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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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.

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.

Methods
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 Board; 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).

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.

Materials and measures

The BPII decision-aid (DA). The BPII DA booklet was informed by the International Patient Decision-Aid Standards (IPDAS) [22] and the Ottawa Decision-Support Framework.
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 would be 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 were 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; Shoe-maker [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 S1 Appendix for a full summary of the DA booklet content.

**Interview guide.** The purpose-designed, semi-structured interview guide (see S2 Appendix) was informed by the Ottawa Acceptability measure [41]. Open-ended questions elicited feedback on the DA’s acceptability and suggested improvements.

**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) (S3 Appendix).

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 [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.

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

Results
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 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%).

Clinical and family involvement characteristics. As seen in Table 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/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%).

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 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).

**Preferred and experienced involvement in decision-making.** As with information, patients and family also indicated strong preferences for patient involvement (Table 2). 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

| Table 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)   |
| **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)        |
| **Yes**                         | --              | 3 (27.3)        |

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Table 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)       |

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more often than family preferred and experienced shared or clinician-led decision-making in consultations (Table 2).

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 2). 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 2).
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 2). 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.

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 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 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 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 4). Accordingly, all but one patient demonstrated adequate knowledge (i.e., > 50% of possible total score, S3 Appendix). 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.

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 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).

Participant feedback on the DA

Participant feedback on the booklet was highly positive across all acceptability domains (Table 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 6.

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 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 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 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 BP II 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 6, IDs 210, 123).

Table 5. Quantitative participant feedback on the decision-aid (DA) in the patient (n = 31) and family (n = 11) samples.

| Perceived ease of use of DA | Patients | | | Family | | |
|----------------------------|---------|---|---|-------|---|
| *Agree/ Somewhat Agree n (%)| 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 | Patients | | | Family | | |
|----------------------------|---------|---|---|-------|---|
| 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 | Patients | | | Family | | |
|----------------------------|---------|---|---|-------|---|
| 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 | Patients | | | Family | | |
|----------------------------------------------------------|---------|---|---|-------|---|
| 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.

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Table 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) |

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 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 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 5). This positive feedback was reiterated in interviews (Table 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.

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.

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.

**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 family) 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.

**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.

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.

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.

Supporting information
S1 Appendix. DA content.
(DOCX)
S2 Appendix. Interview questions.
(DOCX)
S3 Appendix. Knowledge questions.
(DOCX)

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References
1. Yatham LN, Kennedy SH, Parikh SV, Schaffer A, Beaulieu S, Alda M, 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 Disorders. 2013; 15(1):1–44. https://doi.org/10.1111/bdi.12025 PMID: 23237061
2. Grunze H, Vieta E, Goodwin GM, Bowden C, Licht RW, Möller H-J, et al. The World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of bipolar disorders: update 2012 on the long-term treatment of bipolar disorder. The World Journal of Biological Psychiatry. 2013; 14(3):154–219. https://doi.org/10.3109/15622975.2013.770551 PMID: 23480132
3. Fountoulakis KN. Treatment guidelines. In: Fountoulakis KN, editor. Bipolar Disorder: An Evidence-Based Guide to Manic Depression. Verlag Berlin Heidelberg: Springer; 2015. p. 643–58.
4. Fountoulakis KN. Psychosocial treatment and interventions. In: Fountoulakis KN, editor. Bipolar Disorder: An Evidence-Based Guide to Manic Depression. Verlag Berlin Heidelberg: Springer; 2015. p. 627–42.
5. Malhi GS, Adams D, Lamp L, Paton M, O’Connor N, Newton L, et al. Clinical practice recommendations for bipolar disorder. Acta Psychiatrica Scandinavica. 2009; 119(4):27–46.
6. Malhi GS, McAulay C, Das P, Fritz K. Maintaining mood stability in bipolar disorder: a clinical perspective on pharmacotherapy. Evidence Based Mental Health. 2015; 18(1):1–6. https://doi.org/10.1136/eb-2014-101948 PMID: 25165167
7. Hamann J, Heres S. Adapting shared decision making for individuals with severe mental illness. Psychiatric Services. 2014; 65(12):1483–6. https://doi.org/10.1176/appi.ps.201400307
8. Loh A, Simon D, Wills CE, Kristen L, Niebling W, Härter M. The effects of a shared decision-making intervention in primary care of depression: a cluster-randomized controlled trial. Patient Education and Counseling. 2007; 67(3):324–32. https://doi.org/10.1016/j.pec.2007.03.023 PMID: 17509808
9. LeBlanc A, Herrin J, et al. Shared decision making for antidepressants in primary care: A cluster randomized trial. JAMA Internal Medicine. 2015; 175(11):1761–70. Epub September 28, 2015. https://doi.org/10.1001/jama.2015.5214 PMID: 26414670
10. Perestelo-Perez L, Rivero-Santana A, Sanchez-Afonso JA, Perez-Ramos J, Castellano-Fuentes CL, Sepucha K, et al. Effectiveness of a decision aid for patients with depression: A randomized controlled trial. Health Expectations. 2017; 25(5):1096–105.
11. Mott JM, Stanley MA, Street RL Jr, Grady RH, Teng EJ. Increasing engagement in evidence-based PTSD treatment through shared decision-making: A pilot study. Military Medicine. 2014; 179(2):143–9. https://doi.org/10.7205/MILMED-D-13-00363 PMID: 24491609
12. Watts BV, Schnurr PP, Zayed M, Young-Xu Y, Stender P, Llewellyn-Thomas H. A randomized controlled clinical trial of a patient decision aid for posttraumatic stress disorder. Psychiatric Services. 2015; 66(2):149–54. https://doi.org/10.1176/appi.ps.201400062 PMID: 25322473
13. Hamann J, Langer B, Winker V, Busch R, Cohen R, Leucht S, et al. Shared decision making for in-patients with schizophrenia. Acta Psychiatrica Scandinavica. 2015; 114(4):265–73. https://doi.org/10.1111/j.1600-0447.2006.00798.x PMID: 16968364
14. World Health Organisation. Declaration of Helsinki. British Medical Journal. 1996; 313(7070):1448–9.
15. 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. 2017. Epub 13 January 2017. http://dx.doi.org/10.1080/09638237.2016.1276533.
16. Parker G, Graham R, Hadzi-Pavlovic D, McCraw S, Hong M, Friend P. Differentiation of bipolar I and II disorders by examining for differences in severity of manic/hypomanic symptoms and the presence or absence of psychosis during that phase. Journal of Affective Disorders. 2013; 150(3):941–7. https://doi.org/10.1016/j.jad.2013.05.018 PMID: 23774140
17. American Psychiatric Association. Diagnostic and Stastical Manual of Mental Disorders. 5th ed. Washington DC: American Psychiatric Association; 2013.
18. Parker G, Fletcher K. Differentiating bipolar I and II disorders and the likely contribution of DSM-5 classification to their cleavage. Journal of Affective Disorders. 2014; 152–154:57–64. PMID: 24446541
19. Parker G, Hadzi-Pavlovic D, Tully L. Distinguishing bipolar and unipolar disorders: an isomer model. Journal of Affective Disorders. 2006; 96(1):67–73.
20. Parker G, Fletcher K, Barrett M, Symmott H, Breakspear M, Hyett M, et al. Screening for bipolar disorder: the utility and comparative properties of the MSS and MDQ measures. Journal of Affective Disorders. 2008; 109(1):83–9.
21. Parker G, Graham R, Hadzi-Pavlovic D, Fletcher K, Hong M, Futerman S. Further examination of the utility and comparative properties of the MSQ and MDQ bipolar screening measures. Journal of affective disorders. 2012; 138(1):104–9.
22. Elwyn G, O’Connor AM, Bennett C, Newcombe RG, Politi M, Durand M-A, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). PloS one. 2009; 4(3):e4705. https://doi.org/10.1371/journal.pone.0004705 PMID: 19259269
23. O’Connor A. Ottawa Decision Support Framework Ottawa 2006 [cited 2016 20 October 2016]. https://decisionaid.ohri.ca/odsf.html.
24. Fisher A, Manicavasagar V, Kilin 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 PMID: 26924609
25. Malhi GS, Bassett D, Boyce P, Bryant R, Fitzgerald PB, Fritz K, et al. Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for mood disorders. Australian and New Zealand Journal of Psychiatry. 2015; 49(12):1087–206. https://doi.org/10.1177/0004867415617657 PMID: 26643054
26. Miura T, Noma H, Furukawa TA, Mitsuysasu H, Tanaka S, Stockton S, et al. Comparative efficacy and tolerability of pharmacological treatments in the maintenance treatment of bipolar disorder: a systematic review and meta-analysis. Journal of Affective Disorders. 2016; 195:110–16. https://doi.org/10.1016/j.jad.2016.02.011 PMID: 26969854
27. Oud M, Mayo-Wilson E, Braidwood R, Schulte P, Jones SH, Morris R, et al. Psychological interventions for adults with bipolar disorder: systematic review and meta-analysis. The British Journal of Psychiatry. 2016; 208(3):213–22. https://doi.org/10.1192/bjp.bp.114.157123 PMID: 26932433

28. Calabrese JR, Bowden CL, Sachs G, Yatham LN, Behnke K, Mehtonen O-P, et al. A placebo-controlled 18-month trial of lamotrigine and lithium maintenance treatment in recently depressed patients with bipolar I disorder. The Journal of clinical psychiatry. 2003; 64(9):1013–24. PMID: 14628976

29. Colom F, Vieta E, Martinez-Aran A, Reinares M, Goikolea JM, Benabarre A, et al. A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission. Archives of General Psychiatry. 2003; 60(4):402–7. https://doi.org/10.1001/archpsyc.60.4.402

30. Lam DH, Watkins ER, Hayward P, Bright J, Wright K, Kerr N, et al. A randomized controlled study of cognitive therapy for relapse prevention for bipolar affective disorder: outcome of the first year. Archives of General Psychiatry. 2003; 60(2):145–52. PMID: 12578431

31. McElroy SL, Weisler RH, Chang W, Olausson B, Paulsson B, Brecher M, et al. A double-blind, placebo-controlled study of quetiapine and paroxetine as monotherapy in adults with bipolar depression (EMBOLDEN II). Journal of Clinical Psychiatry. 2010; 71(2):163. https://doi.org/10.4088/JCP.08m0492gre PMID: 20122366

32. Suppes T, Marangell LB, Bernstein IH, Kelly DI, Fischer EG, Zboyan HA, et al. A single blind comparison of lithium and lamotrigine for the treatment of bipolar II depression. Journal of affective disorders. 2008; 111(2):334–43.

33. Young AH, McElroy SL, Bauer M, Philips N, Chang W, Olausson B, et al. A double-blind, placebo-controlled study of quetiapine and lithium monotherapy in adults in the acute phase of bipolar depression (EMBOLDEN II). The Journal of Clinical Psychiatry. 2010; 71(2):150–62. https://doi.org/10.4088/JCP.08m04995gre PMID: 20122369

34. Young AH, McElroy SL, Olausson B, Paulsson B. A randomised, placebo-controlled 52-week trial of continued quetiapine treatment in recently depressed patients with bipolar I and bipolar II disorder. The World Journal of Biological Psychiatry. 2014; 15(2):96–112. https://doi.org/10.3109/15622975.2012.665177 PMID: 22404704

35. 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: Clinicians’ perspective. Australian Psychologist. Accepted.

36. 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):958–71. Epub 21 January 2017. https://doi.org/10.1007/s10597-016-0077-4 PMID: 28102459

37. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. The Cochrane Library. 2017.

38. Sand-Jecklin K. The impact of medical terminology on readability of patient education materials. Journal of community health nursing. 2007; 24(2):119–29. https://doi.org/10.1080/07370010701316254 PMID: 17563283

39. Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): a new measure of understandability and actionability for print and audiovisual patient information. Patient education and counseling. 2014; 96(3):395–403. https://doi.org/10.1016/j.pec.2014.05.027 PMID: 24973195

40. Morony S, McCaffery KJ, Kirkendall S, Jansen J, Webster AC. Health literacy demand of printed lifestyle patient information materials aimed at people with chronic kidney disease: are materials easy to understand and act on and do they use meaningful visual aids? Journal of Health Communication. 2017; 22(2):163–70. https://doi.org/10.1080/10810730.2016.1258744 PMID: 28121226

41. O’Connor A, Cranney A. User Manual—Acceptability. Ottawa: Ottawa Hospital Research Institute; 1996 (updated 2002) [cited 2015 1 June]. https://decisionaid.chri.ca/docs/developer_manuals/UM_acceptability.pdf.

42. Sepucha KR, Borkhoff CM, Lally J, Levin CA, Matlock DD, Ng CJ, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. BMC Medical Informatics and Decision Making. 2013; 13(Suppl 2):S12.

43. 43Tlach L, Thiell J, Härter M, Liebherz S, Dirmeyer J. Acceptance of the German e-mental health portal www.psychenet.de: an online survey. 2016; 4:e2093.

44. 44O’Connor AM. Validation of a decisional conflict scale. Medical Decision Making. 1995; 15(1):25–30. https://doi.org/10.1177/0272989X9501500105 PMID: 7898294
45. Smith SK, Barratt A, Trevena L, Simpson JM, Jansen J, McCaffrey KJ. A theoretical framework for measuring knowledge in screening decision aid trials. Patient education and counseling, 2012; 89(2):330–6. https://doi.org/10.1016/j.pec.2012.07.009 PMID: 22871477

46. Australian Government National Health and Medical Research Council. General guidelines for medical practitioners on providing information to patients 2004 1 August 2016. https://www.nhmrc.gov.au/guidelines-publications/e57.

47. Marteau TM, Dormandy E, Micheie S. A measure of informed choice. Health Expectations. 2001; 4 (2):99–108. https://doi.org/10.1046/j.1369-6513.2001.00140.x PMID: 11359540

48. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O’Neil J, et al. Validation of a preparation for decision making scale. Patient Education and Counseling. 2010; 78(1):130–3. https://doi.org/10.1016/j.pec.2009.05.012 PMID: 19560303

49. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). British Journal of Clinical Psychology. 1992; 31(Pt 3):301–6.

50. Bauer MS, Crits-Christoph P, Ball WA, Dewees E, McAllister T, Alahi P, et al. Independent assessment of manic and depressive symptoms by self-rating: Scale characteristics and implications for the study of mania. Archives of General Psychiatry. 1991; 48(9):807–12. PMID: 1929771

51. O’Connor A. User Manual—Stage of Decision Making2000 (modified 2003) 20 October 2016. http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Stage_Decision_Making.pdf.

52. Degner LF, Kristjanson LJ, Bowman D, Sloan JA, Carriere K, O’Neil J, et al. Information needs and decisional preferences in women with breast cancer. JAMA. 1997; 277(18):1485–92. PMID: 9145723

53. Nolan MT, Hughes M, Narendr a DP, Sood JR, Terry PB, Astrow AB, 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. Journal of Pain and Symptom Management. 2005; 30(4):342–53. https://doi.org/10.1016/j.jpainsymman.2005.04.010 PMID: 16256898

54. De las Cuevas C, Penate W, de Rivera L. To what extent is treatment adherence of psychiatric patients influenced by their participation in shared decision making? Patient Preference and Adherence. 2014; 8:1547–53. https://doi.org/10.2147/PPA.S73029 PMID: 2539840

55. De las Cuevas C, Peñate W, de Rivera L. Psychiatric patients’ preferences and experiences in clinical decision-making: Examining concordance and correlates of patients’ preferences. Patient Education and Counseling. 2014; 96(2):222–8. http://dx.doi.org/10.1016/j.pec.2014.05.009. PMID: 2489480

56. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. Annals of Internal Medicine. 1980; 92(6):832–6. PMID: 7387025

57. Morris NS, MacLean CD, Chew LD, Littenberg B. The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. BMC Family Practice. 2006; 7(1):21.

58. Braun V, Clarke V. Thematic analysis. In: Cooper H, editor. APA Handbook of Research Methods in Psychology. 2. Washington D.C.: American Psychological Association; 2012. p. 57–71.

59. LeBlanc A, Bodde AE, Branda ME, Yost KJ, Herrin J, Williams MD, 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. 2013; 14(1):127.

60. Slade M. Implementing shared decision making in routine mental health care. World Psychiatry. 2017; 16(2):146–53. https://doi.org/10.1002/wps.20412 PMID: 2848878

61. Morant N, Kaminskiy E, Ramon S. Shared decision making for psychiatric medication management: beyond the micro-social: Health Expectations. 2015. https://doi.org/10.1111/hex.12392 PMID: 26260361

62. Charles C, Gafni A, Whelan T, O’Brien MA. Treatment decision aids: conceptual issues and future directions. Health Expectations. 2005; 8(2):114–25. https://doi.org/10.1111/j.1369-7625.2005.00325.x PMID: 15860052

63. Spielberger CD, Gorsuch RL, Lushene RE. Manual for the state-trait anxiety inventory. Palo Alto, CA: Consulting Psychologists Press; 1970.

64. Barr PJ, Forcino RC, Miahra M, Blitzer R, Elwyn G. Competing priorities in treatment decision-making: a US national survey of individuals with depression and clinicians who treat depression. BMJ Open. 2016; 6(1):e009585. https://doi.org/10.1136/bmjopen-2015-009585 PMID: 26747036

65. Van Horn PS, Green KE, Martinsussen M. Survey response rates and survey administration in counseling and clinical psychology: A meta-analysis. Educational and Psychological Measurement. 2009; 69 (3):389–403.

66. Kaminskiy E, Kaminskiy E, Senner S, Senner S, Hamann J, Hamann J. Attitudes towards shared decision making in mental health: a qualitative synthesis. Mental Health Review Journal. 2017; 22(3):233–56.
67. Hersch J, Barratt A, Jansen J, Irwig L, McGeachan K, Jacklyn G, et al. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. The Lancet. 2015; 385(9978):1642–52.

68. 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. https://doi.org/10.1136/bmj.c5370 PMID: 20978060

69. Simmons MB, Elmes A, McKenzie JE, Trevena L, Hetrick SE. Right choice, right time: Evaluation of an online decision aid for youth depression. Health Expectations. 2016; 20(4):714–23. https://doi.org/10.1111/hex.12510 PMID: 27748004

70. Elwyn G, O’Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ: British Medical Journal. 2006; 333(7565):417. https://doi.org/10.1136/bmj.38926.629329.AE PMID: 16908462

71. Stiggelbout A, Pieterse A, De Haes J. Shared decision making: concepts, evidence, and practice. Patient education and counseling. 2015; 98(10):1172–9. https://doi.org/10.1016/j.pec.2015.06.022 PMID: 26215573

72. Seale C, Chaplin R, Lelliott P, Quirk A. Sharing decisions in consultations involving anti-psychotic medication: a qualitative study of psychiatrists’ experiences. Social Science & Medicine. 2006; 62(11):2861–73.

73. James K, James K, Quirk A, Quirk A. The rationale for shared decision making in mental health care: a systematic review of academic discourse. Mental Health Review Journal. 2017; 22(3):152–65.

74. 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. Epub 23 February 2016. https://doi.org/10.1016/j.pec.2016.02.011 PMID: 26924609

75. Puschner B, Becker T, Mayer B, Jordan H, Maj M, Fiorillo A, et al. Clinical decision making and outcome in the routine care of people with severe mental illness across Europe (CEDAR). Epidemiology and psychiatric sciences. 2016; 25(1):69–79. https://doi.org/10.1017/S204579601400078X PMID: 25600424

76. Duncan E, Best C, Hagen S. Shared decision making interventions for people with mental health conditions. Cochrane Database of Systematic Reviews. 2010; 1.

77. Zisman-Ilan Y, Barnett E, Harik J, Pavlo AJ, O’Connell M. Expanding the concept of shared decision making for mental health: systematic search and scoping review of interventions. Mental Health Review Journal. 2017; 22(3):191–213.