Enhancing treatment decision-making in bipolar II disorder: Development and evaluation of a treatment decision-aid for patients and their families

Alana Catherine Fisher

Faculty of Science,
The University of Sydney

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Statement of originality

This is to certify that to the best of my knowledge, the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Name: Alana Catherine Fisher

Signature:

Date: 20/08/2018

Authorship attribution statement

I, Alana Fisher, carried out the research presented within this thesis during my PhD candidature from 2015 to 2018 at the University of Sydney School of Psychology.
I am the first author on all five papers included the thesis (see Chapters 2 – 5, 7), reflecting my substantial contribution to all aspects of these studies, including intellectual input into the study design, developing the study materials, obtaining ethics approval, collecting and managing the data, planning the analysis and writing the manuscripts.

The specific contributions made by myself and all co-authors in each chapter are outlined in Appendix A.

In addition to the statements above, in cases where I am not the corresponding author of a published item, permission to include the published material has been granted by the corresponding author.

Name: Alana Catherine Fisher

Signature:

Date: 20/08/2018

As supervisor for the candidature upon which this thesis is based, I can confirm that the authorship attribution statements above are correct.

Supervisor Name: A/Prof Ilona Juraskova

Signature:

Date: 20/08/2018

Ethical approval

Ethical approval for all studies was obtained through the University of Sydney Human Research Ethics Committee (Protocol No. 2015/197 and 2016/763). Each participant gave written consent before participating in each study. Ethical approval was also obtained from the Black Dog Institute Research Advisory Committee (Protocol No. 2015002 FISHER and 2016011 FISHER). Ethics approval letters are provided in Appendix B.

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List of in-text abbreviations

ABS	Australian Bureau of Statistics
BP	Bipolar disorder (types I and II)
BPI	Bipolar I disorder
BPII	Bipolar II disorder
BDI	The Black Dog Institute
BDNF	brain-derived neurotrophic factor
CALD	Culturally and linguistically diverse (population)
CANMAT	Canadian Network for Mood and Anxiety Treatments
CBT	Cognitive Behavioural Therapy
CPS	Control Preferences Scale
DA	Decision-aid
DALY	Disability adjusted life-years
DCS	Decisional Conflict Scale
DSM	The Diagnostic and Statistical Manual
GP	General Practitioner (i.e., primary care physician)
HREC	Human Research Ethics Committee
IPDAS	International Patient Decision Aid Standards
IPSRT	Interpersonal and social rhythm therapy
ISS	Internal States Scale
M	Mean
MDD	Major Depressive Disorder (i.e., unipolar depression)
NAA	N-acetylaspartate
NHMRC	National Health and Medical Research Council
PARiHS	Promoting Action on Research Implementation in Health Services
PEMAT	Patient Education Materials Assessment Tool
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
SD	Standard deviation
SDM	Shared decision-making
SEM	Standard error of the mean
SILS	Single Item Literacy Screener

SSRI	Selective serotonin reuptake inhibitors
STAI-Y-SF	State Trait Anxiety Inventory – Short Form (State)
UK	The United Kingdom
USA	The United States of America
USYD	The University of Sydney
VCE	Values clarification exercise
$AU	Australian dollars

Abstract

Background/Aims. A diagnosis of bipolar II disorder (BPII) is commonly accompanied by a need to make complex treatment decisions about medications and adjunctive psychological therapies, often for lifetime prophylactic use. As most research on treatment efficacy relates to bipolar I disorder, treatment decisions in BPII have less evidence to support available treatment options and are more finely balanced in terms of their benefit/side-effect profiles. Yet, there is currently no resource to support patients with BPII (and their families) to make evidence-based treatment decisions, which incorporate both patient and clinician preferences (i.e., shared decision-making, SDM). Patient decision-aids (DAs) are interventions designed to facilitate this process. This thesis project aimed to develop and evaluate the first known DA for patients considering BPII treatment options.

Methods. The thesis comprised four phases: i) systematic review of the literature (*n*=13 studies) on communication and decision-making about treatment in mental health, with a focus on bipolar disorders (Chapter 2); ii) qualitative interviews with patients with BPII (*n*=28), their families (*n*=13), and clinicians (*n*=20) (Chapters 3 – 5); iii) development of a DA according to International Patient Decision-Aid Standards (Chapter 6); iv) pilot of the DA to obtain evidence on its acceptability, feasibility, safety, and potential usefulness within a sample of potential end-users (30 patients with BPII, and 10 families; Chapter 7).

Results. Phases i) and ii) identified key informational and decision-support priorities for patients with BPII and their families, as well as clinician-endorsed strategies for addressing barriers to treatment decision-making. These priorities and strategies then informed the content, format and delivery of the DA. Pilot data indicated that potential end-users strongly endorsed the DA, and provided preliminary evidence to support DA-related improvements in treatment decision-making.

Conclusion. This innovative and comprehensive program of research culminated in the development and evaluation of a world-first DA for patients deciding on BPII treatment. The final DA has the potential to facilitate informed treatment decisions, which are both evidence-based and consistent with patient preferences.

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Chapter 1

Chapter 1: Introduction

1.1. Background to bipolar II disorder

1.1.1. What is bipolar II disorder?

Bipolar disorder is a chronic, relapsing and remitting psychiatric disorder that affects a person' s mood, thinking, energy and behaviour [1]. It is characterised by a distinct pattern of 'low' states (depression) and 'high' states (hypomania or mania). Bipolar disorder comprises two main sub-types: bipolar I disorder (BPI) and bipolar II disorder (BPII). Although these sub-types were first recognised in 1974 [2], it was not until 1994 that BPII was formally recognised as a distinct diagnosis in the 4th edition Diagnostic and Statistical Manual of Mental Disorders (DSM-IV, [3]).

According to current DSM-5 [1] criteria, a diagnosis of BPII requires the presence (or history) of a major depressive episode, along with at least one episode of hypomania. Depression in BPII has similar aetiology, course and psychosocial triggers [4] to unipolar depression. The diagnostic criteria are also the same (i.e., minimum two week period of depressed mood and/or diminished pleasure/interest in activities). However, some studies suggest that bipolar depression is more often characterised by melancholic (e.g., psychomotor slowing), atypical (e.g., increased appetite and/or hypersomnia), or psychotic features (e.g., excessive and unfounded guilt), reflecting a greater neurobiological contribution [5]. At the opposite pole, hypomania is characterised by a distinct, minimum four-day period of abnormally and persistently elevated, expansive or irritable mood, and increased energy and activity, which is uncharacteristic for the individual and observable by others [1].

In DSM-5 [1], BPII is considered *less* severe and *less* impairing than BPI due to the reduced severity of the 'highs'. 'Highs' in BPII (hypomania) include many similar symptoms to those in BPI but these are *not* sufficiently severe to require hospitalisation, do *not* include psychotic features, do *not* lead to any marked impairment in functioning, and are of shorter duration (four compared to seven day minimum duration) than those experienced in a manic episode [1]. However, clinical evidence challenges this view and suggests that BPII and BPI are associated with similar psychosocial impairments in functioning, since BPII is associated with more

frequent mood oscillation and shorter recovery time between episodes, greater predominance of depressive episodes [6], and higher risk of suicide [7]. Possible overlaps between BPI and BPII are also supported by a clinically-derived continuum model, the 'bipolar spectrum', whereby unipolar depression (i.e., Major Depressive Disorder; MDD) and bipolar disorder are positioned at opposing poles and degrees of bipolarity are possible, including depression with (hypo)manic features or mixed depression [8].

Despite challenges to the diagnostic distinctiveness of BPI and BPII, a categorical approach persists in DSM-5 [1]. This categorisation is empirically supported on the basis of the possible presence or necessary absence of psychotic features in BPI and BPII, respectively [9]. In addition, DSM-5 has assigned bipolar disorder its own separate chapter, "Bipolar and related disorders", thereby recognising its occurrence within a spectrum of disorders and distinguishing it from unipolar depression and other mood disorders.

1.1.2. Prevalence, onset and course of bipolar II disorder

According to the most recently published Australian National Survey of Mental Health and Wellbeing in 2007 [10], the 12-month prevalence rates of bipolar disorder (both BPI and BPII combined) are 1.8% for men and 1.7% for women. These aggregated prevalence rates are slightly higher than those reported in a 2011 international community survey of eleven countries across the Americas, Europe and Asia (12-month prevalence = 0.4%, 0.3% for BPI and BPII, respectively) [11]. Community estimates are higher, and suggest that BPII is twice as common as BPI (5% vs. 2.4%; [16]). These rates should therefore be considered in the context of substantial inter-country variability [11], measurement differences, and possible changes to the 'true' prevalence of BPII [12]. Higher prevalence rates may also reflect broadening definitions of bipolar disorder (toward the concept of a 'bipolar spectrum'), greater community awareness, and better detection and diagnosis [12].

Age of onset in BPII is difficult to determine because studies tend to define onset as age at initial diagnosis and/or treatment, which may occur up to a decade after the initial onset of symptoms [13]. Reviews estimate the age of onset to be between 20.3 and 26.0 years, with a slightly earlier onset for females [7]. Others report that bipolar

symptoms (usually depression) emerge earlier, between 15 and 19 years of age [14]. Delays in being assigned a diagnosis of BPII are common, with 30-60% of BPII patients reporting a previous (mis)diagnosis of MDD [13]. Reasons given for misdiagnosis include patients' lack of insight into their own hypomanic episodes, poor screening by clinicians, and the fact that individuals with BPII more often seek treatment for depressive symptoms [6, 13].

For most patients with BPII, depressive episodes predominate with relatively infrequent bouts of hypomania. A prospective longitudinal study on the long-term course of BPII [15] demonstrated that, for over a period of 20 years, patients with BPII experienced depressive symptoms approximately 39 times more often than hypomanic symptoms (59.1% versus 1.9% of follow-up weeks). Between episodes of depression and hypomania, these patients spent much of the time unwell, experiencing either syndromal or more commonly subsyndromal (below-threshold) symptoms (13.0% versus 40.9% of follow-up weeks). Furthermore, three-quarters of patients experienced relatively frequent shifts in mood - from depression to hypomania or vice-versa - at least once per year [15].

Periods of depression and hypomania are not always enduring and clearly delineated. Patients with BPII can also experience symptoms of depression and hypomania concurrently (i.e., mixed affective states), as well as rapid cycling, which is defined as the occurrence of four or more mood episodes per year [7]. Both mixed states and rapid cycling are common in BPII (30 – 76%) and more marked in women [16, 17].

1.1.3. Impact of bipolar II disorder on patients, their family, and society

Due to its relatively early onset and chronic course, the impact of BPII on the patient's life can cause considerable disability. Indeed, bipolar disorder (BPI and BPII) is a leading cause of global disease burden, accounting for the 6th highest number of disability adjusted life-years (DALY) amongst mental disorders [18]. Bipolar-related disability extends across psychosocial, physical, financial and occupational domains. Some of the negative psychosocial consequences of BPII include: impoverished interpersonal functioning, stigmatisation, isolation, reduced self-esteem and self-concept, hopelessness and demoralisation [19]. Other consequences include: lost income or compromised careers, relationship and

friendship breakdown, financial stress, alcohol or other substance abuse problems, unwanted sequelae of sexual disinhibition and promiscuity, as well as violent and suicidal behaviours [19]. Furthermore, high rates of comorbidity in BPII (>95%), in particular comorbid anxiety-related disorders [20], together with a protracted course of suboptimal treatment if the patient has previously been misdiagnosed [21], are also likely to worsen the impact of BPII.

Certain features of the BPII course may differentially influence the severity of impact and associated disability. The most comprehensive longitudinal data on BPII-related disability (as separate from BPI) comes from a prospective 20-year follow-up study by Judd and colleagues [22]. Study findings revealed that increments in BPII depression severity (from asymptomatic to subsyndromal to syndromal) were associated with increasing psychosocial impairment in occupational role, interpersonal relationships, hobbies and interests, and overall satisfaction [22]. However, the converse was not observed for hypomania, where symptoms were associated with a non-significant trend towards enhanced psychosocial functioning [22]. Rapid cycling and mixed affective states have been found to be associated with disability and increased risk of suicide [23]. Even when patients with BPII were symptom-free, they had higher levels of psychosocial impairment (M=8.8/20, SEM=0.2) compared to healthy controls (M=7.4/20, SEM=0.04; p<0.05) [22]. In summary, the predominance of depressive episodes, subclinical symptoms between episodes, and high prevalence of both mixed symptoms and rapid cycling, create multiple, chronic sources of disability and impairment in patients with BPII.

The impact of bipolar disorder on patients' families has received limited attention in the academic literature. However, the impact on families may, to some extent, mirror the impact of BPII on the patients themselves. For the families of patients, serious mental illnesses engender both objective/practical burden (e.g., home-related role changes, reduced working hours and income) and subjective/psychosocial burden (e.g., distress and stigma) [24], with objective and subjective burden potentially negatively impacting on one another. For example, increased responsibilities at home may lead to a loss of social support and social isolation, while reduced participation in paid work and resulting financial hardship may trigger depression, anger and grief over loss of prior functioning and future goals [24].

Among the family caregivers of patients with bipolar disorder, this 'constellation' of burden is not uncommon. A substantial proportion of families report reduced working hours (76%) and income (27%), along with 'severe' personal distress (64%) and 'major' stress (71%) [25]. The negative impact of BPII may be further exacerbated when the patient lacks insight into their symptoms, is acutely unwell, or displays symptoms that are particularly distressing and burdensome, such as profound social withdrawal and sadness, or irritability and combativeness [26]. A stressful home environment can also impact negatively on the patient's wellbeing and further exacerbate symptoms or trigger relapse [19]. This highlights the interplay between BPII symptoms, burden and distress both for the patient and their families.

In addition to its 'micro' impact on the patient and their family, BPII also has a significant 'macro' impact on the broader community and society. The 'direct' costs of bipolar disorders (BPI and BPII) include pharmacotherapy, the use of psychiatric services, and hospitalisation whilst the 'indirect' costs include reduced employment and productivity, family/caregiver burden, and increased involvement in the social welfare and criminal justice systems [6]. Again owing to the early onset and life-long course of bipolar disorder, the direct and indirect costs of this condition can amount to significant economic burden. There are no estimates of costs related to BPII specifically, however, a comprehensive Australian study conducted in 2003 [27] calculated bipolar-related costs at $AU1.59 billion. Of these costs, $AU833 million (52%) was attributable to indirect costs made up largely of lost earnings due to BP illness ($464 million). The social and economic burden of bipolar disorder is most evident in work-related domains. A review has demonstrated that a diagnosis of bipolar disorder is associated with a 40% reduction in the likelihood of paid employment and a sevenfold increase in rates of absenteeism [28]. There is also the suggestion that these bipolar-related costs are underestimates given the delays to bipolar diagnosis, or misattribution of costs to (misdiagnosed) unipolar depression [6].

1.1.4. Causes of bipolar II disorder

The causes of BPII can be understood within a biopsychosocial model, which recognises the relative contributions of genetics and neurobiology, as well as

psychosocial factors, lifestyle and environment to the development of mental illness [29]. The strong heritability of bipolar disorder is evidenced by family studies which demonstrate that the lifetime risk is between 40-70% with an affected monozygotic twin, and 5-10% with an affected first degree relative, compared to 0.5-1.5% in individuals without any family history [30]. Moreover, individuals diagnosed with BPII are more likely to have a family member with BPII than BPI, and vice-versa [5]. Few studies have examined the neurobiology of BPII separately from BPI, but a review of findings implicates similar neurobiological changes in BPII as BPI [31]. These include structural and functional abnormalities in subcortical brain regions subserving emotion regulation, sleep and arousal (e.g., insula and thalamus), as well as the frontal brain regions involved in social decision-making and cognition (e.g., orbitofrontal cortex and medial frontal cortex), and the interconnections between these subcortical and cortical areas [31]. BPI and BPII also appear to share many neurochemical abnormalities. Those that are consistently documented include: decreased levels of brain-derived neurotrophic factor (BDNF) while symptomatic, decreased levels of N-acetylaspartate (NAA) and increased glutamate levels across several brain regions while both symptomatic and euthymic (i.e., symptom-free) [31].

Regarding psychosocial and environmental influences, research supports a link between stressful life events and subsequent episodes of depression and (hypo)mania. For example, stressful life events involving disruption to routines and sleep-wake cycles, and excessive focus on goal attainment tend to precede (hypo)manic episodes, while poor social supports and low self-esteem tend to precede depressive episodes [32]. Interestingly, the importance of these factors on symptom expression varies over time, such that, stressful life events are more likely to trigger initial rather than later episodes, and late onset rather than early onset bipolar disorder [33]. This pattern may, in part, be explained by the 'kindling' phenomenon, whereby the occurrence of a bipolar episode increases the likelihood of subsequent episodes occurring. Thus, over time, episodes become less linked to external (environmental) factors and eventually occur independently [34]. In sum, BPII, like BPI, has a primarily neurobiological basis but environmental and psychosocial stressors are implicated as important contributing factors to the onset of symptoms and relapse [31]. The interplay between biological and psychosocial factors in bipolar disorder informs the

basis of treatment approaches, which combine pharmacological and psychological treatments.

1.1.5. Treatment and management of bipolar II disorder

The treatment and management of BPII, as with BPI, focuses on two principal phases: the acute phase (the treatment of depressive and hypomanic symptoms) and the maintenance phase (the long-term preventative treatment of future episodes and relapse prevention, i.e., prophylaxis). Treatments vary according to which phase is being targeted. The treatment of BPII relies largely on assumptions and inferences from the treatment of BPI, as most of the research evidence from large well-designed trials is based on mixed or BPI-only patient samples. There are substantially fewer treatments with high-quality evidence to support their efficacy in BPII compared to BPI. It is still unknown, however, if treatment recommendations derived from efficacy findings in BPI are appropriate and generalisable to BPII [35]. As a result, most published clinical practice guidelines do not differentiate between BPI and BPII subtypes (e.g., [36, 37]) or provide only limited BPII specific recommendations [38]. One exception is the 2018 Canadian Network for Mood and Anxiety Treatments (CANMAT) guidelines [39], which provide a separate section with BPII treatment-specific information. Despite an ongoing lack of consensus regarding the "best" treatment for BPII, a pluralist approach that incorporates both pharmacological and psychological treatments is advocated [19].

The management and prevention of depressive symptoms is often the focus of treatment in BPII. This is due to the fact that depression is the predominant mood state for most patients, is associated with high levels of disability, and leads more patients to seek treatment [40]. Accordingly, the main psychopharmacological treatments in BPII are antidepressant (e.g. selective serotonin reuptake inhibitors, SSRIs) and/or mood-stabilising (e.g. lithium, anti-epileptic, and second generation anti-psychotic) medications [41, 42]. However, there is limited evidence for the safety and efficacy of these medications in the treatment and prevention of BPII depression, compared to BPI and unipolar depression [43].

Researchers argue that the evidence supporting the use/non-use of antidepressants and/or mood-stabilisers in the management of BPI may not apply to BPII [35]. For

example, antidepressant monotherapy is contraindicated in BPI [44], as it has been implicated in (hypo)manic 'switching' (i.e., triggering a shift from a depressive to a hypomanic state), and/or long-term mood destabilisation [23]. These concerns appear less warranted in BPII, given that the likelihood of switching is lower [37, 43], hypomania occurs much less frequently than depression [15], and hypomania is not as functionally debilitating or distressing as mania in BPI [40]. Findings from randomised controlled trials (RCT) have also demonstrated that antidepressant monotherapy was more effective than mood-stabiliser monotherapy in treating BPII depression, with no group differences on hypomanic symptoms [45]. Conversely, other evidence suggests some mood-stabiliser monotherapies may be as effective as antidepressant monotherapy at alleviating depressive symptoms, without the possible antidepressant-related increase in hypomanic symptoms [40].

It is evident that pharmacological interventions play an important role in the treatment of BPII, however, its importance may vary from one patient to another. It is currently recommended [40, 46] that pharmacological treatment include consideration of the patient's personal circumstances, preferences, and experience of the illness in order to improve outcomes. For example, antidepressant monotherapy may be sufficient if: hypomania causes no disruption or stress, symptoms are mild, the patient is unwilling to treat hypomania, and there is no presence or history of mixed affective states (e.g., depression with hypomanic features) or rapid cycling [46]. By contrast, mood-stabilisers may be more appropriate than antidepressants in treating BPII depression in instances of: rapid cycling and frequent mood oscillations, proneness to hypomania, presence or history of depression with mixed (hypomanic) symptoms, poor response to antidepressant monotherapy, or loss of antidepressant efficacy over the long-term [40]. These recommendations, however, draw on an incomplete evidence base and attract differing expert opinions and clinical debate [35, 47].

Although pharmacological treatments form the main approach to treatment in BPII, they may not be adequate in isolation. In the short term, poor adherence to medication is common due to unpleasant side-effects, alleviation of unwanted acute symptoms, and non-acceptance of the diagnosis [48]. In the longer-term, pharmacological treatments alone have limited effectiveness in preventing relapse; 37% of patients taking mood-stabilisers relapse after one year, and 73% after five years [49]. In

addition, patient prognoses and outcomes are significantly improved when pharmacological treatments are used *in conjunction with* psychological treatments [19, 50]. This said, evidence of benefit mainly relates to the maintenance phase of bipolar disorder (BPI and BPII), with limited evidence for the acute phases (depression and (hypo)mania) [36, 39]. Adjunctive psychological treatments may be particularly important in BPII, where the course and severity of illness is not fully explained by neurobiological factors and pharmacological treatments alone [19], and environmental and lifestyle stressors are known to play a contributing role [32]. As for pharmacological treatments, most of the evidence supporting the efficacy of adjunctive psychological treatments relates to BPI-only or mixed patient samples. This precludes the provision of BPII-specific outcomes or recommendations [36].

The most empirically-supported adjunctive psychological treatments for the depressive and maintenance phases of bipolar disorder (both BPI and BPII) are: cognitive behavioural therapy (CBT) (Level I evidence[1]), group psycho-education (Level I), and family-focused therapy (Level II[2])[36]. Interpersonal and social rhythm therapy (IPSRT) (Level III[3]) is also included in current guidelines [36], however, more recent meta-analytic findings did not support its efficacy [51]. Moreover, studies to support the efficacy of these treatments predominantly involve patients with BPI. A common component of these adjunctive treatments is psycho-education in order to enhance adherence to medication, interpersonal and occupational functioning, recognise and manage early warning signs and triggers and accept the diagnosis and acknowledge its impact on lifestyle [50]. A systematic review and meta-analysis of 55 RCTs involving treatment which targeted these four components found a 30% reduction in the rate of relapse at post-treatment and 40% reduction at 1 to 2.5-year follow-ups [51]. Other review findings have shown reductions in symptom severity and improved functional outcomes, including psychosocial functioning and medication adherence, compared to treatment as usual [52]. Although most effective during the maintenance stage [14], different psychological treatments appear to have a

[1] Meta-analysis with narrow confidence interval or replicated double-blind, RCT that includes a placebo or active control comparison (≥ 30 in each active treatment arm).
[2] Meta-analysis with wide confidence interval or one double-blind, RCT that includes a placebo or active control comparison (≥ 30 in each active treatment arm).
[3] One double-blind, RCT that includes a placebo or active control comparison (10 - 29 in each active treatment arm) or health system administrative data.

differential effect on depressive versus hypomanic symptoms. Specifically, treatments focusing on the regularisation of sleep-wake patterns and medication adherence may be more effective for hypomanic symptoms whereas treatments focusing on interpersonal behaviours, communication and problem-solving may be more effective for treating depressive symptoms [52]. Given the current lack of evidence to support the superiority of one psychological treatment over another, especially within the context of BPII, clinicians are encouraged to adopt a flexible approach. Such an approach draws on features from multiple treatment approaches, and can be tailored according to the patient's individual needs and circumstances [19].

In general, although there is Level I evidence for mood stabilisers in BPI [39], there is a paucity of trials that separate outcomes for BPII. Therefore, treatment recommendations are largely made on the basis of BPI, but relative benefit to harm of different medication options specifically for BPII is not well understood. Similarly, the evidence for adjunctive psychological interventions are based largely on patients with BPI and further depend on the target of intervention (i.e. depressive vs (hypo)manic phases)[51]. Hence, the decision as to which combinations of therapies are most suitable for an individual patient is challenging for clinicians and patients alike.

1.2. Treatment decision-making

1.2.1. What is treatment decision-making?

During the course of a physical or mental illness, a patient is required to make numerous decisions regarding their treatment. A treatment decision implies a choice between one or more options, including the option to do nothing (e.g., wait-and-see). These treatment decisions may be made with their doctor and/or other treating clinician (e.g., psychiatrist or psychologist), and/or with significant others (e.g., family members or caregivers). Dyadic decision-making implies the involvement of two parties (e.g., patient-clinician) whereas triadic decision-making implies the involvement of three parties (e.g., patient-family-clinician) [53]. Some examples of treatment decisions may include, but are not limited to: whether or not to commence, change or cease treatment, whether to include an additional or adjunctive treatment, and deciding between different treatment options. Treatments may vary according to

the nature and type of illness and across the illness trajectory but may be pharmacological (e.g., medication-based), psychological (e.g., CBT) or involve a physical intervention (e.g., surgery, electroconvulsive therapy).

Treatment decisions may be relatively simple, straightforward and routine, or complex. Based on audiotaped routine patient consultations with primary care physicians and surgeons, Braddock and colleagues [54] posited that healthcare decisions can be categorised as either basic (e.g., discussing laboratory test), intermediate (e.g., new medication) or complex (e.g., surgical procedure). Categorisation depends on: i) their impact on the patient's life and/or functioning (i.e., minimal, moderate, large), ii) the amount of medical consensus (limited, moderate, complete), and iii) the nature of outcomes (uncertain, certain). A basic decision, for example, would entail minimal impact on the patient, complete medical consensus, and a single, clear outcome. By contrast, a complex decision would entail extensive consequences for the patient, be controversial within the medical community, and result in multiple, uncertain outcomes. In addition, the more complex a decision, the more patient involvement is needed and the more numerous the prerequisites for fully informed decision-making [54].

Most decisions in outpatient clinical practice appear to be 'intermediate' decisions and lie somewhere between the basic and complex poles [54]. By this definition, most decisions about treatment are understood as having incomplete medical consensus and posing some potential risk to patients. This accords with a 2013 review of 3000 treatments (including psychological, medical and surgical interventions), which demonstrated that only a third of these treatments had sufficient evidence to support likely (24%) or clear benefit (11%) [55]. The remaining two-thirds had insufficient evidence to support effectiveness (50%), involved a trade-off between benefits and harms (7%), were unlikely to be beneficial (5%) or likely to be harmful (3%) [55]. On the basis of these review findings, most treatment decisions involve some degree of 'equipoise' (i.e., clinical uncertainty) and have no clear 'best choice'. As a result, treatment decisions are generally considered to be 'preference-sensitive'; such that more than one clinically-viable treatment option exists and patients (together with significant others, e.g., their families) may evaluate options differently depending on their personal values, preferences, and situation [56].

1.2.2. Conceptual models of decision-making in healthcare

From a healthcare perspective, treatment decision-making has been described in terms of three main conceptual models: the paternalistic model, the informed choice model, and the shared decision-making (SDM) model [57]. These models of treatment decision-making can be positioned along a continuum from clinician-led (paternalistic) to patient-led (informed choice) approaches, with SDM positioned in the 'middle ground' between the other two. These models posit that the process of treatment decision-making comprises three distinct stages: *information transfer/exchange* which refers to the information that is shared by the clinician and the patient; *deliberation* which refers to the weighing-up of the benefits and risks associated with treatment options and; *decision* on treatment to implement (including the option to postpone or not pursue treatment) [58]. According to these models, the decision-making stages can occur in a sequential or concurrent fashion, or as a dynamic, iterative process whereby members of the decision-making dyadic/triad move back and forth between the stages [58]. Where these models differ is in their underlying assumptions about the relative involvement of the clinician and the patient, the relative importance given to clinician knowledge of treatment options versus patient preferences, and who assumes authority as the primary decision-maker [58, 59]. More broadly, these models also reflect a gradual shift in societal views and attitudes, the influence of Western bioethics, and changing legal and professional guidelines on patient rights and input in their healthcare.

Up until the 1980s, the paternalistic model was the most prevalent approach to treatment decision-making in Western clinical practice settings. In this model, the clinician takes on a dominant role and the patient a passive role, whereby the clinician's medical knowledge and expertise are of a primary focus when making a treatment decision. Thus, it is the clinician who makes the decision with minimal patient involvement beyond providing consent. According to this approach, the clinician needs to only provide the most relevant medical information and encourages the patient to consent to the treatment option that they consider the best for the patient [57]. Within the paternalistic approach, the clinician is regarded as the 'guardian' of the patient's values and interests [57]. It is assumed therefore that clinician and patient preferences regarding treatment are always perfectly aligned. According to

this approach, the ‘best’ treatment option in the clinician’s view will also be the ‘best’ treatment option in the patient’s view. There is, as a result, no need for any discussion of patient preferences.

Paternalistic models of treatment decision-making have since been challenged on medical, legal, and ethical grounds. Firstly, in medicine there are often multiple, more or less equivalent treatment options with differing benefit-risk profiles or a lack of medical consensus supporting a single ‘best’ treatment option. Secondly, patients have a recognised legal and ethical right to be informed about all treatment options and retain decision-making authority [58, 60]. The extent to which the paternalistic approach persists in current clinical practice varies. This said, there are situations that may favour or necessitate this approach to treatment decision-making. For example, when patients prefer to defer decision-making to their clinician, lack decisional capacity or competence, or are acutely ill and require emergency intervention [60, 61].

The informed choice model represents a diametric shift away from clinician-led styles of decision-making and sees decision-making authority transferred from the clinician to the patient [57]. This model is also regarded as a response to the supposed shortcomings and flawed assumptions of the paternalistic model. In this model, the clinician’s role is to simply disclose to patients information about all available treatment options, along with their associated benefits and risks. The clinician then allows patients to make a treatment decision independently, based on this information together with their values and preferences [59]. As in the paternalistic model, the informed choice model delegates decision-making authority to one party only (the patient as opposed to the clinician). It also posits that the final treatment choice considers only one party’s treatment preferences (those of the patient as opposed to the clinician) [60].

In contrast to the two aforementioned models, SDM models [58, 60] advocate that clinicians *and* patients work *in partnership* in the decision-making process. This process may also involve significant others, such as the patient’s family. Thus, the final treatment choice is mutually agreed upon, involves input from both the clinician and patient, and considers both their treatment preferences. SDM is optimal when

there is some degree of medical uncertainty, that is, the existence of two or more viable treatment options [62]. However, SDM is also applicable to situations where there is strong evidence to support one treatment option over others, but this option poses a significant impact on a patient's quality-of-life or carries high risk (e.g., some surgeries, where SDM is used in conjunction with fully informed consent) [62]. In these situations, Charles and colleagues who established the first and most commonly used model of SDM, outline four essential elements: i) there are at least two parties (i.e., patient and clinician) who are involved; ii) both share information; iii) both express treatment preferences; and iv) both come to a consensus on a treatment decision to implement [58, 60]. Though initially developed in the acute-care context, this model of SDM has also been applied to chronic illness but with an increased emphasis on the patient-clinician relationship, and the possibility of deferring and/or reviewing treatment decisions [63].

In any case, SDM maintains that the clinician and patient are viewed as experts in their own right; the clinician is considered an expert by way of their medical knowledge and clinical experience, whereas the patient is considered an expert of their own lives, values and personal experience of the illness. This is important as differences in patient and clinician perspectives of treatment effects (positive and negative) can arise, and influence the likelihood of the patient implementing the decision over time (e.g., continuing to take medication) [64]. Both forms of expertise are also regarded as necessary for "good quality" treatment decisions that are, by definition, well informed, evidence-based, and congruent with personal values [65].

A somewhat problematic assumption of SDM, however, is that it assumes that patients *want* the same level of decision-making control as their clinician. This is shown to not always be the case; patient (and clinician) preferences for involvement vary [66], and large scale surveys reveal that some patients moderately (23%) or strongly (14%) prefer their clinician to make the final decision [67]. The elicitation of patient preferences for involvement is an often-cited recommendation in the literature [68], yet it is among the most frequently neglected aspects of SDM in clinical practice [69, 70]. Moreover, SDM continues to be conceptualised and operationalised in different ways, with one systematic review identifying 161 definitions of SDM [71]. Indeed, 'pure' step-wise SDM approaches with equal involvement of both parties at

each decision-making stage may be unfeasible in clinical practice [66], whilst 'hybrid' approaches that vary in their degree of patient-clinician collaboration appear more common [72, 73]. Thus, the mutual acknowledgment and two-way exchange of different, but equally valuable patient and clinician perspectives form a central tenet of SDM, and differentiate this approach from other approaches to treatment decision-making. SDM is also at the crux of patient-centred care [59], and is associated with improvements on a number of patient outcomes, such as: satisfaction with care/service delivery, reduced symptoms, improved treatment adherence [74].

Despite its widespread support and link to improved patient outcomes, there are ongoing challenges to SDM in routine clinical practice. In marked contrast to earlier models of healthcare decision-making, SDM involves active clinician-patient involvement and a two-way exchange of information, enabling final decisions that integrate the informed preferences of both the patient and the clinician (and others, e.g. family). As such, the successful implementation of SDM hinges on effective clinician-patient(-family) communication about patient involvement preferences and treatment preferences. Yet, eliciting and negotiating patient preferences remains suboptimal in clinical practice.

1.2.3. Communication and decision-making about treatment in physical health conditions

The 1980s and 1990s saw a growing interest in and endorsement of SDM and/or collaborative decision-making approaches in the management of physical health conditions. This stemmed from increasing recognition of patient choice and autonomy [66], along with concurrent advances in treatment which resulted in more numerous options and thus more 'preference-sensitive' decisions necessitating patient involvement [75]. Consistent with this, a large body of empirical research has focused on patient involvement and the implementation of SDM approaches in physical illness, primarily cancer [66]. Overall, studies demonstrate that most (but not all) patients prefer to be involved in treatment decision-making, especially receiving information about available treatment options [76-78]. This said, some mixed findings emerge with regards to the time of study publication (i.e., more recent studies show a trend towards greater involvement preferences [78]), or the decision-making stage, for example, stronger preferences for involvement in the decision-making process (e.g.,

information sharing and discussion of treatment options) versus making the final decision [77]. Patient characteristics may also influence involvement preferences; more highly educated patients, healthier patients and women are more likely to desire active involvement in decision-making [67, 79] whereas older patients and those with more severe illnesses are less likely [76].

Of concern, studies using patient-report [79, 80] and/or observer ratings [69, 70] of consultation behaviours reveal that around a third (34%, [80]) to over half (~58%, [79]) of oncology patients do not experience their preferred level of decision-making involvement. Of note though, these studies are limited by their focus on dyadic interactions involving only the clinician and patient. Thus, they fail to acknowledge the involvement of others, such as family members, who assume numerous supporting roles and also influence decisional outcomes in treatment decision-making in, for example, the cancer setting [53, 81]. These study findings are also predicated on the notion that patients understand and know what is meant by terms such as 'preferences', 'decisions', and 'options', which may in fact be unfamiliar or, as in the case of decision-making, take place without patients being aware of them [82]. In spite of these limitations, it appears that current SDM practice is suboptimal and has not accounted for, nor responded fully to patient preferences for involvement in their treatment.

1.3. Treatment decision-making in mental health conditions

1.3.1. Communication and decision-making about treatment in mental health conditions

Many mental health conditions, such as unipolar depression, schizophrenia, and bipolar disorder, show a similar chronic pattern to major physical health conditions, including diabetes, coronary heart disease, hypertension, and some cancers. In this way, these mental health conditions are characterised by multiple, complex causal and risk factors, a prolonged course of illness, and at least some degree of functional impairment or disability [83]. The long-term management of these chronic mental health conditions also relies on the successful implementation of informed, evidence-based decisions about treatments, such as consistent adherence to medications and/or psychosocial strategies. Barriers to ongoing treatment adherence may be similar for

both chronic mental health and physical health conditions, such as treatment being a reminder of illness and perceived as being unnecessary due to non-acceptance of illness, and intermittent use of medication to treat certain symptoms only when present and distressing [64]. Moreover, the chronicity of many mental health conditions may place particular importance on effective communication and establishing a strong therapeutic alliance, as these may impact on patient involvement and long-term treatment outcomes [84].

As in physical health conditions, paternalistic approaches to decision-making were also prevalent in mental health conditions. In fact the uptake of SDM approaches in mental health conditions represents an even more recent shift [74, 85]. Consistent with SDM, involving patients as active and informed participants is now recognised as applicable to most treatment decisions in mental healthcare [61, 86, 87]. Accordingly, mental healthcare professionals are increasingly encouraged to adopt a SDM approach in treatment decision-making, both to meet many patients' information and involvement preferences, but also out of an ethical obligation to ensure patient autonomy and informed decision-making [88, 89]. SDM also aligns with the recovery approach to care in chronic illness, where affected individuals have a responsibility to actively self-manage their illness over the long-term [64]. Supporting this, a systematic review of SDM-based treatment programs concluded that they appear particularly beneficial with regards to patient satisfaction, well-being (e.g., depression, anxiety, quality of life), and treatment adherence in the context of chronic illnesses, including mental illnesses, which involve the implementation of long-term decisions [90].

Another important factor favouring the adoption of a SDM approach is that many treatment decisions in mental health are 'preference-sensitive' [61]. These preference-sensitive decisions necessarily require at least some patient involvement, in order to elicit patient preferences for treatment options when multiple viable options exist. However, there are psychiatry-specific situations in which a more paternalistic or directive approach to decision-making may be needed (e.g., suicidal or acutely psychotic patients [61]).

Although many clinicians endorse SDM, and most patients want to be actively involved in treatment decision-making, SDM may prove especially challenging in the mental health setting [85, 91, 92]. Some clinicians have the perception that: i) they already apply SDM principles, ii) SDM permits patients to make decisions that disregard clinician advice, iii) fully-informing patients of treatment side-effects will discourage adherence, and/or iv) that all psychiatric patients lack decisional capacity [93, 94]. Some patients may also be reluctant to engage in SDM due to a perceived lack of skills or knowledge; feeling they are already involved in SDM, feel stigmatised, lack insight, or feel unmotivated to review their treatment decisions following coercion or pressure in the past [61, 95, 96]. In addition to these clinician and patient-reported barriers, another challenge is to *"balance advocacy for an active patient role with individual patients' preference for participation"* (p. 865, [97]). In accordance with this, it is important that clinicians do not assume, but rather elicit and clarify patient preferences, as these may vary not only across patients but also within patients and from time to time. [73, 86].

1.3.2. Involvement of patients

By comparison with general medical conditions, research on treatment decision-making in mental healthcare is still its infancy. To date, most studies have focussed on patients with unipolar depression or schizophrenia. These studies have drawn on a range of different methodologies, making use of both quantitative approaches, such as self-report questionnaires and/or observer ratings of consultations, and qualitative approaches, such as interviews exploring patient and/or clinician perceptions of communication and decision-making. Quantitative studies indicate that people with a mental illness are highly information-seeking, they generally want and expect comprehensive information about their care [98]. These patients prefer to be involved and take an active role in treatment decision-making [98, 99], sometimes to a greater extent than patients with physical health conditions (see [98]). To illustrate this, one mixed sample study showed that patients with depression were more likely to report preferring an active role than patients with diabetes, heart disease, and hypertension [100]. Similarly, about three-quarters (77%) of patients with severe mental illness preferred a shared or autonomous role in decision-making, which is greater than (45% [80] and 47% [79]) or comparable to (~72% see [76]) the proportion of patients with cancer using the same self-report measure. Despite consistent evidence for strong

involvement preferences, psychiatric patients, like other patients [77], do not always desire full control over the final treatment decision [87]. There is also the suggestion that psychiatric patients, like oncology patients, often fail to achieve their preferred level of participation in decision-making [99]. However, unlike some oncology patient samples [79, 80, 101], these patients tend to experience less (rather than more) involvement in decision-making than they prefer. These patients' preference for greater decision-making involvement may be explained by research suggesting that psychiatric patients may receive SDM less often than primary care patients [91].

Although a number of studies report patient perceptions of decision-making, only a few studies provide *observer* reports of decision-making in the psychiatric setting [84, 91]. Three naturalistic studies used a standardised SDM measure (previously validated in the general medical context) to rate psychiatrist behaviours during initial consultations with psychiatric outpatients [102, 103], and physician/GP behaviours with primary care patients with depression [104]. They found that both psychiatrist and GPs generally made limited attempts to involve patients in decision-making (*M*=14.6/100 [104]; *M*=26.7/100 [103]; *M*=43/100 [102]), and SDM was poorly enacted with regards to offering options, eliciting patient's preferred level of involvement, and assessing patient's preferred way of receiving information to assist decision-making [103, 104]. Interestingly, one study [102] found that the psychiatrists' failure to elicit patient preference for information and involvement were not related to patient dissatisfaction in these skill areas, which may be explained by other research showing that not all aspects of SDM predict satisfaction [105]. Although limited by a paucity of studies integrating both observer and patient reports, these consistent findings of low psychiatric patient involvement align with observer ratings of doctor-patient consultations in general medicine [69] and oncology [70].

Taken together, there is a lack of concordance between patient preferences for involvement, experienced levels of involvement, and observed SDM in mental health clinical practice. In light of these findings, endorsing more active patient roles, and advocating SDM approaches appear well justified for patients who are not experiencing acute psychiatric symptoms. Lending further support to this, increased patient involvement and SDM also promote improved patient outcomes, such as

greater patient satisfaction with care [106, 107], treatment adherence [108], amelioration of depressive symptoms [109], and reduced suicidal ideation [110].

The more important priority, however, appears to be an adoption of a more flexible and tailored approach based on greater awareness of patient preferences for involvement [72, 73]. Findings from a qualitative analysis of psychiatric visits [111] found that although clinicians' behaviours were not necessarily reflective of SDM criteria, they still demonstrated an orientation towards patient-centred care. Specifically, while patient-initiated decisions tended to result in higher rates of disagreement (in contrast to SDM), the final decision was more in keeping with patient preferences and involved greater negotiation and discussion of options [111]. Further, patient perceptions of involvement do not always translate to decisions that are well informed and supported, and in line with their values. In a qualitative study with 40 patients with depression, 85% reported they felt involved in the treatment decision-making process, and yet more than three-quarters indicated ambivalence and some degree of decisional conflict (e.g., poor values clarity, feeling overwhelmed, and confused) [96]. These findings suggest that a more active role in decision-making does not necessarily result in good quality decision-making, unless there is appropriate decisional support and an explicit exploration of patient ideas, concerns and expectations [96]. These considerations may be especially pertinent in the mental health context, as mental illness can be associated with feelings of disempowerment, along with a reduced sense of confidence and autonomy [112]. Furthermore, other mental-health related symptoms (e.g., poor concentration and memory, fatigue, lack of motivation) may compromise active patient involvement in decision-making, and necessitate the involvement of family as a form of decision support.

1.3.3. Involvement of the family

In the literature on treatment decision-making in mental health, there is a notable paucity of studies investigating the role of family members and their involvement. This contrasts with common research findings that patients seldom make purely autonomous decisions but rather draw on the support and input of close others (including family and friends) [81, 113, 114]. The academic literature on cancer and other physical health conditions reports that family members frequently attend consultations (64-84%, [115, 116]), assume numerous supporting roles, facilitate

more informed and autonomous decisions, as well as influence decisional outcomes in treatment decision-making [53, 81]. These supporting roles included providing practical (e.g., transporting patients to appointments), emotional (e.g., comforting the patient, and companionship), and informational support (e.g., asking questions, clarifying aspects of the patient's history, ensuring patient understanding), with the latter particularly appreciated by patients [53]. Meanwhile, a qualitative study of mothers who were primary caregivers for a child with depression (aged 15-24 years), found that that their involvement was mainly restricted to practical support (e.g., driving their child to appointments) [72]. As such, these mothers often felt removed from clinical encounters involving treatment decision-making, and/or did not receive the information they wanted about their child from clinicians [72]. Given that adolescence coincides with a need to actively assert ones independence from parents, these findings may not generalise to family involvement in the adult mental health context.

In other mental health literature conducted in adults, family members of patients with a serious mental illness appear to provide *both* emotional and instrumental support [24]. Indeed, as early as 2001, the World Health Organisation's report of Mental Health acknowledged the mutual benefits of clinicians developing an early partnership with family members in a patient's mental healthcare, in terms of information sharing, effective treatment management and fostering the therapeutic alliance ([117] page 58):

> *"Through such a joint engagement, information on a wide range of issues related to the illness can be discussed, family reactions explored, and a treatment plan formulated. Families, in turn, benefit from learning a process of problem solving in order to manage the illness most effectively…*
>
> *"The mutual sharing of knowledge, the professional knowledge of mental health workers (i.e., clinicians), and the knowledge gained by families and consumers through their lived experiences is vital for the development of trust. Without trust, an effective treatment alliance is often not possible."*

Echoing these statements from the World Health Organisation, a more recent review acknowledged the importance of involving families in terms of effective treatment goals and planning, as they can provide important information that is not readily available to health professionals such as specific stressors or triggers, current health and wellbeing, past experience with illness and coping skills [24]. Importantly, there is RCT evidence that family involvement leads to improved patient outcomes [14], possibly because people with stronger support networks are more likely to adhere to treatment and better manage their mental illness [118].

In addition to the benefits of family involvement, a majority of patients with a serious mental illness also want their family involved in their care (78%, [119]). However, patient preferences for family involvement, as for their own involvement, are highly variable [119], and do not concord with actual involvement [24]. For example, only 31-40% of patients reported that their families had had contact with their treatment provider, with a further 40% reporting that their families had never had contact [24]. Furthermore, there may be additional barriers impeding family involvement in mental health compared to physical health conditions, such as concerns over privacy and stigma [119]. Given the profound psychosocial and practical burden that serious mental illness can have on the patient's family [24, 25, 120], the involvement of family in treatment decisions appears justified on ethical and legal grounds [81, 112, 121]. Variation in the type and extent of family involvement – both patient preferences and actual experience – points to a need to explicitly elicit patient preferences for these. This is consistent with patient-centred care, as well as literature recommendations in physical health conditions [81].

1.4. Interventions to support treatment decision-making

Decision-support interventions, such as patient decision-aids (DAs), are tools designed to facilitate SDM, by preparing patients to make informed, values-based decisions about treatment, screening tests, and other aspects of healthcare [122]. DAs come in a variety of formats (e.g., booklets, websites, video), and aim to: i) inform patients about the evidence-based healthcare options available; ii) encourage patients to actively participate in the decision-making process; and iii) guide patients through a deliberative process of considering what is important and matters to them, so that

they can make evidence-based, healthcare choices that are consistent with their values and preferences [123]. At a minimum, DAs presents non-directive information on the decision to be undertaken, the options available, and their related outcomes, including their benefits, side-effects/risks, and uncertainties, based on a comprehensive review of the evidence [122, 124]. Information is presented via a combination of text-based and graphical formats, and uses lay language [123].

A 2017 Cochrane review of 105 DA RCTs for treatment or screening decisions [75] confirmed that DAs are associated with a number of improved patient outcomes, such as: greater knowledge of options, more accurate risk perceptions and better match between care choices and informed patient preferences. Specifically, DAs appeared to enhance patient-clinician communication by increasing the extent to which clinicians were seen to involve patients in decision-making and achieve informed decision-making, patient-clinician agreement regarding satisfaction with the decision and decision-making process, and patient-clinician discussion about the decision [75]. Patient participation in decision-making was also improved across reviewed studies with patients receiving a DA compared to usual care reporting greater involvement, a more active (patient-controlled) role in decision-making, and reduced clinician control over decision-making [75]. While these review findings are promising, it is important to consider that the included studies used different measures to assess patient decision-making involvement, included different comparison groups (e.g., usual care or simple DA), and were conducted in a diverse range of patient populations (e.g., cancer, diabetes, pregnant women). Despite these considerations, there is consistent evidence to suggest that DAs encourage people to be more involved and to become active participants in their own treatment decision-making. The ability of DAs to improve concordance with patient preferences for involvement remains an unknown yet important outcome.

In contrast to the large body of research on the applicability and usefulness of DAs in physical health conditions, research in mental health conditions is scant [125]. An earlier 2010 Cochrane review on interventions to facilitate SDM for people with mental health conditions identified two separate RCT studies; the first involving a DA for inpatients with schizophrenia [126], and the second for a primary care sample of patients with physician diagnosed depression [127]. Meanwhile, the 2017 Cochrane

review of DA RCTs in physical and mental health conditions published through to April 2015 [75] identified two additional studies: one in primary care patients deciding on antidepressants [128] and another in military veterans diagnosed with post-traumatic stress disorder [129]. Consistent with findings in physical health conditions, those patients randomised to receive the mental health DA were more knowledgeable about treatment options and outcomes, and felt (or were rated) as more involved in the decision-making process compared to those receiving usual care [126-128]. Mixed findings were reported with regards to uptake and adherence to evidence-based treatments, and improvements to mental health symptomatology.

Consistent DA-related improvements in patient knowledge and perceived decision-making involvement align with Charles et al. [66], who identify patient knowledge and involvement as the key components of DAs (p. 249):

> *"…advocated as a tool to help physicians involve patients in the treatment decision-making process, i.e., to promote and facilitate shared treatment decision-making and to create more informed patients."*

Moreover, Charles et al. [66] argue against the use of DAs to promote patient outcomes that go beyond the intended purpose and scope of a DA. Some 'unintended' uses of DAs, which still lack adequate empirical support, include decreasing uptake of invasive treatment options (e.g., elective survey). These deviate from the initial aim of a DA, which is to provide patients with non-directional and unbiased information about the available evidence-based treatment options and their associated benefits and risks [66]. Nevertheless, findings from these DA RCTs in mental health are promising and suggest positive effects comparable with those documented in non-mental health conditions [86].

There appears to be a role for DAs to facilitate SDM about treatment options in BPII. Treatment decision-making in this setting is complex with an array of pharmacological and psychological treatments that have varying benefit-risk profiles, and divergent treatment guidelines that lack consensus or specificity to BPII (see section 1.1.5.). Moreover, as a chronic illness, patient engagement and self-

management is needed to prevent future relapses, in line with the recovery approach to care [64].

Even after having made a treatment decision, a significant proportion of patients expressed poor values clarification, feeling uninformed, and other manifestations of decisional conflict [130], which was not alleviated by available sources of informational support. Taken together, these findings suggest a need for improving patient involvement that is more in line with their elicited preferences, as well as facilitating decision-making that is based on a deliberative exploration of the patients' informed values. DAs are capable of fulfilling these objectives [75], but so far none have been specifically designed for BPII.

1.5. Significance and aims of this thesis

To date, no known studies have explored the perceptions and experiences of treatment decision-making in either BPI or BPII from the perspectives of patients, family members and clinicians. It is clear however, that treatment decisions for BPII are complex and necessitate patient involvement that is well informed and supported. The following thesis chapters present an innovative and timely research program, strengthened by its combination of both qualitative and quantitative research methods, and its applied clinical focus. This PhD research program was committed to exploring an under-researched area of inquiry in mental health, and developing an evidence-based decision-support resource that is informed by the views and lived experiences of key stakeholders, including family members whose role, though important, has been largely under-recognised. Research on decision-support resources to facilitate SDM is firmly established in medical healthcare, but is still in its infancy in mental healthcare. The development of such resources is fundamental for providing optimal care about BPII treatment and management, and has potential ramifications for patient quality of life, illness-related burden and treatment adherence.

The overall aim of this multi-stage project is to explore and improve the process of decision-making about the treatment and ongoing management of BPII. More specifically, this project will:

(i) Explore patient, family, and clinician perspectives on BPII treatment decision-making in relation to: information and involvement preferences; perceived barriers, facilitators and modifiers, challenges and related strategies; unmet decisional support and informational needs;

(ii) Develop a decision-support resource/ DA to facilitate SDM in this setting, The development of a DA will be informed by the unmet informational and decisional-support needs identified in **(i);**

(iii) Conduct a pilot study to obtain evidence on the DA's acceptability, safety, feasibility, and potential usefulness in this setting.

1.6. Structure of this thesis

The following chapter, Chapter 2, presents a systematic review of the current empirical literature on communication and decision-making about treatment with a focus on patients with bipolar disorder. In line with aim (i) (see section 1.5), Chapters 3 – 5 provide an in-depth qualitative investigation of treatment decision-making in bipolar II disorder (BPII) from the perspectives of patients, their families, and experienced treating clinicians. Chapter 6 outlines the rationale for, and development of a decision-aid (DA) for treatment decision-making in BPII, thus aligning with aim (ii) (see section 1.5). Following this, Chapter 7 reports on findings from a pilot study of the DA in a sample of potential end-users (as per aim (iii), see section 1.5). Finally, Chapter 8 concludes with a summary of the key findings and implications of the thesis as a whole. Chapters 2, 3, 4, 5, and 7 are reproductions of peer-reviewed journal articles; they retain all their published content with slight formatting changes as appropriate. Minor inconsistencies in headings and subheadings reflect journal-specific requirements and/or feedback from peer-reviewers. Chapter 6 is an unpublished thesis chapter. As a thesis in the style of a "thesis with publications", each chapter is prefaced by a brief paragraph summarising the publication and contextualising it within the overall scope of the thesis.

1.7. References for Chapter 1

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Chapter 2

Chapter 2: Communication and decision-making in mental health: A systematic review focusing on bipolar disorder

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This chapter presents a systematic review of empirical studies of clinician-patient(-family) communication and decision-making about treatment in mental health samples which included patients with bipolar II disorder (BPII). Review findings informed preliminary recommendations for clinicians working in this setting, and were used to guide the subsequent qualitative phases of the PhD research program. Supplementary materials related to this chapter are provided in Appendix C.

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2.1. Abstract

Objectives. To systematically review studies of communication and decision-making in mental health-based samples including patients with bipolar disorder (BP).

Methods. Qualitative systematic review of studies using PsychINFO, MEDLINE, SCOPUS, CINAHL, and EMBASE (January 2000–March 2015). One author assessed study eligibility, verified by two co-authors. Data were independently extracted by two authors, and cross-checked by another co-author. Eligible studies were assessed using a validated quality appraisal by two independent raters.

Results. Of 519 articles retrieved, 13 studies were included (i.e., 10 quantitative/1 qualitative/1 mixed-methods). All were cross-sectional; twelve were rated good/strong quality (>70%). Four inter-related themes emerged: 1) *patient characteristics* and 2) *patient preferences,* 3) *quality of patient-clinician interactions*, and 4) *influence of shared decision-making (SDM)/ patient-centred approach on patient outcomes*. Overall BP patients, like others, have unmet decision-making needs, and desire greater involvement. Clinician consultation behaviour influenced patient involvement; interpersonal aspects (e.g., empathy, listening well) fostered therapeutic relationships and more positive patient outcomes, including: improved treatment adherence, patient satisfaction with care, and reduced suicidal ideation.

Conclusions. This review reveals a paucity of studies reporting Bipolar-specific findings. To inform targeted BP interventions, greater elucidation of unmet decision-making needs is needed.

Practice Implications. Eliciting patient preferences and developing a collaborative therapeutic alliance may be particularly important in BP, and promote improved patient outcomes.

Keywords. Bipolar disorder, treatment, decision-making, communication, patient involvement, patient outcomes

2.2. Introduction

Bipolar disorder (BP) is a chronic, relapsing and remitting disorder of mood, thinking, and behaviour characterised by "lows" (depression) and "highs" (hypo/mania). Current diagnostic classifications recognise two subtypes, BPI and BPII; BPII is considered the less severe due its absence of impairment and psychotic features during "highs" [1]. By contrast, empirical evidence suggests comparable overall impairment across subtypes [2].

Pharmacological treatments represent the primary therapy for the acute treatment and long-term prophylactic management of BP [3]. Indeed, pharmacotherapy decisions in BP may be especially challenging, due to an incomplete evidence base [4], and high potential side-effect and quality-of-life burden of options [3, 5]. Further, treatment adherence–a well-documented problem among BP patients [6]-depends on the subjective value that BP patients assign to treatment efficacy versus side-effect burden [4].

Given medical uncertainty underlies BP treatment decisions, and the potential link between patient involvement and outcomes, patients should participate in treatment decisions. Patient involvement is particularly important in BP, as patients are responsible for actively self-managing their illness to prevent further relapse and/or recurrence [3, 7]. To this end, mental healthcare professionals are increasingly encouraged to practice shared decision-making (SDM) in patient treatment and management. SDM is well-suited to treatment decisions that are sensitive to patient values and preferences, as in BP [8]. Key elements include: providing patients with treatment option information, checking patient understanding of options and involvement preferences, and incorporating both patient and clinician perspectives and preferences into final decisions [9].

A prominently-cited model of SDM by Charles and colleagues [10, 11] recognises three decision-making stages: *information exchange* (providing information about treatment options), *deliberation* (discussing treatment preferences), and *deciding on the treatment to implement* (selecting a specific treatment option from the range of presented options). Each stage may involve the clinician, the patient and/or others (e.g., family or friends). Then, depending on patient's level of involvement, patients

may assume a passive, collaborative, or active role resulting in more clinician-led, shared, or more patient-led decision-making, respectively. Although mostly applied model to the acute care context, Charles et al.'s model is also applicable chronic illnesses that require ongoing decision-making and patient self-management, as with BP [12]. Of note, a systematic review highlighted that Charles et al.'s model [10, 11] emphasised more SDM elements than other prominently-cited models [13]. Based on this, it provides a comprehensive and integrative model of SDM [13].

Although informative, existing reviews of communication and treatment decision-making in mental health have methodological limitations (e.g., single database, [14]), been limited in scope (e.g., only RCTs, [15]) and have focused almost exclusively on unipolar depression and/or schizophrenia [16, 17]. Thus, findings may not generalise to BP. Firstly, BP patients might be expected to differ from others (e.g., schizophrenia) in terms of their preferences and experience of involvement in treatment decision-making [14], given the fluctuating nature of BP symptoms and associated disability together with periods of wellness. Secondly, treatment decision-making in BP may be more complex than in unipolar depression, as treatment addresses two distinct, though sometimes co-occurring sets of symptoms, depression and (hypo)mania [18]. Finally, a collaborative approach to illness management is perhaps of greater importance in BP than in other mood-based disorders (e.g., unipolar depression), given that long-term treatment relies heavily on patient self-management to prevent illness (prophylaxis) rather than the treat of illness symptoms as they occur [19].

To date, no known systematic reviews have focused on studies comprising BP patient samples. To address this gap, this qualitative systematic review aimed to synthesise quantitative and qualitative studies exploring communication and decision-making outcomes in mental health-based samples including BP patients. Where possible, the review aimed to draw preliminary comparisons between patient groups to elucidate any differences (and/or similarities) between BP and other mental health conditions. The review's scope was restricted to cognitively competent adult patients receiving voluntary mental healthcare.

2.3. Methods

2.3.1. Search strategy

To minimise the potential for publication bias a comprehensive, systematic approach was employed; electronic searches were conducted using multiple scientific literature databases (PsychINFO, MEDLINE, SCOPUS, CINAHL, EMBASE), manual searches of included article reference lists, and follow-up searches of articles related to published conference abstracts. Search results were limited to English-language articles published January 2000 to end March 2015, to capture the current clinical findings. Quantitative, qualitative, or mixed methodologies were all eligible. For a comprehensive list of search terms see Box 2.1.

Box 2.1. Database search terms

Level 1

patient OR client OR consumer OR "patient involvement" OR "patient participation"

AND

Level 2

consultation OR "medical encounter" OR "medical visit" OR "medical setting" OR "psychiatric setting" OR clinician OR psychiatrist OR psychologist OR "health professional" OR doctor OR physician

AND

Level 3

Bipolar* OR "Bipolar disorder"[a] OR "Bipolar affective disorder"[a] OR "Bipolar mood disorder"[a]

AND

Level 4

communicat* OR decision* OR "decision making" OR collaborat*

AND NOT

Level 5

pediatric* OR paediatric* OR alzheimer* OR dementia OR cancer OR oncolog*

Additional limits: English language only, published January 2000 – present.

Notes:

"two word phrase" = two adjacent words to be considered as a single phrase

OR = any of the search terms appearing at this level may be included

AND = at least one search term at each level must be included

AND NOT = none of the subsequent search terms (i.e., Level 5) may be included.

* = include all possible word endings (e.g., collaborat* = collaboration, collaborate, collaborative etc.)

[a] = Dependent on mapped subject heading for database.

Initially returned articles were independently title-screened by two authors (AF, FK) for irrelevant or review papers, conference abstracts, and duplicates. In cases of ambiguity, abstracts were consulted. All abstracts and full-texts were then independently screened for eligibility by the same two authors (AF, FK) according to specified criteria (Box 2.2). Additional articles were identified by a manual search of references lists and screened for eligibility according to the same criteria (Box 2.2). Discrepancies were discussed and resolved. One author assessed final study eligibility (AF), verified by two co-authors (IJ, FK).

Box 2.2. Eligibility criteria	
Types of studies:	Quantitative or qualitative (primary and secondary analyses of data sets) studies including: – Interviews/focus groups – Surveys – Consultation audit-studies (audio- or video-taped consultations, consultation observation) ***Exclusion:*** *Review papers, editorials, commentary/discussion papers, papers published in languages other than English, papers not available in full text*
Types of participants:	Communication/decision-making must have included one of the following participants: – Adult patients (>18 years) with a diagnosis of Bipolar Disorder (I or II) ***Exclusion:*** *Studies where patients not able to fully engage in the consultation (e.g. impaired decisional capacity; acutely psychotic), studies where BP patient sample not clearly defined, or comprise ≤ 10% total patient sample.* – Adult companions involved in the consultation (including spouse, family members, friends) ***Exclusion:*** *Studies where the companion had a unique responsibility (e.g. paid caregiver, proxy)* – Treating clinicians/ health professionals
Types of settings:	Any type of medical setting (including but not limited to: psychiatric, allied health, hospital, clinic, primary care, community mental health centre, inpatient, outpatient)

Types of communication:	Any form of clinician-patient communication and/or decision-making (including behaviours, attitudes, perceptions, self-report) ***Exclusion:*** *Studies where communication and/or decision-making mentioned only in passing, and primarily in relation to other concepts (e.g., aspect of therapeutic relationship/alliance, clinician-related qualities)*

2.3.2. Data extraction

Both inductive and deductive techniques were used for data extraction. Main study aims and findings were recorded by the first author, who then organised studies according to key topics. A preliminary list of common themes was then created and later refined via iterative discussions with a co-author (IJ). Studies were then organised deductively according to a standard format (design, method, sample, measures, results and summary). Two authors (AF, FK) independently extracted all data, which were later cross-checked for accuracy by another co-author (IJ).

2.3.3. Quality assessment

Study quality was assessed according to standardised criteria for quantitative and qualitative studies [20], which are provided in Appendix C. This assessment tool has been used to rate study quality in previous systematic reviews of medical decision-making [21] and includes an extensive manual for quality scoring with definitions and detailed instructions. Two authors (AF, FK) independently rated the quality of all eligible studies. On each criterion, studies were rated from 2 to 0, depending on whether the criterion was satisfactorily met ("yes"=2), partially met ("partial"=1), or not met ("no"=0). Krippendorff's alpha, used to estimate inter-rater reliability, was 0.85 (95% C.I.=0.73-0.94, based on 1000 bootstrapped samples), indicating excellent agreement [22]. Based on its summary score [4], each study was allocated a quality percentage (0-100%), which corresponded to limited (<50%), adequate (50-70%), good (71-80%), or strong quality (>80%) [23].

[4] Total sum = [number of "yes"] + [number of "partials"*1]; total possible sum [quantitative studies] = 28 – [number of "N/A"*2] or total possible sum [qualitative studies] = 20; summary score: total sum/ total possible sum.

2.4. Results

The search returned 513 articles. Manual reference searches yielded an additional 5 articles, along with 1 additional citing article. Of these, 97 duplicates and 387 irrelevant articles were removed (see Figure 2.1). Thirty-five abstracts were screened for eligibility, based on which 15 articles were excluded. Full-text screening of the remaining 20 articles excluded a further 7 articles, leaving 13 studies for final inclusion (see Figure 2.1).

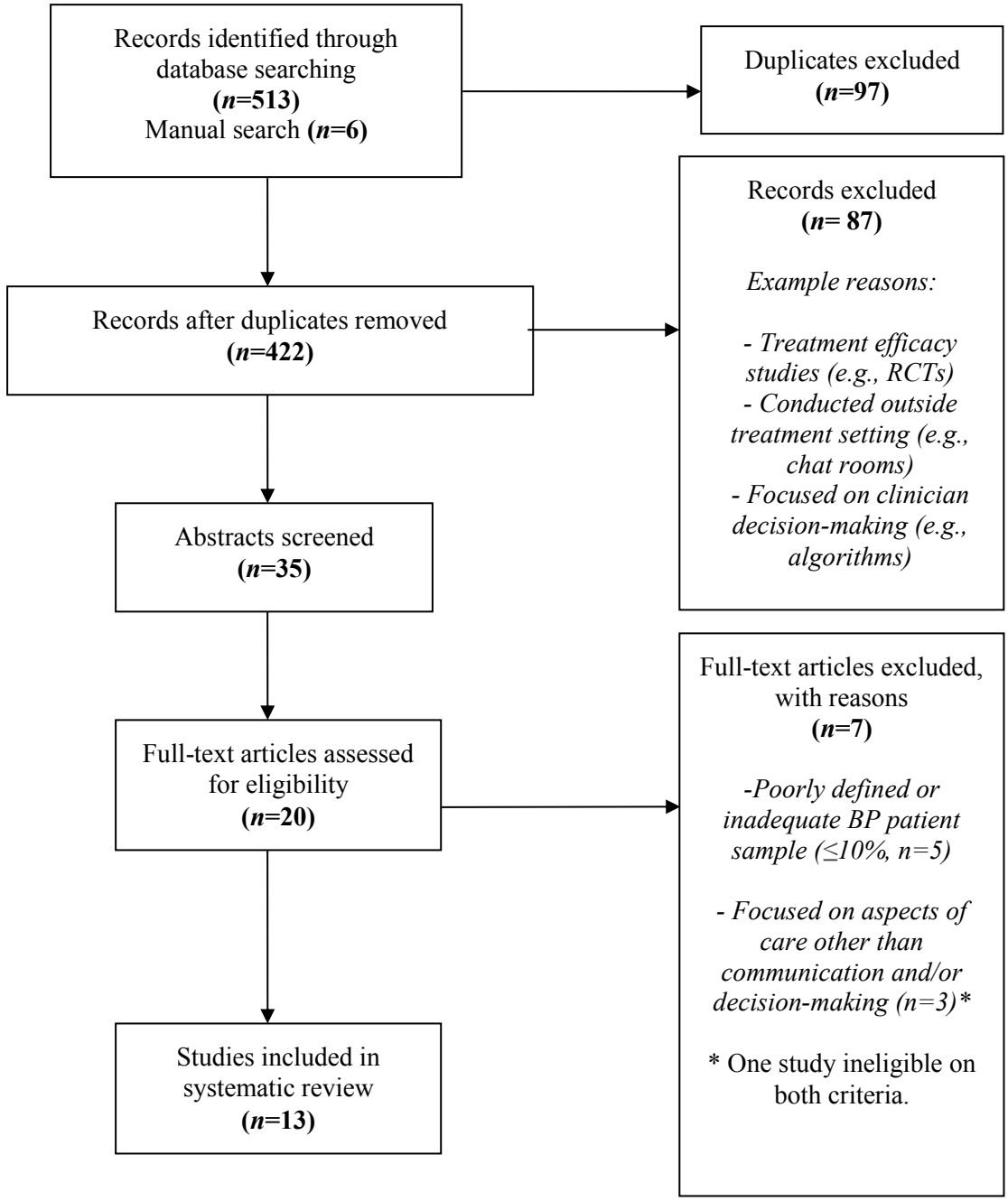

Figure 2.1. PRISMA Flow diagram of study selection.

2.4.1. Study characteristics

Table 2.1 summarises eligible study characteristics, including: quality rating, proportion of BP patients, use of (non-)validated measures, and main results. All studies were cross-sectional and conducted in outpatient settings. Most studies were published since 2010 (*n*=9/13) and from the United States (*n*=8). Analyses tended to be retrospective or secondary analyses of data from larger studies (*n*=8). All studies except one [24] were rated good (*n*=2) or strong (*n*=10) quality (*M*=85.8%) [23].

As seen in Table 2.1, most studies included a mixed psychiatric patient sample (*n*=11). The proportion of BP patients (across subtypes) ranged 12%-98% of the total sample; only two studies had BP-only samples [25, 26]. Diagnosis-specific findings were often not reported (*n*=8); no differentiation was made between BPI/II subtypes. Patient samples were heterogeneous with respect to age and gender: patient age ranged (*M*=36-54.3 years); some samples were gender-balanced, others had a female (*n*=5,62-66%) or male majority (*n*=3,76-89%). Predominant methods were patient-report questionnaires and observer consultation-ratings, less common methods were semi-structured patient interviews [27, 28], focus group [26] or audit of consultation notes [24]. In consultation-based studies, clinicians were either psychiatrists or nurse practitioners, or trainee GPs [24]. All consultation studies coded only dyadic (clinician-patient) interactions. Patients in two qualitative studies alluded to (potential) family involvement in decision-making [27, 28].

Table 2.1. Tabulated summary of included study findings (*N*=13)

Authors **Year** **Country** **Theme(s)**	**Quality rating**	**Approach, Design & Method**	**Sample & Setting**	**Measures specific to results** **Key: (+)/(-)= validated/ unvalidated measure**	**Results**	**Summary**
Quantitative studies						
De las Cuervas et al., 2014a Spain *Patient preferences* *Influence of SDM/ patient-centred approach on patient outcomes*	85% a, k	**Design:** Cross-sectional **Method**: Socio-demographic survey & self-report questionnaires	**Bipolar sample:** *n*=118 bipolar patients (12.2% total) **Overall sample:** *N*=967 patients (*M* age = 49.6 years; 62.9% females) **Response Rate:** 79% **Setting:** Community mental health services **Mental health discipline:** Psychiatry	(+) Morisky Medication Adherence Scale (MMAS-8) (+) Control Preferences Scale (CPS, administered twice)	- 64.3% patients preferred shared decisional control; 28.6% a passive approach; 6.7% an active approach. - Experienced roles were passive (78.1%); collaborative (21.6%); and active (0.3%). - Preferred and experienced roles were concordant for half patients; mismatch resulted from preferring a more active role than experienced. - Self-reported adherence higher for patients with concordant preferred/experience decision-making roles than for patients with discordant	- Psychiatric outpatients prefer shared/collaborative approaches to discussion making. - Almost half of patients do not experience their preferred level of decision-making control in consultations with their psychiatrists; most of these patients experience less involvement than preferred. - Achieving a preferred level of involvement (be it active, passive or collaborative) is associated

			Provider type: Psychiatrist		decision-making roles (p<.001); this pattern did not differ for different levels of involvement.	with increased medication adherence.
De las Cuervas et al., 2014b Spain *Patient characteristics* *Patient preferences*	90% a, j	**Design:** Cross-sectional **Method**: Socio-demographic survey and self-report questionnaires	**Bipolar sample:** *n*=67 patients (13.2% total) **Overall sample:** *N*=507 **patients** (*M* age = 48.4 years; 62.1% females) **Response Rate:** 76% **Setting:** Community mental health services **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist	(+) Control Preferences Scale (CPS, administered twice) (+) Multidimensional Health Locus of Control (MHLC) (+) General Perceived Self-Efficacy Scale	- 63.5% patients preferred shared decisional control; 34.7% a passive approach; 1.8% an active approach. - Experienced roles were passive (86%) or collaborative (14%). - Older age, lower self-efficacy, positive external HLC, and negative internal HLC predicted stronger preferences for more passive decision-making styles. - Being older age, male, and having low self-efficacy, predicted experiencing a passive decision-making style. - 47% patients reported concordance between preferred and experienced role; 52% preferred a more active role than experienced; 1% more passive. - Consistent role mismatch across all disorders; patients with personality disorders preferred more active/collaborative role (70%) than	- Psychiatric outpatients prefer shared/collaborative approaches to discussion making. - About half of patients do not experience their preferred level of decision-making control in consultations with their psychiatrists; most of these patients experience less involvement than preferred. - Socio-demographic and attitudinal characteristics of patients influence preference and experience of more active/collaborative or more passive decision-making styles. - Some differences in preferred and experience roles emerge for different psychiatric disorders; Bipolar disorder does not appear to differ from other psychiatric disorders in this respect.

					others; patients with schizophrenia and personality disorders experienced more passive role (90%) than others.	
Frankel et al.,* 2013 USA *Quality of patient-clinician interactions*	75% a, e, f, h, m	**Design:** Cross-sectional **Method**: Audiotaped psychiatric visits	**Bipolar sample:** *n*=28 patients (23% total) **Overall sample:** *N*=124 patients (*M* age = 43.2 years; 51% males); *n*=8 prescribers (5 psychiatrists, 3 nurse practitioners). **Response Rate:** 97% **Setting:** Community mental health centre **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist and NP	(-) Purpose-designed coding system for agenda setting; identified 10 essential and 9 non-essential elements (rated present or absent/ partial/complete).	- A majority of encounters showed >= 1 essential element; 10% encounters showed no essential elements; no encounters showed >= 6 essential elements. - Commonly absent elements were orienting the patient to the visit (96.8% absent), eliciting a statement of patient concerns (66.1%), and elicit full breadth of concerns at beginning of visit (89.5%). - Approximately half of visits showed partial (27.4%) or complete (26.6%) rapport building.	- Overall, prescribers showed quite poor involvement of patients in agenda setting; mostly commonly missing elements related to patient-centredness and partnership building. - Prescribers are inconsistent in their rapport building during consultations.
Fukui et al.,* 2013 USA	100%	**Design:** Cross-sectional **Method**: Audiotaped psychiatric visits	**Bipolar sample:** *n*=18 patients (14.1% total) **Overall sample:** *N*=128 patients (*M*	(-) Shared Decision-making (SDM) scale adapted from (+) Informed Decision-making Scale.	- Mean rated SDM was 9.7 out of 18 - Mean rated patient initiation score was 1.8 out of 9. - 46% of consultations involved a "basic" decision; 54% involved an	- Overall, clinicians' exhibited low levels of SDM, and patients exhibited low levels of active involvement.

Quality of patient-clinician interactions			age = 43.4; 50.8% females); *n*=8 providers (5 psychiatrists, 3 nurse practitioners). **Response Rate:** 69% **Setting:** 3 community mental health centres **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist and NP		"intermediate" or "complex" decision. - 79% consultations achieved patient-clinician agreement; 21% included some disagreement. - More complex decisions (*B*=2.467, *p*<.001) and more patient initiation (*B*=0.767, *p*<.001) predicted more SDM; accounted for 37.6% variance. - Eliciting patient preferences (*B*=0.767, *p*<.001, OR=3.97) predicted greater patient-clinician agreement; accounted for 52.5% variance.	- Clinicians successfully involved patients more in decisions with less medical consensus and decisions which posed greater potential risk to the patient. - Eliciting patient preferences may be a key way of increasing patient-clinician agreement in making a decision. - N.B. Consultations comprised predominantly progress-check visits and 25% did not involve any clinical decisions.
Ilgen et al.,* 2009 USA *Influence of SDM/ patient-centred approach on patient outcomes*	90% e, j	**Design:** Cross-sectional **Method**: Socio-demographic survey and self-report questionnaires.	**Bipolar sample:** *N*=423 patients (98% of total, *M* age = 49.0 years, 76% male; *n*=164 BPI, *n*=45 BP NOS, *n*=4 BPII) **Response Rate:** N/A **Setting:** Veterans receiving inpatient and outpatient mental health treatment	(+) Health Care Climate Questionnaire (HCCQ) (+) Patient Health Questionnaire (PHQ-9) suicide ideation item (+) Morisky Medication Adherence scale (MMAS-8).	- Patients reporting a lower medication adherence and a less collaborative therapeutic relationship were more likely to report suicidal ideation (*p*'s <.001) - Patients reporting a collaborative therapeutic relationship were less likely to report suicidal ideation in the two weeks prior (OR = 0.97, *p*<.001)	- In addition to medication adherence, establishing a therapeutic relationship that patient perceive as collaborative may act as a buffer against suicidal ideation amongst patients with BP.

			Mental health discipline: Psychiatry **Provider type**: NS			
Klingaman et al.,* 2015 USA *Patient preferences* *Influence of SDM/ patient-centred approach on patient outcomes*	73.2% e, g, l	**Design:** Cross-sectional **Method**: Self-report questionnaires	**Bipolar sample:** *n*=76 patients (32% total) **Overall sample:** *N*=239 veterans with serious mental illness (*M* age = 54.0 years, 89% male) **Response Rate:** N/A **Setting:** Veterans receiving inpatient and outpatient mental health treatment **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist and NP	(-) Purpose-designed questionnaire based on (+) validated measure of patient satisfaction (+) Behaviour and Symptom Identification Scale (BASIS-24) (+) Scale to Assess Therapeutic Relationship (STAR-P) (-) 3-item scale of shared decision-making (SDM) preferences.	- A large majority of patients (75.7-93.4%) preferred their clinician to offer them options and ask their opinion about mental health treatments. - Positive collaboration (*B*=.15, *p*<.01) and positive clinician input (*B*=.18, *p*<.001) predicted greater patient satisfaction during visits. Unsupportive clinician input did not. - Preferences for a more shared/collaborative approach to decision-making (*B*=-.06, *p*<.05) predicted lower patient satisfaction.	- Most people with serious mental illness, desire involvement in treatment decision-making, though preferences may be stronger for particular aspects of decision-making. - Patients who prefer a SDM approach report lower satisfaction with visits which may hint at a potential mismatch between preferred and experienced roles in decision-making in this context. - Patient satisfaction is enhanced by their perceptions of a positive and collaborative therapeutic relationship.
Llewellyn-Jones et al., 2001	61.1% a, b, e, f, h, j	**Design:** Cross-sectional **Method**: Audit of consultation notes	**Bipolar sample:** *n*=24 patients (12% total)	(-) Routine clinical practice question "Do you have any questions you would	- Most common questions in patients with BP included reductions in medication (12.5%) and fitness to drive (12.5%), similar to patients	- Similar to patients with schizophrenia and unipolar depression, patients with BP tend

UK *Quality of patient-clinician interactions*			**Overall sample:** *N*=200 patients (mostly with schizophrenia [32%] or unipolar depression [26%]) seen by consultant psychiatrist (78%) or trainee GP (22%). **Response Rate:** N/A **Setting:** Outpatient clinics **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist or GP	like to ask?" Patient replies and case note diagnoses recorded.	with schizophrenia (19% asked about stopping medication, 9% asked about reducing medication), unipolar depression patients (7.7% asked about medication termination). - 50% of patients with BP had no questions, comparable to of schizophrenia patients (57%) and unipolar depression patients (40%). 21% of patients with anxiety and 33% with personality disorders had no questions.	to ask questions related to medication. - Questions about medication reflect a desire to stop or reduce medication. - Patients with BP, similar to patients with schizophrenia, ask less questions of their clinician than patients with other mental disorders (i.e., depression, anxiety, personality disorders). - Low rate of question asking may reflect difficulties in discussing symptoms and medication issues, or barriers to participation during psychiatric visits.
Park et al.,* 2014 USA *Patient characteristics*	95% h	**Design:** Cross-sectional **Method**: Self-report questionnaires	**Bipolar sample:** *n*=63 patients (26% total) **Overall sample:** *N*=239 patients (*M* age = 54.3 years, 89% male) and *N*=21 prescribers (13 psychiatrists, 8 NPs).	(-) 3-item scale of shared decision-making (SDM) preferences. (+) Behaviour and Symptom Identification Scale (BASIS-24)	- 85% of patients indicated preference for choices and to be asked their opinions about their mental health treatment by their clinician. - 61% of patients showed preference to rely on their clinician's knowledge rather than obtaining information	- Patient preferences for SDM appear to depend on the stage of the decision-making process; patients almost uniformly endorse their clinician offering options and asking their opinions about mental health treatments. - Preferences for SDM appear to be strong among patients with

Patient preferences			**Response Rate:** N/A **Setting:** Two outpatient mental health clinics **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist or NP	(+) Scale to Assess Therapeutic Relationship (STAR-P)	about their mental illness on their own. - 64% of patients would prefer their clinician to make the final decisions about their mental health treatment. - Preference for clinician knowledge and clinician-led decisions were positively correlated (r=.54, p<.001). - Patients were more likely to prefer seeking mental health information on their own if they were employed (B=.76, p=.007), had tertiary education (B=.66, p=.004), and had a diagnosis of BP (B=.60, p=.054), depression (B=.82, p=.01), or PTSD (B=.92, p=.03,versus schizophrenia). - Patients were more likely to prefer relying on their clinician's knowledge if they were Caucasian (B=-.86, p<.001), or reported a stronger therapeutic relationship (B=-.06, p=.002).	higher education, and a diagnosis of BP, depression or PTSD compared to schizophrenia. - Patients preferring a more paternalistic/passive decision-making style report a stronger therapeutic relationship which may be attributable to greater concordance between preferred and experienced roles in decision-making participation.
Salyers et al.,* 2012	97.5% f	**Design:** Cross-sectional **Method**: Audiotaped consultations	**Bipolar sample:** n=37 patients (22% total)	(-) Shared decision-making scale/coding system (SDM-18) adapted from (+)	- Clinical decisions (in 75% of consultations) included; stopping (8%) or adding (18%) a medication, changing time/administration (18%)	- Important aspects of SDM are commonly absent during psychiatric visits; even though clinicians demonstrate a more

USA *Quality of patient-clinician interactions*	**Overall sample:** *N*=170 patients (*M* age = 43.6 years, 52% males) and *N*=8 providers (5 psychiatrists, 3 NPs). **Response Rate:** N/A **Setting:** Community mental health centres **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist and NP	Elements of Informed Decision-making Scale.	or dosage (18%) of current medication (18%), deciding not to change medication when alternative offered (40%), deciding on non medication alternative (49%). - 46% decisions were "basic"; 52% intermediate; and 2% complex. - Reciprocal/complete discussion was most common in consumer's goal and context of decision (92%), clinical nature of decision (63%), alternatives (58%, most commonly nonmedication), consumer's preference (56%). - Most commonly absent was discussion of patient's desire for others' input (90%), and patient's understanding (52%). - Most SDM elements were initiated by clinician, except for discussion of patient QoL (66%). - 79% decisions were made in full patient-clinician agreement; 15% patients and 6% clinicians agreed reluctantly.	SDM approach for more complex decisions, the minimum required levels of SDM are not achieved in a substantial proportion of visits. - Most SDM is initiated by clinicians rather than patients, and a majority of decisions are made in full clinician-patient agreement. - Although SDM is associated with longer consultation times, this was attributable to the greater complexity of decisions requiring SDM rather than SDM per se.

					- After controlling for decisional complexity, no relationship between SDM and visit length. - Minimum required SDM was achieved in 61% basic and 46% of intermediate/complex decisions. - More SDM behaviours were observed in intermediate/complex decisions than basic decisions (p<.001).	
Stacey et al., 2008 Canada *Patient preferences* *Influence of SDM/ patient-centred approach on patient outcomes*	82.5% a, e, j, k	**Design:** Cross-sectional **Method**: Semi-structured interviews and self-report questionnaires.	**Bipolar sample:** n=25 patients (26.5% total) **Overall sample:** N=94 patients (Median age = 40 years, 66% females) **Response Rate:** 91% **Setting:** Psychiatric hospital outpatient services and community hospital **Mental health discipline:** Psychiatry **Provider type**: NS	(-) Population Needs Assessment Tool based on Ottawa Decision Support Framework. (+) Decisional Conflict Scale (+) Control Preferences Scale, modified	- Most common treatment decisions involved taking medications (n=35) - 40/67 patients were uncertain about a recent treatment decision, often resulting in "wavering between choices" (57% versus 9% when certain), difficulties in decision-making commonly manifested as feeling distressed/upset (70%) or worrying (69%). - Uncertain patients were more likely to feel uniformed, have unclear values, feel less supported (p<.001), to report lacking motivation (p=.012) or skills/ability to make decision (p=.026), and have greater supportive	- Over half of patients who have made a recent treatment decision remain uncertain; often due to feeling uniformed, unclear about values, or lacking support. - More than 90% patients with depression and bipolar disorder wish to make treatment decisions either alone or collaboratively with their clinician, over half prefer to involve family and/or friends. - Family involvement, if it occurs, is usually perceived as supportive, and patients do not feel pressured

					family involvement (28/66 vs 4/27 certain). - Patients preferred to discuss decision with psychiatrist (89%), friends (62%), and family (45%); preferred support resources were pamphlets (82%) and developed by health professionals (95%).	either by them or by their clinician. - This patient group are generally information seeking, although greater exposure to information about outcomes associated with options may contribute to uncertainty. - Pamphlets developed by healthcare professionals appear to be the preferred information support resource.
Sylvia et al.,* 2013 USA *Influence of SDM/ patient-centred approach on patient outcomes*	88.6% b, j, m	**Design:** Cross-sectional **Method**: Self-report questionnaires	**Bipolar sample:** *N*=3337 patients (71.1% BPI, 28.9% BPII) **Response Rate:** N/A **Setting:** Outpatient clinics specialised in BP treatment **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist	(-) Purpose-designed scale of medication adherence, Affective Disorders Evaluation (+) Helping Alliance Questionnaire, patient version (+) Care Satisfaction Questionnaire.	- After controlling for clinical factors associated with poor adherence, patient perceptions of a therapeutic relationship that was strong (e.g., feeling understood), positive (e.g., having good relationship), and collaborative (e.g., jointly working on problems) positively predicted a higher likelihood of medication adherence (OR's <1.0, *p*'s<.05). - Higher levels of patient satisfaction with care (e.g., feeling respected, helped, and being attended to on	- Feeling liked and liking the clinician, having a positive and meaningful relationship, involving collaborative problem solving appear to contribute to medication adherence. - Patient perceptions of clinician respect, helpfulness and efficiency also contribute to medication adherence.

					time) positively predicted a higher likelihood of medication adherence (*p*'s<.05).	
Qualitative studies						
Bilderbeck et al., 2014 UK *Quality of patient-clinician interactions*	92.5% d, p	**Design:** Cross-sectional **Method**: Semi-structured interviews post-assessment and at 6 months' follow-up.	**Bipolar sample:** *n*=5 patients (18% total) **Overall sample:** *N*=28 patients (*M* age = 36 years, 64% female). **Response Rate:** N/A **Setting:** Community mental health teams, a specialist mood disorders clinic, and outpatient therapeutic service **Mental health discipline:** Psychiatry **Provider type**: Psychiatrist or other	(-) Qualitative semi-structured interview topic schedule exploring patient experience of assessment by clinical staff in secondary psychiatric care. Specific topics included: expectations, suggestions for improvement, and feelings about the outcomes of their assessment. Follow-up interviews inquired about longer-term perceptions of	- Five broad themes emerged: (i) wanting an explanation and help; (ii) wanting consistent and continuous care; (iii) struggling to communicate and be understood (e.g. feeling unable to answer questions or communicate internal mood states); (iv) wanting to feel involved and informed in diagnosis and treatment decisions; (v) wanting to be acknowledged but often feeling dismissed and discredited by clinicians time constraints and inflexibility. - Many patients felt family and/or friends could facilitate communication with clinician and that stigma was neglected from discussion.	- Patients identified several communication barriers and difficulties during clinical assessments, which were in part due to the nature of their symptoms. Family and friends may play supporting or facilitative roles in this setting. - Patients are not as involved and informed about their diagnosis and treatment decisions as they would like and feel necessary. - Specific clinician behaviours are considered important by patients, and their absence may result in feelings of abandonment, frustration or being dismissed/discredited. These include being empathetic and listening, acknowledging patient

				assessment and diagnosis.		problems and concerns, and being flexible about treatment options.
Mixed methods studies						
Sajatovic et al.,* 2005 USA *Quality of patient-clinician interactions*	85% e, j, n, p	**Design:** Cross-sectional **Method**: Self-report questionnaire and focus groups.	**Bipolar sample:** *N*=52 patients (85% BPI, 15% BPII, *M* age = 43.8 years, 73% females) **Response Rate:** N/A **Setting:** Community mental health centre **Mental health discipline:** Psychiatry **Provider type**: NS	(+) Drug Attitude Inventory (-) Open-ended focus group question eliciting essential qualities for an effective patient-provider relationship.	- On average, 87.5% of patients adhered to psychotropic medication and 84.7% to scheduled clinic visits. - Essential qualities for an effective patient-provider relationship included patient-centred, provider-centred, and interactional qualities. - Patient-centred qualities included willingness to disclose information; and help and/or information-seeking behaviours. - Crucial provider-centred qualities included being a good-listener and responding to clients' feelings, allowing patients to talk and be heard, and admitting limits of one's knowledge. Patient concerns related to a lack of discussion of alternative therapies and failure to acknowledge medication side effects.	- These patient identified elements of an effective patient-provider relationship that may have contributed to their high levels of treatment adherence. - An effective relationship relies on patient and clinician qualities/ behaviours, as well as aspects of the interaction itself. - Patients described themselves as needing to be open with information and assertive, while clinicians were described as needing to be a good-listener, sensitive, and flexible. - The extent to which decision-making is collaborative depends on severity of symptoms, and being informed, and patients appreciate the circumstances in which illness management may

	- Interactional qualities included flexibility in consultation length, variability in the desired amount of involvement based on bipolar symptoms and disability, and belief that "giving more weight" to clinician opinions and "trusting" clinicians in making decisions was important for illness management when they felt insufficiently informed or too symptomatic to do so.	benefit from a more clinician-led approach to decision-making.

Notes: * = Secondary analysis of data drawn from separate study.

Score of 1 or 0 on the Standard Quality Assessment Criteria for Evaluating Primary Research Papers (Kmet et al., 2004) (Item number from quantitative [QN] and qualitative [QL] studies quality rating checklist)

Provider types include; NP = Nurse Practitioner, GP = General Practitioner, NS = Not Specified, Other = various .

a Question description [QN 1; QL 1]; b Study design [QN 2; QL 2]; c Study context description [QL 3]; d Theoretical/empirical connection [QL 4]; e Sampling strategy [QN 3; QL 5]; f Subject characteristics reported [QN 4]; g Data collection methods [QN 5, 6, 7, ; QL 6]; h Means of assessment reported [QN 8]; i Sample size [QN 9]; j Data analysis [QN 10; QL7]; k Estimate of variance reported [QN 11]; l Controlled for confounding [QN 12]; m Results reported in sufficient detail [QN 13]; n Verification procedure to establish credibility [QL 8]; o Conclusions supported by the results [QN 14; QL 9]; p Reflexivity of the account [QL 10].

2.4.2. Primary themes

Four primary themes emerged: i) *patient characteristics*, i.e., individual beliefs about self, clinical and/or demographic characteristics pertinent to decision-making; ii) *patient preferences* for decision-making style and involvement, and patient decisional-support needs; iii) *quality of patient-clinician interactions,* i.e., in-consultation behaviours within a SDM/patient-centred approach, the therapeutic alliance, and patient-/clinician-related qualities that facilitate or impede this process; iv) *influence of SDM/patient-centred approach on patient outcomes,* e.g., care satisfaction, uncertainty, treatment adherence, and suicidal ideation, and associations with SDM/patient-centredness.

2.4.3. Theme 1: Patient characteristics

Two studies examined the predictors of patient socio-demographic characteristics on preferences for, and experience of, decision-making roles and involvement [29, 30], with inconsistent findings. These discrepancies may be due to one study assessing general involvement preferences using a single-item measure [29] and the other separate involvement preferences for the decision-making stages using a multi-item measure [30]. Older age and being male predicted stronger preferences for, and greater likelihood of experiencing, less involvement in decision-making in general [29]. When decision-making stages were assessed separately, being Caucasian predicted preferences for less involvement (i.e., relying on clinician's knowledge; [30], whereas higher education predicted preferences for greater involvement (i.e. independent information gathering, and patients making decisions on their own; [30].

In addition to socio-demographic variables, patient diagnosis was also found to influence preferences and/or experience of decision-making. However, findings were inconsistent regarding whether patients with BP differed from other psychiatric patients in their preferences for, or experience of decision-making involvement (yes [30], no [29]). When differences were seen, BP patients showed a trend towards preferring more independent information-gathering (p=.054), but not for actually making the decision on their own [30]. As with non-modifiable (socio-demographic and diagnostic) patient characteristics, a negative relationship with modifiable patient characteristics was also found (low self-efficacy, external health locus of control) [29].

2.4.4. Theme 2: Patient preferences

Patient preferences for involvement and decision-making style were quantitatively assessed in five studies [28-32]. In studies examining *decision-making preferences as a single construct*, a majority of patients reported preferring an active or collaborative decision-making role [28, 29, 31]. Specifically, patients -including BP patients- preferred sharing decision-making with their clinician (38.3-64.3%) or making the final decision alone (1.8-52.1%). A minority of the patients in these studies reported preferring a passive role (8.5-34.7%). Qualitative studies revealed that patients' desired involvement level varied according to their current BP symptoms and disability. Differences in BP symptoms and disability did not relate to differences in BP subtype, as these were also reported within patient samples comprising a single subtype (BPII) [27]. Rather, such variability related to within-individual changes over time. Thus, "trusting clinicians" and "giving more weight" to clinician opinions were important for illness management when patients felt insufficiently informed or too symptomatic to do so [26].

When looking at *decision-making preferences as a multi-dimensional construct*, there was greater variability in patient preferences for theirs' versus the clinicians' involvement [30, 32]. Most patients wanted to be informed and asked their opinion of treatment options (75.7-93.4% [30, 32]), but preferred to rely on their clinician for giving professional advice (versus independent information-gathering, 61%) and making the final treatment decision (64%) [30]. Variability was also seen in terms of *whom* patients with BP and depression wished to involve in treatment discussions, and *where* they wished to source information about treatment options from. Most patients preferred discussions with their treating clinician (i.e., psychiatrist, 89%), but around half also preferred to have treatment discussions with friends (62%) and family (45%) [28]. Preferred information-support resources were those developed by health professionals (95%), and in pamphlet format (89%), yet some also preferred CD-Roms (44%), and information provided by pharmaceutical companies (21%) [28].

In two studies assessing *both* patient preferences and self-reported experience of decision-making involvement [29, 31] over half of participants (52%) reported a mismatch between preferred and actual levels of involvement. This discordance

between preferred/experienced roles was significant for all psychiatric diagnoses including BP ($X^2(2)=7.83$; $p<0.005$), underlined by patients wanting greater in decision-making than they experienced [29, 31]. This latter finding was echoed in qualitative studies, where patients reported wanting to feel informed about diagnosis and be involved in treatment decisions, but that this was seldom realised in practice [27].

2.4.5. Theme 3: Quality of patient-clinician interactions

Six studies investigated the quality of patient-clinician interactions; with two studies using semi-structured patient interviews [26, 27] and four studies coding consultation behaviours [24, 33-35]. These latter studies used either purpose-designed coding systems [24, 33] or a previously validated coding system adapted to the mental health setting [34, 35]. Consultation studies tended to focus on clinician behaviours [33-35] rather than patient behaviours [24, 34, 35]. Consultation studies usually pooled findings across the heterogeneous clinician types (e.g., psychiatrists and nurse practitioners, psychiatrists and GPs) [24, 33, 35], which precluded clinician comparisons. One study compared clinician types (psychiatrists and nurse practitioners) and found no differences on SDM outcomes [34]. Consultations were usually evaluated in terms of observed patient involvement, and shared and/or informed decision-making. Across patients with BP, schizophrenia and depression, a large proportion of treatment discussion and decision-making related to medication [24, 28, 35], such as stopping, reducing, continuing or changing medication, or deciding on a non-medication alternative (e.g. join support group, attend counselling). In BP patients alone, 12.5% of all consultation questions related to reductions in current medication [24]. Observed patient involvement during consultations was low across agenda setting and decision-making [33, 34]. Patients also initiated very few decision-making behaviours [34, 35], with rates of question-asking particularly low amongst BP patients (50%), compared to some patient groups (unipolar depression, anxiety, or personality disorders, 60-79%) but not all (schizophrenia, 43%) [24].

While, in general, clinicians' involvement of patients was relatively poor, they varied in the extent to which they practised SDM. More commonly, clinicians engaged patients in discussions about treatment goals and preferences, and treatment alternatives [35]. Less commonly, clinicians engaged in partnership-building or

patient-centredness [33], checked patient preferences for others' involvement (e.g., family) and understanding of information [35]. Indeed, minimum SDM requirements were achieved in less than half of immediate/complex decisions (46%) [35]. Immediate/complex decisions also formed the majority of treatment decisions in the community mental health setting (54%) [33, 35]. Immediate/complex decisions were defined as having a moderate-to-extensive impact on the patient (e.g., side effects and/or risk), involving some degree of medical uncertainty, and potentially posing a risk to patients.

Despite an overall low patient involvement and suboptimal SDM engagement, a number of consultation-related factors lead to higher SDM levels. Greater SDM was associated with more complex decisions [34, 35] and a greater number of patient-initiated SDM behaviours [34]. Interestingly, greater SDM was not associated with longer consultation times, after controlling for level of decisional complexity [35]. Although patient-clinician agreement on the final treatment decision was common (79%) [34, 35], agreement was more likely when the clinician elicited patient treatment preferences [34], which accounted for a large proportion of variance in agreement (52%) [34]. No specific findings per psychiatric group were reported in either study. Together these findings suggest a role of both patients and clinicians in initiating and facilitating SDM, which is also moderated by the complexity of decisions being made.

In a similar vein, patient-related, clinician-related, and interactional qualities were all identified as influencing effective patient-clinician communication. BP patients felt they needed to be open and share information with clinicians, and be proactive in their health- and/or information-seeking [26]. However, patients also reported barriers to communication [27], such as difficulties recalling information, and feeling pressured to accurately answer clinicians' "ambiguous" questions [27]. Family members and/or friends were identified as means for overcoming these communication barriers [27], and family involvement in treatment discussions was perceived as mostly supportive [28].

Several clinician interpersonal behaviours, both positive and negative, were identified by patients in two qualitative studies [27] [26] and in one consultation study [33]. To

build rapport, BP patients said clinicians needed to be a good listener, allow patients time to talk and be heard, show empathy and sensitivity to their patients' feelings, and admit the limits of their clinical knowledge [26, 27]. By contrast, barriers to rapport-building included patients being pressured by time constraints, patients feeling unheard, dismissed or discredited by clinicians who did not acknowledge their problems, clinicians being inflexible with treatment options, or prescribing medication over engaging in a meaningful discussion of patient problems [27]. Indeed, rapport-building was commonly absent from psychiatric consultations, with only half of psychiatrists and nurse practitioners demonstrating either partial (27.4%) or complete (26.6%) rapport-building [33].

2.4.6. Theme 4: Influence of SDM/patient-centred approach on patient outcomes

Five studies examined the influence of SDM/ patient-centred approaches on various patient-reported outcomes. Outcomes of interest included: medication adherence in BP and mixed patient samples [25, 31, 36], suicidal ideation in BP [36], care satisfaction in BP and mixed patient samples [25, 32], and decisional uncertainty about treatment choices in BP and unipolar depression [28].

Although not always tested directly, a supportive therapeutic relationship and patient satisfaction with care were commonly associated with more positive patient outcomes. Namely, patients who perceived their therapeutic relationship as strong (e.g., feeling understood), positive (e.g., having a good relationship), and collaborative (e.g., jointly resolving problems), were more likely to indicate improved medication adherence [25], reduced suicidal ideation [36], and greater patient satisfaction with psychiatric visits [32]. In the two studies involving BP patients only, these associations were evident even after controlling for clinical factors associated with poorer BP outcomes (e.g., rapid cycling, earlier onset of illness, medication non-adherence) [25, 36]. By contrast, uncertainty regarding chosen treatment was associated with feeling less supported in decision-making [28]. Decisional uncertainty was not alleviated by information-seeking, as information-seeking rates were higher among uncertain patients [28].

Across studies, patients who were satisfied with their care and decision-making, and experienced their preferred involvement level, reported more positive outcomes. In

two studies, patient satisfaction with care in BP [25] and satisfaction with treatment decision-making [28] were associated with better medication adherence and lower decisional uncertainty, respectively. Similarly, patients reported better medication adherence when they experienced their preferred decision-making style, whether passive, active or collaborative [31]. Lower care satisfaction was found when patients preferred shared/collaborative decision-making [32].

2.5. Discussion and conclusion

This is the first known systematic review of empirical studies focusing on communication and decision-making among individuals with BP. Derived from studies of good to strong quality [23], the review findings centre around four inter-related themes mapping onto three sequential aspects decision-making: decision antecedents (*patient characteristics* and *patient preferences*), decision process (*quality of patient-clinician interactions*), and decision outcomes (*influence of SDM/ patient-centred approach on patient outcomes*). These three aspects have been previously identified in a systematic review of SDM measures within the general medicine and psychiatric settings [37]. Of note, these aspects of decision-making provide a broader context to Charles et al.'s model [10, 11] of SDM as they highlight: i) the patient characteristics and preferences that likely shape the purported decision-making stages (information exchange, deliberation, and final decision-making), ii) the extent to which patients are/feel involved during these stages and where shortcomings exist, and iii) how clinician SDM behaviours and patient perceptions of involvement during these stages may relate to outcomes. Findings also build on a recent systematic review of decision-making needs in mental health [14]. However, Tlach et al.'s review did not include any studies of BP patients and was limited to four studies identifying decision topics (medication and non-medication treatments, general treatment issues and treatment setting, lifestyle, working and living conditions).

2.5.1. Patient characteristics and preferences for SDM

Our review findings point to increasing interest in the applicability of SDM and patient-centredness in the mental health setting. By and large, study findings were reported across mixed patient samples precluding BP specific conclusions. When patient outcomes were reported separately for the different psychiatric diagnoses, BP patients differed from other patient groups in some studies [24, 30] but not all [29].

Compared to patients with schizophrenia, BP patients reported a trend towards *wanting greater* involvement in decision-making (i.e., more independent information-gathering) [30]. Yet, compared to patients with depression, anxiety and personality disorders, BP patients *exhibited fewer* involvement behaviours during consultations (i.e., less question-asking) [24]. These differences should be interpreted with some caution given that they derive from studies of heterogeneous quality (adequate: [24]; strong: [29, 30]). However, findings align with a recently published cross-sectional survey of patients with BP or depression [38]. In this survey, BP patients were more information seeking than patients with depression; actual decision-making involvement also differed across groups, however, involvement preferences did not [38]. Thus, it is unlikely that diagnostic factors alone are predictive of either individual patient involvement preferences or actual involvement, but may play a contributing role. Although not specific to BP, it is important to recognise that BP has a relatively early onset, is chronic and marked by periods of fluctuating symptomatology severity. By contrast, other psychiatric disorders may be more situationally-focused with later onset (e.g., unipolar depression). The chronic, relapsing and remitting nature of BP, accompanied by periods of euthymia may predispose BP patients to want greater involvement in treatment decision-making compared to other patients. However, the disability and diminished insight associated with acute BP symptoms may impair these patients' ability to actively participate in consultations.

As in the medical setting [39, 40], psychiatric patient preferences for involvement show a mixed relationship with demographics (e.g., age, education;[29, 30]), clinical factors (e.g., BP symptom severity;[41]), and individual-based beliefs (e.g., health locus of control and self-efficacy;[29]). Of note, this relationship appears to be less consistent with socio-demographic characteristics but more consistent with symptom severity, again paralleling the medical setting [39, 40]. Therefore, mental health professionals would be remiss to assume patient involvement preferences based on socio-demographic characteristics. Poorer mental health status may be a better proxy of a patient's involvement preferences. When experiencing more severe symptoms, BP patients are likely to prefer more clinician-led decision-making. However, given that patients with depression report strong information preferences regardless of

symptom severity [42], eliciting preferences with each patient remains a necessary step.

Similarly to medical conditions [43], psychiatric patients – including those with BP – wish to be informed and involved in treatment decision-making [27-29, 31]. This said, patient preferences varied across the decision-making stages. Patients almost universally want to be offered and informed about treatment options (the *information exchange* and *deliberation stages*)[11] yet a smaller proportion of patients wanted to make the final decision about treatment themselves. One explanation for variability in patient involvement preferences may be differences in the measures used (i.e., single item versus multi-item measures) [39]. Alternatively, this variability may reflect patients perceiving greater benefit in "the process of involvement" (i.e., information exchange and deliberation) than in "actual decisional responsibility" (i.e., who makes the final decision on treatment to implement) [44]. Based on these findings, clinicians cannot assume that BP patients desire active involvement throughout the whole decision-making process [44], and thus need to check their preferences at different stages.

2.5.2. Patient experience of SDM and its influence on outcomes

Despite strong patient preferences for involvement in consultations, it appears that patients with BP are often less involved than they desire [27, 29, 31]. These findings are corroborated by studies showing overall poor patient involvement by clinicians, and suboptimal SDM in more complex treatment decisions (according to criteria by Braddock et al. [45]). Discordance between patients' preferred and actual involvement levels, may be explained by clinicians' failure to elicit patient involvement preferences [35]. Further, mismatch between preferred and experienced roles [29, 31], may also explain why preferring SDM predicted lower patient satisfaction with psychiatric consultations [32], while preferring clinician-led decisions predicted a stronger therapeutic relationship [30]. Reviews of patients with schizophrenia and depression also report achieving less involvement than desired [16, 46, 47]. Among general medical patients, some report less involvement than desired [48], with others reporting greater involvement than desired [49]. These discrepant findings may point to psychiatric patients having stronger involvement preferences than patients in general medicine. More likely, however, is that patients tend to experience less involvement in psychiatric consultations than in general medical consultations [50].

Interestingly, observer ratings of patient-clinician consultation interactions revealed two categories of patient involvement: instrumental and interpersonal. The instrumental aspects of patient involvement and SDM comprised clinicians' functional behaviours: presenting treatment options, eliciting patient treatment goals and preferences [33, 35]. Meanwhile, the interpersonal aspects of patient involvement included patients feeling heard and acknowledged, and being responded to with sensitivity and empathy [26, 27]. Both instrumental and interpersonal aspects were valued and considered important by patients, including those with BP [26]. These findings fit with an expanded definition of patient involvement [51], which encompasses more objective aspects of "being" involved as well as more subjective aspects of "feeling" involved. "Feeling" aspects of patient involvement are argued to be less tangible and unable to be externally observed, yet both "being" and "feeling" involved likely contribute to patient's self-reported involvement post-consultation [44, 51]. The notion that both "being" and "feeling" involved contribute to patient's own evaluations involvement [44, 51], also accords with relational understandings of

patient autonomy [52]. Relational autonomy proposes that relational aspects of the clinician-patient interaction may foster (e.g., clinician listening to patients) or impair (e.g., clinician dismissing patients' concerns) a patient's sense of autonomy [52]. Thus, to enhance patient involvement clinicians should address not only the functional aspects of their behaviour but also their interpersonal manner with patients.

A strong, positive and collaborative therapeutic alliance was associated with several positive BP patient outcomes, including reduced suicide risk, better medication adherence, and patient satisfaction in care [25, 32]. Of note, the therapeutic alliance appeared "buffer" against clinical factors associated with poorer BP outcomes. Patient satisfaction with care and achievement of preferred involvement levels also appear related to better medication adherence in BP [25, 26]. Indeed, patient satisfaction and achievement of involvement preferences may be indicative of a strong therapeutic alliance [32], based on mutual trust, respect and understanding of treatment goals [53]. These findings echo others showing the importance of the therapeutic alliance in chronic mental health conditions, such as BP, both to promote patient engagement and treatment adherence [8, 19]. Therefore developing a strong therapeutic alliance appears to be a priority for both BP patients and their treating clinicians.

2.5.3. Limitations

Although findings from the small number of reviewed studies are informative and based on good quality research, they are limited in several ways. Firstly, most studies utilised mixed patient samples and did not report psychiatric disorder-specific findings. This is likely due to most reviewed studies employing convenience sampling, which often resulted in a smaller proportion of BP patients compared to other patient groups and precluded group comparisons. Further, in studies that did report BP-specific findings, no differentiation was made between the BP subtypes (I and II). The presence of psychotic features in BPI but not BPII may interfere with BPI patients' ability to make decisions and report their preferences for, and perceptions of involvement in decision-making. Thus, definitive conclusions cannot be drawn regarding individuals with BP, and future BP-specific studies would benefit from distinguishing between BPI and BPII patients whose capacity for decision-making involvement may differ. Although the present review should be treated as exploratory,

it nevertheless highlights areas of potential clinical interest and future research directions.

Secondly, only patients receiving voluntary mental healthcare were included in the current review. Although this inclusion criterion was applied to ensure that findings reflected cognitively competent patients with decisional capacity, this also limits the generalisability of findings. Thirdly, retained studies included a variety of clinicians, including psychiatrists, nurse practitioners, and GPs without any psychiatric speciality. This heterogeneity in provider types reflects the nature of mental health practice but may also influence clinician-patient communication and patient involvement in decision-making. Fourthly, a number of studies comprised samples that were "older aged" or non-gender-balanced; therefore the current findings may not be representative of the broader adult population with BP, or mental illness more generally. Fifthly, the reviewed studies were mostly descriptive surveys and cross-sectional design. Patient-reported preferences or outcomes may vary over time and differ from those depicted at the time point studied. Finally, all studies captured only one perspective of the communication and decision-making process, either the patient's or trained observer's, but not the clinician's. As clinicians, patients, and family members are all involved and exert influence on the decision-making process to some extent [54], examining one party's perspective or behaviour is unlikely to provide a complete picture of events. Therefore, there is a need to investigate the viewpoints and experiences of all stakeholder groups, in order to address unmet decisional-support needs and inform clinical recommendations.

2.5.4. Conclusion

This systematic review highlighted a paucity of studies on communication and treatment decision-making in BP. Nevertheless, it provides a valuable synthesis of the existing high-quality literature, with a focused discussion of quantitative and qualitative findings as they relate to BP patients. To date, this patient group has been largely neglected in the literature, which has mostly focused on other psychiatric populations. Preliminary clinical recommendations are proposed, however further research is needed to discern BP-specific decision-support needs and involvement preferences.

2.5.5. Practice implications

Although BP-specific findings are limited, findings from the reviewed studies have a number of implications for clinical practice in the psychiatric setting. The good to strong quality of most of the reviewed studies also lends credibility and confidence to preliminary clinical recommendations (summarised in Table 2.2). Findings highlight that BP patients tend to prefer an active-collaborative decision-making role, and desire greater levels of involvement than what they are currently experiencing. This said, a BP diagnosis by itself is unlikely to explain the involvement preferences of individual patients. Thus, to optimise patients' decision-making involvement, clinicians are advised to check and tailor their involvement of patients on the basis of individual patient preferences. Although, more research is needed to delineate the involvement preferences of BP patient specifically, targeted BP interventions to enhance and tailor involvement appear warranted. Patient decision-aids (DAs) may be potentially useful in the BP setting, as these are evidence-based interventions designed to increase patient involvement and promote more informed, values-based treatment decisions [55]. While decision-aid use in mental health is still scant, there is promising evidence supporting their efficacy in depression and schizophrenia [15, 55, 56]

Table 2.2. Preliminary clinical recommendations based on reviewed studies

1.	To optimise patient involvement in treatment decision-making, clinicians should tailor the level of involvement to patient preferences.
2.	Targeted SDM interventions, such as decision-aids, may be useful for BP patients to facilitate their treatment decision-making involvement.
3.	Interpersonal and rapport-building aspects of clinician behaviour appear particularly important with BP patients. Clinician behaviours which may strengthen the collaborative relationship with BP patients include: being a good listener, showing sensitivity to patient's feelings, allowing patients time to talk and be heard, admitting limits to one's knowledge (e.g., in cases of medical uncertainty, other clinical expertise).
4.	Clinicians are advised to assess each patient's involvement preferences: (i) at different stages of the decision-making process; (ii) in response to changing BP symptom severity; and (iii) on a case-by-case basis and not generalise preferences across patients.
5.	Clinicians should not assume a patient's desired level of involvement in treatment decisions based socio-demographic characteristics (e.g., age, education level, ethnicity).
6.	Clinicians should raise the subject of family involvement with patients and elicit their preferences for this.

In addition to patient DAs that enhance the functional aspects of SDM (i.e., patient knowledge, clarification of values and preferences), a clinician's interpersonal behaviours may also enhance patient autonomy and perceived involvement. In BP patients especially, these behaviours likely foster the therapeutic alliance and in turn more positive patient outcomes. Improving the interpersonal aspects of patient-clinician interactions may prove particularly challenging, however. Limited evidence supports the positive effects of SDM interventions on interpersonal rapport [57]. This said, interventions targeting *both* patients and clinicians lead to greater improvements in SDM compared to those targeting only patients or only clinicians [57]. This may also be the case for interventions to promote the interpersonal aspects of patient involvement.

Before clinicians set out to engage patients more in decision-making, it is important that they first assess patient involvement preferences. Specifically, patient preferences for involvement should be assessed at different stages of the decision-making process, and in response to changing BP symptom severity, but not based on socio-demographic characteristics (e.g., age, education level, ethnicity). Finally, BP patients

acknowledge that family members facilitate effective consultation communication; a majority of patients also wished to engage family and friends in treatment discussions. Therefore clinicians should raise the subject of family involvement with BP patients and elicit their preferences for this. This strategy has been proposed by a review of family involvement in medical consultations, where family attendance tends to be more common (16-86%) [21] than in mental health consultations (31-40%) [58]. Even though family appear less likely to attend mental health consultations, clinicians may discuss with patients their preferences for family involvement, and any potential barriers to involving family to the extent patients prefer. Indeed, identified barriers to family involvement [21] may be particularly salient in the BP setting (e.g., perceived stigma and lack of understanding, concerns about privacy and confidentiality, and discussion of sensitive topics). If the patient does wish to involve their family, it is therefore important to discuss and address any potential benefits of family involvement in relation to their treatment goals [58].

2.6. References for Chapter 2

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Chapter 3

Chapter 3: A qualitative exploration of patient and family views and experiences of treatment decision-making in bipolar II disorder.

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Fisher A, Manicavasagar V, Sharpe L, Laidsaar-Powell R, Juraskova, I. A qualitative exploration of patient and family views and experiences of treatment decision-making in bipolar II disorder. Journal of Mental Health. 2018;27(1):66-79. https://doi.org/10.1080/09638237.2016.1276533

This chapter reports on a qualitative study, which sought to explore the views and experiences of treatment decision-making among patients with bipolar II disorder (BPII) and their families. Findings elucidated key informational and decisional-support priorities and unmet needs in this setting; these were used to inform the content, format, and delivery of the decision-aid (DA, see Chapter 6). Ethics approval letters are provided in Appendices B1 and B2; supplementary materials related to this study are provided in Appendix D.

Author contributions
Conception and design: AF, IJ
Participant recruitment: AF
Data collection: AF
Data analysis and interpretation: AF, IJ, RL-P, LS
Manuscript drafting: AF
Manuscript critical review: All authors
Review of final manuscript: All authors

3.1. Abstract

Background. Treatment decision-making in bipolar II disorder (BPII) is challenging, yet the decision-support needs of patients and family remain unknown.

Aim. To explore patient and family perspectives of treatment decision-making in BPII.

Method. Semi-structured, qualitative interviews were conducted with 28 patients with BPII-diagnosis and 13 family members with experience in treatment decision-making in the outpatient setting. Interviews were audiotaped, transcribed verbatim and analysed thematically using framework methods. Participant demographics, clinical characteristics, and preferences for patient decision-making involvement were assessed.

Results. Four inter-related themes emerged: 1) *Attitudes and response to diagnosis and treatment*; 2) *Influences on decision-making;* 3) *The nature and flow of decision-making*; 4) *Decision support and challenges*. Views differed according to patient involvement preferences, time-since-diagnosis, and patients' current mood symptoms.

Conclusions. This is the first known study to provide in-depth patient and family insights into the key factors influencing BPII treatment decision-making, and potential improvements and challenges to this process. Findings will inform the development of BPII treatment decision-making resources that better meet the informational and decision-support priorities of end users.

Declaration of interest. This research was partly funded by a Postgraduate Research Grant awarded to the first author by the University of Sydney. No conflicts of interest declared.

Keywords. Bipolar II disorder, treatment decision-making, patient involvement, qualitative, barriers, facilitators, qualitative.

3.2. Introduction

While shared decision-making (SDM) in mental health is increasingly encouraged [1] there is evidence that in many psychiatric illnesses, patients do not achieve their desired level of involvement in treatment decision-making [2, 3].

One disorder with a relative paucity of evidence on patient involvement in treatment decision-making is bipolar II disorder (BPII) [4], a chronic and relapsing psychiatric condition involving depressive and hypomanic episodes [5]. Further, there are particular challenges for BPII patients that may make their treatment decisions unique and more complicated than in other mental health conditions. These include: a more limited evidence-base to support treatment choices [6], more finely balanced decisions due to high potential side-effects of mood-stabilisers [7] absence of debilitating psychotic symptoms [5], and that hypomanic symptoms may enhance rather than impair perceived psychosocial functioning [8]. Thus, BPII patients may require additional support to make evidence-informed treatment decisions that integrate their preferences [7]. Patients' family members facilitate medical decision-making, by providing emotional, informational, practical, decisional support and/or advocacy to the patient [9]. Yet, little is known about family involvement the mental health setting, and specifically bipolar disorder [10].

This study explored: i) the nature of clinician-patient-family decision-making about BPII treatment; ii) unmet patient/family needs for information and decision-support; and iii) decision-making barriers and facilitators.

3.3. Materials and methods

3.3.1. Participants

Patients: Adults, aged 18-65 years, diagnosed with bipolar II disorder (BPII) who were currently making or had recently made (i.e., within the past 12 months) a non-/medication-related treatment decision were eligible. Participants were referrals to: i) a clinical service specialising in mood and bipolar disorders in metropolitan Sydney, or ii) the clinical service's BPII psycho-education group. BPII diagnosis was based on a "consensus diagnostic decision" between at least two assessing psychiatrists with expertise in mood and bipolar disorders [11]. To establish BPII diagnosis, all patients

were clinically assessed by an intake psychiatrist who made a lifetime clinical diagnosis of BPII applying clinician-judged criteria. These criteria took into account DSM-5 symptom criteria [5] but did not impose the minimum duration criterion for hypomania (4 days). This criterion is largely arbitrary and not of clinical significance [11, 12]. Approximately a third of patients were also assessed by a second independent psychiatrist. Prior to clinical assessment, patients also completed the 27-item Mood Swings Questionnaire [13], which has sensitivities and specificities of 70-82% and 78-98% in tertiary patient referral samples [14, 15].

Family members: Adults, aged 18-65 years, whose family member had: i) an adult BPII diagnosis (18+ years), and who had ii) attended at least one consultation involving treatment decision-making, and/or had iii) experience helping their family member make treatment decisions outside consultations were also invited to participate. Family were identified through patients; however, patient participation was not a pre-requisite.

All participants required English proficiency and informed consent capacity. Patient exclusion criteria also included: i) comorbid substance abuse disorder and ii) concurrent neurological/major psychiatric condition. Recruitment continued until data saturation (i.e., no new information after three consecutive interviews) [16]. Ethical approval for all aspects of the study was obtained.

3.3.2. Procedure

A clinic research assistant introduced the study to eligible patients following their clinical assessment, and passed on contact details of interested patients to the study coordinator (AF), who had no pre-existing relationship with the patients. Patients attending the psycho-education group responded to an expression-of-interest flyer at meetings. Eligible family members were identified through patients who were then contacted by AF.

AF telephoned interested patients to explain the nature and purpose of the study, i.e., to investigate patient and family views and experiences of decision-making about treatment for BPII. At this time, AF also obtained verbal consent to post/email a study pack containing: an information sheet, written consent form, family expression-of-

interest form, and pre-interview questionnaire. Upon receiving the completed questionnaire and written consent form, a one-off telephone interview was arranged. The same procedure was followed for interested family. Post-interview, patients completed a verbally-administered mood measure.

3.3.3. Qualitative data collection

The researcher conducting the interviews (AF) was trained in conducting semi-structured qualitative interviews by two experienced qualitative health psychology researchers (IJ, RL-P) and received ongoing supervision and advice in response any issues that arose in interviews (e.g., establishing when and how to prompt for further information).

Purpose-designed, semi-structured interview protocols (Appendix D) were informed by SDM models [17-19], the Ottawa decisional support framework [20] and similar qualitative studies in mental health (depression) [21] and medical populations (cancer) [22]. Parallel interview protocols were developed for patients and family members. During the interview, participants were asked about general aspects of BPII treatment decision-making (e.g., patient and family involvement, clinician behaviours), followed by a more focused discussion of a consultation involving an actual treatment decision with reference to key decision-making stages, such as *information exchange* (sharing of decision-relevant clinical and personal information), *deliberation* (expressing and discussing treatment preferences), and *making a final decision* (reaching an agreement on treatment to follow) [17, 18].

3.3.4. Quantitative measures

Preferences for involvement in decision-making were assessed using adapted, parallel versions of the *Control Preferences Scale* (CPS) [23-25]. The CPS has been previously validated in outpatients with a mental illness, including bipolar disorder [26-28].

Patients' current mood state and symptomatology were assessed using the *Internal States Scale* (ISS) [29]. This 17-item self-rating scale comprises four subscales: 'Activation', 'Wellbeing', 'Depression Index', and 'Perceived Conflict', all rated on a Likert-type scale from 0 ('rarely in the past 24 hours') to 100 ('very much so in the

past 24 hours'). Scores on the Activation and Wellbeing Subscales are used to determine current mood states, as follows: hypomania (Activation: ≥155; Wellbeing: ≥125), Mixed state (Activation: ≥155, Wellbeing <125), Euthymia (Activation: <155, Wellbeing: ≥125), Depression (Activation: <155; Wellbeing:<125) [30].
The Activation and Depression Index subscales correlate highly and specifically to clinician ratings of hypomanic (r=0.60) and depressive (r=0.84) symptoms, respectively [29].

Demographic and clinical characteristics were collected using a purpose-designed self-report questionnaire.

3.3.5. Data analysis

Questionnaire data were analysed using SPSS version 22. Frequency analyses analysed all categorical variables (e.g., highest level of education obtained), whilst descriptive analyses analysed all continuous variables (e.g., age diagnosed with BPII).
Interviews were audio-recorded and professionally transcribed verbatim. Interview data were then analysed thematically [31] using framework methods as outlined in Ritchie et al [32]:
1) *Familiarisation with the data*: AF conducted all interviews, cross-checked each transcript against the audio-recording, and read each transcript several times;
2) *Creating a thematic framework*: a preliminary thematic framework was based on independent analyses of 20% of transcripts by IJ and RL-P. Data were independently organised according to concepts, themes, and subthemes. Different interpretations of the data were discussed together with LS until consensus was reached on the main framework themes;
3) *Indexing*: with the assistance of NVivo11, AF coded all transcripts according to the framework, with new themes and revisions discussed with IJ;
4) *Charting*: themes and supporting quotes from each transcript were transferred by AF to the framework matrix with participants as rows and themes as columns. At this stage, MS Excel was utilised as a computerised qualitative data analysis tool [33];
5) *Mapping and Interpretation*: the framework was examined within and across themes and participants to identify patterns, and relationships. In line with the flexibility afforded by thematic analysis [31, 34], analyses were guided by both deductive (literature-based) and inductive (data-driven) approaches, within a realism

paradigm [35]. To ensure methodological rigour, a proportion of the transcripts (20%) were cross-coded by another co-author (RL-P) and discrepancies discussed and resolved before proceeding with coding the entire dataset. Secondly, the thematic map was developed in consultation with two co-authors (IJ, RL-P), who have expertise in treatment decision-making and qualitative analysis. In addition, a subsample of participants (*n*=6 patients, *n*=2 family) who had agreed to provide feedback, were sent a summary of findings and provided feedback on the research team's interpretations of the data (i.e., member checking) [36].

3.4. Results

3.4.1. Participant characteristics

Twenty-eight of the 40 patient participants (70%) and 13/20 family participants (65%) who agreed to be contacted, completed both the questionnaire and interview. Patient and family interviews lasted *M*=35 minutes (*SD*=10.16) and *M*=33 minutes (*SD*=15.47), respectively.

A majority of patients (64%) had been diagnosed within the past 12 months. Many family members (54%) were the patient's spouse/partner, who had been diagnosed over 12 months ago (85%). Most patients (78.6%) and family (61.5%) reported having recently decided on treatment, or having an established treatment plan. Most patients (71.4%) and family (84.6%) also indicated that relapse prevention/mood stability was their main treatment goal (Tables 3.1 & 3.2).

Regarding involvement preferences, a similarly large majority of patients and family preferred patient/family-led or SDM in both clinician-patient-family (86% patients, 85% family) and clinician-patient (82% patients, 92% family) scenarios. At interview, patients variously reported euthymia (32%), hypomania (32%), depression (18%) or mixed-state (18%; Table 3.2).

Table 3.1. Socio-demographic characteristics of patients (*n*=28) and families (*n*=13)

	Patients	**Family**
	***M* (*SD*)**	***M* (*SD*)**
Age	41.61 (13.06)	48.38 (13.47)
	***n* (%)**	***n* (%)**
Gender (female)	19 (67.9)	10 (76.9)
Relationship to patient		
Spouse/partner	--	7 (53.9)
Mother	--	3 (23.1)
Sister	--	2 (15.4)
Friend	--	1 (7.7)
Highest qualification		
Year 12/ HSC or below	5 (17.9)	2 (15.4)
TAFE certificate/ diploma	8 (28.6)	3 (23.1)
University degree	11 (39.3)	6 (46.2)
Postgraduate degree	4 (14.3)	2 (15.4)
Current employment		
Working full-time	12 (42.9)	7 (53.8)
Working part-time	6 (21.4)	2 (15.4)
Not employed/ Retired/ Home-duties	5 (17.9)	3 (23.1)
Studying	3 (10.7)	--
Other (e.g., PT work, study)	2 (7.1)	1 (7.7)
Country of birth		
Australia	20 (71.4)	10 (76.9)
Other (e.g., UK, Netherlands)	8 (28.6)	3 (23.1)
Language spoken at home		
English	26 (92.9)	12 (92.3)
Other (e.g., Dutch, Turkish)	2 (7.1)	1 (7.7)
Present marital status		
Single or dating	12 (42.9)	2 (15.4)
Married/ living with partner	10 (35.7)	9 (69.2)
Separated or divorced	6 (21.4)	2 (15.4)
Current living arrangement		
By yourself/ independently	9 (32.1)	2 (15.4)
With partner (and/or children)	14 (50)	10 (76.9)
With other family members	3 (10.7)	--
With non family members	2 (7.1)	1 (7.7)

Any children		
No	18 (64.3)	5 (38.5)
Yes	10 (35.7)	8 (61.5)
Patient/Family dyads		
No	19 (67.9)	5 (41.7)
Yes	9 (32.1)	8 (61.5)

Table 3.2. Patient clinical characteristics for patients (*n*=28) and families (*n*=13)

	Patient	**Family**
	***M* (*SD*)**	***M* (*SD*)**
Age first diagnosed BPII	39.21 (13.59)	34.69 (13.59)
	***n* (%)**	***n* (%)**
Time since BPII diagnosis		
< 1 month	9 (32.1)	--
1 - 12 months	6 (32.1)	5 (38.5)
1 - 5 years	2 (7.1)	1 (7.7)
5 + years	8 (28.6)	7 (53.9)
Pre-BPII diagnoses		
No	4 (14.3)	8 (30.8)
Depression	11 (39.3)	7 (53.8)
Anxiety	1 (3.6)	--
Depression and anxiety	12 (42.9)	1 (7.7)
Yes, other (e.g., Personality disorder)	2 (7.1)	1 (7.7)
Episodes since BPII diagnosis *		
More than once per month	15 (53.6)	5 (38.5)
4 or more times per year	5 (17.9)	3 (23.1)
About 2-3 times per year	7 (25.0)	2 (15.4)
Less than once per year	1 (3.6)	2 (15.4)
Episode type since BPII diagnosis		
Mainly hypomanic episodes	15 (53.6)	1 (7.7)
Mainly depressive episodes	12 (42.9)	6 (46.2)
Equal depression/ hypomanic	--	3 (23.1)
Mainly euthymic/ subdromal	1 (3.6)	2 (15.4)
Clinicians seen for BPII [a]		
Psychiatrist	28 (100)	13 (100)
Psychologist	20 (71.4)	12 (92.3)
GP	25 (89.3)	12 (92.3)
Counsellor	8 (28.6)	5 (38.5)

Mental healthcare nurse	7 (25.0)	6 (46.2)
Current stage BPII treatment		
Considering/ yet to decide on treatment	4 (14.3)	3 (23.1)
Recently decided	10 (35.7)	8 (61.5)
Established plan to continue	12 (42.9)	--
Established plan to change	2 (7.1)	1 (7.7)
Other (e.g., no plan in place)	--	1 (7.7)
Current medication		
None	3 (10.7)	1 (7.7)
Mood-stabiliser only (incl. anticonvulsants)	10 (35.7)	4 (30.8)
Antitypical antipsychotic	1 (3.6)	--
Mood-stabiliser plus atypical antipsychotic	3 (10.7)	3 (23.1)
Mood-stabiliser plus antidepressant	5 (17.9)	3 (23.1)
Atypical antipsychotic plus antidepressant	1 (3.6)	1 (7.7)
Combination of all three types	5 (17.9)	1 (7.7)
Psychological interventions		
Yes (e.g., CBT, Mindfulness)	20 (71.4)	12 (92.3)
Goal of BPII treatment*		
Treat current depression	3 (10.7)	1 (7.7)
Treat current hypomania	--	--
Prevent relapse long-term	20 (71.4)	11 (84.6)
Other (e.g., treat depression and prevent relapse)	5 (17.9)	--
Other chronic medical condition		
Yes (e.g., Hypothyroidism, diabetes)	11 (39.3)	7 (53.8)
Family attended consultation		
Yes	16 (57.1)	11 (84.6)
Usual attendance in consultation		
Usually patient alone	24 (85.7)	8 (61.5)
Mix alone and accompanied	4 (14.3)	5 (38.5)
Patient involvement preferences, triadic (based on CPS)		
Patient-led alone	4 (14.3)	1 (7.7)
Patient-led with family/clinician	14 (50.0)	6 (46.2)
Patient/family-led with clinician	3 (10.7)	1 (7.7)
Patient/family/clinician shared	2 (7.1)	3 (23.1)
Family-led with patient/clinician	--	--
Clinician-led with patient/family	4 (14.3)	2 (15.4)
Clinician-led alone	--	--

Patient involvement preferences, (based on CPS)		
Patient-led alone	--	--
Patient-led with clinician	13 (46.4)	6 (46.2)
Patient/clinician shared	10 (35.7)	6 (46.2)
Clinician-led with patient	5 (17.9)	1 (7.7)
Clinician-led alone	--	--
Mood state at time of interview (based on ISS)		
Depressed	5 (17.9)	--
Hypomanic	9 (32.1)	--
Mixed state	5 (17.9)	--
Euthymic/ subsyndromal	9 (32.1)	--

* = remaining family members indicating "don't know"

3.4.2. Qualitative findings

Qualitative analyses yielded four inter-related themes, comprising several subthemes (Figure 3.1): 1) *Attitudes and response to diagnosis and treatment*; 2) *Influences on decision-making;* 3) *The nature and flow of decision-making*; and 4) *Decision support and challenges*. Overall, family and patient participants expressed concordant views, and most themes were similarly represented among patient and family participants. The use of the term "participants", without qualification, denotes instances where views were expressed to a similar extent by both patients and family; the use of "patients" or "family" denotes instances where views were expressed only by that group. Illustrative quotes are presented in Tables 3.3 – 3.4.

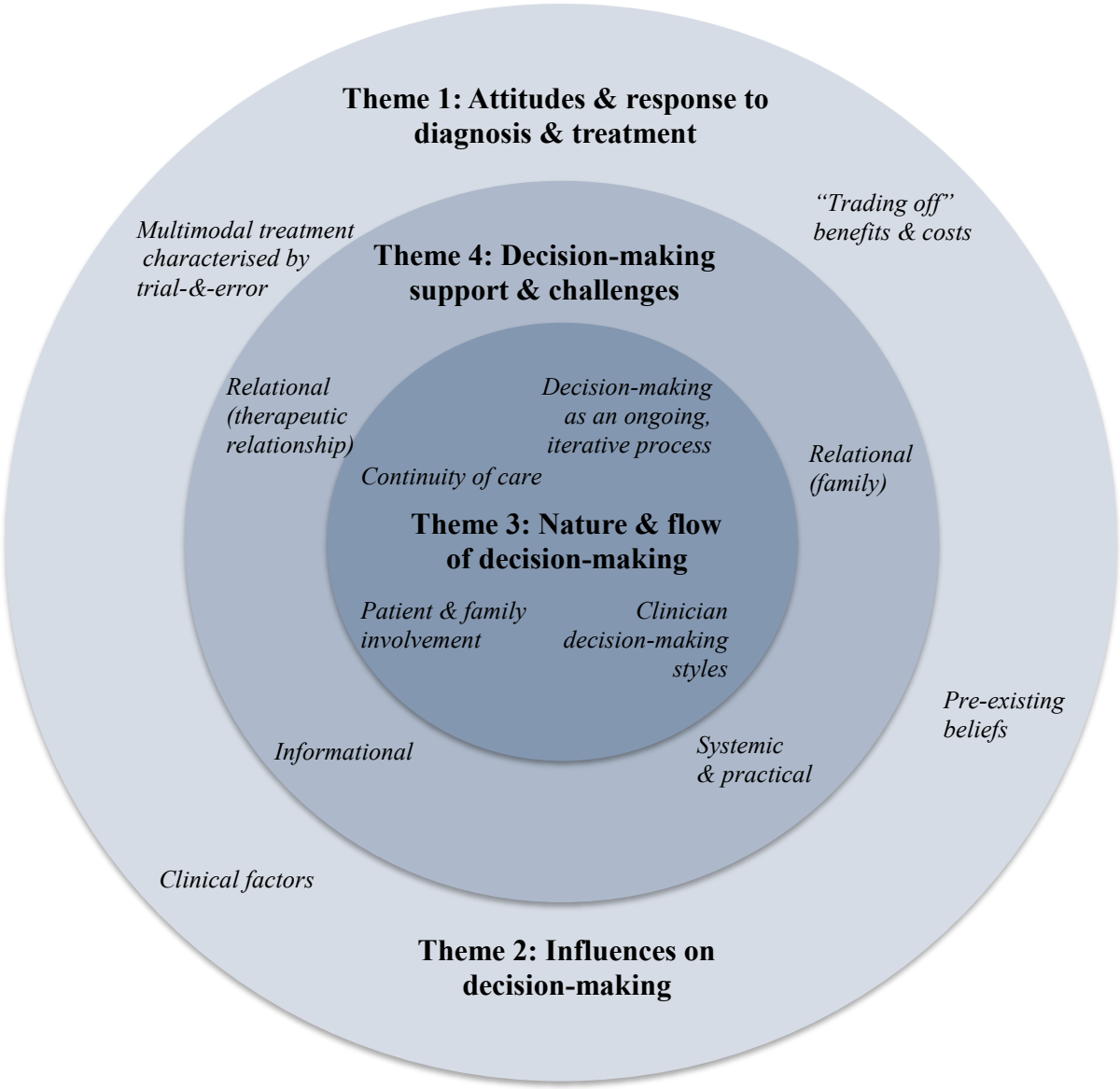

Figure 3.1. Diagrammatic summary of themes and *subthemes* based on BPII patient and family data. The three overlapping circles highlight the overlapping and non-linear nature of the themes, which do not conform to any hierarchy.

3.4.3. Theme 1: Attitudes and response to diagnosis and treatment

Theme 1 comprised attitudes towards treatment options and treatment approaches, which influenced participant engagement with treatment decision-making in this setting (Table 3.3). Attitudes appear at the peripheries of Figure 3.1, as they are often presented from the outset of decision-making, or are determined by pre-existing treatment characteristics (e.g., multimodal approaches, clinical uncertainty).

Table 3.3. Illustrative patient and family quotations for Theme 1: *Attitudes and response to diagnosis and treatment* and Theme 2: *Influences on decision-making*.

Subtheme	Illustrative patient quotations	Illustrative family quotations
1.1. Multimodal treatment characterised by trial-and-error	*I guess it's this holistic approach to managing ...it was about the medication, the counselling options, the maintaining exercise and meditation, and the fish oil.* (Multimodal approach, Patient 109) *... I could actually be on the same merry-go-round here … So that made me feel a bit less positive about it….hearing [from the psychiatrist]... if plan A fails then we can go to plan B and plan B fails we can go to plan C... feeling a bit less sure about the process* (Uncertainties of treatment, Patient 109)	*During the initial period immediately after diagnosis there was a lot of trying different medications to see which ones would work…. It felt like guesswork even on the part of the professionals. We'll try this one, we'll try that one. It's that sense of trial and error* (Trial-and-error, Family 218)
1.2. Attitudes and response to treatment	*"…it's better to be a bit dopey and overweight rather than being depressed 90% of the time...So you've got to weight up their pros, the benefits and costs and things."* (Trading off benefits versus costs, Patient 117) *With one medication in particular I found it really successful [in stabilising mood] but it was a really difficult decision because it's made me put on a significant amount of weight....my life just became completely unmanageable and that was the trade-off. ..... I decided to eventually just come off that medication completely* (Trading off benefits versus costs, Patient 134)	

2.1. Clinical	*…. when you're depressed or even when you're [hypo]manic, sometimes I experience a high level of confusion and an inability to think logically... when you're presented with options... it's not possible to think through the solutions.* (Impact of symptoms, Patient 106)	*I have bipolar too... [so I] have a good understanding...what she [my partner] is going through so we can talk about it. When you're seeing the psychiatrist... [I encourage her to] ask definite questions which they are then obliged to answer, [which] is the one thing I've learnt.* (Family history of mental illness, Family 207)
2.2. Pre-existing beliefs about self.	*I'm independent… I make all the other decisions in life on my own so it's just something you have to do.* (Patient 111) *I'm not very proactive so it's good to given suggestions and then being made to decide on them because if it was left to me I probably wouldn't do anything.* (Patient 122)	

Multimodal treatment characterised by trial-and-error

Participants reported mostly medication-based decisions (starting new/adjunctive medication, change medication type/dose) but also psychological-based decisions (CBT) and lifestyle modifications (e.g., exercise). Accordingly, most participants noted that treatment needed to be *"holistic"* and involve multiple clinicians (psychiatrists/GPs/psychologists) (Patient 109; Table 3.3).

Patients and family noted that medication options carried inherent uncertainty. This uncertainty often made treatment decisions more difficult and based on *"trial-and-error"* (Family 218; Table 3.3). For some participants, this uncertainty and *"hit and miss"* process engendered feelings of frustration, confusion, hopelessness, and perceived discrediting of clinician expertise (Patient 109; Table 3.3).

Attitudes and response to treatment

Patient and family participants expressed *varying attitudes to treatment options* (medication/psychological-based), which strongly influenced patient willingness or reluctance to start/continue treatment. Of note, patients respondents without current mood symptoms (euthymic) were more likely to express positive (*n*=5) compared to negative medication attitudes (*n*=3), which contrasted with patient respondents with current depressive or hypomanic/mixed state symptoms who expressed more negative (*n*=7) than positive medication attitudes (*n*=1). Positive medication attitudes were also more salient amongst patients previously treated with antidepressants for depression and/or anxiety, who felt mood-stabilisers would deliver greater benefits.

Several participants reported *"trading-off" treatment benefits and costs.*

Approximately half of patients assigned greater value to the perceived medication benefits (mood stability) and believed these outweighed the costs (side-effects). This view was only expressed by patients and supported their willingness to start/continue medication (Patient 117; Table 3.3). The remaining half of participants, including patients with currently depressed mood and family, felt medication costs (burdensome side-effects) outweighed benefits (Patient 134; Table 3.3).

3.4.4. Theme 2: Influences on decision-making

Theme 2 comprised pre-existing patient and family characteristics, which participants believed made treatment decisions more or less difficult (Table 3.3). Again, these characteristics appear at the peripheries of Figure 3.1 as they are already present when patients/family start considering treatment options.

Clinical

Persistent treatment resistance/non-response appeared to make decision-making more difficult for some patients (futility) but easier for others, especially those with a previous diagnosis of depression and/or anxiety. These latter participants found the decision to commence mood-stabilisers easier given years of incomplete antidepressant response, and more strongly endorsed the potential benefits of mood-stabilisers. Overall, a family history of mental illness had a positive influence on treatment decision-making (empathy) (Family 207; Table 3.3).

Participants reported that it was best to time decision-making while euthymic, noting that *depressive and hypomanic symptoms had a negative impact* on their decision-making engagement (Patient 106; Table 3.3). Depressive symptoms reportedly diminished patient's ability and desire to be the primary decision-maker, and resulted in patients deferring decisional responsibility to clinicians and/or family. Patients were mostly happy to do this, but still wanted to be involved to some degree. When hypomanic, meaningful patient engagement was also difficult (irrational/impulsive decision-making).

Pre-existing beliefs about self

Patient personality traits and beliefs about oneself influenced decision-making in various ways. Patients viewing themselves as independent often preferred, and reported more active decision-making involvement (Patient 111; Table 3.3). By contrast, patients viewing themselves as more dependent were more inclined to defer decisional responsibility to the clinician (Patient 122; Table 3.3).

3.4.5. Theme 3: Nature and flow of decision-making

Theme 3 described how the decision-making process unfolds both within and outside consultations, highlighting the relative contributions of the clinician, the patient, and

the family, and their interplay (Table 3.4). This theme is at the core of decision-making in this setting (Figure 3.1), because it characterises how decisions are made within current clinical practice.

Decision-making as an ongoing process requiring continuity-of-care

Medication-related decision-making was often described as fluid, and subject to ongoing review in response to persistent mood instability and/or unpleasant side-effects (Family 206; Table 3.4). Patients appeared to like revisiting decisions at follow-up consultations with their psychiatrist/GP (Patient 137; Table 3.4). A few participants were *"comfortable"* they made the *"right"* medication decision, which mainly stemmed from a positive treatment response.

Consistent with this ongoing decision-making process, many participants also appreciated the need for *continuity-of-care.* More participants reported that they received good continuity-of-care than not, which usually existed alongside an ongoing, healthy therapeutic relationship with a GP/psychiatrist (Patient 140; Table 3.4). In contrast, inadequate continuity-of-care reportedly led to patients feeling unsupported and lacking knowledge to manage their illness (Patient 111; Table 3.4).

Table 3.4. Illustrative patient and family quotations for Theme 3: *Nature and flow of decision-making* and Theme 4: *Decision-making support and challenges*.

Subtheme	Illustrative patient quotations	Illustrative family quotations
3.1 Decision-making as an ongoing process requiring continuity-of-care	*I go and see him [GP] every week to two weeks. We'll decide, "Yes, okay we can up the dose a little bit now," we're doing it very slowly. He'll ask me whether there's any side effects...Then we make decisions whether to increase the dose. It's good.* (Patient 137) *For the last four years that I've been seeing him [Psychiatrist], things have been going a lot better because I feel like it's more individualised treatment.* (Good continuity-of-care, Patient 140) *... there's never been any ongoing "are you taking it, how are you going with it". So there's probably something missing there....if a GP has prescribed you some medication there should be some sort of follow up.* (Poor continuity-of-care, Patient 111)	*...it's like a progressive thing. We're looking at, there's a sense of... medication trying... see how it works for you, what, how.* (Family 206)
3.2. Clinician decision-making styles	*I know when I first started lithium back in 2010, the doctor said I needed to take it and I said no. He said... they'd start me on that. I felt more like they were telling me what I had to do*. (Clinician-led decision-making, Patient 140)	

	…. the decision was made in co-operation...if there was a lack of respect [for] my decision from the doctor's perspective [GP]... the doctor didn't do that...the doctor was happy to trust my judgement (Shared decision-making, Patient 124) *When I went to see the psychiatrist, and that was just a once-off, there wasn't a lot of discussion about what any alternative treatments might be. It was pretty much that this is the drug of choice for bipolar II.* (Clinician-led information exchange, Patient 137) *I told him [Psychiatrist] exactly how I felt about gaining weight and some of the drugs making me more aggressive or really flat. He listened to that and he told me why he suggested the drug he did* (Shared deliberation, Patient 133)	
3.4. Patient involvement and autonomy	*I'll always talk to other people and see what they think but ultimately I'll always make the decision myself* (Patient as ultimate decision-maker, Patient 117) *I've been involved in increasing it [medication], so I've chosen when to take more….and [my psychiatrist] he's said that I know myself and what I want to do, and that's fine…..I have a lot of*	*I just saw his [patient] role was to make the decision himself and mine was to support it.* (Patient as ultimate decision-maker, Family 206)

	insight into my mood and I said to my psychiatrist that I thought I needed to be back on antidepressants. (Patient as ultimate decision-maker, Patient 140)	
3.5. Family involvement	*...If I talk to them [family] about it [medication] they say if something sounds like the right thing….Sometimes I will discuss it with my husband…* (Family involvement outside consultations, Patient 128) *… If there's a need for another person to put a point of view across, where I'm not able to do it, she [wife] will come along..* (Factors influencing family involvement, Patient 120)	*.... I sort of chimed in to mostly try to describe her behaviour for the doctor's [Psychiatrist's] benefit, to give him a bit more of an idea about how [my sister] she'd been….she was trying to describe some of her behaviours I felt that they weren't very accurate. I would discuss them a little bit as well.... to provide a slightly more accurate description of her health...* (Family involvement in consultations, Family 225)
4.1. Relational (family)	*My ex-partner will often ask me questions about the decisions I'm making, to clarify in my own head what's going on. Like she just wants to know that I'm clear about why I'm doing what I want to do….there are times when I'm almost incapable of making decisions and it's been helpful for me to have someone that I trust from a personal point of view.* (Benefits of family involvement for patients, Patient 106)	*...to come along and participate in some of the consults [with the psychologist]…I could see the quality of that clinician….I understand it better, then I can support [patient name] in that [form of treatment].... it sort of gives me credence to want to support that decision, to put that money into that area.* (Benefits of family involvement for family, Family 206).
4.2. Relational (Therapeutic relationship)	*….. [My GP has] just always given me the time to talk...being very compassionate... responsive to my saying that I didn't feel like the antidepressants that I was on were working....being sort of interested in that process.* (Collaborative therapeutic relationship, Patient 109)	

	…Sometimes I don't feel that they [clinicians] really listen to you as an individual. They've got their set routine that they go through with people and that's it... [not] really listening and assessing me....They didn't take the time to really talk to me and find out whether there were other underlying issues. (Non-supportive therapeutic relationship, Patient 125) *....when I mentioned [antipsychotic brand name] Seroquel the GP didn't really seem to know it that well so he actually had to look up information on it.... it just made me a little uneasy that I'm not getting the best possible treatment here.* (Limitations to clinician expertise, Patient 112)	
4.3. Informational	*[Accessing information] to feel more in control as opposed to having a situation that is totally foreign. Getting information like that just puts me in a better position to, to be decisive....that applies to any medicine that I take.* (Supporting role of information, Patient 120) *So, fitting my medication in with my lifestyle and considering that as well. I think giving people those ideas of what they need to consider in making treatment decisions. That would be helpful.* (Potential benefits of decision-support tool, Patient 140)	*While I was able to read research papers, I didn't understand a lot of what I was reading even though I've got tertiary qualifications, but they're not in a medical science area so some of the language in that was quite foreign.* (Unmet information needs, Family 218)

Clinician decision-making styles

Regardless of involvement preferences, many participants reported engaging in predominantly clinician-led decision-making and being *"told what to do"* about medication (Patient 140; Table 3.4). This lack of patient agency usually occurred when they were symptomatic with reduced decisional capacity.

Participants reported that they experienced shared decision-making (SDM) less often than clinician-led decision-making. SDM appeared more common within a longstanding therapeutic relationship, among participants who preferred patient-led/SDM, and when patients' family had attended consultations (Patient 124; Table 3.4).

Both pre-/post-consultations, most patients and some family reported being proactive in *information seeking*, mostly using online sources (Google, leading mood disorder organisations) to supplement clinician-provided information. A few patients appeared to avoid information-seeking as a self-protective strategy (being *"put off"* by negative medication information).

Within consultations, most patients and family described clinician-led *information exchange*, whereby psychiatrists/GPs provided information (benefit/side-effect profiles, safety information) about their *"recommended"* medication option. Several participants noted minimal discussion of options; often only one treatment was presented by their treating clinician without any alternatives (Patient 137; Table 3.4).

In-consultation *discussion about treatment preferences* was reportedly mostly clinician-led, with clinicians expressing their treatment preference with limited discussion of patient treatment preferences. Some patients reported volunteering their treatment preferences to clinicians (Patient 133; Table 3.4). One patient-family dyad described a more collaborative *"weighing-up the pros and cons"* (Patient 133 and husband).

Notably, clinician-led information exchange and deliberation was reported by all recently-diagnosed (<1 year) participants, and by all participants preferring clinician-

led decision-making, however it was also commonly reported by participants preferring patient-led/SDM.

Post-decision, a few participants preferring patient-led/SDM reportedly *ignored clinician advice* (discontinued prescribed medication), particularly when it was inconsistent with their treatment preferences, or to *"take charge"* over their illness.

Patient involvement and autonomy

Almost all (patient/family) participants felt that the patient should be the ultimate decision-maker, but acknowledged that both clinician and patient expertise should inform treatment decision-making (Patient 117; Family 206; Table 3.4). Most patients also felt that their decision-making autonomy was supported and respected (Patient 140; Table 3.4).

Reasons given for active patient involvement included treatment decisions being *"about them"* and *"their brain"*, having lived illness experience, the possibility of adverse medication effects, and because BPII required ongoing management.

Family involvement

Family involvement typically occurred outside consultations, ranging from patients informing family about a decided-upon treatment (minimal), to always deliberating options with their family pre-decision (active). Absent or dominant family involvement was less-commonly reported. Both patients and family noted that family primarily acted as a sounding-board (talking through patient treatment preferences/feelings/concerns), which was a role more often assumed by partners/spouses than other family (e.g., parent, sibling). Family also provided reassurance post-decision, or encouraged treatment seeking/adherence in response to adverse effects or worsening symptoms (Patient 128; Table 3.4). These two roles were more commonly reported by patients, and by family, respectively.

Family attendance at consultations tended to be intermittent, which is supported by patients' self-report (57% had family attend). Some participants reported that clinicians sometimes initiated family involvement (inviting family into consultation). Within consultations, family roles were mostly as information support (giving the

clinician patient information), and as a monitor of patient accuracy (clarifying/elaborating on patient accounts) (Family 225; Table 3.4). This latter role was expressed only by family members themselves.

Family involvement was mainly influenced by: pre-existing relationship dynamics (estranged, close-knit), family respect for patient autonomy and confidentiality, and strength of the therapeutic relationship. Consultation-related factors included: patient's need for additional informational support (due to disabling symptoms), at important treatment milestones (shortly post-diagnosis), and when treatment options directly impacted on the family (financially) (Patient 120; Table 3.4). Most of these factors were mentioned by both patients and family, however, patients more commonly referred to pre-existing relationship dynamics (with their family and clinician).

Participants, both patients and family, often linked their support for patient autonomy to family expressing their treatment preferences indirectly and without coercion (i.e., *"suggesting", "encouraging"* options without *"steering", "pushing", "enforcing"*).

3.4.6. Theme 4: Decision-making support and challenges

Theme 4 outlined factors influencing how decision-making unfolded. This theme also elucidated a number of (unmet) decision-support needs spanning relational, informational, and systemic domains. (Table 3.4). This theme is more proximal to the core of decision-making (Figure 3.1) as challenges and supports were present "in real time", as decision-making occurred.

Relational (family)

Outside consultations, both patients and family noted that *family involvement benefited decision-making* by: reassuring patients when concerned or uncertain about medication efficacy, facilitating more realistic expectations (delayed benefits), and providing encouragement in light of adverse medication effects. Patients, in particular, also valued their family acting as a sounding-board because this consolidated and clarified patient treatment preferences (Patient 106; Table 3.4).

Within consultations, family involvement served two primary decision-making benefits: providing clinicians a more detailed and/or accurate account of patient symptoms, and enhancing the family's own understanding of BPII and the rationale for various treatments. When family were party to discussion about the rationale behind recommended treatments, they could more easily participate in post-consultation deliberations (Family 206; Table 3.4). These views were similarly represented in patient and family accounts.

Primary barriers to family involvement included a lack of knowledge/understanding of BPII and treatment options, as well as perceived family burden and worry, which was only noted by patients. According to both patients and family, maintaining open lines of communication with family reportedly facilitated discussion of patient treatment concerns as well as adverse treatment effects impacting on family (reduced libido).

Relational (Therapeutic relationship)

Participants valued a *therapeutic relationship* that was based on trust, collaboration, empathy and respect for patient treatment preferences (Patient 109; Table 3.4). The absence of these clinician qualities led to negative patient-clinician interactions (Patient 125; Table 3.4). Some participants linked the therapeutic relationship to various outcomes, including: patient satisfaction with care, greater patient confidence in starting/changing/continuing treatments, more open communication and, in turn, improved clinician understanding of the patient's treatment preferences. Patients especially appreciated having a good therapeutic relationship when unwell, because they felt more confident to defer decisional responsibility to clinicians.

Patients and family reported mixed perceptions of *clinician expertise* (both clinical knowledge and knowledge of the patient). Several patients reported GPs lacking the "*expected*" expertise of BPII and medication options, which undermined the GP's credibility in the patients' eyes (Patient 112; Table 3.4). Perceived good GP/psychiatrist expertise in BPII instilled greater patient trust in the clinician, and willingness to follow treatment advice.

Informational

Patient stories (e.g., online chat-rooms/forums) reportedly fostered greater patient/family understanding of symptoms, complemented more medical/clinically-based information, and validated patients' lived experience of the illness. A few participants felt that personal accounts of the illness were not credible (*"rubbish"*), were negatively-biased (*"discouraging"*), or had a negative psychological impact (felt *"wary"* about medication).

Accessing information reportedly benefited patients' decision-making, by: patients feeling more in control and confident in decision-making, and dispelling medication fears by understanding the expected benefits/side-effects (Patient 120; Table 3.4). These views were predominantly expressed by participants preferring patient-led/SDM. Two recently diagnosed patients noted that medication-based information better prepared them for consultations *("knowing what to say", "which questions to ask"*), and communicating their medication preferences.

Regarding content, *participants reported preferences* for evidence-based, unbiased lay information on a broad range of medication and psychological options, medication effects and rationale for use. Patients and family also endorsed personalised information, which acknowledged that treatment choice was sensitive to patient circumstances.

Regarding format, all patients and family preferred written as opposed to verbal information. Most participants expressed a preference for hardcopy information (e.g., booklet/factsheet) as opposed to online information. Participants believed hardcopy information allowed patients privacy, could be taken home, and provided a tangible point-of-reference for patients to refer to outside consultations, and was more reliable than internet-provided information.

Commonly-cited *unmet information needs*, included a lack of comprehensiveness regarding the full range of available treatment options, easy-to-understand medical information, and a consolidated point-of-reference to supplement consultations (Family 218; Table 3.4).

To better support unmet information needs, participants were specifically asked about the development of a future *decision-support resource*. Potential participant-reported benefits included incorporation of patient values into treatment decisions, consideration of how medication *"fits into their life"* and *"tailor it to their lifestyle"* (Patient 140; Table 3.4), and the ability to actively weigh-up options, enhance patient question-asking in consultations, and clinician understanding of medication effects on the patient and their life. These potential benefits were mainly reported by participants with a recent BPII diagnosis (<1 year) and/or preferences for patient-led/SDM.

Systemic and practical

Several participants highlighted *difficulties in accessing* psychiatrists and psychologists due to high costs, residing outside metropolitan areas, and limited government-subsidies. Limitations to mental health service access and affordability negatively impacted on patients' continuity-of-care (infrequent appointments) and formation of therapeutic relationships.

Inadequate consultation times with GPs/psychiatrists reportedly led to treatment decision-making that seemed overly *"prescriptive"*, precluding a meaningful, patient-centred discussion of medication options (Patient 109; Table 3.4). Scheduling longer and follow-up consultations reportedly allowed patients to better consider options, and made them more likely to adhere to treatment (Patient 131; Table 3.4).

3.5. Discussion

This is the first known study to provide in-depth exploration of patient/family perspectives on BPII treatment decision-making. As depicted in Figure 1, decision-making about BPII treatment is essentially an ongoing, iterative process supported by good continuity-of-care, and a balance between clinician-patient(-family) involvement. Integral to decision-making are various challenges and supports, which manifest as decision-making occurs. Additionally, patients/family have pre-existing characteristics and treatment attitudes, which predispose them to certain treatment preferences and having more/less decision-making involvement.

Patient autonomy and involvement in treatment decision-making is highly valued in this setting. Yet, patient reports of actual involvement suggest lower-than-preferred

involvement, as previously reported [37]. In general, it appears that clinician-led decision-making is the "default" in this setting, irrespective of patient involvement preferences. In addition to patient symptoms, time constraints, failure to establish a strong therapeutic relationship, and limited patient knowledge about illness/treatment may all explain clinician-led decision-making [38], especially among recently-diagnosed patients. While clinician-led decision-making meets some patients' involvement preferences, it does not meet most patients' preferences [39]. Given that patients preferring shared or patient-led decision-making are most likely to be disadvantaged by current clinician-led decision-making styles, there is a particular need for SDM interventions in the BPII treatment setting.

Discussion and integration of patient attitudes and preferences for treatment appears crucial in this setting. Specifically, patients varied in the value they ascribed to medication side-effects versus therapeutic benefits. Whereas some participants prioritised medication benefits, a similar proportion prioritised medication side-effects when making a decision. This "trading-off" of benefits/costs then impacted on patient's un/willingness to commence and/or continue medication. Of note, the various mood states participants were experiencing also appeared to influence medication attitudes, with euthymic patients expressing more positive attitudes compared to those experiencing hypomanic or depressive symptoms, thus reinforcing the particular need to regularly discuss treatment preferences in this population. Further, when treatment choice did not match patient preferences, this undermined treatment adherence, which is consistent with studies examining the preferences of outpatients with depression [40].

This link between patient preferred treatment choice and adherence to treatment was especially the case amongst patients preferring patient-led and/or SDM, who are more likely to want their treatment preferences considered. A collaborative/SDM approach may optimise BPII treatment decision-making, by facilitating discussion and consideration of what matters most to patients, which may differ from clinician priorities [41]. SDM interventions may be useful for better involving these patients/family in making specific and deliberative treatment decisions [42, 43]. Decision-aids (DAs), for example, are one empirically-supported SDM intervention which provide patients/family with evidence-based, non-directional information about

available treatment options and outcomes. Importantly, DAs also include values clarification exercises which are designed specifically to assist patients/family to consider their preferences and deliberate on the varying benefits/costs of the different treatment options [43].

Almost uniformly, patients and family strongly endorsed patient involvement and autonomy in treatment decision-making. Similar to a qualitative study in depression [44], relational, informational, and systematic factors all appeared to underlie patient perceptions of autonomy and patient-centred care, and other decision-making outcomes. When present, a positive, trusting and collaborative therapeutic relationship appeared to enable patients to achieve their involvement and treatment preferences. Importantly, perceived clinician expertise and trust made patients comfortable to defer decisional control when experiencing reduced decisional capacity. By contrast, when the therapeutic relationship was precarious, patients tended to reported poorer outcomes, including reduced decision-making autonomy, less preference-based decisions, and poorer adherence. A strong, collaborative therapeutic relationship appears particularly important in chronic mental illnesses like BPII [45] where treatment decision-making is subject to ongoing review and rests on good continuity-of-care.

Other relational factors, such as family involvement also supported treatment decision-making within/outside consultations. Significantly, patients preferring patient-led and/or SDM were more likely to achieve their involvement preferences if a family member had attended consultations. Two forms of family involvement may explain why family attendance was related to patients' achieving their involvement preferences. Firstly, family provided clinicians with comprehensive and personalised knowledge of the patient's circumstances (information-support). Secondly, family who attended consultations were better equipped to help patients clarify their understanding of, and preferences for treatment (sounding-board). Thus, family attendance at consultations may improve patient and clinician understanding of patient preferences, and ensure treatment decisions consider these. This explanation aligns with "shared mind" [46], whereby family can enhance patient autonomy in decision-making by facilitating "shared knowledge" (knowing the patient-as-a-person) and "shared deliberation" (mutual construction of preferences). This said,

there were a number of reported barriers to family involvement in this setting (e.g., patient confidentiality, perceived family burden and distress), and thus is it essential that any family involvement occurs in line with patient preferences [4]. Providing patients with private opportunities to discuss distressing topics, even when family is present, is key, and clinicians could achieve this by inviting family into consultations partway through [9].

Participants identified several unmet informational needs and decision-support priorities, which are consistent with previous surveys in bipolar [39] and have important implications for clinical practice. Specifically, it is important that clinicians understand patient preferences for involvement in decision-making, and integrate patient preferences into treatment choice. To better engage patients with BPII in the decision-making process, clinicians could discuss with patients: i) both their own recommended treatment option/s as well as alternative, evidence-based treatment options, and ii) patient attitudes towards and preferences for treatment options. Seeking to maintain an ongoing relationship with these patients, where feasible, is also crucial to enabling patients with BPII to adopt a more active role in their treatment decision-making and choose treatments that are consistent with their preferences. Encouraging family involvement, to the extent desired by patients, can also facilitate the decision-making process especially when sharing information and deliberating on options. To effectively implement these improvements in clinical practice, SDM interventions, such as question-prompt lists, decision-aids, are likely to be helpful [43, 47], as they have been shown to improve patient knowledge of available treatment options and outcomes and perceived decision-making involvement in depression and schizophrenia [48]. Moreover, these informational and decision-support priorities are not unexpected, given that both patients and family endorsed "multimodal" treatment approaches, proactive information-seeking, and viewed patients as the ultimate decision-maker. These views are commonly endorsed in mental health [39, 49], making these findings relevant not only to potential decision-support interventions for BPII but for other mental health conditions too.

Study limitations include the "opt-in" recruitment and potential self-selection bias; findings may reflect the views of more interested patients and family. Secondly, approximately half of participants did not have their family participate in the study.

Thus, patient-reported experiences of family involvement and decision-making may not correspond with family views, and vice-versa.

In accordance with broader patient perspectives of patient-centred care in bipolar disorder [50], BPII patients and family appreciate treatment decision-making that is well-informed, respects patient preferences and needs, and involves patients. Yet, patient preferences for information, decision-making, and treatment choice appear not fully met. The present findings point to a number of potential avenues for future research. These include: systematically comparing and contrasting patient and family views with those of other key stakeholders in the decision-making process (e.g., treating clinicians), and ascertaining the extent to which patient mood states and other patient-/family-related characteristics influence attitudes towards and uptake of effective treatment options. This information is needed to discern how clinician perceptions may facilitate or impede effective decision-making in this setting, as well as to identify when and whom to best target with BPII-specific decision-making interventions. Findings will also inform the development and evaluation of a patient treatment decision-aid to enhance patient/family knowledge and involvement, and optimise clinician-patient(-family) collaboration in treatment decision-making.

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Chapter 4

Chapter 4: A qualitative exploration of clinician views and experiences of treatment decision-making in bipolar II disorder.

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This chapter reports on a qualitative study, which sought to explore the views and experiences of treatment decision-making among clinicians with experience working with patients with bipolar II disorder (BPII). Findings elucidated key informational and decisional-support priorities and unmet needs in this setting; these were used to inform the content, format, and delivery of the decision-aid (DA, see Chapter 6). Ethics approval letters are provided in Appendices B1 and B2; supplementary materials related to this study are provided in Appendix E.

Author contributions
Conception and design: AF, IJ
Participant recruitment: AF
Data collection: AF
Data analysis and interpretation: AF, IJ, RL-P, LS
Manuscript drafting: AF
Manuscript critical review: All authors
Review of final manuscript: All authors

4.1. Abstract

Aim. This study qualitatively explored clinicians' views and experiences of treatment decision-making in BPII.

Methods. Semi-structured interviews were conducted with 20 practising clinicians (*n*=10 clinical psychologists, *n*=6 GPs, *n*=4 psychiatrists) with experience in treating adult outpatients with BPII. Interviews were audiotaped, transcribed verbatim and thematically analysed using framework methods. Professional experience, and preferences for patient involvement in decision-making were also assessed.

Results. Qualitative analyses yielded four inter-related themes: 1) *(non-)acceptance of diagnosis and treatment*; 2) *types of decisions*; 3) *treatment uncertainty and balancing act*; and 4) *decision-making in consultations*. Clinician preferences for treatment, professional experience, and self-reported preferences for patient/family involvement seemed to influence decision-making.

Discussion. This study is the first to explore clinician views and experiences of treatment decision-making in BPII. Findings demonstrate how clinician-related factors may shape treatment decision-making, and suggest potential problems such as patient perceptions of lower-than-preferred involvement.

Keywords. Bipolar II disorder, treatment decision-making, qualitative, clinician attitudes, patient involvement, family involvement.

4.2. Introduction

Bipolar disorder is a chronic, relapsing and remitting psychiatric disorder characterised by episodes of depression ('lows') and hypo/mania ('highs') [1]. Effective long-term management relies heavily on patient self-management and warrants collaborative approaches to decision-making about treatment [2]. Shared treatment decision-making (SDM) involves *both* the clinician and the patient (and others') working together to make a treatment decision based on their relative expertise and preferences for treatment options [3, 4]. SDM is increasingly recognised as important and applicable to many treatment decisions in mental health [5], where more than one treatment option is feasible and final treatment choice is sensitive to patient preferences.

Compared to bipolar I disorder, treatment choices in bipolar II disorder (BPII) are more variable with regards to clinical evidence and patient preferences. This is because much of the high-quality research on treatment efficacy has been evaluated in patients with bipolar I disorder, leading to a paucity of published BPII-specific treatment recommendations (e.g. [6]). Further, there is an ongoing lack of clinical consensus over the use of antidepressants (with/out mood-stabilising medications) in treating BPII depression, [7, 8] the far more predominant mood state [9, 10]. Lastly, as individuals with BPII do not experience psychotic features during their hypomania, the perceived benefits of mood-stabilising medication may be outweighed by potential side-effects [11].

The application of SDM continues to present a challenge to mental health, especially to the treatment and management of bipolar disorder. In a systematic review of bipolar disorder, patient-reported involvement did not match their stated preferences [12]. Further, observed levels of SDM and patient involvement often did not meet minimum *a priori* criteria for informed decision-making [13] when options involved some degree of medical uncertainty, and potentially posed a risk to patients. However, the review identified no studies investigating clinician perceptions of how treatment options are discussed and treatment decisions made [12]. Limited existing qualitative studies of clinician views have focused on treatment decision-making in schizophrenia (e.g., [14]) and unipolar depression [15]. However, these disorders are distinctly different to BPII and patient preferences for, and actual involvement in their

own treatment decisions can be expected to be different to those with schizophrenia [16] and depression [17]. There is a need to better understand SDM in bipolar disorder and especially the role of clinicians in this process.

Clinician views may be used to supplement independent observer ratings of SDM in consultations [18] as these ratings do not capture the full scope of decision-making behaviours (e.g., partnership building) that influence patient-reported involvement and decision quality. Evidence indicates that patients evaluate similar clinician SDM behaviours (e.g., clinician-provided information and deliberation of treatment option) in different ways (i.e., perceiving SDM versus patient-led decision-making) [19]. Discrepancies can arise between patient-reported and observed SDM [19], and between patient and clinician perceptions of patient involvement in decision-making [20]. Thus, an examination of clinician views may highlight aspects of treatment decision-making that are not readily captured by consultation ratings and explain discrepant patient and clinician views, clarify the underlying reasons for clinician behaviours, or patients experiencing less involvement than desired.

The present study aimed to qualitatively explore clinicians' views and experiences of treatment decision-making with BPII patients in an outpatient setting. Specifically, this study aimed to elucidate: i) the nature of BPII treatment decision-making; ii) factors that appear to shape the decision-making process; and iii) the respective roles and involvement of the clinician, patient, family (and others) in decision-making.

4.3. Methods

4.3.1. Participants

Participants were 20 practising clinicians with experience in treating adults with bipolar II disorder (BPII). Clinicians were both medical practitioners (i.e., psychiatrists, general practitioners [GPs]) and clinical psychologists, and worked in various clinical practice settings, including general and specialist care clinic and government-subsidised and private practice settings. Clinicians were recruited through: i) the Black Dog Institute (BDI), a clinical service specialising in the assessment and treatment of mood and bipolar disorders in the Sydney metropolitan

area; ii) BDI-organised professional development workshops; and iii) e-newsletters to clinicians signed-up to BDI mailing-lists.

Purposive sampling was used to obtain maximum variation on characteristics likely to influence views and/or experiences of treatment decision-making – i.e. years of clinical practice, professional specialty (psychiatry, general practice, clinical psychology), and level of BPII patient contact. Recruitment continued until data saturation, a concept used to describe the point at which three consecutive interviews fail to reveal any new information or insights [21]. Ethical approval was obtained for all aspects of the study from The University of Sydney Human Research Ethics Committee and the Black Dog Institute Research Advisory Committee.

4.3.2. Procedure

Expression-of-interest flyers were provided at BDI staff meetings, professional development workshops, and disseminated via clinician emailing-lists. Interested clinicians were invited to contact the researcher at the University of Sydney (AF), who explained the rationale for the study and obtained verbal consent to post/email a study pack to potential participants. The study pack contained an information sheet and consent form, and a brief pre-interview questionnaire. Two text and/or email reminders were sent to participants one and two weeks' after sending the study pack. Upon receiving the participant's completed questionnaire and consent form, a one-off telephone interview of approximately 30-40 minutes duration was arranged. Informed consent was obtained from all individual participants included in the study.

4.3.3. Qualitative data collection

A semi-structured interview protocol (Appendix E) was purpose-designed and informed by widely-cited models of SDM [3, 4, 22], the Ottawa decisional support framework [23] and previous qualitative studies of treatment decision-making in mental health (e.g., unipolar depression [24]) and medical populations (e.g., cancer [25]). To establish the focus on BPII, clinicians were asked at the beginning of their interview to describe the range of patients they had treated with BPII as well as the course that these patients' illness has taken over the time in the time they treated them.

In this paper we report on clinician perceptions of decision-making about BPII treatment, including clinician-patient-family involvement, and pre-existing factors influencing this process. Other topic results from this qualitative study, such as practice challenges and clinician strategies, are to be reported elsewhere ([26], see Chapter 5).

4.3.4. Quantitative measures

Clinician preferences for their own and others' (i.e., patients and family) involvement in treatment decision-making were assessed using an adapted version of the *Control Preferences Scale* (CPS, [20, 27, 28]). This two-item, self-report scale measured involvement preferences both in dyadic (clinician-patient) and triadic scenarios (clinician-patient-family). The CPS has been used to assess physician perceptions of patient involvement in decision-making about cancer treatment [20], and in outpatients including those with bipolar disorder [29-31].

Demographic, clinical and professional characteristics (e.g., age, gender, years in clinical practice, typical patient presentation and treatment types) were collected using a purpose-designed self-report questionnaire. Participants also indicated whether, which, and how often family members attended consultations.

4.3.5. Data analysis

Descriptive and frequency analyses of questionnaire data were conducted using SPSS version 22. Interviews were audio-recorded and professionally transcribed, and then thematically analysed [32] using framework methods [33]. Analysis followed five main steps [34]:

1) *Familiarisation with the data*: AF conducted all interviews, cross-checked each transcript against the audio-recording for accuracy, and read each transcript a number of times.

2) *Creating a thematic framework*: based on independent analyses of 20% of transcripts by AF and RL-P, a preliminary thematic framework was developed. Data were organised according to themes and sub-themes. Working collaboratively with IJ and RL-P, different interpretations of the data were discussed collaboratively until consensus was reached on the main themes.

3) *Indexing*: using NVivo11, all transcripts were coded by AF according to the framework. Any new themes arising during this stage and revisions were discussed with IJ.
4) *Charting*: At this stage, AF used MS Excel as a computerised qualitative data analysis tool [35], such that themes and supporting quotes from each transcript were transferred to a framework matrix with participants as rows and themes as columns.
5) *Mapping and Interpretation*: to identify patterns and relationships, the framework was examined within and across themes and participants.

To ensure methodological rigour, a proportion of the transcripts (20%) were cross-coded and discrepancies discussed and resolved before proceeding with coding the entire dataset. Secondly, the thematic map was developed in consultation with two co-authors, IJ and RL-P, who have expertise in treatment decision-making and qualitative analysis. All authors certify responsibility for study conduct, data analysis and interpretation, and reporting.

4.4. Results

4.4.1. Participant characteristics

Demographic and clinical characteristics are presented in Table 4.1. Twenty of the 30 clinicians who agreed to participate completed both the questionnaire and interview (67% response rate). Recruitment was balanced across medical practitioners (psychiatrists: *n*=4, GPs: *n*=6) and clinical psychologists, *n*=10). Interviews lasted on average 34 minutes (Range: 21-51 minutes).

All clinician subgroups were highly experienced (*M*s= 13.70-19.25 years, range: 3-30). Half of psychiatrists (50%) and a majority of clinical psychologists (70%) indicated they specialised in the assessment/treatment of bipolar and other mood disorders. Most GPs (83%) indicated no mental health speciality. All clinicians reported that both medication and psychological-based interventions were typically part of their patients' treatment. All except one psychiatrist preferred patient(/family)-led or shared decision-making in both dyadic (clinician-patient) and triadic (clinician-patient-family) scenarios (Table 4.1).

Table 4.1. Clinician demographic/ professional characteristics and patient characteristics.

		Psychiatrists (*n*=4)	**GPs (*n*=6)**	**Clinical Psychologists (*n*=10)**
Age	***M*(*SD*)**	53.25 (11.44)	55.83 (11.0)	50.50 (10.46)
Gender (female)	***n*(%)**	2 (50.0)	4 (66.7)	7 (70.0)
Mental health speciality	***n*(%)**			
Bipolar and other mood disorders		2 (50.0)	--	7 (70.0)
Other (e.g., Trauma, Psychosis)		2 (50.0)	1 (16.7)	2 (30.0)
None		--	5 (83.3)	1 (10.0)
Years in speciality	***M*(min-max)**	19.25 (8.0-28.0)	16.83 (4.0-30.0)	13.70 (3.0-30.0)
Hours direct patient contact p/w	***M*(min-max)**	22.50 (16.0-30.0)	24.83 (12.0-50.0)	18.90 (10.0-30.0)
Hours direct contact with BPII patients p/w	***M*(min-max)**	7.25 (4.0-12.0)	3.67 (1.0-8.0)	4.15 (0.5-12.0)
Most common BPII patient presentation	***n*(%)**			
Depressed		2 (50.0)	5 (83.3)	5 (50.0)
Mixed state		1 (25.0)	--	1 (10.0)
Euthymic/ subsyndromal		--	1 (16.7)	3 (30.0)
Other (e.g., heterogenous)		1 (25.0)	--	1 (10.0)
Most common medication in BPII	***n*(%)**			
Mood-stabiliser only (Lithium, anticonvulsants)		1 (25.0)	2 (33.3)	3 (30.0)
Antidepressant only		--	--	1 (10.0)
Mood-stabiliser and antidepressant		1 (25.0)	2 (33.3)	4 (40.0)
Mood-stabiliser and atypical antipsychotic		--	--	1 (10.0)
Other (e.g., polypharmacy of above)		2 (50.0)	2 (33.3)	1 (10.0)

Psychological interventions	***n*(%)**			
Yes (e.g., CBT, Mindfulness, Wellbeing plans)		4 (100.0)	6 (100.0)	10 (100.0)
% BPII patients attending with family (1 +)	***M*(min-max)**	32.50 (0.0-60.0)	8.67 (0.0-20.0)	7.50 (0.0-15.0)
Most common attending family [a]				
Spouse/ Partner		2 (50.0)	3 (50.0)	6 (60.0)
Parent		1 (25.0)	2 (33.3)	1 (10.0)
Preferences for patient involvement (triadic, clinician-patient-family) [a]	***n*(%)**			
Patient-led with family/clinician		1 (25.0)	3 (50.0)	5 (50.0)
Patient/family-led with clinician		1 (25.0)	--	2 (20.0)
Patient/family/clinician shared		1 (25.0)	3 (50.0)	1 (10.0)
Clinician-led with patient/family		1 (25.0)	--	--
Preferences for patient involvement (dyadic, clinician-patient)	***n*(%)**		--	--
Patient-led alone			1 (16.7)	--
Patient-led with clinician		3 (75.0)	2 (33.3)	8 (80.0)
Patient/ clinician shared		--	3 (50.0)	2 (20.0)
Clinician-led with patient		1 (25.0)	--	--

Notes [a] = For clinicians reporting family attendance.

4.4.2. Qualitative findings

Qualitative analyses yielded four themes, each comprising several subthemes: 1) *Non-acceptance of diagnosis and treatment*; 2) *Types of decisions;* 3) *Treatment uncertainty and balancing act*; and 4) *Decision-making in consultations*. As can be seen in Figure 4.1, these themes appeared to be inter-related in both an overlapping and cyclical manner. According to clinicians, patient acceptance of diagnosis and treatment (Theme 1) influenced patient willingness to engage in treatment decision-making and accept different treatment options (Theme 2). Uncertainty in treatment options, and need to balance treatment benefits/side-effects (Theme 3) also influenced clinician thoughts about how decision-making occurred in consultations, including patient involvement and incorporation of treatment preferences (Theme 4). Illustrative patient and family quotes are presented in Tables 4.2 – 4.5.

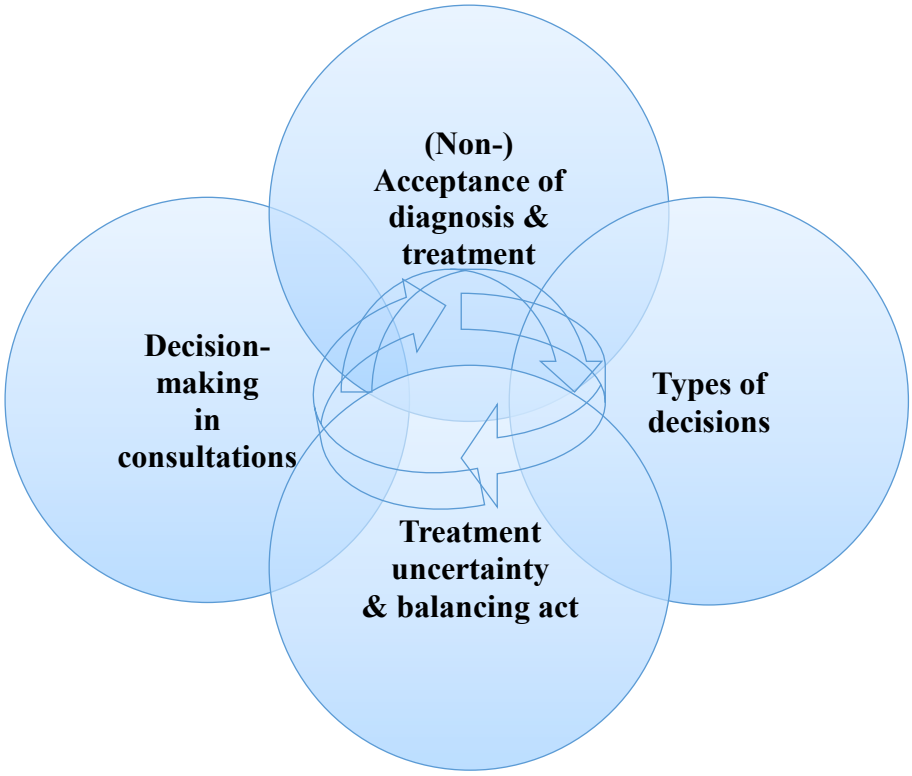

Figure 4.1. Schematic illustrating main themes.

4.4.3. Theme 1: (Non-)Acceptance of diagnosis and treatment

Theme 1 (see Table 4.2) captured clinician perceptions of the link between patients accepting their BPII diagnosis and accepting treatment, especially medication. This theme is positioned at the top of Figure 4.1 because it is an antecedent to treatment decision-making from point of diagnosis and continues to exert influence overtime.

Whether the diagnosis and treatment are accepted or not affected the types of decisions (e.g., discussions around medication), how decisions occurred in consultations (e.g., patient involvement), and the relative value given to benefits versus side-effects. Clinicians-identified strategies for facilitating diagnosis/treatment acceptance by their patients/clients are also encompassed within this theme.

Link between diagnosis and treatment acceptance

For many clinicians, patient acceptance of diagnosis was considered to be a pre-requisite for treatment acceptance, especially the need to take medication (GP 324, Table 4.2). This said, acceptance of diagnosis by itself was reportedly not sufficient for treatment acceptance.

Several clinicians attributed the link between accepting diagnosis and accepting treatment to the life-long, prophylactic nature of medication-based treatment for BPII. As such, patients generally needed to first accept that BPII was a chronic and relapsing disorder before they could accept the need for treatment, which is primarily prophylactic and usually involves long-term mood-stabilising medication (Clinical psychologist 318, Table 4.2). By contrast, one psychiatrist felt that a positive response to medication legitimised BPII diagnosis and encouraged acceptance.

Facilitating treatment acceptance

The most commonly cited strategy for facilitating patient acceptance of diagnosis/treatment was patient education and understanding, namely the nature of BPII illness (chronic, relapsing) and the *"need for ongoing management"* (long-term, prophylactic) (GP 326, Table 4.2). Two clinicians also felt that family involvement facilitated patient acceptance by helping patients to recognise that they are *"not like this all the time"*, and to disassociate their illness from their "well" self (psychiatrist 307, Table 4.2).

Table 4.2. Illustrative clinician quotations for Theme 1: (*Non-)Acceptance of diagnosis and treatment*

Subtheme	Illustrative clinician quotations
1.1. Link between diagnosis and treatment acceptance	*"The first one is accepting and understanding their condition. You can't even move into explaining treatments or getting adherence to treatment without people understanding the nature of things."* (GP 324) *"....until the diagnosis is accepted it's very hard to get them [patients] to accept the fact that they're probably going to need this medication for the rest of their life..... so without acceptance treatment adherence is very difficult."* (Clinical psychologist 318)
1.2. Facilitating treatment acceptance	*"They (patients) need help to understand why they need ongoing management.... helping to correct people's knowledge and false information about the medication. Trying to help her to understand the value of taking something long term to prevent being in such a bad place again."* (GP 326) *"Some people [patients] can feel quite strongly that this is them and this is their personality and I think that's when family can be so important for them… if they know actually you're not like this all the time."* (Psychiatrist 307)

4.4.4. Theme 2: Types of decisions

Theme 2 (Table 4.3) highlighted the decisions that clinician reported that they, patients, and patients' family encounter within the BPII treatment setting. These decisions were described as multifactorial, difficult, and sensitive to patient values. This theme focused on treatment decisions, i.e., what clinicians and patients are deciding on, and therefore appear within the body of Figure 4.1.

"It's not just about medication" – multifactorial decisions

Many clinicians spoke about the multifactorial nature of treatment decisions, which included medication together with psychosocial and lifestyle approaches. Clinicians, especially psychologists, reported engaging patients in a range of different treatment decisions; with medical practitioners more commonly discussing medication decisions only (Table 4.3). There was an ebb and flow to decision-making such that decisions were seldom "final" but were rather iterative and could be revisited at a later time point. Medication options were more actively discussed at certain points in the illness trajectory (e.g., post-diagnosis, when patient more symptomatic, or non responding to current treatment) whereas psychological options were more actively discussed at other points (e.g., during maintenance, when patient well-stabilised with/out medication).

Several clinicians also alluded to a multidisciplinary approach to patient care, and supported patients to seek treatment from other specialists, usually psychiatrists or psychologists. This view was more prevalent among clinicians without a bipolar specialty, who acknowledged the limits of their own expertise and others' complementary expertise.

Table 4.3. Illustrative clinician quotations for Theme 2: *Types of decisions*

Subtheme	Illustrative clinician quotations
2.1. "It's not just about medication" – non-medication related decisions	*"I guess helping them navigate the treatment decision around medicine but also more broadly helping people in terms of looking at what's going on in their life, in their work life, in their personal relationships and within themselves, including adapting to illness and treatment."* (Psychiatrist 328)
2.2. Clinician considerations	*"…if somebody has, has very low depressive and hypomanic symptoms.... there'd be more of a choice of whether they do want to go down the medication pathway."* (Clinical psychologist 308) *"....more perfectionistic or some people have higher levels of anxiety so you want to tread very carefully when you're talking about decisions because too much uncertainty that's actually quite anxiety provoking. So you've got to kind of limit the options to some extent...."* (Clinical psychologist 301)
2.3. "Difficult" decisions	*"The biggest issue is whether or not to start taking mood stabilising medications….The difficulty in managing medication…. [And that] many people really do not want to take medications... the main problem is the side effects of the medications and the fact that it's lifelong medication, that's something that people object to."* (GP 332) *"…(one health professional) he's kind of said this or (another health professional) she's said this and then the client is left a little bit unsure about what they want to do. They may be a bit fearful around taking medication…"* (Clinical psychologist 308)

2.4. Decisions as value sensitive	*"...it's usually a question of what the evidence says in the scientific literature about what are effective treatments and there are a number to choose from. But then it's also an important sort of question about patient preference often in terms of the side effect profile."* (Psychiatrist 309) *"...the psychotic thinking in other conditions makes the whole thing (around treatment decision-making) more complex and means that the medication is an almost essential as opposed to a value choice. I have met people with bipolar II who manage over time without medication and become very good at managing their illness..."* (Clinical psychologist 321)

Clinician considerations

Apart from patients' acceptance of diagnosis, clinicians identified a number of patient characteristics that influenced their treatment decision-making. Symptom severity was reported as having a significant impact on patient involvement, while the course and severity of illness episodes influenced whether pharmacological treatments were necessary (clinical psychologist 308, Table 4.3). Other commonly cited patient characteristics, included pregnancy (which precluded certain medication options), low socio-economic status (limiting their access to services and internet-based information content), *"more perfectionistic"* personality styles with lower tolerance of uncertain outcomes or *"higher levels of anxiety"* (associated with preferences for more or less patient involvement in decision-making) (clinical psychologist 301, Table 4.3).

"Difficult" decisions

All clinician groups identified medication-based decisions as the most difficult for patients, because of the: lifelong nature of mood-stabilising medication; potential for side-effects, negative associations with mood-stabilisers *("crazy tag"*) versus antidepressants, and the changing evidence base for medication options (GP 332, Table 4.3). Further, two psychologists described aspects of decisional conflict amongst their patients. This manifested as *"being unsure about what they wanted to do"*, due to conflicting clinician recommendations and/or negative preconceptions or past experiences with medication, and being uncertain and anxious about whether the right decision was made (clinical psychologist 308, Table 4.3).

Value-sensitive decisions

Almost all clinicians felt that ongoing medication was almost always a necessary part of BPII treatment, especially for the treatment and prevention of depressive symptoms. This said, almost a quarter of clinicians mentioned that decision-making was preference-sensitive with regards to *deciding between* the available medication options. In this instance, decision-making needed to consider up-to-date clinical evidence alongside "*patient preference in terms of the side effect profile*" (psychiatrist 309, Table 4.3). Only clinicians preferring patient-led and/or SDM expressed this view.

Decision-making was also described as preference-sensitive with regards to the treatment of hypomanic symptoms, which lacked psychotic features in BPII. One psychologist noted that psychotic features in bipolar I disorder made "*the medication an almost essential as opposed to a value choice"* as in BPII (clinical psychologist 321, Table 4.3).

4.4.5. Theme 3: Treatment uncertainty and balancing benefits/costs

Theme 3 (Table 4.4) highlighted the inherent *uncertainty* in treatment options and difficulties *balancing* treatment benefits and costs. These formed salient characteristics of BPII treatment options (Theme 2) that have a significant impact on how decision-making occurs in consultations (Theme 4). Thus, this theme is positioned between Themes 2 and 4 in Figure 4.1.

Uncertainties of treatment

Almost half of clinicians acknowledged the uncertainty of (mainly medical) treatment options, such as that decision-making was based on *"an educated guess"*, had *"no hard and fast rules"*, and was *"full of intangibles"* and *"unknowns"* rather than *"absolute knowledge"* (psychiatrist 307, Table 4.4). Uncertainty related to whether a particular medication would be efficacious for a particular patient and/or result in unwanted side-effects (clinical psychologist 318, Table 4.4). Inherent treatment uncertainties, together with changing patient attitudes to medication (e.g., reluctance to accept the diagnosis and treatment) meant that decision-making was an ongoing process that was continually subject to review (clinical psychologist 318, Table 4.4).

Fewer clinicians acknowledged that treatment uncertainties had a negative psychological impact on patients, invoking fear, anxiety and worry. All clinician groups, but especially psychologists, expressed this view. Some clinicians highlighted that the various *"unknowns"* in decision-making made SDM necessary and *"very important"* (clinical psychologist 301, Table 4.4).

Table 4.4. Illustrative clinician quotations for Theme 3: *Treatment uncertainty and balancing act*

Subtheme	Illustrative clinician quotations
3.1. Uncertainties of treatment	*"...I can only make an educated guess on what will best suit them [patients]. But at the end of the day it's about you trying things and seeing what best suits the person."* (Psychiatrist 307) *"... the thing that makes it [treatment decision-making] so difficult is that there's so many intangibles.....it's not based on absolute knowledge. A decision about if I take Lithium [mood-stabiliser] or if I take Lamotrigine [anticonvulsant]. Is that going to take away my symptoms? It's often not clear….is it better to stay with the one that's not working well but is at least working partially or try something else?"* (Clinical psychologist 318) *"So once a decision's made it's not finished. It's continually reviewed and evaluated…"* (Clinical psychologist 318) *"…. I think the difficulty is that there are lots of unknowns and as psychologists what we do try to do is that shared decision making which is obviously is very important."* (Clinical psychologist 301)
3.2. Balancing benefits and costs	*"...most patients would say that getting the right balance of medication for them...can be quite a juggle sometimes and can sort of take time to get right and keep right."* (Psychiatrist 309) *"Seroquel [atypical antipsychotic] is a classic example, they [patients] find that they get really dopey from it and so they don't like that component of it because it makes it hard for them to function daily….sometimes the side effects are perceived to be too negative in comparison to the gains from [that] mood stabiliser."* (Clinical psychologist 305)

Balancing benefits and costs

Several clinicians spoke of having to strike *"the right balance of medication"*, which clinicians felt was acceptable to them and their patients in terms of good treatment efficacy and minimal side-effects. The balance was often precarious ("*a juggle*"), took time and required a number of trials with different medications (psychiatrist 309, Table 4.4). Most clinicians said that treatment side-effects took precedence over efficacy when deciding on the right balance, and mattered more to patients in their decision-making. Anticipated and experienced side-effects (e.g., weight gain, fatigue) were cited as the main reason for patient reluctance to start or continue certain medications (clinical psychologist 305, Table 4.4). These views were more prevalent amongst GPs and psychiatrists. Fewer clinicians felt that patient placed a greater value on treatment benefits and were happy to *"put up with"* unpleasant side-effects. One clinician expressed a more balanced view, saying that patients took into account both treatment efficacy and side-effects.

4.4.6. Theme 4: Decision-making in consultations

Theme 4 (Table 4.5) outlines clinician perceptions of decision-making in consultations. This includes the various stages of decision-making (i.e., information exchange, deliberation, and making a final decision), as well as the relative involvement of patients, family, and clinicians in this process. According to clinicians, the decision-making stages and relative patient-family-clinician involvement seem to depend in part on the types of decisions being made (Theme 2) and the inherent uncertainty of, and need to balance benefits/side-effects of treatment options (Theme 3). Hence, this theme is preceded by and flows on from Themes 2 and 3 in Figure 4.1.

Table 4.5. Illustrative clinician quotations for Theme 4: *Decision-making in consultations*

Subtheme	Illustrative clinician quotations
4.1. Decision-making stages	
Information exchange	*"…we were talking about, what I would recommend as a mood stabiliser for her [this patient]…..fairly broad terms what mood stabilisers were and, discussion of their strengths and weaknesses and, and highlighting some of the potential unwanted or side effects that people tend to worry about"* (Psychiatrist 309)
Giving options	*"I go through with the patient what I think would be an appropriate mix of treatment….I tend to do things to various recipes….So at the end of the day I think I have canvassed all the options."* (GP 333)
Deliberation	*"…we discuss the pros and cons of taking medication and how they [patient] feel about it, why they're hesitant, things like that….just discussing with them how they feel about it, the pros and cons…. sometimes putting out there suggestions"* (Clinical psychologist 308)
4.2. Patient involvement	
Patients as the decision-maker	*"When they [patients] make that final decision your job would be to support them in whatever that decision is and to actually then encourage them to carry it out. But...really the decision is theirs and it's their responsibility."* (Clinical psychologist 301)
	"In the end she [a patient] made the decision but she made it very much with my guidance and we reached a compromise that we both felt comfortable with and felt willing to explore." (GP 324)

Trends and variability in patient involvement	*"I do have quite a few clients with bipolar II who are further down the pathway in that they've been diagnosed for quite some time and they're capable of doing [decision-making] themselves…"* (GP 324)
4.3. Family involvement	*"I think the family members do lots of talking and I think they often have a preference but I must be fair to many of them that often their preference if it isn't chosen, they're okay about it."* (Clinical psychologist 321)
Family involvement in and out of consultations	*"...If I think it would be beneficial to [the patient] and important to have them [the family] come in, I ask "would you mind if I ask them [patient's family] to come in". I respect their [patient's] right to privacy and I respect their opinion and their judgement"* (Psychiatrist 310)
Family attendance at consultations	*"I like to bring in [family] at some stage in the early stages of seeing a new client….we normally have a discussion where I really ask the partner to ask me any questions that they have and we talk about things that have come out in our consultations as well"* (Clinical psychologist 318)

Decision-making stages

In consultations, most clinicians alluded to *information exchange/provision* to patients about medication. Several clinicians also noted that patients supplemented clinician-provided information with their own information which they gathered pre-/post-consultations (e.g., online, discussions with other clinicians and friends/family). Approximately half of these clinicians, especially GPs and psychiatrists, tailored information to the patients' life circumstances or what the patient already knew, or responded to patient preferences for information (desiring a lot of information). For the other half, information exchange appeared to be clinician-led with minimal or no reference to patient involvement at the "information exchange' stage of decision-making. These clinicians tended to only give information relating to a particular medication option (psychiatrist 309, Table 4.5).

Several clinicians reported *outlining options* to patients for treatment. Only a couple of clinicians reported explicitly offering patients alternative treatments to pursue. Another two GPs/psychiatrists appeared to contradict themselves in their accounts. Whilst these clinicians felt they *"canvassed all the options"* for patients, the options reportedly offered seemed restricted by the clinician's own preferences (*"various recipes"*), or influenced by the clinician's perceptions of patient competence (e.g., reliability and likelihood of treatment adherence) (GP 333, Table 4.5).

Most clinicians spoke about the *deliberation stage of decision-making* (i.e., discussion of treatment preferences); with approximately three quarters of clinicians reporting that they employed shared or collaborative approaches. All clinician groups, especially psychologists, and clinicians with a bipolar specialty, reported 'shared' deliberation. This involved an open and frank discussion of patient preferences (*"how they feel about it, the pros, the cons"*), and *"putting out suggestions"* or recommendations (clinical psychologist 308, Table 4.5). To integrate patient preferences, clinicians discussed patient's treatment goals and feelings towards treatment pros/cons, and past medication experiences. This discussion then informed an acceptable treatment plan.

Fewer GPs and psychiatrists described clinician-led deliberation without reference to involving patients in a discussion about their preferences. This clinician-led style of

decision-making was more prevalent amongst medical practitioners without a specialty in bipolar disorders.

Patient involvement

A majority of clinicians considered *patients as the final decision-maker* in treatment decisions. Clinicians supported patients' having the final say because it concerned their lives and was their responsibility to implement the decided-upon treatment (clinical psychologist 301, Table 4.5).

Most clinicians felt that their role was to provide *"guidance"*, *"support"* and *"assistance"* without excessive influence (i.e., *"not telling them what to do"*) (GP 324, Table 4.5). Some clinicians alluded to respect patient autonomy and having to support any decision that was made, even if they did not agree with it. Two clinicians noted that patients desired greater involvement in treatment decision-making than they had, particularly with regards to medication.

In enabling patients to make the final decision, clinicians reportedly practised several SDM elements. This included: providing expert opinion and treatment information within the context of the patient's life, asking questions to check patients' understanding of information and thoughts about treatment, exploring the potential impact of treatment on the patient, suggesting or recommending treatments, listening to patients' treatment concerns and preferences, and trying to accommodate these into a mutually-acceptable course of action.

Several clinicians noted *variability in patient involvement in treatment decision-making*, and identified factors influencing this. Patients reportedly tended to be more involved when they had a longstanding diagnosis and had achieved mood stability, viewed themselves as more proactive/independent, and saw their clinician as a *"human"* with inherent limits to their knowledge (GP 324, Table 4.5). By contrast, patients were reportedly less involved and more likely to defer decision-making to the clinician when they were newly-diagnosed, yet to reach mood stability, viewed themselves as passive, held paternalistic attitudes towards the clinician, were younger, and were making treatment decisions about medications.

Family involvement

Approximately two thirds of clinicians reported on limited *family involvement in treatment decision-making*. Family involvement almost exclusively occurred outside consultations and clinicians reportedly seldom inquired about family involvement or patient preferences for this. Several psychologists with a preference for patient/family involvement in decision-making noted that family were involved but respected patient autonomy, *"their [treatment] preference isn't chosen, they're okay about it."* (clinical psychologist 321, Table 4.5).

For the most part, clinicians reported that *family did not attend consultations*. By contrast, clinicians with a preference for triadic SDM always reported at least some family attendance at consultations. Family attendance was mostly patient-initiated (bringing the family member along) and occurred in line with patient stated preferences, "*their opinion and their judgement"* (Psychiatrist 310, Table 4.5). Clinician-initiated family attendance usually occurred shortly after diagnosis, or when the clinician wanted to give the family an opportunity to ask questions and have their concerns addressed (clinical psychologist 318, Table 4.5).

4.5. Discussion

This is the first known study to explore how clinicians view and experience treatment decision-making in BPII. These findings provide insights into the nature of treatment decisions, and how decision-making unfolds within consultations, as well as factors that seem to influence this process. As seen in Figure 4.1, the themes derived from the data are both interrelated and cyclical (e.g., relationship between balancing uncertain benefits/side-effects of treatment and patient involvement in consultations flowing into acceptance of treatment) and conform to a hierarchy (acceptance of diagnosis and treatment contribute to patient engagement in decision-making). Discussion of noteworthy findings is provided below.

Clinicians identified a number of patient-related characteristics that they considered important in treatment decision-making in BPII. Firstly, according to clinicians, patients who accepted their BPII diagnosis were more likely to accept medication and engage in decision-making about medication. Secondly, clinicians felt that the presence of severe symptoms (either depressive or hypomanic) impeded effective

patient engagement in decision-making. Thirdly, clinicians reported that some patients were more or less inclined to defer decision-making to clinicians based on their personality styles (e.g., independent versus dependent). Of note, these patient-related characteristics were perceived to have a significant impact on BPII patients' ability and motivation to engage in treatment decision-making. Most research on patient involvement in treatment and management decisions in bipolar disorder has not considered these patient-related characteristics, apart from symptom severity (e.g., [36]). This is likely because global assessments of patient involvement using patient-report (e.g., [17]) and consultation ratings (e.g., [37]) seldom capture broader factors influencing patient involvement. "Optimal" patient involvement is likely to vary over the illness trajectory and in response to changing patient symptoms and increasing acceptance [38]. By implication, clinicians need to be flexible in their approach to decision-making, and ensure that patients are involved as much as preferred *at the time*. To do this, clinicians need to explicitly obtain patient preferences for the type and level of decision-making involvement, which was not reported by clinicians in this study or other research [12]. Continuously revisiting patient involvement preferences seems especially pertinent to BPII, which is characterised by fluctuating symptom severity and associated disability, and which relies heavily on patient self-management to prevent illness episodes (prophylaxis).

In addition, facts about treatment choices also influenced clinician approaches to decision-making. According to clinicians, the inherent uncertainty and varying benefit/side-effect profiles of BPII medications made medication-based decisions particularly difficult. Of note, relatively few clinicians reported that the uncertainty inherent in treatments had a negative psychological impact on some patients (e.g., distress, fear, concern), and necessitated SDM. These findings contrast with literature endorsing SDM when mental health treatment options have uncertain and potentially burdensome outcomes [5]. These findings also suggest that clinicians may underestimate the negative psychological impact of clinical uncertainty on patients. When faced with uncertain treatment outcomes, patients may require additional psychosocial support [39], and SDM may help patients to better tolerate uncertainty [40]. Clinician recognition of patients' emotions and responses to treatment options may also increase patient satisfaction with decision-making [41]. Education on these issues appears warranted, especially as clinician expertise in communicating complex

information and coping with patients' emotional and personal reactions has not been found to improve with time and experience [42].

Further, clinicians expressed discrepant views regarding other aspects of treatment: what they perceived patients valued more in treatment options, treatment efficacy versus side-effect burden. While some clinicians felt that patients attributed greater importance to side-effect burden than treatment efficacy, others expressed opposite views. Given that clinicians reported side-effect burden as a major barrier to treatment uptake and adherence, consistent with other research [43], it is important that clinicians openly discuss patient attitudes towards the different features of treatment options. This is especially important considering that clinicians may assume that side-effects are of lesser importance to patients than patients actually perceive them to be [44].

Clinicians almost uniformly supported patient involvement and autonomy in BPII treatment decision-making. The patient was seen as the final decision-maker and, accordingly, most clinicians reported that they practised elements of SDM (e.g., offering options, and checking patient thoughts about treatment). When clinicians described their behaviours during past consultations, however, a more mixed picture of actual patient involvement emerged (as per [45]), with regards to key SDM steps of eliciting patient preferences for involvement and treatment, providing information about and deliberating on available treatment options. Indeed, the extent to which patients were actually involved seemed to commonly depend on the clinician's own preferences for treatment and patient involvement, judgements about patient competence, and health professional background. For example, some clinicians appeared to offer a limited number of treatment options based on their own treatment preferences and beliefs about the patient (e.g., believing the patient to be too unreliable to commit to ongoing medical check-ups for lithium). Further, GPs/psychiatrists and clinicians without a speciality in bipolar disorders appeared less likely to involve patients in deliberation about treatment options compared to clinical psychologists and clinicians with a speciality in bipolar disorders. It may be that specialised clinicians are more proficient at involving these patients in treatment deliberation. System-related factors (e.g., short consultation times) may also reduce shared deliberation with medical practitioners (GPs/psychiatrists) [44] compared to

psychologists in the mental health setting. Alternatively, the apparent disconnect between clinician endorsement of patient involvement and actual patient involvement may be explained by clinician misconceptions that they "are already doing SDM" [45], or the distinction that clinicians make between the process of decision-making (e.g., sharing of information by clinician) and who makes the final decision (patient) [15]. According to this view, patients may be recognised as the final decision-maker but have had limited input in the earlier stages of decision-making. Therefore, it is important that clinicians have access to interventions designed to encourage them to reflect on, and improve their own clinical communication skills. Communication skills training, widely tested within the medical setting, is one such intervention leading to enduring improvements in clinicians' clinical communication skills [46, 47]. Future research comparing clinician-reported steps of SDM with their clinical practice could elucidate specific challenges and define the areas of improvement for targeted training programs.

As well as influencing patient involvement, clinician preferences also appeared to influence family involvement in treatment decision-making. Clinicians were generally unaware of family involvement in treatment decision-making outside consultations, and did not ask patients their preferences for family involvement. These findings align with other consultation studies in mental health showing clinicians rarely ask patient preferences for others' input [48]. Further, family attendance at consultations appeared to be mostly initiated by the patient rather than encouraged by the clinician. By contrast, when clinicians themselves preferred family involvement in decision-making, they were more likely to recognise the influence of family on treatment decisions, appreciate family involvement, and report family attending consultations. Thus, clinician attitudes and behaviours appear to influence whether, and to what extent family are involved in treatment decision-making, which accords with findings from the medical setting [49]. As family involvement, even "behind-the-scenes", influences and benefits patient involvement and treatment decision-making [50-52], it is important that clinicians establish patient preferences for family involvement [49] and identify any barriers to involving family to the extent patients prefer.

The present study has several limitations. Firstly, due to the "opt-in" nature of clinician recruitment and potential for self-selection bias, it is possible that these

findings reflect the views of clinicians who are more interested in treatment decision-making in BPII. Secondly, although attempts were made to recruit clinicians from different health professional backgrounds, the present study included fewer GPs and psychiatrists than clinical psychologists. However, medical practitioners' and clinical psychologists' views were equally represented and data saturation was reached in each of the subgroups. Thirdly, the present clinician sample comprised mostly experienced clinicians. Whilst this limitation may be less pertinent to specialist clinicians, the views and experiences of clinicians in this study may not represent those of less experienced or generalist clinicians, who may be less knowledgeable about and less confident in treating BPII. For example, the GPs included the study may be more knowledgeable about bipolar disorder and the BPII subtype compared to other primary care physicians.

In conclusion, this study provides the first known examination of clinician views and experiences of treatment decision-making in BPII. Findings demonstrate how clinician-related factors (e.g., attitudes towards treatment options) may shape the treatment decision-making process. Findings also suggest potential challenges in treatment decision-making, such as low patient involvement and failure to assess patient attitudes towards treatment options and others' involvement. These shortcomings provide opportunities for clinical practice interventions, such as communication skills training in the mental health setting. However, to fully address these potential shortcomings, clinician-perceived barriers and facilitators to treatment decision-making should be explored in greater depth.

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Chapter 5

Chapter 5: Identifying and addressing barriers to treatment decision-making in bipolar II disorder: Clinicians' perspective.

This chapter is reformatted from the published manuscript:
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This chapter reports on a qualitative study, which sought to investigate the barriers that clinicians encounter, and the strategies they use when making treatment decisions with patients with bipolar II disorder (BPII) and their families. Based on findings, a number of preliminary clinician-endorsed decision-making strategies are proposed. These strategies were used to inform the content, format, and delivery of the decision-aid (DA, see Chapter 6). Ethics approval letters are provided in Appendices B1 and B2; supplementary materials related to this study are provided in Appendix E.

Author contributions
Conception and design: AF, IJ
Participant recruitment: AF
Data collection: AF
Data analysis and interpretation: AF, IJ, RL-P, LS
Manuscript drafting: AF
Manuscript critical review: All authors
Review of final manuscript: All authors

5.1. Abstract

Objective. Treatment decision-making in bipolar II disorder is complex due to limited evidence on treatment efficacy and potentially burdensome side-effects of options. Thus, involving patients and negotiating treatment options with them is necessary to ensure that final treatment decisions balance both clinician and patient preferences. This study qualitatively explored clinician views on (a) effective treatment decision-making, unmet patient needs for (b) decision-support and (c) information.

Method. Qualitative semi-structured interviews with 20 practising clinicians (*n*=10 clinical psychologists, *n*=6 GPs, *n*=4 psychiatrists) with experience treating adult outpatients with bipolar II disorder were conducted. Interviews were audiotaped, transcribed verbatim and analysed thematically using framework methods. Self-report professional experience, and clinician preferences for patient decision-making involvement were also assessed.

Results. Qualitative analyses yielded two inter-related themes: 1) *challenges and barriers to decision-making* and 2) *facilitators of clinician decision-making*. Symptom severity, negative family attitudes, system-based factors and information gaps were thought to pose challenges to decision-making. By contrast, decision-making was supported by patient information, family involvement and patient-centredness, and a strong therapeutic relationship. Clinician views varied depending on their professional background (medical versus clinical psychologist), patient involvement preferences and whether the clinician was a bipolar specialist.

Conclusions. Whilst clinicians uniformly recognise the importance of involving patients in informed treatment decision-making, active patient participation is hampered by unmet informational and decision-support needs. Current findings inform a number of bipolar II disorder-specific, clinician-endorsed strategies for facilitating patient decision-making, which can inform the development of targeted patient decision-support resources for use in this setting.

Keywords. Bipolar II disorder, treatment decision-making, qualitative, clinician views, barriers, strategies.

5.2. Introduction

In shared treatment decision-making (SDM), the clinician and patient (and others, e.g. family) share their respective knowledge and expertise regarding the different treatment options, and deliberate on the benefit-costs of these in relation to the patients' values [1, 2]. Critically, the final decision in SDM would incorporate both parties' preferences. Not only does SDM support patient autonomy and informed decision-making, it is consistent with many patients' preferences for information and involvement in their own mental health treatment decisions [3-5]. Thus, SDM has attracted increasing attention in the literature and in clinical practice for its applicability to many mental health conditions [3, 6-8].

SDM may particularly benefit patient outcomes in chronic mental illnesses, which rely on patients adopting a self-management approach to prevent illness symptoms [9]. Bipolar disorder is one such illness where shared approaches to decision-making and management have been linked to improved outcomes, such as treatment adherence and satisfaction with care [10]. Although SDM has value in both bipolar I and II disorders, SDM may be particularly important and challenging in bipolar type II (BPII), given that treatment options are more finely balanced between clinician and patient preferences. This is due to: the absence of psychosis in BPII [11], lack of psychosocial impairment during hypomania [12], and limited published BPII-specific treatment guidelines which draw on a relative paucity of research to advise first-line mood-stabilising medications (i.e., lithium, lamotrigine, quetiapine) together with adjunctive psychological treatment (i.e., cognitive behavioural therapy, group psycho-education) [13-16].

Despite the importance of collaborative approaches to decision-making, many patients with bipolar disorder continue to experience low levels of involvement in shared treatment decision-making despite expressing a preference for it [17, 18]. This mismatch between preferred and experienced levels of patient involvement in bipolar disorder may not only compromise patient outcomes [19, 20], but also points to barriers to achieving SDM in this population. There remains a dearth of research on SDM in bipolar disorder [18], especially qualitative investigations of key clinician, patient, and family perspectives. In order to maximise patient involvement in

treatment decision-making, in line with their preferences, challenges and enablers to this process need to be examined.

Only one qualitative study has investigated the facilitators of collaboration between clinicians and patients in bipolar disorder specifically [21]. This study identified patient-related barriers, such as symptoms, communicative difficulties, as well as clinician-related barriers, such as poor empathy and listening, and discounting patient concerns. Also identified were several patient-related facilitators, such as open communication and family involvement, and clinician-related facilitators, such as meaningful discussion of patient problems [21]. However, this study did not ask specifically about treatment decision-making, and included only patient perspectives. In fact, no existing studies have explored the views and experiences of clinicians on the process of treatment decision-making in bipolar disorder [18], in contrast to several studies on depression [22, 23] and schizophrenia [24-26]. This represents a significant gap in the literature as both patient- and clinician-initiated behaviours contribute to overall SDM levels within consultations [27]. Thus, clinicians treating BPII have a responsibility to carefully negotiate the various treatment options with patients to ensure that the final treatment decision is shared and balances both their own and their patient's preferences and values.

The present study aimed to qualitatively explore clinicians' views and experiences of BPII treatment decision-making with patients in an outpatient setting. Consistent with the Ottawa decision support framework [28], which posits the link between decisional needs, quality of decision-making, and tailoring of decision-support this study had two principal aims. These were to elucidate: i) the challenges clinicians encounter in meeting patient needs for decision support and information; ii) the perceived barriers and facilitators to effective treatment decision-making.

5.3. Methods

5.3.1. Participants

Eligible clinicians (*N*=26) were those who were currently practising, and had experience in treating adults diagnosed with bipolar II disorder (BPII) within the outpatient setting. This included both medical and non-medical clinicians (i.e.,

psychiatrists, GPs, and clinical psychologists) working across general practice and specialist care. Three recruitment methods were utilised: 1) Clinicians affiliated with the Black Dog Institute (BDI, a clinical service specialising in the assessment and treatment of mood and bipolar disorders); 2) Clinicians attending BDI-organised professional development workshops; 3) Clinicians signed up to receive BDI e-newsletters. Purposive sampling was used to obtain maximum variation on clinician characteristics such as years of clinical practice and professional specialty.

Recruitment continued until data saturation (three consecutive interviews revealing no new information) was achieved [29]. All aspects of the study received ethics approval from The University of Sydney Human Research Ethics Committee (USYD HREC) and the BDI Research Advisory Committee, and complied with the Code of Ethics of the World Medical Association (Declaration of Helsinki)[30].

5.3.2. Procedure

Expression-of-interest flyers were made available at BDI staff meetings, professional development workshops, and disseminated via clinician emailing-lists. Interested clinicians contacted the researcher at USYD (AF) via details provided on the expression-of-interest flyer. The researcher then explained the study rationale to clinicians and obtained verbal consent to post/email a study pack to them, which contained an information sheet and consent form, and pre-interview questionnaire. Participants were sent two reminders, one and two weeks' after the study pack was sent to them. Once the completed questionnaire and consent form were received, a one-off telephone interview was arranged.

5.3.3. Qualitative data collection

A purpose-designed, semi-structured interview protocol (Appendix E) was based on: widely-cited models of SDM [1, 2, 31], the Ottawa decisional support framework [28, 32, 33], and previous qualitative studies of treatment decision-making in the mental health (e.g., unipolar depression [34]) and medical settings (e.g., cancer [35]).

In this paper we report on clinician-perceived challenges to decision-making about BPII treatment, as well as strategies for improving this process. Other results from

this qualitative study, such as clinician-patient-family involvement and the nature of treatment decisions in this setting, will be reported elsewhere.

5.3.4. Statement of reflexivity

The first author (AF), who conducted all interviews, is a female PhD student with a background in clinical health psychology and shared decision-making, and experience in conducting qualitative interviews across a number of patient populations (e.g., bipolar disorder, cancer, traumatic brain injury). Although not trained as a clinical psychologist, AF has developed specialised clinical knowledge in mood and bipolar-related disorders through an Honours degree in Psychology and attendance at professional development workshops for clinical psychologists, GPs and allied health professionals. During and immediately after each interview, AF wrote memos on any initial impressions and noteworthy remarks in order to maintain reflexivity and an awareness of potential personal biases throughout the interview process.

5.3.5. Quantitative measures

Clinician preferences for their own and others' (i.e., patients/family) decision-making involvement were assessed using an adapted version of the *Control Preferences Scale* (CPS, [36-38]). This self-report, two-item scale measured involvement preferences both in dyadic (clinician-patient) and triadic scenarios (clinician-patient-family). For both dyadic and triadic scenarios, participant preferences can be categorised as active (fully patient-led, or patient-led with clinician[/family] involvement), shared (equal clinician-patient[-family] involvement), or passive (fully clinician-led or clinician-led with patient[/family] involvement). The CPS has been used to evaluate physician perceptions of patient involvement in treatment decision-making [38], and in outpatient samples including bipolar disorder [20, 39, 40].

Demographic, clinical and professional characteristics (e.g., age, gender, years in clinical practice, typical patient presentation and treatment types) were collected via a purpose-designed self-report questionnaire. Participants also indicated whether, and how often family members attended consultations.

5.3.6. Data analysis

Descriptive and frequency analyses of questionnaire data were conducted using SPSS version 22. Interviews were audio-recorded and professionally transcribed. The interviews were then thematically analysed [41] using framework methods as outlined by [42]. To ensure methodological rigour, a proportion of the transcripts (20%) were cross-coded by a second co-author (RL-P) and discrepancies discussed and resolved before proceeding with coding the entire dataset. Secondly, the thematic map was developed in consultation with two co-authors, who have expertise in treatment decision-making and qualitative analysis.

5.4. Results

5.4.1. Participant characteristics

Table 5.1 summarises clinicians' demographic and clinical characteristics. Of the 26 clinicians who were approached and agreed to participate, 20 completed both the questionnaire and interview (76.9% response rate). Recruitment was balanced across clinical psychologists (*n*=10) and medical clinicians (psychiatrists, GPs; *n*=10). Interviews ranged from 21-51 minutes in length (*M*=34 minutes).

All clinician groups reported extensive professional experience (*M*s=13.70-19.25 years, Range: 3-30); almost all clinicians (90%) practised in metropolitan areas. Half of psychiatrists (50%) and most clinical psychologists (70%) reported specialisation in the assessment/treatment of bipolar and other mood disorders; most GPs (83%) reported no mental health speciality. All clinicians indicated that medication and adjunctive psychological-based interventions typically made up their patients' treatment. Regarding preferred patient involvement, all except one clinician preferred patient (or family)-led or shared decision-making in both dyadic (clinician-patient) and triadic (clinician-patient-family) consultations (Table 5.1).

Table 5.1. Clinician demographic/ professional characteristics and patient characteristics.

		Psychiatrists (*n*=4)	GPs (*n*=6)	Clinical psychologists (*n*=10)
Age	***M*(*SD*)**	53.25(11.44)	55.83(11.0)	50.50(10.46)
Gender (female)	***n*(%)**	2(50.0)	4(66.7)	7(70.0)
Mental health speciality	***n*(%)**			
Bipolar and other mood disorders		2(50.0)	--	7(70.0)
Other (e.g.,trauma,psychosis)		2(50.0)	1(16.7)	2(30.0)
None		--	5(83.3)	1(10.0)
Years in speciality	***M*(min-max)**	19.25(8.0-28.0)	16.83(4.0-30.0)	13.70(3.0-30.0)
Hours direct patient contact p/w	***M*(min-max)**	22.50(16.0-30.0)	24.83(12.0-50.0)	18.90(10.0-30.0)
Hours direct contact with BPII patients p/w	***M*(min-max)**	7.25(4.0-12.0)	3.67(1.0-8.0)	4.15(0.5-12.0)
Most common BPII patient presentation	***n*(%)**			
Depressed		2(50.0)	5(83.3)	5(50.0)
Mixed state		1(25.0)	--	1(10.0)
Euthymic/subsyndromal		--	1(16.7)	3(30.0)
Other (e.g.,heterogenous)		1(25.0)	--	1(10.0)
Most common medication in BPII	***n*(%)**			
Mood-stabiliser only (lithium,anticonvulsants)		1(25.0)	2(33.3)	3(30.0)
Antidepressant only		--	--	1(10.0)
Mood-stabiliser and antidepressant		1(25.0)	2(33.3)	4(40.0)

Mood-stabiliser and atypical antipsychotic		--	--	1(10.0)
Other (e.g.,polypharmacy of above)		2(50.0)	2(33.3)	1(10.0)
Psychological interventions	***n*(%)**			
Yes (e.g., CBT, Mindfulness, Wellbeing plans)		4(100.0)	6(100.0)	10(100.0)
% BPII patients attending with family (1+)	***M*(min-max)**	32.50(0.0-60.0)	8.67(0.0-20.0)	7.50(0.0-15.0)
Most common attending family †				
Spouse/ Partner		2(50.0)	3(50.0)	6(60.0)
Parent		1(25.0)	2(33.3)	1(10.0)
Preferences for patient involvement (triadic) †	***n*(%)**			
Patient-led with family/clinician		1(25.0)	3(50.0)	5(50.0)
Patient/family-led with clinician		1(25.0)	--	2(20.0)
Patient/family/clinician shared		1(25.0)	3(50.0)	1(10.0)
Clinician-led with patient/family		1(25.0)	--	--
Preferences for patient involvement (dyadic)	***n*(%)**			
Patient-led alone			1(16.7)	--
Patient-led with clinician		3(75.0)	2(33.3)	8(80.0)
Patient/ clinician shared		--	3(50.0)	2(20.0)
Clinician-led with patient		1(25.0)	--	--

† = For clinicians reporting family attendance.

5.4.2. Qualitative findings

Qualitative analyses yielded two inter-related themes, each comprising several subthemes: 1) *Challenges and barriers to decision-making* and 2) *facilitators of clinician decision-making*. Illustrative patient and family quotes are presented in Tables 5.2 and 5.3.

5.4.3. Theme 1: Challenges and barriers to decision-making

Theme 1 (Table 5.2) encompassed clinician perceived challenges to decision-making about BPII treatment. Challenges were diverse, spanning patient-related, clinician-related and family-related factors as well as shortcomings of the healthcare system and available patient information.

Patient-related

A large proportion of clinicians referred to the *negative impact of BPII symptoms* on treatment decision-making. Both hypomanic and depressive symptoms were associated with limited *"chances of making correct decisions"*, a skewed *"frame of reference"* (insight), *"regret [about] decisions"*, and poor *"concentration to make decisions"* (clinical psychologist 318, Table 5.2).

Several clinicians noted that some patients held *a priori treatment preferences*, based on "*preconceived ideas and stigma attached to taking medication"* (GP 332, Table 5.2). Clinicians reported that these presented an obstacle to decision-making because patients with preconceptions about medications (e.g., lithium, sodium valproate) were often reluctant to commence them, or made *"decisions in favour of psychological support"* over pharmacological approaches (GP 332, Table 5.2).

Table 5.2. Illustrative clinician quotations for Theme 1: *Challenges and barriers to decision-making*

Subtheme	Illustrative clinician quotations
1.1. Patient-related *Impact of symptoms and comorbidities*	*"In that depression you get with bipolar II people don't have the concentration to actually make decisions. .....you may regret those decisions. If you are hypomanic….your chances of making correct decisions are much more limited."* (clinical psychologist 318)
A priori treatment preferences	*"Sometimes decisions in favour of psychological support are made because of preconceived ideas and stigma attached to taking medication."* (GP 332)
1.2. Clinician-related *Unhelpful clinician behaviours*	*"He [one patient] was trying to make a decision about […] medication….His GP was very directive…That was an unhelpful way of trying to encourage someone."* (clinical psychologist 319)
1.3. Negative family influences	*"Unhelpful…..family members are more often than not extremely reluctant to accept the diagnosis and that the medication is required in this instance."* (GP 332)
	"…over-involved family members…..not allowing the individual to make their own decisions….in trying to support are also disempowering the individual." (psychiatrist 307)
1.4. System-based	*"….with bipolar, you want more than just ten [Medicare] sessions…but some people can't afford to continue seeing the psychologist beyond those ten."* (clinical psychologist 308)

	"…when it's a 10 or maybe 15 minute consultation they [patients] can feel that they've just been given the next script…that tends to be less satisfying for them." (clinical psychologist 304)
1.5. Inadequacies in available patient information	*"…when really they [patients] still only have a small amount of information…people do struggle with that and tend to want my opinion…"* (psychiatrist 328) *"…trying to communicate information around medication into a digestible form….information about medication for someone who doesn't have a medical or pharmacology background is really difficult to absorb"* (psychiatrist 328)

Clinician-related

Almost half of clinicians noted potentially *unhelpful clinician behaviours* that impeded decision-making. These included: a lack of open and honest communication (about medication options/outcomes), inadequate expertise, a lack of rapport or patient trust, and being *"very directive"* with limited patient input (clinical psychologist 319, Table 5.2). An overly directive (paternalistic) approach was linked to a power imbalance between the patient and their clinician. Inadequate rapport or trust, and poor communication were associated with limited time with the patient, and clinicians being over-familiar with medications (due to highly specialised knowledge), respectively.

Negative family influences

Over half of clinicians, especially psychologists, reported family behaviours or attitudes that were detrimental to decision-making. The most commonly expressed attitude was the family's reluctance *"to accept the diagnosis and…that the medication is required*" (GP 332, Table 5.2). These family attitudes/behaviours resulted in patients being reluctant to commence treatment, prematurely discontinue medication, or be less successful at implementing psychological strategies. Specifically, some family (especially parents) were reported to undermine the patient's autonomy, by becoming *"overly-involved"* or *"taking on too much"* in a patient's treatment decision-making (psychiatrist 307, Table 5.2).

System-based challenges/barriers

Almost half of clinicians noted system-related barriers to decision-making. These included: poor access and affordability of specialist services (psychologists/psychiatrists), time constraints during consultations, and a lack of multidisciplinary communication or coordination between clinicians with different professional training. A lack of accessibility and affordability reportedly led to patients prematurely discontinuing psychological treatment, or limiting available options (clinical psychologist 308, Table 5.2). Consultations perceived as excessively short reportedly led to lower patient satisfaction due to reduced continuity of care and more prescriptive decision-making where *"they've just been given the next script"* without any meaningful discussion with the patient (clinical psychologist 304, Table 5.2).

Inadequacies in available patient information

Almost half of clinicians, especially those preferring patient-led decision-making, noted gaps in current BPII patient information (both patient-sourced/clinician-provided information). A few clinicians, mainly psychologists, noted a general lack of written/online information and patient understanding of BPII illness and medication effects (especially long-term benefits/prognosis). Two GPs/psychiatrists also noted that where medication information is available (either online or via patient factsheets), it was often *"difficult to absorb"* and too complicated for patients to understand (psychiatrist 328, Table 5.2). The lack of information or availability of highly technical information reportedly compromised decision-making because patients came to consultations insufficiently informed to make decisions or more likely to defer to the clinician (psychiatrist 328, Table 5.2).

5.4.4. Theme 2: Facilitators of clinician decision-making.

Theme 2 (Table 5.3) highlighted clinician strategies for facilitating decision-making, such as patient information and education, encouraging family involvement and patient involvement, and fostering a strong therapeutic relationship. These facilitators mapped onto similar domains (e.g., patient-/clinician-related, informational and systemic) to those discussed in Theme 1.

Table 5.3. Illustrative clinician quotations for Theme 2: *Facilitators of clinician decision-making*

Subtheme	Illustrative clinician quotations
2.1. Making time – Structuring consultations	*"… almost 100% of the time I don't prescribe on the first session.....it's much better for people to go away, think about that [treatment options], reflect on what we've talked about, talk to family, talk to partners and come back. I try and get people back within a week…this is a big decision. And by doing that there's a much better compliance."* (psychiatrist 307)
2.2. Patient information and education **facilitating** decision-making	
Patient information needs and preferences	*"When you put a patient on medication they want to know what are the risks and side effects of medication. Having clear information about what they can expect…being able to answer their questions is important."* (GP 325)
	"…all the evidence-based treatments and look how they fit into the recovery….it would be very good to have a spectrum of treatment options." (clinical psychologist 313)
Supporting role of information	*"….information...is really helpful [for] people to come to a decision…ask more appropriate questions about treatment….a lot more knowledgeable about the medication that I was recommending....and weighing the options."* (psychiatrist 309)
Value of others' lived experience	*"....reading other people's stories are really helpful...it's always just so much more credible when you hear it from someone who's in that position."* (clinical psychologist 303)

2.3. Clinician perceptions of family as a resource	
Encouraging and facilitating family involvement	*"I certainly like to involve [family]. If there is a significant other I encourage them to be involved and encourage the patient to see me…..I need to educate them about the illness as well as to educate the patient."* (GP 327)
	"...the contribution from family members can be really valuable because….they known them [patients] quite well [and] what they're normally like....that person can often provide a bit of a different perspective for the patient.....bring a trusted person with you then it's not such an uneven sort of setting...." (psychiatrist 309)
Family engagement for patient treatment engagement	*"The more they [family] can get involved in the understanding….and know, the more they are likely to make informed decisions. If they're not onside they have a much more powerful effect than any therapist has."* (clinical psychologist 318)
2.4. Patient-centredness and involvement	*"…it's such an important part of clinical practice that the patient really feels like they've made choices about their treatment."* (psychiatrist 309)
	"I think an individual autonomy and right to make decisions around their treatment is a really important part of recovery. That people feel empowered and in a sense guided but being able to make the final decision themselves." (psychiatrist 328)

2.5. Therapeutic relationship	*"…it does seem to be a bit of a question of trust. But also the trust goes the other way as you get to know a patient, I often say to patients that the aim of all of this is for you to become the expert."* (psychiatrist 309) *"If a client knows that you know what you're talking about, and they've got a good relationship with you I think fundamentally you enlist the relationship and just say now trust me on this one."* (clinical psychologist 318)
2.6. Inter-professionalism and continuity of care	*"...When their initial diagnosis is made I always arrange a psychiatric referral...it gives them [patient] a chance to raise questions with someone different, to hear the information from someone who's an expert and get a different point of view…"* (GP 324) *"I monitor very frequently which means there's not this sense of being sent off to oblivion with some new medication and…no sense of someone watching it and monitoring it."* (GP 324)

Making time – Structuring consultations

Over half of clinicians, mainly GPs/psychiatrists and clinicians with a speciality in bipolar disorders, felt that making time (e.g., scheduling longer consultations) and structuring decision-making over multiple consultations facilitated the treatment decision-making process. Usually, in the first consultation (which sometimes involved patient diagnosis), treatment options would be presented. Patients would then be encouraged to find out more about these options (via clinician-provided information or independent information gathering) and deliberate them with family/friends. In a second follow-up appointment, the patient and clinician would discuss these options further and then make final treatment decisions.

According to clinicians, structuring decision-making over more than one consultation engendered several patient benefits. Patients were reportedly more informed, asked more questions, had options explained more comprehensively, were more satisfied with decision-making (through feeling more involved), and had better treatment adherence (psychiatrist 307, Table 5.3). Two psychiatrists pointed out that this style of decision-making was more an option in BPII because the need to bring the illness under control quickly is not as pressing (as sometimes the case in bipolar I disorder).

Patient information and education facilitating decision-making

Several clinicians (*n*=5) made reference to *patient information needs and preferences* (GP 325, Table 5.3). Two clinicians reported that their patients with BPII had particularly strong information preferences (e.g., *"hungry"* for information).

In order to support the development of a patient decision-making resource, clinicians were asked their preferences/recommendations. All three clinician groups made recommendations; almost three quarters of clinicians made recommendations relating to content and features, and recommendations mostly came from clinicians who preferred patient-led decision-making. Clinicians uniformly felt that the optimal time of delivery for a patient decision-making resource was shortly after diagnosis, as this coincided with when patients were frequently considering their treatment options. Regarding content, clinicians felt that information should cover a broad *"spectrum of treatment options"* including medication and psychological treatments. Information on treatment benefits/side-effects, rationale for medication use, and longer-term prognosis were all perceived as helpful (clinical psychologist 313, Table 5.3).

Although a few clinicians placed greater importance on side-effect and safety information, one clinician felt that more information on treatment benefits and prognosis was needed. Another two clinicians indicated that including some background information on the illness (symptoms, course) was necessary, especially as treatment decisions were made in the knowledge that BPII was a life-long, remitting illness.

In terms of proposed features of decision-making resources, clinicians felt that information should be specific, easy-to-read and free of medical jargon. Clinicians also valued evidence-based, reliable information with an Australian focus. Several clinicians endorsed including exercises to help patients consider which features of the different treatment options mattered most to them (i.e., values-clarification methods) alongside clinically-based information about options. This is because clinicians felt that values motivated decision-making, reflected the varied presentations of BPII and its treatment, and the resource would be more engaging for patients.

Several clinicians, especially those with a bipolar speciality, alluded to *the supporting role of information* in facilitating treatment decision-making. Clinician-provided psycho-education during consultations was valued and often supplemented patient resources providing written information. Both these forms of information reportedly enabled patients to be *"more knowledgeable"* about their illness and treatment options, *"ask more appropriate questions about treatment"*, more actively *"weighing up options"*, and have greater autonomy (psychiatrist 309, Table 5.3). One clinician also noted that such resources, when used in consultations could serve as a prompt for discussing treatment options in a structured way.

Clinician-provided psycho-education and written information resources was also thought to facilitate treatment decision-making in a number of ways. Firstly, written information and the resulting knowledge potentially increases patient empowerment and optimism towards treatment (knowing that it is a treatable illness with various treatment options). Secondly, the provision of such information is important in dispelling common myths and misconceptions around medication (e.g., that it is addictive).

Almost half of clinicians reported benefits of patients hearing *others' lived experience* with BPII. Reported benefits included: greater credibility than clinician-provided information, providing realistic treatment goals for patients, reduced feelings of patient isolation, and acknowledging the variable presentations of BPII (clinical psychologist 303, Table 5.3).

Clinician perceptions of family as a resource

Many clinicians were unaware of the extent of family involvement that their patients used in making decisions, which is consistent with self-report questionnaires indicating family rarely attended consultations (*M*=13% of consultations had family attend). Despite this, over half of clinicians felt that *family involvement benefited treatment decision-making*. Further, a third of clinicians, all of whom specialised in bipolar disorders, *actively encouraged family involvement* in decision-making (e.g., inviting family/significant others to attend appointments where important treatment decisions were likely to be made).

Most-commonly, family who attended consultations were perceived to provide valuable informational support to both clinicians and patients. Informational support included providing additional information about the patient's illness history and symptoms, identifying problem areas and treatment targets that mattered to them and the patient, and communicating information between different clinicians if patients were unable to (e.g., due to symptoms). Family also purportedly helped to equalise potential power imbalances between the patient and clinician and provided reassurance for the patient (psychiatrist 309, Table 5.3).

Several clinicians viewed *family engagement as playing an important role in facilitating patient treatment engagement.* Patients were perceived as more engaged with treatment when family were involved, informed, and *"on-side"* with treatments. When family were not involved (and by implication, likely to be uninformed about) a patient's treatment decision-making they reportedly often challenged the validity of treatment decisions, which could lead to patient non-adherence to treatment (clinical psychologist 318, Table 5.3). Of note, the benefits of family involvement were noted more frequently by clinicians preferring patient/family-led and/or triadic (clinician-

patient-family) SDM than those preferring patient-led or clinician-led decision-making.

Patient-centredness and involvement

Half of clinicians reported that involving patients was critically important to treatment decision-making, and was aligned with most patient involvement preferences (psychiatrist 309, Table 5.3). According to clinicians, the need to involve patients was well-justified. Patients were seen as bringing recognised expertise to treatment decision-making due to their lived experience and treatment-relevant values. By involving patients and incorporating patient values into treatment decisions, patients reportedly were more informed about treatment choices, had increased feelings of decisional control and greater satisfaction, and better treatment adherence (both psychological strategies and medication) (clinical psychologist 318, Table 5.3).

A few clinicians noted instances where they took a more directive approach in decision-making. These instances included patient preferences for minimal participation in decisions, or when patients had reduced decisional capacity (i.e., due to symptoms). Similarly, when clinicians felt that their patients' preferred option was *"not good",* they also saw the need to be more directive in their advice. However, most clinicians still tried to involve patients in decision-making as much as possible.

Therapeutic relationship

Half of the clinicians, irrespective of patient involvement preferences, reported that a strong, collaborative therapeutic relationship founded on mutual trust was imperative to good treatment decision-making (psychiatrist 309, Table 5.3). Medical practitioners, in particular, felt that mutual trust facilitated the discussion of treatment options, more open and honest patient communication, and clinician-led decision-making when patient capacity was compromised (clinical psychologist 318, Table 5.3).

Other qualities which clinicians felt they needed to achieve for a "good" therapeutic relationship conducive to effective decision-making included being welcoming and open, non-judgemental, and non-authoritarian. Clinicians emphasised the collaborative aspects of the therapeutic relationship, describing it as a *"partnership"*

or *"shared journey"* between the patient and clinician. Collaboration was considered by one psychologist as a buffer against clinician-patient disagreement in treatment decisions.

Inter-professionalism and continuity of care

Over half of clinicians endorsed engaging different clinicians in treatment decision-making for a number of reasons. Both psychiatrists and GPs acknowledged that psychiatrists had more specialist knowledge and served as a good back-up for GP's ongoing management of medication. Clinicians reports that many patients preferred a multidisciplinary team approach, and that clinician consensus reassured patients that treatment recommendations were sound (GP 324, Table 5.3).

Despite this notion of multidisciplinary teams managing patient care, clinicians highlighted the importance of a "leading" clinician to ensure continuity of care for the patient and their family. Several clinicians perceived good continuity of care, in the form of regular appointments with the same clinician, as critical to treatment and ongoing treatment decision-making. Two clinicians reported practising good continuity of care by arranging frequent follow-up appointments, which allowed them to monitor the patient and encourage patients to reflect on their treatment decisions (GP 324, Table 5.3).

5.5. Discussion

This is the first known study to investigate clinician-perceived barriers and facilitators to BPII treatment decision-making. Further, clinicians gave insightful suggestions as to ways that patient decision-making could be improved. These strategies were often targeted directly to changing the discussed barriers. These findings form the basis of preliminary clinician-endorsed strategies for effective decision-making in BPII, outlined below and in Table 5.4.

Table 5.4. Preliminary clinician-endorsed strategies to address challenges in treatment decision-making in BPII.

Challenges	Strategies
Patient-related	
Impact of symptoms and comorbidities	*Structuring consultations–Making time* - Allowing greater deliberation of options, less impulsive, hasty decisions affected by mood. *Therapeutic relationship* - Enlist when patient symptomatic - Buffers against clinician-patient disagreement about treatment choice
A priori treatment preferences	*Patient-centredness and involvement* - Moderate patient involvement - Incorporate patient values into decision-making *Structuring consultations–Making time* - Giving patients time to deliberate options between consultations and access information about options to make more involved, informed decisions *Patient information and education supporting decision-making* - Meeting patient information needs and preferences *Supporting role of information* - More actively weigh up treatment options, be more informed about options and illness.
Clinician-related	*Interprofessionalism* - Involving different health professionals with complementary expertise to address gaps in clinician's own expertise *Patient-centredness and involvement* - Incorporating patient values into treatment decisions, coming to mutual agreement
Non-supportive clinician input	*Encouraging and facilitating family involvement.* - Reduce clinician-patient power imbalance - Provide personalised knowledge of patient *Therapeutic relationship* - Non-directive, non-authoritarian - More open and honest communication - Fosters mutual trust and rapport

Negative family influences	*Structuring consultations–Making time* - Encouraging patients to deliberate/discussion options with family between consultations, prior to coming to treatment decision *Facilitating family engagement for treatment engagement* - Encouraging family attendance in line with patient preferences - Identifying treatment targets that matter to them and the patient - Ensuring involved and informed about treatment
System-based	*Structuring consultations-Making time* - Scheduling longer appointments with regular follow-ups *Inter-professionalism and continuity of care* - Regular appointments with 'leading' clinician - Engaging clinicians with different health professional backgrounds - Team approach to patient care and management *Supporting role of information* - Prepare patients to ask more appropriate questions - Serves as prompt for discussing treatments in more structured, efficient way - Greater independence and autonomy in decision-making; discouraging prescriptiveness/script-pad approach to decision-making
Inadequacies in available patient information	*Meeting patient information needs and preferences* - Comprehensive, evidence-based and easy-to-understand information on range of treatment options - Values clarification exercises to make more readable *Supporting role of information* - Encourages patients to be more informed and knowledgeable about illness and treatment options - Mobilises patient involvement in decision-making; more active question-asking and more active weighing-up/ deliberation of options. *Value of others' lived experience and personal stories* - Useful supplement to clinical information

5.5.1. Structuring consultations

More than half of clinicians, mainly GPs and psychiatrists, reportedly structured their consultations in order to facilitate more informed and active patient involvement in treatment decision-making. "Splitting" decision-making over at least two consultations reportedly encouraged patients to be more informed about, and clearer on their preferences for treatment decision-making. Of note, this strategy maps onto Elwyn and colleagues' [31] three key steps of SDM for clinical practice: *choice talk*, *option talk*, and *decision talk*, which are linked by ongoing deliberation occurring outside clinical consultations via discussion with others and information/decision-support resources. Importantly, this strategy, which has previously been advocated as an effective strategy in the medical setting, potentially addresses a number of decision-making challenges also identified by the sample (see Table 5.4). Structuring consultations allows patients the time to process information before reaching a decision, and helps clinicians more optimally schedule when final treatment decisions are made. In this way, clinicians can balance the need to act promptly to restore positive mental health and need to have a well thought out and accepted decision. Thus, impulsive and/or reactive decisions and decisional regret might be avoided.

5.5.2. Allowing deliberation of treatment options outside consultations

Encouraging patients to deliberate on treatment options between consultations reportedly increased the likelihood of involving family involvement in information gathering and treatment discussions. Given that family rarely attend consultations [43], involving family during post-consultation discussions gives them the opportunity to contribute to treatment preferences prior to reaching a final treatment decision. Indeed, patients appreciate when family act as a sounding board for treatment discussions outside consultations [5], whilst engaging family helps to mobilise them as effective supports and partners in illness management and to facilitate patient autonomy [35]. Finally, structuring decision-making over multiple consultations may compensate for short consultation times, a common systemic barrier [23, 44] that was associated with poorer decision quality in this study (i.e. more clinician-led, "prescriptive" decision-making and potentially/reportedly lower patient satisfaction with decision-making).

5.5.3. Supplementing clinician psycho-education with patient information resources

Providing patients with information about their illness and treatment options emerged as a key decision-support strategy. Both clinician-provided psycho-education and written patient information resources (e.g., factsheets, recommended websites) reportedly facilitated the decision-making process by addressing a number of clinician-reported barriers (see Table 5.4). Specifically, written patient information resources were perceived as helping patients to: reconsider preconceived treatment preferences, make more efficient use of short consultations, and better understand their treatment options/preferences rather than deferring to clinician expertise. As patients were able to consult these resources outside consultations, patients arrived better prepared to initiate treatment discussions, which results in greater integration of patient preferences into treatment decisions in mental health [45]. Additionally, written patient information resources may benefit clinicians in-consultation, by facilitating clearer and more structured treatment discussions with patients, and by identifying gaps in patient knowledge about treatment options, which are seldom assessed [46].

5.5.4. Improving patient information resources

Acknowledging that many patients still lacked a comprehensive understanding of treatment options, effects, and longer-term outcomes, clinicians identified priorities for future decision-support resources. These included: comprehensive and easy-to-understand, evidence-based information that is specific to BPII, and covers a broad spectrum of treatments (medication and psychological-based) options and outcomes. These priorities align with well-established recommendations in the literature for patient information resources [47]. Clinicians also endorsed the inclusion of values-clarification exercises, which are a key component of patient decision-aids (DAs) and may facilitate better alignment between patient preferences and treatment choice, as in depression and schizophrenia [48].

5.5.5. Fostering the therapeutic relationship

Consistent with clinicians placing a high value of patient-centredness and involvement, many endorsed the therapeutic relationship as integral to effective treatment decision-making. This supports other findings that successful adaptation of SDM to chronic care [49] and mental health [8, 50] settings requires greater emphasis

on partnership-building and the therapeutic relationship. Critically, a therapeutic relationship founded on mutual trust reportedly alleviated patient-clinician disagreement over treatment and made patients with acute symptoms more comfortable deferring decision-making responsibility to clinicians. Indeed, patient trust is seen by psychiatrists as a "prerequisite" for SDM [24]. Thus, fostering the therapeutic relationship in BPII may counteract unsupportive clinician behaviours (e.g., being overly directive/coercive, authoritarian), and support better continuity of care through better treatment engagement [10].

5.5.6. Facilitating family involvement

In addition to patient involvement, several clinicians also acknowledged the importance of family involvement in treatment decision-making. Encouraging and facilitating family involvement, especially within consultations, may overcome a number of barriers to treatment decision-making (see Table 5.4). Firstly, family provision of informational support within consultations may be of particular benefit when patients are symptomatic and cannot communicate their treatment preferences as effectively [51]. Secondly, having family attend consultations and serve as "a second pair of ears" [35, 52] may foster better continuity of care through improved communication of information between clinicians. Lastly, involving family within consultations may strengthen their support of treatment decisions by permitting clinicians to educate family about BPII illness and the rationale for treatment options, and for family to express their treatment preferences and clarify any concerns [43]. Given that clinicians linked family involvement to BPII patient outcomes, both positive (e.g., improved treatment adherence) and negative (e.g., premature discontinuation of medication), ensuring family are informed and involved, to the extent desired by patients, is important.

Although clinicians uniformly endorsed some views of treatment decision-making, it was evident that clinician views varied depending on their professional background (medical versus clinical psychologist), preferences for patient involvement in decision-making and level of expertise/specialty treating BPII patients. For example, clinicians with a preference for patient-led decision-making were more likely to identify inadequacies in available patient information, and endorse a patient decision-making resource. Further, clinicians specialised in bipolar disorders were more likely

to structure their consultations in order to optimise decision-making, and actively encourage family involvement in decision-making. These clinician-related factors have not been systematically explored within other qualitative studies of clinician views in unipolar depression [22, 23] and schizophrenia [25, 26]. These findings highlight the importance of inter-professionalism in mental health [44], where clinicians from different backgrounds collaborate to deliver integrated patient care based on complementary expertise.

In considering the present findings, a number of clinician-endorsed strategies may also be applicable to treatment decision-making in bipolar I disorder. For example, fostering the therapeutic relationship and providing patients with supplementary information resources in order to facilitate i) greater patient involvement and ii) treatment decisions that are consistent with patient treatment preferences are both reasonable goals, as bipolar I disorder is also a life-long remitting illness which relies on patient education and patient self-management. Other strategies, however, may be less applicable to bipolar I disorder, such as structuring decision-making over multiple consultations to permit deliberation outside consultations. This is because bipolar I disorder may require clinicians to act more promptly to restore mood stability, especially if a current or impending manic episode involves psychotic features. An interesting avenue for future research would be to elucidate differences between bipolar I and II disorders in terms of how clinicians approach and involve patients in treatment decision-making.

Despite the present study strengths, such as including both medical professionals and clinical psychologists, there are some limitations. Firstly, the present clinician sample was biased towards mostly experienced clinicians, many of whom specialised in bipolar and other mood disorders. Thus, the views and experiences of clinicians in this study may not represent those of less experienced clinicians, who may be less knowledgeable about and confident in treating BPII. Secondly, the "opt-in" nature of clinician recruitment creates the potential for self-selection bias. Thus, the present findings may reflect the views of clinicians who are more interested in treatment decision-making in BPII. However, it is likely that those with this expertise and a preference for SDM are best placed to advise on ways to minimise the barriers towards effective decision-making in patients with BPII.

This sample of experienced, practising clinicians acknowledged that treatment decision-making in BPII is hampered by numerous barriers, which span patient-related, clinician-related, relational, systemic, and informational domains. These clinicians also proposed a number of complementary facilitators and strategies for optimising treatment decision-making in BPII, which they described within their own and others' clinical practice, and which serve to address various barriers and challenges. Whilst clinicians uniformly recognised the importance of involving patients in informed treatment decision-making, they also identified a number of challenges to active patient participation. These findings can inform the development of BPII-specific decision-support resources, designed to educate and involve these patients in, values-congruent decision-making about their own treatment.

5.6. References for Chapter 5

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Chapter 6

Chapter 6: Rationale for and development of the decision-aid (DA)

This chapter firstly summarises the qualitative study findings presented in Chapters 3, 4, and 5, and provides a rationale for developing a treatment decision-aid (DA) to assist patients with bipolar II disorder (BPII) and their families. Secondly, this chapter presents a step-by-step outline of the DA development and planned evaluation process (Chapter 7, and Appendix G), in accordance with International Patient Decision Aid Standards (IPDAS) and other literature recommendations. The final DA is presented in PDF format in Appendix H.

6.1. Rationale for a DA

The initial qualitative phase of this PhD research program (see Chapters 3, 4, 5) elucidated key priorities for information and decision-support in the BPII treatment setting. Importantly, these qualitative findings provided a comprehensive, "360-degree" view of the treatment decision-making process from the patient, family and clinician perspectives. All participant groups endorsed similar barriers and facilitators to effective decision-making; namely, decision-making that involves patients (and family) to the extent preferred (by the patient), and results in evidence-informed treatment decisions that incorporate patient values and life circumstances. The development of patient decision-aid (DA) was well-endorsed by both patients and family, as well as all clinician groups. ***Importantly, a DA stands out as an appropriate intervention for improving treatment decision-making and as an effective strategy to address a number of unmet needs for information and decision-support in this setting.***

Patients with BPII, their families, and clinicians placed a high value on patient involvement in treatment decision-making and uniformly felt that patients should retain authority in the final decision. Despite this, it was evident in many participant accounts that real world clinical practice fell short of the stated ideal for patient involvement. The shared decision-making (SDM) stages of information exchange and deliberation, as described by participants, were often clinician-led with limited discussion of alternative treatment options and patient preferences for treatment. As a result, a substantial proportion of patients, especially those who were recently diagnosed or who preferred patient-led/SDM, did not experience their preferred level

of involvement in consultations regarding treatment. Although uncommon, when patient did not experience their preferred level of decision-making involvement, nor preferred choice of treatment, they appear more likely to have negative outcomes, such as treatment non-adherence. By contrast, when clinicians employed more collaborative decision-making styles and actively involved patients (e.g., asked questions, elicited treatment preferences) this led to more positive patient outcomes, such as improved knowledge, satisfaction with care and decision-making, treatment adherence, engagement and continuity-of-care. Taken together, these results suggest that patients, especially those with a recent BPII diagnosis and/or stronger preferences for involvement, have unmet treatment preferences and involvement needs. A patient DA is well-placed to address these unmet needs by encouraging more active patient involvement and better alignment between patient treatment preferences and final treatment choice.

Patient knowledge and understanding of treatment options emerged as a key contributor to effective decision-making in this setting. According to patients, families and clinicians, well-informed treatment decisions relied on having comprehensive, unbiased and easy-to-understand information about a broad range of evidence-based treatments [1-3]. Many clinicians reportedly provided patients with information resources with the aim of informing patients about, and encouraging them to deliberate on treatment options. However, all participant groups acknowledged that existing treatment information resources were inadequate for supporting informed treatment decisions. In addressing this unmet need, a strong evidence base [4] supports the use of DAs in helping patients to: i) be more knowledgeable about treatment options, ii) have more accurate benefit/risk perceptions, iii) take a more active role in decision-making, and iv) make informed treatment choices that are based on their values and preferences. By providing these patients with a consolidated source of information to take away and read, such as a DA, it is likely that patients will come to their follow-up consultation better informed about options. Moreover, by presenting a balanced summary of treatment option benefits and side-effects along with values clarification exercises, patients will be able to more actively consider option pros and cons with respect to their personal values, and be better prepared to state their treatment preferences to clinicians.

When comparing clinician interviews to those with patients and family, it was evident that clinicians were largely unaware of family involvement in treatment decision-making. Indeed, family involvement was mostly limited to outside consultations, with patients appreciating the decision support family provided and acknowledging that family views were taken into account in their decision-making. Given the potential for family to support or derail the treatment decision-making process, an intervention that effectively engages family in these decision-support roles is warranted. One aspect of family involvement that patients perceived as beneficial was the family acting as a sounding board, which involved family encouraging patients to reflect on their treatment preferences and concerns and weigh up options in a way that fitted with the patient's perspective. Families acting as a sounding board generally occurred during post-consultation deliberations, so providing patients with a DA for use outside consultations is likely to enhance family involvement at a point when family are already most likely to be involved. The inclusion of a comprehensive, evidence-based information resource negates the need for family to rely on patient recall. It also ensures family can be sufficiently informed about available options even if they have not attended consultations, which was cited as a barrier to their involvement in post-consultation deliberations. Further, the inclusion of values clarification exercises in the DA helps to formalise the use of the family as a sounding board and makes patients' reasons for leaning towards one option over another more transparent. In sum, a patient DA encourages patients to involve their family in conversations and deliberations that they identify as beneficial.

6.2. Development and evaluation of the DA

The content and formatting of the treatment decision-aid (DA) booklet was guided by: the International Patient Decision Aid Standards (IPDAS) [5]; best available clinical evidence [6-9]; in-depth qualitative interviews with key stakeholders (i.e., 28 patients, 13 family members, and 20 treating clinicians) [1-3] (see Chapters 3, 4, and 5); and iterative review by an expert advisory group comprising senior-level researchers with expertise in DA development and evaluation, patients with bipolar II disorder (BPII), their family and treating clinicians. The steps in the development of the DA are outlined in the following sections.

6.2.1. A systematic approach to DA development and evaluation

To ensure a systematic approach to developing and evaluating the current DA, the DA development team followed the steps outlined in O'Connor and Jacobsen [10]:

1) Assess need

The need for a DA stemmed from the unmet decision-making needs identified in key informant interviews with patients with BPII, and their families who were facing or had faced a decision about treatment as well as treating clinicians (see section 6.1. and Chapters 3, 4, 5). Decisions about medication for prophylaxis (relapse prevention) were regarded as especially important and difficult for all stakeholder groups given the high levels of uncertainty inherent in treatment options, the need to make value trade-offs between treatment benefits and costs, as well as patient variability in preferences for outcomes. Moreover, patients reported a lack of knowledge about/understanding of the full range of medication and psychological treatment options, less-than-preferred involvement in decision-making, and treatment choices that were inconsistent with their preferences [2].

Systematic reviews of the literature further underscored the need for a treatment DA in the BPII setting. The most recent Cochrane review of randomised controlled trials (RCT) of DAs for treatment and screening decisions identified only two DAs for mental health conditions, one for schizophrenia and one for depression [11]. Since this review was published, another two DAs have been developed for depression [12, 13]. Our own systematic review of communication and decision-making about treatment in mental health conditions including bipolar disorder [14] (see Chapter 2), found that minimum shared decision-making requirements were achieved in less than half of immediate and/or complex decisions, according to established criteria [15]. Immediate or complex decisions were defined as having a moderate-to-extensive impact on the patient (e.g., side effects and/or risk), involving some degree of medical uncertainty, and potentially posing a risk to patients. These decisions have attributes (i.e., uncertainty, side-effects) which characterise medication decisions in BPII. Taken together, the need for a treatment DA in BPII is well justified.

2) Assess feasibility

The feasibility of the current DA was determined in a number of ways. Firstly, sufficient evidence was available on the benefits and risks of treatment options to incorporate into the DA (see section 1 above). Secondly, the development team comprised researchers with expertise in DA development and evaluation, as well as practising clinicians with expertise in the treatment and assessment of BPII who were able to provide access to relevant dissemination networks. More broadly, the DA development and evaluation project formed part of established and successful partnerships with the Black Dog Institute (BDI), a tertiary outpatient clinical service, and BeyondBlue, a national mental health awareness agency. Collaboration with recognised leaders in the awareness, assessment and treatment of mood and bipolar-related disorders was thought to enhance the DA's exposure among patients and treating clinicians, thus expediting dissemination of this decision-making resource into broader clinical practice. Thirdly, the development team engaged stakeholders in all aspects of the DA development (qualitative interviews to assess needs, expert working party review, pilot/usability testing) which was key to promoting the DAs relevance, feasibility and usefulness among potential end users [16]. Moreover, the timing of DA delivery, i.e., shortly after patient diagnosis, is consistent with the usual delivery of care, when clinicians commonly introduce treatment options and encourage patients to become more informed about, and consider, their preferences for treatment options. Such timing will allow for the DA (if successful) to be readily integrated into current mental health services in a timely, accessible and acceptable manner.

3) Define the objectives of the DA

The objectives of the DA were designed to address unmet decision-making needs as well as incorporate priorities for decision-support in the BPII treatment setting.

Specific objectives related to *quality in decision-making* regarding treatment for relapse prevention in BPII were to improve patients':

i) Certainty and comfort in decision-making (i.e., reduce decisional conflict);
ii) Knowledge and understanding of available treatment options and their outcomes;

iii) Involvement in decision-making, so that patients experience their preferred level of involvement;

iv) Informed treatment choices, which are consistent with patient preferences and values;

v) Preparedness to make a treatment decision.

Specific objectives related to *quality of decision outcomes* regarding treatment for relapse prevention in BPII were to:

vi) Reduce patient regret about treatment decision;

vii) Increase patient uptake of effective medical and psychological interventions.

4) Identify the framework of decision support

The Ottawa framework of decision support was chosen to guide the DA development [17], as it recognises and addresses several problems that patients, families and clinicians reported during patient decision-making about treatment options for their bipolar disorder (see Chapters 3, 4, and 5) [1-3]. These included inadequate knowledge about treatment options and outcomes, unrealistic expectations of benefits/costs, unclear values regarding treatment, high uncertainty and decisional conflict, and limited perceived support and skills in shared decision-making.

5) Select the methods of decision support to be used in the DA

The DA incorporated a number of methods to support decision-making and address decision-making problems (see section 4) above). To address inadequate knowledge, the DA provided information on BPII illness as well as treatment options and outcomes. To address unrealistic expectations of benefits/costs of treatment options, the DA provided probabilistic information about the likelihood of benefits/costs, using numerical and graphic illustrations (100 person dot diagrams with shading in a row rather than randomly, together with absolute risk information describing respective proportions of people/occurrences in the diagram) [18]. The DA also encouraged more realistic expectations of the benefits/costs by providing balanced 'bona-fide' patient and family quotes to exemplify the key benefits and costs of each treatment option. To promote clarification of values and address decisional conflict, the DA included explicit values clarification ("weight scale") exercises, which asked

patients to consider the personal importance of benefits/costs of each treatment option. These exercises sought to clarify for patients (and their families) treatment values/preferences and integrate these into their treatment choice. To illustrate the values clarification process, patients (and their families) were also provided with three example exercises showing patients who held different values, and thus different preferences for a treatment option. Finally, to address perceptions of limited support and skills in shared decision-making, the DA provided structured guidance in the form of step-by-step decision-making guides and question prompt lists.

6) Select the designs and measures to evaluate the DA

As with development, the evaluation of the DA involved an effective and ongoing stakeholder-engagement approach. Engaging stakeholders during the DA's development and evaluation is key to ensuring the DA's relevance and usefulness among potential ender-users, patients with BPII and their family [16]. With these considerations in mind, *a pilot/usability study* (see Chapter 7) was conducted, which involved potential end users (patients with BPII and their family) who were either: actively considering treatment options (the DA target population); or have already made a BPII treatment decision and are therefore experienced in the decision-making to provide informed feedback.

The measures selected for the pilot study were designed to identify any preliminary trends in the DA's usefulness, and included a combination of validated and purpose-designed questionnaires (see Chapter 7 section 7.3.4. for specific measures). The validated measures have been widely used to assess the effectiveness of DAs in improving decision-making quality (quality of the decision-making process) and decision quality (quality of decision outcomes) [18]. Based on conceptual and empirical grounds, the primary outcome chosen to evaluate the DA's potential usefulness was decisional conflict. Conceptually, lower levels of decisional conflict reflect patients feeling well-informed about the available treatment options and outcomes, clear about their values for treatment, and well-supported to make an effective decision. These attributes align with the overarching goal of DAs – to help patients to make informed, preference-sensitive decisions, especially in situations where there is no clinically superior treatment option and treatment choices may be more influenced by patient preference (see [19]). Indeed, decisional conflict is

arguably more appropriate than treatment-related knowledge as a primary outcome measure. Knowledgeable patients may still lack the support needed to integrate their knowledge of treatment options and outcomes with their values and come to an effective decision [20]. In addition, empirical reasons supported the use of decisional conflict as a primary outcome measure, including: high-quality evidence to support DA-related reductions in decisional conflict [11], and review findings demonstrating that the Decisional Conflict Scale [21] is superior to most other primary outcome measures used in DA trials with respect to its psychometric properties, clinical sensibility, and appropriateness or consistency with IPDAS decision process criteria [5, 22]. Secondary outcomes using validated measures, include: i) congruence between preferred/experienced levels of patient involvement in decision-making (via two administrations of an adapted version of the Control Preferences Scale [23]; ii) preparation for decision-making scale [24]; iii) informed, values-based choice measure [25]; and iv) decisional regret [26]. As with decisional conflict, these secondary outcomes have all been identified as key indicators of DA effectiveness [18].

In addition to the validated measures, a purpose-designed knowledge measure was developed based on: i) current NHMRC guidelines for providing information to patients about medical treatment/intervention(s) [27, 28], ii) relevant IPDAS criteria for information (1, 3, 4, 5, 6) and probabilities (1, 3, 4, 6, 7) [5], iii) knowledge measures used in previous DA development/evaluation studies [29], and iv) theory-informed, competency-based approaches to assessing knowledge [30]. Both gist (conceptual) and verbatim (numerical) knowledge were assessed because they represent two independent systems of processing and recalling information, that is, extracting the core meaning versus precise detail [30]. Secondly, gist and verbatim knowledge appear do differentially impact on decision-making. Specifically, gist knowledge appears to be more enduring and more strongly influences decision-making compared to verbatim knowledge, likely because it is less affected by stress and anxiety which impair comprehension of information [31, 32]. Also included in the pilot/usability study were semi-structured interview questions to elicit acceptability information and supplement the questionnaires with more in-depth qualitative feedback on the DA during the pilot/usability testing. The interview guide

was adapted from previous DA pilot studies [33] and the Ottawa Acceptability measure [34].

7) Plan dissemination

The DA was developed and evaluated in collaboration with the BDI. As a recognised world-leader in this area, the BDI will greatly enhance the DA's dissemination into broader clinical practice. Once evaluated (and if successful), the DA will be disseminated in hard-copy (booklet) form through the BDI clinics and professional development workshops for GPs and allied health professionals. The DA will also be made widely available as a free download in electronic format (PDF) through the BDI's existing webpages for patients/family and clinicians on bipolar disorder treatments. Postcards containing introductory information and web-access details will be disseminated to GP practices Australia-wide, so that treating GPs can make patients with BPII aware of this resource. The DA's combined offline and online delivery will: i) promote its rapid and widespread dissemination, ii) ensure the information remains in step with best available clinical evidence, and iii) promote the DA's ongoing uptake among Australian adults, who are increasingly "Internet-connected" (~ 83% in 2012-2013) [35] and tend to seek their health information online [36].

6.2.2. Qualitative interviews with key stakeholders/informants

In line with a stakeholder-engagement approach to DA development [12, 16], the DA prototype was informed by the unmet decision-making needs reported by patients, their family, and clinicians, with the aim of facilitating more active and informed patient role in their treatment decision-making. Through a series of large, in depth qualitative studies (outlined in Chapters 3, 4 and 5), the DA development group were able to assess and contextualise the nature of these needs, and identify informational and decisional-support priorities among patients with BPII and their family. Qualitative findings relevant to the DA development were tabulated and summarised for patient/family and clinician groups according to three areas: content, formatting/presentation, and delivery (see Table 6.1).

By and large, patient/family and clinician groups identified similar priorities for these areas, however, priorities were also included even if they were only identified by one

stakeholder group. In terms of *content*, patients/family and clinicians all wanted the DA to present a broad range of BPII-specific medication and adjunctive psychological treatment options, with a focus on options for relapse prevention (see Chapters 3 and 4). All stakeholder groups also felt that it was necessary for the DA to acknowledge the preference-sensitivity of treatment choice/s and include values clarification methods for deliberating options. In terms of *formatting*, patients/family and clinicians all prioritised unbiased, evidence-based information using plain language [2, 3]. Although patients/family and clinicians tended to prefer hardcopy information (e.g., booklet, factsheet) clinicians pointed out the DA could also be made available online. In addition, patients/family groups felt that information should be organised into sections for ease of navigation. In terms of delivery, all stakeholder groups stated a preference for delivering the DA shortly after patient diagnosis, as this is when patients are first presented with, and are considering treatment options. This said, the iterative and ongoing nature of decision-making in BPII (see Chapters 3 and 4) would permit the DA to be used by patients who have a longer-standing diagnosis and are re/considering treatment options in response to unpleasant side-effects or treatment which has not been highly effective. Moreover, all stakeholder groups agreed that the DA would be best provided to patients as a supplementary information resource during consultations with their clinician, but that the DA's primary intended use would be prior to or between consultations involving discussion and decision-making about treatment options. Additionally, clinicians stated that the DA could be also used within consultations as a prompt for discussing different aspects of treatment options in a more structured, systematic way [1].

Table 6.1. Summary of BPII treatment DA priorities based on interviews with patients (*n*=28), families (*n*=13) and clinicians (*n*=20)

	Patients/families	Clinicians
Content	- Specific to bipolar II disorder. - Some background information on the illness (symptoms, course, chronic, remitting nature of illness). - Broad range of medication and non-medication-based options (incl. psychological interventions, lifestyle and/or complementary options). - Focus on options for relapse prevention (prophylaxis). - Medication effects and rationale for use. - Expected benefits/efficacy and side-effects (both short and long-term), along with rationale for recommending one type of medication over another. - **List of available additional resources and psychosocial support services.** - Patient/ personal stories/others' lived experience of illness and medication, **acknowledges the individualised nature of BPII illness (as opposed to population-based descriptions).** - Values clarification exercises alongside clinically-based information: - Acknowledgement that treatment choice is sensitive to patient values and life circumstances. - Encourage active reflection on, and understanding of option pros and cons within context of life circumstances and values. - Separate information for family members on (e.g., how to support someone with BPII, illness symptoms and course). - **A question prompt list outlining patient questions for their clinician.**	- Specific to bipolar II disorder. - Some background information on the illness (symptoms, course, chronic, remitting nature of illness). - Broad range of medication and non-medication-based options (incl. psychological interventions, lifestyle and/or complementary options). - Focus on options for relapse prevention (prophylaxis). - Medication effects and rationale for use. - Expected benefits/efficacy and side-effects (both short and long-term), along with rationale for recommending one type of medication over another. - **Safety aspects.** - **Longer-term prognosis (probably course and outcome of illness)** - Patient/ personal stories/others' lived experience of illness and medication, **present treatment goals/decisions for patients to consider for themselves.** - Values clarification exercises alongside clinically-based information: - Acknowledgement that treatment choice is sensitive to patient values and life circumstances. - Encourage active reflection on, and understanding of option pros and cons within context of life circumstances and values. - Separate information for family members on (e.g., how to support someone with BPII, illness symptoms and course).

Formatting/ presentation	- Written information. - Hardcopy information (e.g., a booklet, factsheet or brochure). - Clearly-worded and easy-to-understand - Use of plain language. - Evidence-based, unbiased, reliable - **Produced by a reputable organisation.** - Balanced presentation of benefits and side-effects. - **Easy-to-understand graphics depicting the level of evidence supporting particular treatment options (e.g., "thumbs up" icon).** - **Organised into separate sections starting from more general to more specific information.**	- Written information - Hardcopy, or available online via referred website. - Clearly-worded and easy-to-understand - Use of plain language. - Evidence-based, unbiased, reliable - **Australian focus.** - Balanced presentation of benefits and side-effects. - **Optimistic and hopeful tone.**
Delivery	- Shortly after diagnosis when presented with/considering treatment options. - Used prior to, or between consultations involving treatment discussions. - Clinician provided **and/or made available at the clinic they attended.** - Supplement clinician in-consultation provided information/education. - Given after consultation in which treatment options presented. Read prior to follow-up consultation involving further deliberation and final decision-making.	- Shortly after diagnosis when presented with/considering treatment options. - Used prior to, or between consultations involving treatment discussions. - Clinician provided during consultations. - **Also in-consultation as a prompt for discussing the different aspects of treatment options in a structured way.** - Supplement clinician in-consultation provided information/education. - Given after consultation in which treatment options presented. Read prior to follow-up consultation involving further deliberation and final decision-making.

Note = **bolded items** indicate items identified by that stakeholder group only.

On the basis of these informational and decision-support priorities, the DA development team derived a table of contents for the DA prototype (Table 6.2). The table of contents sought to integrate all of the content areas identified by stakeholder groups as important (see Table 6.1). These included a description of a range of available medical and psychological treatment options together with a rationale for their use, inclusion of text-based and graphical representations of information, separate information section for family members, an in-consultation question prompt

list and values clarification exercises. For completeness, the table of contents was also cross-checked against IPDAS criteria [5].

Table 6.2. DA prototype content list

1.	**Explanation of the booklet's rationale and aim** including: - Focus on treatment options for prophylaxis in patients with recent BPII diagnosis - Acknowledgement of incomplete evidence base, potential for adverse effects, and that treatment choice is sensitive to patient values and life circumstances. - Encourage active reflection on, and understanding of option pros and cons within context of life circumstances and values.
2.	**Background to BPII illness** (symptoms, course, chronic and remitting nature, need for prophylactic treatment approach).
3.	**Description of medication options and rationale for use** (incl. different medication classes mood-stabilisers, antipsychotics, anticonvulsants, adjunctive antidepressants) including potential benefits as well as potential risks/safety aspects and side-effects (short and long term).
4.	**Description of (adjunctive) psychological interventions and rationale for use** (CBT, mindfulness, wellbeing strategies) including potential benefits as well as potential adverse effects/ "costs" (short and long term).
5.	**Description of other (evidence-based) complementary options and rationale for use** including potential benefits as well as potential adverse effects/ "costs" (short and log term).
6.	**100 dot diagrams depicting treatment efficacy outcomes** (mood stability/episode prevention) for options
7.	**100 dot diagrams depicting side-effects** (weight gain, fatigue, "cognitive dulling/fogginess", sexual dysfunction) for options
8.	Tabulated summary of **medication options pros/ cons**
9.	Tabulated summary of **psychological interventions pros/ cons**
10.	**Information for family members** – how to support someone with BPII and decision-making about treatment.
11.	**Step-by-step decision-making guide** for making a decision regarding treatment in BPII
12.	**Question prompt list** – questions to ask clinician and space to write additional comments/notes/questions
13.	**Personalised worksheets** (value clarification exercises) to help patients/family (i) weigh up the 'pros' and 'cons' of treatment options by rating the importance of related concerns and benefits; (ii) indicate their treatment choice.
14.	**List of "further contacts"** detailing reliable websites for additional information (BDI, Beyond Blue, Bipolar carers) and local psychosocial services (BPII wellbeing program, REACH programs, Medicare information for accessing psychologists & psychiatrists)
15.	**Acknowledgments and Reference list** and developer details/ year last updated
16.	**Glossary** of clinical/medical terms

6.2.3. Review of best available clinical evidence

The IPDAS stipulate that DAs present information based on syntheses of scientific evidence that are comprehensive and up-to-date, and subject to critical appraisal [5, 37]. To provide the best available clinical evidence on treatment options and

outcomes for the prevention of relapse in bipolar disorder, the DA development team consulted recent meta-analytic reviews of medical [9] and psychological treatment options [38]. Most of the studies included in these meta-analytic reviews involved mixed-samples of patients with BPI and BPII; there were no published meta-analytic reviews of studies involving samples of patients with BPII only. This said, the DA development team only consulted the meta-analytic data for treatments recommended as first-line/level 1 evidence-supported options for relapse prevention in BPII [6, 7]. These meta-analytic reviews were chosen because they included comprehensive search methods, were specific to relapse prevention in bipolar disorder, reported odd ratios for overall relapse and specific depressive versus hypo/manic relapse, included studies of patients with BPII cited in up-to-date clinical guidelines [6, 7], and included only randomised or quasi-randomised trials with follow-ups of at least 3 months to assist with comparability across medication and psychological treatment options in the DA.

The selection of treatment options to include in the DA was primarily guided by up-to-date clinical guidelines for relapse prevention in bipolar disorder, in consultation with clinician experts. At the time of DA development, the medication treatment options (lithium, lamotrigine, and quetiapine) were all first-line treatments for relapse prevention in bipolar II disorder according to current CANMAT guidelines [6], which are the only clinical guidelines to include a separate section specific to relapse prevention in BPII. Meanwhile, the psychological treatment options (cognitive behavioural therapy and group psycho-education) were the only bipolar disorder-specific psychological interventions to be supported by level 1 evidence according to current guidelines for Australia and New Zealand [7]. Finally, information on the potential side-effects or risks of medication options was mainly sourced from double-blinded randomised placebo-controlled trials (where available). Information relating to long-term adverse effects (i.e., 5-20 years) or very rare risks (e.g., Stevens-Johnson Syndrome) was sourced from large-scale naturalistic (population-based) studies or open-label clinical studies. All information relating to adverse effects was consistent with that presented in current international consensus-based guidelines for the safety monitoring of treatments for bipolar disorders [39].

6.2.4. Iterative working party review

Once an initial DA prototype was drafted by the PhD candidate it was subject to iterative review by an expert advisory panel comprising:

- clinical academics/research psychologists with expertise in DA development and evaluation (*n*=2),
- practising psychiatrists (*n*=2) and clinical psychologists (*n*=2) with expertise in the assessment and treatment of bipolar-related disorders,
- practising primary care physicians (i.e., general practitioners, GPs) with (*n*=1) and without (*n*=1) expertise in mental health,
- patients with BPII (*n*=3), and their families (*n*=2) who had previously made/helped make a decision about treatment for relapse prevention.

In line with IPDAS [5], and in order to minimise potential biases, the content/format review comprised both members of the development team who were involved in producing DA (*n*=4) as well as others (*n*=8) who were not involved in producing the DA. The working party included members with complementary areas of expertise; for example, those with expertise in DA development and evaluation had limited expertise in the assessment and treatment of bipolar-related disorders and vice versa. This "360-degree" approach ensured a comprehensive review of potential problems with the DA (e.g., comprehensibility, safety issues) as well as suggested modifications to the DA.

The DA underwent a total of 14 iterative "cycles". A cycle was defined as one prototype/version of the DA; each new cycle involved showing a previous version to a member of the working party and making at least one change to create a new prototype. Cycles were organised such that members of the development team were collectively consulted at the beginning and end of prototype development. In the interim, clinicians, patients and family were individually consulted; the order in which each member of the working party was approached ensured that the DA was iteratively reviewed by clinicians and patients/family on an alternating basis, rather than consecutively reviewed first by clinicians and then by patients/family, or vice-versa.

To carry out the DA content/format review, a two-step process was used. As a first step, a member of the working party was emailed a PDF copy of the DA and asked to read it through in order to familiarise themselves with content/format. Secondly, the PhD candidate arranged a one-off face-to-face or Skype meeting (as needed) with the working party member to go through the DA together and elicit their thoughts and opinions on content/format. Open-ended questions focused on areas such as: i) comprehensibility and completeness of written information and graphics; ii) acceptability, i.e., anything that clinicians/patients/their family anticipated that would present as problematic or that patients would like/dislike or present; usability; and iii) any suggested improvements or modifications. Working party members were also asked to give their thoughts and opinions on any other areas they felt were relevant and not covered by questions asked.

Major revisions to the DA prototype based on working party feedback included:

Content

- Inclusion of section introducing the different clinicians (psychiatrists, psychologists, primary care physicians/GPs) who may play a role in BPII treatment/management, and the key differences between them.
- Reiterating for patients that the treatment options presented in the DA are not exhaustive and that other medication and psychological treatment options may be recommended based on patient needs (feedback given by: 1 x psychiatrist, 1 x clinical psychologist).
- Inclusion of "real world" probabilities to familiarise patients/family with the likelihood of events occurring (1 x family).
- Retaining only bipolar-specific psychological treatment options supported by Level 1 evidence (i.e., cognitive behavioural therapy and group psychoeducation) (1 x clinical psychologist).
- Inclusion of complementary treatment options (e.g., Omega 3 fish oils) and comment on the current state of evidence in BPII relapse prevention (1 x GP).
- Inclusion of directions for "Involving your clinician" in the values clarification exercises (1 x GP).
- Inclusion of additional advantages and disadvantages for cognitive behavioural therapy (1 x patient, 2 x family), and group psycho-education (1 x patient, 1 x family).

Format

- Presenting 100-person icon arrays for overall relapse prevention (depression, hypo/mania, mixed episode, other) and specific relapse prevention (depression and hypomania) separately (1 x DA expert, 1 x patient).
- Replacing relative estimates of treatment efficacy (based on meta-analytic risk ratios) with absolute estimates pooled across the studies included in meta-analyses (i.e., 50 in 100 people).
- Inclusion of text boxes below 100 person icon arrays to reiterate the main message/s about treatment efficacy for each treatment option (1 x DA expert, 1 x patient).
- Adjusting colours in 100 person icon arrays to enhance contrast (1 x DA expert, 1 x patient, 1 x family).
- Inclusion of separate pros/cons rating scale within values clarification exercises for family to complete (1 x GP, 1 x family).
- Redesigning second values clarification exercise for psychological treatment options (2 x patients).

When deciding whether to make a suggested revision to the DA, the development team leader (the PhD student AF) checked that the suggested revision was consistent with i) IPDAS criteria ([5], see Table 6.3), and ii) the informational and decision-support priorities identified by stakeholders (see Table 6.1). In situations where a decision was not clear, the student consulted with other members of the development team until agreement was reached. Once a final DA draft was approved by members of the working party, the DA content/format was reviewed by a professional copy-editor for low health literacy and designed/formatted by a professional graphic/visual designer. Low health literacy copy-editing is an important yet often overlooked step in the development of SDM interventions [40], and ensured that those patients/family with lower health literacy can understand and effectively use the DA information. This is a necessary consideration as ~60% of Australian adults lack basic health literacy [41]. Changes to the DA based on the healthy literacy review, mostly included: i) simplifying some terminology/vocabulary; ii) simplifying sentence structure/word order; and iii) reordering some subsections within the DA to make more logical flow of information. A subsequent independent assessment of the DA's health literacy levels, using the Patient Education Materials Assessment Tool

(PEMAT; [42]), yielded "understandability" scores of 76%, placing the DA in the "superior" range for easy to understand and use patient education materials [43]. Secondly, professional graphic design/formatting was a necessary development considerations as both visual features (i.e., text appearance, visuals, layout and design) and content features (i.e., message content, text appearance, visuals, layout and design, and language complexity) of written health communication materials may impair or enhance reader comprehension [44].

6.2.5. Evaluation of quality and rigor

To ensure quality and rigor, the DA development was guided by IPDAS [5]. These widely-used and supported consensus-based criteria comprise 47 items to assess the quality of decision-support technologies across nine dimensions (ten dimensions for test/screening decisions), such as: *information* which includes sufficient details about treatment options to make a specific decision; *values* as in describing the positive and negative features of options and outcomes and asking patients to consider the importance of these); and *development* processes which include in/formal needs assessment of potential end users, involvement of potential end users in expert review and pilot/usability testing. These criteria were used to firstly guide DA development, and then assess the DA prototype in order to identify areas of lower quality (e.g., use of jargon-based rather than plain language) and make improvements to subsequent versions. The IPDAS checklist, as applied to the final DA prototype (see Appendix H), appears in Table 6.3.

In addition, an independent, experienced rater, who was external to the DA development team, assessed the quality of the DA content, presentation of information, and development process using the IPDASi v.4 [45]. Based on the rater's assessment, the booklet *qualified* as a DA (met all six qualifying criteria, see Table 6.3). Thus, the booklet clearly described the target health condition (BPII), the index decision to be made (i.e., to decide between first-line medication options and whether or not to have adjunctive psychological treatment to prevent relapse), the available treatment options and their associated positive features, negative features, and potential consequences.

In its final version, the booklet could also be *certified* as a DA because it scored 3 or more on all certifying criteria (Table 6.3). A review on the feasibility and application of these IPDAS criteria to a sample of 30 DAs included in the 2014 Cochrane Review [11] found that only ~10% of the reviewed DAs met all these certifying criteria [46]. On this basis, the current DA is set apart from many other existing DAs, most which would require minor modifications in order to be certified.

In terms of *quality* criteria, the DA booklet met all but two relevant criteria (scored 3 or more, see Table 6.3) and scored 80 out of a possible score of 92. This quality rating suggests that this DA booklet is superior to many other existing DAs (*Med* = 54.79 [46]). This said, the quality of the DA could be further enhanced by: i) conducting field-testing with clinicians/practitioners who counsel patients who face this decision; and ii) reporting on readability levels or justifying why these may not be an appropriate index of patients' comprehension of the content. Moreover, at this stage, some quality criteria relating to the evaluation of the DA were only supported by preliminary evidence (see pilot study, Chapter 7), and would need to be re-applied pending results from the future planned RCT phase.

Table 6.3. Quality assessment of the final DA (see Appendix H) according to IPDAS criteria* [5]

Dimension	Item	Yes/No and explanation
Information *Providing information about options in sufficient detail for making a specific decision*	**1.** The decision support technology describes the health condition or problem (intervention, procedure or investigation) for which the index decision is required.[a]	**Yes, pages 6-7.**
	2. The decision support technology describes the decision that needs to be considered (the index decision).[a]	**Yes, page 6.**
	3. The decision support technology describes the options available for the index decision.[a]	**Yes, pages 16, 43.**
	4. The decision support technology describes the natural course of the health condition or problem, if no action is taken.[c]	**Yes, page 13.**
	5. The decision support technology describes the positive features (benefits or advantages) of each option.[a]	**Yes, pages 23, 30, 37, 50, 57.**
	6. The decision aid describes negative features (harms, side effects or disadvantages) of each option.[a]	**Yes, pages 24-25, 30-32, 51, 58.**
	7. The decision support technology makes it possible to compare the positive and negative features of the available options.[c]	**Yes, pages 40-41, 60-61** (Summary tables).
	8. The decision support technology shows the negative and positive features of options with equal detail (for example using similar fonts, order, and display of statistical information).[b]	**Yes**. Same typeface and size, similar order of information, and combined use of statistical and text-based information.
Probabilities *Presenting outcome probabilities*	**1.** The decision support technology provides information about outcome probabilities associated with the options (i.e. the likely consequences of decisions).[c]	**Yes, pages 20-22, 27-29, 34-36, 47-49, 54-56.**
	2. The decision support technology specifies the defined group (reference class) of patients for which the outcome probabilities apply.[c]	**Yes.** Control/reference group defined as placebo (medication options) or medication plus treatment-as-usual (psychological options).

		Treatment group defined by medication-type (medication options) or medication plus adjunctive psychological treatment-type (psychological options).
	3. The decision support technology specifies the event rates for the outcome probabilities (in natural frequencies).[c]	**Yes, pages 20-22, 27-29, 34-36, 47-49, 54-56.**.
	4. The decision support technology specifies the time period over which the outcome probabilities apply.[c]	**Yes, pages 20-22, 27-29, 34-36, 47-49, 54-56.**
	5. The decision support technology allows the user to compare outcome probabilities across options using the same denominator and time period.[c]	**Yes.** Treatment efficacy data based on meta-analyses of studies all with follow-ups of at least 3 months (up to 3 years).
	6. The decision support technology provides information about the levels of uncertainty around event or outcome probabilities (e.g. by giving a range or by using phrases such as ‘‘our best estimate is…’’)[b]	**Yes.** Graphical and statistical ranges presented for some outcomes (e.g., “20-25 in 100 people”, “10-30 in 100 people”; **pages 24, 42**). Qualitative ranges presented for some outcomes (e.g., “Estimates… vary…”, “It is unclear…”; **pages 14, 30**)
	7. The decision support technology provides more than one way of viewing the probabilities (e.g. words, numbers, and diagrams).[c]	**Yes, pages 20-22, 27-29, 34-36, 47-49, 54-56.** Words, numbers and 100 person diagrams all used for all options.
	8. The decision support technology provides balanced information about event or outcome probabilities to limit framing biases.[b]	**Yes, pages 20-22, 27-29, 34-36, 47-49, 54-56.** Consistent presentation of outcome probabilities across all treatment options.
Values *Clarifying and expressing values*	**1.** The decision support technology describes the features of options to help patients imagine what it is like to experience the physical effects.[a]	**Yes, pages 19, 26, 33.** Inclusion of illustrative patient/family quotes to describe features of each treatment option. (e.g., “*it [quetiapine] made me put on a significant amount of weight...”)*
	2. The decision support technology describes the features of options to help patients imagine what it is like to experience the psychological effects.[a]	**Yes, pages 45, 52.** Inclusion of illustrative patient/family quotes to describe features of each treatment option.

		(e.g., *"CBT is quite useful because it's not just medication, it's changing your way of thinking…")*
	3. The decision support technology describes the features of options to help patients imagine what it is like to experience the social effects.[a]	**Yes, page 19.** Inclusion of illustrative patient/family quotes to describe features of each treatment option. (e.g., ***"****Lithium kind of has bad associations... 'doped up' people in mental wards that sort thing").*
	4. The decision support technology asks patients to think about which positive and negative features of the options matter most to them.[c]	**Yes, pages 77-83.** Via values clarification exercises
Decision guidance *Structured guidance in deliberation and communication*	**1.** The decision support technology provides a step-by-step way to make a decision.[c]	**Yes, page 66.**
	2. The decision support technology includes tools like worksheets or lists of questions to use when discussing options with a practitioner.[c]	**Yes, pages 68-70, 77-83.** Via question prompt list and values clarification exercises
Development *Using a systematic development process*	**1.** The development process included finding out what clients or patients need to prepare them to discuss a specific decision.[c]	**Yes.** In depth qualitative interviews conducted with patients and family. Interview guides based on Ottawa decisional support framework [17].
	2. The development process included finding out what health professionals need to prepare them to discuss a specific decision with patients.[c]	**Yes.** In depth qualitative interviews conducted with psychiatrists, GPs, and clinical psychologists. Interview guides based on Ottawa decisional support framework [17].
	3. The development process included expert review by clients/patients not involved in producing the decision support technology.[c]	**Yes.** Content/format review included 3 patients, 2 family members not involved in producing DA.
	4. The development process included expert review by health professionals not involved in producing the decision aid.[c]	**Yes.**

		Content/format review included 1 psychiatrist, 2 GPs, 1 clinical psychologist not involved in producing DA.
	5. The decision support technology was field tested with patients who were facing the decision.[c]	**Yes.** Phase I pilot/usability testing conducted in patients/family who were currently facing decision (as well as patients/family who had already faced decision).
	6. The decision support technology was field tested with practitioners who counsel patients who face the decision.[c]	**No.** Field testing with health professionals was not deemed necessary as: i) this group was not the intended target group of potential users; ii) DA intended for use in the home or other private setting, primarily before/after clinical encounters.
Evidence *Using a systematic development process*	**1.** The decision support technology (or associated documentation) provides citations to the studies selected.[c]	**Yes, pages 97-99.**
	2. The decision support technology (or associated documentation) describes how research evidence was selected or synthesised.[c]	**Yes, page 96.** Treatment efficacy data based on best available clinical evidence, i.e., meta-analytic reviews of medication and psychological options. Side-effect/risk data based on well-designed placebo-controlled trials and/or large scale naturalistic studies (long-term lithium outcomes).
	3. The decision support technology (or associated documentation) provides a production or publication date.[b]	**Yes, page 94.**
	4. The decision support technology (or associated documentation) provides information about the proposed update policy.[b]	**Yes, page 94.** Next proposed update in 2 years from production date, i.e., January 2019.
	5. The decision support technology (or associated documentation) describes the quality of the research evidence used.[b]	**Yes, pages page 96.**

		Treatment efficacy data based on best available clinical evidence, i.e., meta-analytic reviews of medication and psychological options. Side-effect/risk data based on well-designed placebo-controlled trials and/or large scale naturalistic studies (long-term lithium outcomes).
Disclosure *Disclosure and transparency*	**1.** The decision support technology (or associated technical documentation) provides information about the funding used for development.[b]	**Yes, page 94.**
	2. The decision support technology includes author/developer credentials or qualifications.[c]	**Yes, page 94.**
Plain language	**1.** The decision support technology (or associated documentation) reports readability levels (using one or more available scales).[c]	**No** Noted that the DA was professionally copy-edited for low health literacy levels. A health literacy review using the Patient Education Materials Assessment Tool (PEMAT; Shoemaker [42]) yielded "understandability" scores of 76%, placing the DA in the "superior" range for easy to understand and use patient education materials [43].
DST evaluation	**1.** There is evidence that the decision support technology improves the match between the features that matter most to the informed patient and the option that is chosen.	**Yes, preliminary evidence based on pilot evaluation.** As evidenced by high proportion of patients indicating values-based informed choice (see Chapter 7).
	2. There is evidence that the patient decision support technology helps patients improve their knowledge about options' features.	**Yes, preliminary evidence based on pilot evaluation.** As evidenced by patients' high-levels of subjective/objective knowledge of treatment options and outcomes (see Chapter 7)

Notes.

*Test criteria excluded (pertain to decision support technologies directed at investigations or screening tests).

a = qualifying criteria

b = certifying criteria

c = quality criteria

6.3. Summary

This chapter described the comprehensive development and planned pilot testing of the treatment DA for patients with BPII and their families. A systematic approach to DA development and evaluation was undertaken, which included ongoing engagement of key stakeholders and potential end users. Quality and rigor in the DA development were ascertained via established international criteria, which are currently considered to be "gold standard". This development process ensures that the final DA is a relevant, evidence-based resource for the target population. The use of well-developed outcome measures ensures rigorous evaluation of the DA's potential efficacy at improving decision-making and relevant patient outcomes.

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Chapter 7

Chapter 7: Development and pilot of a decision-aid for patients with bipolar II disorder and their families making decisions about treatment options to prevent relapse.

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This chapter reports on the development and piloting of a decision-aid booklet (DA) for patients diagnosed with bipolar II disorder (BPII) and their families who are deciding on medication and psychological treatment options for relapse prevention. The DA content, format and delivery was informed by the unmet informational and decision-support needs of these patients and their families (Chapter 3, 4) as well as the clinician-perceived strategies for addressing decision-making barriers (Chapter 5, see Chapter 6 for full outline of the development process). Pilot findings revealed that the DA was highly acceptable, feasible, and safe to use amongst this sample of potential end-users, and potentially useful at improving treatment decision-making in this setting. Findings also guided the design of a future planned randomised controlled trial of the DA (Appendix G). Ethics approval letters are provided in Appendices B3 and B4; supplementary materials related to this study are provided in Appendices F1 – F3. A copy of the final DA booklet is provided in Appendix H.

Author contributions
Conception and design: AF, IJ
Participant recruitment: AF
Data collection: AF
Data analysis and interpretation: AF, IJ
Manuscript drafting: AF
Manuscript critical review: All authors
Review of final manuscript: All authors

7.1. Abstract

Introduction. Treatment decisions in bipolar II disorder (BPII) are finely-balanced and sensitive to patient preferences. This pilot study evaluated a decision-aid booklet (DA) for patients with BPII (and their family) to obtain evidence on its acceptability, feasibility, safety, and usefulness in potential end-users.

Methods. The DA booklet was developed according to International Patient Decision-Aid Standards. Thirty-one patients diagnosed with BPII and their families (*n*=11), who were currently making or had previously made treatment decisions, participated. Participants read the DA and completed validated and purpose-designed questionnaires. A follow-up semi-structured telephone interview elicited more in-depth DA feedback (*n*=40).

Results. Patients and family endorsed the DA booklet as: easy-to-use (100% agree), useful in treatment decision-making (100%), presenting balanced (patients = 96.8%, family = 100%), up-to-date (93.5%, 100%) and trustworthy information (93.5%, 100%) that did not provoke anxiety (93.5%, 90.9%). All participants stated that they would recommend the DA to others. Following DA use, all except one participant (97.6%) demonstrated adequate treatment knowledge (>50% score). Patients reported low decisional conflict (*M*=18.90/100) following DA use and felt well-prepared to make treatment decisions (*M*=4.28/5). Most patients (90.3%) indicated uptake of treatments consistent with the best available clinical evidence. Additionally, a large proportion of patients made an informed choice about medication (65.5%) with adjunctive psychological treatment (50.0%), based on adequate knowledge and their treatment values. Interview findings further supported the DA's acceptability among participants.

Discussion. Pilot findings indicate that patients with BPII and their family consider this DA booklet highly acceptable and useful in making evidence-based treatment decisions that align with their treatment preferences.

Keywords: bipolar II disorder; decision aid; treatment; shared decision-making; knowledge; decisional conflict.

7.2. Introduction

A diagnosis of bipolar II disorder (BPII) is commonly accompanied by a need to make complex treatment decisions about mood-stabilising medications and adjunctive psychological therapies, often for lifetime prophylactic use. These decisions are challenging, both from a clinical and a patient perspective. Firstly, there are limited BPII-specific clinical guidelines [1, 2], which reflect limited evidence to support available treatment options in individuals with BPII [3, 4]. Next, there are a number of viable medical and adjunctive psychological treatment options available with varying benefit/cost profiles. Some medication options can have significant potential side-effects, for example, cognitive dulling and weight gain [5, 6], which some patients may perceive as outweighing any immediate therapeutic benefits. Thus, these "preference-sensitive" treatment decisions need to incorporate the best available clinical evidence, clinician judgement, and patient preferences [7].

To date, no known resources have been developed to facilitate more informed and active patient (and family) involvement in BPII treatment decision-making. Patient decision-aids (DAs) are evidence-based interventions for potentially improving shared treatment decision-making (SDM) in BPII. DAs are designed to help patients make specific and deliberative healthcare choices, by weighing up the pros ('benefits') and cons ('costs') of all available options whilst considering their personal values/preferences. Emerging evidence from randomised controlled trials (RCT) supports the effectiveness of six known mental health treatment DAs, for unipolar depression [8-10], post-traumatic stress disorder [11, 12], and schizophrenia [13]. In light of these promising findings, and in the absence of any BPII-specific DAs, this pilot study aimed to:

1) obtain preliminary evidence on the acceptability, safety, feasibility and potential usefulness of a newly-developed DA booklet for patients with BPII and their family making decisions about prophylactic treatment (for relapse prevention); and
2) establish the feasibility, relevance and acceptability of the procedures and measures used, to inform the design of a RCT evaluation of the DA.

7.3. Methods

7.3.1. Participants

Patients: Adults with a clinical diagnosis of bipolar II disorder (BPII) who were currently making or had previously made decisions about their treatment (medical or non-medical) were eligible to participate.

Family members: Adults whose family member had: i) an adult BPII diagnosis (18+ years), and who had ii) attended at least one consultation involving treatment decision-making, and/or had iii) experience helping their family member make treatment decisions outside consultations were also invited to participate. Patient participation was *not* a pre-requisite for family member participation.

Exclusion criteria for both samples were: i) insufficient English proficiency; ii) inability to provide informed consent; ii) (comorbid) substance abuse disorder; iv) other major psychiatry/neurological disorder or cognitive impairment.

Ethics approval was obtained from the University of Sydney (USYD) Human Research Committee and the Black Dog Institute (BDI) Research Advisory Committee; the study was carried out according to the principles outlined in the Declaration of Helsinki [14].

Participants were recruited through the following pathways: A. patient referrals to BDI (with family members identified through patients) an outpatient clinical service specialising in the assessment and treatment of mood disorders; B. patient/family attendees at the BDI's BPII support groups; C. purposively-sampled participants from previous research [15] who had agreed to be contacted regarding future research participation; D. members of Australia-based online community forums/social-media platforms for people affected by mood disorders (patients and family) (*BeyondBlue*, *SANE* and *LIVIN'*).

The use of multiple recruitment pathways ensured a mix of participants who were *actively* considering treatment options - the DA target population (i.e. pathway A); or who had *already* made a BPII treatment decision (i.e. pathways B-D).

For patients recruited through pathways A-C, BPII diagnosis was based on a "consensus diagnostic decision" between at least two assessing psychiatrists with expertise in mood and bipolar disorders [16]. To establish BPII diagnosis, all patients were clinically assessed by an intake psychiatrist who made a lifetime clinical diagnosis of BPII applying clinician-judged criteria. These criteria took into account DSM-5 symptom criteria [17] but did not impose the minimum duration criterion for hypomania (4 days). This criterion is largely arbitrary and not of clinical significance [16, 18]. Approximately a third of these patients were also assessed by a second independent psychiatrist. Prior to clinical assessment, patients also completed the 27-item Mood Swings Questionnaire [19], which has sensitivities and specificities of 70-82% and 78-98% in tertiary patient referral samples [20, 21]. For patients recruited through pathway D, BPII diagnosis was based on self-report. We required, however, that these patients had been diagnosed with BPII by a mental health specialist (i.e., psychiatrist) as opposed to general physician (GP) (i.e., primary care provider).

7.3.2. Procedure

For the patient referral sample (pathway A) a clinic research assistant introduced the study to eligible patients following their clinical assessment, and gave the contact details of interested patients to the study coordinator at USYD (AF). Purposely-sampled participants (pathway C) were contacted directly by AF via their provided contact details to introduce the study and ascertain their interest in participating. All other participants responded to an expression-of-interest flyer, which was disseminated via the support group meetings and online forums (pathways B and D, respectively).

AF telephoned interested participants to explain the nature and purpose of the study and obtain verbal consent to post/email a study pack containing: an information sheet and consent form, a copy of the DA booklet and a study questionnaire. Upon receiving the completed questionnaires and written consent form, a one-off telephone interview was arranged.

7.3.3. Materials

The BPII decision-aid (DA)

The BPII DA booklet was informed by the International Patient Decision-Aid Standards (IPDAS) [22] and the Ottawa decisional support framework [23]. Content, formatting and design were based on: a systematic review [24], the best available evidence (e.g., clinical guidelines [1, 2, 25], meta-analyses [26, 27] and well-designed, placebo-controlled RCTs [28-34]); in-depth qualitative interviews with patients (*n*=28), family (*n*=13), and clinicians (*n*=20) [15, 35, 36]; and iterative review by an expert working party. The BPII DA was a 100 page A5 booklet, with information divided into three main sections (via dividing tabs): Medication Options, Psychological Options, and Making Decisions. Throughout, the DA provides evidence-based, lay information using text and graphics on the known efficacy and benefits/costs of the current first-line medications (e.g., lithium, lamotrigine, quetiapine) [1, 2] and Level-1 evidence-supported psychological treatments (e.g., individual cognitive behavioural therapy [CBT], group psycho-education) [25] for relapse prevention in BPII specifically. Values clarification exercises (VCE's) help patients/family consider their preferences and deliberate on the benefits/costs of the different treatment options. Other (i.e., second-line and/or adjunctive) medications and psychological treatment options were excluded due to limited data supporting their efficacy specifically for patients with BPII. Including these other options was deemed superfluous to the main purpose of a DA, which is to support patients facing 'preference-sensitive' decisions. That is, deciding between treatment options that are supported by *similar* evidence, and thus clinical uncertainty remains with regards to which option is superior (i.e., equipoise) [37].

The DA's readability levels were not assessed, as readability may not be an appropriate index of comprehensibility when patient information materials contain multisyllabic medical terminology [38]. This terminology was necessary to include and were defined in simple, descriptive terms in the DA's glossary. As a more appropriate alternative to assessing readability levels, the DA was professionally copy-edited for low health literacy levels. In addition, health literacy review using the Patient Education Materials Assessment Tool (PEMAT; Shoemaker [39]) yielded

"understandability" scores of 76%, placing the DA in the "superior" range for easy to understand and use patient education materials [40].

The DA is designed for patients/family to use before and/or after clinical consultations in which treatment options for relapse prevention/maintaining mood stability are discussed. Thus, the DA is *not* intended to replace treatment discussions with their managing clinician, but rather support and prepare patients to have these discussions. See Appendix F1 for a full summary of the DA booklet content.

Interview guide

The purpose-designed, semi-structured interview guide (see Appendix F2) was informed by the Ottawa Acceptability measure [41]. Open-ended questions elicited feedback on the DA's acceptability and suggested improvements.

7.3.4. Measures

Purpose-designed and validated measures evaluated the DA's acceptability and potential usefulness in terms of key decision quality constructs [42]. Asterixed measures (*) were completed by patients only.

Participant DA feedback was assessed using an adapted measure from previous acceptability studies of mental health decision-support [43]. Participants indicated their agreement on the DA's *perceived ease of use* (8 items), *perceived usefulness* (9 items), *attitudes towards using* (3 items), and *perceived trustworthiness/bias* (4 items). Four agreement categories were collapsed into agree (agree/somewhat agree) and disagree (disagree/somewhat disagree).

Measures of decision-making quality

*Perceived difficulties with decision-making** were assessed using the 16-item validated Decisional Conflict Scale (DCS; α's=0.78-0.92) [44]. Five subscales measured patients' feelings of being: i) uncertain about the treatment options, ii) uninformed, iii) unsupported, iv) unclear about values in decision-making, and v) unable to make an effective decision (scores 0-100). A total score (0-100) indicated overall decision-making difficulties. Lower scores denoted less decision-making difficulty.

Objective knowledge of treatment options and outcomes employed a competency-based approach [45], whereby 14 forced-choice items assessed conceptual/gist (9 items yielding possible total scores 0-18; "*true*", "*false*", "*don't know*") and numerical/verbatim (5 items yielding possible total scores 0-20; A-E responses) knowledge of information contained in the DA. Assessed domains were based on current NHMRC guidelines for medical practitioners on giving information to patients for informed consent purposes [46]. Based on Smith et al. [45], responses were scored according to an *a priori* marking scheme, with the threshold for adequate knowledge for informed choice (*yes/no*) set at > 50% of total possible score (i.e., score of 20 or more out of 38) (Appendix F3).

Subjective/perceived knowledge of treatment options and outcomes was assessed via a 15-item purpose-designed measure, whereby participants indicated how well they had understood (1=*didn't understand at all* to 5=*understood very well*) information contained in the DA. Again assessed knowledge domains were based on current NHMRC guidelines [46].

*Informed, values-based choice** was determined via a composite measure of objective knowledge (see above), attitudes, and treatment choice. Attitudes towards medication and psychological options were assessed using two Likert-type scales, which each contained four items. Each item was anchored by opposing positive/negative adjectives (e.g., 1=*Beneficial*, 7=*Harmful*) [47]. Patients also indicated their (hypothetical) treatment choice after reading the DA (e.g., medication/s with/out adjunctive psychological treatment versus no medication/treatment). Patients were defined as making an informed choice if they had adequate objective knowledge (i.e., > 50%) [45] and made a treatment choice that was consistent with their values (e.g., *positive* attitudes towards medication/s *plus* indicating intentions to take up medication/s) [47]. A median split categorised patients with positive attitudes (≥median) or negative attitudes (<median) [47].

Preparation for decision-making scale* assessed via 10 items patient perceptions of the DA's usefulness in preparing them to make treatment decisions (α's=0.92-0.96)

[48]. Each item was rated from *not at all=1* to *a great deal=5* yielding a mean possible score of 1-5.

Measures of sample characteristics

Anxiety levels were assessed using the 6-item short form of the State Trait Anxiety Inventory (STAI-Y-SF) [49].

*Symptom severity/mood state** within the past 24 hours was self-reported using the 17-item Internal States Scale (ISS) [50]. Each item was rated from 0 (*rarely*/*not at all*) to 100 (*very much so*/*most of the time*). The combination of total scores on the Activation (<155 or ≥155) and Wellbeing (<125 or ≥125) subscales indicated the patient's current mood state.

Stage of decision-making scale categorised patient's (lack of) readiness to engage in decision-making, from not thinking about treatment choices (item 1) to actively deliberating on options (item 3) to having already made a treatment decision (item 5) [51].

Preferred and experienced levels of patient involvement in decision-making were assessed via two administrations of the single-item adapted Control Preferences Scale (CPS) [52, 53]. Concordance/discordance was indexed via (dis)agreement between the two ratings [54, 55].

Information preferences were assessed using an adapted version of the Cassileth Information Styles questionnaire [56]. Items elicited preferences regarding the amount (1-5) and type (*enough to care for self*; *only good*; *all information, good and bad*) of medical information.

Health literacy was measured via the Single Item Literacy Screener (SILS) [57]: "*How often do you need to have someone help you read instructions, pamphlets, or other written material from your doctor or pharmacy?*". (*never*=1 to *always*=5). Scores of >2 reflect some difficulties understanding written health materials. To

control for mood symptoms as a potential confound, the item was reworded for patients to include: *"When not experiencing symptoms of depression or hypomania…"*

Demographic, clinical and family involvement information was obtained via a purpose-designed self-report questionnaire.

7.3.5. Data analyses

Descriptive and frequency analysis of the quantitative questionnaire data used IBM SPSS version 23. Qualitative analyses of participants' interview responses used a thematic approach [58] to inform the relevant quantitative findings.

7.4. Results

7.4.1. Sample demographics

Of the 49 patients and 20 family members who agreed to participate, 30 patients and 10 family members completed both the questionnaire and follow-up interview lasting approximately 30 minutes on average (response rates: 61.2% and 50%, respectively). An additional one patient and one family member completed the questionnaire only. Due to the way in which participants were approached for this study (e.g., patient referrals from a private clinic), limited information is available for those patients and family who agreed to participate but did not go on to complete study procedures. Of those participants who were able to be contacted, reasons for non-participation included: lack of interest and time/other competing commitments (n=2), significant change in personal circumstances (moving overseas, undergoing divorce, n=2), not receiving the study package in the post (n=2), and hospitalisation for mood symptoms (n=1).

Sample demographics are summarised in Table 7.1. Patients were aged on average 36.67 years, (SD=12.63), and family on average 46.64 years (SD=15.87). Both samples comprised mostly women (77.4% patients, 81.8% family), the majority were Australian-born (80.6%, 72.7%) with university level education (58.1%, 63.7%) and engaged in part-time/full-time work (70.9%, 72.8%).

Table 7.1. Demographic characteristics of patient (*n*=31) and family (*n*=11) samples

	Patients	**Family**
	***M* (*SD*)**	***M* (*SD*)**
Age	36.87 (12.63)	46.64 (15.87)
	n (%)	**n (%)**
Gender		
Female	24 (77.4)	9 (81.8)
Relationship to patient		
Parent	--	5 (45.5)
Spouse/partner	--	3 (27.3)
Sibling	--	2 (18.2)
Child	--	1 (9.1)
Highest qualification		
Year 12/ HSC or below	7 (22.6)	2 (18.2)
TAFE certificate/diploma	6 (19.4)	2 (18.2)
University degree	14 (45.2)	4 (36.4)
Postgraduate degree	4 (12.9)	3 (27.3)
Current employment		
Working full-time	13 (41.9)	4 (36.4)
Working part-time	9 (29.0)	4 (36.4)
Studying	3 (9.7)	--
Not employed/retired/home-duties	5 (16.1)	3 (27.3)
Other (e.g., part-time work & study)	2 (6.5)	--
Country of birth		
Australia	25 (80.6)	8 (72.7)
Other (e.g., UK, Japan)	6 (19.4)	3 (27.3)
Language spoken at home		
English	30 (96.8)	11 (100)
Other (Turkish)	1 (3.2)	--
Current relationship status		
Married/living with partner	17 (54.8)	10 (90.9)
Single/dating	10 (32.3)	--
Separated or divorced	4 (12.9)	1 (9.1)
Current living arrangement		
With partner (with/out children)	16 (51.6)	9 (81.8)
By yourself/independently	5 (16.1)	2 (18.2)
With other family members	5 (16.1)	--
With non-family members	5 (16.1)	1 (9.1)
Patient/family participant pairs	--	3 (27.3)

7.4.2. Clinical and family involvement characteristics

As seen in Table 7.2, an equal number of patients reported having a recent (<12 months, 41.9%) or longer-standing BPII diagnosis (1-5 years ago, 41.9%). Meanwhile, over half of family participants had a family member with a longer-standing BPII diagnosis (54.5%). Both patients and family participants indicated slightly elevated anxiety at the time of the study (~one *SD* above age-matched community norms, *M*=46.56, 44.55, respectively).

Patients and family reported that they/their family member experienced mainly depressive or equal depressive/hypomanic episodes (83.9, 81.8%, respectively). Almost half of patients (45.2%) and two-thirds of family participants (63.9%) reported that they/their family member was currently taking a mood-stabiliser medication. Around two-thirds of patients (61.3%) and a third of family (36.4%) reported that they/their family member was undertaking psychological treatment. Most patients and family nominated relapse prevention as their/their family member's current treatment goal (77.4%, 81.8%, respectively).

Most patients and family participants indicated that family had attended at least one consultation regarding BPII treatment (71%, 81.8%, respectively), however, patients usually attended consultations alone/unaccompanied (77.4%, 81.8%).

Table 7.2. Clinical characteristics of patient (*n*=31) and family (*n*=11) samples

	Patients	**Family**
	***M* (*SD*)**	***M* (*SD*)**
Age diagnosed with BPII	34.16 (11.96)	32.64 (12.96)
State anxiety (20 - 80)	46.56 (13.23)	44.55 (15.72)
	***n* (%)**	***n* (%)**
Time since BPII diagnosis		
<1 month	5 (16.1)	--
1 – 12 months	8 (25.8)	4 (36.4)
1-5 years	13 (41.9)	6 (54.5)
5 + years	5 (16.1)	1 (9.1)
BPII episodes – (perceived) frequency		
More than once per month	10 (32.3)	2 (18.2)
4 or more times per year	11 (35.5)	3 (27.3)
2-3 times per year	5 (16.1)	5 (45.5)
About once per year	4 (12.9)	--
Less than once per year	1 (3.2)	1 (9.1)
BPII episodes – (perceived) type		
Mainly depressive episodes	15 (48.4)	3 (27.3)
Equal depression/hypomania	11 (35.5)	6 (54.5)
Mainly hypomanic episodes	4 (12.9)	1 (9.1)
Mainly euthymic/subsyndromal	1 (3.2)	1 (9.1)
Current mood state (ISS)		
Hypomania	13 (41.9)	--
Euthymia	7 (22.6)	--
Depression	6 (19.4)	--
Mixed state	5 (16.1)	--
Current medication/s		
Mood stabiliser only (incl. anticonvulsants)	14 (45.2)	7 (63.6)
Atypical antipsychotic	--	1 (9.1)
Antidepressant	2 (6.5)	--
Mood stabiliser plus atypical antipsychotic	2 (6.5)	--
Mood stabiliser plus antidepressant	4 (12.9)	--
All three types	4 (12.9)	1 (9.1)
No medication	5 (16.1)	2 (18.2)
Current psychological treatment		
Yes (e.g., CBT, counselling)	19 (61.3)	4 (36.4)
Current goal of BPII treatment		
Prevent recurrence/relapse	24 (77.4)	9 (81.8)

Treat current depression	3 (9.7)	--
Treat current hypomania	--	1 (9.1)
Other (e.g., combination of above)	4 (12.9)	--
Don't know	--	1 (9.1)
Family attended consultation/s		
Yes	22 (71)	9 (81.8)
Usual attendance in consultation/s		
Usually patient alone	24 (77.4)	9 (81.8)
Attends accompanied	3 (9.7)	1 (9.1)
Sometimes alone or accompanied	4 (12.9)	1 (9.1)

7.4.3. Pre-existing decision-making characteristics

Information preferences and decision-making stage

Both patients and family preferred to receive a large amount of information (*M*=4.82, 4.91/5, respectively) and most wanted "as much information as possible, good or bad" (87.1, 90.9%, respectively) (Table 7.3). In terms of decision-making stage, 77.4% of patients and 63.6% of family indicated that they/their family member were either currently considering treatment options, or had already made a treatment decision but were willing to reconsider these options. No participants indicated health literacy-related difficulties (scores < 2).

Table 7.3. Pre-existing decision-making characteristics of patient (*n*=31) and family (*n*=11) samples

	Patients		**Family**	
	***M* (*SD*)**		***M* (*SD*)**	
Information preferences - *amount* (/5)	4.82 (0.42)		4.91 (0.30)	
	***n* (%)**		***n* (%)**	
Information preferences – *type*				
As much information as possible, good or bad	27 (87.1)		10 (90.9)	
Only information to take care of myself/my family	4 (12.9)		1 (9.1)	
Involvement in decision-making (dyadic)	***Pref***	***Exp***	***Pref***	***Exp***
Patient-led with/out clinician[b]	12 (38.7)	14 (45.2)	8 (72.7)	9 (81.8)
Shared/collaborative	12 (38.7)	9 (29.0)	3 (27.3)	1 (9.1)
Clinician-led with/out patient[c]	7 (22.6)	8 (25.9)	--	1 (9.1)
Involvement in decision-making (triadic)	***Pref***	***Exp***	***Pref***	***Exp***
Patient-led with/out clinician/family[b]	22 (71)	22 (71)	11 (100)	10 (90.9)
Shared/collaborative	2 (6.5)	2 (6.5)	--	--
Clinician-led with/out patient/family[c]	7 (22.6)	6 (19.4)	--	--
No family involvement	--	1 (3.2)	--	--
Experienced preferred level of patient involvement (dyadic)				
Yes	19 (61.3)		4 (36.4)	
Experienced preferred level of patient involvement (triadic)				
Yes	17 (54.8)		8 (72.7)	
Patient decision-making stage				
Not begun to think about choices but interested	1 (3.2)		--	
Considering options now	9 (29.0)		--	
Already made a decision, willing to reconsider	15 (48.4)		7 (63.6)	
Already made a decision, unlikely to change mind	6 (19.4)		4 (36.4)	
Read the DA				
Just briefly	1 (3.2)		1 (9.1)	
Just parts relevant to me	3 (9.1)		2 (18.2)	
Quite thoroughly	8 (25.8)		4 (36.4)	
From cover to cover	19 (61.3)		4 (36.4)	

Notes:

[a] Participants indicated perceived/experienced levels of clinician-patient(-family) involvement in the most recent consultation involving BPII treatment decision/s. This consultation may have occurred prior to/after exposure to the DA.

[b] Combines "fully patient-led decision-making" and "patient-led decision-making with clinician (and family) input"
[c] Combines "fully clinician-led decision-making" and "clinician-led decision-making with patient (and family) input"

Preferred and experienced involvement in decision-making

As with information, patients and family also indicated strong preferences for patient involvement (Table 7.3). Overall, patients and family mostly preferred and experienced either patient-led or shared decision-making in consultations involving BPII treatment decision/s. A smaller proportion of patients compared to family preferred and experienced patient-led decision-making. Further, patients more often than family preferred and experienced shared or clinician-led decision-making in consultations (Table 7.3).

Regarding concordance, 61.3% of patients (*n*=19) and 36.4% of family (*n*=4) experienced their preferred level of patient involvement in the most recent *dyadic (clinician-patient)* consultation involving BPII treatment decision/s (Table 7.3). By contrast, 54.8% of patients (*n*=17) and 72.7% of family (*n*=8) experienced their preferred patient level of involvement in the most recent *triadic* (*clinician-patient-family*) consultation involving BPII treatment decision/s (Table 7.3).

Read the DA

All participants reported reading the DA and most also indicated good engagement; 87.1% of patients and 72.8% of family participants read the DA "quite thoroughly" or "cover to cover" (Table 7.3). Participants were not asked how long it took them to read through the DA, however, participants were expected (and encouraged) to review the DA over a number of sittings (as opposed to a single sitting). This said, participants who volunteered this information during interviews noted that reading through the DA took approximately 40 – 45 minutes.

7.4.4. Decision-making quality characteristics

Uptake of effective treatment option

After reading the DA, almost all patients (90.3%) indicated that they would take up an effective treatment option: mostly a medication option (48%) or combination of medication/s plus an adjunctive psychological treatment (41.9%, Table 7.4). Remaining patients (*n*=3, 9.7%) indicated that they were unsure or chose to delay treatment uptake.

Decision-making difficulties and preparation

With regards to their hypothetical treatment choice, patients indicated low levels of decisional conflict on their total score (*M*=18.90/100) and on each of the subscales (*M*=8.87–30.11/100) (Table 7.4), on average. Only the uncertainty subscale had average scores over 25 (30.11/100), indicating that some patients felt unsure/unclear about which option was best for them. On average, patients also indicated that the DA prepared them well to make treatment decisions (*M*=4.28/5).

Knowledge and understanding of treatment options

Patients and family reported good subjective understanding of the DA treatment options and outcomes (*M*=4.45, 4.36/5, respectively, Table 7.4). Objective knowledge was similarly high; patients and family were highly knowledgeable in terms of average total (*M*=32.04, 34.41/38, respectively), conceptual and numerical knowledge (Table 7.4). Accordingly, all but one patient demonstrated adequate knowledge (i.e., >50% of possible total score, Appendix F3). Additional post-hoc analyses were conducted on adequate knowledge about treatment options and outcomes. Using a cut-off score of >75% instead of >50%, these analyses revealed that, even with the more stringent cut-off score, the large majority of both patient (*n*=24, 77.4%) and family (*n*=9, 81.8%) participants still demonstrated adequate knowledge of treatment options and outcomes.

Table 7.4. Decision-making quality characteristics of patient (*n*=31) and family (*n*=11) samples

	Patient	**Family**
	***n* (%)**	***n* (%)**
Uptake of effective treatment options (as per DA)[a]		
Medication/s only	15 (48.4)	--
- Lithium	1 (3.2)	--
- Lamotrigine	8 (25.8)	--
- Quetiapine	1 (3.2)	--
- Combination of above medications	2 (6.5)	--
Medication/s plus adjunctive psychological treatment	13 (41.9)	--
No treatment uptake/ unsure	3 (9.7)	--
	***M* (*SD*)**	***M* (*SD*)**
Decisional conflict (/100)[a]		
Total	18.90 (13.90)	--
Uncertainty	30.11 (24.97)	--
Informed	13.98 (14.65)	--
Values	8.87 (12.16)	--
Support	15.32 (14.45)	--
Effective decision	24.40 (19.25)	--
Preparation for decision-making (/5)	4.28 (0.61)	--
Subjective understanding of treatment options (/5)	4.45 (0.57)	4.36 (0.50)
Objective knowledge of treatment options		
Total score (/38)	32.04 (4.43)	34.41 (3.81)
Conceptual/gist knowledge (/18)	15.16 (2.72)	16.73 (1.85)
Numerical/verbatim knowledge (/20)	16.87 (2.88)	16.32 (5.18)
	***n* (%)**	***n* (%)**
Adequate level knowledge of treatment options (Total score > 50%, see Appendix F3 for scoring)*	30 (96.8)	11 (100)
Attitudes medication options (as per DA)*		
Positive (at or above median)	20 (64.5)	8 (72.7)
Negative (below median)	9 (29)	3 (27.3)
Attitudes adjunctive psychological options (as per DA)*		
Positive (at or above median)	21 (67.7)	7 (63.6)
Negative (below median)	9 (29)	4 (36.4)
Informed treatment choice (yes)[a]		
Medication/s uptake	19 (65.5)	--
Medication/s plus adjunctive psychological treatment uptake	15 (50.0)	--

[a] = based on hypothetical choice/uptake after reading the DA

* Note remaining percentage = missing data

Attitudes towards treatment options and informed treatment choice

The majority of patients and family expressed positive attitudes towards the presented medications (64.5%, 72.7%, respectively) and adjunctive psychological treatments (67.7%, 63.6%, respectively) for BPII relapse prevention (Table 7.4).

Based on congruence between patient's knowledge and treatment attitudes, 65.5% made an informed choice about medication uptake and 50.0% made an informed choice about taking-up adjunctive psychological treatment. All remaining patients made a treatment choice that was based on adequate knowledge (except *n*=1) but was incongruent with their treatment attitudes (e.g., negative attitudes towards medication, yet decided to take-up medication).

7.4.5. Participant feedback on the DA

Quantitative participant feedback on the booklet was highly positive across all acceptability domains (Table 7.5). The qualitative interview data reflected these mostly positive attitudes. Differences between patients and family or those participants with a recent (<12 months) versus longer-standing (1 year +) diagnosis are noted below. These differences were minimal overall, however. For illustrative participant quotes, see Table 7.6.

Table 7.5. Quantitative participant feedback on the decision-aid (DA) in the patient (*n*=31) and family (*n*=11) samples

	Patients		Family	
	Agree/ Somewhat Agree	**Disagree/ Somewhat Disagree**	**Agree/ Somewhat Agree**	**Disagree/ Somewhat Disagree**
	***n* (%)**	***n* (%)**	***n* (%)**	***n* (%)**
Perceived ease of use of DA				
Font easy-to-read	31 (100)	--	11 (100)	--
Easy-to-use	31 (100)	--	11 (100)	--
Clearly organised information	30 (96.8)	1 (3.2)	11 (100)	--
Design appealing	31 (100)	--	11 (100)	--
Easy-to-understand information	31 (100)	--	11 (100)	--
Colours pleasant	31 (100)	--	11 (100)	--
Pictures relevant	31 (100)	--	11 (100)	--
Important information easy-to-find	31 (100)	--	11 (100)	--
Perceived usefulness of DA				
Content interesting	31 (100)	--	11 (100)	--
Useful in making a treatment decision	31 (100)	--	11 (100)	--
Right amount of information included	31 (100)	--	10 (90.9)	1 (9.1)
Information I needed included	31 (100)	--	10 (90.9)	1 (9.1)
Helped with my concerns	30 (96.8)	1 (3.2)	10 (90.9)	1 (9.1)
Found links to information and other resources	28 (90.3)	3 (9.7)	11 (100)	--
Learnt something new	29 (93.5)	2 (6.5)	11 (100)	--

Made it easier to discuss treatment options with family	26 (83.9)	4 (12.8)	10 (90.9)	1 (9.1)
Made it easier to discuss treatment options with (my) clinician*	28 (90.3)	3 (9.7)	10 (90.9)	--
Attitudes towards using DA				
Would recommend to others in my situation	31 (100)	--	11 (100)	--
Would go back and re-read sections	30 (96.8)	1 (3.2)	11 (100)	--
Information did *not* make me anxious (safety check)	29 (93.5)	2 (6.5)	10 (90.9)	1 (9.1)
Perceived trustworthiness and balance of information in DA				
Information trustworthy*	29 (93.5)	1 (3.2)	11 (100)	--
Information up-to-date*	29 (93.5)	1 (3.2)	11 (100)	--
Equal emphasis placed on each of the medication options	30 (96.8)	1 (3.2)	11 (100)	--
Equal emphasis placed on each of the adjunctive psychological options	31 (100)	--	11 (100)	--

*Remaining percentage = missing data

Perceived ease of use

All participants except one patient agreed that the DA was easy-to-use, and contained information that was easy-to-understand and clearly-organised (Table 7.5). Qualitative feedback echoed this, with most participants commenting that the DA was well-laid out and provided *"plain" "straightforward"* information, with balanced use of text and graphics (Table 7.6, IDs 143, 107). About half of participants (*n*=17), in particular patients (*n*=16), felt that it would be helpful to have a clinician go through the DA to introduce medications and highlight the different DA sections.

Perceived utility

All patients and all except one family member agreed that overall, the DA was useful for making a treatment decision-making (Table 7.5). Despite this, several participants, especially those with a longer-standing diagnosis, indicated that the information in the DA did not specifically: help them with their concerns, provide them other resources, teach them something new, and/or make it easier to discuss treatment options. Participants commented that the DA was a *"good starting point*" and especially useful for those with a recent BPII diagnosis because it clearly summarised the main available options in terms of their pros (e.g., efficacy) and cons (e.g., side-effects). Participants reported that the visual aids (e.g., colour-coded summary tables, 100-person dot diagrams) enhanced the DA's usefulness, because they permitted cross-comparisons between the different treatment options in a structured and guided way. Several participants commented that access to comprehensive and specific benefit/risk information helped them to feel more informed, in control, and "*active consumers"* (Table 7.6, IDs 210, 123).

The usefulness of DA section on family member involvement in treatment decision-making revealed somewhat mixed views. Some patients and family - who had a recent diagnosis or were yet to involve family/be involved - found this section increased their awareness of the practical ways of involving family and/or served as an impetus to involve family. Ten patients and two family participants explained that this section had limited relevance to them as family were not involved, or they had already involved family.

Attitudes towards using the DA

All participants agreed that they would recommend the DA to others in their situation (Table 7.5). Two patients and one family member indicated that reading the DA made them feel anxious. During interviews, these participants attributed their anxiety to reading about the more "serious" side-effects and incomplete efficacy of medications at preventing relapse, yet they endorsed this information as necessary and important (Table 7.6, IDs 120, 219). Contrastingly, a few participants noted that reading the DA reduced their anxiety because the information provided them with reassurance and a sense of "control".

Perceived trustworthiness and balance

Participants agreed that the DA provided a trustworthy, unbiased presentation of the treatment options (Table 7.5). This positive feedback was reiterated in interviews (Table 7.6, IDs 115, 118, 120).

Nine participants, mainly those with a longer-standing diagnosis, suggested that the DA includes a clearer rationale for selecting lithium, lamotrigine and quetiapine as provided medication options, and emphasise that other options are available; and explain that patients may need to supplement these medications or try other medications.

Of note, most patients (*n*=24) and family (*n*=7) felt that the inclusion of patient/family quotes was helpful in giving positive but realistic expectations of treatment outcomes. The quotes were endorsed as a valuable *"person-based"* supplement to the *"clinical"* and *"statistical"* type information presented.

Other qualitative findings – suggested changes and additions

Half of patients (*n*=15) and most family members (*n* = 6) did not suggest including any additional DA content. Suggested additions included: more information on the evidence base relating to complementary therapies (e.g., exercise, mindfulness); clarification on other commonly-prescribed medications for bipolar (e.g., sodium valproate); and the fact that finding the 'right' medication offering the most therapeutic benefit and fewest side-effects takes time.

Table 7.6. Illustrative participant quotes on DA acceptability feedback

Acceptability domain	Illustrative participant quotes
Perceived ease of use	*"…I liked the tabs, {made the DA…] easy to navigate… [I] liked how it [the DA] is set out, very user friendly, clear and well explained and easy to read…"* (Patient ID143, female 24 yrs, dx < 1 month) *"…[I liked the use of…] calming and neutral colours. Subsections useful in helping to locate info. Design is good and the text was broken up into small sections; this made a good balance between the text and the images, diagrams…"* (Patient ID107, male 28 yrs, dx > 5 yrs)
Perceived usefulness	*"…[The DA is…] the most solid thing I've got in terms of knowing the options and not just relying on the psychiatrist and the psychologist and their recommendations. You can tailor the options to you and you can decide the side effects that are worth while and give more control."* (Family ID210, wife of 40 yrs male patient dx 2 yrs). *"…[The DA was…] really helpful. The information was in-depth and gave you a good clear understanding of the options. [It's a..] useful tool… when you're first diagnosed you don't know where to start and are reliant on medical professionals."* (Patient ID123, female 50 yrs, dx 4 yrs)
Attitudes towards using	*"… Seeing some of the negative, side effects can be daunting but I'm someone who likes to know everything…"* (Patient ID120, female 32 yrs, dx < 1 month)

	"... Probably the fact that it [the DA] talks about family involvement and helping with the decision-making […made me anxious]. We've not really been involved. [But]... after reading that I went to see my son's psychiatrist to see how I can help him manage better." (Family ID219, mother of 28 yrs, male patient dx 3 yrs)
Perceived trustworthiness and balance	*"...the information [in the DA was] straight-up, not biased at all"* (Patient ID115, female 23 yrs, dx 2 yrs) *"...[the DA] just gave the evidence as it is…"* (Patient ID118, male 46 yrs, dx > 5 yrs) *"...[the DA's balanced view] helped with making one's own informed decision…"* (Patient ID120, female 32 yrs, dx < 1 month)

7.5. Discussion

This paper reports on the development and pilot of the first BPII-specific decision-aid (DA) to assist patients and their families to make decisions about treatment options to prevent relapse. Quantitative and qualitative feedback provided evidence of the DA's acceptability in terms of its perceived ease of use, usefulness, trustworthiness and balance, and attitudes towards using the booklet. Evidence of safety using the DA was derived from participant ratings of whether the DA information provoked anxiety/stress, along with state anxiety levels. Feasibility evidence was derived from the pilot process itself, and identifying any recruitment or procedure-related challenges. Evidence of the DA's potential usefulness in improving BPII treatment decision-making was assessed via numerous measures of decision-making quality, such as: decisional conflict, knowledge of treatment options and outcomes, perceived involvement in decision-making, and (hypothetical) uptake of evidence-based treatments which are congruent with patient preferences/values (i.e., informed choice). Importantly, the DA appears to be an appropriate resource for its target population, given that there were few differences between patients with a recent diagnosis (i.e., the target DA population) and those with a longer-standing diagnosis. Taken together, these findings are informative for the design of a future planned RCT to determine the DA's potential efficacy at improving BPII treatment decision-making compared to usual care.

7.5.1. Acceptability

Both quantitative and qualitative feedback confirmed that the DA had high acceptability amongst this sample of potential end-users. High acceptability is not surprising given that the DA's content and format adhered to expert consensus-based international criteria (i.e., IPDAS) [22], were informed by the unmet informational and decision-support needs of potential end users [15], and were subject to rigorous iterative review by key stakeholder groups [59]. Moreover, strong endorsement of the DA among potential end-users is likely to support its successful future uptake and implementation in clinical settings, which is a challenge many decision-support interventions encounter [60].

Although participants uniformly endorsed the DA's usefulness in treatment decision-making in general, some patients and family members indicated that the DA did not

provide them with any new information nor facilitate treatment discussions with their family and/or treating clinician. A possible explanation of these findings is that the current high information-seeking, health literate sample had actively sought out and/or been provided with most of the DA-based information in the earlier stages of diagnosis, when this information is also most relevant. Further, this DA, like others [37], was designed to target a *specific* treatment decision at a *specific* point in the BPII trajectory. It was therefore beyond the DA's scope to address other potential relation-based factors acting as supports or barriers to treatment decision-making, such as pre-existing family tensions and the strength of the therapeutic relationship [15, 35, 36], which are posited as especially important for shared decision-making (SDM) in mental health [61]. Although DAs are tools designed to facilitate SDM, they should not be considered synonymous with, nor sufficient for SDM [62]. Thus, embedding this DA in the broader care context may enhance its usefulness in supporting treatment discussions with clinicians. Indeed, about half of patients and family expressed a preference to use the DA in conjunction with their treating clinician. Clinicians are also likely to support using the DA in consultations, given that it incorporates a number of clinician-endorsed decision-support strategies [35], and its development involved substantial input from expert clinicians.

7.5.2. Safety and feasibility

Participant feedback and self-report suggested that the DA content is not anxiety provoking and is therefore safe to use in this setting. State anxiety levels, although slightly elevated compared to non-clinical samples, were consistent with clinical norms for psychiatric samples [63], and were thus considered not specific to using the DA. Reinforcing this, the vast majority of patients and family indicated that reading the DA did *not* make them stressed or anxious. Those who did report experiencing some anxiety mostly attributed this to reading about adverse side-effects from medication. However, these participants, like other mental health patients [64], valued knowing this side-effect information and acknowledged that it was necessary for fully informed decision-making [46]. These findings align with those from a recently published Cochrane review of DA effectiveness, which indicate that exposure to a DA does not result in increased anxiety levels [37].

This pilot also demonstrated that the DA's provision to these patients (and their families) is feasible. Firstly, the chosen recruitment strategies resulted in a large proportion of patients with a recent BPII diagnosis who were currently considering or open to reconsidering their treatment options. These patients are at the decision-making stage whereby DAs are most useful [51] and thus form the DA's target population. Secondly, response rates for both the patient (61.2%) and family (50%) samples were above the weighted average for similar research in counseling and clinical psychology, 49.6% [65]. Thirdly, both participant groups also indicated good engagement with the DA, with all indicating that they read the DA, with most reading it thoroughly. These encouraging response rates and high engagement with the DA suggest that the pilot procedure did not present any major barriers to patient/family participation, and provide preliminary support for the DA's delivery within a community-based clinical setting.

7.5.3. Potential usefulness

In addition to participant feedback, the DA's potential usefulness was also supported by well-established measures of DA effectiveness [42]. After reading the DA, both patient and family were highly knowledgeable about treatment options and outcomes, based on current national guidelines on informed patient consent to medical interventions [46]. Namely, increased knowledge is one of the primary outcomes for assessing DA effectiveness [37], and has consistently been identified as enabling patient participation in decision-making and treatment uptake [66]. A majority of patients (65.5%) also made a decision that was congruent with their informed treatment values for medication, and half of patients (50%) for adjunctive psychological treatments, respectively). This said, the remaining patients made a treatment choice that was *not* consistent with their treatment attitudes. This finding was mainly attributable to patients being knowledgeable about treatment options, and choosing to take up medication with/out adjunctive psychological treatment despite their negative attitudes towards treatment. DAs are designed to target patient knowledge not attitudes. Therefore, this finding does not negate the value of this DA; i.e., helping patients to make informed, evidence-based choices. Indeed, greater knowledge of treatment side-effects and more realistic expectations of treatment benefits may indirectly impact on treatment attitudes. Furthermore, these informed choice rates compare favorably to RCT findings showing higher rates of informed

choice amongst patients exposed to a DA for mammography (24%), [67], and bowel cancer screening (34%) [68], compared to usual care. Informed choice also represents an important DA outcome in the context of these 'preference-sensitive' decisions [37, 42].

In addition to making an informed choice, over 90% of patients made a treatment decision that was concordant with the best-available evidence (as per the DA). These high uptake rates closely align with those from a pre-/post- evaluation of an online DA for depression in young adults (93%) [69]. Of note too, similar proportion of patients chose to take up medication with/without adjunctive psychological treatment, which is encouraging as it provides support for the unbiased, non-directional nature of DAs [70], and patients' awareness of choice [71]. These findings also challenge possible mental health clinician reluctance to engage patients in SDM, which stems from the concern that patients who receive balanced information on the adverse side-effects, and uncertain efficacy of available treatment options, would be less likely to accept evidence-based treatments [60, 72].

Paralleling these positive decision-making *outcomes*, the quality of the decision-making *process* was also high. After reading the DA, patients indicated feeling well-prepared to make treatment decisions and reported low levels of decisional conflict. This indicates that patients felt confident, well-informed and well-supported in decision-making, clear about their treatment values, and able to make an effective decision. Indeed, low decisional conflict has garnered amongst the most attention and support in the empirical literature on DA effectiveness [37], and is regarded as a hallmark attribute of decision-making quality [42]. Notably, the obtained decision conflict total and subscale means (<25) are associated with patients more successfully following through with their treatment decision [44], which also aligns with one of the primary rationales for SDM, that SDM improves adherence to treatment [73]. These means also compare to those reported in RCTs where outpatients receiving a DA reported significantly lower decisional conflict for depression (M=20.3) [9], (M=23.85) [10] or PTSD treatments (M=32.5), [12], compared to usual care. By contrast, the uncertainty subscale mean (>25) indicated that some patients were feeling uncertain about their treatment decision after reading the DA. Other RCTs of mental health DAs report higher means or larger ranges on the uncertainty subscale

relative to the other decisional conflict subscales [9, 10]. However, elevated levels of uncertainty are not necessarily unexpected or undesirable in this context, as they may reflect that the DA increased patient's knowledge and thus afforded them better understanding of inherent uncertainty in the treatment options, and greater awareness of choice between numerous available options.

Another key outcome of DA effectiveness in decision-making is increased patient perceptions of involvement [37]. Consistent with this, only a small proportion of participants reported experiencing clinician-led decision-making in both dyadic and triadic consultations. However, it was not possible to determine whether patient and family reports of experienced involvement referred to consultations they attended before or after using the DA. That said, almost half of patients and two thirds of family member reported *not* experiencing their preferred level of patient involvement. This lack of concordance, either due to experiencing a more active or passive decision-making role than desired, may be especially pronounced in patients with bipolar disorder [24] who desire higher levels of involvement compared to other psychiatric patients but demonstrate fewer "active" behaviours (e.g., question-asking) in consultations [74]. Determining the DA's effectiveness at improving the concordance between patients' preferred and experienced involvement remains an important avenue for future intervention research. Indeed, concordance is associated with lower patient unmet needs, which in turn influence outcomes relevant to treatment adherence [54] such as the therapeutic relationship and quality-of-life [75].

Of note, pilot findings suggest the selected validated and purpose-designed measures were appropriate. Participants did not appear to encounter problems self-administering these measures (e.g., few missing data), and observed means/standard deviations aligned with similar DA RCTs [9, 10]. Other DA evaluation measures, such as satisfaction with decision and decisional regret [37], may serve as important additions to a future RCT to assess the DA's longer-term impact on patient outcomes.

Finally, to evaluate the DA's use in a future RCT using a larger, more representative patient sample, it is necessary to consider appropriate design changes to accommodate individuals who are more symptomatically-impaired, less health literate, and/or have fewer resources than the current pilot sample. Based on the PEMAT assessment [39],

recommended changes to further strengthen the DA's usability and understandability for individuals with low health literacy levels, (i.e., items scoring 0 or "disagree") include: removing information or content that distracts from the DA's purpose; using more common everyday language (e.g., replacing the following; pg. 18: "circumstances" with "life situation"; pg. 25 "minimise" with "reduce as much as possible"); and ensuring that all visual aids have clear titles and/or captions (e.g., adding titles and captions to all graphs and diagrams). For lower functioning individuals, the DA has the potential to be used during discussions with their clinicians and their families. Indeed, some patients and family (*n*=16 and 1, respectively) indicated a preference for in-consultation use in the current pilot study.

7.5.4. Limitations

Some limitations include the 'opt-in' recruitment methods, with the potential for self-selection bias. Secondly, the current findings may not generalise to patients and family with lower education, symptom-related functioning and/or health literacy levels. Nor may findings fully capture the preferences and decision-making characteristics of patients who are *actively* considering their treatment options, given that the majority of patients had already made a treatment decision by the time they reviewed the DA. Of note though, there were no apparent differences between participants who were symptomatic and those who were euthymic, nor between participants who were currently considering their treatment options and those who had made a treatment decision in the past. This lack of differences may be due to the fact that patients experiencing acute mood symptoms were excluded from the research, and that this self-selecting sample was likely more interested in/engaged with the treatment decision-making process regardless of whether or not they had already made a treatment decision. This said, as a pilot study, the small sample size (30 patients, 10 family members) precluded any formal statistical analyses of between-group differences.

Further, the current pilot design was not able to determine whether using the DA led to improvements on patient/family outcomes (e.g., high knowledge, low decisional conflict) because outcomes were assessed only at post-DA use and it did not include a control group. A future RCT phase will clarify any DA-specific improvements.

7.5.5. Conclusion

This innovative DA addresses numerous unmet decisional-support needs identified by patients with BPII and their family [15], and adds to the relative paucity of evidence-based interventions for promoting SDM in mental health [76, 77]. Supporting the pilot aims, the DA was highly acceptable among potential end-users, and was feasible and safe to deliver to newly-diagnosed patients who are considering their treatment options to prevent relapse. Assessed factors related to both quality of the decision-making *process* (e.g., decisional conflict) and *outcomes* (e.g., knowledge and values-concordant choice) confirmed the DA's potential usefulness for supporting informed treatment choices in the BPII setting.

7.6. References for Chapter 7

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Chapter 8

Chapter 8: Final discussion and conclusion

8.1. Overview of thesis

This thesis comprised a comprehensive, multi-phase program of research, which culminated in the development and evaluation of a decision-aid booklet (DA) to assist patients with bipolar II disorder (BPII) and their families to make informed decisions about treatment options for relapse prevention. This PhD research program took a step-wise approach, with each phase informing the aims and scope of the subsequent phases. Further, the program involved a range of research methodologies, namely: a systematic review of the empirical literature (Chapter 2), qualitative interviews with key stakeholders (Chapters 3, 4, 5, 7), consultation and iterative review by an expert working party (Chapter 6), and self-report validated and purpose-designed questionnaires (Chapters 3, 4, 5, 7).

The systematic review (Chapter 2) provided an introductory overview of the current empirical literature in terms of triadic (patient-family-clinician) decision-making about treatment in the mental health setting, with a focus on patients with bipolar disorder (I and II) disorder. In light of a paucity of empirical studies specific to patients with bipolar disorder (Chapter 2), we needed to conduct an in-depth qualitative investigation of the treatment decision-making process, to elucidate the perceived barriers and facilitators to effective treatment decisions (Chapters 3, 4, 5). These qualitative studies explored multiple stakeholder perspectives, which had been lacking in the previous literature (Chapter 1), and which offered more in-depth "360-degree" insights into the views and experiences of *all* core members of the decision-making triad (i.e. patients with BPII, their family and expert medical and non-medical treating clinicians).

Findings from the qualitative research phase both complemented and built on the systematic review findings in the following ways: firstly, qualitative findings confirmed some of the results from the systematic review (e.g., that patients with BPII desire greater information and involvement, which is sensitive to their current mood symptoms). Further, the systematic review led to a number of preliminary clinical recommendations, several of which aligned with the clinician-endorsed strategies in the subsequent qualitative studies (e.g., importance of a collaborative therapeutic

relationship, and need to facilitate family involvement as desired by patients). However, in contrast to the systematic review, the qualitative studies more clearly delineated and provided novel insights into the decision–making process specific to the BPII population and setting (e.g., family perspectives of their own involvement the decision-making process, and patient preferences for decision-support resources).

Of note, the need for a patient DA in BPII stemmed from the informational and decision-support needs identified during the qualitative research phase (Chapters 3, 4, 5). The objectives, content, format, and delivery of the final DA were further refined and contextualised via a systematic development process guided by consensus-based international standards for DAs [1, 2], literature recommendations, and iterative review by an expert working party of key stakeholders/informants (Chapter 6). Finally, the pilot study (Chapter 7) evaluated the DA's acceptability, safety and potential effectiveness at improving the quality of the decision-making process and outcomes (e.g., being well-informed, well-supported, clear about available options and making choices that reflect personal values/preferences). Not only are these quality measures well-established in the DA literature, they also align with the goals that BPII patients, their families, and expert clinicians prioritise when making treatment decisions (Chapters 3, 4, 5). Thus, the final evidence-based DA represents a strongly endorsed, specific and targeted resource addressing the unmet informational and decision-support needs of patients with BPII.

8.2. Summary of principal significant findings

8.2.1. The broader context of shared-decision-making (SDM)

This program of research provided timely, novel insights into the process of treatment decision-making within a mental health population that had previously received little empirical attention. The systematic review (Chapter 2) provided an "expanded" view of shared decision-making (SDM) in bipolar disorder (I and II), which went beyond the three discrete steps of decision-making in Charles et al.'s model [3-5] to include decision antecedents (*patient characteristics* and *patient preferences*), decision process (*quality of patient-clinician interactions*), and decision outcomes (*influence of SDM/ patient-centred approach on patient outcomes*). The qualitative studies (Chapters 3, 4, 5) further demonstrated the importance of the broader context on SDM

in the BPII setting. Here, background patient factors (e.g., current symptoms, illness chronicity, experience with medications) appeared to "set the scene" for patient attitudes and response to treatment, as well as their interactions with clinicians during treatment decision-making. These clinician-patient-family interactions then had a substantial impact on treatment outcomes. For example, patients who were recently diagnosed with BPII were more likely to experience less decision-making involvement than they preferred, and be prescribed medications that did not align with their treatment values/preferences, which then adversely impacted on their adherence to treatment. These findings exemplified how patient experience and perspectives influence the decision-making process and outcomes, and thus should guide the informational and decision-support priorities in this setting.

8.2.2. Link between decision-making process and outcomes

The systematic review and qualitative studies yielded themes linking the decision-making *process* to decision *outcomes*. These themes included: *"quality of clinician-patient interactions"* and *"influence of SDM/patient-centred approach on patient outcomes"* (see Themes 3 and 4 of systematic review, Chapter 2); *"nature and flow of decision-making"* (see Theme 3 of patient/family interviews, Chapter 3) and *"decision-making in consultations"* (see Theme 4 of clinician interviews, Chapter 4). Across all phases of the research, process and outcomes emerged as distinct yet interrelated aspects of decision-making in the BPII setting. This is consistent with how DA effectiveness has been conceptualised and measured in the literature [6, 7], and highlights how a decision-support intervention may mediate improvements in both process and outcomes. Specifically, across the systematic review and qualitative findings (Chapters 2-5), decision outcomes were improved when the decision-making process integrated patient preferences for involvement and treatment choices (i.e., was patient-centred) and involved a strong, positive, and collaborative therapeutic relationship. Improved decision outcomes were operationalised as: higher patient satisfaction with the treatment decision and better uptake and implementation of chosen treatments.

These findings suggest that enhancing the decision-making process – via the provision of targeted and specific decision-support tools – is a pre-cursor to improving decision-making outcomes. This suggestion was supported by the DA pilot

(Chapter 7), where positive findings on process-related measures (e.g., low decisional conflict, high preparation for decision-making) were accompanied by positive findings on outcome-related measures (e.g., high proportion of patients choosing treatments consistent with clinical guidelines, and making informed choices based on their treatment values). It was also important to target decision support to the decision-making process given that patients (and family) reported valuing the "process of involvement" (being informed about, and deliberating on available treatment options) (Chapters 2, 3), which often contrasted with clinician-reported behaviour (Chapter 4). In other words, clinicians tended to focus more on the decision outcome than process, placing greater emphasis on patients making the final decision (i.e., "actual decisional responsibility", see Chapter 4) [8].

8.2.3. Need for values clarification regarding treatment options

With the aim of enhancing the decision-making process, qualitative findings also signalled the need for a decision-support tool to include values clarification methods or exercises (VCEs). These are exercises designed to guide patients through a deliberative process of weighing up the positive ('pros') and negative ('cons') features of each treatment option against their preferences, values and life circumstances. Patients, family and clinicians all spoke about the "preference-sensitive" nature of BPII treatment decisions; they recognised the uncertainty inherent in the available treatment options and felt that final treatment choices should be guided by patient values for treatment (Chapters 3, 4, 5). Interviews with patients and their families (Chapter 3) further clarified that patients differ in how much value they ascribed to the benefits (e.g., treatment efficacy) versus the costs (e.g., side-effects) of available treatment options. This "values trade-off" in turn determined patient preferences for, and willingness to start/adhere to treatment options. Similarly, clinicians held differing opinions with regards to the importance patients placed on the benefits relative to the costs of treatment options (Chapter 4). Thus, VCEs were deemed necessary, both as a method for: i) patients to consider their treatment values in a structured and deliberate way; and ii) making explicit and transparent the discussion of treatment values between patients, their families, and treating clinicians. Of note, VCEs form a core component of DAs [9-11], and distinguish DAs from standard patient psycho-education materials [1, 2], as well as simpler SDM interventions to increase patient involvement in treatment discussions (e.g., question

prompt lists [12]; Option Grids [13], AskShareKnow questions [14]). The need to include VCEs therefore strengthened the rationale for a DA specifically, in favour of other interventions to encourage SDM.

8.2.4. Incorporating clinician strategies into decision support

The final DA incorporates a number of the preliminary clinician-endorsed strategies to address challenges in BPII treatment decision-making (Chapter 5). Firstly, the DA is timed to be delivered to patients during/after a consultation where treatment options are introduced, and before consultation/s where treatment options are decided on. This timing is therefore in keeping with the clinician-recommended approach of *"Structuring consultations – Making time"* and allowing deliberation of options outside consultations (see clinician strategies Table 5.4, Chapter 5). This approach of "splitting" the decision-making stages across initial and follow-up consultations, reportedly encourages patients to: i) more carefully deliberate on treatment options, ii) have the opportunity to involve family members/significant others in treatment discussions, and iii) make more efficient use of short consultation times by arriving better informed and prepared to make treatment decisions that are less affected by current mood symptoms (Chapter 5). Supporting this, pilot findings (Chapter 7) revealed that after using this DA, patients were highly knowledgeable about the available treatment options and felt well-prepared to make treatment decisions.

In addition, the final DA has scope to facilitate other key clinician-endorsed strategies (Chapter 5). For example in the pilot study, the DA's content and format were highly acceptable amongst patients and their families, which lends support to *"meeting patient information needs and preferences"* (see Table 5.4, Chapter 5). Next, the DA appears to support *"patient-centredness and involvement"* (see Table 5.4, Chapter 5), through its inclusion of VCEs to assist patients to incorporate their treatment values into treatment decision-making. This is evidenced by the fact that a large proportion of pilot study patients reported experiencing patient-led/shared decision-making (SDM), and made informed, values-based treatment choices (Chapter 7). Moreover, the DA represents a practical resource for *"encouraging and facilitating family involvement"* (see Table 5.4, Chapter 5) by including a separate section that outlines for patients (and their families) the roles (and benefits) that family members can assume during the treatment decision-making process in/out of consultations. Finally,

pilot findings suggested that patients' families engaged well with the information in the DA, and were highly knowledgeable about treatment options and outcomes after reviewing the DA (Chapter 7), which addresses two patient-/family-reported barriers to family involvement in BPII treatment decision-making (i.e., family's lack of engagement with, and understanding of treatment information, see Chapter 3).

However, some clinician-endorsed strategies were beyond the scope of the current DA. These include strategies relating to the therapeutic relationship, inter-professionalism, and continuity-of-care (see Table 5.4, Chapter 7). By not incorporating these strategies, some patient-related, clinician-related and system-based challenges to treatment decision-making remain. For example, the DA cannot address existing shortcomings in the patient's therapeutic relationship with their clinician (e.g., lack of mutual trust, clinician's authoritative behaviour), nor their clinician's lack of specialised knowledge/expertise in BPII treatment. The DA may, however, standardise the decision-making process, and thus help to mitigate the effects of a poor therapeutic relationship (Chapters 2, 3, 4, 5) and/or limited clinician speciality (Chapters 4, 5) on the decision-making process and outcomes. Irrespective of the therapeutic relationship or clinician speciality, the DA informs patients about the available treatment options, and assists them to deliberate on their values towards options in a way that is non-directional, evidence-based and promotes patient autonomy. In addition, DA provision may "indirectly" address other prevailing system-based challenges, such as short consultation times [15, 16], by making patients more informed about, and better prepared to discuss their treatment options at follow-up consultations.

8.3. Implications and future directions

This program of research, which explored the BPII treatment decision-making process and produced a DA to address unmet informational and decision-support needs, has several implications for future research and clinical practice.

8.3.1. Implementing the DA in clinical practice

In developing the current BPII DA, this thesis included a comprehensive development and evaluation process (see Chapters 6, 7). It was, however, beyond the scope of the current thesis to include a DA implementation phase. Indeed, the implementation of

DAs in clinical practice is a relatively neglected area of research and warrants increased empirical attention. Despite a substantial body of research supporting the efficacy of DAs [17], it is acknowledged that the use of DAs in clinical practice is variable, and typically low [18]. Sub-optimal DA use may reflect the paucity of formal implementation studies of DAs. In addition, most reviews have focused on identifying the general barriers and facilitators to SDM, and offer few practical strategies to overcoming implementation challenges [16, 18, 19]. This research gap may be especially pertinent to the mental health setting, where there may be additional cultural and attitude-based challenges (e.g., patient self-stigma, clinician judgments about patient competence) to the routine use of DAs in clinical practice, and implementing SDM more broadly [19]. Although practical implementation strategies are lacking, the literature offers some directions for future DA research. Namely, future DA efficacy studies need to expand their current focus on assessing the short-term cognitive and affective impact on patients (i.e., decisional conflict and knowledge), to include other factors that impact on long-term and sustainable clinical practice change, such as cost-effectiveness and efficiency [20].

Nonetheless, the current DA development process included methods aimed at optimising the DA's future implementation in clinical practice. These included: i) systematically investigating clinician, patient, and family views and experiences of decision-making, along with associated challenges, and enablers for change; ii) assessing the unmet informational and decision-support needs and preferences of potential end-users (Chapters, 3, 4, 5), and using these to guide the DA content, format/design, and delivery mode/timing (Chapter 6); iii) integrating the DA into the clinician's usual delivery of care and staging of decision-making, i.e., provide the DA at a time when clinicians usually provide patients/their families with information resources to consider treatment options (Chapter 5); iv) ongoing stakeholder engagement during the DA review process to ensure their agreement with the DA content/format (Chapter 6); and v) assessing the acceptability and feasibility of the DA within a sample of potential end-users (Chapter 7). In hindsight, several of these methods were consistent with the PARiHS framework (Promoting Action on Research Implementation in Health Services) [21, 22], which posits that three elements, *evidence*, *context*, and *facilitation*, guide the successful implementation of research into evidence-based practice. With regards to optimising the *evidence*, key

decisions in the DA development process were based on *evidence* that combined multiple sources of knowledge and information, namely: research evidence, clinical experience, and patient experience. With regards to optimising the *context*, the timing and mode of DA delivery were sensitive to the culture of clinical practice, including its prevailing values, practices, and available resources. Also relevant to optimising the *context*, the DA was evaluated using multiple methods and sources of information, such as subjective and objective measures of decision quality, and semi-structured interviews about patient-family experiences of using the DA to make decisions. According to the PARiHS framework, these data on evidence and context can then be used to determine the most appropriate *facilitation* method, in order to enable the DA's implementation into practice [23].

Rates of patient participation in the pilot study (Chapter 7) may also guide the DA's future implementation into practice. Thirty patients participated in the DA pilot study, which corresponds to 35.7% of the 84 patients diagnosed with BPII at the BDI during the same eight-month recruitment period (February – October 2017; personal communication M. Hoeschen 16/02/2018). This participation rate is similar to (37%) [24] or markedly higher than (~10%) [25] in other studies of DA use within community-based primary care settings, where use has been either elective (opt-in) and/or without any financial incentive. This participation rate suggests modest 'Reach' within the eligible patient population (i.e., individuals affected by BPII), as per the RE-AIM framework [26]. Although comparable to rates reported elsewhere in the literature, this rate provides impetus for investigating potential barriers to DA uptake. Admittedly, the pilot study did not include a clinician sample, however, the DA content was reviewed by experienced treating clinicians (Chapter 6), and incorporated several clinician-endorsed strategies for addressing challenges to treatment decision-making (see section 8.2 and Chapter 5). Thus, it is likely that clinicians working in the BPII setting would find the DA acceptable, which is a major barrier to implementing DAs [18]. A future pilot study is needed to confirm the DA's acceptability and feasibility amongst clinicians, and to investigate the potential barriers and/or facilitators to the DA's use in routine clinical practice.

8.3.2. Clinician-targeted interventions to support SDM

In its current form, the DA facilitates a self-directed or 'guidance'-based approach to treatment decision-making of patients with BPII and their families [27]. Thus, future research could supplement current DA provision with concurrent training and resources for clinicians who treat patients with BPII. A 2014 Cochrane Systematic Review found that interventions were most effective at promoting SDM (e.g., observed and patient-perceived involvement in decision-making), when they targeted both patients and clinicians rather than one group or the other [28]. In this context, clinician-targeted interventions might include training seminars to educate clinicians about the DA, its purpose and potential usefulness, and to increase clinician's self-efficacy with using the DA in their clinical practice.

In addition, the current DA content could be adapted to create supplementary "in-consultation" resources for clinicians. One simple adaptation would be to print out key pages of the DA (e.g., the treatment option summary tables) and use these during the consultations when discussing the pros and cons of the treatment options. Indeed, the *"ShareD-BD"* RCT protocol [29] – published since the DA pilot study (Chapter 7) – describes a SDM intervention for bipolar disorder (types I and II), which comprises an in-consultation DA, standardised decision-making process using SDM components, and clinician training. This "multi-component" approach to SDM interventions is in keeping with the aforementioned recommendations, and may enhance SDM uptake and related outcomes in bipolar disorder. This intervention may, however, may overlook the specific decision-making needs and preferences of patients with BPII (versus BPI), whose treatment decisions are supported by relatively limited evidence and may be more finely-balanced in terms of treatment benefits and costs [30]. Another potential resource is an Option Grid, which help clinicians – especially less experienced clinicians – to standardise their information provision and encourage patients to visualise (and compare) the available treatment options [13]. One recently published example is an Option Grid for deciding on anti-psychotic medications [31]. In user-testing, patients with long-term psychosis perceived the Option Grid as potentially useful and feasible in routine psychiatric care, and especially valued its use within consultations [31]. As a standalone (rather than supplementary) intervention, however, an Option Grid may not meet the high information needs of patients with BPII, and fact that key decision-making stages

occur outside/between consultations for these patients (e.g., deliberation with their families, see Chapter 3).

Greater targeting of clinicians also aligns with patient/family preferences; about half of the pilot participants reported wanting the clinician's assistance with using the DA (Chapter 7). Future research is needed to confirm whether combining the current patient DA with clinician-targeted interventions increases its efficacy and uptake in clinical practice [28]. To this end, the PhD student (AF) has already been in discussions with the Black Dog Institute (BDI), where most of the participating patients were recruited. The BDI's education program coordinators have expressed interest in presenting the DA at their clinician education workshops, and in producing a manual/resources for general practitioners (GPs). This said, a more systematic research program into the acceptability and potential uptake of such training / interventions by clinicians is needed.

8.3.3. Future iterations of the DA

Other potential avenues for research include the development and evaluation of other DA iterations for BPII. Future DA iterations include a DA for difficult to engage, at-risk populations (e.g., young adults and their families) and/or an online adaptation/website. A recently published systematic review of SDM interventions in patients with mood disorders highlights that such iterations are needed [32]. This review identified 10 interventions for specific MDD populations with potentially higher unmet needs (e.g., adolescents and the elderly), but none for bipolar disorder [32]. Indeed, the unmet informational and decision-support needs reported by patients with BPII and their families may be more prominent among young adults, who are more likely to be newly-diagnosed, and prefer more active decision-making involvement than they currently experience in clinical practice (Chapter 3). An online DA offers several benefits that distinguish it from the current booklet version. These benefits may also be especially pertinent to young adults. For example, an online DA would: i) promote the DA's rapid and widespread dissemination at a national and international level; ii) reach patients who reside in remote and rural areas and do not have ready access to specialised mental health clinics (like the BDI); iii) ensure the information remains in step with the best available clinical evidence, and iv) promote the DA's uptake among young adults, who are among the most "Internet-connected"

Australians (~ 98%) [33] and tend to seek their health information online [34]. Additionally, findings from a recent uncontrolled trial showed that, after using an online DA, young adults with unipolar depression felt involved in their treatment decision-making, and made evidence-based treatment decisions they were satisfied with [35]. These findings provide preliminary empirical support for the potential usefulness of an online DA for young adults with BPII. For more detail on this planned future research see Appendix G, which includes a protocol paper describing a parallel Phase II randomised control trial (RCT) to evaluate a novel decision-aid website (DA) to support young adults with BPII (under review). The DA pilot study provided directions for the RCT (Chapter 7), such as assessing decision outcomes at follow-up to determine the longer-term effects on receiving the DA, and whether any short-term positive effects are maintained over time. Although not undertaken as part of the PhD candidature, this research phase was informed by, and builds on the program of research undertaken by the PhD student.

8.4. Limitations of the current research

Whilst the current research program posits many strengths (see following section 8.4), there are a number of limitations that warrant attention. Firstly, the empirical components of this research program (Chapters 3-5, 7) employed "opt-in" recruitment strategies for patients with BPII, their families, and clinicians. Both the qualitative studies and the pilot study used a multifaceted recruitment approach and purposive sampling in order to increase heterogeneity within the samples and ensure a representative range of views and experiences. However, the possibility of self-selection bias remains, such that the recruited participants may be more interested in the treatment decision-making process and more likely to hold positive views towards decision-support provisions. In light of this, it is not known whether the current findings are generalisable to others in the BPII population; a larger scale RCT will help to confirm this (see Appendix G).

Secondly, the large majority of patients and clinicians were recruited through the BDI, a tertiary outpatient clinical service that specialises in the assessment and treatment of mood and bipolar-related disorders. Thus, the clinician-patient(-family) interactions that most patients and clinicians described may not be typical in the

community, but relate to a highly specialised treatment setting. To address this issue and capture a greater cross-section of experiences, studies recruited patients with recent and with longer-standing BPII diagnoses (Chapters 3, 7), and clinicians with varying levels of professional experience and specialisation (Chapters 4, 5). Moreover, all participants were encouraged to reflect on their experiences of treatment decision-making across a range of clinical settings (e.g., community mental health services, primary care settings) and health providers/patients.

In addition to the specialised clinical setting in which most participants were recruited, it is important to also consider patient characteristics. In both the qualitative and pilot studies (Chapters 3, 7), the vast majority of patients and family members were native English speakers and of Western cultural backgrounds (92.9 – 96.8%). By contrast, 2016 Census results reveal that over 28% of Australian residents were born overseas, with the largest growth coming from neighbouring Asian countries [36]. Thus, culturally and linguistically diverse (CALD) individuals were underrepresented in this research. This limitation is common in the SDM research, yet there is a pressing need to adapt SDM interventions (such as DAs) to patients from CALD backgrounds [37]. This is because these patients may have lower self-efficacy with regards to communication with clinicians, be more likely to defer decision-making to the clinician, and have different preferences for family involvement in decision-making compared to patients of Western cultural backgrounds [38, 39].

Due to the small number of GPs (n=4) and psychiatrists (n=6) recruited in the clinician qualitative studies (Chapter 4, 5), it was not possible to compare these two clinician groups since within-group theoretical saturation was not reached [40] (see also Chapters 4, 5). Qualitatively comparing these two groups may have provided interesting novel insights into the BPII treatment decision-making process, especially given that some qualitative differences were noted between these medically-trained clinicians and clinical psychologists. A more in-depth comparison of the decision-making attitudes and practices of GPs and psychiatrists could also inform recommendations for increasing inter-professionalism in this setting. Indeed, many clinician participants endorsed inter-professionalism as a BPII decision-making strategy. More broadly, inter-professional approaches to SDM expand the clinician-patient dyad to address both individual-level factors (clinician-patient-family) and

system-level factors (professional organisations, health care policies, workplace culture) [41]. These factors are widely acknowledged as facilitators or barriers to adopting SDM [16], and addressing both levels may be especially relevant to decision-making about medication in mental health [42].

Another potential limitation to this research program is that it did not include independent observer perspectives of clinician-patient (-family) interactions and treatment decision-making. The decision to not include observer perspectives, via coding of video/audio-recording of consultations to obtain an objective account of decision-making behaviours, and instead focus on the views and subjective experiences of patients, their families and clinicians was deliberate, and consistent with the overarching research aims. First, the systematic review (Chapter 2) and qualitative studies (Chapters 3, 4, 5) revealed that both patient- and clinician-related factors influenced the decision-making process, and patients did not define their decision-making involvement in terms of a discrete set of observable SDM behaviours (Chapters 2, 3). Instead, patients valued less tangible, interpersonal aspects of "feeling" involved [43], which is consistent with more recent research on patient perspectives of patient-centred care in bipolar disorder [44]. These aspects could not be captured by commonly-used measures assessing clinician SDM behaviours in consultations (e.g., the OPTION to measure the extent to which clinicians involve patients in decision-making, [45]). Next, it was critical that the end-users themselves defined the unmet decision-making needs, in order to inform the DA content and format and ensure that they viewed it as acceptable and potentially useful. Using observer measures to identify unmet needs was not appropriate for this purpose, given that they are not sensitive to patient preferences and priorities for information and decision-support.

8.5. Strengths of the current research

Limitations notwithstanding, this program of research has a number of strengths that distinguish it from previous research and add to its significance. Firstly, this research program employed both qualitative and quantitative methods, and benefitted from the complementary strengths of each approach. For example, the use of a quantitative self-report measure, the Control Preferences Scale (CPS, [46], see Chapters 2-5, 7),

allowed us to: i) characterise and compare the participant samples in terms of their decision-making involvement preferences, ii) compare our samples to other mental health-based samples in the literature, and iii) determine whether stated involvement preferences influenced qualitatively described attitudes and experiences of treatment decision-making. On the other hand, qualitative methods such as semi-structured interviews were useful in: i) exploring complex phenomena which had previously received scant empirical attention (e.g., family perspectives of their involvement, Chapter 3), and ii) clarifying and giving greater context and nuance to participant responses on the quantitative measures (e.g., the dynamic and fluid nature of patient involvement preferences according to the stage of decision-making, and severity of illness symptoms (Chapters 3, 4).

Next, the initial step in this research program was a systematic review, which identified key literature gaps and priorities for research in the BPII setting. One key literature gap was a limited number of qualitative studies and absence of multiple stakeholder perspectives of the decision-making process. Both these limitations were then addressed in the qualitative phase, which afforded an in-depth exploration and comparison of patient, family, and clinician views and experiences of BPII treatment decision-making. In this way, findings from the systematic review directly guided the aims and scope of the subsequent studies, and ensured that these studies provided novel and informative additions to the existing literature.

Furthermore, the DA content and format was guided by theory (i.e., the Ottawa decisional support framework [47]), international standards [1, 2], and literature recommendations for the development and evaluation of DAs [48]. As testament to this rigorous and systematic development process, the final DA satisfied all except two IPDAS quality criteria (field testing DA with clinicians, and providing readability scores), which were argued to be not applicable in the current context (see Table 6.3, Chapter 6). Further, pilot study findings (Chapter 7) supported IPDAS-endorsed criteria for establishing that a DA is effective, namely: decision quality (e.g., patients making informed, values-based choices) and decision processes leading to decision quality (e.g., patients reporting low decisional conflict). By adhering to "gold standard" IPDAS criteria, we ensured that the current DA presented high quality information and: i) used a systematic development process, with ongoing and

meaningful engagement of potential end-users; ii) used up-to-date scientific evidence, via extensive searching of systematic reviews, RCTs, official clinical guidelines, and any additional clinical evidence; iii) addresses usability issues, via health literacy review and revisions by patients/their families; iv) has a clear dissemination plan. In this way, the current DA overcame many of the common shortcomings of patient health information materials, which vary widely in terms of the quality of their information content and quality of their development process [49].

A final strength of this research program was the DA pilot study (Chapter 7), which considered both the feasibility and the future implementation of research findings into clinical practice. The pilot study served an important dual purpose in the DA's development and evaluation: first, it obtained evidence on the acceptability, feasibility, safety and potential usefulness of the DA; and second, it informed the design of a planned Phase II RCT study (Appendix G). A Phase II RCT is a necessary though frequently overlooked step in the evaluation of psychosocial interventions [50]. In addition, the pilot study made use of well-established, validated measures of DA effectiveness (e.g., decisional conflict, informed choice) as well as purpose-designed measures (e.g., subjective/objective knowledge), which were rigorously developed and informed by theory and clinical practice guidelines [51, 52]. These considerations ensure that the final DA represents a resource that can be readily integrated into routine patient care (i.e., via acceptability, feasibility) to foster a more active and informed role in treatment decisions (i.e., via potential usefulness) for patients with BPII and their families.

8.6. Conclusion

In summary, this thesis presents a multi-phase program of research, which included an in-depth qualitative exploration of patient, family, and clinician views and experiences to inform the development of an innovative treatment DA for patients with BPII and their families. The DA's development followed "gold standard" international criteria, and involved ongoing engagement of all core members of the decision-making triad. The pilot study confirmed the DA's potential usefulness at addressing the numerous unmet informational, involvement, and decision-support needs identified by patients with BPII and their families. The substantive involvement

of key stakeholders throughout the DA development and evaluation mirrors a broader shift towards greater involvement of consumers in SDM research [37], and also recognises the potential benefits of consumer involvement, such as increased relevance to community needs and more effective translation of research findings to deliver improved health outcomes [53].

The final DA (see Appendix H) is the first for the BPII population, and helps to bridge the gap between mental health and physical health conditions in the provision of evidence-based patient/family-centred SDM interventions. Mental health services have been slow to enact SDM, even though this approach is widely endorsed [54], and is already commonplace in medical settings, such as oncology. This is somewhat paradoxical, as patients with chronic mental illnesses, such as BPII, often need to play a much more active role in their own self-management than patients with cancer, for example, because patient education, medication adherence and lifestyle changes are key to reducing long-term relapse risk and functional impairment. This said, recent years have seen increased momentum in the development and evaluation of evidence-based tools to support SDM in the mental health setting; Cochrane reviews published in 2010 [55] and 2014 [56] identified the same two RCTs of DAs for mental health conditions, whereas the current 2017 update identified an additional two [17].

Finally, the current DA not only integrates a number of BPII clinician-endorsed decision-making strategies, it also aligns with drafted Australian standards *"Standard Two: Partnering with Consumers"*, which encourage clinicians and patients to partner together *"…to plan, communicate, set goals and make decisions about the current and future care''* (see [37] p. 18). Thus, the final DA not only has implications for greater adoption of SDM within the BPII setting, it also provides a model resource for supporting patients with other mental health conditions to make informed treatment decisions, which are consistent with patient values and preferences.

8.7. References for Chapter 8

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Appendix A

Appendix A – Signed author attribution statements

Publication 1 (comprising Chapter 2): Fisher A, Manicavasagar V, Kiln F, Juraskova, I. Communication and decision-making in mental health: A systematic review focusing on bipolar disorder. Patient Education and Counseling. 2016;99(7):1106-20. https://doi.org/10.1016/j.pec.2016.02.011

AF conceived and designed the study, developed the search strategy/protocol, extracted and analysed and interpreted the data, wrote and critically revised the manuscript. VM interpreted the data and provided critical review of the manuscript. FK extracted the data and provided critical review of the manuscript. IJ conceived and designed the study, interpreted the data and provided critical review of the manuscript.

_____	_____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date
_____	_____20/08/2018_____
Felicity Kiln	Date
_____	_____20/08/2018_____
Ilona Juraskova	Date

Publication 2 (comprising Chapter 3): Fisher A, Manicavasagar V, Sharpe L, Laidsaar-Powell R, Juraskova, I. A qualitative exploration of patient and family views and experiences of treatment decision-making in bipolar II disorder. Journal of Mental Health. 2018;27(1):66-79. https://doi.org/10.1080/09638237.2016.1276533

AF conceived and designed the study, recruited participants, collected and analysed and interpreted the data, wrote and critically revised the manuscript. VM and LS interpreted the data and provided critical review of the manuscript. RL-P analysed and interpreted the data, and provided critical review of the manuscript. IJ conceived and designed the study, interpreted the data, and provided critical review of the manuscript.

_____	____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date
_____	_____20/08/2018_____
Louise Sharpe	Date
_____	_____20/08/2018_____
Rebekah Laidsaar-Powell	Date
_____	_____20/08/2018_____
Ilona Juraskova	Date

Publication 3 (comprising Chapter 4): Fisher A, Manicavasagar V, Sharpe L, Laidsaar-Powell R, Juraskova, I. A qualitative exploration of clinician views and experiences of treatment decision-making in bipolar II disorder. Community Mental Health Journal. 2017;53(8):958-971. https://doi.org/10.1007/s10597-016-0077-4

AF conceived and designed the study, recruited participants, collected and analysed and interpreted the data, wrote and critically revised the manuscript. VM and LS interpreted the data and provided critical review of the manuscript. RL-P analysed and interpreted the data, and provided critical review of the manuscript. IJ conceived and designed the study, interpreted the data, and provided critical review of the manuscript.

_____	_____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date
_____	_____20/08/2018_____
Louise Sharpe	Date
_____	_____20/08/2018_____
Rebekah Laidsaar-Powell	Date
_____	_____20/08/2018_____
Ilona Juraskova	Date

Publication 4 (comprising Chapter 5): Fisher A, Manicavasagar V, Sharpe L, Laidsaar-Powell R, Juraskova I. Identifying and addressing barriers to treatment decision-making in bipolar II disorder: Clinicians' perspective. Australian Psychologist. 2018;53(1):40-51. https://doi.org/10.1111/ap.12264

AF conceived and designed the study, recruited participants, collected and analysed and interpreted the data, wrote and critically revised the manuscript. VM and LS interpreted the data and provided critical review of the manuscript. RL-P analysed and interpreted the data, and provided critical review of the manuscript. IJ conceived and designed the study, interpreted the data, and provided critical review of the manuscript.

_____	____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date
_____	____20/08/2018_____
Louise Sharpe	Date
_____	_____20/08/2018_____
Rebekah Laidsaar-Powell	Date
_____	____20/08/2018_____
Ilona Juraskova	Date

Publication 5 (comprising Chapter 7): Fisher A, Sharpe L, Anderson J, Manicavasagar V, Juraskova I. Development and pilot of a decision-aid for patients with bipolar II disorder and their families making decisions about treatment options to prevent relapse. PLoS ONE. 2018;13(7): e0200490. https://doi.org/10.1371/journal.pone.0200490

AF conceived and designed the study, recruited participants, collected and analysed and interpreted the data, wrote and critically revised the manuscript. JA, LS and VM interpreted the data and provided critical review of the manuscript. IJ conceived and designed the study, interpreted the data, and provided critical review of the manuscript.

_____	____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Josephine Anderson	Date
_____	_____20/08/2018_____
Louise Sharpe	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date
_____	____20/08/2018_____
Ilona Juraskova	Date

Chapters 1, 6, 8 (unpublished thesis chapters): The PhD student, AF wrote and critically revised the thesis chapters**.** PhD supervisors IJ, LS, JA, and VM provided critical review of the thesis chapters.

_____	____20/08/2018_____
Alana Fisher	Date
_____	_____20/08/2018_____
Ilona Juraskova	Date
_____	_____20/08/2018_____
Louise Sharpe	Date
_____	_____20/08/2018_____
Josephine Anderson	Date
_____	_____20/08/2018_____
Vijaya Manicavasagar	Date

Appendix B

Appendix B1 – Ethics approval letter from the University of Sydney Human Research Ethics Committee (qualitative studies)

THE UNIVERSITY OF SYDNEY

Research Integrity
Human Research Ethics Committee

Friday, 17 April 2015

Dr Ilona Juraskova
Psychology; Faculty of Science
Email: ilona.juraskova@sydney.edu.au

Dear Ilona

I am pleased to inform you that the University of Sydney Human Research Ethics Committee (HREC) has approved your project entitled "**A qualitative exploration of patient, family and health professional views and experiences of treatment decision-making in Bipolar II Disorder**".

Details of the approval are as follows:

Project No.: **2015/197**

Approval Date: **04 April 2015**

First Annual Report Due: **04 April 2016**

Authorised Personnel: **Juraskova Ilona; Fisher Alana; Manicavasagar Vijaya;**

Documents Approved:

Date Uploaded	Type	Document Name
01/04/2015	Advertisements/Flyer	Email invitation for HPs
01/04/2015	Advertisements/Flyer	EOI flyer for HPs
01/04/2015	Advertisements/Flyer	EOI letter for family members
01/04/2015	Participant Consent Form	PCF family member
01/04/2015	Participant Consent Form	PCF for HPs
01/04/2015	Participant Consent Form	PCF for patients
01/04/2015	Participant Info Statement	PIS for family
01/04/2015	Participant Info Statement	PIS for HPs
01/04/2015	Participant Info Statement	PIS for patients
06/03/2015	Interview Questions	Interview items for patients
06/03/2015	Telephone Scripts	Telephone script for patients
06/03/2015	Questionnaires/Surveys	Interview items for health professionals
06/03/2015	Questionnaires/Surveys	Internal states scale for patients
06/03/2015	Telephone Scripts	Telephone script for family members
06/03/2015	Telephone Scripts	Telephone script for health professionals
06/03/2015	Questionnaires/Surveys	Questionnaire for family members
06/03/2015	Questionnaires/Surveys	Questionnaire for health professionals
06/03/2015	Questionnaires/Surveys	Questionnaire for patients
06/03/2015	Interview Questions	Interview items for family members
06/03/2015	External Ethics Approval	Approval from Black Dog Institute

Research Integrity
Research Portfolio
Level 6, Jane Foss Russell
The University of Sydney
NSW 2006 Australia

T +61 2 8627 8111
F +61 2 8627 8177
E ro.humanethics@sydney.edu.au
sydney.edu.au

ABN 15 211 513 464
CRICOS 00026A

THE UNIVERSITY OF SYDNEY

HREC approval is valid for four (4) years from the approval date stated in this letter and is granted pending the following conditions being met:

Condition/s of Approval

- Continuing compliance with the National Statement on Ethical Conduct in Research Involving Humans.
- Provision of an annual report on this research to the Human Research Ethics Committee from the approval date and at the completion of the study. Failure to submit reports will result in withdrawal of ethics approval for the project.
- All serious and unexpected adverse events should be reported to the HREC within 72 hours.
- All unforeseen events that might affect continued ethical acceptability of the project should be reported to the HREC as soon as possible.
- Any changes to the project including changes to research personnel must be approved by the HREC before the research project can proceed.
- Note that for student research projects, a copy of this letter must be included in the candidate's thesis.

Chief Investigator / Supervisor's responsibilities:

1. You must retain copies of all signed Consent Forms (if applicable) and provide these to the HREC on request.
2. It is your responsibility to provide a copy of this letter to any internal/external granting agencies if requested.

Please do not hesitate to contact Research Integrity (Human Ethics) should you require further information or clarification.

Yours sincerely

Dr Stephen Assinder
Chair
Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

Appendix B2 – Ethics approval letter from the Black Dog Institute Research Advisory Committee (qualitative studies)

BLACK DOG INSTITUTE

Hospital Road
Prince of Wales Hospital
Randwick
NSW 2031

Telephone 61-2 9382 4530
Facsimile 61-2 9382 8208
Email blackdog@blackdog.org.au
Website www.blackdoginstitute.org.au

ABN 12 115 954 197

4th March, 2015

Dear Alana,

This letter is to notify you that your study entitled *"A qualitative exploration of patient, family and health professional views and experiences of treatment decision-making in Bipolar II Disorder"* has received formal approval by the Research Advisory Committee to be conducted at the Black Dog Institute.

The ID number for the study is **2015002 FISHER**. Please quote this number in all future correspondence regarding this study.

Please note that you cannot commence the research project until final approval has been obtained by an Ethics Committee.

Once ethics approval has been received, please forward a copy of the ethics approval notice for me to keep in our records.

Kindest regards

Kristy Delmas
Research Manager

Appendix B3 – Ethics approval letter from the University of Sydney Human Research Ethics Committee (DA pilot and RCT evaluation)

THE UNIVERSITY OF SYDNEY

Research Integrity & Ethics Administration
Human Research Ethics Committee

Tuesday, 27 September 2016

Dr Ilona Juraskova
Psychology; Faculty of Science
Email: ilona.juraskova@sydney.edu.au

Dear Ilona

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

I am pleased to inform you that your project has been approved.

Approval is granted for a period of four years from **13 September 2016** to **13 September 2020.**

Project Title: Pilot and Phase II RCT evaluation of a treatment decision-aid for patients with bipolar II disorder and their family.

Project No.: **2016/763**

First Annual Report Due: **13 September 2017**

Sites Approved: **Black Dog Institute (BDI) Clinic**

Authorised Personnel: **Juraskova Ilona; Sharpe Louise; Fisher Alana; Manicavasagar Vijaya L; Anderson Josephine;**

Documents Approved:

Date	Version	Document
25/08/2016	Version 1	EOI flyer Beyond Blue/SANE
25/08/2016	Version 1	EOI flyer for patients family
25/08/2016	Version 1	Family Pilot questionnaire
25/08/2016	Version 1	Patient & Family Pilot Interview
25/08/2016	Version 1	Patient PCF RCT
25/08/2016	Version 1	Patient Pilot questionnaire
25/08/2016	Version 1	Patient PIS RCT
25/08/2016	Version 1	Patient RCT Follow-up Invitation
25/08/2016	Version 1	Patient RCT questionnaire baseline T0
25/08/2016	Version 1	Patient RCT questionnaire follow-up T2
25/08/2016	Version 1	Patient RCT questionnaire post-decision T1
25/08/2016	Version 1	PCF Family Pilot
25/08/2016	Version 1	PCF Patient Pilot

Research Integrity & Ethics Administration
Research Portfolio
Level 2, Margaret Telfer Building (K07)
The University of Sydney
NSW 2006 Australia

T +61 2 9036 9161
E human.ethics@sydney.edu.au
W sydney.edu.au/ethics

ABN 15 211 513 464
CRICOS 00026A

THE UNIVERSITY OF SYDNEY

25/08/2016 Version 1	PIS Family Pilot
25/08/2016 Version 1	PIS Patient Pilot

Special Condition/s of Approval

1. To ensure compliance with the State Records Act, clinical trials data needs to be retained for a minimum of 15 years. Please update your Participant Information Statements and submit new versions on a Compliance with Special Conditions of Approval in IRMA.

2. As you are recruiting participants through the Local Health District you will need ethics approval from the appropriate LHD HREC which is registered with the NHMRC.

Special Conditions of Approval for Clinical Trials

- Clinical Trials must be registered on a clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). For trials conducted in Australia or New Zealand registration should be on the Australian New Zealand Clinical Trial Registry before recruitment of the first subject (http://www.anzctr.org.au/).

- **This letter constitutes ethical approval only.** This project cannot proceed at any site until the necessary research governance authorisation is obtained. If your study is sponsored by the University or is to be conducted on a University of Sydney site you may need to comply with additional University governance requirements prior to commencing. Please contact the Clinical Trials Governance Office at clinicaltrialgovernance.research@sydney.edu.au.

Condition/s of Approval

- Research must be conducted according to the approved proposal.

- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.

- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
  - Serious or unexpected adverse events (which should be reported within 72 hours).
  - Unforeseen events that might affect continued ethical acceptability of the project.

- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).

- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.

- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.

- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.

- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.

- The Ethics Office may conduct audits on approved projects.

THE UNIVERSITY OF SYDNEY

- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Associate Professor Stephen Assinder
Chair
Human Research Ethics Committee (HREC 1)

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).

Appendix B4 – Ethics approval letter from the Black Dog Institute Research Advisory Committee (DA pilot and RCT evaluation)

9 August 2016

Dear Ms Fisher and Associate Professor Anderson,

This letter is to notify you that your study entitled "*Pilot and Phase II RCT evaluation of a treatment decision-aid for patients with bipolar II disorder and their family.*" has received formal approval by the Research Advisory Committee to be conducted at the Black Dog Institute and for recruitment to occur within the Depression Clinic.

The ID number for the study is **2016011 Fisher**. Please quote this number in all future correspondence regarding this study.

Please note that you cannot commence the research project until final approval has been obtained by an Ethics Committee.

Once ethics approval has been received, please forward a copy of the ethics approval notice for me to keep in our records.

Kind regards

Kathryn Woodcock
Research Manager

Black Dog Institute
Hospital Road Randwick NSW 2031
T: +61 2 9382 8362
k.woodcock@blackdog.org.au
www.blackdoginstitute.org.au
/blackdoginst

Black Dog Institute

Appendix C

Appendix C – Checklist for assessing the quality of quantitative and qualitative studies.

Criteria for quantitative studies (2 = fully met, 1 = partially met, 0 = not met)
1 Question/objective sufficiently described?
2 Study design evident and appropriate?
3 Method of subject/comparison group selection or source of information/input variables described and appropriate?
4 Subject (and comparison group, if applicable) characteristics sufficiently described?
5 If interventional and random allocation was possible, was it described?
6 If interventional and blinding of investigators was possible, was it reported?
7 If interventional and blinding of subjects was possible, was it reported?
8 Outcome and (if applicable) exposure measure(s) well defined and robust to measurement/misclassification bias? Means of assessment reported?
9 Sample size appropriate?
10 Analytic methods described/justified and appropriate?
11 Some estimate of variance is reported for the main results?
12 Controlled for confounding?
13 Results reported in sufficient detail?
14 Conclusions supported by results?

Criteria for qualitative studies (2 = fully met, 1 = partially met, 0 = not met)
1 Question/objective sufficiently described?
2 Study design evident and appropriate?
3 Context for the study clear?
4 Connection to a theoretical framework/wider body of knowledge?
5 Sampling strategy described, relevant and justified?
6 Data collection methods clearly described and systematic?
7 Data analysis clearly described and systematic?
8 Use of verification procedure(s) to establish credibility?
9 Conclusions supported by the results?
10 Reflexivity of the account?

Appendix D

Appendix D – Overview of patient [family] interview guide

General discussion:

1) **Types of decisions**

a) What are the kinds of decisions you have (had)[/ has your family had] to make when it comes to managing your bipolar II disorder?

b) What kinds of treatment decisions have you [has your family] discussed with your [their] clinician?

2) **Decisional conflict**

c) Which decisions have been the most difficult [for your family] to make when managing your [their] bipolar II disorder?

d) What has made these decisions difficult?

e) What is needed to make deciding between different options less difficult?

3) **Decision support (barriers and facilitators)**

f) How have you [has your family] felt when making these decisions?

g) Has your [their] clinician supported you [them] when making decisions about treatment? If so, how? How about your family and friends?

4) **Suggestions for support and resources**

h) Is there anything else, for example information booklets or online exercises that would help better support you [your family] when making decisions about treatment?

i) What would you like these to look like?

5) **Patient/ family involvement**

j) Who has been involved when making decisions about your [family's] treatment?

k) What do you think about your [your family's] level of involvement in decisions? How about others' level of involvement?

l) Have there been any challenges, or things that have made it difficult for you [your family] to be as involved as they'd like in making decisions about treatment?

Focused discussion:

6) Decision-making stages

Thinking about a specific decision- we are now going to try to break down the steps of when decisions are made. Can you give me one example of a decision that needed to be made about your bipolar II disorder while in consultation with a health professional. Now keep that example in mind.....

Information gathering

a) Outside this consultation, did you [your family] seek any information about your [their] illness and treatment?

Information exchange

b) Can you tell me about how the information about different options was discussed in the consultation?

Deliberation (process of expressing/discussing treatment preferences)

c) Once the information had been discussed, how did you [your family] weigh up the pros and cons before coming to a decision?

d) Did you (and your family member, if present) think or talk more about options once you left the consultation? What happened?

Decision

e) When it came down to making the decision, how involved were you (was your family member, if present)? What was your role/their role?

f) When it came down to actually making the decision, who do you think had the most influence?

Decisional monitoring

g) Have you thought any more about the decision you [your family] made?

Reflecting on decision making process

h) Do you feel anything was missing (or left out) in the decision-making process? If so, what?

i) Did anything about making your decision that not meet your expectations? If so, what?

Decision-aid

j) We are looking to develop a decision-support resource to help patients and family make decisions about their treatment. What sort of information would be helpful to include?

Appendix E

Appendix E - Clinician interview guide

General discussion:

7) Types of decisions

a) What are the kinds of decisions you have (had) to make with patients managing their bipolar II disorder?

b) What kinds of treatment decisions do you spend time discussing with patients?

8) Decisional conflict

c) Which decisions have been the most difficult to make with patients managing their bipolar II disorder?

d) What has made these decisions difficult?

e) What is needed to make decision-making less difficult?

9) Decision support (barriers and facilitators)

f) How do you usually make decisions about treatment for bipolar II disorder?

g) How do you support your patients' decision-making about treatment? How about their family and friends?

10) Suggestions for support and resources

h) Is there anything else, for example information booklets or online exercises, which would help better support you in your decision-making about treatment?

i) What would you like these to look like?

11) Patient/ family involvement

j) Who is involved in the decision-making process about patients' treatment?

k) What do you think about patients participating in decisions? Others' involvement?

l) Are there any challenges to involving patients in decision-making about treatment?

Focused discussion:

12) Decision-making stages

Can you give me a couple of examples of a decision that needed to be made about a patient's bipolar II disorder while in consultation with them. Keep those examples in mind.....

k) Who aside from you and the patient is generally present during these consultations?

Information gathering

l) Outside these consultations, are you aware of patients seeking information about their illness and treatment?

Information exchange

m) Can you tell me about how the information about different options is discussed in the consultation?

Deliberation (process of expressing/discussing treatment preferences)

n) Once the information has been discussed, what happens when the different options are being weighed up within consultations?

o) Do you and the patient (and their family member) talk or think more about options after this consultation? What happens generally?

Decision

p) When it comes down to making the decision, how involved are you (is the patient/ their family)?

q) When it comes down to actually making the decision, who do you think has the most influence?

Decisional monitoring

r) Have you reflected any more about the decisions made in these consultations?

Reflecting on decision making process

s) Do you feel anything was missing (or left out) in the decision-making process? If so, what?

t) Did anything about the decision-making process not meet your expectations? If so, what?

Decision-aid

u) We are looking to develop a decision-support resource to help patients and family make decisions about their treatment. What sort of information would be helpful to include?

Appendix F

Appendix F1 – Summary of the decision-aid (DA) contents

DA section	Outline of included content
General introduction	Outlined the purpose of DA, intended use/patient group, available treatment option
Bipolar II disorder background	Outlined types and prevalence of bipolar disorder, describing mood cycles, and types of treating clinicians
Introduction to medication options	Introduced the three first-line medication options (lithium, lamotrigine, quetiapine) in text and via flowchart, their effectiveness and ongoing, iterative nature of treatment decision-making
Medication option 1: Lithium	Introduced lithium, when lithium is recommended, its effectiveness at preventing different types of relapse via text and 100 person dot diagrams; outlined possible advantages (benefits) and disadvantages (side-effects/risks) of lithium over short, medium, long-term; included bona-fide patient/family member quotes relating to perceived pros and cons of lithium
Medication option 2: Lamotrigine	See above for lithium, with rewording as appropriate
Medication option 3: Quetiapine	See above for lithium, with rewording as appropriate
Summary table of advantages/disadvantages of medication options	Tabulated summary using traffic light info-graphic and colour-coding to denote advantages and disadvantages of lithium, lamotrigine, and quetiapine
Introduction to add-on (adjunctive) psychological options	Introduced the two level-1 evidence adjunctive psychological options (CBT and group psycho-education) in text and via flowchart, the rationale for having psychological treatment in addition to medication for relapse prevention, their key/overlapping components.
Psychological option 1: Cognitive Behavioural Therapy (CBT)	Introduced CBT, when CBT is recommended, its effectiveness at preventing different types of relapse via text and 100 person dot diagrams; outlined possible advantages (benefits) and

	disadvantages (side-effects/risks) of CBT; included bona-fide patient/family member quotes relating to perceived pros and cons of CBT
Psychological option 2: Group Psycho-education	See above for CBT, with rewording as appropriate
Summary table of advantages and disadvantages of add-on psychological options	Tabulated summary using traffic light info-graphic and colour-coding to denote advantages and disadvantages of CBT and group psycho-education
What is the role of complementary therapy?	Defined complementary therapy; introduced Omega-3 fatty acids and outlined current state of evidence in terms of relapse prevention
How can family members be involved in decision-making?	Outlined the potential roles and benefits of family involvement in decision-making both within and outside consultations with clinicians
Making treatment decisions that are right for you	Step-by-step guide on things to do/consider when making a treatment decision
Making the most of your time with your clinician	Gave examples of and addressed common patient barriers to asking clinicians questions; included "Ask-Share-Know" questions and question prompt list
Worksheets: What is important to you about your treatment?	Included values clarification exercises (with weight scale visual aids) for each medication and psychological treatment option, patient examples, and suggestions for involving family members and clinicians in completing these exercises
Further resources	Provided list of links to Australian-based websites/online resources
Glossary of key terms	Defined in lay language all medical/clinical terminology in the DA
Acknowledgments	Named and acknowledged development team, members of expert working party; indicated month/year that information is current, month/year of next planned update
Reference list and further research	Outlined the type of research/evidence used to base included treatment options and inform treatment efficacy data, list of key empirical studies/reviews

Appendix F2 – Telephone interview guide

Question 1: Initial Response

a) In your words what do you think is the purpose of this booklet?

b) What were your first impressions of this booklet?

c) What did you like about it? What was the best part?

d) What did you dislike about it? How can we improve on it?

e) Was there anything in the booklet that made you stressed or anxious?

f) Overall do you think a booklet like this is useful for a person to use when they are trying to decide about medication and psychological options to prevent relapse in bipolar II?

Question 2: Design

Do you have any comments about the 'look' or 'design' of the booklet, e.g., the colours; the images; the size of the writing; anything about the way it is presented?

Question 3: General length and content

a) What did you think about the length of the decision aid? Was it:

Too long

The right length

Too short

b) Was there:

Too much information

The right amount of information

Not enough information

Question 4: Assistance with booklet

Would it have been helpful if a clinician went through some of the pages with you before you looked through the booklet? If so, which ones?

Question 5: Wording

Were there any sentences or sections in the booklet that could have been clearer?

Question 6: Now we will go over specific sections

a) Turn to pages 16-17: Was the explanation of the different medication options clear?

b) On pages 42-43: Was the explanation of the different add-on psychological options clear?

c) Did you like that we included other people's comments (in grey italics) on the pros and cons of each option?

d) Turn to pages 16 and 42: Are you clear about the options available?

Yes

No

e) In your own words, what are the options available (tick if mention option):

Medications (lithium, lamotrigine, quetiapine)

Adjunctive psychological treatments (CBT, group psycho-education)

f) What did you think of the 100 person dot diagrams (showing how effective options are at preventing relapse)? On pages 27 – 29: As an example, can you go through with me what each of these diagrams mean?

g) Do you have any comments about the description of the advantages/ benefits of each treatment option? How about in the summary tables?

h) Do you have any comments about the description of the disadvantages/ side-effects of each treatment option? How about in the summary tables on pages 40-41 and pages 60-61?

i) In terms of the presentation of the options, would you say that it favoured any particular option or did it provide a balanced view:

Taking a particular medication over others

(State which: _____)

Having a particular adjunctive psychological treatment over another

(State which: _____)

Balanced view

j) On pages 63 - 65, titled Information for family members: was this section useful?

k) Page 71: Worksheets:

i) Were the instructions on how to use the worksheets clear?

ii) Do you think the worksheets are a good idea? Did you find them useful?

l) Page 84: Further resources:

i) Would you access any of these websites?

ii) Would you recommend any other websites?

Question 7 - Comprehensiveness

a) Are there any topics or questions that you feel were not covered in the booklet that should be included?

Yes (i) If yes, please tell us what you think should be added)

No

b) Are there any topics or information that you think should not have been included in the booklet?

Yes (ii) If yes, please tell us what you think should be removed?)

No

Appendix F3 – Summary of purpose-designed knowledge items and scoring rubric

		"Adequate knowledge" is defined as a pass mark of > 50% (i.e., at least 20 out of 38 marks) To have adequate knowledge, participants must either: - Get correct all conceptual/gist knowledge items (18 marks) ***plus*** at least 2 marks on numerical/verbatim knowledge items (2 marks) **ALTERNATIVELY** - Get correct all numerical/verbatim knowledge items (20 marks). In this way, participants cannot have "adequate knowledge" on the basis of conceptual/gist knowledge alone, instead they either need to have a combination of conceptual/gist and numerical/verbatim knowledge, or numerical/verbatim knowledge alone [2, 3]. Note that each applicable NHMRC guideline was assessed with a conceptual and/or numerical question.
NHMRC guidelines on information to be given for informed consent [1]	**DA-related Conceptual (gist) knowledge – 9 questions x 2 marks (/18)**	**DA-related Numerical (verbatim) knowledge – 5 questions x 4 marks (/20)**
1) The possible of likely nature of the illness or disease		**1)** Over the long term, *how much of the time will the average person with BPII spend WITHOUT ANY SYMPTOMS*? ANSWER: 24 weeks per year (46% of the time) without any symptoms.

		Almost one half of the time (~ 24 weeks per year) = 4 marks Just over one third of the time (~ 19 weeks per year) = 3 marks Less than one fifth of the time (~ 8 weeks per year) = 2 marks Almost never (1 - 2 weeks per year) = 1 mark Almost all the time (45 -50 weeks per year) = 0 marks
2) The proposed approach to treatment:		
i) **what the proposed approach entails**	**2) i)** Taking medication *together with* psychological treatments is more effective than medication *only* for preventing relapse in BPII. True (correct) = 2 marks False/Don't know = 0 marks	
ii) **the expected benefits**	**2) ii)** Lithium, lamotrigine, and quetiapine differ in terms of how effective they are at preventing hypomania. True (correct) = 2 marks	**2) ii)** Imagine a group of 100 people taking quetiapine. *About how many people taking quetiapine* will *RELAPSE in general*? ANSWER: 23 in 100 people will experience relapse in general.

	False/Don't know = 0 marks	About one quarter (~25 in 100 people) = 4 marks About one third (30-40 in 100 people) = 3 marks Almost one half (45-50 in 100 people) = 2 marks Less than fifth (10-15 in 100 people) = 1 marks Almost everyone (~90 in 100 people) = 0 marks
iii) **common side effects and material risks of any intervention**	**2) iii)** Lamotrigine is associated with sedation, weight gain, and sleepiness/drowsiness. True/Don't know = 0 marks False (correct) = 2 marks	**2) iii)** Imagine a group of 100 people starting lamotrigine. *About how many in 100 people* will experience non-serious (benign) rash within the first 2 months? ANSWER: 8-9 in 100 people Almost one tenth (5-10 in 100 people) = 4 marks About one quarter (~25 in 100 people) = 3 marks About one third (30-40 in 100 people) = 2 marks About one half (~50 in 100 people) = 1 mark More than three quarters (75+ in 100 people) = 0 marks
iv) **whether the intervention is conventional or experimental**	**2) iv)** N/A	**2) iv)** N/A

v) **who will undertake the intervention**	**2) v)** In Australia, clinical psychologists have training to provide cognitive behavioural therapy (CBT). True (correct) = 2 marks False/Don't know = 0 marks	
3) Other options for treatment	**3)** Lithium, lamotrigine, and quetiapine are the only available medication options that your clinician will recommend to you. True/Don't know = 0 marks False (correct) = 2 marks	
4) The degree of uncertainty of any diagnosis arrived at	N/A (DA not related to diagnosis)	N/A (DA not related to diagnosis)
5) The degree of uncertainty about the therapeutic outcome	**5)** We still do NOT know which out of lithium, lamotrigine, and quetiapine is *the most* effective at preventing relapse in BPII. True (correct) = 2 marks. False/Don't know = 0 marks.	

6) The likely consequences of not choosing the proposed treatment, or of not having any treatment at all.	**6)** A person with BPII who does *NOT* take any medication is at greater risk of relapse compared to a person with BPII who *DOES* take medication. True (correct) = 2 marks. False/Don't know = 0 marks.	**6)** Imagine a group of 100 people treated with medication but WITHOUT any add-on or adjunctive psychological treatment. *About how many in 100 people* will relapse within 2 years? ANSWER: 50 in 100 About half (~50 in 100 people) (i.e., 50 > 10%)= 4 marks About one third (30-40 in 100 people) (i.e., 50 +/- 25%) = 3 marks About one quarter (~25 in 100 people) (i.e., 50 +/- 50%) = 2 marks More than three quarters (~80 in 100 people) (i.e., 50 +/ - 75%) = 1 mark. Almost everyone (~99 in 100 people) (i.e., 50 +/- 100% +) = 0 marks.
7) Any significant long term physical, emotional, mental, social, sexual or other outcome that may be associated with a proposed intervention.		**7)** Imagine a group of 1000 people taking lithium over the long-term. *How common* is it for these people to experience complete kidney (renal) failure? ANSWER: 5 in 1000 Uncommon (1-9 in 1000 people) = 4 marks Rare (Less than 1 in 1000 people) = 3 marks Common (50-100 in 1000 people) = 2 marks Very common (~500 in 1000 people) = 1 mark Experienced by almost everyone (~900-990 in 1000 people) = 0 marks.

8) The time involved.	**8)** The actual number of sessions in psychological therapies (cognitive behaviour therapy and group psycho-education) varies from one person to another. True (correct) = 2 marks. False/Don't know = 0 marks.
9) The costs involved, including out of pocket expenses.	**9)** Lithium, lamotrigine, and quetiapine are *all* subsidised by the PBS, and so cost a similar amount. True/Don't know = 0 marks. False (correct) = 2 marks.

1. Australian Government National Health and Medical Research Council. General guidelines for medical practitioners on providing information to patients2004 1 August 2016. Available from: https://www.nhmrc.gov.au/guidelines-publications/e57.
2. Smith SK, Barratt A, Trevena L, Simpson JM, Jansen J, McCaffery KJ. A theoretical framework for measuring knowledge in screening decision aid trials. Patient education and counseling. 2012;89(2):330-6.
3. Smith SK, Trevena L, Simpson JM, Barratt A, Nutbeam D, McCaffery KJ. A decision aid to support informed choices about bowel cancer screening among adults with low education: randomised controlled trial. BMJ. 2010;341:c5370.

Appendix G

Appendix G – Submitted RCT protocol paper

Phase II Randomised Controlled Trial of a patient decision-aid website to improve treatment decision-making for young adults with bipolar II disorder: a feasibility study protocol

Fisher, Alana.[1,2], Sharpe, Louise.[1] , Costa, Daniel. [3], Anderson, Josephine.[4], Manicavasagar, Vijaya. [4], Juraskova, Ilona.[1,2].

1. School of Psychology, Brennan MacCallum Building (A18), The University of Sydney, NSW, 2006, Australia.
2. Centre for Medical and Evidence-based Decision-making (CeMPED), Level 6, Chris O'Brien Lifehouse (C39Z), The University of Sydney, NSW, 2006, Australia
3. Sydney Medical School, Edward Ford Building (A27), The University of Sydney, NSW, 2006, Australia
4. The Black Dog Institute, Hospital Road, Prince of Wales Hospital, Randwick, NSW, 2031, Australia.

Abstract

Background/Aims: This paper describes the protocol for a feasibility study for a parallel Phase II randomised control trial (RCT) aiming to evaluate a novel decision-aid website (e-DA) to support young adults with bipolar II disorder (BPII), and their families.

Material and methods: The e-DA was developed according to the International Patient Decision-Aid Standards (IPDAS). Participants will be 40 young adults (18-30 years) referred to a specialist outpatient clinical facility, who have a confirmed clinical diagnosis of BPII. Participants will be randomised (1:1) to receive access to the clinic's online factsheets/website with (Intervention) or without (Control) the e-DA. A series of validated and purpose-designed questionnaires will be administered at baseline (T0), immediately post-decision (T1), and 3 months post-decision (T2). Questionnaires assess key decision-making constructs related to decision-making quality, including: decisional conflict, subjective and objective treatment knowledge, values-based informed choice, concordance between preferred/actual decision-making involvement, preparation for decision-making, and decisional regret. Self-report symptom severity and anxiety will ascertain the safety of e-DA use. The focus of analyses will be to assess effect sizes, in order to guide a future RCT.

Discussion: This feasibility study will evaluate a world first, evidence-based online decision-support resource, a DA website, for young adults with BPII and their families who are deciding on treatment options for relapse prevention. Findings will determine the e-DA's feasibility in RCT procedures (i.e., outpatient clinical setting) and provide estimates of effect sizes on outcomes related to improving treatment decision-making and patient outcomes in a sample of potential end-users, compared to usual care.

Trial Registration: This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) - ACTRN12617000840381

Keywords: Bipolar II disorder; treatment decision-aid; decisional conflict; informed choice; randomised controlled trial; young adults.

Introduction

Young adults (18-30 years) have the highest prevalence of mental illness relative to any other age group [1]. In particular, affective disorders (including mood and bipolar-related disorders) are both more prevalent [1] and more burdensome [2] amongst young adults. Although bipolar II disorder (BPII) is around twice as common as bipolar I disorder (BPI) in community (5% vs. 2.4% of samples; [3]), BPII remains largely understudied, with few high quality research studies on treatment efficacy [4, 5]. Young adulthood is a critical time period for onset of BPII, with an average age of onset estimated at 20 years [6]. As a chronic, relapsing, and burdensome psychiatric condition with a focus on long-term adherence to prophylactic treatment, BPII relies heavily on patient education and self-management to prevent future episodes. It is therefore essential that targeted, patient-centred interventions are developed to address the treatment needs of young adults newly diagnosed with BPII.

Decision-making about treatment in BPII represents one area in pressing need of targeted, patient-centred interventions. Shared treatment decision-making (SDM) is increasingly advocated in serious mental illnesses [7]. SDM involves the clinician and the patient partnering together to share their understanding of available treatment options, and their views about the advantages and disadvantages of these. There are ongoing barriers to achieving SDM in BPII, with patients and their families expressing numerous unmet informational and decisional-support needs [8-10]. As a result of suboptimal involvement, patients and families often felt that treatment decisions were not made in line with their treatment preferences [8-10]. Moreover, these unmet needs are likely to be greater among young adults, who tend to prefer greater decision-making involvement compared to older cohorts [11]. In order to better support treatment decision-making in BPII, young adults would benefit from interventions that are designed to encourage their active and informed participation in treatment decision-making that is both evidence-based and concordant with their values.

SDM interventions, such as patient decision-aids (DA), represent a key step in facilitating young people's informed uptake of and effective adherence to evidence-based medication and adjunctive psychological treatment options, which, in turn, are likely to reduce their risk of relapse. DAs are interventions (e.g., booklets, brochures,

websites), which present patients with unbiased, evidence-based information on all available healthcare options, and then guide patients through a deliberative process of actively weighing-up the benefits/costs of available treatment options. This enables decision-making that is both evidence-based and considerate of patient preferences and life circumstances. The effectiveness of DAs across an array of treatment/screening decisions in physical health (e.g., cancer, diabetes) is well-established [12], and similar DA effectiveness is also emerging for mental health conditions, such as schizophrenia [13] and depression in adults [14-16] and in young people [17]. Compared to usual care, DA interventions significantly improve patient knowledge of available treatment options and outcomes, increase patient feelings of involvement, and reduce patient feelings of regret, uncertainty, being uninformed, unsupported and unclear about their values towards treatment choices [13]. Despite these promising findings, no known treatment DAs have been developed specifically for BPII.

Aims

This DA will be the first of its kind, and aims to address the gap between initial advances made in treatment decision-making in other serious psychiatric illnesses, such as depression and schizophrenia, and BPII.

This protocol paper describes the proposed evaluation of a novel DA website (e-DA) to support young adults with BPII and their families. The e-DA is adapted from a DA booklet, which was piloted in a sample of potential end-users [18]. A website adaptation was warranted for this young adult population, in order to integrate tailored content together with more advanced interactive features and navigation capabilities.

This study employs a parallel-group randomised design in order to determine the e-DA's acceptability and feasibility in an outpatient clinical setting. As a feasibility study, we do not propose any specific hypotheses. Instead the focus of analyses will be to assess DA-related effect sizes on an established battery of outcome variables, in order to guide a future RCT phase. The battery of outcome variables relate to the quality of the decision-making process and decision quality (i.e., quality of the choice made. Variables are drawn from previous RCTs of DAs for mental health [13-16],

and medical conditions [12], the Ottawa decision-support framework [19, 20], and international consensus-based standards on establishing the effectiveness of DAs [21]:

The quality of the decision-making process

i) Feeling well-informed, certain, and well-supported in the treatment decision, and clear about values/preferences (i.e., low levels of decisional conflict);

ii) Good (subjective) understanding of treatment options and outcomes

iii) Concordance between preferred and actual levels of decision-making involvement

iv) Good preparation for decision-making

v) Low levels of regret about the treatment decision

Decision quality – Quality of the choice that is made

vi) Good (objective) knowledge about treatment options and outcomes;

vii) Informed treatment choices, in line with patient preferences/values (i.e., values-based, informed choice).

viii) Higher uptake of effective medical and psychological interventions.

Further, we do not expect that e-DA use will be associated with harm. That is, it is *not* anticipated that receiving the DA will lead to:

ix) Higher depression or hypomania symptomatology

x) Higher state anxiety;

xi) Medication non-adherence.

Materials and Methods

Design

This study is a feasibility study with 1:1 parallel randomisation to either the intervention (DA website) or active control (BDI webpage/online factsheets on bipolar disorder treatments). Assessment occurs at three time points: i) baseline (T0); ii) post-treatment decision (T1); and iii) three months follow-up (T2).

Participants and setting

Participants will be recruited through the Black Dog Institute (BDI), a specialist outpatient clinical and research facility, which specialises in the assessment and treatment of mood and bipolar-related disorders.

Inclusion criteria

To be eligible, participants will be young adult patients aged 18-30 years old, who: i) have a confirmed clinical diagnosis of BPII; ii) have recovered from an acute mood episode (as determined by an assessing psychiatrist), and iii) are considering treatment options for maintaining mood-stability/relapse prevention. The selected 30 year age cut-off for patient inclusion brings the current protocol into line with other research on self-management strategies for young adults with bipolar disorder [22], acknowledges the common delay between onset of BPII symptoms and diagnosis, and captures the full peak onset period for BPII (15-30 years, [23]). To ensure that patients are at the stage of making a treatment decision, they will be consecutively recruited immediately following their consultation with a psychiatrist in which treatment options are presented and discussed.

Exclusion criteria

These include: i) lack of English proficiency; ii) lack of capacity to provide informed consent; iii) experiencing acute/severe hypomanic, depressive or mixed mood symptoms (as determined by assessing psychiatrist); iv) a concurrent neurocognitive or psychiatric condition; and v) no computer/internet access. In addition, patients participating in the BDI's concurrent RCT comparing the efficacy of lithium versus lamotrigine for BPII treatment (ANZCTR; ACTRN12616001702404) will not be eligible to participate in this trial.

Ethical approval to conduct this study was obtained from the University of Sydney Human Research Ethics Committee (USYD HREC, 2016/763) and the Black Dog Institute Research Advisory Group (2016011 Fisher). The RCT protocol is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12617000840381). Any important modifications to the study protocol (e.g., change to eligibility criteria) will be communicated to relevant parties (e.g., USYD, BDI, ANZCTR) in advance via their respective online portals.

Procedure

The study procedure is illustrated in Figure 1. Recruitment flow and procedure will follow CONSORT guidelines [24] including independent randomisation of participants, use of standardised measures to ensure rigorous, controlled testing of outcomes, and consideration of real-world implementation factors such BDI's existing service delivery model.

Following their diagnostic/treatment review consultation with a psychiatrist at the BDI, clinic staff will ask eligible patients for their permission to have their details passed onto the USYD research team. A researcher (AF) will then contact the potential participant to explain the study, answer any questions, and obtain verbal agreement to participate. Participants will be emailed a link and individual login details to the DA website (www.bipolardecisionaid.com.au). Upon logging into the website and indicating their consent to participate, participants will be asked to complete baseline questionnaires (T0). Once baseline measures are completed, participants will be randomised (1:1) via an inbuilt site-generated random sequence to receive usual care either with (Intervention) or without access to the DA website (Control). Only participants in the Intervention group will be provided access the full DA website; Control participants will be provided restricted access to the login-page and questionnaires only. Usual care/attention control will comprise: access to the existing BDI webpage and downloadable factsheets on treatments for bipolar disorder (https://www.blackdoginstitute.org.au/clinical-resources/bipolar-disorder/treatment), as well as any information materials that BPII patients are routinely provided with, or advised to consult at their BDI appointment. Neither participants nor the trial researchers will be blinded to participants' group assignment.

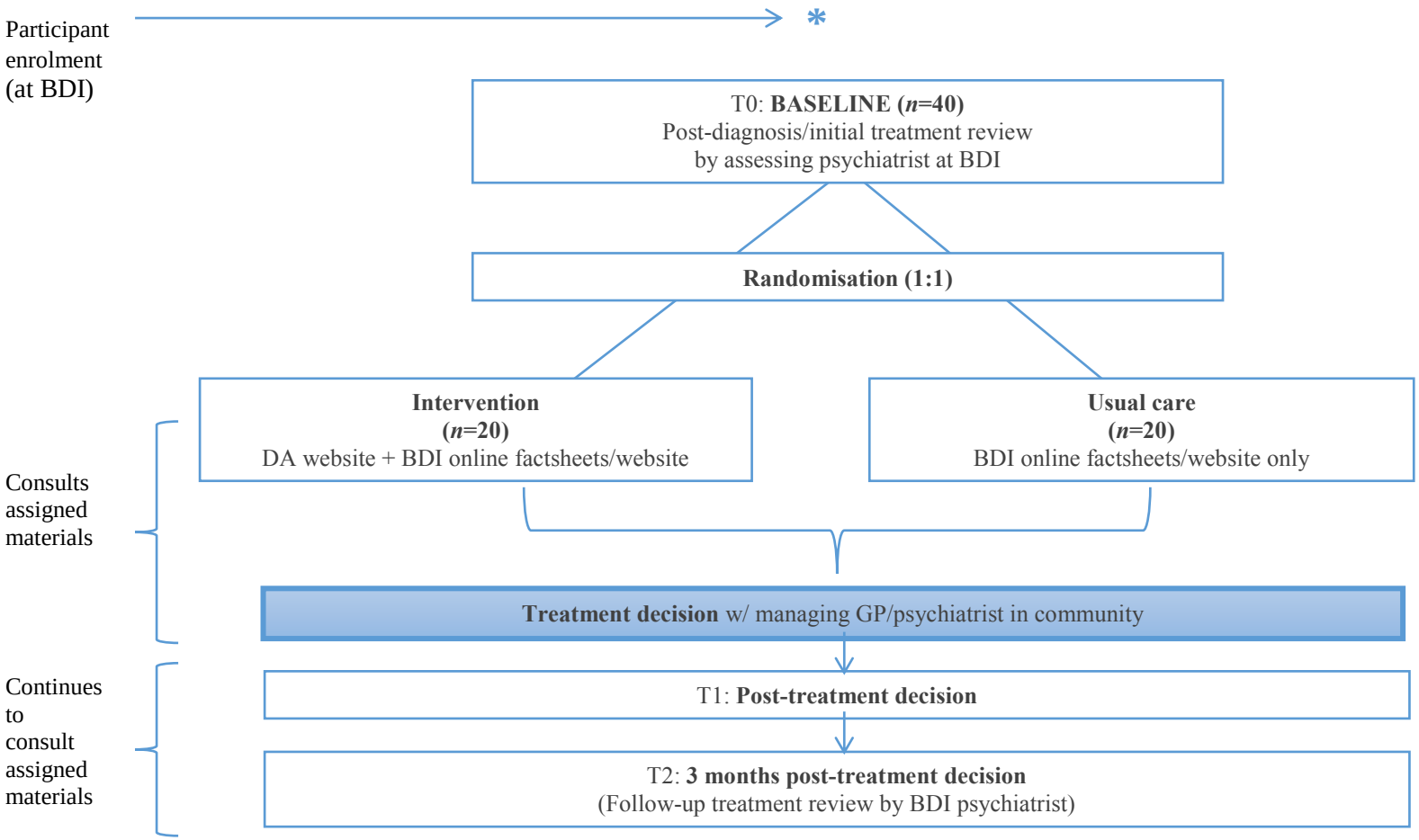


Figure 1. Flow-chart illustrating RCT procedure.

Four weeks after completing baseline measures (T0), during which time participants have unlimited access to the BDI and DA websites, participants will complete another set of questionnaires post-treatment decision (T1, ~ 3 weeks post-T0) and again at three months' follow-up (T2, ~ 3 months post T1) [43]. To ensure fidelity to the protocol and promote retention, participants will be sent email/text prompts and up to three weekly reminders (as needed) to complete the questionnaires. The proposed assessment times were chosen to coincide with important time points in patients' decision-making to ensure that they receive the intervention when most useful to them: i.e. when patients are first presented with treatment options by BDI psychiatrist (T0), shortly after they decide on the most appropriate treatment option/s with their managing GP/psychiatrist (T1), and review selected treatment with BDI psychiatrist (T2). In line with ethics requirements, any study participant may request to withdraw from the study at any time and without reason.

Materials and Measures

The DA

The DA explains the main available medication and adjunctive psychological treatment options for relapse prevention in BPII, based on current guidelines for first-line maintenance treatment in BPII [25] with specific sections for young adult patients and their families. It provides evidence-based, unbiased information, reviewed and professionally copy-edited for low health literacy levels. Lay information is presented using text and graphics on the rationale for and efficacy/known benefits/costs of each treatment option. Interactive values clarification exercises are included to assist patients/family to consider their preferences and deliberate on the benefits/costs of the different treatment options.

The content and format of the BPII DA was developed by the research team, and was informed by: best available clinical evidence and systematic review [26]; extensive qualitative interviews with key stakeholders (28 patients, 13 family, and 20 clinicians) [8-10]; and International Patient Decision Aid Standards (IPDAS) [27]. Initial drafts of the DA underwent iterative review by an expert advisory group, comprising DA experts (academic/research, *n*=2), patients with BPII (*n*=3) and their families (*n*=2) who had previously made or were making a treatment decision, and practising psychiatrists (*n*=2), clinical psychologists (*n*=2) and GPs (*n*=2) with at least 10 years'

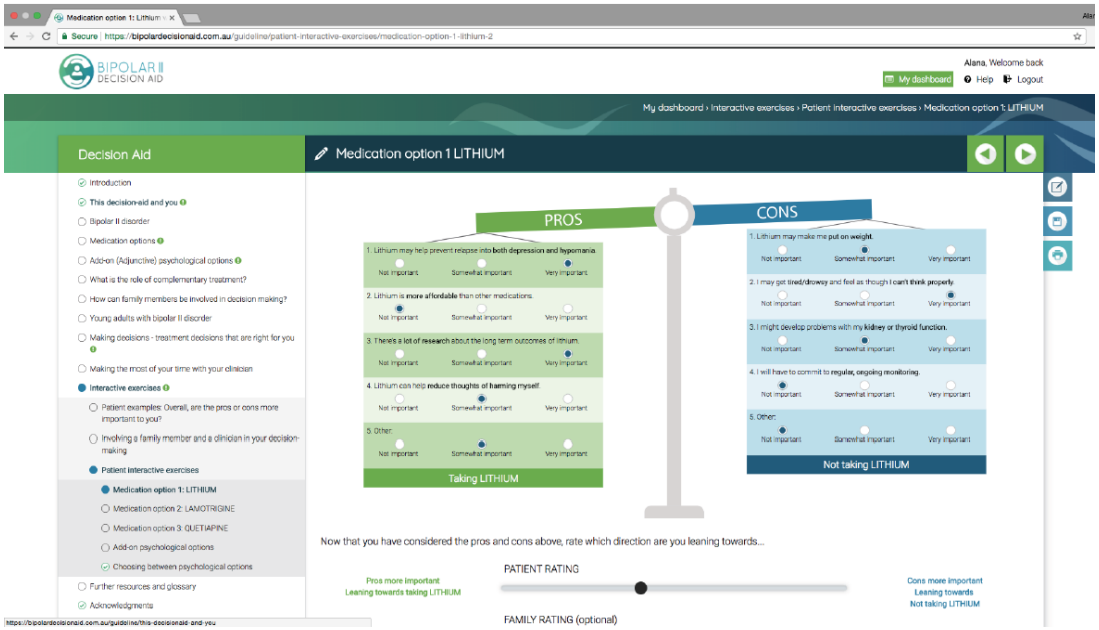
experience in treating mood and bipolar-related disorders in an outpatient setting. Moreover, proposed additions and modifications to the DA's young adult website content (e.g., self-management strategies for young adults with BPII [22], impact of alcohol/recreational drug use on BPII symptoms and medication) and design (e.g., additional images of young adults) were endorsed (75-100% agreement) via structured interviews with young adults with BPII (*n*=12) and their family (*n*=7). A final version of the DA was reviewed and approved by the expert advisory group.

The e-DA: Website design and development

The e-DA content was developed into a custom-designed interactive website by professional web-designers and developers experienced with developing evidence-based health resources. Web design/development included a systematic co-development process involving: prototyping and iterations to the user-interface and key features of the site, focus testing and usability/acceptability testing with potential end-users. Usability/acceptability testing with potential end users (2 patients, 2 family, 6 clinicians) identified and addressed suggested changes pertinent to the website content (additional information, clarifications, typographical errors, wording), format (improvements, errors) and usability (additional features, navigation issues) prior to commencing the RCT evaluation.

The final e-DA interactive website (www.bipolardecisionaid.com.au) contains a series of drop-down menus listing the information sections and respective subsections. After logging in and viewing the orientation page/dashboard, participants are free to access the information sections in whichever order they wish, to afford maximum flexibility. However, participants are required to first access/view all sections marked as containing essential information, before proceeding to the values clarification exercises (Figure 2), and then the questionnaires. These exercises are highly interactive and visually respond to participant input in real-time; for example, the weight-scale leans in one direction or the other as the participant rates the importance of treatment features. Patient preferences can then be saved and reviewed at a later date if desired. To ensure fidelity during the RCT evaluation and monitor adherence, participants' individual use of the website (page views, time spent on page etc.) will be tracked via the website's inbuilt analytics software. Additional information on participants' general use of the DA website (e.g., bounce rate; defined as the

percentage of site users who navigate away from the site after viewing only one page) will be tracked using Google Analytics (analytics.google.com; ID: 103244832).



Questionnaire measures

Participants will complete a series of validated and purpose-designed questionnaires at each time-point (T0, T1 and/or T2). For the time-point/s at which questionnaires will be administered see Table 1. Selected measures are drawn from previous RCTs of DAs in mental health conditions (depression: [14-16]; schizophrenia: [13]) and the broader DA literature [28].

Table 1. Administration of participant outcome measures

Measure	Baseline (T0)	Post-treatment decision (T1)	3 months' follow-up (T2)
Demographics/ Clinical information*	X		
Technology Acceptance Measure*		X	
Quality of the decision-making process			
Decisional Conflict Scale		X	
Subjective understanding of treatment*		X	X
Control Preferences Scale [a]		X	
Preparation for Decision-making Scale		X	
Decisional Regret Scale			X
Decision quality			
Objective knowledge of treatment*		X	X
Informed Choice Measure [b] *		X	X
Attitudes towards treatment*		X	X
Treatment choice/uptake*		X	
Safety			
Internal State Scale		X	X
Morisky Medication Adherence		X	X
State-Trait Anxiety Inventory		X	X

* Purpose-designed or adapted for use in study
[a] T0 and T1 administrations combined to assess concordance between preferred (T0) and actual (T1) involvement in treatment decision-making.
[b] Composite of objective knowledge of treatment (adequate levels, >50% possible total score), attitudes towards treatment, and treatment choice/uptake.

Quality of the decision-making process measures

Decisional conflict referring to participant perceptions of uncertainty, being uninformed, unsupported and having unclear values in decision-making will be assessed using the 16-item validated Decisional Conflict Scale (DCS; α's=0.78-0.92) [29].The DCS is considered superior to most other primary outcome measures used in DA trials with respect to its psychometric properties, face validity, and appropriateness or consistency with IPDAS decision process criteria [30, 31].

(Subjective) Understanding of treatment options and outcomes will be assessed via a purpose-designed questionnaire containing 15 Likert-type scale items. Items cover

domains stipulated by NHMRC guidelines for medical practitioners on providing information to patients [32].

Concordance between preferred and actual levels of decision-making involvement will be assessed via discrepancies between ratings on two administrations (pre-/post-decision) of the single-item adapted Control Preferences Scale [33, 34], as per [35].

Preparation for Decision-making Scale (10 items) will assess participants' perceptions of the DA's usefulness in helping them recognise that a decision needs to be made, and preparing them to make treatment decisions (α's=0.92-0.96) [36].

Regret or remorse associated with treatment decision will be assessed via the 5-item validated Decisional Regret Scale (α's=0.81-0.92) [37].

Decision quality measures

(Objective) Knowledge of treatment options and outcomes will be assessed via a purpose-designed questionnaire containing 14 forced-choice items, which relate to conceptual (gist; 9 items) and numerical (verbatim; 5 items) knowledge. As above, items are based on NHMRC guidelines [32].

Values-based, Informed-choice will be a purpose-designed composite measure adapted from Marteau et al.'s informed choice measure [38]. Values-based, informed-choice will indexed by participants who have adequate knowledge (>50% on *Objective Knowledge*, as per [39]) and who indicate a clear treatment preference/choice (e.g., take a certain medication or not) that aligns with their self-report attitudes to medication and psychological treatments [38]. To assess treatment attitudes, participants will rate their level of agreement on eight items, each of which contain a pair of opposing adjectives to describe either medication or psychological treatment (e.g., medication is 'important'/ 'unimportant'), as per [38].

Uptake of effective treatment options will be assessed by having participants indicate which treatment option they chose (e.g., medication with or without psychological treatment versus <u>*no*</u> medication +/- psychological treatment or unsure/delayed decision-making).

Other measures

Participant feedback on e-DA's acceptability (i.e., perceived ease of use, usefulness, attitudes towards using/user acceptance, and trustworthiness and balance of information) will be assessed via a 24-item questionnaire adapted from the Technology Acceptance Measure [40]. This measure also asks about the extent to which participants actually accessed the DA website.

Demographics and clinical information will be elicited at baseline via a purpose-designed self-report questionnaire which includes items on age, education, time of BPII diagnosis, current medication/psychological treatment/s (if any), and pattern of BPII symptoms (e.g., frequency and predominant mood episode type).

To determine that DA use is not associated with any harm/safety issues, participants will also complete additional validated self-report measures of *symptom severity* (16-item Internal State Scale, [41]), *state anxiety* (6-item short-form of the State-Trait Anxiety Inventory state scale, [42]) and *medication adherence* (8-item Morisky Medication Adherence Measure, [43].

Sample size and feasibility

Because the purpose of this study is not to test hypotheses about efficacy but to examine feasibility and acceptability, and to estimate efficacy parameters (e.g., effect size) to inform a future RCT, formal sample size calculation is inappropriate. Using guidelines provided by Hertzog [44], and based on the observation that decisions aid interventions typically produce large effects, we determined that a sample of 20 per group is sufficient. In 2014, 380 patients presented to the BDI with BPII. Of these patients, 61% who were approached to take part in research agreed to participate. It is estimated that 40% of BPII patients will be eligible to take part in this study (i.e., young adults out of acute episode), which equates to 152 eligible patients per year. To maximise recruitment and study feasibility, there are also provisions to expand recruitment to additional sites as needed. Estimating a 61% uptake rate (~ n=92), the research team envisages no difficulty in achieving the target of 40 participants within the planned 12-month active recruitment timeframe.

Planned statistical analyses

The focus of the analysis will be on description of the acceptability and feasibility outcomes, comparing the e-DA intervention group to the control (usual care) group. In addition to descriptive statistics (means and standard deviations for variables that are approximately continuous, medians and inter-quartile ranges for ordinal variables, and frequencies for categorical variables), we will also examine standardised mean differences. Group differences on all other outcomes will also be examined using standardised mean differences. These standardised mean differences will be used to partially inform sample size for the main RCT, although we will use them in conjunction with estimates of effect size from other research given the limitations of interpreting effect sizes in small studies [45].

Discussion

Most people who develop bipolar disorder in their lifetime will have experienced symptoms by age 25 [46]. As a chronic, relapsing and highly burdensome illness, BPII relies heavily on patients implementing a self-management approach of taking prophylactic medications, monitoring symptoms and making behavioural changes in response to symptoms to reduce relapse risk [47]. As such, it is crucial that young adults with BPII are encouraged to adopt an active role in their illness management as early as possible, preferably from the point of diagnosis. Indeed, most patients with BPII, especially young adults and those with a recent diagnosis, prefer a more active role in their treatment decisions than they currently report experiencing in clinical practice. Further, a lack of knowledge and involvement in one's own treatment has been found to compromise optimal BPII management, resulting in poorer patient outcomes [8-10, 26, 48-50].

Of note, the current e-DA recognises that people with BPII are faced with unique and more complicated treatment decision-making challenges. For example, in comparison to depression, schizophrenia and BPI disorder, the evidence base for treatment efficacy in BPII is considerably more limited [25]. Much of the evidence for medication and psychological treatment efficacy in BPII is derived from studies predominantly with BPI. In BPI, the benefits of mood stabilisers are clear because they prevent psychotic, manic episodes which interfere with patients' psychosocial functioning. However, in BPII, there is an absence of psychotic symptoms [51][[52],

and patients typically feel that hypomanic episodes help rather than impair perceived psychosocial functioning [53]. As such, the trade off with high potential side-effects of mood-stabilisers is less clear in BPII. With greater ambiguities in the benefits of prophylactic medications in BPII, patients are more likely to discontinue treatment, placing them at heightened risk for relapse.

To address these clinically important and persistent unmet decision-making needs among young adults, this feasibility study will evaluate a world first, evidence-based online decision-support resource, a DA website, for young adults with BPII who are deciding on treatment options for relapse prevention. The e-DA targets both the *quality of the decision-making process* and *quality of the decision made*, two distinct yet related constructs of decision-making quality [28]. In terms of decision-making quality, it is expected that the e-DA will be associated with effects indicating that young adults: i) feel well-informed, certain and supported, and clear about their values in treatment decision-making, ii) achieve their preferred level of involvement in treatment decision-making, and iii) feel prepared to make treatment decisions. In terms of decision quality, it is expected that the e-DA will assist young adults to: i) be knowledgeable about treatment options and outcomes, and ii) make informed treatment decisions that are in line with the best available clinical evidence, as well as their preferences for treatment.

Both the feasibility and implementation of research findings into clinical practice have been considered from the inception of this study. Firstly, the proposed feasibility study is a necessary though frequently overlooked step in the evaluation of psychosocial interventions [54]. This study will identify any potential feasibility and acceptability issues with implementing the DA into practice and provide the opportunity to rectify these prior to conducting a future RCT in a larger, multi-site study. Further, once efficacy is established, the DA's online delivery will: i) promote its rapid and widespread dissemination, ii) ensure the information remains in step with best available clinical evidence, and iii) promote the DA's uptake among young adults, who are among the most "Internet-connected" Australians (~98%) [55] and tend to seek their health information online [56].

Also relevant to implementation, is the effective and ongoing engagement of key stakeholders, which has been integral to the development and evaluation of this DA website. An effective and ongoing stakeholder-engagement approach to DA development is critical to ensuring the DA's relevance and usefulness among young adults with BPII [57]. The initial need for an online DA derives from the unmet decision-support needs identified by patients, their families, and clinicians for patients to take a more active and informed role in their BPII management. A series of qualitative studies contextualised the nature of these needs and identified informational priorities among young adults with BPII [8-10], as did consultation with key stakeholders as part of an expert advisory group.

Finally, the timing of DA delivery, i.e., shortly after patient diagnosis, is consistent not only with patient preferences but also with the usual delivery of care, when clinicians commonly introduce treatment options and encourage patients to become more informed about, and consider, their preferences for treatment options. If found to be efficacious, such timing will facilitate the DA's successful implementation into current mental health services.

The e-DA website represents a resource that can be readily integrated into routine patient care to foster a more active and informed role in treatment decisions for young adults with BPII. Mental health services have been slow to enact SDM, even though this approach is widely endorsed [7], and is already commonplace in medical settings, such as oncology. This is somewhat paradoxical, as patients with chronic mental illnesses, such as BPII, often need and want to play a more active role in their own self-management than patients with cancer, for example, because patient education, medication adherence and lifestyle changes are strongly related to long-term relapse risk and functional impairments. Therefore, the proposed e-DA would not only have important implications for BPII treatment, it could also be adapted to other chronic mental illnesses commonly affecting young adults where self-management and decision-making involvement are also important, such as anxiety. Greater adoption of SDM via dissemination of decision-making resources in mental health settings has the potential to significantly enhance the management and outcomes of many psychiatric illnesses.

Trial status

Active recruitment (First participant recruited 07/12/2017).

List of abbreviations

ANZCTR = Australian and New Zealand Clinical Trials Registry; BDI = Black Dog Institute; BPII = bipolar II disorder; DA = decision-aid; RCT = Randomised Controlled Trial; SDM = Shared Decision-making, USYD = The University of Sydney.

Declarations

Ethics approval and consent to participate

Ethics approval to conduct this study (including participant consent procedures) was obtained from the University of Sydney Human Research Ethics Committee (2016/763) and the Black Dog Institute Research Advisory Group (2016011 Fisher). The University of Sydney is the trial sponsor as per CONTRACT_RESEARCH/48_1 (signed 1/9/2016).

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors of this protocol disclose no financial conflict of interest pertinent to this study. The authors of this manuscript do not receive funding from any for profit pharmaceutical, psychological or device manufacturer, nor do they receive any royalties or other monetary benefits, directly or indirectly, from the use of decision-aids. No contractual agreements limit authors access to data, and as such, all authors will have access to the final dataset. The Centre for Medical and Evidence-based Decision-making (CeMPED), with whom AF and IJ are affiliated, makes effective decision-aids available online free of charge at: http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml

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Authors' contributions

AF, IJ, LS contributed to the design of the study, and the grant application for funding. AF conceived and designed the study and wrote the first draft of the manuscript. All authors made critical revisions to subsequent drafts of the manuscript. All authors approved the final version of this manuscript.

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Appendix H

MAKING TREATMENT DECISIONS THAT ARE RIGHT FOR YOU…

A decision-aid to help people with Bipolar II Disorder and their families make decisions about treatment

Contents

How can this booklet help you to make decisions about your treatment?

What is the purpose of this booklet?

The purpose of this booklet is to help people with bipolar II disorder (BPII) who are in partial or full **remission** to make an informed decision about treatment. The information may help people to decide:

- *between* available medication options
- *whether or not* to have add-on (**adjunctive**) psychological treatment.

What information does this booklet include?

There is information about:

- BPII and its symptoms
- the treatments available
- pros (benefits) and cons (risks/side effects) of each option
- questions that you may like to ask your clinician
- advice on how to make a decision that will best suit your values and goals
- examples of how other people in similar situations have approached treatment decisions.

This booklet is designed to add to, but *not replace*, discussions that you will have with your psychiatrist, GP or psychologist and your family about the options available to you.

Depending on your life situation, your **clinician** may not discuss all the options that appear in this booklet, or might discuss other options. *This booklet is another resource you can use to ensure that you are making a decision that is right for you.*

What is bipolar II disorder?

This booklet is about BPII, which is a type of mental health condition that affects a person's mood, energy, thoughts and behaviour. A person who has BPII experiences mood "cycles", involving "lows" (**depression**) and "highs" (**hypomania**). These "cycles", especially lows, usually occur a number of times in a person's lifetime.

For more information about BPII, including the clinicians who are involved in BPII treatment, see page 10.

What treatment options are available?

Mental health professionals can recommend long-term treatment for BPII. The goals of long-term treatment are to:

- keep the person well
- prevent "cycles"
- reduce the impact of "cycles", to improve quality of life.

There are many available treatment options to prevent relapse in BPII. For most people, medication is the main treatment and psychological treatment is an add-on (also called an **adjunct/ adjunctive** treatment). Psychological treatment is not meant to replace medication.

There are different types of medication and psychological treatments to choose from depending on your situation. Each treatment option has its own possible benefits, side effects and risks.

Your decisions about medication and psychological treatments are not "final". You will probably check in with your clinician about how treatment is working and revisit your decisions a number of times.

Who is this booklet for?

This booklet is for people who:

- have recently been diagnosed with BPII
- are showing few, mild symptoms or no symptoms of BPII (known as being in partial or full **remission** from depression and/or hypomania)
- are seeing a doctor and considering treatment options *to maintain wellness and prevent relapse*.

You may or may *not* already be on medication, for example, antidepressants.

The information may also be helpful to a family member or other support person who is helping you make a decision about treatment.

This booklet is *not* meant for people who aren't seeing a **clinician** to discuss treatment options, and it is *less helpful* for people who are currently experiencing severe or intense (**acute**) symptoms of depression and/or hypomania.

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* The following sections contain a lot of clinical information and new terms. If you are finding it difficult to read all at once, it may helpful to come back and re-read it at another time. There is also a glossary of all **bolded** terms on page 87.

Bipolar II disorder

What are the types of bipolar disorder?

Bipolar disorder is a mental health condition that affects a person's mood, energy, thoughts and behaviour.

There are two main types: bipolar I disorder (BPI) and bipolar II disorder (BPII). They are both lifelong conditions that involve **mood cycles** or mood swings, where a person experiences 'lows' (**depression**) and 'highs' (**hypomania**/**mania**).

These mood swings can last a number of days (four or more days for hypomania) to a number of weeks (two or more weeks for depression).

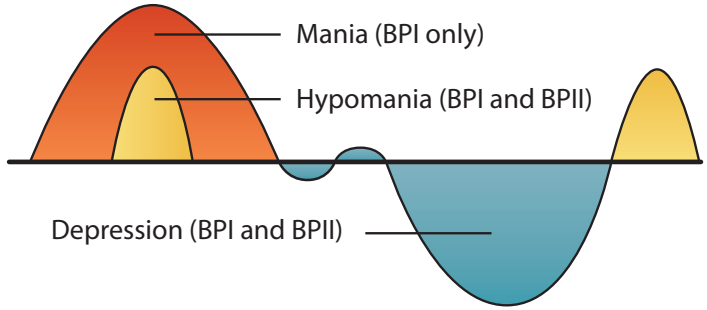
A person with BPI or BPII can also experience **mixed states**, meaning they have symptoms of both depression and hypomania at the same time.

For more information on 'lows' and 'highs', see page 12.

How is bipolar II disorder different from bipolar I disorder?

People with BPI and BPII disorder both experience a combination of depressive and hypomanic episodes. However, people diagnosed with BPI disorder experience **full manic episodes**, which are longer and more severe 'highs'. People diagnosed with BPII disorder do not experience full manic episodes.

Diagram shows the types of 'low' and 'high' episodes in BPI and BPII.



	Bipolar I disorder (BPI)	Bipolar II disorder (BPII)
'Lows'	• Similar in both. May include psychotic experiences.	• Similar in both. **Unlikely** to include **psychotic experiences.**
'Highs'	• Longer, more severe; **includes mania** • Difficulties carrying out work, social, and family commitments as normal • May require hospitalisation • May include psychotic experiences	• Shorter, milder • Can usually carry out work, social, and family commitments as normal or with minimal disruption • **Does not** usually require hospitalisation. • **No** psychotic experiences

People with BPII disorder tend to experience more depressive episodes and have shorter recovery time between episodes, compared to BPI disorder. Although the highs are shorter and milder in BPII disorder, it is still a serious condition and can affect a person's life.

What do 'lows' and 'highs' look like?

'Lows' or **depression** usually lasts from a couple of weeks to a couple of months. During this time, you may experience low mood (*sadness or flatness*) and a *loss of interest or pleasure* in most things, as well as:

- changes in appetite, such as having no appetite or eating too much and losing or gaining weight
- getting too little sleep or sleeping too much
- feeling physically slowed down, tired or having little energy
- feeling troubled or nervous (agitated)
- feeling hopeless and helpless
- having difficulties concentrating
- having thoughts of suicide.

'Highs' or **hypomania** usually lasts from a few days to a few weeks. During this time, you may feel *excessively happy, elevated or irritable* or more *'wired'* and *'hyper'* than normal, as well as:

- feeling more confident
- needing less sleep but still feeling rested
- being more talkative
- having racing thoughts and ideas which flit from topic to topic
- having difficulties concentrating
- feeling physically agitated or overly driven to pursue goals
- being overly involved in activities that feel good or are pleasurable (such as sex or taking drugs) despite possible negative outcomes.

What are the mood cycles like in bipolar II disorder?

In 2003, Judd and colleagues found that over a 20 year period the average person with BPII disorder experiences 2-3 cycles per year (both with and without treatment). Over the long term, 'lows' are much more common than 'highs'.

The average person with BPII disorder spends:

- around 24 weeks of the year (46%) without any symptoms.
- around 19 weeks of the year (36%) experiencing symptoms of depression.
- around 1 week of the year (1-2%) experiencing symptoms of hypomania.
- around 8 weeks of the year (17%) experiencing mixed or mild symptoms.

It is important to note that these symptoms are averages and do not reflect a person's individual experience.

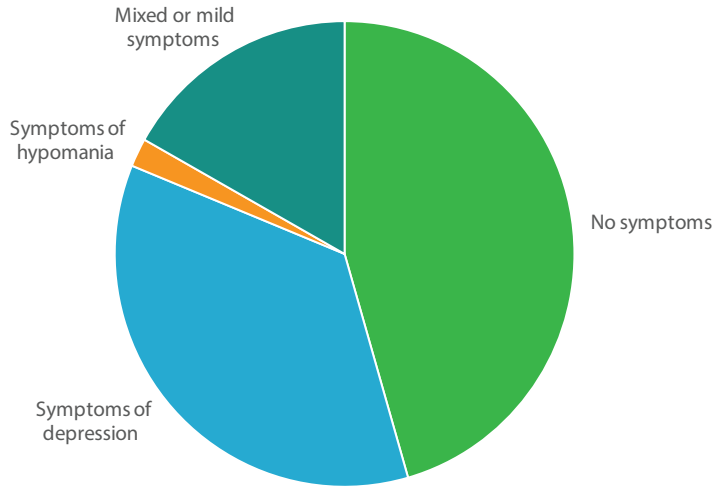


Diagram shows the percentages of weeks per year that the average person with BPII spends with symptoms.

For most people diagnosed with BPII disorder, mood cycles are **recurrent**, meaning they happen repeatedly over time. Between episodes, you may be mostly well and/or symptom free (**euthymic**), or you may experience mild symptoms (**subsyndromal symptoms**).

However, some people experience one cycle after another, which is a more long-term (**chronic**) pattern of illness. People who relapse four or more times in a year have what is known as **rapid cycling** bipolar disorder.

How common is bipolar II disorder?

There may be different criteria used to diagnose BPII disorder, so estimates on how common BPII is vary.

People can be diagnosed at different ages. Most people experience their first episode in their early 20s, but might not be diagnosed until much later.

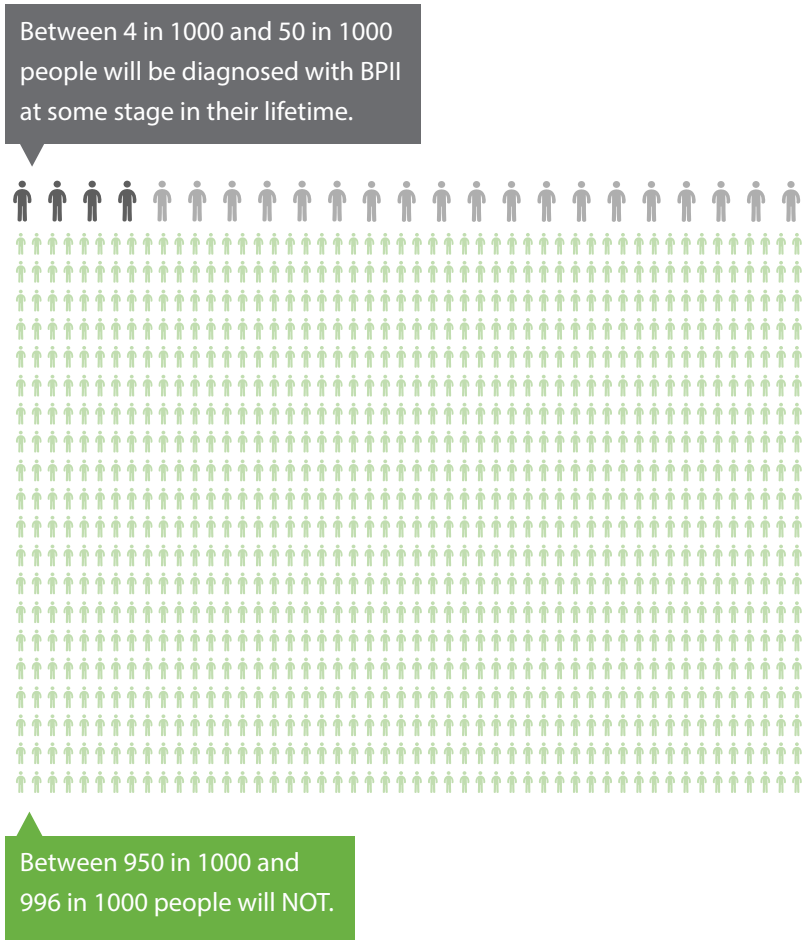
Evidence suggests that between **4 in 1000** and **50 in 1000 people** will be diagnosed with BPII at some stage in their lifetime.

Which clinicians are involved in treating bipolar II disorder?

It is likely treatment for BPII will involve three main health professionals: a psychiatrist, a GP, and a psychologist. There are important differences between these clinicians.

A psychiatrist is a medical doctor who has done extra training to specialise in mental health. They can prescribe medicines and can help a GP to manage medications. In the treatment of BPII, psychiatrists often confirm diagnosis.

A GP, like a psychiatrist, is a medical doctor but usually has limited training in mental health. GPs can also prescribe medicines and



are usually involved in the general, day-to-day management of medications. In the treatment of BPII, GPs often coordinate care and provide referrals to other clinicians or services.

A psychologist has qualifications in psychology and is *not* a medical doctor. Like psychiatrists, psychologists have also done training to specialise in mental health, but *cannot* prescribe medications. In the treatment of BPII, psychologists often help people to develop strategies to stay well and reduce the impact of mood episodes when they occur.

MEDICATION OPTIONS

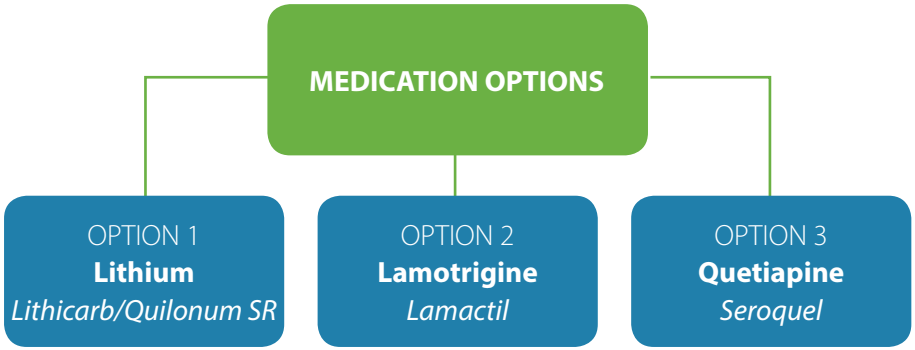
For most people with a diagnosis of bipolar II disorder (BPII), long-term medication is the main treatment for staying well and preventing relapse.

This section will help you to understand the different medication options recommended for Bipolar II disorder.

Which medications are recommended in bipolar II disorder?

Most available guidelines only give recommendations on treating bipolar I (BPI) disorder. This is because most high-quality research on treatments has been done in patients with BPI.

Only one set of up-to-date guidelines includes recommendations about medication to prevent relapse of BPII. There is evidence for three types of common medications:



These three options are presented in detail in the following sections. For a summary of the advantages and disadvantages of these medication options, see pages 40-41.

There is a similar amount of evidence for the three medication options described in this booklet. Because only very few studies have looked at medication in BPII separately, recommendations about medication are based on a combination of research and what most clinicians agree are the most appropriate treatment options (**clinical consensus**).

However, these are not your only medication options. Your clinician may also recommend:

- a combination of these medications
- another mood-stabilising medication (e.g. sodium valproate or olanzapine)
- antidepressant medication (e.g. fluoxetine or sertraline).

The medication option your clinician recommends to you will depend on your individual needs and life situation.

How effective will medication be for me?

The following sections explain some of the possible benefits and risks of the medication options.

Before trying any particular medication, it is impossible to know if it will be effective at preventing relapse *for you as an individual*. Instead, your clinician may talk to you about the general chances (or likelihood) of a certain outcome. To give you an idea about how this might be expressed, here are some familiar examples:

- About **92 in 100** trains will run on time in Sydney.
- About **80 in 100** people will lodge their tax returns to the Australian Tax Office on time.
- About **60 in 100** overseas trips made by Australians are for holidays.
- About **25 in 100** babies born in Australia today will live to be 100 years old.
- In 40 years time, less than **11 in 100** people will live in areas outside the four major capital cities in Australia.
- About **1-2 in 100** pregnant women in Australia will give birth to twins in any year.

Statistics information is about a group of people, not you as an individual. You may be asked consider the statistics about a certain medication and the information about it before deciding to try it or not.

Finding the right medication

It may take some time to find the 'right' medication option for you. You will probably check in with your clinician about how treatment is working and revisit your decision a number of times.

If you decide to take medication, it is important that you take it consistently as that it can be effective and prevent relapse as much as possible. Staying on medication long-term (adherence) can be challenging, but it can help to set habits about taking the medication, develop a good relationship with your clinician and consider some psychological treatments (see pages 42-43).

MEDICATION OPTION 1

LITHIUM

"My wife was put on lithium and things progressed very quickly into the very positive ... She's been stable…"

"To me, lithium kind of has bad associations ... 'doped up' people in mental wards, that sort thing."

What is lithium?

- Lithium is also known as *Lithicarb* or *Quilonum SR*. It is one of the most widely-used and studied medications for treating bipolar disorder.
- Research shows that lithium helps strengthen nerve cell connections in parts of the brain involved in regulating mood, thinking and behaviour.
- The dose prescribed is based on your blood levels. There is a working (therapeutic) range, which is 0.6-0.8 mmol/litre.
- Lithium is the oldest mood-stabiliser. New medications are often compared or measured against it.
- It acts on a person's central nervous system (brain and spinal cord) to "stabilise" mood.

When is lithium recommended?

Lithium may be better suited to people who experience:

- clearly defined episodes of **hypomania** and **depression**
- long periods of wellness
- normal levels of functioning between episodes
- more severe or more frequent highs than lows
- a tendency towards suicidal thoughts or behaviours.

How effective is lithium at preventing relapse?[1]

1) One group of studies looked at how effective lithium is at preventing any type of relapse.

When comparing people taking lithium versus people taking no medication, these studies show that:

ANY TYPE OF RELAPSE

LITHIUM	NO MEDICATION
67 in100 people will **NOT RELAPSE**	**43 in100** people will **NOT RELAPSE**
	
33 in100 people taking lithium will **RELAPSE** within 3 months up to 2 years	**57 in100** people taking no medication will **RELAPSE** within 3 months up to 2 years

2) Another group of studies looked at how effective lithium is at preventing relapse into depression.

When comparing people taking lithium versus people taking no medication, these studies show that:

RELAPSE INTO DEPRESSION

LITHIUM	NO MEDICATION
70 in100 people will **NOT RELAPSE** into depression	**66 in100** people will **NOT RELAPSE** into depression
	
30 in100 people taking lithium will **RELAPSE** into depression within 3 months up to 2 years	**34 in100** people taking no medication will **RELAPSE** into depression within 3 months up to 2 years

1 Meta-analysis based on randomised controlled trials (RCTs) of relapse in people with bipolar I and II disorders from 3 months up to 3 years. (Lithium dose: to achieve 0.5-1.5 mEq/l).

3) Another group of studies has looked at how effective lithium is at preventing relapse into hypomania.

When comparing people taking lithium versus people taking no medication, these studies show that…

RELAPSE INTO HYPOMANIA

LITHIUM	NO MEDICATION
84 in100 people will **NOT RELAPSE** into hypomania	**73 in100** people will **NOT RELAPSE** into hypomania
	
16 in100 people taking lithium will **RELAPSE** into hypomania within 3 months up to 2 years	**27 in100** people taking no medication will **RELAPSE** into hypomania within 3 months up to 2 years

Studies show that lithium is better than no medication at preventing all types of relapse. It appears to be good at preventing both depression and hypomania, but it may be better at preventing hypomania than depression.

What are the possible ADVANTAGES of taking lithium?

- Lithium is effective at preventing both depressive and hypomanic/mixed relapse.
- Lithium can reduce the risk of suicidal thoughts and behaviours. These anti-suicidal properties are unique to lithium.
- There is less weight gain associated with lithium than other medications (for example, quetiapine and olanzapine).
- Most people are able to continue taking lithium even if they do experience some side-effects. Around 84 in 100 people continued taking lithium in a study lasting 18 months.
- Lithium is subsidised by the PBS (Pharmaceutical Benefits Scheme), meaning that the Australian government covers part of the cost of this medication to make it more affordable. Check your eligibility for this scheme via: www.pbs.gov.au/info/general/faq#WhoiseligibletoreceivebenefitsunderthePBS

What are the possible DISADVANTAGES of taking lithium?

Short-term

- Lithium may take longer to take effect (2-4 weeks) compared to other medications for BPII.
- Within the first 4 months of starting/increasing lithium, people commonly experience:

Dry mouth	**53 in 100 people** (53%)
Increased thirst	**49 in 100 people** (49%)
Nausea/vomiting	**47 in 100 people** (47%)
Upset stomach	**43 in 100 people** (43%)
Increased need to urinate (pee)	**33 in 100 people** (33%)
Cognitive 'dulling' (i.e., difficulties remembering, slowed down thinking)	**20-25 in 100 people** (20-25%)

In general, these side effects tend to pass.

Mid-term

- Within the first 18 months of taking lithium to prevent relapse, people *also* may experience:

Headache	**19 in 100 people** (19%)
Tremor	**17 in 100 people** (17%)
Sleepiness/drowsiness or fatigue	**13 in 100 people** (13%)
Weight gain of ≥ 7% of body weight *	**10-12 in 100 people** (10-12%)

*For a person weighing 70kg = ~ 5kg gain

For most people, these symptoms are mild to moderate in intensity and do not stop them taking lithium.

Long-term

- **Regular, ongoing monitoring** is needed for:
  - blood **serum levels,** to ensure they remain in the therapeutic range and avoid lithium toxicity.
  - **kidney function**,
  - **thyroid function** and
  - **weight gain**.

This usually involves urine and blood tests, and body weight measurement every 3-6 months.

- Over the long-term (5+ years on average) approximately **13-14 in 100** people taking lithium will experience **clinical hypothyroidism.** This means the thyroid gland is under-active. This condition can be treated with thyroid hormone replacement medication.
- Over the long-term (20+ years on average) about **1-2 in 100** people taking lithium will experience **chronic kidney disease**.
- About **5 in 1000** people taking lithium will experience **complete kidney (renal) failure**. This is uncommon.

With regular, ongoing monitoring you can greatly reduce the risk of possible long-term side effects.

MEDICATION OPTION 2

LAMOTRIGINE

"Lamotrigine is a relatively new drug, it has a good evidence base. We felt very relieved and positive about it."

"The thing that bothers me about lamotrigine ... is a very serious skin condition and I think: what sort of chemical am I putting into my body?"

What is lamotrigine?

- Lamotrigine is also known by its brandname *Lamictal*. It is a type of anticonvulsant or antiepileptic medication.
- Originally, studies found that lamotrigine controlled seizures in epilepsy but studies also found that it is effective at stabilising mood in bipolar disorder.
- Research shows that lamotrigine changes brain chemicals associated with mood.
- To help prevent relapse, the usual dose for lamotrigine is 50-200 mg/day.

When is lamotrigine recommended?

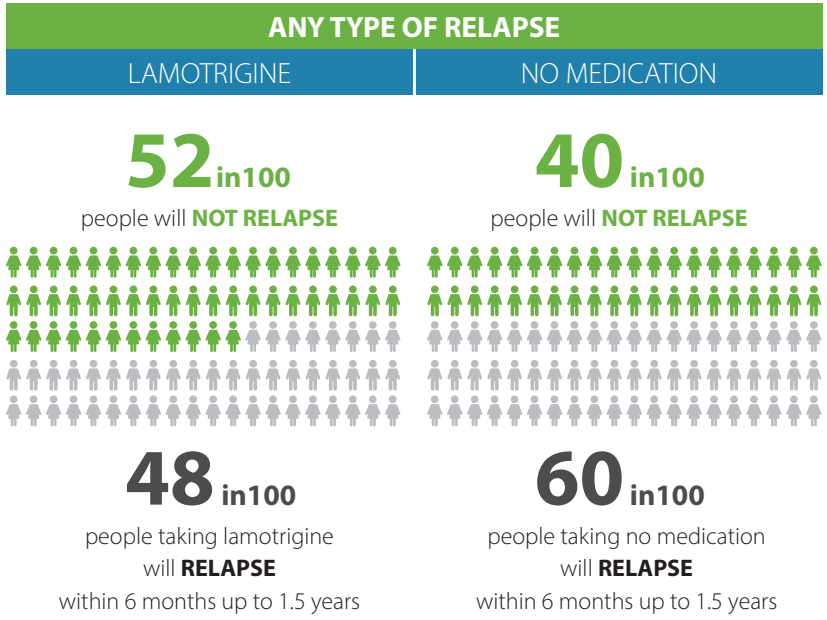
Lamotrigine is best suited to people with BPII who experience:

- more severe and more frequent lows than highs
- episodes of **depression** and **hypomania** that are not clearly defined (non-distinct)
- mixed symptoms of depression and hypomania at the same time (**mixed episode**)
- at least four episodes of depression and/or hypomania in a year (**rapid cycling**).

How effective lamotrigine at preventing relapse?[2]

1) One group of studies looked at how effective lamotrigine is at preventing any type of relapse.

When comparing people taking lamotrigine versus people taking no medication, these studies show that:



2 A meta-analysis based on studies of relapse in people with bipolar I and II disorders from 3 months up to 3 years (Lamotrigine dose: 100-500mg/day).

2) Another group of studies looked at how effective lamotrigine is at preventing relapse into depression.

When comparing people taking lamotrigine versus people taking no medication, these studies show that:

RELAPSE INTO DEPRESSION

LAMOTRIGINE	NO MEDICATION
71 in100 people will **NOT RELAPSE** into depression	**62 in100** people will **NOT RELAPSE** into depression
	
29 in100 people taking lamotrigine will **RELAPSE** into depression within 6 months up to 1.5 years	**38 in100** people taking no medication will **RELAPSE** into depression within 6 months up to 1.5 years

3) Another group of studies looked at how effective lamotrigine is at preventing relapse into hypomania.

When comparing people taking lamotrigine versus people taking no medication, these studies show that:

RELAPSE INTO HYPOMANIA

LAMOTRIGINE	NO MEDICATION
81 in100 people will **NOT RELAPSE** into hypomania	**77 in100** people will **NOT RELAPSE** into hypomania
	
19 in100 people taking lamotrigine will **RELAPSE** into hypomania within 6 months up to 1.5 years	**23 in100** people taking no medication will **RELAPSE** into hypomania within 6 months up to 1.5 years

Studies show that lamotrigine is better than no medication at preventing all types of relapse. It appears to be better at preventing depression than hypomania.

What are the possible ADVANTAGES of taking lamotrigine?

- Lamotrigine is effective for preventing depressive relapse, which is the most common mood state in BPII.
- Lamotrigine has few side effects compared to other medications for BPII. It does NOT cause:
  - weight changes – lamotrigine is considered a 'weight neutral drug'
  - cognitive 'dulling' – people do not tend to have trouble concentrating, focussing or remembering things
  - sleepiness/drowsiness – people taking lamotrigine may feel more energetic
  - problems with sexual functioning – this is reported by less than 1 in 100 people taking lamotrigine.
- Most people are able to continue taking lamotrigine even if they do experience side effects. In a study lasting 18 months, around 91 in 100 people continued taking lamotrigine for the duration of the study.
- Lamotrigine does not require regular ongoing monitoring over the long-term.

What are the possible DISADVANTAGES of taking lamotrigine?

- Lamotrigine is not currently subsidised by the PBS (Pharmaceutical Benefits Scheme) for BPII, meaning that this medication costs more than some others available.

Short-term

- It is unclear if lamotrigine is effective at preventing hypomanic/mixed episodes, meaning that you may need to take add-on medication/s to deal with these symptoms.

- Within the first 2 months of starting lamotrigine, people may experience:

Benign (or non-serious) rash	**8-9 in 100 people** (8-9%)
Serious (**Steven-Johnson's** like) rash.	**1 in 10,000 to 1 in 1000 people** (0.01-0.1%)

Rash requiring hospitalisation and stopping medication. This rash is rare but can cause death (<5 in 100 people who develop it and do not stop medication or receive proper treatment).

- When starting lamotrigine, it may take 2-3 months to reach the working (therapeutic) dose. Dose increases need to be done slowly to avoid developing rash.
- Within the first 4 months of taking lamotrigine, people may experience side effects, such as headache, nausea/vomiting, infection and dizziness.

In the first 2 months of starting lamotrigine, it is important to remain alert as most rashes develop during this time.

If you notice any signs of a rash, don't take your next dose of lamotrigine and immediately contact your GP or psychiatrist for consultation. This may help you to avoid the complications associated with serious rash.

Mid-term

- Within the first 18 months of taking lamotrigine to prevent relapse, people can commonly also experience:

Headache	**18 in 100 people** (18%)
Nausea/vomiting	**17 in 100 people** (17%)
Infection	**12 in 100 people** (12%)
Dizziness	**8 in 100 people** (8%)

For most people, side effects in the medium term are mild to moderate in intensity and do not stop them taking lamotrigine.

MEDICATION OPTION 3

QUETIAPINE

"For me, quetiapine has less scary side effects … I was more inclined to trust it."

"With quetiapine, I found it really successful [in stabilising mood], but it made me put on a significant amount of weight."

What is quetiapine?

- Quetiapine is also known by its brand name *Seroquel*. It is a newer (second generation) type of antipsychotic medication.
- Even though quetiapine is an 'antipsychotic' it can stabilise mood and prevent relapse in conditions like BPII, where the person does *not* experience psychotic episodes.
- Quetiapine helps to stabilise mood by restoring the balance of natural substances (neurotransmitters) in the brain.
- To help prevent relapse, the usual dose for quetiapine is 10-25 mg daily.

When is quetiapine recommended?

Quetiapine may be a good 'all-rounder' medication for people with BPII disorder who experience:

- a similar number of 'lows' and 'highs'
- depressive and hypomanic symptoms at the same time (**mixed episodes**)
- at least four episodes of depression and/or hypomania in a year (**rapid cycling**)
- are not sleeping enough

How effective quetiapine at preventing relapse?[3]

1) One group of studies looked at how effective quetiapine is at preventing any type of relapse.

When comparing people taking quetiapine versus people taking no medication, these studies show that:

ANY TYPE OF RELAPSE

QUETIAPINE	NO MEDICATION
77 in100 people will **NOT RELAPSE**	**53 in100** people will **NOT RELAPSE**
	
23 in100 people taking quetiapine will **RELAPSE** within 1 up to 2 years	**47 in100** people taking no medication will **RELAPSE** within 1 up to 2 years

2) Another group of studies looked at how effective quetiapine is at preventing relapse into depression.

When comparing people taking quetiapine versus people taking no medication, these studies show that:

RELAPSE INTO DEPRESSION

QUETIAPINE	NO MEDICATION
89 in100 people will **NOT RELAPSE** into depression	**75 in100** people will **NOT RELAPSE** into depression
	
11 in100 people taking quetiapine will **RELAPSE** into depression within 1 up to 2 years	**25 in100** people taking no medication will **RELAPSE** into depression within 1 up to 2 years

3 A meta-analysis based on RCT studies of relapse in people with bipolar I and II disorders from 3 months up to 3 years (Quetiapine doses 300-800mg/day).

3) Another group of studies looked at how effective quetiapine is at preventing relapse into hypomania.

When comparing people taking quetiapine versus people taking no medication, these studies show that:

RELAPSE INTO HYPOMANIA

QUETIAPINE	NO MEDICATION
88 in100 people will **NOT RELAPSE** into hypomania	**78 in100** people will **NOT RELAPSE** into hypomania
	
12 in100 people taking quetiapine will **RELAPSE** into hypomania within 1 up to 2 years	**22 in100** people taking no medication will **RELAPSE** into hypomania within 1 up to 2 years

Studies show that quetiapine is better than no medication at preventing all types of relapse. It appears to be good at preventing both depression and hypomania relapse.

What are the possible ADVANTAGES of taking quetiapine?

- Quetiapine is effective at preventing both depressive and hypomanic/mixed relapse.
- It is possible to reach the working (therapeutic) dose of quetiapine more quickly than with other medications for BPII, such as lamotrigine.
- Most people are able to continue taking quetiapine even if they experience side effects. In a study lasting one year, about 92-94 in 100 people continued taking quetiapine. However, the side effects of quetiapine depend on the dose taken.

What are the possible DISADVANTAGES of taking quetiapine?

- Quetiapine is not currently subsidised by the PBS (Pharmaceutical Benefits Scheme) for BPII, meaning that this medication costs more than some others available.

Short-term

- Within the first 2-3 months of taking quetiapine, people experience the following side effects:

Sleepiness/drowsiness	**17-19 in 100 people** (17-19%)
Cognitive 'dulling' (i.e., difficulties remembering, slowed down thinking)	**5-16 in 100 people** (5-16%)
Weight gain ≥ 7% of body weight*.	**3-12 in 100 people** (3-12%)

*For a person weighing 70kg = ~ 5kg gain.

Weight gain is more common when taking higher doses of quetiapine and generally plateaus within first 10 weeks of treatment.

Mid-term

Within the first year of starting quetiapine, people may experience the following side effects:

Changes to their metabolism (e.g. blood sugar and cholesterol levels)*. * It is unclear if these changes put people at higher risk of type II diabetes.	**7-15 in 100 people** (7-15%)
Weight gain ≥ 7% of body weight*. * For a person weighing 70kg = ~ 5kg gain.	**6-10 in 100 people** (6-10%)
Headache	**11-14 in 100 people** (11-14%)
Sleepiness/drowsiness	**6-7 in 100 people** (6-7%)
Dry mouth	**3-6 in 100 people** (3-6%)
Movement and muscle control problems	**2-3 in 100 people** (2-3%)

In most patients, these side effects are mild to moderate in intensity and become less severe over 1-4 months of treatment.

Long-term

- Regular, ongoing monitoring of blood sugar levels, cholesterol and weight gain is required. This usually involves urine and blood tests, and body weight measurement every 3-6 months.

Note many of the possible side effects of quetiapine depend on the dose taken.

= Possible disadvantage that is serious and may involve stopping treatment.

= Possible disadvantage that can be managed/tolerated.

= Possible advantage.

	Lithium	Lamotrigine	Quetiapine
Effectiveness	Effective against **both hypomania and depression relapse.**	**More effective against depression relapse.** Uncertain how effective against hypomanic relapse.	Effective against **both hypomania and depression relapse.**
Tolerance of side effects	**84 in 100** people	**91 in 100** people	**92-94 in 100** people
Cognitive 'dulling' (i.e. difficulties thinking)	**20-25 in 100** people	**No link**	**5-16 in 100** people
Sleepiness/ drowsiness	**13 in 100** people	**No link**	**6-19 in 100** people
Weight gain (> 7% of body weight)	**10-12 in 100** people	**No link**	**6-10 in 100** people
Toxicity/safety	Under-active thyroid = **13-14 in 100** people Chronic kidney disease = **1-2 in 100** people Complete kidney failure = **~ 5 in 1000** people	Non-serious rash = **8-9 in 100** people. Serious rash = **1 in 10,000 to 1 in 1000** people.	Metabolism changes = **7-15 in 100** people
Long-term monitoring	**Required**	Generally **not** required**.** Remain alert to rash.	**Required**
Time to take effect	**Longer time** to take full effect than some other medications.	**Longer time** to take full effect than some other medications.	**Shorter time** to take full effect than some other medications.
Cost/ affordability	**PBS subsidised** Costs less than some other medications.	**Not** PBS subsidised for BPII. Costs more than some other medications.	**Not** PBS subsidised for BPII. Costs more than some other medications.

ADD-ON (ADJUNCTIVE) PSYCHOLOGICAL OPTIONS

This section will help you to understand the different add-on psychological options recommended for bipolar II disorder (BPII).

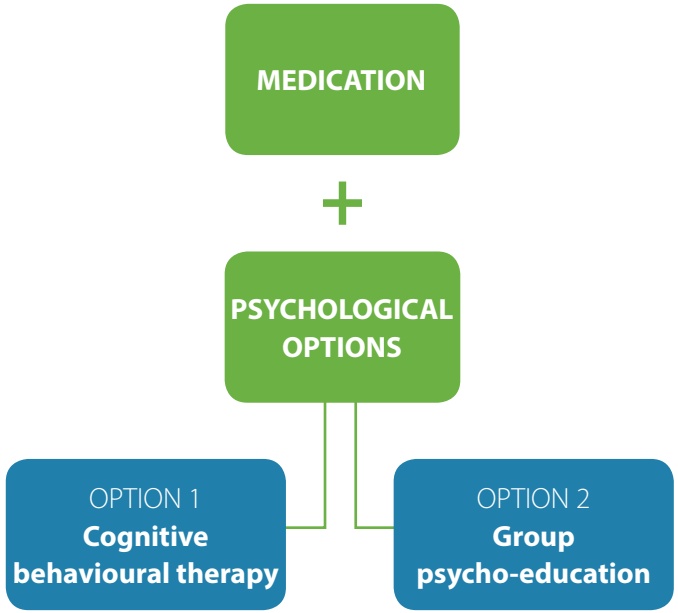
Why are psychological treatments recommended in bipolar II disorder?

Although medication forms the main treatment for most people with BPII, people may still relapse into **depression** or **hypomania** even when they are taking medication. 'Real-world' studies of people with bipolar I and II disorders suggest that on average, *for any type of episode (depression or hypomania)*:

WITHIN 2 YEARS	WITHIN 5 YEARS
50 in100 people will **NOT RELAPSE**	**10-30 in100** people will **NOT RELAPSE**
	
50 in100 people treated with medication will **RELAPSE** within 2 years	**70-90 in100** people treated with medication will **RELAPSE** within 2 years

Because medication *does not offer complete protection against relapse in BPII*, **adjunctive** psychological interventions or **'talking therapies'** are added to help prevent relapse.

Studies show that when used together with medication, two bipolar-specific psychological treatments are effective in preventing relapse:



These two psychological treatments are presented in detail in the following sections. For a summary of the advantages and disadvantages, see pages 60-61.

There are other psychological treatments available which may also be helpful to you.

For more information about other psychological treatments, such as **family-focussed therapy (FFT)** and **interpersonal and social**

rhythm therapy (IPSRT), talk to your clinician (see Australian Psychological Society – "Find a psychologist" under *Further Resources* on page 86.)

All of these psychological treatments appear to:

- be more effective at preventing relapse than medication only and usual care
- be similar in terms of effectiveness, suggesting that any of these treatments will help
- have a number of common core strategies, such as ways you can prevent relapse and stay on medication.

Because of this, it is up to you to consider which psychological treatment fits in best with your life and preferences. As with medication, the option your clinician recommends will depend on your individual needs and life situation. Your clinician may also combine elements of these psychological treatments with others to help you in the most effective way.

PSYCHOLOGICAL OPTION 1

COGNITIVE BEHAVIOURAL THERAPY (CBT)

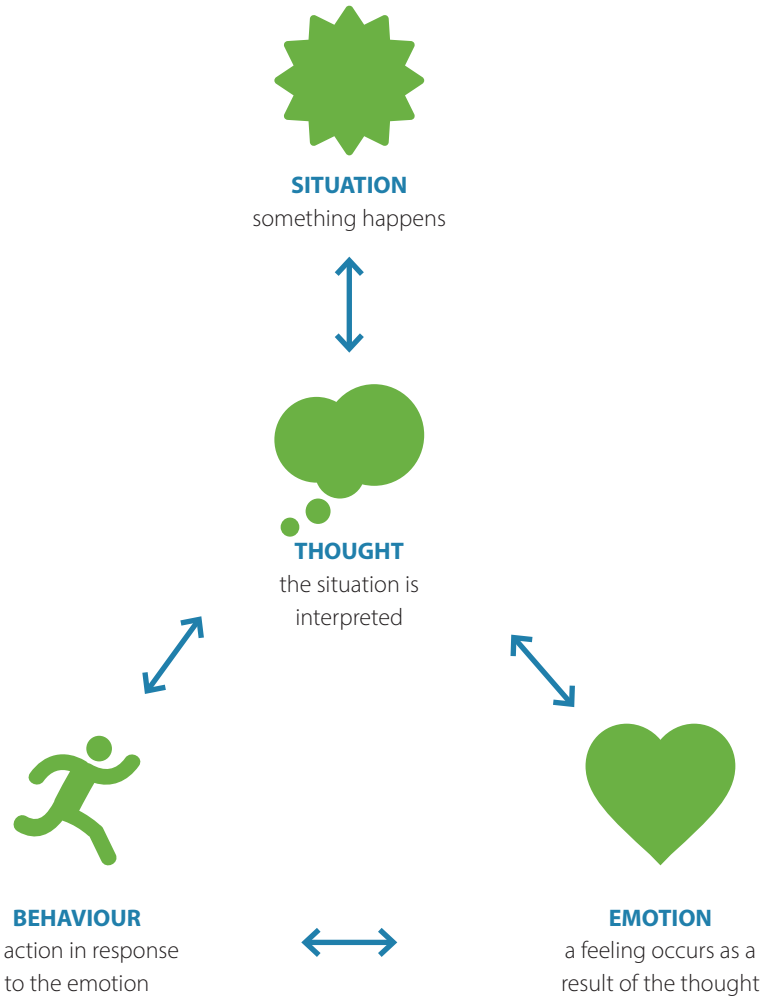
"CBT is quite useful because it's not just medication, it's changing your way of thinking…"

"I've done a bit of CBT, but I don't think it does anything for me…"

What is cognitive behavioural therapy?

Cognitive behavioural therapy (CBT) is a type of psychological treatment that focuses on how people can change themselves. As seen in the diagram on page 46, this treatment:

- focuses on the idea that any situation can be taken in a number of ways. How a person thinks about or interprets a situation can influence their feelings about it (emotions) and their reaction to it (behaviour).
- explains that if a person thinks about a situation in a negative way, this can lead to feelings and reactions that are unhelpful and unwanted.
- helps the person with BPII to develop strategies to challenge and change wrong or unhelpful thinking, emotions and behaviours. Some examples of these types of thoughts are: *"I am a hopeless failure"* or *"No one is interested in what I have to say."*
- aims to decrease symptoms and relapse risk.
- CBT includes 6-20 hour-long weekly sessions for up to six months. The actual number of sessions will vary from one person to another based on individual needs. It is usually recommended to attend CBT sessions over the longer-term.



A model showing the main parts of cognitive behavioural therapy (CBT)

How effective is CBT at preventing relapse?[4]

1) One group of studies looked at how effective add-on CBT is at preventing any type of relapse.

When comparing people doing add-on CBT versus people having usual care these studies show that:

ANY TYPE OF RELAPSE	
MEDICATION + CBT	MEDICATION + USUAL CARE
51 in100 people will **NOT RELAPSE**	**35 in100** people will **NOT RELAPSE**
49 in100 people doing add-on CBT will **RELAPSE** within 6 months up to 2 years	**65 in100** people having usual care will **RELAPSE** within 6 months up to 2 years

4 Meta-analyses based on randomised controlled trials (RCTs) of relapse in people with bipolar I and II disorders with follow-ups of at least 3 months.

2) Another group of studies looked at how effective add-on CBT is at preventing relapse into depression.

When comparing people doing add-on CBT versus people having usual care, these studies show that:

RELAPSE INTO DEPRESSION

MEDICATION + CBT	MEDICATION + USUAL CARE
70 in100 people will **NOT RELAPSE** into depression	**55 in100** people will **NOT RELAPSE** into depression
	
30 in100 people doing add-on CBT will **RELAPSE** into depression within 6 months up to 2 years	**45 in100** people having usual care will **RELAPSE** into depression within 6 months up to 2 years

3) Another group of studies looked at how effective add-on CBT is at preventing relapse into hypomania.

When comparing people doing add-on CBT versus people having usual care, these studies show that:

RELAPSE INTO HYPOMANIA

MEDICATION + CBT	MEDICATION + USUAL CARE
72 in100 people will **NOT RELAPSE** into hypomania	**66 in100** people will **NOT RELAPSE** into hypomania
	
28 in100 people doing add-on CBT will **RELAPSE** into hypomania within 6 months up to 2 years	**34 in100** people having usual care will **RELAPSE** into hypomania within 6 months up to 2 years

Studies show that taking medication AND doing add-on CBT is better than medication and usual care at preventing all types of relapse. It appears better at preventing depression than hypomania.

What are the possible ADVANTAGES of CBT?

- Up to 10 CBT sessions with a psychologist are covered by Medicare rebate with a GP referral under the Australian Government's Better Access Initiative.
- CBT is a highly accessible treatment. Most clinical psychologists in Australia have training in this approach. To find someone in your area, see Australian Psychological Society – "Find a psychologist" under *Further Resources* on page 86.
- Treatment is individually-tailored to your patterns of thinking, emotions and behaviours.
- Skills learnt in CBT are useful, practical and helpful strategies that can be incorporated in everyday life to help coping even after treatment has finished.
- CBT sessions can be arranged at a time/day that fits into your schedule.
- Includes education about BPII (psycho-education).
- May help you to stay on prescribed medication. This is called adherence. More people report good adherence to medication when doing add-on CBT (89 in 100 people) versus people only taking medication and not receiving CBT (67 in 100 people).
- Most people are able to continue with and complete therapy. About 84 into 100 people were able to continue therapy sessions in a study lasting one year.

What are the possible DISADVANTAGES of CBT?

- CBT often requires more than 10 sessions per calendar year, the maximum number covered by Medicare rebate. At this point, people wanting to continue therapy will probably need to pay full fees, unless their private health insurance covers part of the fee.
- To gain access to the Medicare rebate, the person needs to first make an appointment with their GP to get a referral.
- Some people find it emotionally demanding/distressing to talk about thoughts, feelings or experiences.
- You may be asked to complete home-based practice tasks between therapy sessions, which requires dedication and motivation.
- If there are broader issues (e.g. family conflict, workplace stresses), other therapies may be more helpful.
- Not everyone likes the structure of CBT.
- The one-on-one format means you don't have direct support from other people who have BPII (peer support).
- It may take time to find a psychologist whom you feel is a good match and 'right' for you. You might have to meet with a couple of psychologists before finding one you want to work with.

PSYCHOLOGICAL OPTION 2

GROUP PSYCHO-EDUCATION

"It was really good getting all the 'ins and outs' from both medical personnel and also from people who were diagnosed with bipolar and told us how to deal with it."

"At an early stage, I'd go to some group sessions but I found them not very helpful, and I didn't really want to continue doing those."

What is group psycho-education?

Psycho-education is a type of specialised education for people with a particular illness. This helps people learn about a condition, such as bipolar II disorder (BPII).

However, group psycho-education also refers to formal programs led by a clinician or other health professional that aim to help people become 'experts' at managing their BPII. The programs focus on:

- overall awareness of BPII, including triggers and early warning signs
- the importance of taking medication as prescribed (adhering to medication)
- keeping moods stable.

There are a variety of group psycho-education programs available, both face-to-face and online. Because the focus is on learning, it is not really considered 'therapy'. However, it is not clear if many available group psycho-education programs help to prevent relapse in BPII. More research is also needed to evaluate shorter face-to-face and online programs.

Research has mostly been done on face-to-face programs. Some studies looked at about 21 weekly sessions of 90 minutes over six months. These programs used step-by-step guides (manuals) and showed psycho-education was effective.

How effective is group psycho-education at preventing relapse?[5]

1) One group of studies looked at how effective add-on group psycho-education is at preventing any type of relapse.

When comparing people participating in add-on group psycho-education versus people having usual care, these studies show that:

ANY TYPE OF RELAPSE

MEDICATION + GROUP PSYCHO-EDUCATION	MEDICATION + USUAL CARE
41 in100 people will **NOT RELAPSE**	**16 in100** people will **NOT RELAPSE**
	
59 in100 people participating in add-on group psycho-education will **RELAPSE** within 6 months up to 2 years	**84 in100** people having usual care will **RELAPSE** within 6 months up to 2 years

5 Meta-analyses based on RCT studies of relapse in people with bipolar I and II disorders with follow-ups of at least 3 months.

2) Another group of studies looked at how effective add-on group psycho-education is at preventing relapse into depression.

When comparing people participating in add-on group psycho-education versus people having usual care, these studies show that:

RELAPSE INTO DEPRESSION

MEDICATION + GROUP PSYCHO-EDUCATION	MEDICATION + USUAL CARE
71 in100 people will **NOT RELAPSE** into depression	**41 in100** people will **NOT RELAPSE** into depression
	
29 in100 people participating in add-on group psycho-education will **RELAPSE** into depression within 6 months up to 2 years	**59 in100** people having usual care will **RELAPSE** into depression within 6 months up to 2 years

3) Another group of studies looked at how effective add-on group psycho-education is at preventing relapse into hypomania.

When comparing people participating in add-on group psycho-education versus people having usual care, these studies show that:

RELAPSE INTO HYPOMANIA

MEDICATION + GROUP PSYCHO-EDUCATION	MEDICATION + USUAL CARE
57 in100 people will **NOT RELAPSE** into hypomania	**38 in100** people will **NOT RELAPSE** into hypomania
	
43 in100 people participating in add-on group psycho-education will **RELAPSE** into hypomania within 6 months up to 2 years	**62 in100** people having usual care will **RELAPSE** into hypomania within 6 months up to 2 years

Studies show that taking medication AND doing add-on group psycho-education is better than medication and usual care at preventing all types of relapse. This also appears to be good at preventing both depression and hypomania.

What are the possible ADVANTAGES of group psycho-education?

- Group psycho-education can be a good starting point for people reluctant to do 'therapy'. Different individual therapies can be tried later.
- Group meetings can give members the opportunity to:
  - support one another
  - share common experiences
  - reduce feelings of isolation
  - help confirm the individual's experience of illness.
- Psycho-education can help with acceptance of a BPII diagnosis, making the illness seem more 'normal' or less frightening.
- It can increase knowledge about BPII and managing relapse and provide practical skills for daily life.
- Most people are able to continue with and complete psycho-education. Around 73 in 100 people were able to continue psycho-education sessions over a six-month period.
- Many group psycho-education programs are affordable. Some are covered by Medicare with or without having to pay a one-off fee. Other groups require members to pay for workbooks and make a weekly gold coin donation.
- There are a variety of programs available. These include shorter face-to-face and online programs. For more information, see "The REACH program" and "Moodswings" under *Further Resources* on page 86.

What are the possible DISADVANTAGES of group psycho-education?

- The program is not flexible to individual schedules. Given the group format, there is usually a set meeting time and place, and you may have to travel to attend.
- Information and activities are general enough to meet the needs of the group, but may not fit in with your individual needs and preferences.
- You may not be comfortable in a group setting, which involves speaking in front of others and sharing personal information.
- You may not be able to identify with others' experiences and/or find these discouraging.
- If you share information that you want to keep private, you can't guarantee that it won't be shared outside the group. However, it is strongly encouraged that group members are respectful and don't break each others' trust.
- Sessions can be long (90 minutes) over six months so requires ongoing commitment and motivation to attend. However, the actual number of sessions offered varies.
- Group psycho-education may help you to stay on medications (adherence). However, research shows that people participating in group psycho-education appear to stay on *some but not all* medications more consistently than people having usual care.

"For me... it's this holistic approach to managing my illness... it's about the medication working together with the psychological options."

Summary table of ADVANTAGES and DISADVANTAGES of add-on psychological options

= Possible disadvantage that is serious and may involve stopping treatment.

= Possible disadvantage that can be managed/tolerated.

= Possible advantage.

	Cognitive behavioural therapy (CBT)	Group psycho-education
Accessibility (Is the therapy widely available?)	**Highly accessible** treatment.	**Limited** number of meeting venues.
Cost/ affordability	**Up to 10 sessions covered by Medicare rebate, then full fees.**	**Mostly affordable.**
Engagement (Number of people who continue with and complete therapy)	**84 in 100** people	**73 in 100** people
Flexible for your schedule	**Flexible** for your schedule.	**Not flexible** for individual schedules.
Focus on problem areas	May **not** focus enough on broader issues	May **not** focus enough on individual issues
Medication adherence (Will it help you stay on your prescribed medication?)	**Better adherence** to medication.	**Better adherence** to **some medications** only.
Privacy/ confidentiality	**Safeguarded** by clinician-patient confidentiality**.**	May be **more limited** due to group setting**.**
Tailored to individual's needs	**Individually-tailored**.	May **not** fit individual needs and life situation.
Time commitment	**6–20 sessions** of **1 hour** over about **6 months**.	**Up to 21 weekly sessions** of about **1.5 hours** over **6 months**.

What is the role of complementary treatment?

Many people with bipolar II disorder (BPII) express an interest in **complementary treatment** options to help to prevent relapse into either **depression** or **hypomania**.

Complementary treatments are treatments that are used *together with* conventional or mainstream medicine, such as medications and psychological treatments. By being used as add-on (**adjunctive**) treatments, complementary treatments may help lessen symptoms.

There are a number of complementary treatment options available, but there is little evidence for them in BPII apart from **omega-3 fatty acids**.

Can omega-3 fatty acids help to prevent relapse in bipolar II disorder?

In bipolar disorder, one complementary treatment that has received a lot of interest is omega-3 fatty acids or fish oils. These are found naturally in plant and marine life but fish oil supplements can also be purchased in capsule form over-the-counter (without prescription) from the pharmacy or some supermarkets.

The latest Australian guidelines for bipolar disorders (I and II) mention evidence showing that omega-3 fatty acids help to reduce **symptoms of depression** when used with medication. However, omega-3 fatty acids do not appear to help reduce symptoms of hypomania.

When it comes to preventing relapse, there is still not enough evidence to know if adding omega-3 fatty acids to medication helps to prevent **relapse** in BPII.

Current guidelines do not make recommendations about omega-3 fatty acids as a treatment option for preventing relapse in BPII or complementary treatment. If you are taking omega-3 fatty acids or are interested in taking them, discuss this with your GP or psychiatrist.

How can family members be involved in decision-making?

Bipolar II disorder (BPII) can affect not only you, but also those close to you, including family members[6]. For this reason, involving family in preventing relapse can be important, because family members are often the first to notice the early warning signs of relapse. Family members can also help when you are starting or continuing treatment.

Your family can also be involved or contribute to decision-making about treatment. There are different ways that they can be involved.

At appointments with clinicians (consultations)

Family members can help give the clinician helpful information about:

- your illness history and symptoms
- what is 'normal' and what is 'not normal' or out of character for you
- what matters most to you (e.g. your values, goals and preferred treatment options)
- how well you are responding to treatment and coping with side effects.

During consultations, family can give your clinician helpful information.

6 Family members may also include other support people, such as friends, colleagues or neighbours.

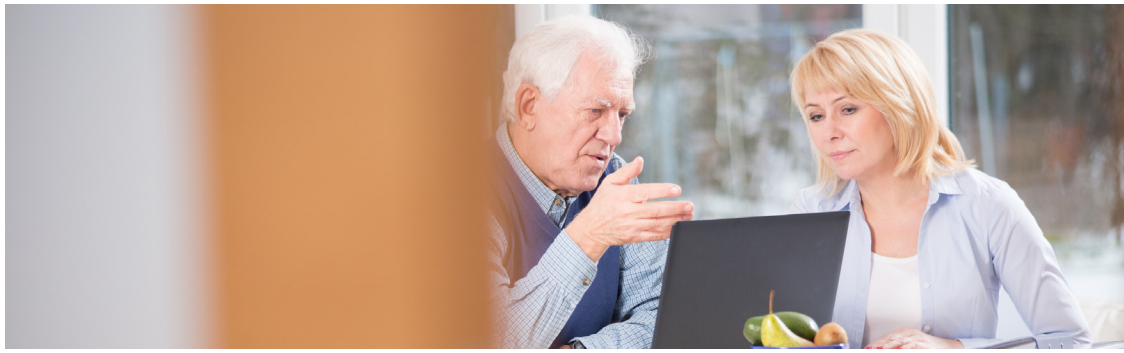
Attending consultations can also be helpful for family members, as they can:

- ask questions
- discuss any concerns about recommended treatment options
- better understand the treatment options
- discuss options with you after the consultation before coming to a final decision.

Outside consultations with clinicians

At home, your family members can help you to:

- reflect on what is important to you and what matters to you about the different treatment options, so you have a clearer idea of your preferences
- weigh up the pros (i.e. benefits) and cons (i.e. side effects or risks) of all of the treatment options available, and how they would impact you
- get more information about the recommended treatment option
- have more realistic expectations about treatment benefits (for example, there may be **delayed effects**)
- work through any concerns, uncertainties or reluctance you have about starting or continuing treatment.



Your family may also encourage you to continue seeing your clinician, especially if your side effects or symptoms worsen.

Outside consultations, family can help gather information and consider the available treatment options.

Many people with BPII appreciate the support of family members and wish to involve family members when making decisions about treatment. Clinicians usually also appreciate family involvement.

People with BPII may wish to involve family in a small way or in a large way, or at different stages of decision-making (for example, before or after discussing treatment options with their clinician, before or after making a decision).

As long you are well enough, it is ultimately your choice *how* and *how much* to involve your family in decisions. Keeping this in mind, it is important that your family talks to you about how much they would like to be involved and if they would like to attend a consultation.

Making decisions - treatment decisions that are right for you

The previous sections have outlined the main options for people with bipolar II disorder (BPII).

Not everyone will feel the same about what to do next. The following seven steps may help you to make decisions about which medication and psychological treatment options you wish to take up:

1. Decide on the **level of involvement that you want from your clinician** and tell them your preferences.
2. Decide on the **level of involvement that you want from your family** and tell them your preferences.
3. Understand your **current options.**
4. Review the **pros (benefits) and cons (side effects/risks)** of each option.
5. Assess **how important the pros and cons** of each option are to you.
6. Get **more information** and **clarify** any uncertain areas by asking questions.
7. Work out **which option/s** you are leaning towards.

Making the most of time with your clinician

"Even just having questions you can ask your doctor about is helpful …. when you go to the appointments, you know what you want to talk about."

It is important to feel informed about bipolar II disorder (BPII) and your treatment options. Having the answers you want may help you to feel more confident about your choice and more in control of your treatment.

When you have an appointment or consultation with your clinician, you should have time to ask questions. Some people are afraid to ask questions, but it is your right to do so.

It is completely acceptable and important to ask your clinicians questions and raise options when discussing your treatment.

Five key points about question-asking in consulations:

1. Many clinicians like to be asked questions
2. Question-asking does NOT challenge the professional expertise of the clinician
3. Question-asking does NOT mean that patients do not trust the clinician
4. Question-asking does NOT show that patients lack respect for the clinician
5. Clinicians do NOT think that patients who ask questions are "more difficult" or "worse" to deal with.

During the consultation, your clinician will not know if you are confused about something or need more information unless you

ask about it. You might need to ask the same questions more than once if you don't understand. Don't be afraid to ask your clinicians the same questions again.

You also might have more questions after you have had a chance to think things over, so you can also ask how you can get information outside of the consultations. It is important to know a good, reliable source of facts about BPII treatment.

What are some questions to ask your clinician?

Below are three quick questions that may be **useful in getting key information about your condition** from your clinician:

For more information see: www.askshareknow.com.au

Other questions

Your clinician may not be able to answer all your questions at the time, but they can help direct you to where to find answers.

Below is a list of some other questions you may find helpful to discuss with your clinician after you have received a diagnosis of BPII and are discussing treatment options.

Tick (✓) the questions you want to ask.

- ☐ *What is going on with my illness?*
- ☐ *What is the best way to manage it now?*
- ☐ *Do you recommend starting treatment?*
- ☐ *What treatment options do you recommend?*
- ☐ *What would be the aim of these treatment options?*
- ☐ *How likely it is that each treatment option will help me?*
- ☐ *How likely is that my symptoms will respond?*
- ☐ *How likely is it that I will remain stable with this treatment and for how long?*
- ☐ *What side effects could I expect from treatment?*
- ☐ *Is there anything that can be done to treat these side effects?*
- ☐ *What has been the experience of other patients when on this treatment?*
- ☐ *How often will I need to come for treatment reviews?*
- ☐ *How long until the treatment starts working?*
- ☐ *How will I be monitored? Would would make me need to change treatment?*
- ☐ *If treatment does not seem to be working, when would we stop/ consider other options?*
- ☐ *How do my other existing health conditions affect my treatment?*
- ☐ *How much will treatment cost?*
- ☐ *How could my lifestyle be affected (e.g. daily activities, sexual life)?*

- [ ] *Can you recommend any other sources of information about the treatment options?*
- [ ] *What happens if I choose not to have treatment at this time?*
- [ ] *Who will organise/manage my care?*
- [ ] *Who else will be available to support me?*
- [ ] *Do you recommend any complementary treatments?*
- [ ] *Can you give me any advice on how to cope better?*
- [ ] *Is there someone I can talk to who has been through this treatment?*
- [ ] *Is there anything else I should do at this time?*
- [ ] *When will my next follow-up appointment be?*
- [ ] *Is there support available to help my partner/family?*

Write down any other questions you would like to ask

- [ ] .....
  .....
- [ ] .....
  .....
- [ ] .....
  .....
- [ ] .....
  .....

Worksheets: What is important to you about your treatment?

"I'm an individual and what works for one person wouldn't work for another."

"It's helpful having ideas of what I need to consider in making treatment decisions … [such as] fitting my medication in with my lifestyle."

Any treatment decision involves weighing up the likely benefits of the treatment (**pros**) with the side effects, risks and other possible negative impacts of the treatment (**cons**).

To help you make your own decision, we have provided the following blank worksheets where you can go through the pros and cons of the options and rate how important these are to you (pages 77–80). There are also examples of how some other people with BPII viewed the pros and cons of the options available.

Before completing the worksheets it is a good idea that you think about your pattern of highs and lows. Reread page 12 which describes what highs and lows look like and decide which signs you experience more and which signs cause you the most problems.

Each pro or con statement has three options describing how important you consider the issue to be. By circling one of the options you can indicate how important each issue is to you.

Circling	"Very important"	▶	Means that the issue is **a very big concern** to you.
Circling	"Somewhat important"	▶	Means that the issue is **a small concern** to you.

Circling "Not important" ▶ Means that the issue is **not a concern** to you.

Patient examples: Overall, are the pros or cons more important to you?

For example: One of the cons of quetiapine (*Seroquel*) is that it can cause sleepiness and drowsiness. If a person feels that they will be able to handle this (i.e. this issue is of no concern), they circle that it is "Not important" for them.

It can be hard to deal with sleepiness and drowsiness during the day.

"This is not really an issue for me."

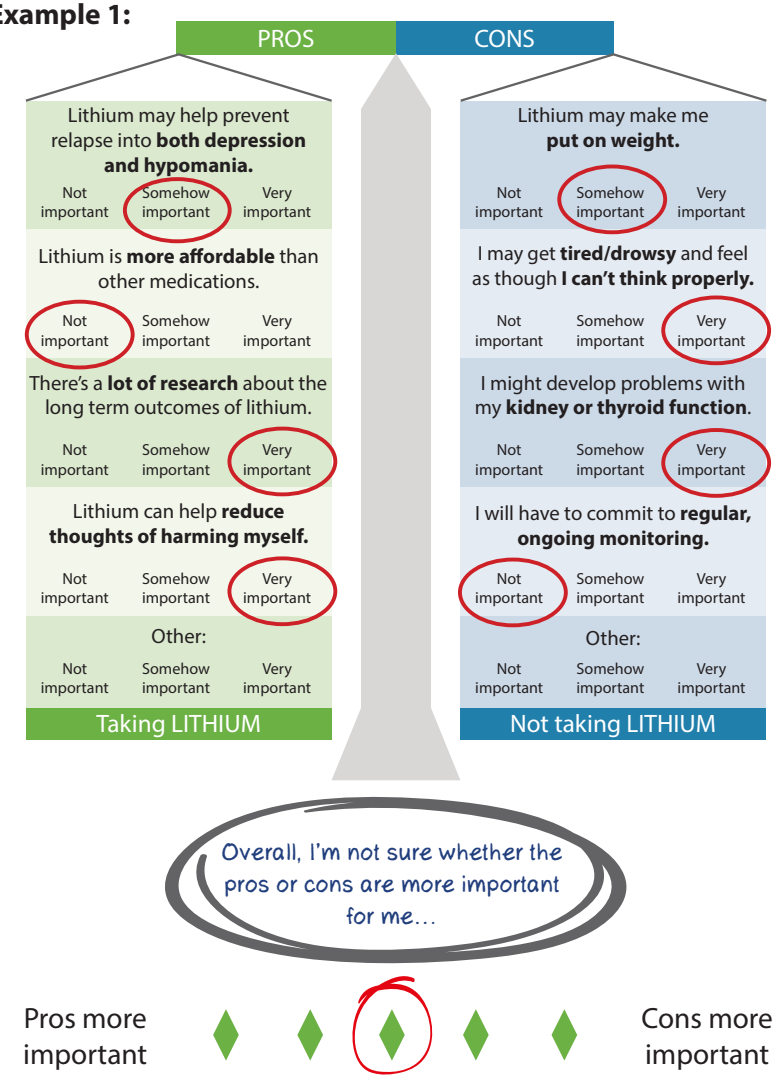
Somewhat important

Very important

After rating how important you consider each statement to be, look at whether you have rated more of the pros as somewhat/very important OR more of the cons as somewhat/very important. This will help you to understand how you feel overall. At the bottom of the worksheet, you can then indicate which way you are leaning in your decision by circling one of the five diamonds. See some examples over the page.

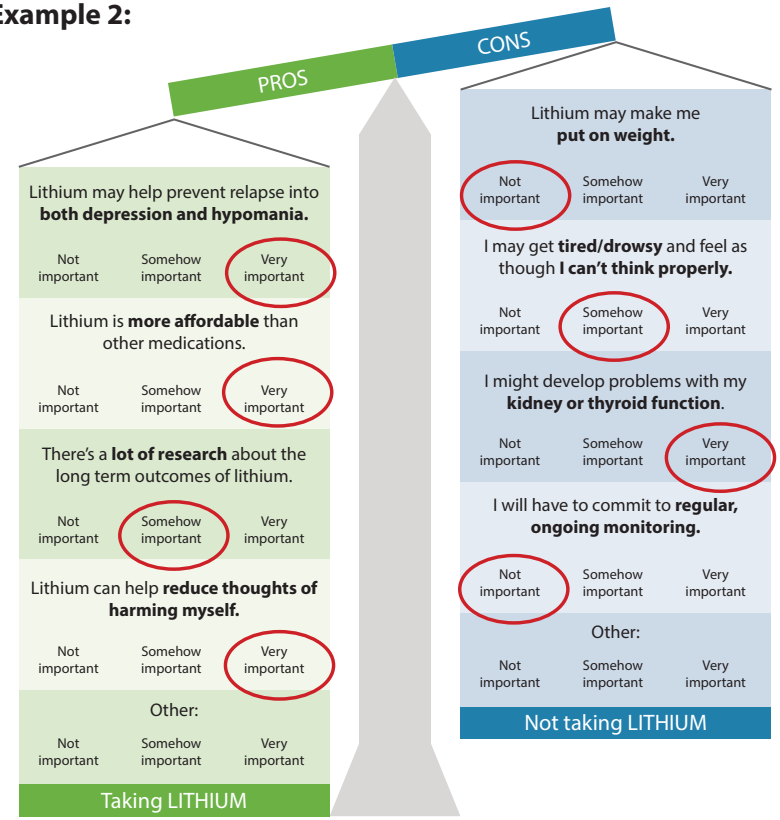
Overall, are the pros or the cons more important to you?

Example 1:



By circling the third diamond in the middle, this person is indicating they are still unsure (50/50) about choosing this treatment option. In this situation, it may be a good idea to discuss the options more with their clinician.

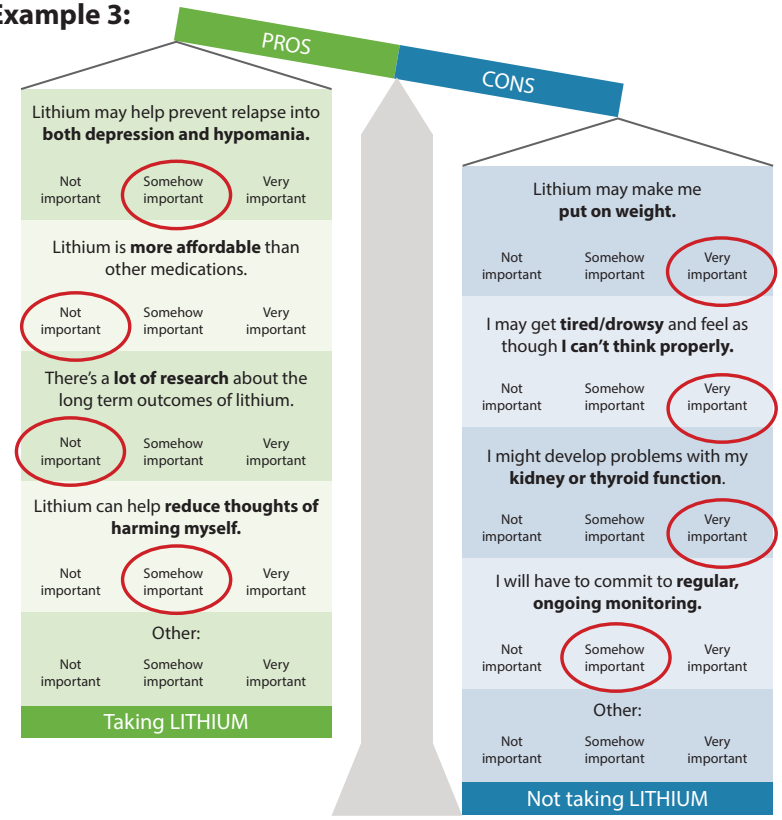
Example 2:



Overall, the pros are more much important to me than the cons…

By circling the first diamond to the left, this person is indicating they are leaning towards choosing this treatment option.

Example 3:



Overall, the cons are slightly more important to me than the pros…

By circling the fourth diamond to the right, this person is indicating they are leaning towards not choosing this treatment option.

Involving a family member

"My partner will often ask me questions about the decisions I'm making, to clarify in my own head what's going on. She wants to know that I'm clear about why I'm doing what I want to do."

If you would like to involve your family member/support person in your decision about how to manage your BPII, you may also like to give that person worksheets. If the person uses the worksheets, you may like to discuss each of your answers together.

This can help a family member/support person to share in the choice about treatment option/s to manage your BPII, so you can make the decision together.

Involving your clinician

"I told my clinician exactly how I felt about gaining weight … He listened to that and he told me why he suggested the medication he did. It was basically looking at the pros and the cons and seeing what you can do."

You may also like to go through these worksheets with your clinician. Once you have completed all the sections of the worksheet, you can discuss your answers with the clinician. This can be a helpful conversation starter and way for you to share what is important to you and what matters to you with each of the treatment options.

After you discuss the pros and cons of options further, your clinician may make a recommendation that suits your values and preferences.

PATIENT WORKSHEET
Medication option 1: LITHIUM

PROS	CONS
Lithium may help prevent relapse into **both depression and hypomania.**	Lithium may make me **put on weight.**
Lithium is **more affordable** than other medications.	I may get **tired/drowsy** and feel as though **I can't think properly.**
There's a **lot of research** about the long term outcomes of lithium.	I might develop problems with my **kidney or thyroid function**.
Lithium can help **reduce thoughts of harming myself.**	I will have to commit to **regular, ongoing monitoring.**
Other:	Other:
Taking LITHIUM	Not taking LITHIUM

Not important | Somehow important | Very important

How important are the pros and cons to you overall?

PATIENT RATING

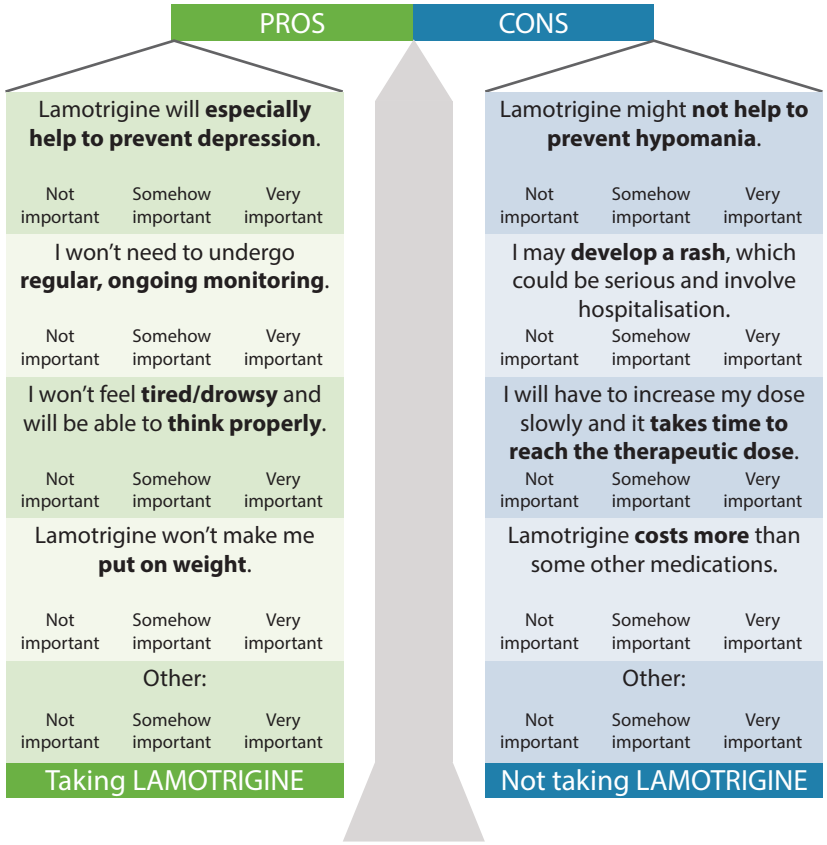
Pros more important ◆ ◆ ◆ ◆ ◆ Cons more important

FAMILY RATING (optional)

Pros more important ◆ ◆ ◆ ◆ ◆ Cons more important

Leaning towards taking LITHIUM ⟷ **Leaning towards NOT taking LITHIUM**

PATIENT WORKSHEET
Medication option 2: LAMOTRIGINE



How important are the pros and cons to you overall?

PATIENT RATING

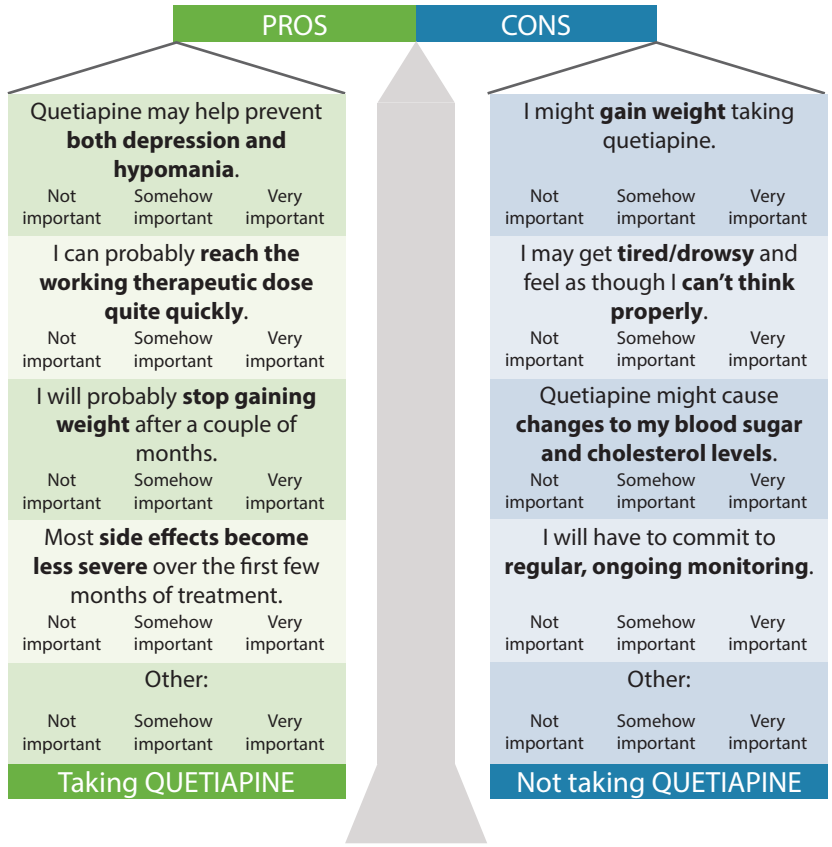
Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

FAMILY RATING (optional)

Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

Leaning towards taking LAMOTRIGINE ⟷ **Leaning towards NOT taking LAMOTRIGINE**

PATIENT WORKSHEET
Medication option 3: QUETIAPINE



How important are the pros and cons to you overall?

PATIENT RATING

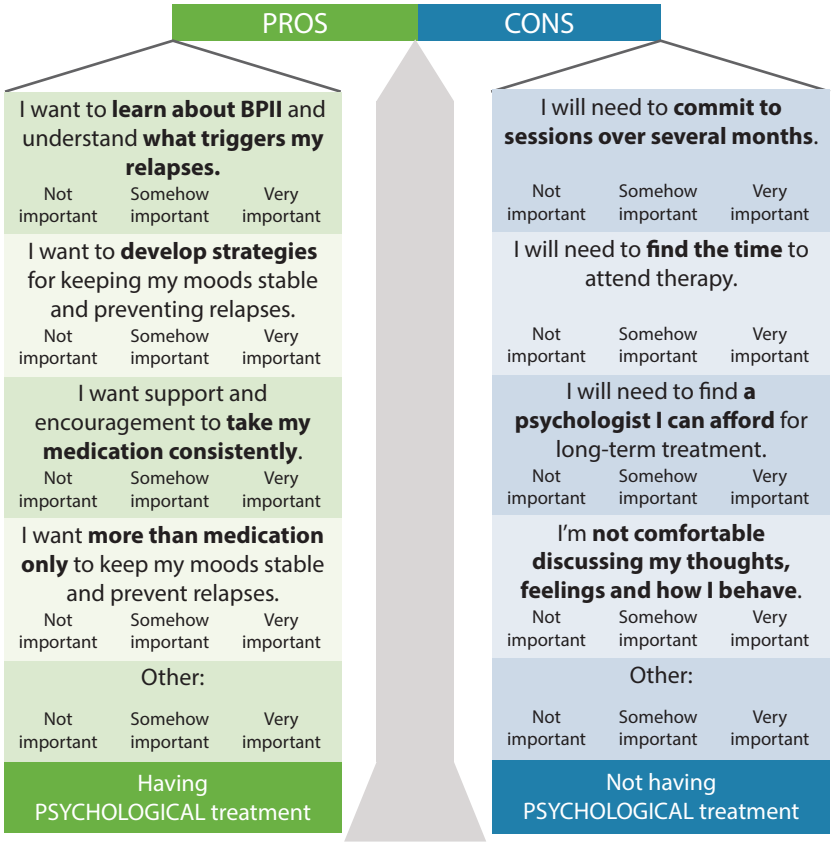
Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

FAMILY RATING (optional)

Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

Leaning towards taking QUETIAPINE ⟷ **Leaning towards NOT taking QUETIAPINE**

PATIENT WORKSHEET
ADD-ON PSYCHOLOGICAL OPTIONS



How important are the pros and cons to you overall?

PATIENT RATING

Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

FAMILY RATING (optional)

Pros more important ♦ ♦ ♦ ♦ ♦ Cons more important

Having PSYCHOLOGICAL treatment ⟷ **Not having PSYCHOLOGICAL treatment**

If you thought pros were more important than cons, then you are leaning towards medication plus psychological treatment. Some people may want to access the different benefits of *both* Cognitive behavioural therapy (CBT) and group psycho-education, but if you prefer to pursue one psychological option over the page is a strategy for making your choice.

PATIENT WORKSHEET – Choosing between psychological options:

CBT versus group psycho-education

This section helps you to work out which features of the add-on psychological treatments are most important to you. To start, choose with a tick (✓) from the list which features of treatment are most important to you. By following the instructions below you'll be able to see *which psychological treatment option is better for you*: CBT or group psycho-education.

	Is this important to you? (✓ if yes)
1) Individual-tailored treatment that is fitted to my personal needs.	
2) Group-based treatment that will allow me to meet other people with BPII.	
3) Treatment is one-on-one, involving only my clinician and me.	
4) Treatment focuses on reducing the thoughts emotions and behaviours which cause me problems.	
5) Treatment focuses on becoming educated about my illness, triggers and early warning signs.	
6) Gives me a simple starting point for treatment; I can move onto other treatments later.	
7) Treatment is flexible to my individual schedule.	
8) Treatment sessions may be led by clinicians other than a psychologist (e.g. social worker or mental health nurse).	

Now count how many blue items you ticked ☐

Now count how many green items you ticked ☐

- *If you ticked more of the blue items, you are leaning more towards CBT.*
- *If you ticked more of the green items, you are leaning more towards group psycho-education.*

It is possible that you value features of both CBT and group psycho-education. The psychological treatment option/s with *more* ticks fits in *more* with your values and preferences. *When seeing a psychologist or other clinician they will assess your main concerns and help you decide which parts of psychological treatments are likely to be most helpful to you.*

Further resources

"Getting information helps me to feel more in control … it just puts me in a better position to be decisive."

Many people seek information on the Internet about treatments, research and support services for bipolar II disorder (BPII). Not all information is accurate or reliable, so make sure you discuss any questions, ideas or concerns with your clinician first.

Listed below are Australian-based websites of leading mental health organisations and other information resources, which can be trusted. The information on these sites is general (not specific to your situation), so it is important to discuss your situation with your clinician. Your clinician can also recommend other reliable websites.

INFORMATION AND SUPPORT

Black Dog Institute

www.blackdoginstitute.org.au
Info line: (02) 9382 4530

The Black Dog Institute offers specialist mood disorders assessment, treatment and information. It contributes to research in the area and offers education programs.

Beyondblue

www.beyondblue.org.au
Info line: 1300 22 4636

Beyondblue is dedicated to improving understanding and acceptance of depression, anxiety, bipolar disorder and postnatal depression. You can access free online or printed information on these disorders and their treatment. The site also has symptom checklists, advice on how to find a GP or psychologist in your area and a directory of mental health internet services.

SANE Australia

www.sane.org
Helpline: 1800 18 SANE
(9am-5pm and messages can be left after hours)

SANE offers helpful information and support for people with bipolar disorder, their families and friends. It also focuses on improving the overall health of people with mental illness. SANE campaigns for better services and attitudes towards people with mental illness. Through its online helpline, SANE will try to answer any questions you have about mental illness.

Bipolar Caregivers

www.bipolarcaregivers.org

Provides guidance and information for caregivers (closer family, friends, carers, support people) about bipolar disorder diagnosis, treatment and management; how to support a person with bipolar disorder; ways caregivers can take care of themselves; and dealing with bipolar disorder and the personal impact on caregivers. Information is also available as a printable PDF.

Headspace
www.headspace.org.au
Info line: (02) 8624 1348

Headspace offers support, information and health services for young people (age 12-25) with mental health problems and their families at 30 centres throughout Australia.

Moodswings
www.moodswings.net.au

This is a comprehensive online psycho-education based program for people with bipolar disorder, which has been developed and evaluated by the University of Melbourne.

The REACH program
http://www.blackdoginstitute.org.au/public/gettinghelp/blackdogsupportgroups.cfm

REACH is a 9-week psycho-educational wellbeing group for people with bipolar disorder or depression. The website provides information about topics covered, eligibility criteria, and details on upcoming groups.

Australian Psychological Society – "Find a psychologist"
https://www.psychology.org.au/FindaPsychologist

This is an online search engine providing information and contact details for over 2,400 practising psychologists Australia-wide. It allows users to search for a psychologist based on area/location, client issue, services offered, therapeutic approaches and Medicare billing status.

Glossary of key terms

Term	Definition
acute symptoms	Symptoms that are short lasting but require urgent treatment because they tend to be more intense or severe. The opposite of acute is **chronic.**
adjunct/ adjunctive treatments	Treatments that supplement or are added on to the main treatment.
bipolar disorder	A type of mental health condition that affects a person's mood, energy, thoughts and behaviour. There are two types of bipolar disorder: bipolar I disorder and bipolar II disorder.
chronic symptoms	Symptoms that are long-lasting and have long-term effects. The opposite of chronic is **acute**.
circadian rhythms	Changes to your body, behaviour and thinking that follow a roughly 24-hour (daily) cycle. These changes occur mainly in response to light and darkness in a person's environment.

Term	Definition
clinical consensus	When a group of experts agree on a particular area of clinical knowledge, for example the use of a particular treatment in BPII. These experts agree that this knowledge is based on the latest evidence.
clinician	A health professional who sees patients.
complementary treatment	A type of treatment that gets used together with conventional or mainstream treatment, such as medications and **psychological** treatments. An example of a complementary treatment is taking fish oil supplements in addition to medication to help lessen symptoms of depression.
cons	The disadvantages of a particular option. Cons of a type of treatment might include the risks, side effects, safety concerns or harms, or other negative features.
cycle	Experiencing an episode of depression, mania or hypomania followed by a period of wellness or by another episode. This may be called a mood swing and can happen periodically over time.

Term	Definition
delayed effects	When there is a period of time or 'delay' between starting to take a new medication and that medication starting to produce results or 'work'.
depression	A 'low' mood lasting two weeks or more, characterised by sadness or flatness as well as a loss of interest or pleasure in most things.
episode/mood episode	An instance or period of time when a person experiences symptoms of depression, mania or hypomania.
euthymic/ euthymia	A 'normal' non-depressed and reasonably positive mood. When euthymic, a person is not experiencing symptoms of either **depression** or **hypomania** and is feeling well or recovered.
family-focussed therapy	A type of psychological treatment and is a therapy that involves both the person with BPII and their family; they are considered a "unit". It is based on evidence that stress and interactions in the family have an influence on relapse, and aims to improve communication and problem-solving skills in the family to avoid relapse.

Term	Definition
hypomania	A 'high' mood characterised by feeling excessively happy, elevated or irritable or more wired and hyper than usual. Hypomania is shorter and less severe than **mania**, and does not include **psychotic** experiences. It occurs in BPII, but may also occur in bipolar I disorder.
interpersonal and social rhythm therapy (IPSRT)	A type of psychological therapy based on the idea that stressful life events and unstable or disrupted daily routines can interfere with **circadian rhythms** in people with BPII. Unstable circadian rhythms are linked to poor wake/sleep cycles which can trigger hypomania or depression. IPSRT aims to manage illness symptoms and prevent relapse by introducing routines aimed at stabilising circadian rhythms via stabilising social rhythms (e.g., fixing wake time across 7 days of the week, keeping regular job hours).
mania/ full manic episode	A 'high' mood which is characterised by feeling excessively happy, elevated or irritable or more 'wired' and 'hyper' than usual. Mania is longer and more severe than **hypomania**, and may include **psychotic** experiences or require hospitalisation. Mania does not occur in BPII, it only occurs in bipolar I (BPI) disorder.

Term	Definition
mixed states/ mixed episode	When a person experiences symptoms of **depression** or **hypomania** at the same time.
omega-3 fatty acids	A type of polyunsaturated fatty acids that occur naturally in certain fish (e.g. salmon, swordfish, tuna) and plants (e.g. flaxseed, walnuts, canola oil).
pharmacological	Treatment options that involve medication.
pros	The advantages of a particular option. Pros of treatment might include the benefits, safety, or other positive aspects of a treatment.
psychological treatments	Treatments that help a person to understand and work through problems by identifying and changing patterns of thinking and behaviour. These treatments also help people to learn skills so they can cope with challenges in their life as they arise. These are also called psychotherapies or **talking therapies**.
psychotic (experiences) or psychosis	When a person perceives or interprets things (hallucinations or delusions) so differently from other people around them that they are said to be disconnected from reality.

Term	Definition
rapid cycling	When a person experiences four or more episodes of **depression** or **hypomania** in a year.
recurrent symptoms	When symptoms return or happen time-after-time.
remission	When symptoms have improved or subsided so that they can be managed and are not getting any worse.
Stevens-Johnson syndrome	A rare, serious disorder of the skin and mucus membranes. It appears as a red or purplish rash that spreads and blisters. It is associated with high fever and a general sense of feeling unwell. The rash usually begins on the upper torso, upper extremities and/or face.
subsyndromal (symptoms)	Milder symptoms that are not severe enough to be diagnosed as a full episode of **depression** or **hypomania**.

Term	Definition
talking therapies	A general term for **psychological** treatments that involve talking to someone (e.g. a psychologist) who is trained to help address difficulties or problems in your life and manage them better through developing strategies.

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A/Prof Ilona Juraskova
School of Psychology
Brennan MacCallum Building (A18)
University of Sydney, NSW, 2006
Australia.

CeMPED Centre for Medical Psychology & Evidence-based Decision-making

THE UNIVERSITY OF SYDNEY

Black Dog Institute

Australian Rotary Health Research Fund
www.arhrf.org.au

Reference list and further research

The information used in this resource is based on the most up-to-date, best available evidence. Key studies and reviews are listed below. A clinician or local librarian can assist you to access this information.

All information on the effectiveness of treatment options at preventing relapse is sourced from meta-analyses of randomised controlled trials (RCTs), which are considered the highest possible level of evidence.

The medication treatments presented in this resource (lithium, lamotrigine and quetiapine) are **all recommended as first-line treatments** for relapse prevention in bipolar II disorder in up-to date clinical guidelines. This means that the medical establishment generally accepts all these medications as appropriate for initial treatment. Information on the potential risks or side effects of medication options is sourced from well-designed RCTs or large-scale naturalistic (population-based) studies.

The psychological treatments presented in this resource (cognitive behavioural therapy and group psycho-education) are **both supported by Level 1 Evidence** in up-to-date clinical guidelines on bipolar disorder. This is considered the highest possible level of evidence, which comes from a systematic review of RCTs.

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