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

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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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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.

2.5. Outcome assessments

2.5.1. Primary outcome

The primary outcome measure was patient-perceived involvement in medical decisions measured with the patient-rated Combined Outcome Measure for Risk Communication and Treatment Decision-making Effectiveness (COMRADE) (Edwards et al., 2003). COMRADE consists of two subscales (satisfaction with communication and confidence in decision) comprising 20 items scored on a 5-point scale. Higher scores indicate higher patient-perceived involvement.

2.5.2. Secondary outcomes

2.5.2.1. Post encounter survey

(a) Overall satisfaction

We used the patient-rated Client Satisfaction Questionnaire (CSQ)-8 (Nguyen et al., 1983). The CSQ-8 comprises eight items, scored on a 4-point scale. Higher scores indicate higher overall satisfaction with received care.

(a) Consultation duration

We recorded the duration of the initial consultation.

(a) Looking up treatment options/treatment received

Participants were requested to report (i) whether they had examined the treatment options in more detail outside the service in addition to the decision aids between the initial and decision-making consultations (*yes/no*, SDM arm) or (ii) whether they had examined the treatment received at initial consultation outside the service after initial consultation (*yes/no*, control arm).

(a) Sharing information with others

We also asked patients (i) whether they had discussed the diagnosis and treatment options with others outside the service between initial and decision-making consultations (*yes/no*, SDM arm) or (ii) whether they had discussed the treatment received at initial consultation with others outside the service after initial consultation (*yes/no*, control arm).

2.5.2.2. Long-term survey

(a) Persistence of treatment

Persistence *of* treatment, defined as a clinic visit, was described by using stratified Kaplan–Meier survival curves, namely, the time from decision-making consultation (SDM arm) or initial consultation (control arm) to the occurrence of a dropout. Dropouts were defined as patients who did not attend the follow-up visits during the 6-month trial period and who could not be assessed again for specific reasons. Patients who had to stop their treatment for specific reasons such as illegal action, referral to a local clinic, or participation withdrawal were categorized as censoring.

(a) Severity of depressive symptoms

Participants completed the 16-item QIDS-SR (Rush et al., 2003) at each visit during the 6-month trial period.

(a) Medication adherence

For the participants who took medication, medication adherence was measured with a visual analog scale (VAS), a measurement instrument for subjective attitudes of how much medicine they had taken. Participants reported medication use at the time of each follow-up appointment by indicating a position along a continuous line between zero and ten at each visit during the 6-month trial period.

Table 1
Sociodemographic characteristics of study participants.

Characteristic	Intervention (n = 35)	Usual care (n = 53)
Female, n (%)	15 (42.9)	25 (47.2)
Age (years), mean (SD)	21.8 (1.9)	22.1 (2.0)
Education		
Undergraduate, n (%)	29 (82.9)	40 (75.5)
Postgraduate, n (%)	6 (17.1)	13 (24.5)
API decision-making score, mean (SD)	16.6 (2.0)	15.1 (2.3)
API information-seeking score, mean (SD)	33.3 (4.2)	33.9 (3.8)
Preference in decision-making style		
Make decision alone, n (%)	2 (5.7)	0 (0.0)
Share the decision, n (%)	31 (88.6)	47 (88.7)
Leave decision to clinician, n (%)	1 (2.9)	5 (9.4)
Missing, n (%)	1 (2.9)	1 (1.9)
Diagnosis		
Major depressive disorder, n (%)	24 (68.6)	44 (83.0)
Depressive phase of bipolar disorder, n (%)	11 (31.4)	9 (17.0)
QIDS-SR score, mean (SD)	13.9 (4.0)	15.1 (4.4)

API: Autonomy Preference Index.
QIDS-SR:Quick Inventory of Depressive Symptomatology Self Report.

2.6. Participants' characteristics

At baseline, sociodemographics (gender, age, and education), preference (autonomy preference and preference in decision-making style) (Ende et al., 1989), and clinical characteristics (diagnoses and depression severity) were collected (Table 1).

2.7. Sample size

To estimate the sample size of the study, G*Power 3.1.9.2 software was used to facilitate power analysis. The primary outcome was the comparison of COMRADE sum scores immediately after treatment decision-making between the SDM arm and the control arm. According to our review of the literature, no study had used COMRADE for outpatients with mood disorders. In the trial by Hamann et al. (2006), among patients in the acute psychiatric ward, the mean difference between the SDM arm and the control arm for COMRADE was 9.8 points. Our samples were composed of academically advanced university-age outpatients without cognitive dysfunction. Thus, we estimated a mean difference of 15 points between the SDM arm and the control arm. The standard deviation of each arm was estimated to be 20 points based on the results of Hamann' s trial (2006). Considering a two-sided significance level of 5% and a power of 80%, 27 participants in each arm was sufficient to detect the assumed difference.

2.8. Statistical analysis

We calculated descriptive statistics for sociodemographic characteristics of study participants and outcomes by each group. For group comparisons, Mann–Whitney U tests were used for continuous variables, and χ^2 tests were used for categorical variables. P value <0.05 was considered statistically significant. Occurrences of treatment dropout in the 6-month trial period were compared between the two arms by Kaplan–Meier survival curves and the log-rank test. Severity of depressive symptoms and medication adherence during the 3-month

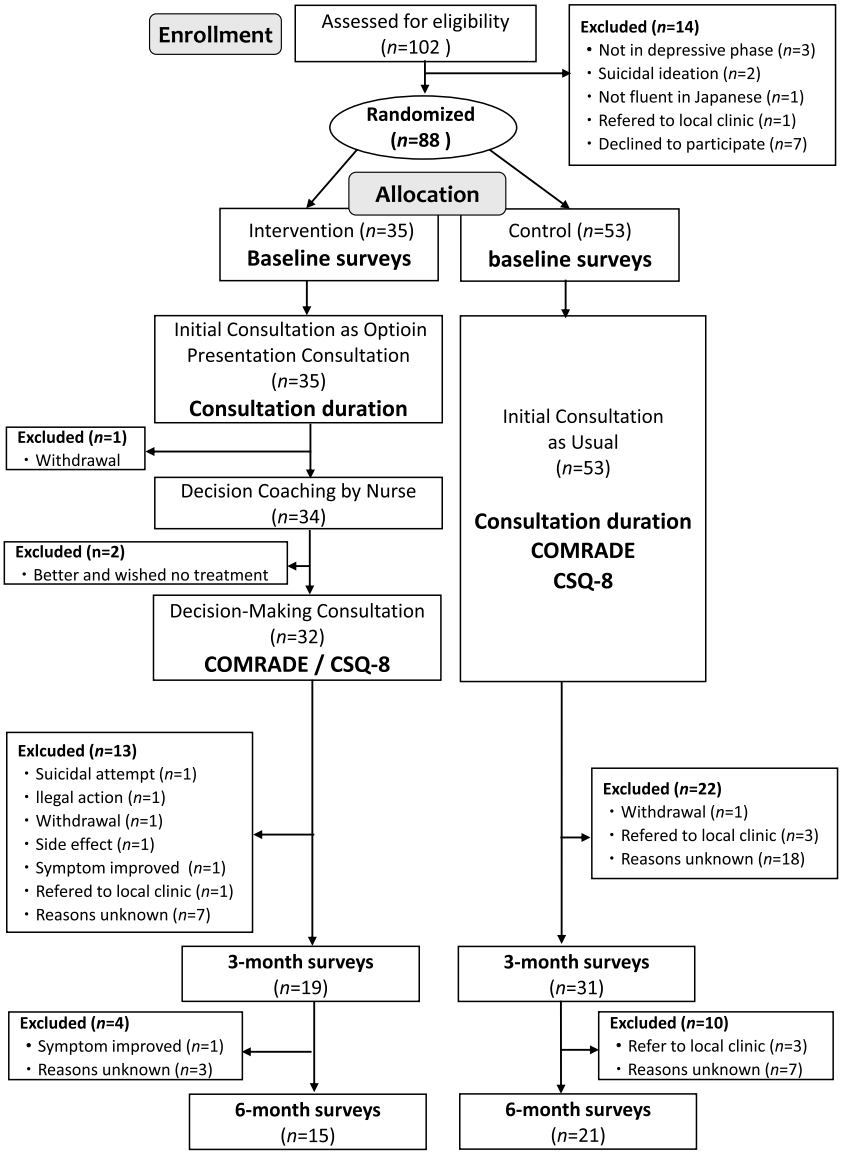

Fig. 1. CONSORT flow diagram. Of 102 patients assessed for eligibility, 14 were excluded before randomization. Then, 88 patients were randomly allocated to either intervention or control. Of 35 patients in the intervention, one withdrew after initial consultation, two were excluded after decision coaching by a nurse, 13 were excluded before 3-month follow-up, and four were excluded before 6-month follow-up. Of 53 patients in the control group, 22 were excluded before 3-month follow-up and 10 were excluded before 6-month follow-up.

and 6-month trial period and the long-term outcomes were analyzed according to the intention-to-treat principle by using the last-observation-carried-forward approach. All statistical analyses were conducted using SPSS version 25.0.

2.9. Ethical approval

This trial was approved by the Waseda University Research Ethics Committee (ref: 2012-194) and registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000009239) before the commencement of data collection. All participants provided written informed consent before entering the trial.

3. Results

3.1. Participant flow and characteristics

Of the patients aged 20 years or older who had newly visited the service and reported of a depressive state during the enrollment period, 125 patients did not fulfill the criteria of a DSM- IV diagnosis of major depressive episode and were diagnosed with adjustment disorder. Notably, 102 patients were diagnosed with a major depressive episode. However, of these 102 patients, three patients had a QIDS-SR score of 5 points or less, two exhibited suicidal ideations, one did not speak Japanese fluently, and seven did not consent to participate. Another patient was referred to a local doctor and exited the service before randomization.

Eighty-eight patients were eligible for inclusion (Fig. 1).

3.2. Outcomes

3.2.1. Primary outcome

Participants in the SDM arm reported significantly higher patient-perceived involvement in medical decision making compared with the control arm (COMRADE satisfaction with communication: $P < 0.001$; COMRADE confidence in decision: $P = 0.005$, Table 2).

Table 2
Postintervention group comparisons.

	Intervention (n = 35)	Usual care (n = 53)	P value
Patient risk communication, median (IQR)			
COMRADE communication	44 (9)	38 (7)	<0.001[a]
missing, No. (%)	3 (8.6)	0	
Patient confidence, median (IQR)			
COMRADE confidence	41 (6)	37 (7)	0.005[a]
Missing, No. (%)	3 (8.3)	0	
Patient overall satisfaction, median (IQR)			
CSQ8	24 (2)	24 (3)	0.723[a]
Missing, No. (%)	3 (8.6)	0	
Duration of consultation, median (IQR)			
Minutes	26 (5)	24 (22)	0.983[a]
Missing, No. (%)	0	0	
Looked up treatment options/treatment, *n* (%)			
Yes	28 (80)	32 (60.4)	0.088[b]
No	4 (11.4)	13 (24.5)	
Missing, No. (%)	3 (8.6)	8 (15.1)	
Shared information with others, *n* (%)			
Yes	18 (51.4)	23 (43.4)	0.656[b]
No	14 (40)	22 (41.5)	
Missing, No. (%)	3 (8.6)	8 (15.1)	

IQR: interquartile range.
[a] Mann–Whitney U test.
[b] χ^2 test.

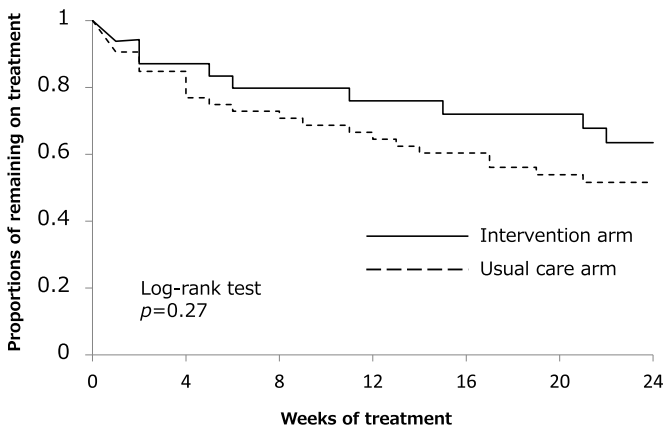

Fig. 2. Kaplan–Meier analysis of treatment persistence among the intervention arm and the usual care arm. The horizontal axis shows weeks of treatment, and the vertical axis indicates proportions of patients remaining on treatment. The continuous line is treatment persistence from decision-making consultation among the intervention group, and the dotted line is treatment persistence from initial consultation among the control group. Dropouts were defined as patients who did not attend the follow-up visits during the six-month trial period and who could not be assessed again for specific reasons. Patients who had to stop their treatment for specific reasons such as illegal action, referral to a local clinic, and participation withdrawal were categorized as censoring. The P value is a log-rank test.

Table 3
Three- and six-month comparison of depression symptoms.

	Intervention (n = 35)	Usual care (n = 53)	P value
Depression symptoms, QIDS, median (IQR)			
3-month	10 (6)	10 (8)	0.762
6-month	10 (9)	10 (9)	0.629

Mann–Whitney U test.
IQR: interquartile range.

3.2.2. Secondary outcomes

3.2.2.1. Postencounter survey. No significant difference was observed between the two arms in self-reported overall satisfaction with care (CSQ8) (P = 0.723, Table 2), and also no significant difference was observed in the duration of consultation between the two arms (P = 0.983, Table 2).

Regarding the question of whether the treatment options were examined outside the service, 88% (28/32) of participants in the SDM arm reported that they had examined the treatment options in more detail outside the service in addition to the decision aids provided. Additionally, 71% (32/ 45) participants in the control arm reported that they had examined the treatment received at initial consultation outside the service. No significant differences were observed between the two arms as for this (χ^2 = 2.2, P = 0.088, Table 2).

Regarding the question of whether they had discussed with others outside the service, 56% (18/32) of the participants in the SDM arm reported they had, and 51% (23/45) of the participants in the control arm reported they had. This finding did not represent a significant difference (χ^2 = 0.2, P = 0.656, Table 2).

Table 4
Three- and six-month comparison of medication use.

	Intervention (n = 22)	Usual care (n = 44)	P value
Medication use, VAS scale, median (IQR)			
3-month	9.0 (2.7)	9.1 (2.3)	0.910
6-month	9.2 (4.9)	8.9 (2.3)	0.872

Mann–Whitney U test.
IQR: interquartile range.

3.2.2.2. Long-term survey. No statistically significant difference was observed between the two arms in persistence of treatment (log-rank test, P = 0.27, Fig. 2) during the 6-month trial period. Additionally, no significant differences were observed in depression symptoms in the 3-month and 6-month trial period (QIDS-SR: P = 0.762 at 3 months; P = 0.629 at 6 months; Table 3). Among the participants who received pharmacological treatment, no significant difference was observed between the two arms in terms of medication adherence (VAS: P = 0.910 at 3 months; P = 0.872 at 6 months; Table 4).

4. Discussion

This study was the first SDM trial for outpatients with a first episode of mood disorders among university students to evaluate patient-perceived involvement during treatment decision making. Compared with usual care, this SDM program increased patient-perceived involvement without extending the duration of consultation.

The typical ages of university students coincide with a peak period for mood disorder onset, particularly for first episodes (Ibrahim et al., 2013). The benefits of providing improved mental health care for these students with a first episode of mood disorders are likely to be crucial. In particular, patient participation in treatment decision making has become a high-prioritized necessity in mental health care systems in recent years worldwide (Thompson, 2007). The guidance from the National Institute for Health and Care Excellence (NICE) also recommends that professionals involve individuals with depression in their treatment and care (NICE, 2009). Although most psychiatric patients want to understand the diagnosed illnesses and related treatments and be involved in their care and remedies (Hamann et al., 2007), clinicians do not always address patients' concerns regarding these matters (Barr et al., 2016). Thus, similar to our program, development of a systematic structure to ask patients their preferences for treatment could improve the quality of care.

The strengths of our study include a high rate of informed consent acquisition and no potential harm for participants even with more time before treatment commencement than usual care. In other trials of SDM for major depressive disorder (Loh et al., 2007; LeBlanc et al., 2015; Perestelo-Perez et al., 2017), SDM interventions have been conducted

during one consultation or one session. According to our review of the literature, our SDM program is the first in the psychiatric field to enable deliberation time outside the service.

A power imbalance exists between the patient and clinician (Strickler et al., 2009). Indeed, patients with depression tend to hesitate to speak of their concerns and thoughts to clinicians (Sawada et al., 2012). Our SDM program uniquely provides a sufficient amount of deliberation to allow for preparation to reveal concerns at the decision-making consultation. Moreover, external deliberation outside the service is worthwhile because patients can discuss the options with loved ones (Aoki et al., 2019). SDM should be a process that involves family members in the intervention (Hamann and Heres, 2019).

We also observed that university students are inclined to discuss their personal matters with their parents or other adults around them as they transition to adulthood. Even in the control arm, most patients returned home and spoke to their loved ones while conducting a search for the treatment received in their consultation. Furthermore, academically advanced university students can easily access the internet more than individuals of older ages. Therefore, SDM interventions in university students may be less beneficial than those in targeted populations less likely to state their concerns or search for information. A few SDM trials have targeted acutely ill inpatients upon first admission with schizophrenia (Ishii et al., 2017) or multicultural patients including non-native English speakers such as Latinos and Asians with various mental illnesses (Alegria et al., 2018). Further development and investigations of SDM intervention could focus on populations with difficulty accessing information or low health literacy.

Regarding the long-term survey, no significant differences were observed in depressive symptoms, treatment adherence, and medication use between arms. A limited number of trials of SDM for outpatients with mood disorders have also attempted to evaluate symptoms or adherence. Loh et al. (2007) conducted a cluster-randomized controlled trial based on SDM with a decision aid for depression treatments in primary care settings. Although patient satisfaction was significantly higher in the SDM arm compared with the control arm, no significant differences were observed in treatment adherence or depression severity 6 to 8 weeks later between the two arms. LeBlanc et al. (2015) also carried out a cluster-randomized controlled trial based on SDM with a decision aid for antidepressant medication during consultation in primary care practices. Although the SDM intervention significantly improved patients' decision conflict, knowledge, and satisfaction, no discernible effect was observed on medication adherence and depression outcomes at 3 months and 6 months. Thus, the procedure of treatment decision making in the initial phase might not affect long-term clinical outcomes.

Several limitations of this study should be acknowledged. First, the trial was conducted as a single-center study and comprised mainly undergraduate and graduate students. Thus, the results cannot be generalized directly to other populations. Second, we used only self-report scales and subjective questionnaires, which might be subject to bias. Third, the sample was relatively small, although this number fulfilled the calculated sample size. Fourth, a slight difference was observed between the samples in the two arms despite our calculation and estimation of an appropriate sample size. As a result, our trial might not have had an adequate sample size to detect a difference between the two arms. Fifth, psychiatrists overlapped between the intervention and the control. Therefore, further research with a multicenter cluster design and a larger sample size might be useful for a definitive confirmation of our findings.

In conclusion, we evaluated a 7-day SDM program for university students with a first episode of mood disorders comprising deliberation outside clinical services, a decision aid, and collaborative care from a clinician and public health nurse. This program proved feasible and increased patient-perceived involvement without increasing the amount of time the clinicians usually spend with patients.

Declaration of Competing Interest

Author Koichiro Watanabe has received manuscript fees or speaker's honoraria from Astellas Pharma, Daiichi Sankyo, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceutical, Meiji Seika Pharma, Mitsubishi Tanabe Pharma, MSD, Otsuka Pharmaceutical, Pfizer, Shionogi, Sumitomo Dainippon Pharma, and Yoshitomi and has received research/grant support from Astellas Pharma, Daiichi Sankyo, Eisai, MSD, Mitsubishi Tanabe Pharma, Meiji Seika Pharma, Otsuka Pharmaceutical, Pfizer, Shionogi, and Sumitomo Dainippon Pharma and is a consultant of Eli Lilly, Otsuka Pharmaceutical, Pfizer, Sumitomo Dainippon Pharma, Taisho Toyama Pharmaceutical, and Takeda Pharmaceutical. Author Yoshikazu Takaesu has received speaker's honoraria from Eisai, Eli Lilly, Meiji Seika Pharma, Mitsubishi Tanabe Pharma, Otsuka Pharmaceutical, and Yoshitomi Pharmaceutical and has received research/grant support from Eisai, Meiji Seika Pharma, and Otsuka Pharmaceutical. The other authors declare no conflict of interest.

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Supplementary materials

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