10	4 9	27
	18-30 31-45 46+	0 4 10	0 4 9	27
Participant WL29 F 66		IG	CG	
	M F	4 10	4 10	28
	18-30 31-45 46+	0 4 10	0 5 9	28
Participant HC30 F 52		IG	CG	
	M F	4 10	4 11	29
	18-30 31-45 46+	0 4 10	0 5 10	29

IG=12 CG=13 **=IG**
IG=10 CG=13 **=IG**
IG=12 CG=13 **=IG**
IG=14 CG=13 **HC28 = CG**
IG=20 CG=19 **WL29 = CG**
IG=20 CG=21 **HC30 = IG**

Appendix T. **Letter to participants care coordinators**

Sussex Partnership NHS
NHS Foundation Trust

Date (letter sent when pt recruited)

Dear *(named care coordinator)*,

Re: Improving information for people with Bipolar Disorder REC: 12/LO/1615

I am writing to inform you that *(patient's name and dob)* is participating in the above study which is being conducted jointly by Sussex Partnership NHS Foundation Trust and researchers at UCL School of Pharmacy.

The purpose of the study is to evaluate, through a randomised controlled trial, the impact of providing individually tailored information about bipolar and its treatment compared to treatment as usual.

The study has been funded by an NHS National Institute for Health Research: Research for Patient Benefit programme grant (NIHR RfPB) and has received full NHS ethics approval (REC: 12/LO/1615) and approval from Susses partnership NHS Foundation Trust Research and Development department (Ref CSP 87823).

The study involves participants completing baseline questionnaire measures either in hospital or at home with a member of our team. Following this, they are allocated at random to receive either a written information resource alongside a tailored education session with a member of the research team or treatment as usual. Then after 6-8 weeks participants will complete follow-up questionnaires with a member of our team.

For your information, we enclose a copy of the Participant Information Sheet. If you have any questions about the research please do not hesitate to contact either myself on 020 7874 1297, Kelly Humphryes or Philippa Case (MHRN Clinical Studies Officers) 01273 265921.

Yours sincerely

Lindsay MacDonald
Study Coordinator

Enc: Copy of the Participant Information Sheet

Appendix U. **Letter notifying TAU participants of their group allocation**

Date

Sussex Partnership NHS
NHS Foundation Trust

Dear

Re: Improving information for people with Bipolar Disorder REC: 12/LO/1615

You recently completed a questionnaire with a member of our research team at (insert hospital and ward) as part of the study named above. Thank-you for completing this first questionnaire.

This letter is to let you know that you have been assigned to the usual care group for this study. This means that you will continue to receive the standard care and information from your care team.

Half of all people in the study will receive usual care and the other half will receive new written tailored information. This type of study is called a randomised controlled trial (RCT) and is the best way of researching new approaches to treatment to find out which are the best ones. To find out we need to compare the different approaches. We put people into groups and use a different approach with each one. The results in the two groups are compared. To try to make sure the groups are the same to start with, patients are put into groups at random (by chance).

You have been randomly allocated to the usual care group. Although you will not be receiving the new approach you will still be making an important contribution to our research project by taking part.

Everyone in both groups will be asked to complete a second questionnaire about 2 months after their first appointment with the researcher. This should take no longer than about 30 minutes and will take place in a location convenient for your, for example in your home or where your care team work.

You will receive £20 to compensate for your time in taking part in the study.

Your help with this study is very much appreciated.

If you have any questions about this study, please contact me at 020 7874 1297 or by e-mail l.macdonald@ucl.ac.uk , or you can write to me at the address below.

Yours sincerely,

Lindsay MacDonald
Study Coordinator

Appendix V. **IBiD intervention tailoring**

Bipolar: A question of balance

Intervention content tailoring

Correct order

Bipolar
Bipolar beliefs
Stigma
Taking control
Medications meanings
Medication – necessity
Medication – concerns
Medication – practical
Self-monitoring
Working with health professionals

Gets section
Does not automatically receive section

Page	Tailoring	Detail	EA01	WL02	WM08	EB09	CO10	WM12
Title page								
How we hope this booklet can help you								
Understanding bipolar (2 pages)								
Mood mapping								
Is there a cause of bipolar? (2 pages)								
A long journey to diagnosis Making sense of the diagnosis: Does taking medication mean I have to accept I am ill? (2 pages)								
Will I always have bipolar?	Acute beliefs	IPQB_2	3 (acute)	10 (chronic belief)	0 (acute)	10 (chronic belief)	10 (chronic belief)	10 (chronic belief)
'There's such a lot of stigma about giving yourself a label' (2 pages)							No stigma beliefs	
Taking control								
Medications prescribed for bipolar								

Making an Informed choice about medications prescribed for bipolar								
Your thoughts and feelings about taking medication (3 pages)								
I don't feel ill, so why should I continue to take my medication?	Illness identity Necessity beliefs	IPQ_9 BMQ necessity items	0 (does not agree with diagnosis) Average 2	10 (full agreement with diagnosis) Average 4	0 (does not agree with diagnosis) Low necessity beliefs	10 (full agreement	10 (full agreement with diagnosis) High necessity beliefs	10 (full agreement with diagnosis) High necessity beliefs
I don't feel like the medication is working	Necessity beliefs	BMQ IPQ_4 treatment control	Average 2	Average 4	Low necessity beliefs	Strong treatment control	High necessity beliefs IPQ_4 = 10 treatment extremely helpful.	High necessity beliefs IPQ_4 = 10 treatment extremely helpful.
Medication changes: Why does the medication I am given keep changing?								
I've been on the same medication for years, do I need to change?								
I'm worried about the side-effects from these medicines (3 pages)	Side-effect concerns	BMQ_C6 BMQ_C11	All disagree or SD	All disagree or SD	All agree or SA	Numerous moderate side-effects But disagree for BMQ items	Numerous moderate side-effects	Only agree for Diazepam (But reports multiple symptoms of moderate to severe)
I sometimes worry about whether there might be long-term effects of taking these medicines.	LT effects concern	BMQ M1_BMQ_C2	Strongly Disagree Disagree Disagree Disagree	Disagree Agree Strongly Disagree	Disagree	Uncertain/ Agree	Agree for Valproate	SA/A for Lithium & Diazepam
I sometimes worry that I might become addicted to or dependent on the medicines I'm taking.	Dependence concern	BMQ M1_BMQ_C5 M1_BMQ_C8	All disagree or SD	All disagree or SD	Uncertain	Concerns about dependence	Agree for Valproate	Only agree for Diazepam
I dislike the way these medicines make me feel	Med effects concerns	M1_BMQ_C10 M1_BMQ_C11	C10 & C11 All disagree or SD	Uncertain Disagree Disagree C11 all disagree	Agree and SA	Uncertain	C10 & C11 All disagree or SD	Agree/ Uncertain for Diazepam
Taking medication is an unwelcome reminder of my condition	Reminder concerns	BMQ M1_BMQ_C9	All disagree or SD	All disagree or SD	Uncertain	Agree 2/3	All disagree or SD	Only agree for Diazepam

I tend to hide the fact that I am taking these medicines from other people	Hiding concerns	BMQ M1_BMQ_C7	All disagree or SD	All disagree or SD	Disagree	All disagree	All disagree or SD	All SD
Taking these medicines affects my daily life	Disruption Concerns	BMQ M1_BMQ_C4	All disagree or SD	All disagree or SD	Strongly agree	All disagree	Strongly agree for 2/3 meds	Only agree for Diazepam
Alcohol, bipolar and your medication	SIMS	SIMS_12	None needed	About right	About right	About right	None needed	About right
'Sometimes I find it difficult to take my medication' (3 pages)	BMQ – practical barriers				Practical barriers	Sometimes forget to take one med (MARS)	No practical barriers reported	No practical barriers reported
What should I do if I am having any problems and who should I contact in an emergency?								
Monitoring your symptoms and looking after yourself (2 pages)								
Getting the most from your consultations (2 pages)								
Useful resources								

Page	**Tailoring**	**Detail**	**HC15**	**HC16**	**CO21**	**HM24**
Title page						
How we hope this booklet can help you						
Understanding bipolar (2 pages)						
Mood mapping						
Is there a cause of bipolar? (2 pages)						
A long journey to diagnosis Making sense of the diagnosis: Does taking medication mean I have to accept I am ill? (2 pages)						
Will I always have bipolar?	Acute beliefs	IPQB_2	Response 10	Response '6'	Response 8 but 'very unsure about bipolar as was previously schizophrenia'.	Response 10, but answering for situation as no understanding of bipolar.

'There's such a lot of stigma about giving yourself a label' (2 pages)			Stigma beliefs strong	No stigma beliefs	No stigma beliefs	1.86
Taking control						
Medications prescribed for bipolar						
Making an Informed choice about medications prescribed for bipolar						
Your thoughts and feelings about taking medication (3 pages)						
I don't feel ill, so why should I continue to take my medication?	Illness identity Necessity beliefs	IPQ_9 BMQ necessity items	Necessity mixed	Response '9' High necessity beliefs	Response '9' High necessity beliefs	Low necessity beliefs and no understanding of bipolar
I don't feel like the medication is working	Necessity beliefs	BMQ IPQ_4 treatment control	Necessity mixed 6 for IPQ control	Good treatment control High necessity beliefs	Good treatment control (9) High necessity beliefs	Low necessity beliefs and low treatment control
Medication changes: Why does the medication I am given keep changing?						
I've been on the same medication for years, do I need to change?						
I'm worried about the side-effects from these medicines (3 pages)	Side-effect concerns	BMQ_C6 BMQ_C11	BMQ few concerns but many in SAQ	No side effect concerns Or SAQ reporrted	BMQ few concerns but some severe in SAQ	Agree for Olanzapine and many side effects in SAQ
I sometimes worry about whether there might be long-term effects of taking these medicines.	LT effects concern	BMQ M1_BMQ_C2	Agree	No LT effect concerns	No LT effect concerns	Agree
I sometimes worry that I might become addicted to or dependent on the medicines I'm taking.	Dependence concern	BMQ M1_BMQ_C5 M1_BMQ_C8	Agree	Disagree	Disagree	Agree for Zopiclone
I dislike the way these medicines make me feel	Med effects concerns	M1_BMQ_C10 M1_BMQ_C11	Disagree	Disagree	Disagree	Uncertain for Olanzapine
Taking medication is an unwelcome reminder of my condition	Reminder concerns	BMQ M1_BMQ_C9	Agree	Disagree	Disagree	Agree for Olanzapine

I tend to hide the fact that I am taking these medicines from other people	Hiding concerns	BMQ M1_BMQ_C7	Agree	Disagree	Disagree	Agree for Olanzapine
Taking these medicines affects my daily life	Disruption Concerns	BMQ M1_BMQ_C4	Disagree	Disagree	Disagree	Agree for Olanzapine
Alcohol, bipolar and your medication	SIMS	SIMS_12	Too little	None receieved	About right	None received
'Sometimes I find it difficult to take my medication' (3 pages)	BMQ – practical barriers		Sometimes difficulty in remembering	Sometimes difficulty in remembering	No practical barriers reported, MARS full compliance	Some practical difficulties
What should I do if I am having any problems and who should I contact in an emergency?						
Monitoring your symptoms and looking after yourself (2 pages)						
Getting the most from your consultations (2 pages)						
Useful resources						
Completing your own mood chart (4 pages)						

Page	**Tailoring**	**Detail**	**WM25**	**HC26**	**WR27**	**HC30**	
Title page							
How we hope this booklet can help you							
Understanding bipolar (2 pages)							
Mood mapping							
Is there a cause of bipolar? (2 pages)							
A long journey to diagnosis Making sense of the diagnosis: Does taking medication mean I have to accept I am ill? (2 pages)							
Will I always have bipolar?	Acute beliefs	IPQB_2	Response 10	Response 10	Response 10	Response 10	
'There's such a lot of stigma about giving yourself a label' (2 pages)			2.03	2.39	2.89	2.10	
Taking control							
Medications prescribed for bipolar							

Making an Informed choice about medications prescribed for bipolar							
Your thoughts and feelings about taking medication (3 pages)							
I don't feel ill, so why should I continue to take my medication?	Illness identity Necessity beliefs	IPQ_9 BMQ necessity items	Low necessity beliefs Good understanding	Low necessity beliefs Low understanding of bipolar	High necessity beliefs Full agreement with diagnosis	Uncertain necessity for Olanzepine, Venlafaxin, Mirtazepine Agreement with diagnosis 6 for understanding.	
I don't feel like the medication is working	Necessity beliefs	BMQ IPQ_4 treatment control	Low necessity beliefs and 5 treatment control	Low necessity beliefs, 8 for control	High necessity beliefs 10 for treatment control	Uncertain necessity beliefs, 8 for treatment control	
Medication changes: Why does the medication I am given keep changing?							
I've been on the same medication for years, do I need to change?							
I'm worried about the side-effects from these medicines (3 pages)	Side-effect concerns	BMQ_C6 BMQ_C11	Agree Some severe side-effects	Side effects from Halperidol/ Mild moderate in SAQ	Side effects from Lithium, Quetiapine, Clonazepam SAQ – many severe.	SE for Olanzepine & mirtazepine. Some moderate SE on SAQ.	
I sometimes worry about whether there might be long-term effects of taking these medicines.	LT effects concern	BMQ M1_BMQ_C2	Strongly agree	Agree Valproate & Halperidol	Agree for Lithium, Clonazepam	Agree for Olanzepine, Venlafaxin, Mirtazepine	
I sometimes worry that I might become addicted to or dependent on the medicines I'm taking.	Dependence concern	BMQ M1_BMQ_C5 M1_BMQ_C8	Strongly agree	Disagree for all	Agree for Lorazepam, Zolpidem & Clonazepam	Agree for Olanzepine, Venlafaxin, Mirtazepine	
I dislike the way these medicines make me feel	Med effects concerns	M1_BMQ_C10 M1_BMQ_C11	Strongly agree	Agree Halperidol	Agree Quetiapine, Lorazepam,	Agree for Mirtazepine	

					Zolpidem, Clonazepam		
Taking medication is an unwelcome reminder of my condition	Reminder concerns	BMQ M1_BMQ_C9	Disagree	Agree Halperidol	Disagree for all	Disagree for all	
I tend to hide the fact that I am taking these medicines from other people	Hiding concerns	BMQ M1_BMQ_C7	Agree	Disagree for all	Agree for Lorazepam only	Disagree for all	
Taking these medicines affects my daily life	Disruption Concerns	BMQ M1_BMQ_C4	Strongly agree	Disagree for all	Disagree for all	Agree for Venlafaxin, Mirtazepine	
Alcohol, bipolar and your medication	SIMS	SIMS_12	About right	Too little	None needed	About right	
'Sometimes I find it difficult to take my medication' (3 pages)	BMQ – practical barriers		No practical barriers reported, MARS full compliance	Sometimes difficulty in remembering Sometimes forget Valproate	Sometimes difficulty in remembering	Sometimes difficulty in remembering Sometimes forget all meds	
What should I do if I am having any problems and who should I contact in an emergency?							
Monitoring your symptoms and looking after yourself (2 pages)							
Getting the most from your consultations (2 pages)							
Useful resources							
Completing your own mood chart (4 pages)							

Appendix W. **Example of Patient Information Sheets for medications**

Sussex Partnership NHS
NHS Foundation Trust

Valproate (pron. val-pro-eight)

What is valproate used for?
Valproate is the name of the active part of sodium valproate (also known as Epilim®, Episenta®), valproic acid (Convulex®) and semisodium valproate (Depakote®). It is mainly used to help treat the symptoms of bipolar mood disorder (especially mania but also depression as well) and epilepsy. It can help stop people having seizures or fits if taking higher doses of clozapine. It is also used to help the symptoms of some other conditions e.g. headache. It is made as tablets, capsules, crushable tablets, a sugar-free liquid, a syrup, granules and injection.

What is the usual dose of valproate?
The usual dose of valproate is around 400-2000mg a day, but this depends on what you are taking it for.

How should I take valproate?
Swallow the tablets with at least half a glass of water whilst sitting or standing. This is to make sure that they reach the stomach and do not stick in your throat. For the liquid and syrup, use a medicine spoon, dropper or oral syringe. Use it carefully to make sure you measure the correct amount. Episenta® capsules can be emptied onto cold food or drink and swallowed straight away without chewing, as can the granules.

When should I take valproate?
Take your valproate as directed on the medicine label. Try to take it at regular times each day. Taking it at mealtimes may make it easier for you to remember as there is no problem about taking valproate with or after food. If the label says to take it once a day this is usually best at bedtime as it may make you drowsy at first.

What are the alternatives to valproate?
This will depend on what you are taking it for. There are many other medicines for epilepsy; and other medicines (e.g. quetiapine, olanzapine, lithium), talking therapies and treatments mood disorders.

How long will valproate take to work?
This will depend on what you are taking it for. Please look at one of the "Handy charts" for more help and advice.

How long will I need to keep taking valproate for?
This will depend on what you are taking it for but is likely to be for several months or years.

Is valproate addictive?
Valproate is not addictive but you should not stop it suddenly (see the next question).

Can I stop taking valproate suddenly?
It is unwise to stop taking it suddenly, even if you feel better. Your symptoms can return if treatment is stopped too early. This may occur some weeks or even months after valproate has been stopped. When the time comes, you should withdraw valproate by a gradual reduction in the dose over several weeks. You should discuss this fully with your doctor, nurse or pharmacist.

What should I do if I forget to take a dose of valproate?
Take the missed dose as soon as you remember unless it is within about 4 hours of your next dose. If you remember after this just take the next dose as normal. Do not try to catch up by taking two doses at once as you may get more side-effects. You should tell your doctor about this next time you meet. If you have problems remembering your doses (as many people do) ask your pharmacist, doctor or nurse about this.

Can I drink alcohol while I am taking valproate?
If you drink alcohol while taking valproate it may make you feel more sleepy. This is particularly important if you need to drive or operate machinery and you must seek advice on this.

Will valproate affect my other medication?
Valproate has a few interactions with other medicines:

- Valproate should only be used with care with phenytoin
- If you have enteric coated tablets or capsules, do not take indigestion remedies at the same time of day
- The effects of valproate can sometimes be increased by erythromycin or fluoxetine
- The effect of valproate can be decreased by antiretrovirals, some antibiotics (e.g. meropenem), carbamazepine, topiramate or oxcarbazepine
- Valproate can sometimes decrease the effect of olanzapine
- You should have no problems with "The Contraceptive Pill" and valproate (but see the last question).
- Valproate can increase the effect of tricyclics (e.g. dosulepin, lofepramine), some antiretrovirals for HIV (e.g. zidovudine), carbamazepine, lamotrigine, phenobarbital, rufinamide, tiagabine or phenytoin.

Not all of these interactions happen in everyone. Some of these medicines can still be used together but you will need to follow your doctor's instructions carefully. There are many other possible drug interactions.

What sort of side-effects might occur if I am taking valproate?

The table below will show you some of the main side effects you might get from valproate.

Side effect	What happens	What to do about it
COMMON *(more than about 1 in 10 people might get these)*		
Increase in appetite and weight gain	Eating more and putting on weight.	A diet full of vegetables and fibre should help prevent weight gain.
UNCOMMON *(less than about 1 in 10 people might get these)*		
Gastric irritation	You have an upset stomach. This usually happens at the start of treatment.	Take your valproate with or after food. If this is severe or does not go away, see your doctor now.
Hair loss	Some of your hair falls out and may seem thinner. This stops after a while.	Discuss with your doctor. This can be upsetting for some people. Sometimes it grows back a little curly.
Nausea	Feeling sick.	If it is bad, contact your doctor.
RARE *(less than about 1 in 100 people might get these)*		
Sleepiness	Feeling sleepy or sluggish.	Don't drive or use machinery. This usually happens early in treatment and should go away. Ask your doctor if you can take your valproate at a different time.
Impaired liver function	Your liver is not working very well.	You may feel sleepy, be sick, lose your appetite and your skin may look yellow. Stop taking valproate and see your doctor now.
Tremor	Feeling shaky.	Your dose of valproate may be too high. Talk to your doctor.
Ataxia	Being unsteady on your feet.	Your dose may be too high. Contact your doctor now.
Confusion	Your mind is all mixed up.	Your dose may be too high. Contact your doctor now.
Lethargy	You feel tired all the time and don't feel like doing anything.	Your dose may be too high. Contact your doctor now.
Thrombocyto-penia and impaired platelet function	Low numbers of platelets in your blood. The platelets that are there may not work very well.	You may bruise without reason and bleed easily. Stop taking valproate and see your doctor now.
Rash	A rash or itching seen anywhere on the skin.	Stop taking your valproate and contact your doctor now.

Do not be worried by this list of side effects. Some people get no side effects at all and others may get some effects that are not listed in this table. If you think you might have a side effect to your medicine, you should ask your doctor, nurse or pharmacist. If you want to know more, go to our website for links to other websites with more information.

Will I need a blood test if I am taking valproate?

You will need some tests to check on your blood levels and liver for the first 6 months or so.

Can I drive or cycle while I am taking valproate?

You may feel a bit sleepy at first when taking valproate. You should be careful as it may slow down your reaction times. Until this wears off, or you know how valproate affects you, do not drive or operate machinery.

What about pregnancy?

You **must** get **expert advice** if you want to become pregnant while taking valproate. If you unexpectedly find you are pregnant don't panic, don't stop taking the valproate, but see your doctor straight away. There are some things you can do to reduce the risk to your unborn child (e.g. the dose, how often you take it, taking folic acid as well) and you also need to think about the risks of becoming ill again e.g. epilepsy or bipolar disorder.

The small print: This leaflet is to help you understand about your medicine. You should also read the manufacturer's Patient Information Leaflet (PIL). You may find lots more on the internet but beware as internet-based information is not always accurate. Do not share medicines with anyone else. Go to our website for fuller answers to these and many other questions e.g. driving, women's health, how it works, doses and interactions, and about the conditions. The "Handy charts" will help you compare the main medicines for each condition, how they work and their side effects.

Appendix X. **COREQ Checklist for Chapter 7**

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	7.2
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	6.4.12
Occupation	3	What was their occupation at the time of the study?	6.4.12
Gender	4	Was the researcher male or female?	n/a
Experience and training	5	What experience or training did the researcher have?	6.4.12
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	7.2
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	7.2
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	7.5.8
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7.3
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7.2
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	7.2
Sample size	12	How many participants were in the study?	7.4
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7.4
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7.2
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	n/a
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	Table 7.1
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Apppendix BB
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	n/a
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7.2
Field notes	20	Were field notes made during and/or after the inter view or focus group?	n/a
Duration	21	What was the duration of the inter views or focus group?	7.4
Data saturation	22	Was data saturation discussed?	7.5.8
Transcripts returned	23	Were transcripts returned to participants for comment and/or	n/a

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	7.3
Description of the coding tree	25	Did authors provide a description of the coding tree?	Figs 7.1 & 7.2
Derivation of themes	26	Were themes identified in advance or derived from the data?	7.3
Software	27	What software, if applicable, was used to manage the data?	7.3
Participant checking	28	Did participants provide feedback on the findings?	n/a
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	7.4
Data and findings consistent	30	Was there consistency between the data presented and the findings?	7.4
Clarity of major themes	31	Were major themes clearly presented in the findings?	7.4
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	7.4

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Appendix Y. **Confirmation of ethical approval for IBiD qualitative evaluation**

NHS
Health Research Authority

NRES Committee London - Queen Square
HRA Head Office
Skipton House
80 London Road
London
SE1 6LH

Tel: 020 797 22580

21 October 2013

Professor Rob Horne
Head of Department of Practice & Policy, Director of Centre for Behavioral Medicine
UCL School of Pharmacy
UCL School of Pharmacy, Mezzanine Floor
BMA House, Tavistock Square
London
WC1H 9JP

Dear Professor Horne

Study title:	**A pilot randomised controlled trial of a theory-based, tailored intervention designed to address perceptions of illness and treatment, for people prescribed medication for Bipolar Disorder.**
REC reference:	**12/LO/1615**
Amendment number:	**Substantial Amendment 1- Revised Documentation- Protocol V3**
Amendment date:	**20 September 2013**
IRAS project ID:	**87823**

The above amendment was reviewed at the meeting of the Sub-Committee held on 17 October 2013.

Ethical opinion

No ethical issues.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter to Control Group Participants	1	01 August 2013
Participant Consent Form	1	01 August 2013
Notice of Substantial Amendment (non-CTIMPs)	Substantial Amendment 1- Revised Documentation- Protocol V3	20 September 2013
Participant Information Sheet	3	01 August 2013
Participants Information Sheet- Interviews	1	01 August 2013
Semi Structured Interview Schedule	1	01 August 2013

Covering Letter	Letter from Lindsay MacDonald	24 September 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

12/LO/1615:	**Please quote this number on all correspondence**

Yours sincerely

pp

Dr Yogi Amin
Chair

E-mail: NRESCommittee.London-Central@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Tanya Telling, Sussex Partnership NHS Foundation Trust*

Appendix Z. **IBiD qualitative evaluation Patient Information Sheet**

Sussex Partnership NHS
NHS Foundation Trust

Improving Information for people with Bipolar Disorder (IBiD)

Your views about the study

Participant Information Sheet

Invitation

Thank-you for taking part in the study, we are very grateful for your time.

We would like to invite you to take part in one final thing. We are interested to hear your views of what it was like to take part in the study.

Before you decide whether or not to take part it is important for you to understand why we are asking this and what it will involve. Please take time to read this information carefully. A member of our team can go through the information with you and answer any questions you may have.

What is the purpose of this part of the study?

This part of the study will help us to identify how we can improve the design of future studies like this. We would like to make sure that people are able to take part without too much inconvenience and that being part of the study fits in with their lives.

Because this is a new study, being carried out for the first time, it is important to know how people have found the experience and what they thought of any information they have been given.

Why have I been chosen?

You have been chosen because you have taken part in the main research study. We are inviting everyone who has taken part in the study to participate in this follow-up interview.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to change your mind at any time and without giving a reason. A decision not to take part, or a decision to withdraw at any time, will not affect the care that you receive.

What will happen to me if I take part?

If you are interested in taking part after reading this Information Sheet please contact us using the contact details at the end of this information sheet.

If you decide to take part, we will arrange a convenient time to carry out the interview. The interview will take place over the telephone or in a location convenient for you, and you will be asked about your experience of taking part in the study. We will ask for your permission to audio-tape the interview so we have an accurate record. Only the research team will listen back to the recording. This should take no more than 30 minutes.

Will my taking part in the interview be kept confidential?

Yes. All the information you give during the interview will be confidential and only the research team will have access to your responses. All information you provide will be stored securely. The notes from your interview will not have your name on them, (a number will be used instead) so it will not be

possible for people to match any information to you personally. The study complies with data protection laws.

What are the possible benefits of taking part?

By taking part in the interview you will help us to find out about people's experience of the study and you will help us learn if this approach is helpful.

What are the possible disadvantages of taking part?

It is unlikely that there are any risks or disadvantages of taking part.

Who is organising and funding this study?

This study is being led by Professor Rob Horne, Professor of Behavioural Medicine at UCL School of Pharmacy in collaboration with Sussex Partnership NHS Foundation Trust. The research is being funded by the Research for Patient Benefit Programme, National Institute for Health Research. The study is part of a PhD being undertaken by Miss Lindsay MacDonald.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the London Queen Square Research Ethics Committee (Ref No: 12/LO/1615) as well as by the Research and Development Department within your local NHS trust. Contact details of the London Queen Square Research Ethics Committee: Health Research Authority, HRA Head Office, Skipton House, 80 London Road, London SE1 6LH. Phone: 020 7972 2584

What should I do now?

If you are interested in taking part in the interview after reading this Information Sheet please contact me using the details below.

Lindsay MacDonald (Researcher), UCL School of Pharmacy.
Phone: 020 7874 1297
Email: l.macdonald@ucl.ac.uk
Address: Dept. of Practice and Policy, UCL School of Pharmacy
Mezzanine Floor, BMA House, Tavistock Square
London WC1H 9JP

Thank-you for taking the time to read this information

Appendix AA.**IBiD qualitative evaluation consent form**

Sussex Partnership NHS
NHS Foundation Trust

Centre number:
Participant Identification Number:

Improving Information for people with Bipolar Disorder
Your views about the study

CONSENT FORM

Name of Researcher leading the study: Professor Rob Horne

Contact Researcher: Lindsay MacDonald

	Please initial box
1. I confirm that I have read and understand the participant information sheet dated, 02/08/13 (Version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree to my interview being audio-taped for the purposes of the study and any personal information will be removed.	
4. I understand that in the event that I disclose information which may indicate new risk to myself or others, the researcher will be obliged to follow Trust risk procedures that may require release of my personal data.	
5. I agree to take part in the interview.	

.....	.....	.....
Name of participant	Date	Signature
.....	.....	.....
Name of researcher	Date	Signature

Appendix BB.**Semi-structured interview schedule for IBiD participants**

Semi-structured interview schedule for IBiD participants

The interview schedule will be adapted to be appropriate to each individual participant.
Introduce self and remind purpose of interview.
Reiterate confidentiality
No right or wrong answers, interested in your personal experience with the study.

1	What made you decide to participate? Probe - What kind of things did you consider? How did you find the explanation of what would be involved? What did you think of the timing of the study? (ie approached whilst in hospital)
2	How did you find completing the first questionnaires while you were in the hospital? Probe – length of time, arranging appointment, type of questions, timing of baseline.
3	How did you feel about being assigned to the group receiving usual care/ the new information?
4	**Intervention group** How did you find the session? What did you think of the booklet? (What were the most/ least useful sections?) What did you think of the exercises in the booklet? Did you share any of the information with anyone in your care team? Was there anything missing? Would you recommend the information to other people with a diagnosis of bipolar? How did you feel about timing of the session?
	Both groups... What information did you receive about bipolar and medication? From the ward? From other sources? When did you receive the information? How do you feel it answered your questions/ addressed any concerns you had about medication? If any medication changes – how were any changes to the dose or type of medication you were taking decided on?
5	How did you find completing the last questionnaires after you were discharged from hospital? Probe – length of time, arranging appointment, type of questions, timing of follow-up.
6	Overall, how did you feel about being involved in the study?
7	What, if anything else, would help with your understanding or getting the best from your medication?
8	Is there anything else we have not already covered you would like to tell us about?

Appendix CC. **Advertisement for SDM study**

Your involvement in decisions about your treatment for Bipolar Disorder

We are conducting a survey to find out more about how involved people with a diagnosis of bipolar disorder are in decisions about their care and how this relates to how they feel about the medications they are prescribed.

By taking part, you can enter into a prize draw to win one of 3 £50 Amazon vouchers.

Who can take part?

If you are over 18 years of age, live in the UK, have a diagnosis of bipolar disorder and have been prescribed medication for this, you are eligible to take part.

What will taking part involve?

We will ask you to complete some online questionnaires. These will ask for;

- your views and experience of making decisions about your care and treatment
- how you feel about your medications for bipolar disorder.

It should take no more than 15 minutes to complete the survey.

The survey is completely confidential and has received ethical approval from UCL Research Ethics Committee (6811/001). All information you provide will be stored securely in agreement with the Data Protection Act.

Please click on the link below to find out more and to take part in the survey.

https://uclpharmacy.eu.qualtrics.com/SE/?SID=SV_3e0RONc5SWdPS6h

Lindsay MacDonald (PhD Researcher), UCL School of Pharmacy.

Email: l.macdonald@ucl.ac.uk

Appendix DD. **SDM study PIS and questionnaire**

Default Question Block

Your involvement in decisions about your treatment for Bipolar Disorder

Participant Information Sheet

We would like to invite you to take part in our research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and contact us if you have any questions.

What is the purpose of the study?
This study aims to find out more about how involved people with a diagnosis of bipolar disorder are in decisions about their care and how this relates to how they feel about the medications they are prescribed.

We hope that by understanding this better we can begin to develop ways of helping people to become more involved in and better informed about their care and to help people find the best treatment for them.

Who can take part in the study?
If you are over 18 years of age, live in the UK, have a diagnosis of bipolar disorder and have been prescribed medication for this, you are eligible to take part.

What does participating in the study involve?
If you are interested in taking part after reading this information we will ask you to complete a consent from on the next page. If you consent to take part, you will be asked to complete an online questionnaire. This should take about 15 minutes.
The questionnaire will ask for your views and experience of making decisions about your care and treatment and how you feel about your medications as well as your thoughts about your diagnosis and some questions about how you are feeling at the moment.

Will my taking part in this study be kept confidential?
Yes. All the information you give during the study will be confidential and only the research team will have access to your responses. All information you provide will be stored securely in agreement with the Data Protection Act.

Are there any benefits to taking part?
Taking part in this study may not have any direct benefits. However, if you provide your contact details, you will be entered into a prize draw to win one of 3 x £50 Amazon vouchers.

What are the possible disadvantages of taking part?
It is unlikely that there are any risks or disadvantages of taking part in this study. If however, you feel you need support or information after completing the questionnaires we have provided contact details for support organisations at the end of the study.

What if I change my mind?
You can choose to leave the study at any point whilst completing the questionnaires.

What will happen to the results of the research study?
The results of the study will be written up for publication in an academic journal. If you would like a copy of the published results of the study, please give your contact details at the end of the questionnaire and we will send them to you when they become available.

Who is organising and funding this study?
This study is being led by Professor Rob Horne, Professor of Behavioural Medicine at UCL School of Pharmacy. The research is being funded by the National Institute for Health Research. The study is part of a PhD being undertaken by Miss Lindsay MacDonald.

Who has reviewed the study?
This study has been reviewed and approved by UCL Research Ethics Committee (6811/001).

Where can I get further information about the study?
For further information about the study please contact:
Lindsay MacDonald (PhD Researcher), UCL School of Pharmacy
Email: l.macdonald@ucl.ac.uk

Thank-you for taking the time to read this information

Your involvement in decisions about your treatment for Bipolar Disorder

Consent Form

Name of Researcher leading the study: Professor Rob Horne

Contact Researcher: Lindsay MacDonald

This study has been approved by the UCL Research Ethics Committee (6811/001):

Thank you for your interest in taking part in this research.

1. I confirm that I have read and understand the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

3. I understand that my information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

Please select one of the options below

I have read the information above and I agree to participate in the study.	I do NOT wish to participate in the study
○	○

This study aims to find out more about how involved people with a diagnosis of bipolar disorder are in decisions about their care and how this relates to how they feel about the medications they are prescribed.

We hope that by understanding this better we can begin to develop ways of helping people to become more involved in and better informed about their care and to help people find the best treatment for them.

The survey should take around 15 minutes to complete.

Please answer the questions as completely and honestly as possible.

Please don't feel that you have to spend a long time over each question. Often the first answer that comes to you is the best.

The questionnaire is completely confidential and your responses will be seen only by the research team.

Medicines prescribed for your bipolar

We would like to ask you about the medicines you are prescribed for bipolar.

We know that you may be taking several different medicines for bipolar and that you may have different views about each one.

We would therefore like to ask you about your medicines separately.

Please write the names of each medication you are taking for bipolar in the boxes below. Don't worry about spelling.

If you are taking a lot of medications and you don't want to tell us about all of them then just complete the ones you do wish to tell us about.

	Medication	How do you take this medication?		How long have you been prescribed this medication, on this occasion?
	Name	Tablet	Injection	(please specify approximately also stating weeks/ months/ years)
1		○	○	
2		○	○	
3		○	○	
4		○	○	
5		○	○	

Your views about ${q://QID8%231/ChoiceTextEntryValue/1/1}

Please think about **${q://QID8%231/ChoiceTextEntryValue/1/1}** when answering the questions on this page.

We would like to ask for your views about this medicine. Below are statements that other people have made about their medicines.

Please show how much you agree or disagree with them by selecting one response for each statement.

There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on this medicine	○	○	○	○	○
Having to take this medicine worries me	○	○	○	○	○
My life would be impossible without this medicine	○	○	○	○	○
I sometimes worry about long-term effects of this medicine	○	○	○	○	○
Without this medicine I would be very ill	○	○	○	○	○
This medicine is a mystery to me	○	○	○	○	○
My health in the future will depend on this medicine	○	○	○	○	○
This medicine disrupts my life	○	○	○	○	○
I sometimes worry about becoming too dependent on this medicine	○	○	○	○	○
This medicine protects me from becoming worse	○	○	○	○	○
This medicine gives me unpleasant side effects	○	○	○	○	○
I tend to hide the fact that I am I am taking this medicine from other people	○	○	○	○	○
I sometimes worry about becoming addicted to this medicine	○	○	○	○	○
Having to use this medicine is an unpleasant reminder of my condition	○	○	○	○	○
This medicine makes me feel 'flat'	○	○	○	○	○
I dislike the way this medicine makes me feel	○	○	○	○	○
I need to take this medicine to prevent going into hospital	○	○	○	○	○

Using ${q://QID8%231/ChoiceTextEntryValue/1/1}

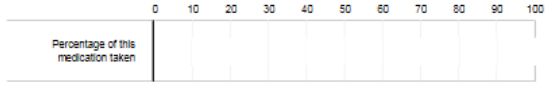
Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use **${q://QID8%231/ChoiceTextEntryValue/1/1}**.

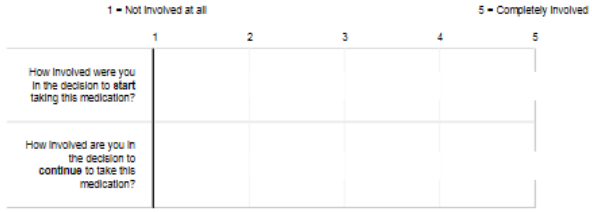
Here are some ways in which people have said that they use their medicines. For each of the statements, please select the option which best applies to you.

	Always	Often	Sometimes	Rarely	Never
I forget to take them	○	○	○	○	○
I alter the dose	○	○	○	○	○
I stop taking them for a while	○	○	○	○	○
I decide to miss out a dose	○	○	○	○	○
I take less than instructed	○	○	○	○	○

Approximately what percentage of **${q://QID8%231/ChoiceTextEntryValue/1/1}** do you think you take?
Please move the slider along the line to show this, for example, if you think you take about half of this medication, move the slider to 50%.



Your involvement in decisions about **${q://QID8%231/ChoiceTextEntryValue/1/1}**



Thank-you for telling us about this medication.
If you wish to tell us about your next medication (if applicable) please click 'Next medication'.
If you wish to skip to the next section about your experience in being involved in decisions about your treatment, please click 'Skip to next section'..

○ Next medication ○ Skip to next section

Your views about ${q://QID8%231/ChoiceTextEntryValue/2/1}

Please think about **${q://QID8%231/ChoiceTextEntryValue/2/1}** when answering the questions on this page.

We would like to ask for your views about this medicine. Below are statements that other people have made about their medicines.

Please show how much you agree or disagree with them by selecting one response for each statement.

There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on this medicine	○	○	○	○	○
Having to take this medicine worries me	○	○	○	○	○
My life would be impossible without this medicine	○	○	○	○	○
I sometimes worry about long-term effects of this medicine	○	○	○	○	○
Without this medicine I would be very ill	○	○	○	○	○
This medicine is a mystery to me	○	○	○	○	○
My health in the future will depend on this medicine	○	○	○	○	○
This medicine disrupts my life	○	○	○	○	○
I sometimes worry about becoming too dependent on this medicine	○	○	○	○	○
This medicine protects me from becoming worse	○	○	○	○	○
This medicine gives me unpleasant side effects	○	○	○	○	○
I tend to hide the fact that I am I am taking this medicine from other people	○	○	○	○	○
I sometimes worry about becoming addicted to this medicine	○	○	○	○	○
Having to use this medicine is an unpleasant reminder of my condition	○	○	○	○	○
This medicine makes me feel 'flat'	○	○	○	○	○
I dislike the way this medicine makes me feel	○	○	○	○	○
I need to take this medicine to prevent going into hospital	○	○	○	○	○

Using ${q://QID8%231/ChoiceTextEntryValue/2/1}

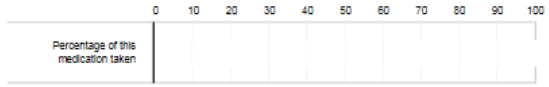
Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use **${q://QID8%231/ChoiceTextEntryValue/2/1}**.

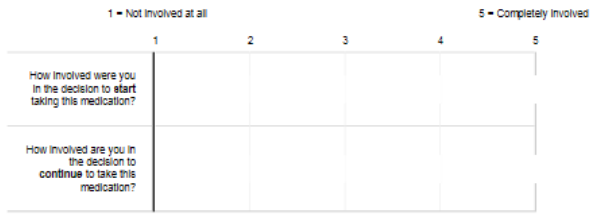
Here are some ways in which people have said that they use their medicines. For each of the statements, please select the option which best applies to you.

	Always	Often	Sometimes	Rarely	Never
I forget to take them	○	○	○	○	○
I alter the dose	○	○	○	○	○
I stop taking them for a while	○	○	○	○	○
I decide to miss out a dose	○	○	○	○	○
I take less than instructed	○	○	○	○	○

Approximately what percentage of **${q://QID8%231/ChoiceTextEntryValue/2/1}** do you think you take?
Please move the slider along the line to show this, for example, if you think you take about half of this medication, move the slider to 50%.



Your involvement in decisions about **${q://QID8%231/ChoiceTextEntryValue/2/1}**



Thank-you for telling us about this medication.
If you wish to tell us about your next medication (if applicable) please click 'Next medication'.
If you wish to skip to the next section about your experience in being involved in decisions about your treatment, please click 'Skip to next section'..

○ Next medication ○ Skip to next section

Your views about ${q://QID8%231/ChoiceTextEntryValue/3/1}

Please think about **${q://QID8%231/ChoiceTextEntryValue/3/1}** when answering the questions on this page.

We would like to ask for your views about this medicine. Below are statements that other people have made about their medicines.

Please show how much you agree or disagree with them by selecting one response for each statement.

There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on this medicine	○	○	○	○	○
Having to take this medicine worries me	○	○	○	○	○
My life would be impossible without this medicine	○	○	○	○	○
I sometimes worry about long-term effects of this medicine	○	○	○	○	○
Without this medicine I would be very ill	○	○	○	○	○
This medicine is a mystery to me	○	○	○	○	○
My health in the future will depend on this medicine	○	○	○	○	○
This medicine disrupts my life	○	○	○	○	○
I sometimes worry about becoming too dependent on this medicine	○	○	○	○	○
This medicine protects me from becoming worse	○	○	○	○	○
This medicine gives me unpleasant side effects	○	○	○	○	○
I tend to hide the fact that I am I am taking this medicine from other people	○	○	○	○	○
I sometimes worry about becoming addicted to this medicine	○	○	○	○	○
Having to use this medicine is an unpleasant reminder of my condition	○	○	○	○	○
This medicine makes me feel 'flat'	○	○	○	○	○
I dislike the way this medicine makes me feel	○	○	○	○	○
I need to take this medicine to prevent going into hospital	○	○	○	○	○

Using ${q://QID8%231/ChoiceTextEntryValue/3/1}

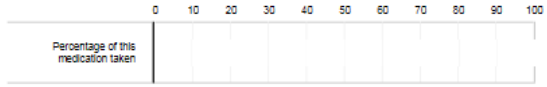
Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use **${q://QID8%231/ChoiceTextEntryValue/3/1}**.

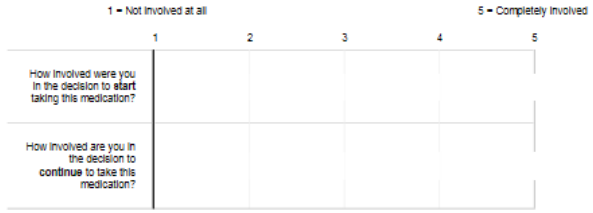
Here are some ways in which people have said that they use their medicines. For each of the statements, please select the option which best applies to you.

	Always	Often	Sometimes	Rarely	Never
I forget to take them	○	○	○	○	○
I alter the dose	○	○	○	○	○
I stop taking them for a while	○	○	○	○	○
I decide to miss out a dose	○	○	○	○	○
I take less than instructed	○	○	○	○	○

Approximately what percentage of **${q://QID8%231/ChoiceTextEntryValue/3/1}** do you think you take?
Please move the slider along the line to show this, for example, if you think you take about half of this medication, move the slider to 50%.



Your involvement in decisions about **${q://QID8%231/ChoiceTextEntryValue/3/1}**



Thank-you for telling us about this medication.
If you wish to tell us about your next medication (if applicable) please click 'Next medication'.
If you wish to skip to the next section about your experience in being involved in decisions about your treatment, please click 'Skip to next section'..

○ Next medication ○ Skip to next section

Your views about ${q://QID8%231/ChoiceTextEntryValue/4/1}

Please think about **${q://QID8%231/ChoiceTextEntryValue/4/1}** when answering the questions on this page.

We would like to ask for your views about this medicine. Below are statements that other people have made about their medicines.

Please show how much you agree or disagree with them by selecting one response for each statement.

There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on this medicine	○	○	○	○	○
Having to take this medicine worries me	○	○	○	○	○
My life would be impossible without this medicine	○	○	○	○	○
I sometimes worry about long-term effects of this medicine	○	○	○	○	○
Without this medicine I would be very ill	○	○	○	○	○
This medicine is a mystery to me	○	○	○	○	○
My health in the future will depend on this medicine	○	○	○	○	○
This medicine disrupts my life	○	○	○	○	○
I sometimes worry about becoming too dependent on this medicine	○	○	○	○	○
This medicine protects me from becoming worse	○	○	○	○	○
This medicine gives me unpleasant side effects	○	○	○	○	○
I tend to hide the fact that I am I am taking this medicine from other people	○	○	○	○	○
I sometimes worry about becoming addicted to this medicine	○	○	○	○	○
Having to use this medicine is an unpleasant reminder of my condition	○	○	○	○	○
This medicine makes me feel 'flat'	○	○	○	○	○
I dislike the way this medicine makes me feel	○	○	○	○	○
I need to take this medicine to prevent going into hospital	○	○	○	○	○

Using ${q://QID8%231/ChoiceTextEntryValue/4/1}

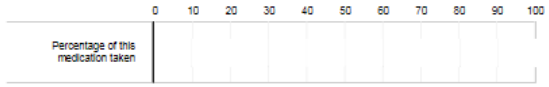
Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use **${q://QID8%231/ChoiceTextEntryValue/4/1}**.

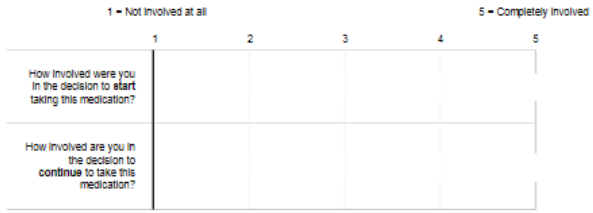
Here are some ways in which people have said that they use their medicines. For each of the statements, please select the option which best applies to you.

	Always	Often	Sometimes	Rarely	Never
I forget to take them	○	○	○	○	○
I alter the dose	○	○	○	○	○
I stop taking them for a while	○	○	○	○	○
I decide to miss out a dose	○	○	○	○	○
I take less than instructed	○	○	○	○	○

Approximately what percentage of **${q://QID8%231/ChoiceTextEntryValue/4/1}** do you think you take?
Please move the slider along the line to show this, for example, if you think you take about half of this medication, move the slider to 50%.



Your involvement in decisions about **${q://QID8%231/ChoiceTextEntryValue/4/1}**



Thank-you for telling us about this medication.
If you wish to tell us about your next medication (if applicable) please click 'Next medication'.
If you wish to skip to the next section about your experience in being involved in decisions about your treatment, please click 'Skip to next section'..

○ Next medication ○ Skip to next section

Your views about ${q://QID8%231/ChoiceTextEntryValue/5/1}

Please think about **${q://QID8%231/ChoiceTextEntryValue/5/1}** when answering the questions on this page.

We would like to ask for your views about this medicine. Below are statements that other people have made about their medicines.

Please show how much you agree or disagree with them by selecting one response for each statement.

There are no right or wrong answers. We are interested in your personal views.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
My health, at present, depends on this medicine					
Having to take this medicine worries me					
My life would be impossible without this medicine					
I sometimes worry about long-term effects of this medicine					
Without this medicine I would be very ill					
This medicine is a mystery to me					
My health in the future will depend on this medicine					
This medicine disrupts my life					
I sometimes worry about becoming too dependent on this medicine					
This medicine protects me from becoming worse					
This medicine gives me unpleasant side effects					
I tend to hide the fact that I am I am taking this medicine from other people					
I sometimes worry about becoming addicted to this medicine					
Having to use this medicine is an unpleasant reminder of my condition					
This medicine makes me feel 'flat'					
I dislike the way this medicine makes me feel					
I need to take this medicine to prevent going into hospital					

Using ${q://QID8%231/ChoiceTextEntryValue/5/1}

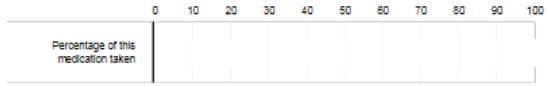
Many people find a way of using their medicines which suits them. This may differ from the instructions on the label or from what their doctor has said.

We would like to ask you a few questions about how you use **${q://QID8%231/ChoiceTextEntryValue/5/1}**.

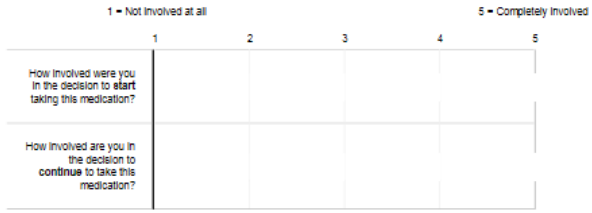
Here are some ways in which people have said that they use their medicines. For each of the statements, please select the option which best applies to you.

	Always	Often	Sometimes	Rarely	Never
I forget to take them					
I alter the dose					
I stop taking them for a while					
I decide to miss out a dose					
I take less than instructed					

Approximately what percentage of **${q://QID8%231/ChoiceTextEntryValue/5/1}** do you think you take?
Please move the slider along the line to show this, for example, if you think you take about half of this medication, move the slider to 50%.



Your involvement in decisions about **${q://QID8%231/ChoiceTextEntryValue/5/1}**



Your experiences of being involved in decisions about medicines for bipolar

These are statements which other people have made about being involved in decisions about their medicines.

Please indicate the extent to which your **experiences** match the statements by selecting the appropriate option.

	Very often	Often	Sometimes	Rarely	Never
The decision to start or stop taking medicines is mine, not my doctor's					
I am pressured into choosing the treatment my doctor suggests					
My doctor supports my decisions about medicines, whether or not he/she agrees with them					
My doctor seeks my views about treatment before prescribing a medicine					
I feel that I am actively involved in decisions about my drug treatment					
My doctor asks how I've got on with my medicines					
My doctor describes a range of treatment options, but lets me decide what to do					
I am not given enough information to be actively involved in making choices about treatment					
I am satisfied with the contribution I make to decisions about my medicines					
My doctor explains to me why he/she wants me to take a medicine					

Your views on making decisions about treatment

We are interested in your **views and preferences** on decisions about treatment for bipolar.

Please indicate the extent to which you agree or disagree with each statement by selecting the appropriate response.

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
The important medical decisions should be made by your doctor, not by you					
You should go along with your doctor's advice even if you disagree with it					
When hospitalized, you should not be making decisions about your own care					
You should feel free to make decisions about everyday medical problems					
If you became unwell, as your illness became worse you would want your doctor to take greater control					
You should decide how frequently you need a check-up					
As you become more unwell you should be told more and more about your illness.					
You should understand completely what is happening inside your body as a result of your illness.					
Even if the news is bad, you should be well informed.					
Your doctor should explain the purpose of your laboratory tests.					
You should be given information only when you ask for it.					
It is important for you to know all the side effects of your medication.					
Information about your illness is as important to you as treatment.					
When there is more than one method to treat a problem, you should be told about each one.					

Information about Medicines

We would like to ask you about the information you have received about your medications prescribed for bipolar disorder.

Please rate the information you have received about each of the following aspects of medication. There are also options to tell us if you did not receive or did not need the information.

Have you received enough information about...

	Too much	About right	Too little	None received	None needed
What the medicines are called					
What these medicines are for					
What they do					
How they work					
How long they take to act					
How you can tell if they are working					
How to use them					
How long you need to be on the medicine					
Whether the medicine will have any unwanted effects (side effects)					
What are the risks of you getting side effects					
What you should do if you experience unwanted side effects					
If you can drink alcohol whilst taking this medicine					
Whether the medicine will interfere with other medicines					
Whether the medication will make you feel drowsy					
Whether the medication will affect your sex life					
What you should do if you forget to take a dose					
How to get a further supply					

Your views about medicines in general

These are statements that other people have made about medicines in general.

Please show how much you agree or disagree with them by selecting the appropriate response

	Strongly Agree	Agree	Uncertain	Disagree	Strongly Disagree
Doctors use too many medicines					
People who take medicines should stop their treatment for a while every now and again					
Most medicines are addictive					
Natural remedies are safer than medicines					
Medicines do more harm than good					
All medicines are poisons					
Doctors place too much trust on medicines					
If doctors had more time with patients they would prescribe fewer medicines					

Your views about your mental health problems

We would like to ask you about your personal views about bipolar disorder.

Please answer the following questions by moving the slider to the number which best describes how you feel at the moment.

How much does bipolar affect your life?

No affect at all 0	1	2	3	4	5	6	7	8	9	Severely affects my life 10
○	○	○	○	○	○	○	○	○	○	○

How long do you think your bipolar will continue?

A very short time 0	1	2	3	4	5	6	7	8	9	Forever 10
○	○	○	○	○	○	○	○	○	○	○

How much control do you feel you have over your bipolar?

Absolutely no control 0	1	2	3	4	5	6	7	8	9	Total control 10
○	○	○	○	○	○	○	○	○	○	○

How much do you think your treatment can help your bipolar?

Not at all 0	1	2	3	4	5	6	7	8	9	Extremely helpful 10
○	○	○	○	○	○	○	○	○	○	○

How much do you experience symptoms from bipolar?

No symptoms at all 0	1	2	3	4	5	6	7	8	9	Many severe symptoms 10
○	○	○	○	○	○	○	○	○	○	○

How concerned are you about your bipolar?

Not concerned at all 0	1	2	3	4	5	6	7	8	9	Extremely concerned 10
○	○	○	○	○	○	○	○	○	○	○

How well do you understand your bipolar?

Don't understand at all 0	1	2	3	4	5	6	7	8	9	Understand very clearly 10
○	○	○	○	○	○	○	○	○	○	○

How much does your bipolar affect you emotionally? (e.g. does it make you angry, scared, upset?)

Not at all affected emotionally 0	1	2	3	4	5	6	7	8	9	Extremely affected emotionally 10
○	○	○	○	○	○	○	○	○	○	○

How much do you agree with your diagnosis?

Don't agree at all 0	1	2	3	4	5	6	7	8	9	Totally agree 10
○	○	○	○	○	○	○	○	○	○	○

Questions about how you feel

Choose the one statement in each group that best describes the way you have been feeling for the past week.

Please note that on this page the word; "occasionally" means once or twice; "often" means several times or more; "frequently" means most of the time

Happiness

- ○ 0 - I don't feel happier or more cheerful than usual
- ○ 1 - I occasionally feel happier or more cheerful than usual.
- ○ 2 - I often feel happier or more cheerful than usual.
- ○ 3 - I feel happier or more cheerful than usual most of the time.
- ○ 4 - I feel happier or more cheerful than usual all of the time.

Self-confidence

- ○ 0 - I do not feel more self-confident than usual.
- ○ 1 - I occasionally feel more self-confident than usual.
- ○ 2 - I often feel more self-confident than usual.
- ○ 3 - I feel more self-confident than usual most of the time.
- ○ 4 - I feel extremely self-confident all of the time.

Need for sleep

- ○ 0 - I do not need less sleep than usual.
- ○ 1 - I occasionally need less sleep than usual.
- ○ 2 - I often need less sleep than usual.
- ○ 3 - I frequently need less sleep than usual.
- ○ 4 - I can go all day or night without any sleep and still not feel tired.

Talking

- ○ 0 - I do not talk more than usual.
- ○ 1 - I occasionally talk more than usual.
- ○ 2 - I often talk more than usual.
- ○ 3 - I frequently talk more than usual.
- ○ 4 - I talk constantly and cannot be interrupted.

Activity levels

- ○ 0 - I have not been more active (either socially, sexually, at work, home or school) than usual.
- ○ 1 - I have occasionally been more active than usual.
- ○ 2 - I have often been more active than usual.
- ○ 3 - I have frequently been more active than usual.
- ○ 4 - I am constantly active or on the go all the time.

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things				
Feeling down, depressed, or hopeless				
Trouble falling or staying asleep, or sleeping too much				
Feeling tired or having little energy				
Poor appetite or overeating				
Feeling bad about yourself—or that you are a failure or have let yourself or your family down				
Trouble concentrating on things, such as reading the newspaper or watching television				
Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual				
Thoughts that you would be better off dead or of hurting yourself in some way				

Some information about your diagnosis

Please select the term or label that you feel best describes your mental health problems.

Please specify what other term or label you feel best describes your mental health problems.

Please tell us at what age you first received a diagnosis of bipolar disorder.

Have you ever been admitted to hospital for mental health issues?

	Yes	No
Voluntary admissions		
Involuntary/ Detained admissions		

Please tell us how recently you were discharged, on your most recent admission.

Some information about you

Your age

Your gender

- Male
- Female
- Prefer not to answer

Your ethnic origin

- White British
- White Irish
- White Other
- Black Caribbean
- Black British
- Black African
- Black Other
- Indian
- Pakistani
- Bangladeshi
- Chinese
- Asian Other
- Mixed ethnicity
- Prefer not to answer

Your Marital status

- Single
- Married/ Civil Partnership/ Cohabiting
- Divorced/ Separated
- Widowed
- Other
- Prefer not to answer

If 'Other' marital status, please specify.

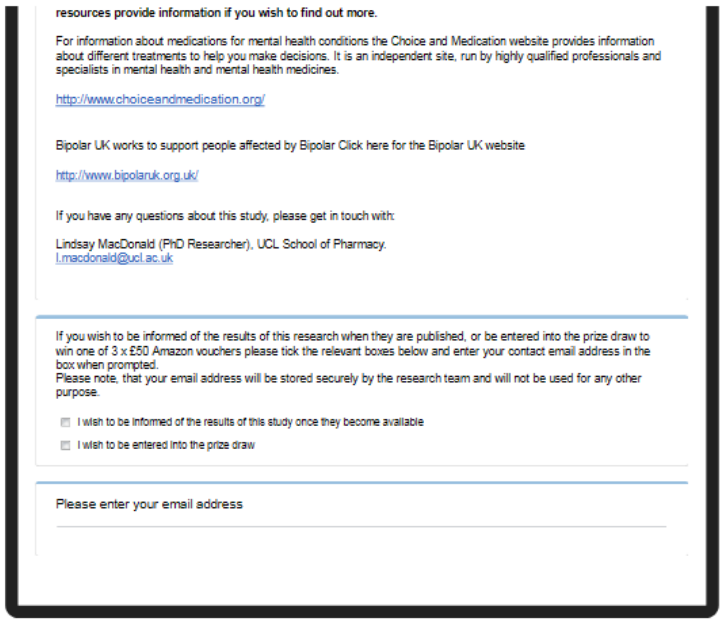
Your highest level of education

- No qualifications
- O Levels/ CSEs/ GCSEs
- Vocational education NVQ/ GNVQ/ HNC/ HND
- A levels/ AS Levels
- Degree
- Higher degree
- Professional qualifications (e.g. nursing, accountancy)

Please use the space below to tell us anything else about the issues covered in this survey.

Thank-you for taking the time to complete this questionnaire. Your response is greatly appreciated.

This questionnaire may have raised thoughts or questions about bipolar, your treatment or care. The following



resources provide information if you wish to find out more.

For information about medications for mental health conditions the Choice and Medication website provides information about different treatments to help you make decisions. It is an independent site, run by highly qualified professionals and specialists in mental health and mental health medicines.

http://www.choiceandmedication.org/

Bipolar UK works to support people affected by Bipolar Click here for the Bipolar UK website

http://www.bipolaruk.org.uk/

If you have any questions about this study, please get in touch with:

Lindsay MacDonald (PhD Researcher), UCL School of Pharmacy.
l.macdonald@ucl.ac.uk

If you wish to be informed of the results of this research when they are published, or be entered into the prize draw to win one of 3 x £50 Amazon vouchers please tick the relevant boxes below and enter your contact email address in the box when prompted.
Please note, that your email address will be stored securely by the research team and will not be used for any other purpose.

- [ ] I wish to be informed of the results of this study once they become available
- [ ] I wish to be entered into the prize draw

Please enter your email address