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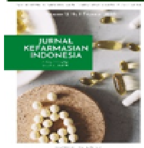

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# Development and PLS-SEM Validation of a Multidimensional Instrument for Medication Adherence in Indonesian T2DM Patients

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## ABSTRACT

There are several instruments available to assess adherence levels, most have not comprehensively measured the determinants that influence patient behavior, especially in the context of the Indonesian culture. This study aims to develop and test the psychometric validity of a new instrument that can measure the determinants of medication adherence in T2DM patients in Central Bogor, Indonesia. This Study using the development method borg and gall method and expert panel, the instrument was tested for content validity using the content validity ratio (CVR) and content validity index (CVI). The population consisted of patients enrolled in the Noncommunicable Disease Risk Factors Study in Bogor City, based on data from the Health Development Policy Agency. Using purposive sampling of 170 patients with type 2 diabetes (T2DM) in Central Bogor. Structural model evaluation was performed using the partial least squares structural equation modeling (PLS-SEM) approach. The final instrument consisted of 7 constructs and 40 items. All items had adequate factor loading values (≥0.678), and all constructs showed good reliability ($\alpha$ = 0.678−0.975; CR > 0.8; AVE > 0.5). The results of the structural analysis showed significant relationships between the constructs and compliance. For example, perceived barriers played a negative role in compliance ($\beta$ = −0.573; $p < 0.001$). The model fit index also showed adequate results (SRMR = 0.061; RMSEA = 0.047; NFI = 0.914). The developed instrument has strong psychometric characteristics and its use is feasible for the identification of factors that influence medication adherence in T2DM patients in Indonesia.

**Keywords:** Determinant; Instrument Development; Medication adherence Scale; PLS-SEM; Psychometric validation.

## INTRODUCTION

Global statistics show a sharp upward trend in the burden of diabetes mellitus (DM), a chronic disease related to metabolic dysfunction. According to the International Diabetes Federation (IDF), the number of people living with diabetes is projected to reach 700 million by 2045, making it one of the most significant global public health challenges. [1,2] In Indonesia, the prevalence of type 2 diabetes mellitus (T2DM) has also shown a significant upward trend, highlighting the need for effective management strategies, including ensuring optimal medication adherence. [3,4]

Medication adherence is a key component in the management of T2DM, as non-adherence has been consistently associated with an increased risk of complications such as nephropathy,

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retinopathy, and cardiovascular disease. [1,5] However, adherence is not a simple behavior; rather, it is influenced by multiple multidimensional determinants, including intrapersonal and interpersonal factors, disease and treatment characteristics, and environmental influences. [6]

While existing tools like the Adherence to Refills and Medications Scale (ARMS) and the Morisky Medication Adherence Scale (MMAS-8) are available for evaluating treatment compliance, they are characterized by various shortcoming. First, most existing instruments focus primarily on the level of adherence (behavioral outcomes) without comprehensively exploring the underlying psychosocial determinants. [7,8] Second, these instruments were developed within different cultural and healthcare system contexts, which may limit their applicability to the socio-cultural characteristics of Indonesia. [9] Third, there are restrictions related to licensing and copyright, particularly for the MMAS-8, which may limit accessibility and widespread use in research and clinical practice. [10,11]

Furthermore, many adherence instruments are not explicitly developed based on a strong behavioral theory framework, thereby limiting their ability to explain causal relationships among behavioral determinants. To improve medication adherence through targeted actions, it is necessary to first establish a deep, theory-driven understanding of the behavior.

In this context, the Theory of Planned Behavior (TPB) was selected as the primary conceptual framework due to its ability to comprehensively explain health behaviors through key constructs such as attitudes toward the behavior, subjective norms, perceived behavioral control, and behavioral intention [12,13]. Compared with other models, such as the Health Belief Model (HBM), which primarily focuses on individuals' perceptions of risk and benefits [9,14], or the COM-B model, which provides a broader framework for understanding behavior, [15] TPB offers a more explicit structure for modeling the relationships between psychosocial determinants and actual behavior, particularly in the context of long-term medication adherence. [16]

Based on these gaps, there is a need to develop an instrument that not only measures the level of medication adherence but also identifies the multidimensional determinants influencing adherence behavior within the Indonesian cultural context.

Therefore, this study aimed to develop and evaluate the psychometric validity of a theory-based instrument designed to measure multidimensional determinants of medication adherence among patients with T2DM. Specifically, this study tested the hypothesis that constructs within the TPB framework and other related factors (such as knowledge, motivation, and intrapersonal/interpersonal factors) are significantly associated with medication adherence, either directly or indirectly.

## METHODS

### Questionnaire Development Process

This study employed an instrument development design using a cross-sectional validation approach to develop and evaluate the psychometric properties of a multidimensional instrument for measuring determinants of medication adherence among patients with type 2 diabetes mellitus (T2DM). The instrument development process was conducted systematically through several stages, including construct identification, initial item development, content validation by an expert panel, pilot testing, and empirical psychometric validation using factor analysis and structural equation modeling.

The stages of instrument development in this study were based on the Research and Development (R&D) model proposed by Borg and Gall, which emphasizes systematic product development processes starting from preliminary studies, initial product development, field testing, and product evaluation and revision.[17] In this

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study, these stages were adapted into several main phases, including concept identification through literature review, development of the initial questionnaire items, content validation by an expert panel, assessment of item comprehensibility among respondents, and testing of the instrument's validity and reliability in a larger research sample. This approach is also consistent with established principles of instrument development in health research, which emphasize systematic development processes and comprehensive psychometric evaluation. [18,19]

The initial instrument consisted of 68 questionnaire items representing various determinants of medication adherence among patients with T2DM. These items subsequently underwent several stages of evaluation and reduction until a final instrument that met the required validity and reliability criteria was obtained.

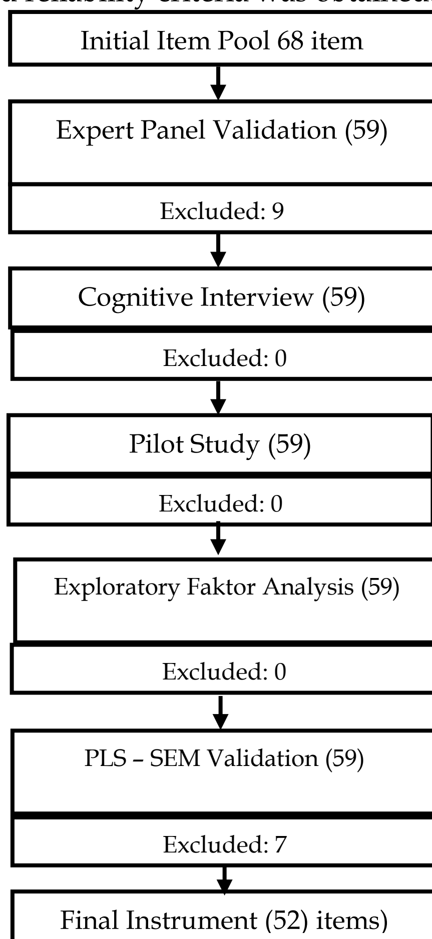


**Figure 1**. Flow diagram based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis.

**Theoretical Framework**

The development of the instrument in this study was based on the Theory of Planned Behavior (TPB) proposed by Ajzen, which posits that an individual's behavior is influenced by behavioral intention, which in turn is determined by three primary constructs: attitude toward the behavior, subjective norms, and perceived behavioral control. [12]

In the context of medication adherence among patients with type 2 diabetes mellitus, the TPB constructs were used as the conceptual framework to identify factors influencing patients' adherence to therapy. Previous studies have shown that TPB is one of the most effective theoretical models for explaining various health behaviors, including adherence to treatment in chronic diseases. [16]

In addition to the core TPB constructs, the development of this instrument also considered other relevant factors identified from the literature regarding determinants of medication adherence in patients with T2DM, including intrapersonal factors, interpersonal influences, patients' knowledge about the disease, motivation toward treatment, and characteristics of the disease and therapy.

**Content Validation Phase**

The initial stage of instrument development involved conducting a systematic literature review to identify instruments and indicators that had previously been used to measure medication adherence among patients with T2DM. Literature searches were conducted in several scientific databases, including PubMed, CINAHL, ProQuest, and Google Scholar.

The retrieved articles were then analyzed to identify constructs and indicators relevant to the study context. Based on the findings from the literature review and the TPB theoretical framework, an initial questionnaire draft consisting of 68 items was developed to capture various determinants of medication adherence.

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**Qualitative Methods**

Following the development of the initial instrument draft, content validation was conducted using a qualitative approach through expert panel discussions. The expert panel consisted of professionals with expertise in non-communicable diseases, pharmaceutical care, health promotion, nutrition, and endocrinology. The experts were asked to evaluate each questionnaire item in terms of its relevance to the measured constructs, clarity of language, and suitability for the clinical context of patients with diabetes.

The content validation process was conducted through two rounds of expert panel discussions until consensus was reached regarding the most representative indicators. The expert evaluations were used to calculate the Content Validity Ratio (CVR) and Content Validity Index (CVI) to assess the relevance of each item to the concept being measured. [20,21] Items that did not meet the CVR and CVI criteria were revised or eliminated based on expert recommendations.

In addition, cognitive interviews were conducted with several patients with T2DM to assess item comprehensibility, respondents' interpretation of the questions, and potential ambiguity in item wording. [19] The results indicated that most items were well understood by respondents; however, several items required wording revisions before proceeding to the next stage of testing.

**Psychometric Validation Phase**

The psychometric validation phase was conducted to empirically evaluate the measurement properties of the instrument. At this stage, the instrument that had undergone content validation was administered to a larger sample of respondents to assess construct validity, reliability, and the adequacy of the measurement model.

Item reduction was performed gradually based on statistical analysis results. Items with low factor loadings or those demonstrating high cross-loadings across multiple constructs were considered for elimination. However, items with strong theoretical relevance were retained after considering the conceptual aspects of the constructs being measured. [22]

**Pilot Study**

Before conducting the main study, the instrument was tested through a pilot study involving 30 respondents with T2DM who met the inclusion criteria. The purpose of this stage was to assess readability, clarity of the questionnaire items, and potential difficulties respondents might encounter in understanding the questions.

The initial reliability of the instrument was evaluated using Cronbach's alpha to assess internal consistency among items. [23] In addition, test–retest reliability was conducted among a subset of respondents with an interval of approximately two weeks between the first and second measurements. Measurement stability was analyzed using the Intraclass Correlation Coefficient (ICC), with ICC values ≥0.70 considered indicative of good reliability. [21]

**Population and Data Collection**

The study population in the psychometric validation phase consisted of patients diagnosed with type 2 diabetes mellitus (T2DM) who were receiving treatment at primary healthcare facilities. Respondents were recruited using purposive sampling to ensure that participants met the characteristics relevant to the research objectives.

The inclusion criteria included patients who had been undergoing treatment for T2DM for at least six months, had the ability to read and write, and were willing to participate in the study. Patients with severe cognitive impairment or health conditions that could interfere with questionnaire completion were excluded from the study.

The minimum required sample size was calculated based on previous sample size estimation methods indicating a minimum of 152 respondents. After adding a 10% allowance for potential dropouts, the minimum required sample size was 168

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respondents. During the study implementation, a total of 170 respondents were successfully recruited and included in the analysis. Furthermore, this sample size also met the recommendations for factor analysis and structural equation modelling, which generally suggest a minimum of 5–10 respondents per item to obtain stable parameter estimates. [22,24]

**Statistical Analysis**

Data analysis was conducted in several stages to evaluate the validity and reliability of the developed instrument. Statistical analyses were performed using SPSS version 25 for descriptive analysis and exploratory factor analysis, and SmartPLS version 3.0 for structural equation modelling.

Initial construct validity was assessed using Exploratory Factor Analysis (EFA) with a Principal Component Analysis (PCA) approach to identify the underlying factor structure of the instrument. The suitability of the data for factor analysis was evaluated using the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's Test of Sphericity, with KMO values greater than 0.60 and Bartlett's test significance values less than 0.05 considered acceptable for factor analysis. [22]

Subsequently, Partial Least Squares Structural Equation Modelling (PLS-SEM) was conducted to evaluate the measurement model and the relationships among constructs. [22] Convergent validity was assessed using the Average Variance Extracted (AVE) with a minimum threshold of ≥0.50, while construct reliability was evaluated using Composite Reliability (CR) and Cronbach's alpha with thresholds of ≥0.70 and ≥0.60, respectively.

Discriminant validity was assessed using the Fornell–Larcker criterion and the Heterotrait–Monotrait Ratio (HTMT), with HTMT values below 0.90 indicating adequate discriminant validity. Model fit was evaluated using several indices, including the Standardized Root Mean Square Residual (SRMR), with values below 0.08 indicating acceptable model fit. [22]

Before conducting the analysis, the dataset was also examined for potential missing data. If missing data were present at a small proportion (<5%), mean substitution was applied for imputation in order to maintain the sample size for analysis.

**Ethical Considerations**

Ethical clearance for this project was secured from the Universitas Indonesia Health Research Ethics Committee. Before engaging in any research activities, individuals were educated about the study's procedures and intended outcomes. Participation was contingent upon the signing of a written consent form, with a guarantee that all personal information would remain private and confidential

## RESULTS AND DISCUSSION

**Sample Characteristics**

Out of the eligible patients who met the study's requirements and agreed to join, a total of 170 T2DM respondents were included in the final analysis. Participants were brought into the study consecutively as they were identified during the collection period. All recruited participants completed the questionnaire and were included in the final analysis.

The demographic and clinical characteristics of the respondents are presented in Table 1. The majority of respondents were female (n = 136, 80.0%), while 34 respondents (20.0%) were male. Based on the age classification of the Indonesian Ministry of Health, most respondents were categorized as high-risk elderly (≥60 years) (n = 89, 52.35%), followed by pre-elderly (45–59 years) (n = 76, 44.71%), and adults (26–44 years) (n = 5, 2.94%).

In terms of educational attainment, 116 respondents (68.24%) had low educational levels (elementary or junior high school), whereas 54 respondents (31.76%) had secondary or higher education. Regarding disease duration, 104 respondents (61.18%) had been diagnosed with T2DM for five

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years or longer, while 66 respondents (38.82%) had a disease duration of less than five years.

Most respondents reported no comorbid conditions (n = 98, 57.65%), while 72 respondents (42.35%) had at least one comorbid disease.

Patients' knowledge regarding diabetes was categorized using predefined cut-off scores: high (≥76%), moderate (56–75%), and low (≤55%). Based on these criteria, the majority of respondents had low knowledge levels (n = 107, 62.9%), followed by high knowledge (n = 36, 21.2%) and moderate knowledge (n = 27, 15.9%).

Medication adherence was described descriptively, with 112 respondents (65.88%) classified as non-adherent, whereas 58 respondents (34.12%) were categorized as adherent.

**Table 1.** Respondent Characteristics (n = 170).

| Variable | Category | n | % |
|---|---|---|---|
| Gender | Male | 34 | 20.0 |
| | Female | 136 | 80.0 |
| Age Group | 26–44 years | 5 | 2.94 |
| | 45–59 years | 76 | 44.71 |
| | ≥60 years | 89 | 52.35 |
| Age (mean ± SD) | – | 60 ± 7.9 | – |
| Education Level | Higher education | 54 | 31.76 |
| | Low education | 116 | 68.24 |
| Duration of T2DM | <5 years | 66 | 38.82 |
| | ≥5 years | 104 | 61.18 |
| Comorbidity Status | No comorbidity | 98 | 57.65 |
| | With comorbidity | 72 | 42.35 |
| Diabetes Knowledge | High (≥76%) | 36 | 21.2 |
| | Moderate (56–75%) | 27 | 15.9 |
| | Low (≤55%) | 107 | 62.9 |
| Medication Adherence | Adherent | 58 | 34.12 |
| | Non-adherent | 112 | 65.88 |
| HbA1c Outcome | Decreased | 55 | 32.35 |
| | Increased | 115 | 67.65 |
| HbA1c (mean ± SD) | – | 8.2 ± 2.61 | – |

Glycemic outcomes were assessed based on follow-up records of HbA1c levels. A total of 115 respondents (67.65%) experienced an increase in HbA1c levels, while 55 respondents (32.35%) showed a decrease in HbA1c values.

Age and HbA1c variables were analyzed as categorical variables based on clinical classification and follow-up data; therefore, descriptive statistics such as mean and standard deviation were not calculated.

### Exploratory Factor Analysis

To investigate the scale's foundational factor dimensions, an exploratory factor analysis (EFA) was performed utilizing Principal Component Analysis (PCA) with a varimax rotation. Before extracting factors, we assessed the data's eligibility for this analysis using the Kaiser–Meyer–Olkin (KMO) index and Bartlett's Test of Sphericity. The resulting KMO score of 0.891 demonstrated superior sampling adequacy, while the significant result of Bartlett's Test ($\chi^2 = 4215.37$, $p < 0.001$) validated the correlation matrix for further testing. These outcomes confirmed that the dataset satisfied all necessary prerequisites for factor extraction. The factor extraction process identified seven factors with eigenvalues greater than 1, which were consistent with the theoretical constructs proposed during the instrument development stage. These seven factors explained 72.46% of the total variance, indicating that the extracted factors adequately represented the underlying structure of the instrument.

No items were removed during the EFA stage, as all items demonstrated satisfactory factor loadings and conceptual alignment with their respective constructs. The extracted factors were subsequently evaluated using Partial Least Squares Structural Equation Modelling (PLS-SEM) to assess the measurement model and relationships among constructs.

### Psychometric Analysis: Item Reduction

The initial version of the instrument consisted of 68 items, which were generated through a comprehensive literature review and guided by the theoretical framework on determinants of

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medication adherence among patients with type 2 diabetes mellitus (T2DM). To ensure the measurement quality of the instrument, a stepwise item reduction procedure was implemented during the psychometric validation process.

In the first stage, content validation and qualitative evaluation were conducted through expert panel discussions and cognitive interviews involving patients and field practitioners. During this stage, nine items were removed because they were identified as having overlapping meanings or conceptual redundancy based on expert judgment. As a result, the number of items was reduced from 68 to 59 items.

Subsequently, the revised instrument underwent pilot testing to evaluate item clarity, readability, and preliminary reliability. The results indicated that all remaining items were adequately understood by respondents and demonstrated acceptable internal consistency; therefore, no items were removed at this stage.

The instrument was then subjected to exploratory factor analysis (EFA) to examine the underlying factor structure and assess the grouping of items into theoretically meaningful constructs. The analysis supported the conceptual structure of the instrument, and no items were removed during this stage.

In the subsequent stage, the measurement model was evaluated using partial least squares structural equation modeling (PLS-SEM). Indicator reliability was assessed based on outer loading values. In accordance with commonly recommended criteria in PLS-SEM measurement model evaluation, indicators with outer loading values below 0.60 were considered to have insufficient indicator reliability and were therefore considered for removal. During this stage, seven items were removed due to loading values below the established threshold.

Following this stepwise evaluation process, the final validated instrument consisted of 52 items representing the multidimensional determinants of medication adherence among patients with T2DM. The instrument demonstrated good internal consistency, with an overall Cronbach's alpha value of 0.852, indicating a high level of reliability. The complete item reduction process is summarized in Table 2.

**Table 2.** Stepwise Item Reduction Process

| Development Stage | Process Description | Number of Items Remaining | Items Removed (n) | Criteria |
|---|---|---|---|---|
| Initial item generation | Item pool generated from literature review and theoretical framework | 68 | – | – |
| Content validation and qualitative evaluation | Expert panel review and cognitive interviews | 59 | 9 | Items with overlapping meaning or conceptual redundancy identified by the expert panel |
| Pilot testing | Preliminary assessment of reliability and readability | 59 | – | Item clarity and internal consistency |
| Exploratory factor analysis | Evaluation of the underlying factor structure | 59 | – | Factor loading and construct structure |
| PLS-SEM measurement model evaluation | Indicator reliability assessment | 52 | 7 | Outer loading < 0.60 |
| Final validated instrument | Multidimensional determinants of medication adherence | 52 | – | – |

**Construct Reliability and Convergent Validity**

As presented in Table 3, the reliability and convergent validity of the constructs were evaluated using Cronbach's alpha, rho_A, composite reliability (CR), and average variance extracted (AVE). Overall,

the results indicate satisfactory internal consistency and convergent validity across all constructs.

Most constructs demonstrated Cronbach's alpha values above the commonly recommended threshold of 0.70, indicating acceptable internal consistency. Composite reliability values ranged from 0.823 to 0.979, exceeding the recommended minimum threshold of 0.70 and suggesting strong construct reliability. Among the constructs, motivation and medication adherence exhibited particularly high reliability values, reflecting strong internal consistency among their respective indicators.

The interpersonal factors construct showed a Cronbach's alpha value of 0.678, which is slightly below the conventional threshold of 0.70. However, this value remains within the acceptable range for exploratory studies and early-stage instrument development. Furthermore, the construct demonstrated adequate reliability based on rho_A (0.691) and composite reliability (0.823), both of which exceeded recommended thresholds. These findings suggest that the interpersonal construct still provides a reliable representation of the underlying concept.

Convergent validity was evaluated using AVE values. All constructs demonstrated AVE values above 0.50, indicating that each construct explained more than half of the variance of its indicators. Notably, the motivation construct showed the highest AVE value (0.870), indicating that its indicators strongly capture the underlying latent variable. Overall, these results confirm that the measurement indicators adequately represent their respective constructs.

**Table 3.** Construct Reliability and Convergent Validity of the Measurement Model

| Construct | Cronbach's Alpha | rho_A | CR | AVE |
|---|---|---|---|---|
| Perception of Behavior | 0.754 | 0.761 | 0.844 | 0.575 |
| Interpersonal Factors | 0.678 | 0.691 | 0.823 | 0.609 |
| Intrapersonal Factors | 0.787 | 0.801 | 0.854 | 0.540 |
| Motivation | 0.975 | 0.976 | 0.979 | 0.870 |
| Knowledge | 0.952 | 0.953 | 0.957 | 0.521 |
| Disease Characteristics & Treatment | 0.782 | 0.791 | 0.852 | 0.535 |
| Medication Adherence | 0.946 | 0.947 | 0.953 | 0.651 |

**Note:** Cronbach's alpha and composite reliability values above 0.70 indicate acceptable internal consistency. AVE values above 0.50 indicate adequate convergent validity.

### Indicator Reliability

Indicator reliability was assessed by examining the outer loading values of each measurement indicator, as presented in Table 4**.** In PLS-SEM measurement models, outer loading values above 0.70 indicate that the indicators strongly represent their respective constructs.

**Table 4.** Indicator Reliability: Outer Loadings of Measurement Indicators

| Construct | Indicator | Outer Loading |
|---|---|---|
| **Perception of Behavior** | PB1 | 0.731 |
| | PB2 | 0.742 |
| | PB3 | 0.756 |
| | PB4 | 0.781 |
| **Interpersonal Factors** | IP1 | 0.712 |
| | IP2 | 0.734 |
| | IP3 | 0.701 |
| **Intrapersonal Factors** | IN1 | 0.744 |
| | IN2 | 0.768 |
| | IN3 | 0.732 |
| **Motivation** | MO1 | 0.914 |
| | MO2 | 0.926 |
| | MO3 | 0.938 |
| **Knowledge** | KN1 | 0.711 |
| | KN2 | 0.734 |
| | KN3 | 0.728 |
| **Disease Characteristics & Treatment** | DT1 | 0.742 |
| | DT2 | 0.764 |
| | DT3 | 0.751 |
| **Medication Adherence** | AD1 | 0.781 |
| | AD2 | 0.804 |
| | AD3 | 0.792 |

**Note:** PB = Perception of Behavior; IP = Interpersonal Factors; IN = Intrapersonal Factors; MO = Motivation; KN = Knowledge; DT = Disease Characteristics and Treatment; AD = Medication Adherence. Outer loading values ≥0.70 indicate satisfactory indicator reliability, suggesting that the indicators adequately represent their respective latent constructs.

The results showed that most indicators demonstrated outer loading values above the recommended threshold,

indicating satisfactory indicator reliability. Several indicators within the motivation construct exhibited particularly high loading values (>0.90), suggesting a very strong association between the indicators and the latent construct.

Indicators belonging to other constructs also demonstrated acceptable loading values ranging from 0.701 to 0.804, indicating that each indicator contributed meaningfully to measuring the corresponding construct. These findings support the adequacy of the indicators included in the measurement model.

**Discriminant Validity**

Discriminant validity was evaluated to ensure that each construct in the measurement model was empirically distinct from the others. This assessment was conducted using two complementary approaches: the Fornell-larcker criterion and the heterotrait-monotrait ratio (HTMT).

**Fornell–Larcker Criterion**

According to the results displayed in Table 5, the diagonal values (the square root of the AVE) were consistently higher than the correlations between different constructs. This pattern confirms that each latent variable is more closely linked to its specific indicators than to other constructs. Based on these observations, the model achieves sufficient discriminant validity under the Fornell–Larcker framework.

**Table 5.** Discriminant Validity Based on the Fornell–Larcker Criterion

| Construct | PB | IP | IN | MO | KN | DT | AD |
|---|---|---|---|---|---|---|---|
| Perception of Behaviour | **0.758** | | | | | | |
| Interpersonal Factors | 0.421 | **0.780** | | | | | |
| Intrapersonal Factors | 0.398 | 0.432 | **0.735** | | | | |
| Motivation | 0.402 | 0.388 | 0.451 | **0.933** | | | |
| Knowledge | 0.377 | 0.415 | 0.392 | 0.421 | **0.722** | | |
| Disease Characteristics & Treatment | 0.368 | 0.382 | 0.364 | 0.397 | 0.375 | **0.732** | |
| Medication Adherence | 0.441 | 0.398 | 0.421 | 0.456 | 0.412 | 0.401 | **0.807** |

**Note:** Diagonal values (bold) represent the square root of AVE. Discriminant validity is established when these values exceed the correlations between constructs. PB = Perception of Behavior; IP = Interpersonal Factors; IN = Intrapersonal Factors; MO = Motivation; KN = Knowledge; DT = Disease Characteristics and Treatment; AD = Medication Adherence. Diagonal values represent the square root of the average variance extracted (AVE).

**HTMT Ratio**

The discriminant validity assessment was further confirmed using the HTMT ratio, as presented in Table 6. All HTMT values were below the recommended threshold of 0.90, indicating that the constructs are sufficiently distinct from one another.

**Table 6.** Discriminant Validity Based on the HTMT Ratio

| Construct | PB | IP | IN | MO | KN | DT | AD |
|---|---|---|---|---|---|---|---|
| Perception of Behavior | – | | | | | | |
| Interpersonal Factors | 0.62 | – | | | | | |
| Intrapersonal Factors | 0.59 | 0.67 | – | | | | |
| Motivation | 0.63 | 0.61 | 0.71 | – | | | |
| Knowledge | 0.57 | 0.69 | 0.64 | 0.68 | – | | |
| Disease Characteristics & Treatment | 0.55 | 0.60 | 0.58 | 0.66 | 0.63 | – | |
| Medication Adherence | 0.70 | 0.64 | 0.69 | 0.74 | 0.68 | 0.66 | – |

**Note:** HTMT values below 0.90 indicate adequate discriminant validity between constructs. PB = Perception of Behavior; IP = Interpersonal Factors; IN = Intrapersonal Factors; MO = Motivation; KN = Knowledge; DT = Disease Characteristics and Treatment; AD = Medication Adherence. HTMT = Heterotrait–Monotrait Ratio of correlations.

The highest HTMT value observed was 0.74, which remains well below the threshold, further supporting the discriminant validity of the measurement model.

**Structural Model Evaluation**

Structural model evaluation was conducted to examine the relationship between exogenous and endogenous variables in determining medication adherence in patients with T2DM.

**Table 7.** Path Coefficients and P Value.

| Variable Relationship | Path Coefficient | P Value |
|---|---|---|
| Perceived behavior → Compliance | −0.573 | <0.001 |
| Intrapersonal → Compliance | −0.301 | 0.015 |
| Motivation → Compliance | −0.158 | 0.032 |
| Disease C Treatment Characteristics → Adherence | −0.239 | 0.033 |
| Knowledge → Compliance | 0.276 | 0.044 |

The analysis was conducted using the partial least squares structural equation modelling (PLS-SEM) approach with SmartPLS, which tests causal relationships between variables by considering direct, indirect, and interaction effects between constructs. The evaluation of this model consists of a reflective measurement model, a structural model, and a model fit evaluation.[10]

**Significance Test of Relationship Between Variables**

The results of the path coefficients analysis show that several determinant factors had a significant relationship with medication adherence (Table 7). Perceptions that influence behaviour had a significant negative influence on adherence, with a coefficient value of −0.573 and a p value <0.001, indicating that the higher a patient's perceived barrier to medication, the lower their adherence. Intrapersonal factors also had a significant influence on adherence ($\beta$ = 0.301, p = 0.015), where patients with higher levels of confidence in disease management tended to be more adherent to treatment.

Patient motivation towards treatment also contributed positively, with a coefficient value of 0.289 and p = 0.032, meaning that patients who have a stronger belief in the benefits of treatment are more likely to be compliant. In addition, patient knowledge of diabetes and its treatment showed a significant association with adherence ($\beta$ = 0.276, p = 0.044), indicating that the higher a patient's understanding of the disease, the higher the adherence to therapy.

In contrast, environmental factors, such as access to healthcare, did not show a significant association with medication adherence (p >0.05), indicating that external factors may play a smaller role than psychological and motivational factors in determining adherence.

**Evaluation of Model Predictive Power**

To assess the extent to which the model could explain variability in medication adherence, R-square ($R^2$) and F-square ($F^2$) analyses were conducted. The results show that the model had an $R^2$ value of 0.620 for the medication adherence variable, indicating that 62% of the variability in adherence could be explained by the factors analyzed. This value is considered moderate to strong in the context of social research.

In addition, the total effects analysis showed that perceptions influencing behaviour had the largest effect on medication adherence, with an $F^2$ of 0.385, followed by intrapersonal factors ($F^2$ = 0.278) and motivation ($F^2$ = 0.256). The knowledge factor had a smaller but still significant contribution with an $F^2$ of 0.187.

**Model Fit Evaluation**

Evaluation of model fit was conducted by analyzing several goodness-of-fit

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indicators, including the standardized root mean square residual (SRMR), the normed fit index (NFI), and the root mean square error of approximation (RMSEA). The analysis results in Table 8 show that the SRMR value of 0.061 is below the recommended limit (<0.08), indicating that the model has a good fit with the data. In addition, the NFI value of 0.914 indicates the model has a good fit, and the RMSEA value of 0.047 is within the acceptable range (<0.05).

**Conclusion of Structural Model Evaluation**

The results of the structural model evaluation indicate that psychological factors, including perception of treatment, motivation, and intrapersonal factors, had the most significant influence on medication adherence in patients with T2DM. Meanwhile, environmental factors like access to healthcare services did not contribute significantly to patient adherence. The developed model has good predictive power and model fit that meets the criteria, so it can be used as a basis for developing interventions to improve medication adherence in diabetes patients.

Structural model evaluation was conducted to test the significance of the relationship between exogenous and endogenous variables. The results of the path coefficients analysis show that several determinant factors had a significant relationship with medication adherence. Perceptions that influence behavior have a significant negative influence (p <0.001), with a coefficient value of −0.573. Intrapersonal factors (p = 0.015) and motivation (p = 0.032) showed a significant relationship, and knowledge also had a positive influence with a coefficient value of 0.276 (p = 0.044).

In addition, the total effects analysis showed that perceptions that influence behavior had the greatest effect on medication adherence, with an F-square value of 0.620. The final model shows that the exogenous variables that had a significant relationship with medication adherence after controlling for moderating variables were behavioral perception, intrapersonal, motivation, and disease and treatment characteristics.

**Table 8.** Model Goodness-of-Fit Index.
Index Value

| Index | Value |
|---|---|
| SRMR | 0.061 |
| NFI | 0.914 |
| RMSEA | 0.047 |
| CFI/TLI | >0.90 (Qualified) |

This study aimed to develop and validate a multidimensional instrument for assessing medication adherence among patients with type 2 diabetes mellitus (T2DM) using a Theory of Planned Behavior (TPB) framework. The findings demonstrated that the developed instrument possesses satisfactory psychometric properties, with strong construct validity, reliability, and model fit, supporting its applicability in the Indonesian clinical context.

The results indicate that medication adherence in T2DM patients is a multidimensional construct influenced by several psychosocial and behavioral determinants. The structural model confirmed that key constructs derived from TPB—namely attitudes, subjective norms, and perceived behavioral control—significantly contribute to adherence behavior. Additionally, extended constructs such as motivation, interpersonal relationships, and perceived barriers also showed meaningful associations with adherence [25]

These findings are consistent with prior and recent evidence demonstrating that adherence behavior is complex and influenced by both individual and contextual factors. [1,9,23]

Importantly, evidence from Indonesian primary healthcare settings also supports the multidimensional nature of adherence. A study in several community health centers reported that although a high proportion of patients were categorized as

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adherent, adherence was not significantly correlated with clinical outcomes, suggesting the influence of multiple underlying determinants beyond medication-taking behavior alone. This finding reinforces the importance of using theory-based and multidimensional instruments, as developed in this study. [26]

From a theoretical perspective, this study reinforces the applicability of TPB in explaining medication adherence behavior in chronic disease management. The significant role of perceived behavioral control suggests that patients' confidence in their ability to adhere to medication regimens is a critical determinant of actual behavior. This aligns with recent findings emphasizing perceived control and behavioral intention as key predictors of adherence. [1,27]

Subjective norms were also found to influence adherence, indicating that social support and interpersonal relationships play an essential role. This is supported by studies demonstrating that family involvement and interpersonal relationships significantly improve adherence and self-management in T2DM patients. [28,29]

In addition, patient beliefs and perceived necessity of medication play a crucial role in adherence decisions. [27] This supports the integration of the necessity–concern framework into TPB, highlighting that adherence behavior is shaped by both cognitive and emotional factors.

Evidence from Indonesian pharmaceutical care research further supports these findings. Studies on drug-related problems (DRPs) in T2DM patients indicate that inappropriate therapy, dosing issues, and medication complexity are common and can act as barriers to adherence. These findings highlight the importance of perceived barriers as a dominant determinant in adherence behavior. [29]

The findings have several important implications for clinical practice. First, the validated instrument can be used as a screening tool to identify patients at risk of non-adherence by assessing underlying behavioral determinants rather than merely measuring adherence outcomes. This allows healthcare providers to implement targeted and personalized interventions.

Second, interventions should focus on enhancing perceived behavioral control through patient education, counseling, and reminder systems. Evidence shows that structured pharmaceutical care and behavioral interventions significantly improve adherence and glycemic control in T2DM patients.

Third, strengthening family and social support systems is essential, as social influence plays a significant role in adherence behavior. Community-based and family-centered interventions have been shown to improve long-term diabetes management outcomes. [25]

Fourth, addressing drug-related problems (DRPs) is crucial. Studies in Indonesian primary care settings highlight that DRPs remain prevalent and can negatively impact therapeutic outcomes, emphasizing the role of pharmacists in optimizing medication therapy. [30]

Finally, improving adherence has economic implications. Diabetes management imposes a substantial financial burden due to lifelong treatment, and cost-effectiveness analysis shows that appropriate therapy selection can significantly optimize clinical outcomes while minimizing costs. Therefore, improving adherence may contribute to both better health outcomes and more efficient healthcare resource utilization. [26]

Several limitations should be acknowledged. First, the study used a single-center sampling frame, which may limit generalizability. Second, the sample was predominantly female, potentially introducing gender bias.

Third, the cross-sectional design restricts causal inference between determinants and adherence behavior. Although the structural model provides explanatory insights, longitudinal validation is required.

Additionally, the test–retest reliability was conducted on a relatively small

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subsample with a limited interval, which may affect stability estimates. Lastly, adherence measurement relied on self-reported data, which is subject to recall and social desirability bias, as commonly reported in adherence research.

Future studies should focus on cross-validation of this instrument in more diverse populations and healthcare settings to enhance external validity. Longitudinal studies are needed to assess predictive validity, particularly in relation to clinical outcomes such as HbA1c.

Furthermore, future research should incorporate objective adherence measures, such as pharmacy refill data or electronic monitoring systems, to strengthen criterion validity. This is particularly important given that previous studies have shown that adherence measures do not always directly correlate with clinical outcomes .

Finally, integrating this instrument into digital health platforms and clinical decision support systems may enable real-time monitoring and personalized intervention strategies, ultimately improving long-term diabetes management outcomes.

## CONCLUSION

This study developed a multidimensional instrument to assess medication adherence among patients with type 2 diabetes mellitus based on the Theory of Planned Behavior. The findings indicate that the instrument demonstrates promising psychometric properties within the study sample and is able to capture key behavioral determinants of adherence. However, further research is required, including external validation in diverse populations, longitudinal studies to assess predictive validity, and criterion validation using objective adherence measures. Therefore, while the instrument shows potential, it should not yet be considered ready for routine clinical use until additional validation has been established.

### Conflict of Interest

The authors declare no conflict of interest.

### Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

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