



## Seven-day shared decision making for outpatients with first episode of mood disorders among university students: A randomized controlled trial

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### ARTICLE INFO

#### Keywords:

SDM  
Decision making  
Decision support techniques  
Decision aid  
Patient participation  
Young adult  
Depression  
Bipolar disorders

### ABSTRACT

Providing appropriate treatment to patients with a first episode of mood disorders is crucial for recovery from the disorders. Although shared decision making (SDM) has been proposed as a promising model in psychiatric practice, an appropriate SDM approach has not yet been established. The aim of the current study was to evaluate the effects of an originally developed seven-day SDM program for outpatients with a first episode of mood disorders among university students. University students with a first episode of mood disorders were randomly allocated into two arms: SDM and control. The participants in the SDM arm received the seven-day SDM program, which included option presentation consultation, external deliberation with a decision aid booklet, decision coaching by a nurse, and decision-making consultation. The control arm received usual care. The primary outcome was patient-perceived involvement. We enrolled 88 participants. Compared with usual care, the SDM program significantly improved patient-perceived involvement in treatment decision making without taking up clinicians' time. The program did not lead to worse symptoms of mood disorders. In conclusion, sharing treatment decision making with university students with a first episode of mood disorders is feasible.

### 1. Introduction

The overall burden of mood disorders—individual, societal, and economic—has been increasing in recent decades despite the availability of reasonably effective pharmacological and psychological treatments (Wittchen, 2012). The onset of mood disorders frequently manifests in individuals aged in their early 20s (Kessler et al., 2007). Research shows that nearly 40% of university students have experienced feelings so depressing that they had difficulty engaging in daily living activities at any time in the past 12 months (American College Health Association: ACHA, 2017). A survey suggested that approximately 15% of university students reported seriously considering suicide, and approximately 3% reported attempting suicide in the past 12

months (ACHA, 2017). These studies suggest establishing an early diagnosis and intervention for university students who fulfill the criteria for the first episode of mood disorders is substantial and urgent.

Shared decision making (SDM) has been proposed as a promising model recommended for routine mental health practice (Slade, 2017); in this process, a medical decision is jointly made by patients and clinicians (Charles et al., 1997). Despite enthusiasm for the application of SDM for mental disorders, according to our review of the literature, no SDM interventions had targeted university-age populations in psychiatry. Hamann et al. (2006) showed that an SDM intervention for inpatients with schizophrenia increased patient-perceived involvement in medical decisions. Additionally, for outpatients with mood disorders, no SDM intervention has assessed patient-perceived involvement

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<https://doi.org/10.1016/j.psychres.2019.112531>

Received 30 April 2019; Received in revised form 21 August 2019; Accepted 23 August 2019

Available online 30 August 2019

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during treatment decision making.

To offer an appropriate approach to increase patient-perceived involvement during treatment decision making, we developed a 7-day SDM program suitable for outpatients with a first episode of mood disorders among university students. The aim of this study was to evaluate the effect of a 7-day SDM program compared with usual care on patient-perceived involvement. We also compared overall satisfaction and consultation times. Furthermore, persistence of treatment, medication adherence, and depression severity in the two arms for the 3- and 6-month trial period were compared.

## 2. Methods

### 2.1. Study design

We conducted a randomized controlled trial. First, we randomly allocated patients diagnosed with a major depressive episode, either major depressive disorder or depressive phase of bipolar disorder (Diagnostic and Statistical Manual of Mental Disorders IV; DSM-IV) (American Psychiatric Association: APA, 1994), for the first time to either the intervention or control arm. Patients in the intervention arm received the 7-day SDM program comprising the three steps described in subsequent sections.

The study was performed between February 2013 and December 2016 in the outpatient service of the health support center of Waseda University, where approximately 200 new outpatients visit per year.

### 2.2. Participants

We included undergraduate and postgraduate students who visited the outpatient service and fulfilled the following criteria: (i) aged 20 years or older, (ii) received a first-time DSM-IV diagnosis of major depressive episode (major depressive disorder or depressive phase of bipolar disorder) (APA, 1994), and (iii) had a baseline 16-item Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR) score of 6 points or greater (Rush et al., 2003).

Individuals were excluded if they fulfilled the following criteria: (i) current substance abuse or dependence, (ii) diagnosis of schizophrenia, (iii) no fluency in Japanese, and (iv) refusal to provide written informed consent. Hospital admission because of severe depression or current suicidality were also excluded and referred to appropriate services.

### 2.3. Randomization

Participants were randomly assigned to one of two arms, following the restricted randomization and minimization method of item 8 in CONSORT2010 (Moher et al., 2012). For the minimization method, we used the three categories of age, sex, and psychiatrist in charge as adjustment factors (Altman and Bland, 2005). The randomization was conducted by a research assistant not directly involved in the study. Clinicians and nurses were not blinded because of the design of the study. A research assistant blinded to group allocation collected data at baseline, after the decision-making consultation, and at each visit during the 6-month trial period.

### 2.4. Interventions

#### 2.4.1. Intervention arm

Before organizing the framework for the SDM program by following the criteria established in the International Patient Decision Aids Standards (Elwyn et al., 2009), we developed three original decision aid booklets, that is, one each for depression treatment, bipolar disorder treatment, and medication treatment in psychiatry; the two booklets contained general information on depression or bipolar disorder and their treatment options for patients undergoing psychiatric treatment for the first time (Appendix 1 for depression/Appendix 2 for bipolar

disorder). The decision aid for medication treatment containing information on medication options such as antidepressants or mood stabilizers (Appendix 3) was provided if medication treatment options were considered and discussed as further treatment. We assessed the feasibility of these booklets elsewhere (Aoki et al., 2013). The resulting SDM program had three steps as follows:

#### Step 1. Initial consultation: option presentation consultation

After thorough examination, the clinician informed the patient of the diagnosis and wrote treatment options on scratch paper for the patient to review at home, for example, watchful waiting with fixing day-night reversal, leaving the university for a respite, light exercise, cognitive behavioral therapy, counseling, or medication treatment such as antidepressants or mood stabilizers. These treatment options were presented with pros and cons and chosen individually with consideration of each patient's situation and lifestyle. The clinician also provided the patient with the decision aid booklet, comprising general information about mood disorders and treatment options. The patient exited the service with the scratch paper and the decision aid booklet.

#### Step 2. External deliberation and decision coaching with a nurse

At home, the patient reviewed the list of treatment options with the decision aid to facilitate the deliberation of treatment options by reviewing the information on the options, including pros and cons, and considering which features of options matter most. A couple of days after the initial consultation, the patient and a public health nurse discussed the treatment options at the service or on the phone. The nurse was trained in assisting the patient with each decision aid booklet, and answering questions, and encouraging the patient to state opinions regarding treatment options. The average duration of the discussions with the nurse was 20 to 30 min.

#### Step 3. Decision-making consultation

One week after the initial consultations, the patient visited the clinician for a decision-making consultation. The clinician clarified the patient's understanding and started discussions on topics that depended on the patient's understanding, for example, by providing explanations that included visual information on the decision aid. The clinician's recommendations were also accepted in this face-to-face discussion. They discussed treatment options and decided on the treatment. The aim was for the patient and clinician to agree regarding further treatment, in line with the informed preferences indicated by the patient's values.

Before we began the study, the clinicians (HC, TF, Y Kakita, and Y Kobayashi) and the public health nurse (YA) underwent a 1-day training on the application of this SDM program in clinical practice, which comprised learning SDM concepts and practicing SDM role-plays. The training was organized by the study coordinator/corresponding author (KW), who had learned SDM concepts and skills from Dr. Hamann, the leading SDM researcher in psychiatry, before the training (Hamann and Watanabe, 2011). One public health nurse (YA) was in charge of decision coaching. YA was instructed in the use of the decision aids and apprised to reply to any questions from the patients and to encourage them not to hesitate to reveal any concerns or contraries. Over the course of this study, both the clinicians and YA had a booster session once every 6 months and regular supervision by KW.

#### 2.4.2. Control arm

Patients in the control arm received usual care and communication regarding their treatments. In the initial consultation, the clinicians decided on further treatment as usual without intending to postpone it for subsequent consultations. Furthermore, clinicians were advised not to access the decision aids during any consultation of the control arm.

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