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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

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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.

1. 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

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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.

2. Aims

As evidenced by the abovementioned literature, recent advances have been made in shared treatment decision-making in other serious psychiatric illnesses, such as depression and schizophrenia, however these advances are yet to be seen in BPII. Thus, the proposed DA will be the first of its kind for BPII, and will help to bridge the SDM gap between this illness and others.

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]:

2.1. 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

2.2. 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 [12]. That is, it is <u>not</u> anticipated that receiving the DA will lead to:

ix) Higher depression or hypomania symptomatology
x) Higher state anxiety;
xi) Medication non-adherence.

3. Materials and methods

3.1. Design

This study is a feasibility study with 1:1 parallel randomisation to either the intervention (DA website) or active control (the Black Dog Institute [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).

3.2. Participants and setting

Participants will be recruited through the BDI, a specialist outpatient clinical and research facility, which specialises in the assessment and treatment of mood and bipolar-related disorders.

3.3. 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.

3.4. 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

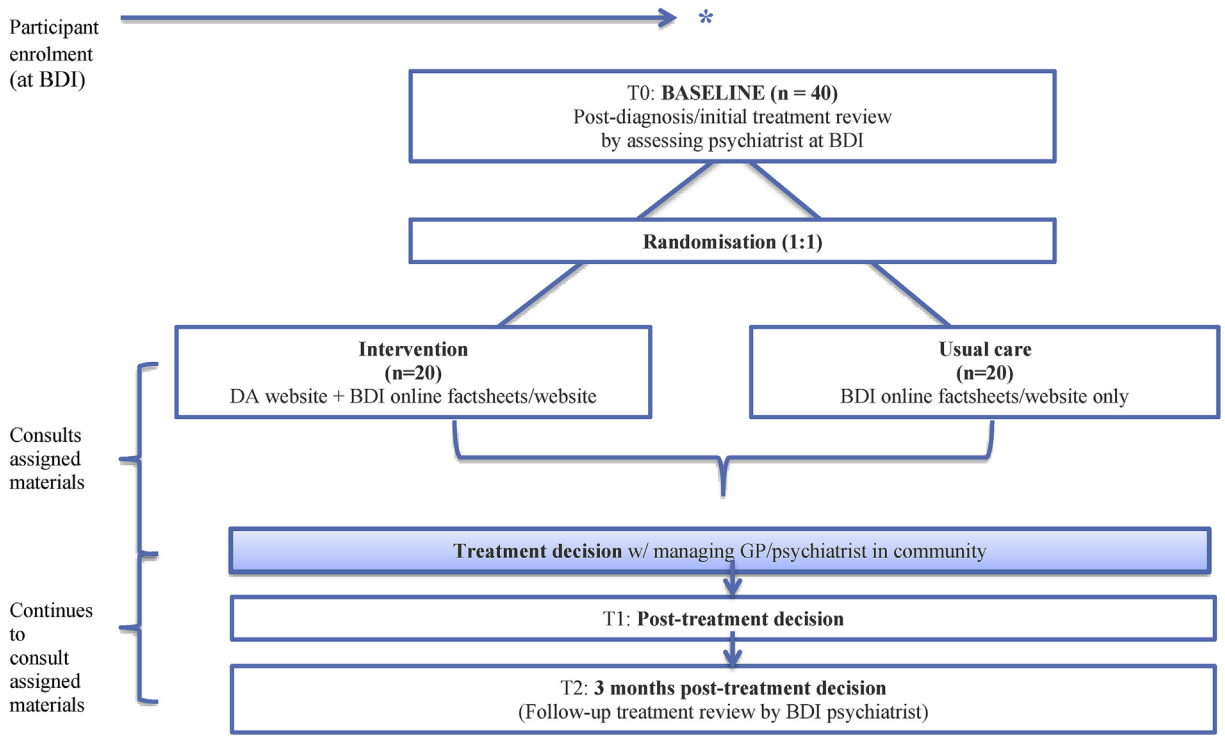

Fig. 1. Flow-chart illustrating RCT procedure.

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.

3.5. Procedure

The study procedure is illustrated in Fig. 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 (the first author, Alana Fisher [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.

Three to 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, the primary time-point) 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.

3.6. Materials and measures

3.6.1. 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 general practitioner/primary care physicians [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.

3.6.2. 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 (Fig. 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).

3.7. 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].

3.8. Quality of the decision-making process measures

Decisional conflict refers to participant perceptions of i) uncertainty, being ii) uninformed, iii) unsupported, and iv) having unclear values in decision-making, and v) being unable to make an effective decision. This will be assessed using the 16-item validated Decisional Conflict Scale (DCS), comprising five subscales (i – v) which all show high internal consistency (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].

3.9. 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 be operationalised by classifying as "informed" any 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 *no* medication ± psychological treatment or unsure/delayed decision-making).

3.10. 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

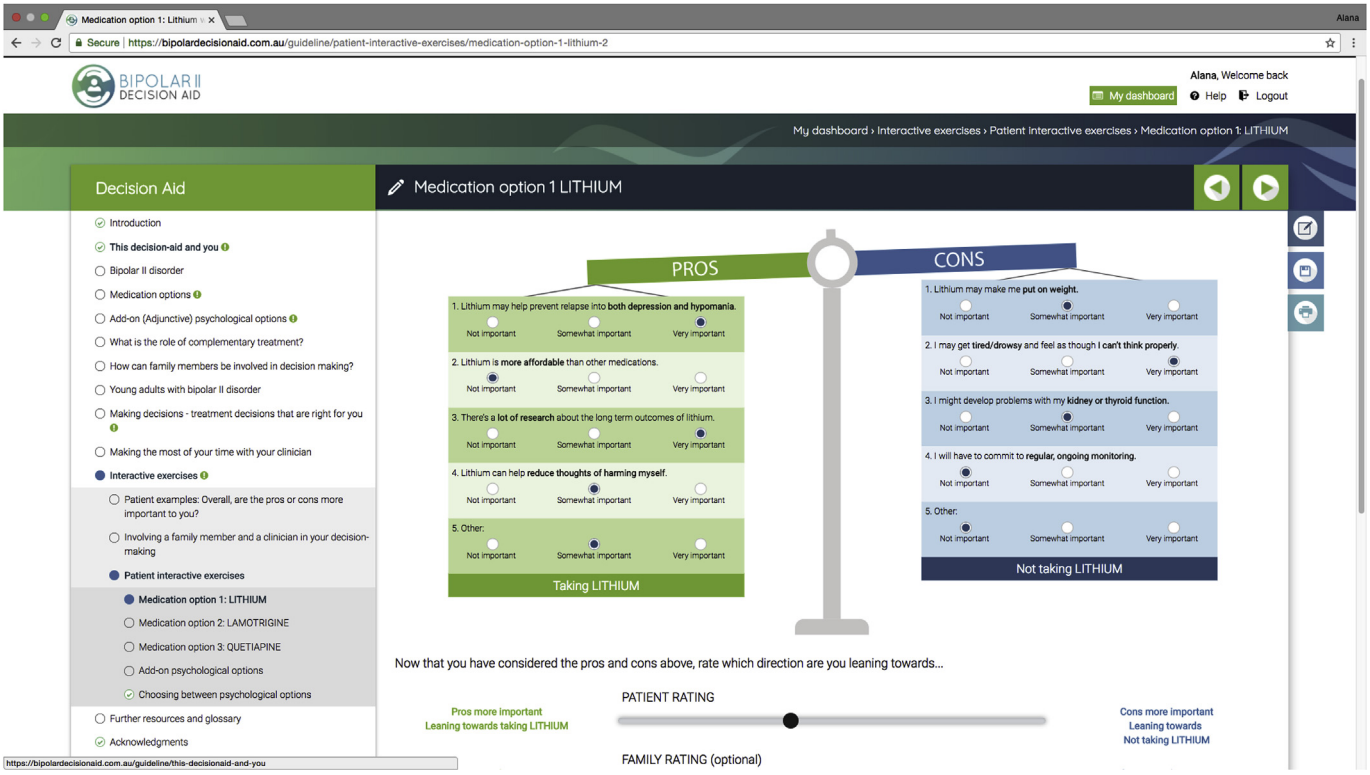

Fig. 2. Screen-shot example of values clarification exercise on website.

scale [42]) and *medication adherence* (8-item Morisky Medication Adherence Measure, [43].

3.11. 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

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	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.

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), and a 30% dropout rate from baseline (T0) to post-treatment decision (i.e., T1, the primary time-point), the research team envisages no difficulty in achieving the target of 40 participants within the planned 12 month active recruitment timeframe.

3.12. 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 be also be examined using standardised mean differences, calculated as the difference between groups in mean change from baseline to post-decision (both immediately [T1] and after 3 months [T2]). These standardised mean differences for the primary outcome (decisional conflict) at immediately post-decision (T1) 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].

4. 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;

AF = Alana Fisher (the first author); BDI = Black Dog Institute; BPII = bipolar II disorder; DA = decision-aid; GP = General Practitioner (i.e., primary care physician); 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.

Conflicts of interest

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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CRediT authorship contribution statement

Alana Fisher: Writing – original draft, Funding acquisition. **Louise Sharpe:** Writing – original draft, Funding acquisition. **Ilona Juraskova:** Writing – original draft, Funding acquisition.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2018.11.004.

References

[1] Australian Bureau of Statistics, National survey of mental health and wellbeing: summary of results, Available from: http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/6AE6DA447F985FC2CA2574EA00122BD6/$File/43260_2007.pdf.

[2] F.M. Gore, P.J. Bloem, G.C. Patton, J. Ferguson, V. Joseph, C. Coffey, et al., Global burden of disease in young people aged 10–24 years: a systematic analysis, Lancet 377 (2011) 2093–2102.

[3] F. Benazzi, Bipolar disorder—focus on bipolar II disorder and mixed depression, Lancet 369 (2007) 935–945.

[4] G.S. Malhi, C. McAulay, P. Das, K. Fritz, Maintaining mood stability in bipolar disorder: a clinical perspective on pharmacotherapy, Evid. Base Ment. Health 18 (2015) 1–6.

[5] G.S. Malhi, D. Bassett, P. Boyce, R. Bryant, P.B. Fitzgerald, K. Fritz, et al., Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for mood disorders, Aust. N. Z. J. Psychiatr. 49 (2015) 1087–1206.

[6] K.R. Merikangas, R. Jin, J.-P. He, R.C. Kessler, S. Lee, N.A. Sampson, et al., Prevalence and correlates of bipolar spectrum disorder in the world mental health survey initiative, Arch. Gen. Psychiatr. 68 (2011) 241–251.

[7] J. Hamann, S. Heres, Adapting shared decision making for individuals with severe mental illness, Psychiatr. Serv. 65 (2014) 1483–1486.

[8] A. Fisher, V. Manicavasagar, L. Sharpe, R. Laidsaar-Powell, I. Juraskova, Identifying and addressing barriers to treatment decision-making in bipolar II disorder: clinicians' perspective, Aust. Psychol. 53 (2018) 40–51.

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

[10] A. Fisher, V. Manicavasagar, L. Sharpe, R. Laidsaar-Powell, I. Juraskova, A qualitative exploration of clinician views and experiences of treatment decision-making in bipolar II disorder, Community Ment. Health J. 53 (2017) 958–971, https://doi.org/10.1007/s10597-016-0077-4.

[11] B. Chewning, C.L. Bylund, B. Shah, N.K. Arora, J.A. Gueguen, G. Makoul, Patient preferences for shared decisions: a systematic review, Patient Educ. Counsel. 86 (2012) 9–18.

[12] D. Stacey, F. Legare, K. Lewis, M.J. Barry, C.L. Bennett, K.B. Eden, et al., Decision aids for people facing health treatment or screening decisions, Cochrane Database Syst. Rev. 4 (2017).

[13] J. Hamann, B. Langer, V. Winkler, R. Busch, R. Cohen, S. Leucht, et al., Shared decision making for in-patients with schizophrenia, Acta Psychiatr. Scand. 114 (2006) 265–273.

[14] A. Loh, D. Simon, C.E. Wills, L. Kriston, W. Niebling, M. Härter, The effects of a shared decision-making intervention in primary care of depression: a cluster-randomized controlled trial, Patient Educ. Counsel. 67 (2007) 324–332.

[15] A. LeBlanc, J. Herrin, e al, Shared decision making for antidepressants in primary care: a cluster randomized trial, JAMA Internal Medicine 175 (2015) 1761–1770, https://doi.org/10.1001/jamainternmed.2015.5214.

[16] L. Perestelo-Perez, A. Rivero-Santana, J.A. Sanchez-Afonso, J. Perez-Ramos, C.L. Castellano-Fuentes, K. Sepucha, et al., Effectiveness of a decision aid for patients with depression: a randomized controlled trial, Health Expect. 25 (2017) 1096–1105.

[17] M.B. Simmons, A. Elmes, J.E. McKenzie, L. Trevena, S.E. Hetrick, Right choice, right time: evaluation of an online decision aid for youth depression, Health Expect. 20 (2016) 714–723.

[18] A. Fisher, L. Sharpe, J. Anderson, V. Manicavasagar, I. Juraskova, 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 13 (2018) e0200490.

[19] A. O'Connor, Ottawa decision support framework Ottawa, [cited 2016 20 October 2016]. Available from: https://decisionaid.ohri.ca/odsf.html.

[20] M. Jacobsen, A. O'Connor, Population Needs Assessment: a Workbook for Assessing Patients' and Practitioners' Decision Making Needs, Ottawa Hospital Research Institute, Ottawa, 1999.

[21] K. Sepucha, R. Thomson, C.M. Borkhoff, J. Lally, C. Levin, D.D. Matlock, et al., Establishing the effectiveness, [cited 27/03/2018], 2012 Upfate of the International Patient Decision Aids Standards (IPDAS) Collaboration's Background Document Chapter L [Internet], 2012 [cited 27/03/2018]. Available from: http://ipdas.ohri.ca/resources.html.

[22] J. Nicholas, K. Boydell, H. Christensen, Self-management in young adults with bipolar disorder: strategies and challenges, J. Affect. Disord. 209 (2016) 201–208.

[23] P.B. Mitchell, C.K. Loo, B.M. Gould, Diagnosis and monitoring of bipolar disorder in general practice, Med. J. Aust. 193 (2010) S1.

[24] K.F. Schulz, D.G. Altman, D. Moher, CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials, BMC Med. 8 (2010) 1.

[25] L.N. Yatham, S.H. Kennedy, S.V. Parikh, A. Schaffer, S. Beaulieu, M. Alda, et al., Canadian network for mood and anxiety treatments (CANMAT) and international society for bipolar disorders (ISBD) collaborative update of CANMAT guidelines for the management of patients with bipolar disorder: update 2013, Bipolar Disord. 15 (2013) 1–44.

[26] A. Fisher, V. Manicavasagar, F. Kiln, I. Juraskova, Communication and decision-making in mental health: a systematic review focusing on bipolar disorder, Patient Educ. Counsel. 99 (2016) 1106–1120, https://doi.org/10.1016/j.pec.2016.02.011.

[27] G. Elwyn, A. O'Connor, D. Stacey, R. Volk, A. Edwards, A. Coulter, et al., Developing a quality criteria framework for patient decision aids: online international Delphi consensus process, BMJ Br. Med. J. (Clin. Res. Ed.) 333 (2006) 417.

[28] K.R. Sepucha, C.M. Borkhoff, J. Lally, C.A. Levin, D.D. Matlock, C.J. Ng, et al., Establishing the effectiveness of patient decision aids: key constructs and measurement instruments, BMC Med. Inf. Decis. Making 13 (2013) S12.

[29] A.M. O'Connor, Validation of a decisional conflict scale, Med. Decis. Making 15 (1995) 25–30.

[30] G. Elwyn, A.M. O'Connor, C. Bennett, R.G. Newcombe, M. Politi, M.-A. Durand,

et al., Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi), PloS One 4 (2009) e4705.
[31] J. Kryworuchko, D. Stacey, C. Bennett, I.D. Graham, Appraisal of primary outcome measures used in trials of patient decision support, Patient Educ. Counsel. 73 (2008) 497–503.
[32] National Health and Medical Research Council, General guidelines for medical practitioners on providing information to Patients2004, Available from: https://www.nhmrc.gov.au/guidelines-publications/e57.
[33] L.F. Degner, L.J. Kristjanson, D. Bowman, J.A. Sloan, K. Carriere, J. O'Neil, et al., Information needs and decisional preferences in women with breast cancer, J. Am. Med. Assoc. 277 (1997) 1485–1492.
[34] M.T. Nolan, M. Hughes, D.P. Narendra, J.R. Sood, P.B. Terry, A.B. Astrow, et al., When patients lack capacity: the roles that patients with terminal diagnoses would choose for their physicians and loved ones in making medical decisions, J. Pain Symptom Manag. 30 (2005) 342–353.
[35] C. De las Cuevas, W. Peñate, L. de Rivera, Psychiatric patients' preferences and experiences in clinical decision-making: examining concordance and correlates of patients' preferences, Patient Educ. Counsel. 96 (2014) 222–228 https://doi.org/10.1016/j.pec.2014.05.009.
[36] C. Bennett, I.D. Graham, E. Kristjansson, S.A. Kearing, K.F. Clay, A.M. O'Connor, Validation of a preparation for decision making scale, Patient Educ. Counsel. 78 (2010) 130–133.
[37] J.C. Brehaut, A.M. O'Connor, T.J. Wood, T.F. Hack, L. Siminoff, E. Gordon, et al., Validation of a decision regret scale, Med. Decis. Making 23 (2003) 281–292.
[38] T.M. Marteau, E. Dormandy, S. Michie, A measure of informed choice, Health Expect. 4 (2001) 99–108, https://doi.org/10.1046/j.1369-6513.2001.00140.x.
[39] S.K. Smith, A. Barratt, L. Trevena, J.M. Simpson, J. Jansen, K.J. McCaffery, A theoretical framework for measuring knowledge in screening decision aid trials, Patient Educ. Counsel. 89 (2012) 330–336.
[40] F.D. Davis, Perceived usefulness, perceived ease of use, and user acceptance of information technology, MIS Q. 13 (1989) 319–340, https://doi.org/10.2307/249008.
[41] M.S. Bauer, P. Crits-Christoph, W.A. Ball, E. Dewees, T. McAllister, P. Alahi, et al., Independent assessment of manic and depressive symptoms by self-rating: scale characteristics and implications for the study of mania, Arch. Gen. Psychiatr. 48 (1991) 807–812.
[42] T.M. Marteau, H. Bekker, The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI), Br. J. Clin. Psychol. 31 (1992) 301–306.
[43] D.E. Morisky, A. Ang, M. Krousel-Wood, H.J. Ward, Predictive validity of a medication adherence measure in an outpatient setting, J. Clin. Hypertens. 10 (2008) 348–354.
[44] M.A. Hertzog, Considerations in determining sample size for pilot studies, Res. Nurs. Health 31 (2008) 180–191.
[45] L. Thabane, J. Ma, R. Chu, J. Cheng, A. Ismaila, L.P. Rios, et al., A tutorial on pilot studies: the what, why and how, BMC Med. Res. Methodol. 10 (2010) 1.
[46] Headspace, Understanding bipolar disorder - for young people, [updated 2016; cited 2016 1 August]. Available from: http://headspace.org.au/young-people/understanding-bipolar-disorder-for-young-people/.
[47] M. Berk, L. Berk, D. Castle, A collaborative approach to the treatment alliance in bipolar disorder, Bipolar Disord. 6 (2004) 504–518.
[48] M. Sajatovic, M. Davies, D.R. Hrouda, Enhancement of treatment adherence among patients with bipolar disorder, Psychiatr. Serv. 55 (2004) 264–269.
[49] M. Sajatovic, M. Davies, M.S. Bauer, L. McBride, R.W. Hays, R. Safavi, et al., Attitudes regarding the collaborative practice model and treatment adherence among individuals with bipolar disorder, Compr. Psychiatr. 46 (2005) 272–277, https://doi.org/10.1016/j.comppsych.2004.10.007.
[50] M. Sajatovic, K. Biswas, A.K. Kilbourne, H. Fenn, W. Williford, M.S. Bauer, Factors associated with prospective long-term treatment adherence among individuals with bipolar disorder, Psychiatr. Serv. 59 (2008) 753–759.
[51] G. Malhi, D. Adams, L. Lampe, M. Paton, N. O'Connor, L. Newton, et al., Clinical practice recommendations for bipolar disorder, Acta Psychiatr. Scand. 119 (2009) 27–46.
[52] American Psychiatric Association, Diagnostic and Stastical Manual of Mental Disorders, fifth ed., American Psychiatric Association, Washington DC, 2013.
[53] L.L. Judd, H.S. Akiskal, P.J. Schettler, J. Endicott, A.C. Leon, D.A. Solomon, et al., Psychosocial disability in the course of bipolar I and II disorders: a prospective, comparative, longitudinal study, Arch. Gen. Psychiatr. 62 (2005) 1322–1330.
[54] K.L. Lavoie, T.S. Campbell, S.L. Bacon, Behavioral medicine trial design: time for a change, Arch. Intern. Med. 172 (2012) 1350–1351.
[55] Australian Bureau Statistics, Household use of information technology, Australia, [cited 2016 July 15]. Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/8146.0Chapter32012-13.
[56] S.R. Cotten, S.S. Gupta, Characteristics of online and offline health information seekers and factors that discriminate between them, Soc. Sci. Med. 59 (2004) 1795–1806.
[57] A. LeBlanc, A.E. Bodde, M.E. Branda, K.J. Yost, J. Herrin, M.D. Williams, et al., Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice decision aid to usual care: study protocol for a randomized controlled trial, Trials 14 (2013) 127.