Original Research

Development and assessment of psychometric properties of Model Medication Adherence (MMA) questionnaire to measure adherence to oral medication among patients with type 2 diabetes mellitus

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Abstract

Introduction: Medication adherence among patients with type 2 diabetes (DM) is assessed in everyday clinical practice.

Objectives: To develop a questionnaire to measure adherence to oral medication among patients with DM and to assess its psychometric properties

Methods: The "Model Medication Adherence (MMA)" questionnaire was developed using the evidence from literature review and interviews with key stakeholders and patients. Answers were set on a five-point Likert scale that scored from 1 to 5, with 15-73 as the possible range of the total score. MMA was drafted in English and translated to Sinhala language by forward- backward translation.

A descriptive cross-sectional study was carried out among adult patients with type 2 DM who attended clinics in Gampaha District General Hospital (DGH). A sample of 150 patients was recruited consecutively. The construct validity of MMA was assessed by Exploratory Factor Analysis (EFA) through Principal Component Analysis (PCA) with Varimax rotation

Results: EFA yielded four factors; sick role behaviour, autonomy, forgetfulness, and barriers that explained 64.36% of the variance of the total score of MMA. Internal consistency was acceptable (Cronbach's alpha 0.73). The test-retest reliability coefficient was 0.85 (p=0.01). Acceptability of the MMA was established by non-response items (none) and the time taken to complete (20 minutes).

Conclusions & Recommendations: MMA is a simple valid questionnaire that adds a novel concept to the adherence literature; sick role and autonomy. It has a good factor structure with established construct validity and is recommended to be used in the clinical setting.

Keywords: *adherence, psychometrics, diabetes mellitus, factor analysis, questionnaire*

Introduction

Before Adherence to diabetic medication is important in achieving the expected glycaemic outcome: especially among adults who are unable to cope with lifestyle changes (1). Assessment of adherence to diabetic medication is mandatory in clinical practice, before adjusting the doses (2). In addition, medication adherence is a service quality indicator (3). Medication adherence is defined as "The extent to which a person's behaviour of taking medication, corresponds with agreed recommendations from a health care professional" (4). Since DM is a chronic disease, continued medication every day with the correct dose and frequency is recommended unless advised by health care professionals.

Medication adherence is a complex human behaviour (5); a patient should decide to visit a medical practitioner, obtain the prescription, visit the pharmacy and get the medication, store medication, get the medication out from the store when needed, and ingest as recommended by the practitioner. Any attempt to measure adherence involves the quantification of a step mentioned above. However, ingestion of the medication is the most proximal step of the adherence and other steps like visiting medical practitioner, collecting and storing the medication will not reflect actual ingestion. The majority of the studies (6-7) on medication adherence are available from developed countries where large electronic databases of population health records are available, adherence to diabetic medication is measured as a proxy measure which captures the medication dispensing to the public; this is possible in a closed pharmacy system where only diagnosed patients with designated medical practitioner has access to medication. Nevertheless, data are collected at an individual patient level, which involves subjective self-reporting in the majority of the studies from Asian countries (8-9) and objective measuring of pill counts (10).

Questionnaires are commonly used to establish adherence to medication since it is simple, inexpensive, reproducible, easy to administer and correlates with other objective methods (11). However, the main disadvantage is over-reporting adherence (12). The majority of the questionnaires are generic versions that measure medication adherence in any disease group. Even though they allow comparing adherence among other disease groups, practical utilization is limited due to the ceiling effect; the majority score high (13-14). In addition, items of the majority of questionnaires reflect that patients stop taking medication only when they are feeling better. However, patients can stop medication for various other reasons, including the perception of experiencing medication side effects, uncertainty about continuing medication when suffering from other illnesses like fever or when they are put on any other treatment, and thinking that a strict dietary control alone is enough. The ideal questionnaire should include items to elicit these reasons. Moreover, some questionnaires measure the associated factors, not the behaviour of adherence, for example the beliefs.

Diabetes mellitus has the lowest level of adherence among chronic diseases which warrants additional exploration and accurate measurement aiming for interventions to improve (4, 15). Assessing adherence to diabetic medication is a crucial need in clinical practice and healthcare service management considering the increasing trend of DM prevalence. Hence, a widely available valid questionnaire that measures adherence behaviour among diabetic patients is a timely need. The objective of this study was to develop a tool to measure oral medication adherence among patients with type 2 DM and to assess its psychometric properties.

Methods

Development of the questionnaire

MMA was developed following a stringent process using several methods. Relevant literature was initially searched to explore the different definitions of adherence, and the operationalization of the construct of adherence.

Semi-structured interviews were conducted among stakeholders of service provision such as health education experts, visiting physicians, sociologists, health education nursing officers, pharmacists and medical officers. At least one person from each category was interviewed and the number of persons interviewed depended on data saturation until no newer themes appeared. In addition, purposively selected five patients who were known to have high and low adherence to medication in a community setting were interviewed. The main reasons for deciding not to take medication as directed were explored.

The item pool was generated by the experience gained through the literature review and results of stakeholder interviews. Items were generated with the use of implicit premises thus normalizing the non-adherence behaviour. Simple questions were worded; unambiguous/double-barrelled, and leading questions were avoided. The generated item pool was reduced and modified with the expert opinion. There were 20 questions in the final item pool (Table 1). Items that measure associated factors of adherence were reduced. The duration of the recall period was decided following extensive exploration. There is evidence that patients tend to remember habitual behaviours rather than recent acute behaviours (16-18): patients' report on their behaviour during last one-month was more accurate than during last one week when compared with electronically stored data (10, 19). Hence, one month recall period was used in this study.

The instrument was developed in English language due to feasibility issues and was translated into the Sinhala language after finalizing it by two linguistic experts. Another two linguistic experts (who were blind to the original English version) back-translated the Sinhala version and the final English version was compared with the original. The final version was forwarded for expert opinion through electronic mail. Pretesting of MMA was done by cognitive probing interviews among five purposively selected study participants in District General Hospital Negombo. It surfaced misunderstandings, and interpretation variability of the questionnaire by the patients. Potential obstacles faced when administering the questionnaire were identified and remedial measures were implemented. A visual guide for the five answers was developed following the pre-test, since patients found it difficult to concentrate on the range of answers.

The validity of the questionnaire (face, content and consensual) was assessed through the Modified Delphi technique. Two public health specialists who were involved in designing questionnaires, two general physicians and a sociologist were invited to participate. In the first round, consented participants were sent a copy of the proposed questionnaire and were requested to give suggestions to improve the content and clarity. The content and the clarity were graded from 1 (highest) to 5 (lowest). The experts were asked to score for each item, and if the score for any item was below 3, they were asked to give an explanation. The suggestions were emailed to the first author separately to maintain anonymity. Modifications were done and the experts were asked for the necessity of any further clarifications. Following the second-round, consensus was reached and the items to be included were finalized. During the third round, an agreed scoring system was sent and participants were asked to rank each scoring system. It was a 14-item interviewer-administered questionnaire on a five-point Likert scale. The first answer was the most socially undesirable answer to give while the last option was the most socially desirable answer to give. Question number 15 was answered only in three points. The possible score ranged between 15-73.

The questionnaire was named "Model Adherence to Medication (MMA)". Though a self-administered questionnaire is suitable to elicit self-care behaviour, since the study population would have different educational levels and physical difficulties

like impaired vision, paralysis of limbs or impaired cognitive skills to complete a questionnaire on their own in a busy setting, an interviewer-administered questionnaire was developed.

Factor structure of the questionnaire

A descriptive study was conducted to describe the factor structure of the newly developed 15- item questionnaire. The study setting was outpatient (including medical and family medical) clinics in Gampaha DGH. The study population comprised diagnosed adult patients (≥18 years of age) with type 2 DM on medication for one year. Patients on insulin treatment and those who had changed their medications during the last three months were excluded.

The sample size was calculated to demonstrate the construct validity of MMA. It is recommended to include 5-10 patients per item to demonstrate the construct validity (20), thus '10 patients per item' was considered with a minimum sample of 150. Daily attendance of DM patients to the relevant clinics was around 10, out of which only 3-5 patients were eligible to participate in the study with more than one year of registration in the clinic. All such eligible consecutive patients who consented to participate were recruited for the study until the sample size was reached.

Data collectors were trained, and a written interviewer guide was given to each. Question number 15 was excluded from the analysis since it contained only three answers which were different from the other questions. Factorability was established by analysing the correlation matrix, anti-image matrix, and sampling adequacy. All the correlation coefficients were over 0.3 except for the change in dose with diet, inconvenience and out-of-stock. Anti-image matrix for diagonals was over 0.5 except for the change in diet. Changing the dose with the diet (changing the medication dose with the meal) was excluded from the analysis. Bartlett's Test for Sphericity was significant and the KMO measure of sampling adequacy was 0.67, representing the average sampling adequacy. Exploratory factor analysis was performed with PCA and Promax rotation.

Reliability was assessed using test-retest method among randomly selected 1/3 of the total study group, one month after the initial encounter by the same interviewers (12). Internal consistency was assessed using Cronbach's alpha to check the average inter-item correlation. Acceptability of the new instrument was assessed by the average time taken to administer the tool.

Results

Semi-structured interviews revealed that the majority of the patients insisted that they took medications as prescribed. Still, they developed hypoglycaemic symptoms while in the ward; there was a discrepancy between prescribed and ingested medication among medical clinic attendees; patients did not buy medication for the prescribed period from private pharmacies; pharmacists (private and government) did not speak to the patients regarding medication adherence. Patients had a surplus of medication at home since they did not adhere to the written doses; they tried herbal as an adjunct to the prescribed; revealing difficulty in adhering to the prescription was thought as a fact to be blamed. Nevertheless, patients decided what is good for themselves based on beliefs about medication, perceived difficulty in affording, and the way they felt. Using medication outside home was embarrassing to the patients since DM was associated with social stigma, through which they were regarded as weak characters with poor eating habits or having done something wrong in the past.

Construct of adherence

A widely used construct of adherence is taking medication as prescribed/agreed recommendation by the physicians. Questionnaires operationalize the

construct as "non-adherence or not taking medication as prescribed". Not taking medication is often viewed as a patient's decision (21). Only a few questionnaires addressed that there are barriers which are out of control to the patients like forgetting, inconvenience, perceived affordability of medication/ non-availability of medications (10, 22). The construct of most questionnaires describes the factors associated; not the construct itself (23).

The operational definition of medication adherence was concluded following semi-structured interviews with healthcare service providers and patients. It was agreed to limit the operational definition to the adherence behaviour itself not creeping into other factors like health beliefs, socioeconimic status which are predictors. There are two operational components of adherence, intentional and non-intentional: intentional adherence is the patient's active decision to continue with medication which is modified by beliefs, subjective norms, perceived control, and non-intentional adherence to barriers and facilitators (4). Considering operational feasibility, MMA quantifies non-adherence behaviour. Non-adherence to medication is operationally defined as "A patient is nonadherent to medication if he/she decides to stop medications intentionally, or fail to take due to forgetting or inconvenience (unintentional)".

Factor structure of the questionnaire

A total of 155 patients who attended diabetic, OPD and family medical clinics in Gampaha Base Hospital were invited to participate. Four patients from the medical clinic and one patient from the OPD clinic refused to participate since they are busy and wanted to go back home soon. Therefore, the non-response rate was 3.3%. The final study sample was 150 participants.

The mean age of the participants was 60.6 years (SD=9.3). The majority (46.4%) of patients were in the 56-65 years age category. The majority of the study participants were females (61.3%), married (69.3%), Sinhala (98%), Buddhists (87.3%) and had got through General Certificate of Education (Ordinary Level) (87.3%). Most of the study participants (42.7%) were currently employed and 44.4% of the participants had an income between Rs. 10,000 – 20,000. Most (30.0%) were in social class iii who were skilled workers.

The observed range of the MMA score was 34-73 with a median of 67. The highest score (73) is observed in 14% of the population. The distribution of the score is skewed to the left and the skewness is -1.3.

Exploratory factor analysis

All the variables show high communalities (>0.5) except variable inconvenience, implying that the factors extracted explain most of the variance in the other variables being analysed. Four components which have eigen values >1 were extracted. Those four components explain 64.36% of the variance and sick role behaviour explained 25.08% of the variance. The correlation matrix is depicted in Table 2, which demonstrates that none of the items are highly correlated. Table 3 depicts the factor loadings of the MMA items. Figure 1 includes the Scree plot which depicted a significant break after 4 components.

Internal consistency was assessed by calculating Cronbach's alpha which is 0.73. Deleting item inconvenience increased Cronbach's alpha up to 0.75. The test-retest reliability coefficient was 0.85 (p=0.01). The average time taken to administer MMA questionnaire was seven minutes in the clinic setting. There were no missing data on the items in the MMA.

Discussion

MMA is a 15-item interviewer-administered questionnaire that was built on a construct consisting of four factors; sick role behaviour,

autonomy, forgetfulness and barriers to adherence. There is good consistency between the items. The measure is stable over time, and acceptable to the patients. According to the authors' best knowledge, MMA is the only non-proprietary questionnaire that quantifies the usual adherence behaviour during the past month and that does not include belief about medication as items in the questionnaire; even though the patient believes that medications cause long-term side effects, they will continue to take medication due to the enormous trust placed on the health care professional.

The absence of a theoretical construct has been the main concern for some questionnaires (E.g., MMAS) (22). Establishing construct validity is important since it demonstrates the theory behind the scale content is correct (5). The evolution of a construct is an ongoing process. New constructs are derived from sociological theory or clinical observations (24). Our study used semi-structured interviews with patients, since they can be used to identify outlier behaviour; others used focus group discussions that are better at eliciting social norms (25).

The identified components following EFA are sick role behaviour, autonomy, forgetfulness and barriers to adherence. Sick role behaviour includes the behaviour/expectations of society when an individual is feeling ill. Patients are supposed to act rationally to get the illness cured. Autonomy includes the right of the patient to take their own decisions about DM medication-taking behaviour; the patient is empowered enough to alter the dose/pills of the prescription if feeling better or whenever he thinks of doing so.

None of the previous studies identified sick role behaviour and autonomy as factors which contribute to the construct of adherence to mediation. Sick role behaviour accounted for most of the variance explained in MMA. Forgetting to take medications, stopping medications when feeling better/worse and the complexity of the drug regimen were the factors identified in MMAS validation in Korea and Thailand (26-27). Single factor structure was confirmed in the four-item Morisky Medication Adherence Scale (28). Eleven factors in ASK20 indicated that each variable did not load to a single factor or each factor did not have a loading of at least three variables (29). Factors identified by EFA in ASK 12 were health beliefs and inconvenience/forgetfulness (30).

The number of items in the questionnaire varies from 8 to 20. Questionnaires with a small number of items have demonstrated ceiling effects (13-14). Added number of items will increase the variability of the scale which in turn improves the classification power (24). The length of the MMA is intermediate.

Internal consistency measures the extent to which all items in a scale measure the same construct (31). Internal consistency of the MMA was Cronbach's alpha 0.73 which is acceptable. This is in contrast to MMAS where lower values around 0.6 were reported in Taiwan (32), Malaysia (33) and Korea (34). This may be due to a reduced number of items in MMAS, lack of an underlying variable or poor correlation between items. Sinhala version of BMQ demonstrated a Cronbach α coefficient of 0.65 while subscales showed values of 0.71, 0.84, and 0.76. Internal consistency was better in MMA than in the other scales.

The test-retest reliability coefficient of MMA was 0.85 ($p=0.01$) which is acceptable demonstrating adequate temporal stability. This is similar to the other scales which showed similar values; MMAS 0.83 in Taiwan, 0.82 for Malaysia, of 0.79 for the Korean version. Sinhala version of BMQ demonstrated > 0.8 for the total scale. Considering all the facts, MMA is a valid questionnaire which measures a new concept of medication adherence: sick role behaviour and autonomy. It can be used in clinical settings to measure medication adherence among clinic attendees with DM and further

development of the concept is recommended.

Limitations

MMA has been specifically developed to measure oral medication adherence among patients attending the clinics. However, patients in the community who do not seek treatment from clinics and those on insulin may respond differently to the MMA. Moreover, in this study only EFA was done to establish psychometric properties; confirmatory factor analysis is yet to be performed.

Conclusions & Recommendations

The developed MMA is a valid and reliable questionnaire with a new concept that measures oral medication adherence among type 2 DM patients attending outpatient clinics. The construct on which the MMA was developed is accurate as demonstrated by the construct validation. It is recommended to further develop this concept and confirm the factor structure with confirmatory factor analysis.

Table 1: Compiled item pool to measure adherence to oral medication among patients with type 2 diabetic mellitus

1.	At least once that I forgot to take (one of) my medicines.
2.	I take (one of) my medicines at a later moment than usual.
3.	I have never (temporarily) stopped taking (one of my) medicines.
4.	I did not take (one of) my medicines for a day.
5.	I have taken all the medication that I should have taken in the previous year.
6.	I take my medicines exactly at the same time every day.
7.	I have never changed my medicine use myself.
8.	In the previous month, I forgot to take my medicine at least once.
9.	I sometimes take (one of) my medicines at a different moment than prescribed (e.g., with breakfast or in the evening)
10.	I once stopped taking (one of) my medicines completely.
11.	When I am away from home, I do not take (one of) my medicines.
12.	I sometimes take less medicine than prescribed by my doctor.
13.	It has happened (at least once) that I changed the dose of (one of) my medicines without discussing this with my doctor.
14.	It has happened (at least) once that I was too late with filling a prescription at the pharmacy.
15.	I take my medicines every day.
16.	It has happened (at least once) that I did not start taking a medicine that was prescribed by my doctor.
17.	I just forget to take my medicines some of the time
18.	I do not take medicine when I take medicine
19.	I worry about how medicine will affect my sexual health
20.	I sometimes forget things that are important to me
21.	Taking medicines more than once a day is inconvenient
22.	I have to take too many medicines a day

Table 2: Correlation Matrix between each item of MMA

Item No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	1.00	.407	.084	.102	.181	.131	.149	.091	.096	.158	.132	.374	.051	.131
2	.407	1.000	.153	-.021	.198	.167	.132	.139	.158	.144	.188	.476	.203	.119
3	.084	.153	1.000	-.012	.614	.279	.304	.125	.134	.036	.095	.073	.055	.182
4	.102	-.021	-.012	1.000	.094	.154	.169	.172	-.028	-.015	-.066	-.109	-.051	-.132
5	.181	.198	.614	.094	1.000	.485	.441	.233	.188	.121	.178	.103	.089	.195
6	.131	.167	.279	.154	.485	1.000	.654	.265	.155	.109	.130	.024	-.019	.119
7	.149	.132	.304	.169	.441	.654	1.000	.145	.153	.125	.170	.059	-.015	-.026
8	.091	.139	.125	.172	.233	.265	.145	1.000	.897	.459	.395	.012	.120	.011
9	.096	.158	.134	-.028	.188	.155	.153	.897	1.000	.506	.442	.040	.173	.016
10	.158	.144	.036	-.015	.121	.109	.125	.459	.506	1.000	.776	.012	.171	.057
11	.132	.188	.095	-.066	.178	.130	.170	.395	.442	.776	1.000	.152	.245	.195
12	.374	.476	.073	-.109	.103	.024	.059	.012	.040	.012	.152	1.000	.095	.165
13	.051	.203	.055	-.051	.089	-.019	-.015	.120	.173	.171	.245	.095	1.000	.137
14	.131	.119	.182	-.132	.195	.119	-.026	.011	.016	.057	.195	.165	.137	1.000

Table 3: Distribution of factor loadings among items in the MMA questionnaire

Item no	Item	Factors			
		Sick role behaviour	Autonomy	Forget fullness	Barriers
9.	How often do you reduce the frequency of taking pills due to feeling sick (E.g., burning stomach pain, faintishness, unfit)	0.87			
8.	How often do you reduce the number of pills per dose due to feeling sick (E.g., burning stomach pain, faintishness, unfit)	0.84			
10.	How often do you reduce the number of pills per dose due to other diseases? (E.g., fever)	0.81			
11.	How often do you reduce the frequency of getting medication due to other diseases? (E.g., fever)	0.73			
5	How often do you get less than the prescribed dose?		0.79		
6.	How often do you decrease the number of pills per dose due to feeling better?		0.79		
7.	How often do you decrease the frequency of taking pills due to feeling better?		0.77		

3.	How often do you change medication doses prescribed by the doctor?	0.68		
12.	How often do you forget to take medicine when you go out?		0.79	
2.	Some patients may forget taking medication while some miss their pills due to reasons other than forgetting. How often do you miss the pills due to reasons other than forgetting?		0.77	
1	How often do you forget to take your medications?		0.74	
14.	How often have you experienced you are short of medicine when you need to take it?			0.74
13.	How often have you felt that taking medication every day is a real inconvenience?			0.56

Table 4: Validated MMA questionnaire

You stated that you are taking medication for diabetes. Experts have identified that there are issues regarding medication taking (drinking) behaviour and we would like to know about your medication taking (drinking) behaviour during **last one month**. There are no right or wrong answers. Please answer the following questions based on your personal experience.

Each statement has five responses to indicate how often on **average** did you follow your behaviour. They are as,

1. Daily
2. Few times a week
3. Once in a week
4. Once or twice in a month
5. Never

Item no	Item
1	Some patients forget to take their medications. How often do you forget to take your medications? 1 2 3 4 5
2	Some patients may forget taking medication while some miss their pills due to reasons other than forgetting like going out, feeling ill. How often do you miss the pills due to reasons other than forgetting? 1 2 3 4 5
3	Patients occasionally alter their prescription dosages without consulting their doctors. How frequently do you alter prescription dosages without seeing a doctor? 1 2 3 4 5
4	How often do you alter your prescription dosage under the. impression that your diet has changed? 1 2 3 4 5
5	How often do you take fewer pills than prescribed? 1 2 3 4 5
6	How often do you reduce the **number of pills** per dose because you feel better? 1 2 3 4 5
7	How often do you reduce the **frequency** of taking pills because you feel better? 1 2 3 4 5

8	How frequently do you reduce the **number of pills** in a dose because you feel sick (for example, a burning pain/ discomfort in stomach, dizziness, or being unfit)?				
	1	2	3	4	5
9	How often do you reduce the **frequency** of taking pills because you are feeling sick? (e.g., burning stomach pain, faintishness, unfit)				
	1	2	3	4	5
10	How often do you reduce **number of pills** per a dose because of other diseases (e.g., fever, diarrhoea)?				
	1	2	3	4	5
11	How often do you reduce the **frequency** of taking pills because of other diseases? (e.g., fever, diarrhoea)				
	1	2	3	4	5
12	How frequently do you **forget** to bring your medication when you go out?				
	1	2	3	4	5
13	How often have you felt that taking medication every day is a real inconvenience?				
	1	2	3	4	5
14	How frequently do you find yourself without enough medicine when you need it?				
	1	2	3	4	5
15	Were you able to take your medications yesterday?				
	None	Some	All		

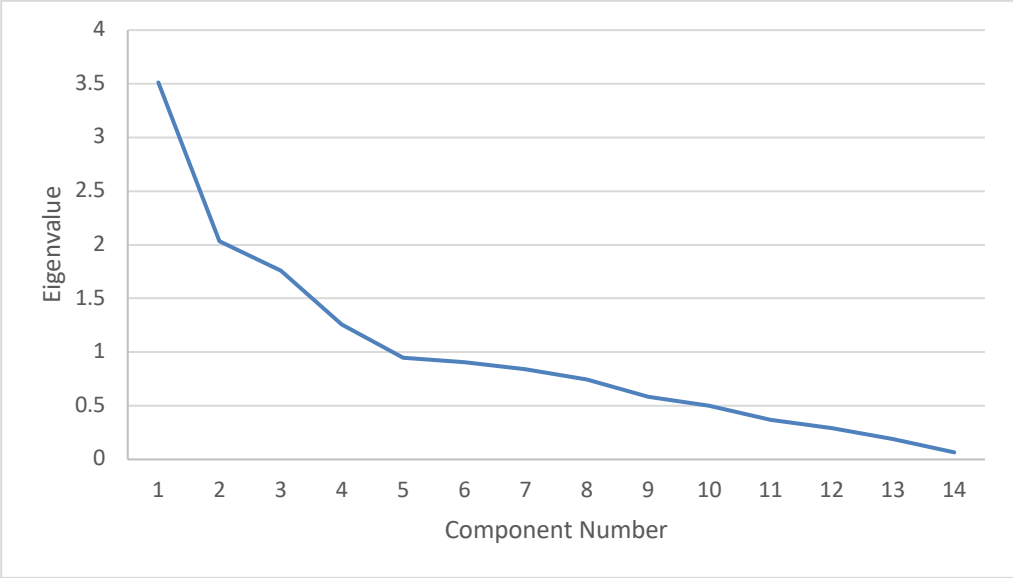

Figure 1: Scree plot result of exploratory factor analysis of the questionnaire

Public Health Implications

- This study adds new knowledge to the adherence literature and the construct of adherence; sick role and the autonomy. Developed MMA is a valid questionnaire that can be used in the clinical setting in Sri Lanka.

Author Declarations

***Competing interests**:* None declared

Ethics approval and consent to participate: The research protocol was approved by the Research Ethics Approval Committees of the Faculty of Medicine, University of Kelaniya and the Medical Research Institute, Sri Lanka. The study was conducted following the ethical standards laid down by the ethics review committee approvals and the Declaration of Helsinki. In addition, administrative approvals were received from the administrators of the DGH Gampaha and the clinical consultants who lead the clinics. Written consent was obtained from all patients after informing them about their rights, risks, and benefits, before their inclusion in the study. Permission was taken from the Medical Superintendent of DGH Gampaha, Medical Officer and the Nursing officer in charge of the clinics were informed.

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Author contributions: SP participated in the design, and implementation of the study, coordinated data collection, performed the statistical analysis and drafted the first version of the manuscript. CA participated in the design, and implementation of the study, performed the statistical analysis, interpreted the data, and helped to draft the manuscript.

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