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Development of a Medication Compliance Determinant Instrument for Low-Middle Literate Patients with Type 2 Diabetes Mellitus

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Abstract

Diabetes, a leading cause of 6.7 million deaths in 2021, poses a significant challenge despite existing interventions. Non-adherence to treatment remains a barrier to diabetes management. However, a comprehensive instrument to assess medication adherence determinants in diabetes patients' population in Indonesia with low-medium literacy levels and following the sociocultural characteristics of Indonesian society has been lacking. This study aimed to develop and evaluate a valid and reliable instrument for measuring medication adherence in type 2 diabetes mellitus patients based on the Borg and Gall model. Through the input of an expert panel, a valid and reliable instrument was developed, which comprised 21 questions and encompassed all medication adherence determinants, with a CVR and CVI value of 1 and a final Cronbach's alpha value of 0.731. This instrument is still being tested and needs to be implemented in the right and wider population to obtain more accurate results.

Keywords: compliance, determinants, development, type 2 diabetes mellitus, questionnaire

Introduction

Southeast Asia ranks second highest in diabetes-related deaths among adults aged 20–79 years, with 1.2 million deaths in 2019 (14.1% of all causes of death).¹ Indonesia ranks seventh among the ten countries with the highest number of diabetes patients, with 10.7 million sufferers.² Complications and adherence to therapy in individuals with diabetes impose an economic burden as they necessitate hospitalization and treatment for comorbidities.² Concerning hospitalization, the average direct medical cost for total treatment in people with diabetes is IDR4,127,180 (USD368.49).³⁻⁴

According to the 2018 Indonesian Basic Health Research data regarding adherence to drinking or injecting antidiabetic drugs in people of all ages, Bali Province has the lowest compliance, at 86.98%.⁵ West Java Province's compliance average is even lower than Indonesia's (89.94%).⁵ Bogor City, West Java Province, is a city with a lower adherence rate (85.22%) compared to the provincial and national averages, despite patient adherence to treatment being a major factor in the successful treatment of diabetes.⁵⁻⁶

A cohort qualitative study in Bogor City identified various factors influencing patient adherence to diabetes

mellitus (DM) treatment, including intrapersonal factors (motivation, experience, knowledge, trauma, forgetfulness, laziness, busyness, conditions); interpersonal factors (medical check-ups, health workers, consultations, services, diagnosis, misinformation, social media, family, health cadres, relatives); treatment and disease characteristics (prescription and herbal drug use, side effects, organoleptic properties, form, taste, type, inappropriate use, complications, diet, physical activity, sports); and environmental factors (economy, culture, queues, distance, service satisfaction, policies, and the health system).⁷

Compliance assessment using a questionnaire is an indirect method of measuring compliance.⁷ Adherence to Refill and Medication Scale (ARMS) is a reliable and valid questionnaire to determine the level of adherence in the Indonesian geriatric population with diabetes.⁸ ARMS and ARMS-7 are comprehensive instruments supported by moderate to high-quality evidence for three measurement properties: structural validity, reliability, and construct validity. Moreover, an Indonesian version of ARMS has demonstrated good reliability, as evidenced by a Cronbach's alpha value of 0.815.⁸⁻¹⁰

Despite the advances that have been made in develop-

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ing instruments to observe adherence, no instrument has been established through an expert panel that was able to simultaneously assess clinical outcomes and questions in the form of perceptions. This study aimed to develop an instrument to identify the determinants of medication adherence in patients with type 2 diabetes mellitus (T2DM) based on qualitative study and an expert panel and to examine its relationship to clinical outcomes of HbA1C. By this instrument, researchers from other countries can discover the determinants of adherence to taking medication for patients with DM.

Method

This study was conducted in several urban villages in Central Bogor Subdistricts, Bogor City, including Babakan, Panaragan, Ciwaringin, Babakan Pasar, and Kebon Kalapa, from September to December 2022. Expert panel interviews were conducted through Zoom meetings on 29 September 2022. The Borg and Gall model, consisting of 10 stages (Figure 1), was utilized in this study.¹¹ The stages were initiated with information col-

lecting, during which keywords were searched, and the results of existing systematic reviews related to the determinants of adherence to the treatment of diabetic patients were examined. The second stage, planning, was then undertaken. At this stage, the variables to be identified and assessed were planned. The third stage, developing a preliminary product form, involved conducting an expert panel comprising six experts for the initial development. Subsequently, preliminary testing was performed to conduct the initial validation of the instrument, which was created based on the input from the expert panel. To facilitate the assessment, a determinant instrument assessment form to the field panelists, including doctors, pharmacists, nutritionists, and nurses were provided.^{12,13}

To obtain content validity index (CVI) values and content validity ratio (CVR) from the instruments that have been created, requires assessment.¹⁴ In the fifth stage, the main product was revised based on expert team suggestions. This stage was followed by field trials conducted on 30 patients with DM in the Central Bogor Subdistrict, wherein quantitative data were collected. The instru-

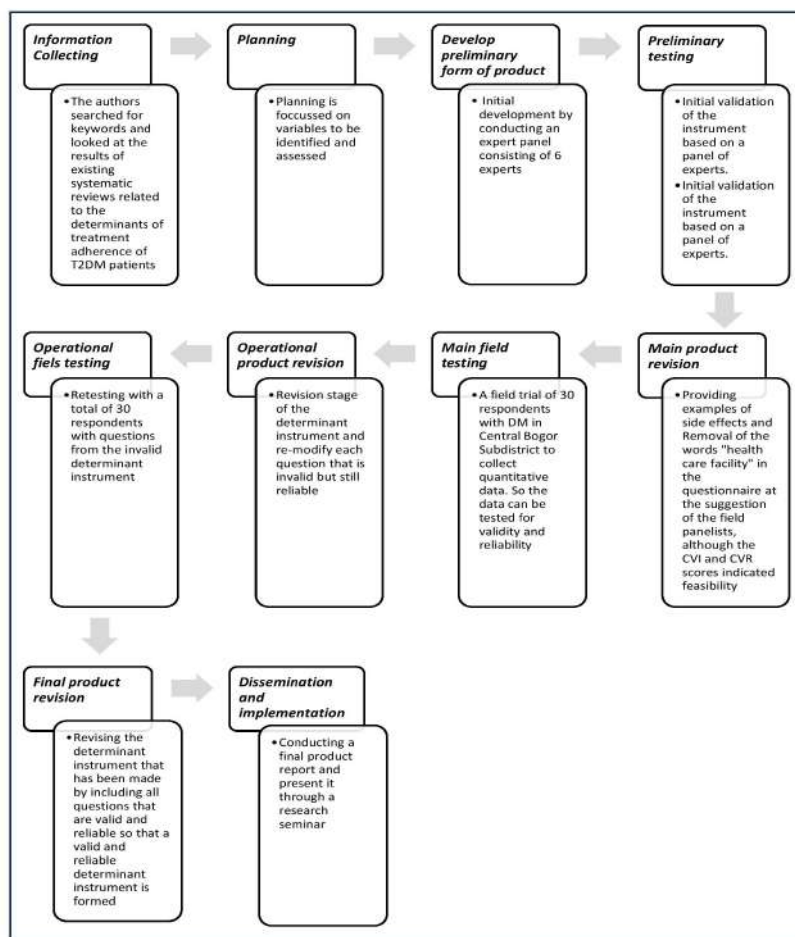


Figure 1. Steps for Build Product

ment's validity and reliability were then tested. Next, the practical product was tested in actual operational circumstances after it had undergone alterations, including modifications to the determinant instrument. This stage involved retesting 30 respondents using questions from the invalid determinant instrument. The next stage was the final product revision, where the determinant instrument was revised to include all valid and reliable questions. Finally, the dissemination and implementation stage entailed creating and presenting a final product report through research results seminars.

The ten stages were selected due to their advantages despite requiring a significant amount of time. These advantages included addressing real and urgent needs (real needs in the here and now) by developing solutions to a problem and generating knowledge for future use; producing a product/model with a high validation value as it undergoes a series of field trials and receiving validation from experts; promoting a continuous process of product/model innovation, aiming to ensure that the products/models are always up-to-date with current demands, and serving as a connection between theoretical and field studies.¹³ This study involved six experts, including professors and Master's students in pharmacy, nutrition, and public health, who each assessed the questions and statements based on their knowledge and experience.

The subject selection was conducted to obtain a review and validation from a panel of health practitioners in the Central Bogor Subdistrict, comprising doctors, pharmacists, nurses, and nutritionists. Data collection involved verbatim transcripts, first-cycle coding, second-cycle coding, and CVI and CVR tests to assess the validity and reliability of the instruments. Validity and reliability tests were performed by administering the instruments to 30 T2DM patients in the Central Bogor Subdistrict, who were part of the Bogor Health Research and Development cohort research data. The respondents' names used in the study were obtained from the Health Development Policy Agency, accessible through <https://www.badankebijakan.kemkes.go.id/>, following specific requirements and procedures.

Results

This study involved seven stages: variable identification, expert panel discussion and review, assessment by field panelists (CVI and CVR), question revision, initial validity and reliability testing, instrument revision, final validity and reliability testing, and instrument completion. Factors influencing treatment adherence in T2DM patients were obtained through a literature search, theory, and verbatim review by six experts. First- and second-cycle coding and validation by a field panelist team were conducted to identify keywords. The results of the coding

cycles are as follows.

Regarding the patients' perceptions of benefits and knowledge, an expert stated, *"Their understanding is that once they have seen the doctor, that's sufficient."* Another expert highlighted the barriers in the environment, stating, *"Access problems persist, especially for those in remote areas, making it challenging to reach health services."*

The patients' perceptions of treatment benefits and knowledge were influenced by their understanding and treatment experience. Good knowledge positively impacted perception, and when patients perceived treatment benefits, they tended to adhere to their treatment. Access to health services, availability, and fear of side effects remained obstacles for patients, affecting their adherence to DM treatment in Indonesia.

An expert said that family support is quite important other than education. *"In fact, we usually work..... Prof. So, of course, this must also come from both the sufferer, meaning the client with diabetes, and must also receive support from the family. So, support from family is quite important."*

Family support was essential in treating patients with diabetes as it provided motivation and positive influence. It was crucial to introduce gradual changes with the support of all family members to overcome potential difficulties. Family involvement included measuring food portions, ensuring consistency in food choices, considering the patient's eating schedule, and providing medication reminders. The patient's family played a pivotal role in the treatment process by acting as companions, promoting healthy habits, and motivating patients to enhance their quality of life.

An expert said medication adherence was related to obstacles, unpleasant experiences, and side effects. *"Well, the biggest obstacle experienced by patients is that they are worried about the side effects of the antidiabetic medicines they are taking, so they stop taking them without consulting a doctor and pharmacists."*

Some patients discontinued antidiabetic medicines without consulting health professionals due to concerns about side effects. Side effects are a common reason for non-compliance with medication. While not all patients experience side effects, those who do may stop taking the medication out of worry.

Another expert cited herbal medicines as related to compliance. *"Because he has a chronic disease, he must have tried all sorts of things, including herbal medicines. It's still better if he doesn't stop taking herbal medicine, but often he takes herbal medicine instead of modern medicine, so he comes with uncontrolled or new complications."*

As a population of a culturally rich country, Indonesians are inseparable from tradition. One such tra-

dition is the consumption of herbal medicines. The use of herbal medicines was carried out as an effort to treat DM. Still, people often do not follow the doctor’s advice and stop modern medicine, which is dangerous.

One expert said the following regarding the frequency of taking medication. *"The frequency of taking medication is often more than once, so if the medication can be taken on a schedule once, the results will be better than if you take it twice."*

The frequency of medication intake directly impacted adherence. To assess adherence among DM patients, 21 questions covered behavior perceptions, intrapersonal and interpersonal factors, disease and treatment characteristics, and environmental factors. Determinants of adherence in T2DM treatment included vulnerability, severity, benefits, self-efficacy, barriers, motivation, knowledge, experience, health services, health workers, family and relatives, drug side effects, herbal medicine use, diet, exercise, medication details, health service system, distance to health facilities, Healthcare Security membership, and education.

To ensure content validity in developing new measurement instruments, this study employed the CVI and CVR methods. Content validity was essential to creating instruments based on theoretical foundations. Initially, a large number of question items were generated to represent a concept or dimension, which were then refined in-

to a smaller set. For instance, in developing a Patient-Centered Communication instrument, the CVI is utilized to evaluate the relevance, clarity, and importance of question items assessed by experts. From the results of the CVI and CVR, the instrument in the form of a questionnaire was built as on Table 1.

Content validity was assessed, resulting in a CVR value of >0.75 and a CVI value of 1 for the overall instrument, indicating excellent content validity. Minor revisions were made based on the panelists’ feedback. A field trial involving 30 DM patients in the Central Bogor Subdistrict evaluated validity and reliability. Preliminary results of the tests are as follows:

- The Determinant Instrument: 4 invalid questions, Cronbach’s Alpha = 0.893
- DKQ-24 Instruments: 10 invalid questions, Cronbach’s Alpha = 0.668
- TSRQ Motivation Instruments: 2 invalid questions, Cronbach’s Alpha = 0.844
- ARMS compliance instrument: 1 invalid question, Cronbach’s Alpha = 0.742

The instrument was revised based on the invalid question, and retesting was conducted with the 30 respondents using the revised determinant instrument. The results of the revision were carried out with the results of the following instruments on Table 2.

Based on feedback from experts and the validity re-

Table 1. Content Validity Index and Content Validity Ratio Assessment

Question	Ne	CVR	Result	CVI	Result
Do you agree that people with diabetes can experience complications from other diseases like kidneys, heart, and eyes?	7	1	Valid	1	Valid
Do you agree that diabetes is a disease that can cause death?	7	1	Valid	1	Valid
Do you agree that taking diabetes medication regularly according to the doctor’s instructions will help to maintain blood sugar levels?	7	1	Valid	1	Valid
Do you agree that people with diabetes find it difficult to get treatment?	7	1	Valid	1	Valid
Are you sure you have been regularly treated at the primary health care (PHC)?	7	1	Valid	1	Valid
Filling out the TSRQ (value calculated)	7	1	Valid	1	Valid
Do you have complaints about diabetes treatment, such as side effects, taste, forgetting to take medication, or other personal things such as what others say, costs, and so on?	7	1	Valid	1	Valid
Filling out the DKQ-24 (value calculated)	7	1	Valid	1	Valid
Are you satisfied with the services provided by PHC?	7	1	Valid	1	Valid
Are you satisfied with the answers from the health workers regarding the questions you asked?	7	1	Valid	1	Valid
Were you not given information (education) about taking medication by health workers?	7	1	Valid	1	Valid
Have you received direct attention from your family regarding your treatment so far?	7	1	Valid	1	Valid
Have you received direct attention from relatives regarding your treatment so far?	7	1	Valid	1	Valid
How much medication are you currently taking?	7	1	Valid	1	Valid
How many times a day do you take the drug?	7	1	Valid	1	Valid
Do you have any complaints after taking the drug?	7	1	Valid	1	Valid
Do you use herbal medicine?	7	1	Valid	1	Valid
During the last three months, have you maintained your diet according to the doctor’s or nutritionist’s instructions?	7	1	Valid	1	Valid
Do you exercise regularly, 30 minutes a day, 5 days a week?	7	1	Valid	1	Valid
Do you experience problems related to the distance to the treatment center?	7	1	Valid	1	Valid
Amount	140	20		20	

Notes: CVR = Content Validity Ratio, CVI = Content Validity Index, TSRQ = Treatment Self-Regulation Questionnaire, DKQ-24 = Diabetes Knowledge Questionnaire-24, PHC = Primary Health Care.

Table 2. Revision of Statement on the Instrument

Before	After
I experienced many obstacles in getting treatment, such as long distances, lack of information from health workers, and not being supported by my family. During treatment, did you have any unpleasant experiences, such as not being served properly by officers, experiencing side effects, being kept away from family/friends, or other experiences?	I feel the obstacles that come from family support in doing the treatment.
In 1 (one) day, do you take 5 (five) different types/types of drugs, including herbal medicine, to treat the disease you are experiencing, such as diabetes or other diseases?	During treatment, did you have any unpleasant experiences, such as: a. Not being served well by officers b. Drug side effects c. Being kept away from friends and family
Do you experience anything unpleasant after taking medication, such as nausea, vomiting, diarrhea, or other uncomfortable feelings, after taking medication?	In 1 (one) day, do you take 5 (five) different kinds of medicine? Do you experience anything unpleasant after taking medication, such as: a. Weakness b. Nausea c. Headache

sults, revisions were made to the instrument (Table 2). Ambiguous questions with the potential for multiple answers were clarified to ensure a definitive “Yes” or “No” response. Modifications were made to the TSRQ motivational instrument by removing two invalid statements (Statement 2: “I am challenged to do this” and Statement 18: “Exercise regularly and paying attention to food is my choice”). The DKQ-24 questionnaire had 10 invalid questions, but no modifications were made due to its simplicity and purpose of assessing knowledge. One question was modified from “Shaking and sweating are a sign of high blood sugar levels” to “Shaking is a sign of high blood sugar levels” to address the possibility of either symptom. The validity and reliability testing yielded a Cronbach’s alpha value of 0.731, indicating the instrument’s validity and reliability as all questions had a higher r count than the r table value (Table 3).

The complete instrument consisted of 10 questions related to patient demographics, 21 questions related to determinants of medication adherence, 7 questions related to motivation, and 24 related to respondents’ knowledge. In measuring adherence, this study used 11 medication adherence questions from the Indonesian version of ARMS. This study was a first step; further testing will be conducted on an appropriate and larger population.

Discussion

The stages of identifying the determinants of adherence to treatment among T2DM patients were derived from a previous study titled “Designing a Model for Handling Factors Causing Non-Adherence to Treatment in Patients with Diabetes Mellitus Type 2.”⁷ Through the analysis of the conducted problems, four factors contribute to non-adherence.⁷ These factors comprise intrapersonal factors, interpersonal factors, drug and disease factors, as well as environmental factors.^{14,15} The results of an existing systematic review titled “Determinants of

Table 3. Validity and Reliability Results of the Instrument Revision

Corrected Item Value	Sig.	r table	Criteria
0.444	0.014	0.361	Valid
0.687	<0.001	0.361	Valid
0.852	<0.001	0.361	Valid
0.444	0.014	0.361	Valid
0.687	<0.001	0.361	Valid
0.687	<0.001	0.361	Valid
0.498	0.005	0.361	Valid
0.498	0.005	0.361	Valid

Factors That Influence Adherence to Treatment of Type 2 Diabetes Patients in Indonesia” revealed the factors influencing treatment adherence among T2DM patients.¹⁶ These factors can be categorized into two groups: factors that can be modified and those that cannot.^{17,18}

Concerning medication adherence, behavior plays a crucial role. One of the behavioral theories widely used in cases of DM patients is the Health Belief Model (HBM).¹⁹⁻²¹ The main concept of HBM consists of five components: perceived susceptibility due to side effects if not adherent to using insulin properly (perceived susceptibility), perceived severity due to disease complications (perceived severity), perceived benefits from using insulin properly (perceived benefit), perceived self-confidence (perceived self-efficacy), and perceived barriers (perceived barrier). Therefore, there is a need for an approach to this.¹⁹

Based on several theories related to instrument development from Borg and Gall,¹¹ this study underwent several stages in this study. The expert panel review served as a reference for determining the determinants as variables in the instrument. This was followed by transcribing the expert panel recordings and providing detailed information through first-and second-cycle coding. Experts emphasized the alignment between theory and

practice, stressing the need to bridge the knowledge–application gap. However, the comprehensive analysis revealed limited progress in perception, behavior, motivation, knowledge, family support, and treatment access. Addressing these challenges required further efforts, strategies, and interventions to advance healthcare.

Determinants of adherence in diabetic patients include susceptibility, severity, benefits, self-efficacy, barriers, motivation, knowledge, experience, health services, health workers, family, relatives, drug side effects, use of herbs, diet, exercise, drug details, health care system, distance to health services, Healthcare Security membership, and education. The panel discussion revealed that these determinant variables, with the support of related studies, have a significant relationship and strong impact on adherence.

While, sex did not significantly affect T2DM patients at health services in Banjarmasin City.²² Moreover, the importance of age, knowledge, and motivation was highlighted in medication adherence.²² Adherence to taking medication can be influenced by the total amount of medication received by T2DM patients at a hospital in Bogor City.²¹ The use of herbal medicines in diabetic patients affects medication adherence.^{23,24} The use of herbal medicines can complicate the treatment regimen received by diabetic patients and lead to low medication adherence. Patients may miss taking prescribed diabetes medication because they already take traditional medicine.^{24,25}

In this study, no significant correlation was found between herbal medicine consumption and adherence to prescribed medications from PHC staff. This result implied that herbal remedies did not affect or predict adherence to conventional medical treatments recommended by health professionals. Patients who used herbal medicines in this study still took their prescribed diabetes medication, but there may have been a delay in the timing of medication intake.^{23,26}

Other studies have also found a relationship between family and health worker support with adherence to anti-diabetic drugs in Jakarta,²⁷ and that education through home pharmaceutical care can improve adherence in Yogyakarta.²⁸ Family support is a vital component that must be included in managing diabetes. Family support can affect medication adherence and facilitate the control of HbA1c levels.²⁹ Families need to realize the importance of providing support and active participation when patients are receiving treatment.²⁹ The assessment instrument was formed and contains all the determinants of medication adherence that have been established based on expert panel discussions, with the aim that each statement or question formed can reflect the determinants of medication adherence that occur in Indonesian society.^{20,30}

The instrument covered various aspects: Perception of Behavior (HBM theory) in statements 1–5, intrapersonal factors (motivation and knowledge) in questions 6–10, interpersonal factors (family support) in questions 11–13, disease and treatment characteristics in questions 14–20, and environmental factors (treatment access) in question 21. It incorporated inputs from keyword searches, expert and field panels, trials, and revisions to effectively represent all factors influencing medication adherence. Preliminary testing involved initial validation by experts, who assessed the instrument using a determinant assessment form.

The assessment yielded the values of CVI and CVR. The content validity was determined by its relevance to T2DM patient characteristics. The CVR values exceeded 0.75 for each criterion, and the CVI value was 1 for the entire instrument. While indicating instrument feasibility, field panelists suggest adding side effect examples and removing “health care facility.”^{9,31} The next stage in developing this instrument was the main field testing. The field trials were conducted on 30 DM patients in the Central Bogor Subdistrict, collecting quantitative data. The next step was to test the validity and reliability of the instrument. This stage entailed the revision of the determinant instrument because some question items were invalid but still reliable, the invalid questions were then re-modified.

Based on the results of the validity and reliability tests as well as the justification from the authors as an instrument, there were several modifications to the TSRQ motivational instrument, which was removing two invalid statements, statement number 2, “*I am challenged to do this,*” and statement number 18 “*Exercise regularly and paying attention to food is my choice.*” In the DKQ-24, there were ten invalid questions. However, because this questionnaire assessed the respondents' knowledge and the questions looked simply, no modifications were made. Except for “Shaking and sweating are a sign of high blood sugar levels,” it was modified to “Shaking is a sign of high blood sugar levels” because one or both symptoms may arise.³¹⁻³⁴

The operational field testing involved retesting the invalid determinant instrument with 30 respondents. The validity and reliability testing showed that all questions had a higher r count value than the r table value, indicating their validity and reliability. The Cronbach's alpha value was found to be 0.731, further confirming its reliability. The final instrument was published after revisions, incorporating all valid and reliable questions, resulting in a comprehensive determinant instrument. This instrument demonstrated validity and reliability, as confirmed through expert panel activities, with a CVR and CVI value of 1 and a final Cronbach alpha value of 0.731. It consisted of 21 questions covering all determinant as-

pects of medication adherence, surpassing previous questionnaires in motivation and knowledge assessment.^{35,36}

Further development is required for this study. The results of the instrument are still in the pilot stage and need to be further assessed for implementation into the population, particularly in streamlining the determinant instrument for medication adherence. The instrument consists of 73 questions alongside the ARMS medication adherence assessment. To enhance respondent convenience requires simplification. Implementing medication adherence determinants independently without the ARMS instrument is challenging, a combined instrument is essential. Additionally, the completion time for the instrument for a single patient range from 30 to 60 minutes, emphasizing the need for practical guidelines and digital design to align with technological advancements and facilitate ease of use.^{37,38}

Conclusion

A breakthrough—a trustworthy instrument for assessing medication adherence in T2DM—has been made as a result of meticulous study and teamwork. Its credibility is ensured by the fact that it was developed by specialists and based on study insights. The right demographic must be targeted while using precision to get maximum effectiveness. Increasing the sample size and participation can improve accuracy and produce robust, representative results that reflect adherence practices.

Abbreviations

DM: Diabetes Mellitus; ARMS: Adherence to Refill and Medication Scale; T2DM: Type 2 Diabetes Mellitus; CVI: Content Validity Index; CVR: Content Validity Ratio; TSRQ: Treatment Self-Regulation Questionnaire; DKQ-24: Diabetes Knowledge Questionnaire-24; PHC: Primary Health Care; HBM: Health Belief Model.

Ethics Approval and Consent to Participate

The development of this determinant instrument has received approval and passed an ethical review from the ethical commission of the Faculty of Medicine, Universitas Indonesia, No. KET-379/UN2.F1/ETIK/PPM.00.02/2022.

Competing Interest

The authors declare that there are no significant competing financial, professional, or personal interests that might have affected the performance or presentation of the work described in this manuscript.

Availability of Data and Materials

The data and materials in this study are available and may be requested from the corresponding author.

Authors' Contribution

IP: Assisted with developing the research question, conducted a litera-

ture review, designed the survey tool, led the data collection, and assisted in interpreting the findings, as well as took the lead role in writing the final written report. RS: Reviewed and assisted with the design of the survey tool, reviewed the Ethics Application, assisted with data entry, led the data analysis, facilitated the research team in an interpretation of the findings, and reviewed the draft of the written report.

RADS: Statistician, assisted in developing the research question, reviewed and contributed to the survey design, assisted in interpreting the survey findings relevant to the clinical community, reviewed and contributed to drafts of the written report. WR: Assisted in the research process throughout the Health Development and Research Agency of the Indonesian Ministry of Health for data research and in developing the survey tool. FSR: Provided writing assistance, set up tables and references, made format adjustments, and edited the content of each section.

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