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ORIGINAL ARTICLE

Development and acceptability of a decision aid for chronic insomnia considering discontinuation of benzodiazepine hypnotics

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Abstract

Aim: To describe the development and acceptability of a decision aid (DA) for chronic insomnia considering discontinuation of benzodiazepine (BZD) and benzodiazepine receptor agonist (BZRA) hypnotics, and if discontinuing, tapering with or without cognitive behavioral therapy for insomnia (CBT-I).

Methods: We reviewed relevant literature describing chronic insomnia to identify options. We used the results of the systematic review and meta-analysis conducted previously to determine the related outcomes of two options: discontinuation of BZD/BZRA hypnotics by gradual tapering alone and discontinuation of BZD/BZRA hypnotics by gradual tapering with CBT-I. We then developed a prototype of DA following the International Patient Decision Aid Standards. A mixed methods survey was conducted to assess the acceptability among patients and healthcare providers.

Results: The prototype consisted of a description of insomnia, options of continuing or discontinuing BZD/BRZA hypnotics (if discontinuing, the options of tapering hypnotics with or without CBT-I), pros and cons of each option, and a value clarification

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exercise. Patients (n = 24) reported that the DA had acceptable language (79%), adequate information (71%), and well-balanced presentation (91%). Healthcare providers (n = 20) also provided favorable feedback.

Conclusion: We developed a DA for chronic insomnia considering discontinuation of BZD/BRZA hypnotics, which was acceptable for stakeholders. The developed DA was designed to support patients and healthcare providers to make a decision about whether to discontinue BZD/BRZA hypnotics.

KEYWORDS

benzodiazepines, chronic insomnia, decision aid, hypnotics, shared decision-making

1 | INTRODUCTION

Insomnia is a common condition that affects 15%-24% of the adult population worldwide.[1-3] Chronic insomnia leads to poor energy, fatigue during the daytime, difficulty concentrating, and poorer quality of life.[4] Clinical guidelines recommend cognitive behavioral therapy for insomnia (CBT-I) as the first-line treatment for insomnia, and that medications, such as benzodiazepines (BZDs) and benzodiazepine receptor agonists (BZRAs), should only be considered if CBT-I is ineffective or unavailable.[5,6] It has also been suggested that BZDs/BZRAs should only be used for a short-term period of up to 4 weeks.[6] However, despite these evidence-based recommendations, BZD/BZRA hypnotics are still being frequently prescribed worldwide for chronic insomnia.[7] The risks of long-term BZD/BZRA hypnotic use include dependence, decline in cognitive function, and hip fractures associated with falls.[8-10] Therefore, safe tapering or discontinuation of BZD/BZRA hypnotics for chronic insomnia is a crucial issue.

Many studies describing procedures for the discontinuation of BZD/BZRA hypnotics such as gradual tapering or adding CBT-I have been conducted thus far.[11] However, there are various challenges for discontinuing BZD/BZRA hypnotics. For example, it may result in a decline in sleep quality and tiredness during the daytime. In addition, withdrawal symptoms, such as nausea and sweating, may occur. Although CBT-I is recommended because of its efficacy,[5,6] it also has disadvantages such as absence of immediate effect, high cost, and prolonged consultation time.[11] Therefore, when considering tapering BZD/BZRA hypnotics, patients might face a conflict between the advantages (eg, reduced anxiety regarding dependence and no longer suffering from the side effects of medication, such as falls, drowsiness, and cognitive decline) and disadvantages of discontinuing medication (eg, not sleeping well, withdrawal symptoms, and cons when adding CBT-I).

Treatment decision-making has moved away from the traditional paternalistic approach, where clinicians controlled the decision-making process. Current approaches promote patient-centered care, such as "shared decision-making" (SDM), which implements a preference-centered discussion that involves two-way conversations about the advantages and disadvantages of each treatment option.[12,13] Recently, decision aids (DAs) have gathered attention as decision-making support tools to facilitate the SDM process between patients and clinicians for specific clinical conditions that require further treatment decisions.[14] DAs are tools designed to help patients participate in decision-making, preparing them to make informed, values-based decisions about healthcare options.[14] DAs present information on the options and support individuals to clarify their own values, which are associated with different features of the options.[14] A recent systematic review of 115 trials of DAs used in various medical fields found that DAs improve patient knowledge, decrease decisional conflict, increase user participation in the decision-making process, and promote concordance between the decisions and personal values of the patient.[15]

A DA that is designed for people who are taking BZD/BZRA hypnotics for insomnia can allow patients to compare the advantages and disadvantages of continuing and discontinuing BZD/BZRA hypnotics. They can then identify their preferences and opinions about continuing or discontinuing medication, discuss these with a professional, and make a decision. However, to the best of our knowledge, there is currently no published DA for people with chronic insomnia who are taking BZD/BZRA hypnotics but considering further treatment.

The aim of this study was to develop a DA for chronic insomnia considering whether to discontinue BZD/BZRA hypnotics; moreover, if discontinuing, whether to taper with or without CBT-I. We also assessed stakeholder acceptability of the DA.

2 | METHODS

2.1 | Study design and conceptual framework

We used the Ottawa decision support framework.[16] and the International Patient Decision Aid Standards (IPDAS) to guide the systematic development of the DA.[17] (Figure 1). The IPDAS are an evidence-based framework of criteria that were established to standardize the content and development process of DAs.[18] The process includes: (1) determining the target population and assessing their decisional needs, (2) forming a steering committee

of experts, (3) conducting a literature review to determine options and related outcomes, (4) developing a DA prototype, (5) acceptability testing the DA prototype with stakeholders, (6) modifying the DA based on the acceptability testing results to develop a final DA, and (7) field testing the final version for effectiveness in real clinical settings.[18]

2.2 | Target population

The target population of the DA was individuals who had been diagnosed with insomnia and had shown improvements in insomnia and health conditions during the daytime following treatment with BZD/BZRA hypnotics. The DA did not target individuals who were on medication but still suffering from insomnia. We assumed that the DA would be used in primary care settings and psychiatric outpatient services.

2.3 | Steering committee

We formed a steering committee that comprised experts on insomnia and DA methodology. This committee included ten psychiatrists who routinely treated people with chronic insomnia, a psychologist who routinely conducted CBT-I, and a psychiatric nurse who was familiar with SDM literature in psychiatry[19] and had experience in developing DAs for mood disorders.[20,21]

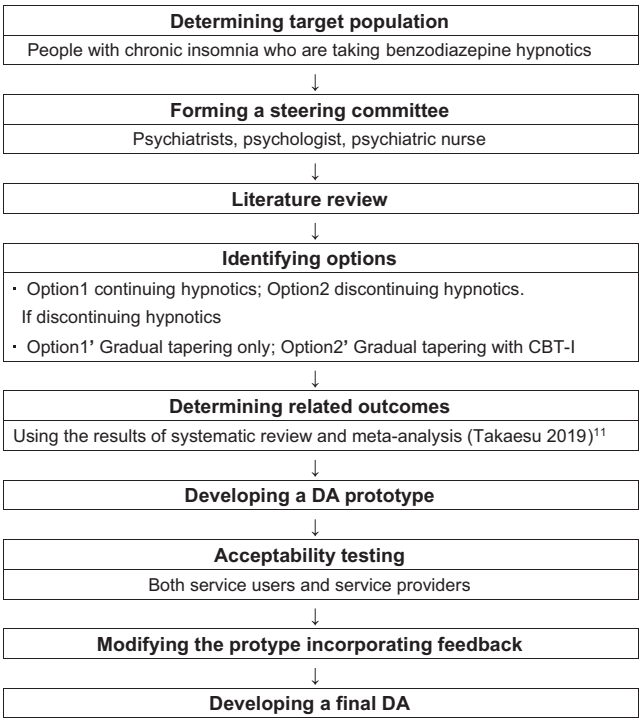

FIGURE 1 Process of developing a DA for chronic insomnia considering discontinuation of hypnotics, following the approach of Coulter et al (2013)

2.4 | Literature review

2.4.1 | Literature review

We reviewed the relevant literature that described chronic insomnia as a health condition and noted positive and negative features of the following options: (1) continuation of BZD/BZRA hypnotics; (2) discontinuation of BZD/BZRA hypnotics, (3) discontinuation of BZD/BZRA hypnotics by gradual tapering alone; and (4) discontinuation of BZD/BZRA hypnotics by gradual tapering and CBT-I. We also searched the references regarding lifestyle changes that individuals with insomnia can carry out as self-management.

2.4.2 | Determining the related outcomes

Regarding the related outcomes of the two options: discontinuation of BZD/BZRA hypnotics by gradual tapering alone and discontinuation of BZD/BZRA hypnotics by gradual tapering with CBT-I, we used the results of systematic review and meta-analysis[11] that we conducted previously, the details of which are as follows: Clinical guidelines recommend CBT-I for insomnia because of its efficacy and low risk of adverse events compared with medication treatment.[5,6] However, we could not find sufficient evidence for the efficacy of CBT-I intervention for discontinuing BZD/BZRA hypnotics. Therefore, we concluded that the effects of CBT-I during tapering of BZDs/BZRAs were unclear. We then conducted a systematic review and meta-analysis to clarify whether CBT-I is effective for discontinuing BZD/BZRA hypnotics in individuals with chronic insomnia in our previous study. Our meta-analysis indicated that short-term (≤3 months) CBT-I with gradual tapering was more effective than gradual tapering alone for discontinuing BZD/BZRA hypnotics.[11] However, there was no significant evidence for long-term (12 months) efficacy of CBT-I for discontinuing BZDs/BZRAs.[11] The details of this systematic review and meta-analysis are reported elsewhere.[11]

2.5 | Prototype development

A DA prototype was developed in accordance with the quality criteria established by IPDAS[17] using the results of the literature in the current research and systematic review[11] in our previous study. There are several types of DAs; some are designed to be used by patients at home to prepare them for discussion with healthcare providers,[22] whereas others, known as conversation DAs, are designed to encourage and aid conversations between patients and healthcare providers to make decisions together during clinical consultations.[22] Our DA combined both functions: a preparation aid for discussions and a conversation aid during consultations. To prepare for discussions with healthcare providers, patients can deliberate on treatment options and identify their values regarding the characteristics of each option, such as being able to sleep and side effects, using

a value clarification exercise. Accordingly, the prototype included questions to be marked placing a check mark (value clarification) and a memo field to be filled at home, which can be discussed with healthcare providers during a consultation. It is important that the DA can be understood by people who do not have medical knowledge, and it has been recommended that they should be described using eighth-grade level language.[23] Therefore, we avoided technical terms, used simple expressions, and expressed probabilities using pictograms. A pictogram is a method that communicates how many people out of 100 will experience the event in a pictorial form that can be easily understood by those of any literacy level.[24] Therefore, we also included pictograms because many evidence-based DAs have used them previously.[15]

2.6 | Acceptability testing

Acceptability testing was performed by surveying stakeholders of the DA. A mixed methods survey was developed according to the validated acceptability scoring tool, which included assessments of the comprehensiveness of the DA with regard to length, amount of information, balance of related information, and its ability to the targeted decision.[25] This is the standard process of DA development and enables improvement for the final version based on feedback.

Patients were recruited from two psychiatric outpatient services in university hospitals. We approached outpatients: (i) aged 20 years or older, (ii) had been taking BZD/BZRA hypnotics at least for three months, and (iii) had shown improvements in insomnia and health condition during the daytime following treatment with BZD/BZRA hypnotics. Healthcare providers who regularly see people with chronic insomnia were recruited from the same services as those used by the patients. For each group, approximately 20 individuals were approached. The sample size was selected in accordance with the methods used in the DA literature for acceptability testing.[26,27] We asked both patients and healthcare professionals to review the DA protype and complete the survey.

The results were used to modify and improve the DA prototype to develop a finalized version that would be acceptable for use in a clinical setting. The field testing for effectiveness of the finalized DA, which is to be carried out in individuals who are deciding whether or not to discontinue BZD/BZRA hypnotics, is not included as it was not the aim of this study.

3 | RESULTS

3.1 | Components of the DA prototype

The developed prototype comprised a 25-page A5 paper booklet. It began with an explanation of the target population, information on how to use the DA, and a description of insomnia. The booklet also contained options for continuing (option 1) or discontinuing BZD/BZRA hypnotics (option 2), the pros and cons of each option, and a value clarification exercise for each option. The prototype then provided a memo field for individuals to note down any additional comments or questions, which can be used during a consultation discussion on whether to continue or discontinue BZD/BZRA hypnotics.

Furthermore, for discontinuing current hypnotics, the prototype provided further options for gradually tapering BZD/BZRA hypnotics without CBT-I (option 1') or with CBT-I (option 2'). For both options, we adopted gradual tapering that involves tapering the dose by 25% or less over 4-8 weeks to prevent rebound insomnia, citing the Japanese guidelines for hypnotics[28] that are based on evidence of previous randomized controlled trials.[29-31] The prototype then provided the pros and cons of these options and a value clarification exercise of each option. In regard to outcomes of the options, we used the outcomes of our meta-analysis, which showed that CBT-I with gradual tapering was more effective than gradual tapering alone for discontinuing BZD/BZRA hypnotics in the short-term (≤3 months), but there was no significant evidence for long-term (12 months) efficacy of CBT-I for discontinuing BZDs.[11] To visualize these outcomes in the DA prototype, we used pictorial diagrams that consisted of 100 faces, where shaded faces represented the proportion of people predicted to experience the outcomes (Figure 2). In addition to presenting the pictorial diagrams with faces, we also explained that the difference between the patients with CBT-I and the patients without CBT-I was statistically clear after three months, but after 12 months the difference was not statistically clear. The prototype also included a memo field for individuals to note down any additional comments or questions, which can be used during a consultation discussion on whether to discontinue BZD/BZRA hypnotics with or without CBT-I.

In the appendices of the DA prototype, we provided examples of lifestyle and behavior changes that can also be implemented by people with insomnia.

Appendix 1 summarizes the contents of the DA prototype.

3.2 | Acceptability testing

3.2.1 | Patients

All 24 patients who were invited to take part in the study reviewed the DA prototype and completed the mixed method questionnaire. The mean age of the participants was 51.2 years and included 10 women and 13 men (1 unknown). Seven patients (32%) had a high school degree or lower level of education, two (10%) had vocational college level education, and 12 (57%) were university graduates.

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

The length of presentation was considered to be just right in 19 of 24 patients (79%); the amount of information was rated as just

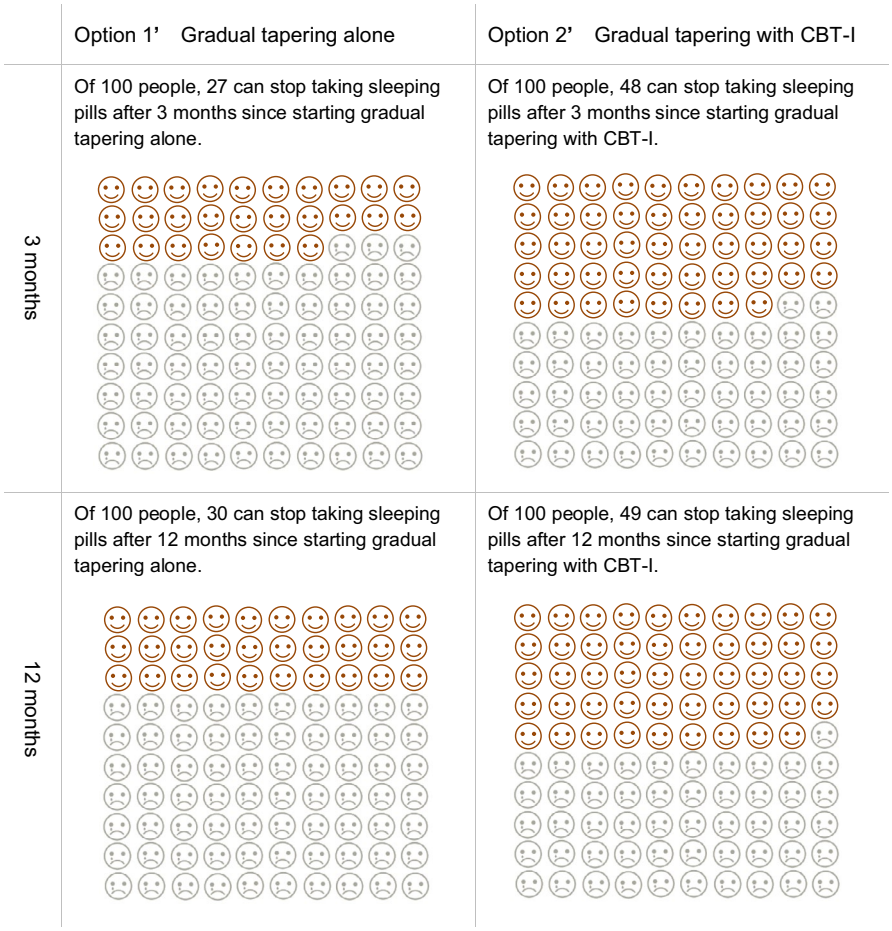

FIGURE 2 Pictorial diagram of outcomes of the DA for gradual tapering alone and gradual tapering with CBT-I

right in 17 of 24 patients (71%); the presentation was considered to be well balanced in 19 of 24 patients (91%); the DA was deemed useful for making the decision of whether to continue taking hypnotics in 21 of 24 patients (87%); 15 of 21 patients (65%) thought that the DA enabled foresight into their chance of success in discontinuing hypnotics; 19 of 22 patients (86%) thought the DA made the decision easy; and 15 of 23 patients (65%) deemed that the DA included enough information to help make the decision to continue or discontinue taking hypnotics.

The narrative feedback included positive comments on the DA prototype from patients. Some examples are provided below:

> "The pros and cons of each option were presented in a matrix, which was easy to understand."
>
> (Patient 8)

> "Because it contains figures and illustrations, it is easy to read."
>
> (Patient 9)

> "I like to be able to objectively weigh my preferences for each option."
>
> (Patient 5)

> "It was a good opportunity to learn important information regarding my treatment."
>
> (Patient 2)

> "The information in the appendices, such as lifestyle changes as self-management, is very useful."
>
> (Patient 11)

Furthermore, there were suggestions to provide additional explanations of some terms.

3.2.2 | Healthcare providers

All 20 psychiatrists who were invited to take part in the study reviewed the booklet and completed the questionnaire. The mean age was 34.3 years and included 10 women and 10 men.

The overall perception of the prototype was favorable (Table 2). The feedback of the psychiatrists described several strengths of the prototype, which included the overall concept, visualization and friendliness of the information, simple language, and well-balanced information for each option. Many participants had positive views of the appendices that contained

examples of lifestyle changes. Moreover, the feedback included recommendations for improving the DA, which are provided below.

> "It should be emphasized that the decision will be made following sufficient deliberation."
>
> (Psychiatrist 15)

> "Information about how less sleep is needed with age should be added."
>
> (Psychiatrist 3)

> "The description, 'the risks of cardiovascular symptoms as adverse events,' seems to be difficult."
>
> (Psychiatrist 20)

> "It would be better to recommend patients to discuss options with family members during deliberation."
>
> (Psychiatrist 21)

TABLE 1 Service user assessment on the way information is presented in each section of the DA prototype (n = 24)

	Mean	SD
About this booklet/Instructions on use	2.88	0.68
What is insomnia?	3.00	0.83
Further treatment options	2.79	0.88
Comparing pros and cons of each option	2.79	0.93
Value clarification	2.96	0.91
Preparation for shared decision-making (n = 22)	2.91	1.02
(When discontinuing medication) Further treatment options	2.75	0.79
(When discontinuing medication) Comparing pros and cons of each option	2.79	0.78
(When discontinuing medication) Comparing consequences of each option (n = 14)	2.79	0.97
(When discontinuing medication) Value clarification	2.96	0.86
(When discontinuing medication) Preparation for shared decision-making	3.00	1.02
Appendices (n = 21)	3.29	0.85

Note: Rating system: five-point Likert scale from 1 to 4, 4 being excellent, 3 for good, 2 for fair, and 1 for poor.

3.3 | Modifying the prototype incorporation feedback

The results of acceptability testing were reviewed by the DA steering committee. We discussed trends in their responses and narrative feedback and took advantages them to improve the DA prototype.

3.4 | Developing the final DA

We developed the final DA (Appendix S1), which contributed to a high quality of DA (Table 3). The developed DA met all IPDAS qualifying criteria (6 of 6), as required for consideration as a DA,[18] and all certification criteria (6 of 6), which deemed the DA to have low risk of

TABLE 2 Perceptions of service providers of the DA prototype (n = 20)

	Mean	SD
It will be easy for me to use.	4.20	0.83
It is easy for me to understand.	4.10	0.85
It will be easy for me to experiment with using the strategy before making a final decision to adopt it.	3.85	0.81
The results of using the strategy will be easy to see.	4.25	0.72
This strategy is better than how I usually go about helping patients decide about tapering hypnotics.	4.30	0.86
This strategy is compatible with the way I think things should be done.	4.15	0.67
The use of this strategy is a more cost-effective than my usual approach to helping patients decide about tapering hypnotics.	3.85	0.93
Compared with my usual approach, this strategy will result in my patients making more informed decisions.	4.45	0.83
Using this strategy will save me time.	3.20	1.24
This strategy is a reliable method of helping patients make decisions about tapering hypnotics.	4.55	0.83
Pieces or components of the strategy can be used by themselves.	4.10	0.85
This type of strategy is suitable for helping patients make value laden choices.	4.30	0.73
This strategy complements my usual approach.	3.85	0.99
Using this strategy does not involve making major changes to the way I usually do things.	3.85	1.14
There is a high probability that using this strategy may cause/result in more benefit than harm.	4.70	0.47

Note: Possible scored range from 1=strongly disagree to 5=strongly agree.

TABLE 3 International Patient Decision Aid Standards criteria met by current decision aid[18]

Item	1. Qualifying Criteria	2. Certification Criteria	3. Quality Criteria
Information	Describes the health condition or problem for which decision is required†	Shows the negative and positive features of options with equal detail†	Describes the natural course of the health condition or problem if no action is taken†
	Explicitly states decision that needs to be considered†		Makes it possible to compare the positive and negative features of available options†
	Describes the options available for the index decision†		
	Describes positive features of each option†		
	Describes negative features of each option†		
Probabilities			Provides information about outcome probabilities associated with the options†
			Specifies the defined group of patients for whom the outcome probabilities apply†
			Specifies the event rates for outcome probabilities†
			Allows the user to compare outcome probabilities across options using the same time period †
			Allows the user to compare outcome probabilities across the same denominator†
			Provides more than 1 way of viewing the probabilities (eg, words, numbers, diagrams)†
Values	Describes what it is like to experience consequence of the options†		Asks patients to think about which positive and negative features of options matter most to them†
Guidance			Provides a step-by-step way to make a decision†
			Includes tools like worksheets or lists of questions to use when discussing options with a practitioner†
Development			Development process included a needs assessment with clients or patients†
			Development process included a needs assessment with health professionals†
			Development process included review by clients/patients not involved in producing the decision support intervention†
			Development process included review by professionals not involved in producing the decision support intervention†
			Field tested with patients who were facing the decision‡
			Field tested with practitioners who counsel patients who face the decision‡
Evidence		Provides citations to the evidence selected†	Describes how research evidence was selected or synthesized†
		Provides a production or publication date†	Describes the quality of the research evidence used†
		Provides information about the update policy†	
		Provides information about the levels of uncertainty around the event or outcome probabilities†	

(Continues)

TABLE 3 (Continued)

Item	1. Qualifying Criteria	2. Certification Criteria	3. Quality Criteria
Disclosure		Provides information about the funding source used for development†	Includes authors'/developers' credentials or qualifications†
Plain Language			Reports readability levels†
Evaluation		Describes what the test is designed to measure‡	Evidence improved match between preferences of the informed patient and the option chosen‡ Evidence patient decision aid helps patients improve their knowledge about options' features‡

†Criteria met by the developed decision aid

‡Criteria to be met with effectiveness testing, not applicable for the current decision aid

harmful bias.[18] Furthermore, the DA fulfilled the majority of IPDAS quality criteria (19 of 23), which demonstrated that strengthen a DA but whose omission does not present a high risk of harmful bias.[18] The conditions of the IPDAS criteria that were met by our DA were highly rated compared with other available Ottawa DAs that address healthcare decisions.[32]

In addition, healthcare providers who will be using this tool will need to be informed regarding its correct use. Therefore, we also developed a manual for healthcare providers to describe the content and how to use this tool in clinical settings (Appendix S2).

4 | DISCUSSION

This is the first study on the development and acceptability of a DA for chronic insomnia considering whether to discontinue BZD/BRZA hypnotics and whether CBT-I should be included as part of the discontinuation.

Despite the recent clinical guidelines discouraging long-term prescription of BZDs/BZRAs because of the high rate of adverse effects,[33] the situation has not improved. This is because there are also disadvantages of discontinuing medication such as not sleeping well and withdrawal symptoms, which causes emotional conflict in patients whether to continue or discontinue medication. Therefore, to address this important issue, we successfully developed a DA to compare the advantages and disadvantages of continuing and discontinuing BZD/BZRA hypnotics following a systematic method of patient-centered care.

Acceptability testing results showed that our DA was accepted and favorably evaluated by people who had already been diagnosed with insomnia and were using hypnotics as well as by professionals who are involved in the treatment of insomnia. This means that the stakeholders who are expected to use the DA confirmed the high quality of the DA. Many participants felt that the DA appeared to be useful during the decision-making process. Thus, this tool has the potential to help patients resolve the conflict that they might have while considering discontinuation of hypnotics. Moreover, the fact that the patients responded positively to this tool is promising for the aim of achieving patient-centered care.

Because, insomnia treatment involves not only medication but also lifestyle and behavior adjustments, our DA included information on lifestyle changes as an appendix. It is noteworthy that this section was specifically highlighted by the patients, and we found that patients were interested in alternative approaches to medication. The DA was 25 pages in total, which included the appendix. This may introduce concerns around whether sufficient time will be available in during a consultation to read all of the information. However, our DA was intended to be read freely by patients at home, with any questions raised to be discussed during further consultations. An explanation of such usage will need to be provided to clinicians.

This study has several limitations. First, our final DA included two options for discontinuing BZD/BRZA hypnotics: discontinuing BZD/BRZA hypnotics by tapering alone or alongside CBT-I. However, currently, CBT-I is not yet available nationwide in Japan; although it is becoming more common, there still remains regional differences. Therefore, continued efforts are required to increase the number of healthcare providers that can provide CBT-I. Second, the sample size was relatively small. Therefore, the results may not be generalizable. Third, although our DA met most of the IPDAS quality criteria,[17] there are still several criteria that can be fulfilled by improving the DA. These include field testing and providing evidence. The quality of the decisions being made by participants piloting the developed DA need to be captured. Therefore, whether the DA reduces decisional conflict of patients should be investigated using measurements, such as the Decisional Conflict Scale or the four-item SURE (Sure of myself; Understand information; Risk-benefit ratio; Encouragement) test. Moreover, we need to assess whether our DA impacts participants' perceptions toward sleep medicine using relevant tools, such as the DBAS (Dysfunctional Beliefs and Attitudes about Sleep) –16. Thus, the next step will be to conduct field testing with patients and healthcare providers. Furthermore, we will need to verify the effects of using the DA during the SDM process to determine whether improvements in insomnia are observed.

Regardless of these limitations, the strengths of the DA, such as the systematic and evidenced-based development process, have enabled us to address important clinical issues and decision-making challenges faced by patients with chronic insomnia and healthcare providers.

We recommend our DA to be used to facilitate SDM between patients and healthcare providers but not to replace dyadic communication. Despite the awareness of SDM as an ideal approach to patient-centered care, the concepts and skills of SDM are not pervasive in Japan. To enable SDM to be accessed more widely, we also need to develop an educational program for both patients and healthcare providers that includes training for implementing the DA during the SDM process in a clinical setting.

5 | CONCLUSION

Using the IPDAS criteria, we successfully developed a DA for chronic insomnia considering discontinuation of BZD/BZRA hypnotics and deciding whether to undergo CBT-I during the discontinuation process. The DA was deemed acceptable by both patients and healthcare providers. The developed DA can be used to facilitate SDM between patients with chronic insomnia taking BZD/BZRA hypnotics and healthcare providers. The next steps are to carry out field testing and verify the effects of the DA during the SDM process.

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CONFLICT OF INTEREST

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AUTHORS' CONTRIBUTIONS

YA: study design, drafting and revising the DA prototype, data analysis and interpretation, revising the DA, drafting the manuscript. YT: study design, drafting and revising the DA prototype, data collection and interpretation, revising the DA, editing the manuscript. MT: study design, revising the DA prototype, data collection and interpretation, revising the DA, editing the manuscript. MS, IO, AS, TU, NK, HY, KK, NW: study design, revising the DA prototype, data 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.

APPROVAL OF THE RESEARCH PROTOCOL BY AN INSTITUTIONAL REVIEWER BOARD

This study was approved by the ethics review board of Kyorin University, Tokyo, Japan (approval number R02-037).

INFORMED CONSENT

All study participants provided informed consent.

REGISTRY AND THE REGISTRATION NO. OF THE STUDY/TRAIL

Not applicable.

ANIMAL STUDIES

Not applicable.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in the supplementary materials (Appendix S3).

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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APPENDIX 1

Contents of the DA for chronic insomnia considering hypnotic discontinuation

Contents		Pages
About this booklet		
	• Description of decision to be considered • Explanation of target population • Instructions for use of the booklet	1-2
What is insomnia?		
	• Objective information on insomnia, such as classification of sleep disorders and diagnostic criteria	3,4
Step1 Further treatment options		
	• Options provided: Continuing or discontinuing hypnotics • For continuing taking hypnotics, information on sleep medications (advantages and disadvantages of each drug category)	5-7
Step2 Comparing each option		
	• A table comparing each option (advantages, disadvantages, and consequences)	8
Step3 Value clarification		
	• A value clarification exercise with a 5-point Likert scale	9
Step 4 Preparation for shared decision making		
	• Memo field to prepare for decision-making consultation	10
(If discontinuing medication) Step1 Further treatment options		
	• Options provided: gradual tapering alone or gradual tapering with CBT-I • Explanation of gradual tapering • Explanation of CBT-I	11-13
(If discontinuing medication) Step2 Comparing each option		
	• A table comparing each option (advantages and disadvantages) • Pictorial diagrams comparing the consequences of each option	14,15
(If discontinuing medication) Step 3 Value clarification		
	• A value clarification exercise with a 5-point Likert scale	16
(If discontinuing medication) Step 4 Preparation for shard decision making		
	Memo field to prepare for decision-making consultation	17
Appendix1 Lifestyle and behavior changes for good sleep		
	• Keeping a sleep diary, changing sleep behavior, avoiding habits that disturb sleep, and progressive muscle relaxation.	18-23
Appendix2 Frequently Asked Questions and Answers		
	• Frequently asked questions and answers regarding sleep medication	24,25

Abbreviations: CBT-I, Cognitive behavioral therapy for insomnia; DA, decision aid.