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The effectiveness and design of informed choice tools for people with severe mental illness: a systematic review

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The effectiveness and design of informed choice tools for people with severe mental illness: a systematic review

Abstract

Background: People with severe mental illness (SMI) report difficulty in making health-related decisions. Informed choice tools are designed to guide individuals through a decision-making process.

Aims: To determine the effectiveness of these tools for people with SMI and to identify what methods and processes may contribute to effectiveness.

Method: A systematic electronic search was conducted for studies published between 1996 and January 2018. The search was updated in March 2020. Studies of any design reporting the development or evaluation of any informed choice tool for people with SMI were considered. A structured, narrative synthesis was conducted.

Results: Ten articles describing four tools were identified. Tools were designed to assist with decision-making around bipolar treatment, smoking cessation and disclosure of mental illness in employment situations. Positive changes in decisional conflict, stage of change, knowledge and self-efficacy were reported for two tools, though insufficient data exists for definitive conclusions of effectiveness. Feedback from service users and attention to readability appeared key.

Conclusions: The evidence base for informed choice tools for people with SMI is limited. Such tools should be developed in stages and include the views of people with SMI at each phase; readability should be considered, and a theoretical framework should be used to facilitate process evaluation.

Introduction

In healthcare, there has been a gradual shift from the paternalistic model, whereby the clinician holds the power, towards greater patient autonomy and control (Barry & Edgman-Levitan, 2012; Kaba & Sooriakumaran, 2007). In several countries, including Australia, Canada, New Zealand, the US and UK, promoting choice has been regarded as significant to modernising health and social care services and has formed part of governments' delivery plans (Coulter, 2010), such as *Creating a Patient Led NHS* in the UK (Department of Health/NHS, 2005) and the evolution of *Standard Two - Partnering with Consumers* within the *National Safety and Quality Health Services Standards* in Australia (Trevena et al., 2017). In mental health services in the UK, this includes providing informed choice of service or treatment and care pathway (Samele, Lawton-Smith, Warner, & Mariathasan, 2007). There is a shift towards providing information to the individual in a way that helps them make an informed 'choice', rather than simply obtaining informed consent, which is more passive (Coulter, Edwards, Elwyn, & Thomson, 2011 ; King & Moulton, 2006; Liu, Burston, Stewart, & Mulligan, 2018; Woolf et al., 2005). Informed choice is central to supporting patient autonomy by ensuring that people make choices in line with their interests, values and preferences and based on all relevant information, as well as being free from coercion (Jepson, Hewison, Thompson, & Weller, 2005; Smith et al., 2010).

To make an informed choice, information must be understood and presented in a balanced way so as not to suggest a right or wrong option (Hope, 2002; Jepson et al, 2005). Uncertainty about which course of action to take when choice among competing options involves risk, regret, loss, or challenge to personal life values is termed 'decisional conflict' (Leblanc, Kenny, O'Connor, & Légaré, 2009). 'Shared decision-making' interventions are available to support individuals' decisions (Elwyn et al., 2012; Légaré et al., 2018). These may be regarded as an

intermediate model between a paternalistic approach and the informed choice model (Charles et al., 1997; Kon, 2010) as they facilitate a collaborative process through which a clinician supports a patient to reach a decision about their treatment (Elwyn et al., 2010). Shared decision-making interventions share similarities with informed choice tools in that they both seek to clarify values, but the decision-making process is different as the decision is shared with a health professional (Drake et al., 2009; Duncan et al., 2010; Elwyn et al., 2010).

People living with SMI commonly report poor continuity of care (Biringier, Hartveit, Sundfør, Ruud, & Borg, 2017) and difficult relationships with health professionals, particularly in primary care (Clifton et al., 2016; Ross et al., 2015), so shared decision-making tools may not be appropriate for everyone within this population. In addition, primary care clinicians face time constraints to using a shared decision-making tool (Gravel et al., 2006), so an informed choice tool may be a more suitable format.

Informed choice tools, also known as ‘decision aids’ or ‘decision support tools’, are used to guide individuals through a decision-making process and aim to reduce decisional conflict by providing the individual with the required information to allow them to make an informed choice, while also including their values in the decision-making process (Barratt, 2008). These tools, including pamphlets, web-based tools or videos, describe the decision to be made and the options available, and help people to think about the options from a personal viewpoint (Stacey et al., 2017). They may include ‘personal stories’, testimonies or videos of people who have faced a similar decision.

In the general population, informed choice tools have been shown to be effective in helping people make decisions about a range of health issues (Stacey et al., 2017). Such tools may be

beneficial for people with SMI, however, a proportion of this population may have difficulty in processing health information (Borzekowski et al., 2009; Castillo, Rosati, Williams, Pessin, & Lindy, 2015; Clausen, Watanabe-Galloway, Baerentzen, & Britigan, 2016; Ferron et al., 2011; Stahl, 2003) which may impact on how informed choice tools are used by them (Borzekowski et al., 2009; Clausen et al., 2016; Ferron et al., 2011). The optimal design for an informed choice tool for people with SMI is unknown. This study addresses this by systematically reviewing the literature to answer the following questions: (1) how effective are informed choice tools for people with SMI in improving decision making outcomes and (2) what methods and processes contribute to the effectiveness of informed choice tools for people with SMI.

Methods

This systematic review is reported in accordance with the 2009 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement (Moher et al., 2009). The review protocol is registered on the International prospective register of systematic reviews (PROSPERO Registration number anonymised for peer review).

Searches

Electronic searches of Cochrane Central Register of Controlled Trials, EBSCOhost, Web of Science, Academic Search Elite, MEDLINE, EMBASE, CINAHL and PsycINFO were conducted (as part of a PhD) in March 2018 for studies published since 1996. The search was updated in March 2020 and an additional study was identified for inclusion (Fisher, Sharpe, Anderson, Manicavasagar, & Juraskova, 2018). Grey literature, i.e. conference abstracts through Open Grey and the Grey Literature Report, was searched and reference lists of included

studies and relevant review articles were reviewed. Searches were restricted to English language publications. The first author of the included studies was contacted by one reviewer (FLG) to find relevant unpublished work. The search strategy, which was adapted from related systematic reviews (Colquhoun, Squires, Kolehmainen, Fraser, & Grimshaw, 2017; Taylor et al., 2017) and checked by a specialist health librarian, included relevant synonyms and search tools to ensure maximum sensitivity. The full list of search terms has been published (Lamontagne-Godwin et al., 2017); this and a full electronic search strategy for one database (MEDLINE) is available as an additional file.

Inclusion and exclusion criteria

We included studies of any design describing the development or evaluation of any informed choice tool targeted specifically for use by adults with SMI, where the aim of the tool was to improve decision making outcomes. Studies of shared decision-making tools which could not be used by people with SMI without input from a healthcare professional were excluded.

For this review, SMI was defined using the ICD-10 (World Health Organisation, 1992, updated 2016) codes as schizophrenia spectrum disorders (F20.0-F20.9), schizoaffective disorders (F25), bipolar affective disorder (F31) and recurrent depressive disorder with psychotic symptoms (F33.3). We included studies where participants were defined by authors as having SMI even when specific diagnoses were not provided (Ferron et al., 2011; Ferron et al., 2016; Brunette et al., 2017). Study participants had to be adults (18 years or over) of any gender with an SMI, however diagnosed, and treated in any setting. Studies of participants with severe depression without psychotic symptoms were excluded from this review as there is evidence that their behaviour around screening decision-making differs from that of people with psychosis (Howard et al., 2010).

Study participants with co-morbid physical illness were eligible. Participants with co-morbid substance abuse disorders were eligible only if they were engaged in treatment for these conditions. Studies with populations involving people with mental disorders other than those defined as severe above (e.g. obsessive compulsive or anxiety disorders) were included only if more than 50% of participants had a diagnosis of SMI, or if data limited to those with SMI were available. Studies not published in English were excluded due to lack of resources for translation.

Study selection

Titles and abstracts were screened independently by one reviewer (FLG) to identify potentially eligible studies. A random sample (10% of the titles and abstracts) was collected by FLG from the total list of abstracts using the Excel RANDBETWEEN function; this sample was sent to the second reviewer (RS) for screening. The second reviewer (RS) was selected for this task because of their different academic background; the aim being to minimise possible discipline-related bias.

Agreement between the two reviewers was 80%; differences were reconciled with a third (EB) and fourth reviewer (CL) through discussion. Cohen's kappa could not be computed due to reviewer one (FLG) having rejected all the titles from the sub-sample reviewed by the second reviewer (RS). The full text of potentially eligible studies was assessed for inclusion by three reviewers (FLG, CL and RS). Disagreements ($n = 4$) were resolved through discussion between the whole team.

Quality assessment

The quality of the included studies was assessed using 'ICROMS' (Integrated quality Criteria for the Review Of Multiple Study designs) (Zingg et al., 2016). This allows reviewers to attribute points to studies for a range of quality criteria, which are assessed using seven dimensions (e.g. managing bias in outcome measurements and blinding, managing bias in sampling or between groups). Scores for each criterion are: Yes (criterion met): 2 points; Unclear: 1 point; No: 0 points. The sum of points attributed to each criterion represents the global quality score for a study. Studies were not excluded based on quality, but assessments of quality informed the data synthesis and interpretation of results. Three reviewers independently assessed study quality (FLG, CL and RS); discrepancies were resolved through discussion.

Data extraction

Data extraction forms were piloted and used by one author (FLG) to develop a data extraction framework, which was then reviewed by two authors (CH and EB). Papers were divided into two categories: 1) those describing the evaluation of a tool (Table 1) and 2) those describing the development of the tool (Table 2). Some papers described both. Data were extracted and synthesised from Table 1 [demographics and setting of participants, intervention evaluation (design, outcomes, results), and main study weaknesses] and Table 2 [demographics and setting of participants, response rate, sample size, methods (tool development, description of tool, use of behaviour change theory) and study weaknesses]. One author (FLG) extracted all the data; a second author (CL) verified half the extracted data while a third author (RS) verified the other half.

Data synthesis

A narrative synthesis of the effectiveness findings from the included studies was produced (Popay et al., 2006). Data from all outcomes reported in the selected studies were included in our synthesis. To assess effectiveness, we considered decisional conflict and knowledge to be primary outcomes, as these are key indicators of improvement in decision-making (Stacey et al., 2017). Meta-analysis was not possible due to insufficient data, heterogeneity in study design and outcome measures used. To identify what methods and processes may contribute to effectiveness, extracted data were reviewed to identify common and key steps used across studies to develop the tools. Steps were agreed through discussion by the entire team.

[Tables 1 and 2 near here]

Results

Search results are summarised in the PRISMA flow chart (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009) (figure 1). Ten studies (Australia: $n = 1$, Germany: $n = 1$, England: $n = 2$ and United States: $n = 6$) were included. These described four tools: a decision aid to assist people with SMI to decisions regarding disclosure of their mental health status in the employment context, termed here '*disclosure tool*' (Brohan et al., 2014a; Henderson et al., 2013); 2) a web-based decision support system to stimulate motivation in people with SMI to quit smoking, termed '*smoking cessation tool*' (Brunette et al., 2011; Brunette et al., 2013; Brunette et al., 2017; Ferron et al., 2011; Ferron et al., 2012; Ferron et al., 2016); 3) a web-based decision aid to encourage patients to participate in decision-making about treatment options for bipolar disorder termed '*treatment choice tool*'; this tool has not been evaluated (Liebherz et al., 2015); 4) a decision aid (booklet) for people with bipolar II disorder and their families making decisions about treatment options to prevent relapse, termed '*relapse prevention tool*'; a feasibility study protocol has been published (Fisher et al., 2018; Fisher et al., 2018b). A description of the tools can be found in Tables 1 and 2.

[Figure 1 near here]

Quality of included studies

Two studies describing the development of the tools did not clearly fit any design category within the ICROMS framework. The treatment choice tool (Liebherz et al., 2015) reported participant responses to an unvalidated survey, whilst the relapse prevention tool (Fisher et al., 2018) used a cross sectional mixed design to assess the tool's acceptability, feasibility, safety and usefulness. Three studies did not meet the minimum quality score attributed to their study design: 15.5/22 (Ferron et al., 2011), 21/22 (Brohan et al., 2014a) and 20.5/22 (Ferron et al., 2012). The quality of these three descriptive studies could only partially be assessed as their study designs lacked an exact fit with the ICROMS framework. One study (Ferron et al., 2016) met the minimum quality score and five scored above it (Brunette et al., 2011; 2013; 2017; Henderson et al., 2013; Liebherz et al., 2015). The main study weaknesses are described in Tables 1 and 2, small sample size and lack of generalizability were common. Overall, the quality of evidence for developmental studies was rated moderate and the quality of evidence for the evaluation studies was rated good.

Evidence of effectiveness

No effectiveness data are available for the treatment choice (Liebherz et al., 2015) and relapse prevention (Fisher et al., 2018) tools. The disclosure tool was evaluated in a pilot and in an exploratory randomised controlled trial (RCT) (Brohan et al., 2014a; Henderson et al., 2013). The smoking cessation tool was evaluated in a pilot study (using a quasi-experimental design) (Brunette et al., 2011), an RCT (Brunette et al., 2013), using secondary analysis of data (Ferron et al., 2012) from the RCT (Brunette et al., 2013), at 6-month follow-up of the RCT (Ferron et al., 2016) and in a randomised, controlled pilot study comparing the smoking cessation tool to

the computerised smoking education tool from the American National Cancer Institute (ANCI) (Brunette et al., 2017). Reported outcomes are included in Table 1 and summarised below.

Primary outcomes

Decisional conflict

This was measured using the validated Decisional Conflict Scale (O'Connor, 1993, updated 2010) in a before and after study ($n = 15$) and an RCT ($n = 79$) of the disclosure tool (Brohan et al., 2014a; Henderson et al., 2013). Both studies met criteria necessary to achieve the minimum quality score. A reduction in decisional conflict associated with use of the tool was seen in all groups (Brohan et al., 2014a; Henderson et al., 2013); a significant difference in favour of the intervention group compared with a usual care control group was found at three-month post use (Henderson et al., 2013) (Table 1).

Knowledge

This was measured in one study ($n = 58$) (Brunette et al., 2013), the primary aim of which was to test the effect of carbon monoxide feedback as an additional component to the smoking cessation tool. This study met minimum quality criteria. At two-month follow-up, intervention group participants reported to research interviewers (type of interview not specified) increased knowledge about the risks of carbon monoxide compared to the control group; the difference was statistically significant. However, there was no difference in rudimentary knowledge about the health consequences of smoking between groups (Table 1).

Other outcomes reported

Stage of change (i.e. the participant's perceived degree of readiness to change their behaviour):

This was measured in five studies (Brohan et al., 2014a; Brunette et al., 2013; Ferron et al.,

2012; Ferron et al., 2016; Henderson et al., 2013); a range of measures was employed. The Stage of Decision Making scale (1-5) (O'Connor, 2000, updated 2003) was used for the disclosure tool (Brohan et al., 2014a; Henderson et al., 2013). The impact of the disclosure tool on the individual's readiness to engage in decision-making was tested in two studies (Brohan et al., 2014a; Henderson et al., 2013) ($n = 15$ and 79 respectively). No statistically significant change was found in any analysis, though improvement was indicated in one group pre and post completion of the tool (Brohan et al., 2014a) and between immediate and three-month follow-up in another (Henderson et al., 2013). The impact of the smoking cessation tool on the stage of change was tested in three studies ($n = 124$, 135 and 124 respectively) (Brunette et al., 2013; Ferron et al., 2012; Ferron et al., 2016) by asking "*Are you seriously thinking about quitting?*" responses were scored using a four-point scale (DiClemente et al., 1991; Donovan, Jones, Holman, & Corti, 1998). Two studies (Brunette et al., 2013; Ferron et al., 2012) did not report their findings for this outcome; in the third study (Ferron et al., 2016) improvement was indicated pre and post use of the tool (Table 1).

Empowerment: This was measured in one study (Henderson et al., 2013) using two subscales of the Boston University Empowerment Scale (Rogers, Ralph, & Salzer, 2010): Factor 1 (Self-esteem–self-efficacy) and Factor 2 (Power–powerlessness). Statistically significant improvement was found in favour of those using the disclosure tool compared to usual care on the Factor 2 subscale, but there was no difference between groups in terms of self-esteem [Table 1].

Attitudes and beliefs

A range of attitudes and beliefs was measured using different tools; some studies adapted validated measures or used parts of one so the validity of findings may be unclear:

Behavioural withdrawal: This was measured in one study of the disclosure tool (Henderson et al. 2013) using an adapted measure. No significant difference between groups was found at any time point.

Behavioural motivation: Four studies assessed whether the smoking cessation tool had any impact on behaviours indicative of motivation to quit smoking (Brunette et al., 2011; Brunette et al., 2013; Ferron et al., 2012; Ferron et al., 2016), though one study (Ferron et al., 2016) is a secondary analysis of data from a parent study (Brunette et al., 2013), so these data were reported twice. All used the Behavioural Motivation Index (Brunette et al., 2011).

Importance of quitting smoking: In one study (Brunette et al., 2017) the primary outcome selected was the proportion of participants who, following use of a smoking cessation intervention (either the smoking cessation tool or the ANCI tool), were using verifiable cessation treatment at the three-month follow-up. This outcome was reported for 6% of participants (no breakdown was given by intervention). Following use of either intervention, participants rated the importance of quitting highly (mean 5.7 ± 1.4 on a 1–7 scale) however intentions to use cessation treatments were relatively low (mean 3.6 ± 1.9 on a 1–7 scale) (Brunette et al., 2017). Authors reported there was no difference between intervention groups in intentions and importance of quitting.

Smoking behaviours: two months after use of the smoking cessation tool, over half (52.9%) of participants in one study (Brunette et al., 2013) reported having engaged in at least one cessation behaviour; this increased to 55.6% at 6 months when and nearly 40% had also initiated at least one type of cessation treatment (Ferron et al., 2016).

Verifiable smoking cessation treatment was tested in three evaluations of the smoking cessation tool (Brunette et al., 2013; Brunette et al., 2017; Ferron et al., 2012). In two studies, one a RCT (Brunette et al., 2013), the other a non-controlled interrupted time series (Ferron et al., 2012), use of the tool was associated with smoking cessation behaviour (51% of participants in the Ferron et al. 2012 study). Approximately 30% of the group initiated a cessation treatment by discussing treatment options with a smoking cessation specialist; a third evaluation (randomized pilot study) reported about 6% over the three-month follow-up period (Brunette et al., 2017). Authors reported that the reason behind the participants' change in smoking behaviour could be due to the flexible design of the smoking cessation tool, which might allow participants to tailor their use of the tool to meet their individual needs (Ferron et al., 2012).

Self-reported abstinence from smoking was tested in two studies which met the minimum quality criteria (Brunette et al., 2017; Ferron et al., 2016). Ferron et al. (2016) reported that overall, the smoking cessation tool engaged most participants into cessation activity: 60 % of participants (N = 74) abstained from smoking for at least one day over the six-month follow-up period. Sustained abstinence was recorded for 29% of participants for at least seven days, while 7% persisted in their abstinence at six-month follow-up (Ferron et al., 2016). Another evaluation assessed whether the rate of treatment initiation and cessation behaviours would be higher among users of the tool in comparison to users of the computerised American National Cancer Institute (ANCI) education tool on smoking cessation (Brunette et al., 2017). No participant from the ANCI group achieved verified abstinence, while almost 15% of participants who used the smoking cessation tool met the study's definition of biologically verified abstinence at the 14-week follow up (Brunette et al., 2017).

Development and design of informed choice tools

Four studies involving participants living with SMI (smoking cessation: $n = 71$, disclosure: $n = 15$, treatment choice: $n = 210$, relapse prevention: $n = 31$ as well as $n = 11$ family members) described the informed choice tools' development (Brohan et al., 2014a; Ferron et al., 2011; Fisher et al., 2018; Liebherz et al., 2015); data are summarised in Table 2 and synthesised below.

Step One: Identify barriers to decision-making

The disclosure (Brohan et al., 2014a) and treatment choice (Liebherz et al., 2015) tools were informed by an initial systematic review of barriers to decision-making (Brohan et al., 2012; Tlach et al., 2014). The smoking cessation tool was informed by a review of smoking cessation interventions for adults with SMI which identified barriers to that behaviour (Ferron, Alterman, McHugo, Brunette, & Drake, 2009). The disclosure tool was informed by a primary qualitative study to explore people's experience of disclosure of their mental health problems (Brohan et al., 2014b). Authors of the relapse prevention tool (Fisher et al., 2018) systematically reviewed studies of communication and decision-making in mental health-based samples including patients with bipolar disorder (Fisher, Manicavasagar, Kiln, & Juraskova, 2016).

Step Two: Theoretically underpin the intervention

The disclosure and smoking cessation tools used the Theory of Planned Behaviour (Ajzen, 1991) to inform content development (Brohan et al., 2014a; Ferron et al., 2011). The disclosure, smoking cessation and relapse prevention tools (Brohan et al., 2014a; Ferron et al., 2011; Fisher et al., 2018) used the Ottawa decision support framework (O'Connor, 1999). Use of these frameworks ensured that the tools were theoretically underpinned (Moore et al., 2015). The theoretical basis for the disclosure tool (Brohan et al., 2014a) was an integrated disclosure

framework developed from a systematic review (Brohan et al., 2012) and qualitative work (Brohan et al., 2014b).

Step Three: Service user-led content development

People with SMI were involved in the development of each tool in different ways. Feedback from people with SMI was collected using semi-structured interviews during the development of the smoking cessation, relapse prevention and disclosure tools (Brohan et al., 2014a; Ferron et al., 2011; Fisher et al., 2018). Questions focused on their general opinions on the tool, other information/experiences which they felt should be included and any amendments to existing information (Brohan et al., 2014a). For the relapse prevention tool, participants were asked to read the tool and then complete validated and purpose-designed questionnaires. A follow-up semi-structured telephone interview elicited additional feedback on the tool (Fisher et al., 2018). Feedback was collected for the treatment choice tool using an online cross-sectional survey (Liebherz et al., 2015). The think-aloud method was also used by authors of the disclosure tool (Brohan et al., 2014a). Think-aloud observations are a validated method to assess user experience and usability of interventions and allows observation of the actual reactions of the participant using the tool (McDonald, Zhao, & Edwards, 2016; van Someren, Barnard, & Sandberg, 1994). The method has been used successfully to test a smoking cessation app with participants who have SMI (Vilardaga et al., 2016).

Step Four: Ensure ease of use

Ease of use was tested in three studies of the smoking cessation tool (Brunette et al., 2017; Ferron et al., 2011; Ferron et al., 2012), one study of the relapse prevention tool (Fisher et al., 2018) and one study of the disclosure tool (Brohan et al., 2014a). The Perceived Usefulness and Ease of Use Scale (Davis, 1989) was adapted and used in an evaluation of the smoking cessation tool to assess participants' perceptions of the usefulness and ease of operating the

tool. Authors of the relapse prevention tool assessed participant feedback using an adapted measure from previous acceptability studies of mental health decision-support tools (Tlach et al., 2016). Participants reported their agreement with the tool's perceived ease of use (8 items), perceived usefulness (9 items), attitudes towards using (3 items), and perceived bias (4 items).

Most participants testing the smoking cessation tool ($n = 124$) reported high levels of satisfaction with the first and second (revised) version of the tool as well as the presentation of the information (Ferron et al., 2012). Results showed an increased ease of use from the first to the last version of the website, which was reflected in participants' reduction in unproductive clicking and with fewer questions asked about how to use the tool (Ferron et al., 2011). An evaluation study of the smoking cessation tool compared it with the computerised ANCI tool (Brunette et al., 2017). Users took part in a semi-qualitative interview (an adapted version of the Perceived Usefulness and Ease of Use Scale) and described how although they felt that both the tool and the ANCI tool were "easy to use," 10.7% of ANCI education users *versus* 3.3% of users of the smoking cessation tool felt it was "hard to understand". In terms of satisfaction, 71.4% of the ANCI education users and 83.4% of users of the tool described the intervention as "good" or "very good".

For the smoking cessation intervention, suggested improvements included integrating a mouse tutorial, using a flat interface, increasing font and button sizes, using a blank background with a simple border graphic and using text to speech software. To ensure usability of the smoking cessation tool, authors consulted previous research on usability for people with schizophrenia (Rotondi et al., 2007) and applied usability guidelines for people with cognitive deficits (United States Department of Human Services, 2010).

Overall, participants ($n = 31$ patients and $n = 11$ family members) testing the relapse prevention tool reported it as easy-to-use and useful in treatment decision-making, presenting balanced, up-to-date and trustworthy information that did not provoke anxiety. Participants ($n = 15$) testing the disclosure tool rated its relevance highly as well as speed and ease of use (Brohan et al., 2014a).

Step Five: Ensure readability

The reading capability level of participants with SMI was checked during the development phase of the disclosure and smoking cessation tools (Brohan et al., 2014a; Ferron et al., 2011). Authors of the disclosure tool refer to the Flesch-Kincaid (Flesch Reading Ease and the Flesch–Kincaid Grade Level) readability tests, while authors of the smoking cessation tool used the US-based web design and usability guidelines (United States Department of Human Services, 2010). Following feedback from participants, interventionists developing the tools revised the readability of their tools to a revised Flesch-Kincaid Grade level of 8.4 i.e. to be understandable by the average US 8th - 9th grader (aged 13-15 years) and from an 8th grade to below 5th grade reading level respectively (Brohan et al., 2014a; Ferron et al., 2011). Further feedback concerning the format and design layout of tools suggested that providing definitions, simplifying language, ‘breaking down’ the information and including verbatim quotes or videos from their peers is helpful. Authors of the relapse prevention tool did not assess its readability levels, as readability was not considered an appropriate index of comprehensibility given the complex medical terminology included in the tool (Fisher et al., 2018). Authors included this terminology which was felt to be necessary and provided definitions in simple, descriptive terms in the tool’s glossary. The tool was professionally copy-edited for low health literacy levels. In addition, a health literacy review of the tool was conducted using the Patient

Education Materials Assessment Tool (Shoemaker, Wolf, & Brach, 2014). The tool scored as an easy to understand and use patient education material.

For online interventions, computer literacy is also important for readability. Computer literacy levels were reported for several studies describing the smoking cessation tool: computer use (>5 times) for 11 out of 21 participants (52.4%) in the intervention group and 6 out of 20 (30%) for the control group (Brunette et al., 2011); computer use (>5 times) for 20 out of 58 participants (34.5%) of the intervention and carbon monoxide monitor group and 29 out of 66 participants (44%) of the intervention only group (Brunette et al. 2013); no computer experience for 30 out of 131 participants (22%), computer use (<5 times): 23 out of 131 (17%) and computer use (>5 times): 82 out of 131 (61%) (Ferron et al., 2012). Brunette et al (2017) reported several computer literacy indicators : being comfortable using a computer : 25 out of 30 participants (83.3%) in the intervention group, 24 out of 28 participants (85.7%) using the ANCI tool and 18 out of 23 participants (78.3%) with no intervention; having their own smartphone : 19 out of 30 (67.9%) for the intervention, 23 out of 28 (76.7%) using the ANCI tool and 21 out of 28 (91.3%) with no intervention; used the Internet in the past year: 29 out of 30 (96.7) for the intervention group, 26 out of 28 (92.9%) using the ANCI tool and 23 out of 23 (100%) for the group with no intervention and lastly use of the Internet to look up health information: 14 out of 30 (46.7%) for the intervention group, 21 out of 28 (75%) using the ANCI tool and 12 out of 28 (52.2%) with no intervention. The Ferron (2011) study did not report data on individual participants ; authors highlighted that many participants lacked exposure to computers (such as difficulty using a mouse) and lacked knowledge on how to navigate a website and had limited to no experience with the web. The treatment choice tool reported on internet use of participants: 195 out of 210 participants (93.3%) used the Internet

daily and 104 out of 210 participants (49.5%) used the Internet more often for general health information searches, minimum once a week up to daily (Liebherz et al., 2015).

Discussion

This systematic review identified four available informed choice tools that people with SMI can use alone without requiring support from a professional. Due to some small sample sizes and heterogeneity between studies, conclusions about the effectiveness of these tools are not possible. Nevertheless, some data exist which suggest that such tools may facilitate a reduction in decisional conflict and movement in stage of change towards decision-making. Improved knowledge was recorded in small sample sizes; more data are required to assess effectiveness. Some decision-specific attitudes improved following the use of a particular tool such as increased empowerment (disclosure tool), behavioural motivation, importance of quitting and self-reported cessation behaviours (smoking cessation tool), although the validity of measures used is uncertain in some cases and data are few so these findings should be interpreted with caution. Step One is important in view of findings that the smoking cessation tool performed better than a tool aimed at the general population (the ANCI computerised smoking education tool) (Brunette et al., 2017). This was the only study to compare a SMI specific tool with that aimed at another population and highlights that there are specific barriers to decision making which are related to having an SMI. This has been found in studies of decisions to take up cancer screening (Clifton et al., 2016) and other health screening (Lamontagne-Godwin et al., 2018) by this population.

The optimal processes for the other identified steps remain unclear however and may vary depending on the decision to be addressed and the population concerned.

Authors of the smoking cessation, relapse prevention and disclosure tools (Brohan et al., 2014a; Ferron et al., 2011; Fisher et al., 2018) sought to increase readability by providing definitions, simplifying the language and breaking down the information. Further simplification of the disclosure tool may have been required for some users, but it was thought that this could risk diluting the complexity of the disclosure decision-making, thus lowering its effectiveness (Brohan et al., 2014a). Hence there is a balance between readability and effectiveness for a proportion of potential users which researchers developing interventions will have to consider.

This review identified limited use of theoretical frameworks in tool development, as recommended by the MRC framework and related guidance (Craig et al., 2008; O’Cathain et al. 2019) – only the smoking cessation and disclosure tools were informed by theory. Lack of use of theoretical framework in the included studies meant that we were unable to determine empirical methods related to optimal effectiveness.

Finally, due to the paucity of available tools and the heterogeneity between them, we were unable to determine the best format for informed choice tools for people with SMI, such as whether paper- or web-based- tools are more appropriate. We identified two paper-based (Brohan et al., 2014a, Fisher et al., 2018) and two web-based tools (Ferron et al., 2011; Liebherz et al., 2015), though no study directly compared the two formats (Ferron et al., 2012). The authors of the relapse prevention tool (Fisher et al., 2018) have published a protocol for a feasibility RCT of a decision aid website (e-DA) to support young adults with bipolar II disorder (BPII), and their families (Fisher et al., 2018b). A systematic review investigating the acceptability of mobile phone- and online- delivered interventions for people with SMI (Berry, Lobban, Emsley, & Bucci, 2016) advised researchers to use qualitative methods to assess acceptability at each phase of intervention development and testing, due to attrition rates in the

completion of modules within an intervention. Authors of another systematic review (Batra et al., 2017) on the use of digital health technology for patients with SMI concluded that long-term data are needed to fully understand its usefulness and acceptability for people with SMI (Batra et al., 2017).

Strengths and limitations of this review

This is the first systematic review to explore the development and evaluation of informed choice tools for people with SMI. Findings inform a list of steps that interventionists can follow when developing such tools for this group. The review includes heterogeneous interventions from different settings and mental health systems, so findings should be interpreted cautiously and the impact of setting considered. The generalizability of our findings may be reduced as we applied a narrow definition of severe mental illness (psychosis), which excluded studies focusing on other mental health conditions such as anxiety disorders or Post-traumatic stress disorder (PTSD). People with these disorders may face different challenges which may not be relevant to those diagnosed with psychosis. It is unlikely that any one tool would be suitable for a very diverse population. A strength of this review is that ICROMS, a robust framework, was used to assess study quality; however a limitation is that it was not fully able to capture the design of the descriptive studies.

Implications for research and practice

Few informed choice tools exist for people with SMI. Preliminary findings suggest these tools may facilitate decision-making, though more data are needed to confirm this. This systematic review provides a preliminary list of steps for interventionists seeking to develop informed choice tools for people with SMI. The development of such tools should proceed in stages and

include the views of people with SMI at each phase. Attention should be paid to readability and computer literacy, which are heterogeneous within this population and important variables to consider when developing an intervention for this group. In addition, emphasis should be placed on addressing the different functional impairment needs that can be present for people with lived experience of SMI. Use of a theoretical framework would assist in determining how interventions may work best to inform adjustments. Future research should establish a solid evidence base regarding the effectiveness of informed choice tools for this group before such tools can be delivered and scaled up into routine practice.

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Table 1. Evaluation Studies

Participants		Intervention evaluation			Main study weaknesses	Global quality score (ICROMS)
Demographics	Setting	Design	Outcomes	Results		
Intervention: Decision aid for disclosure of mental illness to employers (Brohan et al., 2014a)						
<p>N = 15 (8 female)</p> <p>Ethnicity: White British: N = 8 Black African: N = 3 Black Caribbean: N = 1 Black British: N = 1 Other white background: N = 1</p> <p>Diagnosis: Bipolar disorder: N = 7 Schizophrenia: N = 1 Do not know: N = 2</p>	Secondary care	Before and after study	<p>Primary outcomes:</p> <p>(a) stage of decision-making (b) decisional conflict (c) employment-related outcomes</p> <p>Feasibility was tested using measures of: brevity, ease of use, relevance to self and others</p> <p>To obtain further feedback on the informed choice tool: semi-structured interviews</p>	<p>Mean Decisional Conflict Scale scores improved after completing the informed choice tool</p> <p>Mean Stage of Decision-making Scale score reduced (indicating improvement)</p> <p>Participants found the tool quick to use (60%), relevant (60%) and would recommend it to others (80%)</p> <p>80% reported that they would definitely or probably use the tool in making disclosure decisions</p>	<p>Lack of power to detect statistically significant change in outcome scores</p> <p>Small unrepresentative sample – limited generalisability</p> <p>No follow-up</p>	21 (minimum score required: 22)

Participants		Intervention evaluation			Main study weaknesses	Global quality score (ICROMS)
Demographics	Setting	Design	Outcomes	Results		
Intervention: Decision aid for disclosure of mental illness to employers (Henderson et al., 2013)						
<p>N = 79 (control group = 39, intervention group = 40) Control group (20 female)</p> <p>Ethnicity: White: N = 16 Black/Black British: N = 17 Asian/Asian British: N = 2 Other: N = 4</p> <p>Diagnosis: Schizophrenia spectrum: N = 13 Bipolar disorder: N = 6 Mixed: N = 2 Don't know: N = 6</p> <p>Intervention group (18 female):</p> <p>Ethnicity: White: N = 14 Black/Black British: N = 20 Asian/Asian British: N = 1 Other: N = 5 Schizophrenia spectrum: N = 11 Bipolar disorder: N = 7 Mixed: N = 3 Don't know: N = 5</p>	Vocational services for clients with mental health problems	Exploratory randomised controlled trial	<p>Participants were randomly assigned to use of the tool plus usual care or usual care alone. Follow-up was at three months</p> <p>Primary outcomes: (a) stage of decision-making (b) decisional conflict (c) employment-related outcomes</p> <p>Secondary outcomes: (a) eight-item self-assessment of work performance (short version of the Work Limitations Questionnaire) (b) self-esteem–self-efficacy and power–powerlessness subscales (17 items) of the original Boston University Empowerment Scale</p>	<p>No substantial difference between trial arms for any variable</p> <p>No outcome measures were associated with loss to follow-up</p>	<p>Small sample</p> <p>Skewed distributions of employment-related activity</p>	29 (minimum score required: 22)

Participants		Intervention evaluation			Main study weaknesses	Global quality score (ICROMS)
Demographics	Setting	Design	Outcomes	Results		
Intervention: Decision support system to motivate people with SMI to quit smoking [<i>Let's Talk About Smoking</i>] (Brunette et al., 2011)						
<p>N = 41 (control group = 20, intervention group = 21)</p> <p>Control group (7 female): Ethnicity: African American: N = 17 Other: N = 3</p> <p>Diagnosis: Schizophrenia: N = 19 Other: N = 1</p> <p>Intervention group (7 female): Ethnicity: African American: N = 20 Other: N = 1</p> <p>Diagnosis: Schizophrenia: N = 9 Other: N = 12</p>	<p>Psychosocial rehabilitation centre (provides supported housing and comprehensive psychiatric services)</p>	<p>Quasi-experimental design to test the decision support system among smokers with SMI</p>	<p>Participants were interviewed at baseline and followed up two months later to assess for behaviours indicative of motivation to quit smoking</p> <p>Primary outcome: whether participants became motivated to quit smoking</p>	<p>Two-month follow-up: participants who had used the smoking cessation tool were more likely to have engaged in at least one smoking cessation motivation behaviour (67%) than those in the control group (35%)</p>	<p>Small sample</p> <p>Non-equivalent clinical characteristics of the groups</p> <p>Differing levels of intensity of the experimental and control interventions</p> <p>Authors did not correct for the number of statistical tests</p>	<p>24 (minimum score required: 18)</p>
Participants	Intervention evaluation				Main study weaknesses	

Demographics	Setting	Design	Outcomes	Results	Global quality score (ICROMS)	
Intervention: Decision support system to motivate people with SMI to quit smoking [<i>Let's Talk About Smoking</i>] (Ferron et al., 2012)						
<p>N = 135 (38 female)</p> <p>Ethnicity: Black: N = 64 White: N = 49 Latino: N = 19 Other: N = 22</p> <p>Diagnosis: Schizophrenia/schizoaffective disorder: N = 95 Mood disorder: N = 34 Other : N = 6</p>	Psychiatric rehabilitation centre	Secondary analysis of data from parent study that evaluated an RCT of whether use of feedback from a carbon monoxide monitor was a necessary ingredient in the decision support system	<p>Primary outcomes:</p> <p>(a) process variables, including length of time spent on two tool subsections and choice of video host</p> <p>(b) behavioural outcome variables, including number of behaviours indicative of motivation to quit smoking (e.g. evidence-based treatment initiation)</p>	<p>About a third of the group initiated cessation treatment.</p> <p>Almost a third met with a smoking cessation specialist to discuss treatment</p> <p>Almost 40% of participants discussed using a smoking cessation medication with their doctor.</p> <p>More than 50% of the participants engaged in one or more behavioural indicator of motivation</p>	<p>Monetary compensation provided to participants (\$15) may have contributed to the high feasibility results of the tool</p> <p>The study doesn't allow the "host choice" (i.e. participant can choose gender, ethnicity etc of the "online host" of the tool) aspect to be evaluated (i.e. whether it improves efficacy of the website)</p>	20.5 (minimum score required: 22)

Participants	Intervention evaluation	Global quality
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Demographics	Setting	Design	Outcomes	Results	Main weaknesses	study score (ICROMS)
Intervention: Decision support system to motivate people with SMI to quit smoking [<i>Let's Talk About Smoking</i>] (Brunette et al., 2013)						
<p>= 124 (control group = 66, intervention group = 58) Control group (21 female): Ethnicity: African American: N = 30 White: N = 16 Hispanic: N = 12 Diagnosis: Schizophrenia/schizoaffective disorders: N = 46 Bipolar/depressive disorders: N = 18 Intervention group (14 female): Ethnicity: African American: N = 30 White: N = 26 Hispanic: N = 6 Diagnosis: Schizophrenia/schizoaffective disorders: N = 38 Bipolar/depressive disorders: N = 16</p>	Mental health treatment organisation	Randomised controlled trial	<p>Primary outcome: initiating cessation treatment over two months</p> <p>Secondary outcomes:</p> <ul style="list-style-type: none"> (a) amount and frequency of smoking over the two months (b) satisfaction with the website (c) stage of change (four-point scale, from 'now' to not thinking of quitting smoking) (d) basic knowledge about the health effects of smoking (e) knowledge about carbon monoxide 	<p>At the two-month follow-up participants in the carbon monoxide group increased their knowledge about carbon monoxide</p> <p>Basic knowledge about the health effects of smoking was fairly high and did not increase differentially between groups</p> <p>The main and secondary outcomes did not differ significantly between groups</p> <p>Overall, 32% of participants initiated treatment. The main outcome, initiating cessation medication or counselling, did not differ between groups</p>	<p>Study did not evaluate whether smokers with a particular diagnosis were more or less likely to respond to the intervention.</p> <p>Study did not include a placebo or an attention control condition.</p> <p>Purpose of study was to demonstrate the impact of the tool on treatment use, so there was no comparison group to document the rate of treatment initiation and abstinence in people who did not receive the tool.</p> <p>Self-reported rate of abstinence could be inflated.</p>	29 (minimum score required: 22)
Participants		Intervention evaluation			Global quality	

Demographics	Setting	Design	Outcomes	Results	Main weaknesses	study score (ICROMS)
Intervention: Decision support system to motivate people with SMI to quit smoking [<i>Let's Talk About Smoking</i>] (Ferron et al., 2016)						
<p>N = 124 (35 female)</p> <p>Ethnicity: African American: N = 57 White (non-Hispanic): N = 37 Hispanic: N = 18</p> <p>Diagnosis: Diagnosed with psychotic disorder (schizophrenia or schizoaffective disorder): N = 86 Other: N = 38</p>	Psychiatric rehabilitation centre	Six-month follow-up of a randomised controlled trial	<p>Outcomes:</p> <p>(a) Self-reported abstinence outcomes over 6 months after the intervention: number who tried to quit, number of quit attempts, attained >1 day abstinence, days of abstinence and attained >7 days abstinence</p> <p>(b) Stage of Change</p>	<p>N = 74 reported quitting smoking for at least 1 day over the six-month follow-up period. Average length of self-reported abstinence among quitters was 18 days. N = 36 sustained abstinence for at least 7 days. N = 9 persisted in their abstinence and provided a breath CO<10ppm at 6-month follow-up.</p> <p>Participants' stage of change after intervention significantly predicted abstinence (alongside level of education and smoking cessation treatment). When both treatment use and stage of change after the intervention were included in the model, only treatment use significantly predicted abstinence.</p>	<p>There was no comparison group to document the rate of treatment initiation and abstinence in people who did not receive the website</p> <p>The self-reported rate of abstinence could be inflated (Hawthorne effect)</p>	22 (minimum score required: 22)

Participants	Intervention evaluation	Global
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Demographics	Setting	Design	Outcomes	Results	Main study weaknesses	quality score (ICROMS)
Intervention: Decision support system to motivate people with SMI to quit smoking [<i>Let's Talk About Smoking</i>] (Brunette et al., 2017)						
<p>N = 81 (control group = 23, intervention group = 30, intervention group computerised American National Cancer Institute Education = 28) Control group (11 female) Ethnicity: White: N = 20 Black: N = 2 Hispanic: N = 5 Diagnosis: Schizophrenia/affective disorders: N = 9 Mood/anxiety disorders: N = 14 Intervention group (10 female) Ethnicity: White: N = 17; Black: N = 9; Hispanic: N = 6; Other: N = 4 Diagnosis: Schizophrenia/affective: N = 12 Diagnosis mood/anxiety: N = 18 Intervention group - Computerised National Cancer Institute Education – (9 female) Ethnicity: White: N = 16; Black: N = 10; Hispanic: N = 0; Other: N = 2 Diagnosis: Schizophrenia/affective: N = 14 Diagnosis mood/anxiety: N = 14</p>	Mental health treatment programme	Randomised controlled pilot study	<p>Primary outcome: past 3-month use of verifiable cessation treatment and quit attempts</p> <p>Secondary outcomes: smoking characteristics, self-reported quit attempts with days of abstinence, and biologically verified abstinence at study follow-up visits</p>	<p>Primary outcome: 6% of participants who received an intervention utilised verifiable cessation treatment over the 3-month follow-up period. 13.9% of participants used any type of nicotine replacement therapy, 6.9% reported talking to a doctor about quitting, 6.9% reported talking to a counsellor, and 22.2% reported talking to a friend.</p> <p>Secondary outcome: Those who received the website were more likely to have biologically verified abstinence from smoking and other tobacco product use than those who received the computerised National Cancer Institute education</p>	Small sample - not possible to evaluate moderators and mechanisms of change with use of the tool	25.5 (minimum score required: 22)

Table 2. Development Studies

Participants		Setting	Method			Main study weaknesses	Study design	Global quality score (ICROMS)
Response rate	Demographics		Tool Development	Description of tool	Use of behaviour change theory			
<p>Intervention 1: Decision aid for disclosure of mental illness to employers entitled CORAL (Conceal Or ReveAL) (Brunette et al., 2013) Aim: To assist people with mental health problems in reaching decisions regarding disclosure in the employment context (UK) Mode of delivery: Pamphlet (A4/12 pages) Diagnosis: Bipolar, schizophrenia, other</p>								
N/A	<p>N = 15 (8 female) Ethnicity: White British: N = 8 Black African: N = 3 Black Caribbean: N = 2 Black British: N = 1 Other white: N = 1 Diagnosis: Bipolar: N = 7 Schizophrenia: N = 1 Do not know: N = 2</p>	Secondary care	<ul style="list-style-type: none"> Systematic review was used to inform the components of the tool Participants with mental health condition read and completed the draft tool and rated it for brevity, simplicity and relevance Semi-structured interview data provided further feedback which was used to amend the tool Readability of the tool was tested and adapted following feedback from participants 	<p>Six sections: (a) ‘Pros and cons’ of disclosure (b) my disclosure needs (c) my disclosure values (d) when to tell (e) who to tell (f) making a decision</p> <p>Quotes from interviews supported sections</p> <p>The tool was designed to be used independently from, or as an adjunct to, a clinical encounter</p>	Theory of Planned Behaviour (Ajzen, 1991)	Small sample – lack of generalisability	Mixed-methods pilot study using convenience sampling	21 (minimum score required: 22)

Participants		Setting	Method			Main study weaknesses	Study design	Global quality score (ICROMS)
Response rate	Demographics		Tool Development	Description of tool	Use of behaviour change theory			
<p>Intervention 2: Decision support system to motivate people with SMI to quit smoking entitled <i>Let's Talk About Smoking</i> (Brunette et al., 2017; Ferron et al., 2011; Ferron et al., 2012)</p> <p>Aim: Designed to stimulate motivation in people with SMI to quit smoking by using evidence-based treatment (United States)</p> <p>Mode of delivery: web-based</p> <p>Diagnosis: Severe mental illness (defined as mood or psychotic disorder with persisting functional disability)</p>								
<p>N = 89 participants referred to the study by their clinicians. 80% agreed to participate. Out of the remaining 20%: N = 6 did not respond to attempts to contact them N = 7 did not want to participate N = 4 did not attend the research visit N = 2 lacked the ability to read at a 5th grade level</p>	<p>N = 71 (26 female)</p> <p>Ethnicity: Caucasian: N = 49 African American: N = 22</p>	<p>Secondary care</p>	<ul style="list-style-type: none"> Literature review informed website development Think aloud method used to evaluate the design and layout of the website: <ol style="list-style-type: none"> each section of website was evaluated, then modified following feedback from participants the whole site was evaluated by participants, then modified according to feedback (N = 8) At the end of the programme, the interviewer asked open-ended questions related to the usability and likeability of the website; this was followed by a debriefing Readability of the tool was tested and adapted following feedback from participants 	<p>Stage 1: increase motivation by psychoeducation re personal impact of smoking</p> <p>Stage 2: video including consumer testimonials and text about quitting through use of evidence-based smoking cessation treatments</p>	<p>Health behaviour change theory informed the content</p>	<p>Small sample – lack of generalisability</p> <p>Other groups of people living with SMI may have higher or lower capacity for use of computerised treatments and websites</p>	<p>Mixed methods: three phases of semi-structured interviews</p> <p>T-tests to compare the differences between uses of the first computer programme version and a later version</p>	<p>15.5 (min. score required: 22) (Ferron et al., 2011)</p> <p>25.5 (min. score required: 22) (Brunette et al., 2017)</p> <p>20.5 (min. score required: 22) (Ferron et al., 2012)</p>

Participants		Setting	Method design			Main study weaknesses	Study design	Global quality score (ICROMS)
Response rate	Demographics		Tool Development	Description of tool	Use of behaviour change theory			
<p>Intervention 3: Patient decision aid for affective disorders (Liebherz et al., 2015) Aim: To encourage patients to participate in decision making about their treatment by providing information about the pros and cons of evidence-based treatment options Mode of delivery: web-based [www.psychenet.de] (Germany) Diagnosis: Bipolar disorder</p>								
<p>N = 930 participants with a range of mental disorders started the online survey.</p> <p>Of these N = 493 gave informed consent.</p>	<p>N = 210 (146 female)</p> <p>Ethnicity: Born in Germany: N = 193</p> <p>Diagnosis: Bipolar: N = 210</p>	<p>Web-based</p>	<ul style="list-style-type: none"> • Treatment decisions identified through a systematic literature search and evidence-based treatment options • Patients with bipolar disorder were involved in the development of the informed choice tool. Their information and decision-making needs were explored using an online cross-sectional survey – the data were used to tailor the various components of the informed choice tool • Self-administered questionnaire included items on their internet use (3 items), online health information needs (2 items), their role in decision making (2 items) and important treatment decisions (16 items) 	<p>Three categories of information needs were identified in the survey:</p> <ul style="list-style-type: none"> • general information on bipolar disorder, • information about treatment options • tips on dealing with the condition 	<p>None recorded</p>	<p>Disproportionately high number of women in sample (2.3:1 versus 1.2:1 in European epidemiological studies)</p> <p>Validity of diagnoses restricted due to self-reported diagnoses</p>	<p>Online cross-sectional survey using a self-administered questionnaire</p>	<p>N/A</p>

Participants		Setting	Method			Main study weaknesses	Study design	Global quality score (ICROM S)
Response rate	Demographics		Tool Development	Description of tool	Use of behaviour change theory			
<p>Intervention 4: Decision-aid for patients with bipolar II disorder and their families making decisions about treatment options to prevent relapse (Fisher et al., 2018) Aim: To facilitate more informed and active patient (and family) involvement in BPII treatment decision-making (Australia) Mode of delivery: Booklet (A5/100 pages) Diagnosis: Bipolar II disorder</p>								
N/A	<p><i>n</i> = 31 patients (24 female) and <i>n</i> = 11 family members (9 female)</p> <p>Country of birth: Australia: <i>n</i> = 25 patients <i>n</i> = 8 family members</p> <p>Diagnosis: Bipolar: <i>n</i> = 31</p>	<p>Community clinic specialising in the assessment and treatment of mood disorders</p> <p>And online forums</p>	<ul style="list-style-type: none"> Informed by the International Patient Decision-Aid Standards and the Ottawa Decision-Support Framework <p>Content, formatting and design were based on:</p> <ul style="list-style-type: none"> a systematic review best available evidence (e.g. clinical guidelines, published RCTs and meta-analyses) in-depth qualitative interviews with patients, family members and clinicians iterative review by an expert working party health literacy review using the Patient Education Materials Assessment Tool 	<p>Information was divided into three main sections:</p> <ul style="list-style-type: none"> Medication Options Psychological Options Making Decisions <p>The DA provides evidence-based, lay information using text and graphics on the known efficacy and benefits/costs of the current first-line medications and evidence-supported psychological treatments for relapse prevention in bipolar II disorder.</p> <p>Values clarification exercises help patients/family consider their preferences and deliberate on the benefits/costs of the different treatment options.</p>	none	<p>Small sample – lack of generalisability</p> <p>Participants recruited through online forums self-reported diagnoses</p> <p>No control group</p>	<p>Pilot study</p> <p>Cross-sectional survey using self-administered questionnaires with qualitative interviews follow-up</p>	N/A

Figure 1. PRISMA Flow Diagram