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ORIGINAL ARTICLE

Development and acceptability of a decision aid for major depressive disorder considering discontinuation of antidepressant treatment after remission

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Abstract

Aim: While evidence-based antidepressant treatment is available for major depressive disorder, standard approaches for discontinuation of antidepressants after remission have not yet been established. Decision aids are structured clinical tools that facilitate shared decision-making between patients and healthcare providers. This study aimed to describe the development process and acceptability of decision aids for major depressive disorder following discontinuation of antidepressant treatment after remission.

Methods: We systematically developed a decision aids according to the International Patient Decision Aid Standards. First, a decision aids prototype was created using the results of a systematic review and meta-analysis previously conducted to identify the consequences of continuing and discontinuing antidepressant treatment. Second, a mixed-methods questionnaire (alpha acceptability testing) was administered to patients and healthcare providers to improve the decision aids prototype and develop it into a final version acceptable for clinical settings.

Results: Our decision aids consisted of a description of major depressive disorder, the option to continue or discontinue antidepressant treatment, the advantages and disadvantages of each option, the consequences of each option, and value clarification

exercises for each option. The patients ($n = 22$) reported that the decision aids had acceptable language (91%), adequate information (91%), and a well-balanced presentation (95%). Healthcare providers ($n = 20$) provided favorable feedback. The final decision aids fulfilled all six International Patient Decision Aid Standards qualifying criteria.

Conclusion: We successfully developed a decision aids for discontinuation of antidepressant treatment after remission, which could be used during the shared decision-making process. Further studies are needed to verify the effects of using the decision aids during the shared decision-making process.

KEYWORDS
antidepressant, decision aids, depression, remission, shared decision-making

1 | INTRODUCTION

In recent years, major depressive disorder (MDD) has become an increasingly prevalent mental health condition worldwide, and is on course to become the second leading cause of global health burden by 2030.[1] Therefore, continued improvements in the care of individuals with MDD are crucial. Owing to the evidence-based antidepressant interventions for MDD,[2–4] individuals with MDD can achieve remission by undergoing antidepressant treatment. However, when and how to discontinue this antidepressant treatment after remission has not yet been established. Kato et al.[5] (2021) conducted a meta-analysis of clinical trials comparing the risk of relapse and treatment discontinuation with continued antidepressant treatment versus switching to placebo in patients with MDD who had achieved remission. This meta-analysis found that 83% of MDD patients did not experience recurrence of depressive symptoms when antidepressants were continued, while 63% of patients did not relapse even after discontinuing antidepressants for 18 months.[5] The results of this meta-analysis raised another clinical question: how should we decide whether individual MDD patients ought to continue or discontinue antidepressants after achieving remission in clinical settings?

Sharing evidence with patients is widely considered important, and several treatment guidelines recommend shared decision-making (SDM).[6] Hoffmann et al.[7] (2014) pointed out that even if there is evidence of the intervention, without SDM, evidence-based medicine can turn into evidence tyranny. Decision aids (DAs) are tools that help individuals participate in the SDM process. DAs can clarify the decisions that need to be considered, provide relevant information, describe the outcomes of various options, and identify individual preferences.[8,9] Several DAs for MDD have been developed thus far, including for first-onset MDD,[10] moderate-to-severe MDD,[11] and treatment-resistant MDD.[12] However, to the best of our knowledge, there is currently no DA available for individuals with MDD who have achieved remission and are considering discontinuing antidepressant treatment.

This study aimed to develop a DA for MDD considering continuing or discontinuing current antidepressant treatment after remission, and to assess its acceptability among stakeholders.

2 | METHODS

2.1 | Study design

The Ottawa Decision Support Framework[9] and International Patient Decision Aid Standards (IPDAS)[13] were used to systematically develop the DA (Figure 1). The IPDAS is an evidence-based framework that standardizes the development process and content of DAs.[14] The development process consists of the following: (1) identifying the target population and their decisional needs; (2) assembling a steering committee of experts; (3) carrying out a literature review to identify the options and related outcomes; (4) developing a DA prototype; (5) alpha acceptability testing of the DA prototype in patients and healthcare providers not involved in the development process,(6) adapting and finalizing the DA on the basis of the alpha testing results; and (7) beta testing the final version of the DA to examine its effectiveness in clinical settings.[14]

2.2 | Target population

Our DA targeted individuals with MDD who achieved remission with antidepressant monotherapy. We did not enroll any patients who were undergoing antidepressant treatment but still experienced symptoms of MDD, or those who were taking more than one antidepressant.

2.3 | Steering committee

A steering committee comprising experts on MDD and DA methodologies was assembled. This committee consisted of the authors

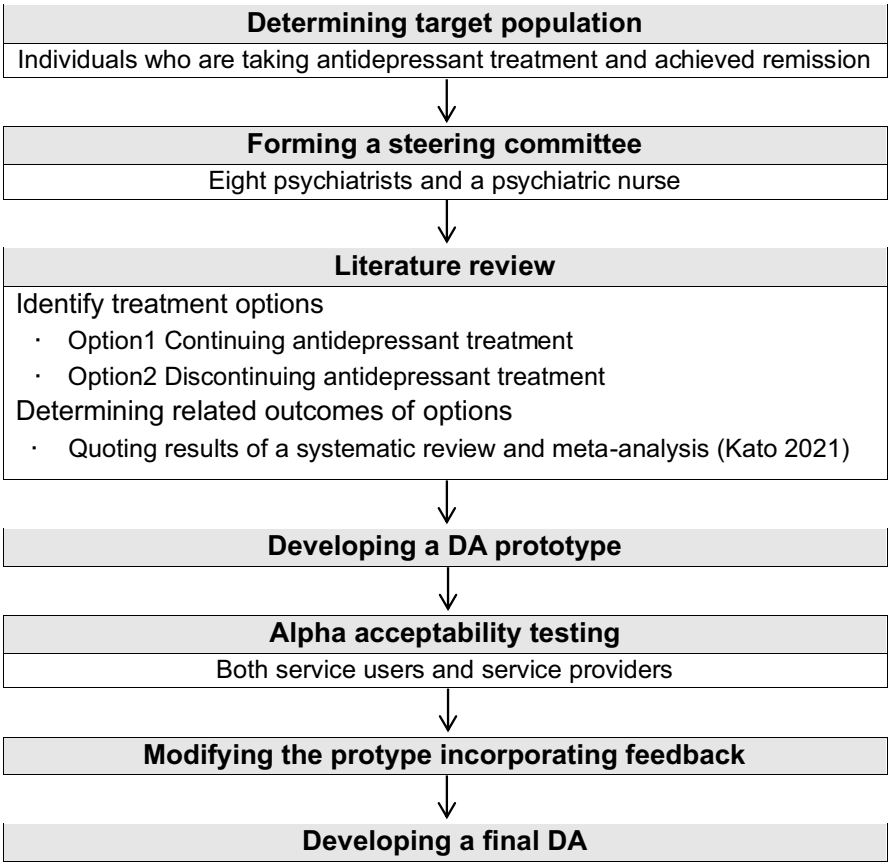

FIGURE 1 Process of developing a decision aids (DA) for depression considering discontinuation of antidepressant treatment, following the approach of Coulter et al.[13] (2013)

of this study: eight psychiatrists who routinely treat patients with MDD and a psychiatric nurse with extensive knowledge of SDM literature in psychiatry[15,16] and previous experience in developing DAs for people with mental illnesses.[10,17,18]

2.4 | Literature review

2.4.1 | Identifying advantages and disadvantages of options

We conducted a literature review to describe MDD as an indexed health condition. We further examined the advantages and disadvantages of two options: continuing or discontinuing antidepressant treatment. We also searched for relevant information such as medication management during the perinatal period and guided return-to-work for people after a leave because of MDD.

2.4.2 | Determining related outcomes of options

Regarding the consequences of two options: continuing and discontinuing antidepressant treatment after remission, we used the results of our systematic review and meta-analysis conducted earlier.[5] This meta-analysis showed whether antidepressant treatment should be continued once remission is achieved, with a focus on trials that compared recurrence rates between remitted individuals who continued the medication that had achieved remission versus those who received a placebo.[5]

2.5 | Prototype development

Using the results of our literature review, we developed a DA prototype in accordance with the IPDAS criteria.[14]

2.6 | Alpha acceptability testing

Alpha acceptability testing was carried out by the stakeholders of the DA. It included the assessment of the comprehensiveness of the DA with respect to length, content, balance of relevant information, and ability to the targeted decision.[19] This process is standard in DA development and allows the use of feedback to improve the final version. A mixed-methods questionnaire was developed according to the validated DA acceptability scoring system.[19] For the quantitative data, the patient assessment was rated on a Likert scale of 1 to 4, and the healthcare providers' perceptions were scored on a scale of 1 to 5. We invited patients who were undergoing antidepressant monotherapy and medical professionals who routinely treated patients with MDD to review the DA prototype and complete the questionnaire. Approximately 20 individuals were approached in each group. The sample size was selected according to the methods used in the DA literature for acceptability testing.[20,21] The results

of the acceptability testing were used to revise and improve the DA prototype to develop a finalized version that would be acceptable for use in a clinical setting.

Beta testing for effectiveness of the finalized DA, to be carried out in individuals considering discontinuation of antidepressant treatment, was not the purpose of this study and was not included.

The study protocol was approved by the Ethics Board of Kyorin University (776–02), Kansai Medical University (2020096), Juntendo Koshigaya Hospital (K20-0002), and Ehime University (2009009). Written informed consent was obtained from the participants.

3 | RESULTS

3.1 | Components of the developed Decision aid prototype

The developed prototype comprised a 28-page A5 paper booklet. The prototype started with an explanation of the target population of the DA and instructions on the use of the DA. The DA then showed objective information about depression, such as symptoms, course, risk of recurrence, characteristics of antidepressant treatment, and gradual tapering when discontinuing antidepressant in the "What is depression?" section. Additionally, the DA provided options for either continuing or discontinuing antidepressant treatment, the advantages and disadvantages of each option, and a value clarification exercise for each option.

In terms of the outcomes of each option, we quoted the meta-analysis we conducted earlier.[5] The meta-analysis found that relapse rate was 20% lower in the antidepressant treatment groups that continued taking the same medication used to achieve remission compared with placebo groups ($P < 0.00001$).[5] Furthermore, the all-cause dropout rates for the antidepressant treatment and placebo groups were 43% and 58%, respectively, and the tolerability rate was ~4% in both groups.[5] To describe these outcomes for each option in the DA prototype, we used pictorial diagrams of 100 faces, where shaded faces represent the proportion of people predicted to experience each outcome (Figures 2 and 3). In the appendices of the DA prototype, we included a self-reported MDD scale that could be used by patients, an explanation of various types of psychotherapy, frequently asked questions on antidepressant treatment, and relevant websites recommended by public institutions or authorized academic institutions. The content and rationale of the DA prototype are summarized in Appendix S1.

3.2 | Alpha acceptability testing

3.2.1 | Patients

All 22 patients with MDD who were undergoing antidepressant treatment reviewed the DA prototype and completed the mixed-method questionnaire. The mean age of the participants was 47.3 years and 11 (50%) were women.

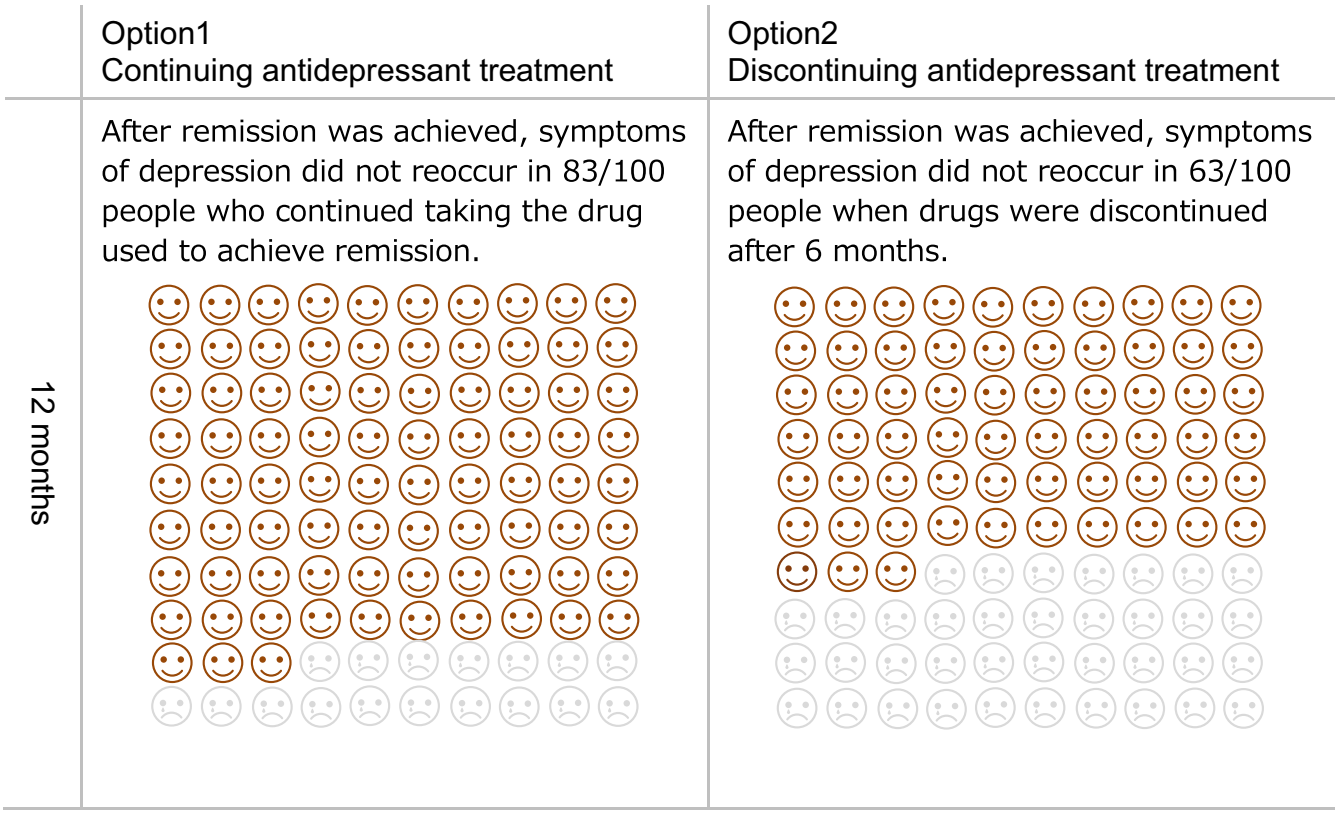

FIGURE 2 Pictorial diagram showing proportion of people who achieved remission and did not have recurrence of depression symptoms following options to continue or discontinue antidepressant treatment

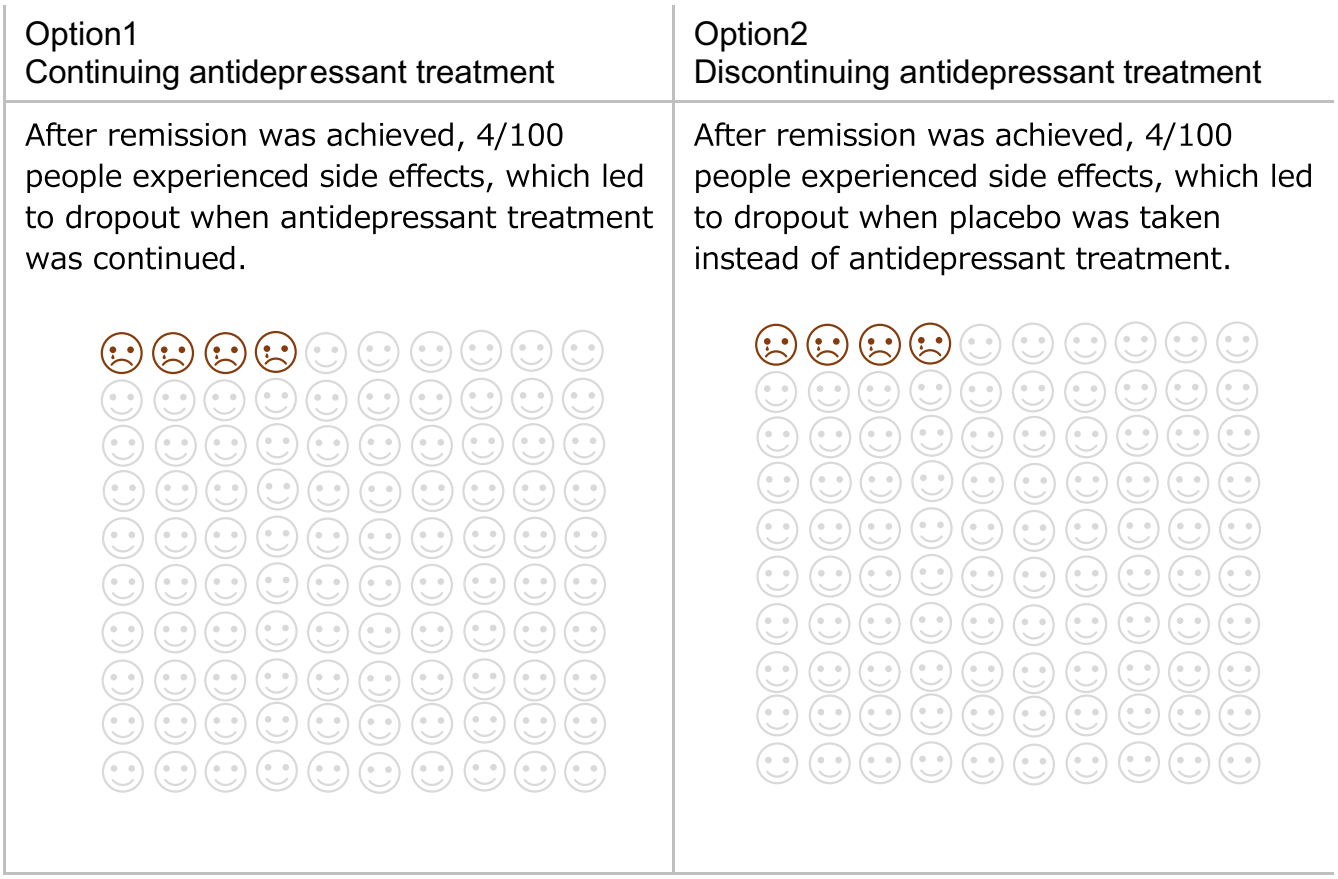

FIGURE 3 Pictorial diagram showing the occurrence of side effects that lead to dropout following options to continue or discontinue antidepressant treatment

TABLE 1 Patient assessment on the way information is presented in each section of the prototype ($n = 22$)

	Mean	SD
About this booklet/Instructions on use	3.18	0.59
What is depression?	3.18	0.59
Further treatment options	3.32	0.57
Comparing pros and cons of each option	3.18	0.66
Comparing consequences of each option	2.91	0.81
Value clarification	3.27	0.46
Preparation for SDM	3.09	0.68
Appendices ($n = 19$)	2.95	0.62

Note: Rating system: four-point Likert scale from 1 to 4, 4 being excellent, 3 for good, 2 for fair, and 1 for poor.
Abbreviation: SD, standard deviation.

The results of the four Likert scales that assessed how well information was presented in each section of the DA prototype were favorable overall (Table 1).

The length of presentation was assessed as just right in 20 of 22 (91%) participants; the amount of information was considered to be just right in 20 of 22 (91%) participants; 20 of 21 (95%) participants thought the presentation was well-balanced; 19 of 21 (90%) participants considered the DA to be useful in making the decision to continue or discontinue antidepressant treatment; 16 of 20 (80%) participants thought that the DA provided ease in foreseeing the outcomes of the two options; 18 of 20 (90%) participants stated that the DA made the decision easy; and 18 of 19 (95%) participants thought the DA included sufficient information to help a person decide whether to continue antidepressant treatment.

The narrative feedback included positive comments on the DA prototype, some examples of which are provided below.

> This seems to be useful not only for learning about depression but also for when I try to explain my condition to others around me.

> I learned things about depression that I did not know.

> I liked the figures and tables because they helped me to understand the information.

> I could fully understand what will happen if I stop medication.

> Unlike the disorganized information on the internet, this was reliable.

> I like the concept of this booklet that further treatment will be determined while discussing with my doctor.

Some participants suggested that inclusion of not only recurrence rates, but also others' experiences of each option would improve the DA. Other suggestions are described below.

> Important information should be underlined or highlighted to make it stand out.

> Information for families of patients would also be useful.

3.2.2 | Healthcare providers

All 20 psychiatrists reviewed the DA prototype and completed the questionnaire. The mean age was 40.4 years and three of the participants were women (15%).

The perceptions of the DA prototype were favorable overall (Table 2). Healthcare providers considered the strengths of the DA prototype to include the; comprehensiveness of the information, simplicity of the content that would be appropriate for any type of healthcare provider, provision of information about how to taper antidepressant medication, and description of the details of the outcomes for discontinuing medication. Some participants commented that the DA would enable providers to standardize the information provided to patients.

Other suggestions for ways to improve the prototype DA are provided below.

> It would be useful to describe the product names as well as the common names of antidepressants in the 'What is depression? ' section.

> The expression, 'symptoms like influenza,' is not appropriate for describing the symptoms experienced when discontinuing antidepressants in the 'What is depression?' part.

3.3 | Modifying the prototype based on stakeholder feedback

The DA steering committee reviewed the results of the acceptability testing. We discussed the response trends and narrative feedback that were used to improve the DA prototype. We added examples of personal stories of patients who followed each option in the DA.

3.4 | Developing the final Decision aid

We developed a final version of the DA (Appendix S2), which we believe has significantly higher quality (Appendix S3). Our DA fulfilled all of the IPDAS qualifying criteria (6 of 6), which is a requirement for any intervention to be considered a DA. If any of these certification criteria are not met, the DA is considered to have a high risk

TABLE 2 Healthcare providers' perceptions of the DA prototype ($n = 20$)

	Mean	SD
It will be easy for me to use	4.00	0.56
It is easy for me to understand	4.05	0.69
It will be easy for me to experiment with using the strategy before making a final decision to adopt it	3.70	0.73
The results of using the strategy will be easy to see	4.15	0.59
This strategy is better than how I usually go about helping patients decide about continuing or stopping antidepressants	3.80	0.62
This strategy is compatible with the way I think things should be done	4.10	0.55
The use of this strategy is a more cost-effective than my usual approach to helping patients decide about continuing or stopping antidepressants	2.95	0.76
Compared with my usual approach, this strategy will result in my patients making more informed decisions	4.10	0.79
Using this strategy will save me time	3.30	1.17
This strategy is a reliable method of helping patients make decisions about continuing or stopping antidepressants	4.05	0.51
Pieces or components of the strategy can be used by themselves.	3.75	0.64
This type of strategy is suitable for helping patients make value laden choices.	4.15	0.59
This strategy complements my usual approach	3.65	0.67
Using this strategy does not involve making major changes to the way I usually do things	3.85	0.88
There is a high probability that using this strategy may cause/result in more benefit than harm	4.10	0.79

Note: Scored range from 1 = strongly disagree to 5 = strongly agree.
Abbreviation: SD, standard deviation.

of harmful bias.[14] Furthermore, the DA fulfilled the majority of the IPDAS quality criteria (18 of 23), which are believed to strengthen a DA, but whose omission does not present a high risk of harmful bias.[14] The IPDAS criteria that were met by our finalized DA were highly rated criteria for other DAs available on the Ottawa DA website (Ottawa Hospital Research Institute), which addresses various health conditions.[22]

4 | DISCUSSION

This is the first study to develop and assess acceptability of DA for patients with MDD considering whether to continue or discontinue antidepressant treatment after remission.

Various DAs have been developed for patients with MDD. For example, Loh et al. (2006) developed a booklet for DA patients who were newly diagnosed with MDD during the SDM process.[23] Aoki et al.[10] (2019) also developed a booklet DA for use during SDM for first-onset MDD in university students. LeBlanc et al. (2015) developed medication choice cards as a DA for patients with moderate-to-severe MDD,[11] and Shillington et al. created an online DA for patients with treatment-resistant MDD.[12] However, a DA has not yet been developed for MDD after remission. Our DA contributes to the existing literature which suggests that patients consider further courses of action after remission.

Discontinuing antidepressant treatment after remission has several advantages and disadvantages. Advantages include that the individual no longer has to take medication every day, meaning that any side effects of the medication can be avoided, and the patients no longer need to worry about avoiding other medications because of possible drug interactions,[24] or about any concerns with pregnancy and breastfeeding.[25] The disadvantages of discontinuing medication include the risk of MDD relapse and potential withdrawal symptoms, such as flu-like symptoms or dizziness.[26,27] Accordingly, when considering the treatment strategy after MDD remission, patients may feel conflicted regarding the advantages and disadvantages described above. Our DA, which is designed for individuals who are taking antidepressant monotherapy, allows patients to compare the advantages and disadvantages of continuing and discontinuing antidepressant treatment. Patients can then develop their own preferences and opinions about continuing or discontinuing medication, discuss them with a professional, and make a decision.

The strength of our DA is the systematic and evidence-based development process, which was confirmed by both patients and healthcare providers who were not involved in the development process. The patients' responses to all questions were positive, and healthcare providers supported the use of our DA in clinical settings. Another strength is that our DA might be useful for maintenance antidepressant treatment in the clinical environment, where polypharmacy is still an outstanding issue.[28] One of the advantages of our DA, which shows the evidence-based consequences of each option: continuing or discontinuing medication, might be a clue to solving this problem.

Based on stakeholder feedback, our finalized DA included personal stories, in addition to the results of our systematic review and meta-analysis. The inclusion of personal stories in DA has both advantages and disadvantages. Despite the potential for biased views,[29] personal stories can help those who are facing healthcare decisions that rely on subjective preferences by aiding in recognizing the decisions to be considered, identifying the options available, and identifying their preferences.[30–32] In fact, many people are interested in understanding the decision-making process of those in similar situations,[33] and will research blogs or experiences online.[10,16] It is also necessary for healthcare providers to inform patients of the potential bias of narrative stories when using DA during the SDM process.

This study has several limitations. Although the DA met the majority of the IPDAS quality criteria,[14] some areas can still be improved in the future. These include field testing and the provision of evidence. Thus, we plan to carry out beta field testing in both patients and healthcare providers. We also plan to verify the effects of using DA during the SDM process.

This DA should be used to facilitate SDM between patients and healthcare providers, but should not replace dyadic communication. Although SDM is considered the pinnacle of patient-centered care,[34] its implementation is not yet widespread. To overcome this issue, we suggest developing educational programs for both patients and healthcare providers that provide the necessary knowledge and skills to effectively use DAs during the SDM process.

5 | CONCLUSION

We successfully developed a DA for patients with MDD who are considering whether to continue or discontinue antidepressant treatment after remission. The DA was considered acceptable by all of the stakeholders. These results could help clinical decisions considering discontinuation of antidepressants after achieving remission in both MDD patients and clinicians.

AUTHOR CONTRIBUTIONS

YA: study design, drafting and revising the DA prototype, data analysis and interpretation, revising the DA, drafting the manuscript. MK, the corresponding author: study design, revising the DA prototype, data collection, data analysis and interpretation, revising the DA, editing the manuscript. YT: study design, revising the DA prototype, data collection, data analysis and interpretation, revising the DA, drafting and editing the manuscript. HB, JI,HH, TI, AT: study design, revising the DA prototype, data collection and interpretation, revising the DA, editing the manuscript. KM: study design, revising the DA prototype, data collection and interpretation, revising the DA, editing the manuscript, funding acquisition. All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current

journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in supporting information (Appendix S4).

ETHICS APPROVAL

The study protocol was approved by the Ethics Board of Kyorin University, Kansai Medical University, Juntendo Koshigaya Hospital, and Ehime University. Written informed consent was obtained from the participants.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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