Psychiatry Research 230 (2015) 643–657

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

A clinical communication tool for the assessment of psychotropic medication side effects

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ARTICLE INFO

Article history:
Received 15 June 2015
Received in revised form
16 October 2015
Accepted 20 October 2015
Available online 22 October 2015

Keywords:
Questionnaires
Antipsychotics
Adverse reactions
Adherence

ABSTRACT

The primary aim was to assess usability of the My Medicines and Me Questionnaire (M3Q) as a self-reported questionnaire for mental health patients to subjectively express side effects experienced with their psychotropic medications. The secondary aim was to evaluate patients' attitudes towards treatment and psychotropic medications following dialogue with their clinicians about side effects. Questionnaires were administered at six adult mental health facilities. A total of 205 participants were divided into intervention (facilitated dialogue) and non-intervention groups (no facilitated dialogue). The mean completion time for the M3Q was 15 min (SD=6.5) with only 11 (5%) patients requiring assistance. The most commonly reported side effect was sedation (77%) and weight gain was ranked as the most bothersome (23%). The previously validated M3Q provided patients with the opportunity to express the impact these effects had on their lives. Side effects were the most common reason given for non-adherence. There were no significant changes in patient attitudes towards treatment and medications in the intervention group, mainly due to the logistical challenges in the clinicians' ability to view the questionnaire for the subsequent meeting with the patient. The M3Q demonstrated its usability in allowing patients to easily express their subjective experiences with side effects.

1. Introduction

Since the 1950s psychotropic medications have played a pre-eminent role in the treatment of mental illnesses (Edward and Alderman, 2013; Awad and Voruganti, 2004). It is well known that whilst these medications reduce symptoms of the illness they can often lead to debilitating side effects (Awad and Voruganti, 2004; McCann et al., 2008; Chapman and Horne, 2013). It is therefore not surprising that the majority of patients (up to 90%) will discontinue pharmacological treatment potentially leading to illness relapse and re-hospitalization (DiBonaventura et al., 2012; Morrison et al., 2000; Lambert et al., 2004). The consequence of this non-adherence to patients, their close contacts and society is immense as it can lead to relationship breakdown, loss of housing, loss of employment, involvement in substance abuse, crime and in the worst outcome suicide (Ascher-Svanum et al., 2008; Yen et al., 2009; Morrison et al., 2000).

In modern psychiatry the notion of recovery as a model of good practice has gained much attention. In a study by Mancini (2005) although many participants acknowledged that psychotropic medications were an important part of their recovery, almost half of them described the debilitating emotional, cognitive and physical side effects of their medications as 'barriers' to recovery (Mancini et al., 2005). Patients often complain about being uninformed and unprepared to deal with these side effects, which sometimes can make them feel worse than the illness itself (McGrath, 2007).

Lack of communication between patients and clinicians has also been identified as a barrier to recovery in mental health patients (McGrath, 2007; Dassori et al., 2003; Mancini et al., 2005; Thompson and McCabe, 2012). Patients generally do not self-report negative effects of treatment; therefore clinicians often underestimate their frequency, severity and subsequently the high possibility of non-adherence (Foster et al., 2008; Naber, 2008). It would therefore seem reasonable to focus on addressing identified

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http://dx.doi.org/10.1016/j.psychres.2015.10.022
0165-1781/

barriers to recovery from the patients' perspective, such as lack of communication and distress caused by medication side effects. As clinicians and patients often find it challenging to initiate dialogue around this issue, self-report side effect questionnaires provide a simple and efficient means for identifying, communicating and monitoring the incidence of these effects and their burden on patient lives (Dassori et al., 2003).

To address this need, in recent years a number of subjective self-report questionnaires (SRQs) have been developed to assess side effects of medications used by mental health patients (Ashoorian et al., 2014). Some of these tools have been validated however due to varying degrees of complexity only a few are actually being used in practice. These questionnaires contain mostly closed questions and therefore provide limited opportunity for the patient to write about their experience with the effects of medications. A key failing of closed-ended questionnaires is that each individual experiences different 'effects' to medications and therefore a blanket approach to categorizing side effects with such questions does not take individual variation into account (McGrath, 2007).

The My Medicines and Me Questionnaire (M3Q) was developed to fill this gap; it contains a combination of closed and open questions (Appendix 1). It has been through a rigorous validation process; including eight focus groups with expert stakeholders to develop the items followed by psychometric testing assessing the validity and reliability of the questionnaire (Ashoorian et al., 2015a, 2015b). The M3Q enables patients to describe in their own words the range of subjective experiences with medications and the impact these experiences have on their lives. The M3Q is not intended as purely a quantitative research tool, but rather a clinical communication tool designed to facilitate a dialogue between the patient and the clinician to address issues that may not come up spontaneously in a routine visit.

The primary aim of this study was to assess the usability of the M3Q as a self-report questionnaire for mental health patients in practice. There are currently no studies assessing changes in mental health patients' attitudes towards treatment and medications following the use of a side effect tool. Therefore the secondary aim was to evaluate the effect of enhanced communication between the clinician and patient on patients' attitudes to their psychotropic medications.

2. Methods

2.1. Ethics

The study was approved by The University of Western Australia Human Research Ethics Committee (HREC). Approval from the North Metropolitan Health Service- Mental Health HREC and Governance Office (Western Australia) was also given, with additional institutional approval granted for each site.

2.2. Study Design

For the primary aim, the level of uptake by patients, time taken to complete and the level of assistance and clarification required for its completion assessed the usability of the M3Q. For the secondary aim, we designed an observational controlled before and after study. The assessment of intervention and non-intervention groups included two SRQs exploring patient satisfaction with medical care and beliefs about medications at baseline and again at three months. Three clinics were assigned as intervention sites (facilitated dialogue) and the other three were assigned as non-intervention sites (no facilitated dialogue). In the intervention site the clinicians were given the opportunity to view the completed M3Q with the aim of stimulating discussion (facilitated dialogue through the use of the questionnaire) with the patients regarding side effects. The following is a description of the three SRQs administered during this study.

2.2.1. My Medicines and Me Questionnaire (M3Q) (Ashoorian et al., 2015a, 2015b)

The M3Q is a novel validated questionnaire (applicable to all psychotropic medication) for identifying medication side effects that mental health patients may be experiencing, and their perceptions of them. The M3Q consists of five sections:

1. A list of self-reported medications and doses.
2. A checklist of 32 possible side effects (included under 11 domains) experienced with a section to list any others not mentioned.
3. A section asking participants to rank the three most bothersome side effects.
4. An open section to allow participants to report the effect of each side effect on daily living, including frequency and severity.
5. A general section of three open questions regarding adherence, perceived benefits of the medication and space for other comments.

Patients were discreetly timed on how long it took them to complete the M3Q. In addition they were assessed on the level of assistance (ability to independently read questions and write answers) and clarification of words they required for completion of the questionnaire.

2.2.2. Patient Satisfaction Questionnaire 18 (PSQ-18) (Ware et al., 1983; Marshall and Hays, 1994)

The PSQ-18 is a validated questionnaire used to gauge the patient's satisfaction with the medical care they are receiving in their attending clinic. The 18 questions are sub-divided into 7 domains: communication, interpersonal manner, financial aspect, time spent with doctor, technical quality, accessibility and convenience, and general satisfaction.

2.2.3. Beliefs about Medicines Questionnaire-Specific (BMQ) (Horne et al., 1999)

This validated questionnaire is comprised of two scales, the BMQ-general and the BMQ-specific. The latter assesses a patient's beliefs about medication usage and pharmacotherapy, whereas the former assesses a patient's beliefs about medications prescribed for a specific illness. The BMQ-specific used in this study consists of 10 items in two subscales, the necessity subscale and the concern subscale. The necessity-concern differential weighs the patient's perceived costs (concerns) against perceived benefits (necessity) of medications. If the differential is positive, the patient perceived necessity of medication outweighs medication concerns.

2.3. Participants

Participants were included in the study if they: (a) were 18 years or older; (b) were at the time of the study taking one or more psychotropic medications (defined as any antidepressant, antipsychotic, anxiolytic or mood stabilizer); (c) possessed basic English proficiency; (d) were able to provide written informed consent; (e) had consent from their treating clinician to participate. Patients were excluded from the study if they: (a) were deemed by their treating clinician to be too acutely unwell to participate; (b) were on locked or forensic wards.

To determine the sample size a review of studies carried out amongst mental health patients looking at the impact of side effects quoted sample sizes ranging from approximately 50–250. For the purposes of this study it was decided a sample size of 200 participants (100 per group) would be the target.

2.4. Recruitment

Participants were recruited between March and May 2013 from five out-patient community based public mental health clinics and one hospital within the North Metropolitan Health Service Perth catchment area. Researchers employed a number of recruitment strategies within the clinics. These included posters and pamphlets, mail outs to randomly selected patients, and approaching potential participants in the waiting room of clinics.

2.5. Data collection

At baseline the SRQs were completed independently by participants, however a researcher was available at all times to provide assistance and verify information if required. At completion the researcher would ensure all questionnaires and demographic sheets were completed to minimize 'missing data'. In the clinics the questionnaires were all completed before or after an appointment with the clinician. At the hospital, patients completed them in their rooms on the wards or sitting areas. Socio-demographic characteristics of the participants were gathered including contact details.

At 3 months (chosen to ensure easier memory recall) following baseline each patient received a letter in the mail informing them of the day and time they would be contacted for a phone interview to complete the PSQ and BMQ questionnaires.