ORIGINAL ARTICLE

TOOL DEVELOPMENT FOR EVALUATING ADHERENCE TO THE MANAGEMENT INPATIENTS WITH TYPE 1 DIABETES MELLITUS

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Background: Type 1 Diabetes Mellitus (T1DM) is a chronic disease that needs strict adherence to maintain the glycaemic control and prevent complications. However, there is a paucity of tools specifically designed for low- and middle-income country (LMIC) context to monitor adherence to T1DM management. The purpose of this study was to construct a self-administered tool to assess adherence to management protocols in T1DM patients. **Methods:** Multi-phase mixed methods study design was used to develop the adherence tool. The three development phases include: item pool construction, content validation, and pilot testing. The item pool construction phase consisted of a scoping review, focus group discussions (FGDs) and in-depth interviews (IDIs). In the second phase, expert validation and cognitive interviews were carried out to refine the questionnaire. Then, a pilot study on 25 T1DM patients was conducted to evaluate the tool's internal consistency and reliability. Thematic and statistical analysis was employed to analyse qualitative and quantitative findings, respectively. **Results:** The developed tool consists of 43 questions, covering different aspects of diabetes care including insulin dosage and administration (16 items), diet (12 items), and exercise (15 items). The tool was contextualised to cater for the needs of local patients and is delivered in the local language, i.e., Urdu. The pilot study demonstrated good reliability (Cronbach alpha=0.78), test-retest reliability (Cronbach alpha=0.67) showing high internal consistency, and construct validity (Cronbach alpha=0.67) for the developed adherence assessment tool. Also, a strong correlation was found between adherence to overall T1DM management and HbA1C levels. **Conclusion:** The developed self-administered tool reliably assesses adherence to T1DM management in LMIC contexts. This tool offers a practical resource to monitor and improve glycaemic control in T1DM patients, tailored to local needs.

Keywords: Diabetes Mellitus; Type 1; Medication adherence; Blood glucose self-monitoring

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INTRODUCTION

Type 1 Diabetes Mellitus (T1DM), an autoimmune disorder affecting the endocrine system, has a crude incidence of 15 cases per 100,000 individuals and a prevalence of 9.5 cases per 10,000 people globally.[1] In T1DM, the immune system attacks and eliminates the insulin-producing pancreatic beta cells leading to reduced insulin and subsequent high blood glucose levels.[2] Although typically diagnosed in childhood or adolescence, onset can also occur in adulthood.[3] Despite the advancements in treatment and technology, these challenges are exacerbated by the unique difficulties young patients face in adhering to T1DM management. exposing them to higher risk of acute complications of T1DM.[4]

Managing T1DM is particularly challenging, requiring strict adherence to treatment protocols. Adherence refers to the degree to which an individual follows specific guidelines, such as those related to medication, diet, or lifestyle changes, as recommended by a healthcare provider.[4] Lack of adherence is common, especially among children and adolescents who are diagnosed with T1DM.[3] Young patients with T1DM often struggle to adhere to glycaemic management strategies due to their limited awareness, developing independence, and potential negligence in their treatment.[5]

Studies show that 93% of young T1DM patients fail to follow their prescriptions and treatments, resulting in increased complications and hospitalisations.[4] A prospective study conducted in the USA showed that blood glucose monitoring frequency (BGMF) decreased from 4.9 to 4.5 checks per day (p<0.02) during the two-year transition period from childhood to adolescence.[6] The study's findings indicated that an increase in HbA1c was associated with a decrease in BGMF of 1.26 (p<0.001). A cross-sectional study in China using self-reported questionnaires with diabetic

patients reported self-monitoring blood glucose (SMBG) adherence rates as low as 54% for adolescents with T1DM.[7] Self-monitoring often declines with age, particularly during adolescence when individuals may face challenges such as decreased self-esteem, stress, or lack of parental support.[8]

Suboptimal diabetes outcomes in adolescents and young adults often involve poor HbA1c levels and inconsistent blood glucose monitoring. These issues can lead to long-term complications, even if glycaemic control improves in the later years.[9,10] Management recommendations for young individuals with T1DM include regular blood glucose monitoring (BGM), accurate calculation and administration of insulin doses, dietary control (such as carbohydrate counting for insulin-to-carbohydrate ratios), regular exercise, timely follow-up visits with a physician, completing laboratory tests as directed, and maintaining necessary medical supplies.[11–15] It is critical to follow all the outlined management to achieve optimal disease control; however, patients often struggle to adhere to these guidelines. Despite the importance of monitoring adherence, there is a lack of tools specifically designed to assess adherence to T1DM management in low- and middle-income countries (LMICs) like Pakistan, where healthcare resources and patient needs may differ significantly. Therefore, tools that accurately assess adherence are essential for effectively managing T1DM patients.[11] Thus, the primary aim of this research is to develop a practical and effective self-administered tool featuring a standardised set of questions to evaluate adherence to management protocols in patients with T1DM.

MATERIAL AND METHODS

We used multi-phase mixed methods study design (Table-1), to develop an effective tool to measure adherence to the management strategies of T1DM.

Table-1 study design (Multiphase Mixed method)

Phase	Qualitative Methods	Quantitative Methods
Phase 1: Item Pool Construction	- Focus Group Discussions (FGDs) - In-depth Interviews (IDIs) - Scoping Review	
Phase 2: Content Validation	- Expert Validation Workshops - Cognitive Interviews - Questionnaire Translation (linguistic validation)	
Phase 3: Pilot Testing	- Qualitative feedback from pilot participants	- Validity testing (correlations, construct validity) - Reliability testing (Cronbach's alpha, test-retest)

The scoping review aimed to explore and describe current methodologies for assessing medication adherence in patients with T1DM. A comprehensive search strategy was employed across databases including Medline, the Cochrane Library, and Embase, using PUBMED and OVID interfaces to identify relevant studies assessing medication adherence in diabetes patients. The review followed the PRISMA scoping review framework to ensure methodological rigor and data credibility. For efficient screening and deduplication of records, RAYYAN software was utilized throughout the process.

This scoping review employs the Population-Context-Concept (PCC) framework[16] to explore adherence to treatment in individuals with T1DM. The population of interest comprises individuals diagnosed with T1DM, while the context encompasses studies conducted worldwide. The primary concept under investigation was adherence to diabetes management protocols

To ensure a comprehensive pool, studies irrespective of study design reporting tools for measuring adherence to exercise, diet control, and insulin management in T1DM patients were included. Whereas studies based on participants with mental health problems or pregnant individuals were excluded. In this scoping review, the studies were screened by three independent reviewers. Two reviewers conducted the initial screening, and any disagreements between them were resolved through discussion with the third reviewer. This collaborative approach ensured a thorough and unbiased selection process

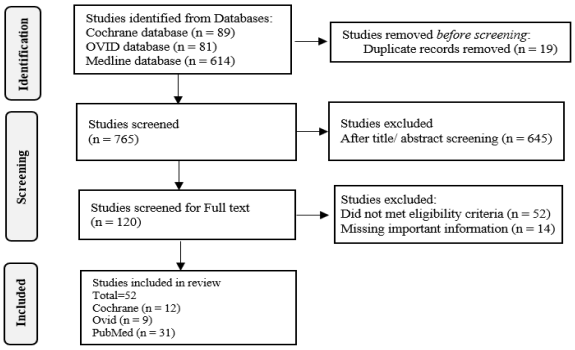

Figure 1: Prisma flow diagram for Scoping review process

Focus Group Discussions (FGDs) and In-depth Interviews (IDIs) were conducted to gather perspectives from healthcare providers, patients, and caregivers on questions for the new adherence tool. Two FGDs were held with T1DM patients and caregivers at Sugar hospital and Research Centre five participants were present in each FGD. Four IDIs were

conducted with a range of healthcare professionals including endocrinologists, medical specialists, medical officers and dieticians to explore their insights on T1DM management and adherence. Overall, data from the scoping review, FGDs, and IDIs were used to develop the questionnaire's content in the first phase of the research.

Two consultative workshops were conducted first at the Institute of Public Health and Social Sciences Khyber Medical University Peshawar, Pakistan. In both workshops, experts from Endocrinology, Public health, Medical Education, Physiotherapy, and family medicine were invited as participants. Four experts from the aforementioned departments of the hospital participated in the first workshop. First, a lead author presented the goals and objectives of the consultative workshop followed by discussion among participants. Each question was thoroughly discussed among the participants, and the panel recommended that some questions that were inappropriate or repeated should be removed while some needed a little modification. Whereas, the second workshop was conducted at the endocrinology department of Northwest General Hospital Peshawar, in which 6 experts (Endocrinology, medical education and public health) participated. In this workshop, the suggested changes from the previous workshop were discussed and some new recommendations were advised by the experts. The experts' feedback helped refine the tool, address deficiencies, and guide future research, significantly improving the tool's quality and relevance. To improve the assessment tool in the form of a questionnaire, cognitive interviews with six T1DM patients were conducted. In these interviews, the aim was to gain insights into participants' perceptions and reaction towards the survey. These findings informed changes that enhanced the tool's efficacy and reliability in interpreting compliance to T1DM self-monitoring. The questions were translated from English to the local language (Urdu) by the language experts, i.e., the English and Urdu department of the University of Peshawar. A back-translation was also used to ensure that the Urdu version of the questionnaire closely reflected the original version.

A pilot study was conducted to test the reliability of a medication adherence questionnaire for T1DM patients. The study involved 25 T1DM patients at the Sugar General Hospital and Research Centre. The pilot study focused to refine the questionnaire by addressing the clarity and validity issues. A scoping review utilized descriptive analysis to synthesize data on methodologies for assessing adherence to management to T1DM. Articles were identified through systematic searches and refined based on inclusion/exclusion criteria. Data extraction highlighted key study characteristics, including methods to measure adherence. The analysis categorized and summarized the various assessment tools. Data from focus group discussions (FGDs), in-depth interviews (IDIs), workshops, and cognitive interviews were analyzed using thematic analysis to identify common themes regarding medication adherence to the management of T1DM. The process involved familiarizing with the data, coding key ideas, and developing themes through clustering similar codes

Quantitative data from questionnaires were analysed using SPSS version 23. Descriptive statistics were used to assess demographic characteristics, such as average blood glucose levels and age. Reliability was evaluated with Cronbach's alpha, test-retest reliability, and inter-rater reliability.

RESULTS

Figure 2 summarises the development process of the adherence questionnaire. Initially, 784 studies were identified, out of which 52 studies were selected for analysis. These studies contributed to a comprehensive understanding of adherence assessment tools and methods summarized in Table 2. The studies identified 55 tools for measuring adherence in diabetes management. Of these, 25 tools were general, 17 focused on diet, 11 on exercise, and 2 on insulin.

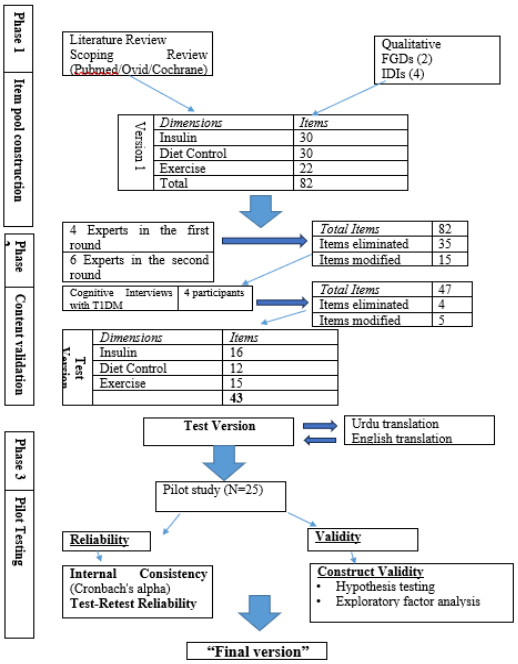

Figure-2: Phases and Activities to design and evaluate the tool

Table-2: Tools identified for measuring adherence to management of Diabetes Mellitus.

Search engine	otal Articles	Tools	Studies	Tools	References
	784	**55**	**52**		
Cochrane	89	12	12	1) Modanloo Adherence to Treatment Questionnaire	1) Mansour *et al*. (2023)
				2) Diabetes Self-Management Profile Self-Report (DSMP-SR)	2) Hilliard *et al*. (2019)
				3) Self-reported physical activity (PAQ)	3) Blake *et al*. (2016)
				4) Seven-day food records	4) McCulloch *et al*. (1983)
				5) Insulin Treatment Satisfaction Questionnaire (ITSQ)	5) Gomez-Peralta *et al*. (2020)
				6) Diabetes Self-Management Profile (DSMP)	6) Oliveira *et al*. (2021)
				7) Self-monitoring acceptability and compliance questionnaire	7) Halimi *et al*. (2001)
				8) 24-Hour Recall Interview	8) Wysocki *et al*. (2000)
				9) 24-Hour Recall Interview	9) Mackey *et al*. (2018)
				10) 2-week diary and two recall measures	10) Nadkarni *et al*. (2010)
				11) Self-Efficacy of Diabetes Self-Management	11) Newton *et al*. (2013)
				12) The Diabetes Regimen Adherence Questionnaire (DRAQ)	12) Glaser *et al*. (2004)
OVID	81	9	9	1) Physical Activity Assessment Tool	1) Alòs *et al*. (2022)
				2) Diabetes Self-Care Activities (SDSCA)	2) Holmes-Truscott *et al*. (2020)
				3) Eating habits (KidMed questionnaire), physical activity (Enkid test)	3) Valverde Tercedor *et al*. (2020)
				4) Physical Activity Questionnaire (PAQ-C; PAQ-A)	4) Francia *et al*. (2020)
				5) Food Frequency Questionnaire (177 items)	5) Gant *et al*. (2018)
				6) Dutch Eating Behavior Questionnaire (DEBQ)	6) Amosova (2018)
				7) Physical Activity Questionnaire for Children (PAQ-C) and Adolescents (PAQA)	7) Francia *et al*. (2018)
				8) The 4-item and 8-item Morisky Medication Adherence Scales (MMAS-4/8)	8) Zongo *et al*. (2014)
				9) Mobile phone-based diabetes diary	9) Arsand *et al*. (2012)
PubMed	614	34	31	1) Self-administered questionnaire (food intake, physical activity, insulin administration)	1) Ahola *et al*. (2010)
				2) Adherence to the self-care recommendations (SCI-R)	2) Casino *et al*. (2021)
				3) Appraisal of Self Care Agency Scale-Revised (ASAS-R)	3) Bottino *et al*. (2020)
				4) Diabetes Self-Management Profile (DSMP)	
				5) Self-Care Inventory-revised (SCI-R)	
				6) Summary of Diabetes Self-Care Activities (SDSCA)	
				7) Self-report adherence scale (Adherence assessment was adapted from Griva *et al*)	4) Broadbent *et al*. (2011)
				8) International Physical Activity Questionnaire (IPAQ).	5) Finn *et al*. (2022)
				9) Mobile-phone-based tool to capture and visualise adolescents' food intake	6) Frøisland,D.H.,& Årsand, E. (2015)
				10) Two mobile phone applications (Diamob, Web-based encrypted SMS-based)	7) Frøisland *et al*. (2012)
				11) Self-report questionnaires from the German Health Interview and Examination	8) Galler *et al*. (2011)
				12) A new adherence questionnaire was developed.	9) Grau-Del Valle *et al*. (2022)
				13) International Physical Activity Questionnaire (IPAQ)	10) Ida *et al*. (2020
				14) Dietary intake was assessed using three 24-hour recalls	11) Jaacks *et al*. (2015)
				15) Diary data (meals, insulin, self-monitored blood glucose)	12) Johansen *et al*. (2011)
				16) Food frequency questionnaires	13) Keel *et al*. (2016)
				17) Physical activity per week	14) Kummer *et al*. (2014)
				18) Physical activity by wearable devices	15) Laguna Sanz *et al*. (2019)
				19) SCI and a structured interview on diabetes adherence	16) Lewin *et al*. (2009)
				20) Eighty-five-item FFQ twice plus three 24-hour dietary recalls	17) Liese *et al*. (2015)
				21) Morisky Adherence Scale	18) Magalhães *et al*. (2018)
				22) Diabetes Self-Management Profile	19) Markowitz *et al*. (2011)
				23) Daily diaries	20) Martyn-Nemeth *et al*. (2017)
				24) 3-day weighed diet record	21) Patton *et al*. (2016)
				25) Self-Care Inventor (SCI)	22) Perez *et al*. (2017)
				26) Diet records	23) Quick *et al*. (2014)
				27) Blood glucose monitoring frequency (BGMF)	24) Rausch *et al*. (2012)
				28) Diabetes Dietary Guidelines Adherence Index (DDGA Index)	25) Sińska *et al*. (2022)
				29) RT-CGM (real-time continuous glucose monitoring) record, insulin dose	26) Stechova *et al*. (2019)
				30) Carbohydrate calculation (CC) and the bolus calculator	27) Tascini *et al*. (2018)
				31) Self-reported and parent proxy-reported questionnaires.	28) Telford *et al*. (2021)
				32) Mobile app	29) Toschi *et al*. (2018)
				33) Log books	30) Toussi *et al*. (2008)
				34) Simple Carb Counting (SCC)	31) Witkow *et al*. (2023)

FGDs AND IDIs:

These focus group discussion sessions were held at the Sugar Hospital and Research Centre in Hayatabad and included 10 participants with patients and their families. The FGDs which took around 40 minutes each explored various multi-faceted issues essential for proper T1DM management. The themes that were identified during these discussions highlighted the realities of present-day T1DM management, which include compliance with medication administration, participants' perception of the importance of physical activities, appropriate meals, complex medication regimens, communication skills in healthcare and clinic environment, quality of life issues, family support, and good knowledge of symptoms.

The study included in-depth interviews (IDIs) with healthcare professionals involved in diabetes management, complementing focus group discussions (FGDs). These interviews provided insights into the factors influencing adherence to Type 1 Diabetes Mellitus (T1DM) management. Four key themes emerged, reflecting differing perspectives among medical officers, dieticians, and endocrinologists.

Medical officers emphasized the importance of proper insulin administration, medication storage, and carbohydrate counting. Dieticians highlighted the complexity of non-compliance, focusing on meal and exercise balance, as well as the role of digital technology. Endocrinologists stressed critical aspects of T1DM self-management, including carbohydrate counting for glycaemic control, management during illness, dietary considerations, family involvement, and the potential of digital tools to enhance patient engagement and adherence

After the scoping review and focus group discussions/interviews, an initial adherence tool was created with 83 questions, focusing on insulin management (30 questions), diet control (30 questions), and exercise (23 questions).

Table-3: Themes generated from In-depth interviews IDIs

Themes from an interview with a Medical officer	
1.	Insulin injection techniques
2.	Storage of Insulin
3.	Injection sites
4.	Empty vials
5.	Carbohydrate counting
Themes from an interview with a Dietician	
1.	Reasons for non-adherence
2.	Balance of activities/diet
3.	Digital technology
Themes from an interview with Endocrinologist	
1.	Carbohydrate counting
2.	Sick day rule
3.	Dietary habits
4.	Family involvement
5.	Digital technology

Table-4: Themes generated from Focus group discussions (FGDs)

Themes from FGDs with patients and carers	
1.	Exercise duration
2.	Daily Routine
3.	Diet control
4.	Insulin dosage
5.	Communication (mobile phone)
6.	Quality of life
7.	Family issues
8.	Signs of hypoglycemia or hyperglycemia
9.	Picture/video evidence
10.	Food diary

Expert validation involved specialists from endocrinology, public health, medical education, physiotherapy, and family medicine to refine the T1DM adherence questionnaire. Two consultative workshops were conducted where the initial 82-item questionnaire was discussed. As a result, 35 items (42.58%) were eliminated due to duplication, irrelevance, or lack of consensus, while 15 items (18.29%) were modified for better clarity and understanding for T1DM patients.

Cognitive interviews were conducted to complement expert validation workshops and gather insights from T1DM patients about the factors related to diabetes self-management. Based on this feedback, four items were removed from the questionnaire due to comprehension issues, and five items were modified for better accuracy.

The third phase of the study tested a self-administered questionnaire for measuring treatment compliance in T1DM patients. The final test version of the T1DM adherence assessment tool included 43 items: 16 regarding insulin, 12 regarding diet control, and 15 regarding exercise. Adherence was scored on a five-point scale from 0 (Never) to 4 (Always), with total scores ranging from 0 to 172, where higher scores indicated better adherence. The study involved 25 participants, with 52% male and 48% female, having a mean age of 17.16 years (±6.51) and a mean HbA1C level of 10.90 (±2.79) (Table 4, 5)

Adherence to T1DM management was generally moderate to high, with strong adherence to insulin therapy but only moderate adherence to dietary control and exercise (Table 5). The reliability analysis of the newly developed adherence tool demonstrated acceptable internal consistency across its scales (Table 7).

Table-5: Descriptive Statistics of Participant Characteristics and Adherence to T1DM Management

	Mean ± SD
Age	17.16 ± 6.51
HbA1C	10.90 ± 2.79
Number of years since diagnosis	5.08 ± 4.69
Adherence to T1DM management	128.80 ± 6.08
Adherence to Insulin	48.56 ± 3.09
Adherence to Diet control	36.96 ± 2.33
Adherence to Exercise	43.28 ± 3.23

Table-6: Frequency and Percentage Distribution of Participant Characteristics

		Frequency	Percentage
Gender	Male	13	52 %
	Female	12	48 %
Occupation	Student	16	64 %
	Housewife	4	16 %
	Shop keeper	5	20 %
History of Hospital Admission	Yes	15	60 %
	No	10	40 %
Availability of Smart Phone	Yes	11	44 %
	Yes (Relative *)	12	48 %
	No	2	8 %

* If relative have mobile phone or not

Table-7: Internal Consistency Reliability (Cronbach's Alpha) of Adherence Dimensions

	No of items	Cronbach Alpha
Adherence to T1DM management	43	0.785
Adherence to Insulin	16	0.607
Adherence to Diet control	12	0.797
Adherence to Exercise	15	0.762

The Inter-domain Correlations among adherence scores across different domains of adherence to T1DM management were examined using Pearson correlation coefficients (table 8). Adherence to overall T1DM management was strongly correlated with adherence to both dietary guidelines ($r = 0.853$, $p<0.01$) and exercise regimens ($r = 0.765$, $p<0.01$). In contrast, adherence to insulin therapy showed a moderate positive correlation with overall T1DM management ($r = 0.522$, $p<0.01$), but did not significantly correlate with adherence to dietary guidelines ($r = 0.159$, $p>0.05$) or exercise regimens ($r = -0.091$, $p>0.05$). Additionally, adherence to exercise regimens was strongly positively correlated with both overall T1DM management ($r = 0.765$, $p<0.01$) and dietary guidelines ($r = 0.730$, $p<0.01$), though it had no significant correlation with insulin adherence. These results suggest that increased adherence in one area is related to increased adherence in all other areas of T1DM self-management. Thus, further stressing the importance of the multifaceted and holistic approach to T1DM management in order to improve outcomes for the patients.

Table-8: Inter-domain correlations of adherence tool to T1DM management

	Adherence to T1DM management		Adherence to Insulin		Adherence to diet control		Adherence to exercise	
	Pearson correlation	*p*-value	Pearson correlation	*p*-value	Pearson correlation	*p*-value	Pearson correlation	*p*-value
Adherence to T1DM management	1		.522	.007	.853**	<.001	.765	<.001
Adherence to Insulin	.522	.007	1		.159	.449	-.091	.665
Adherence to diet control	.853	<.001	.159	.449	1		.730	<.001
Adherence to exercise	.765	<.001	-.091	.665	.730	<.001	1	

DISCUSSION

The T1DM Adherence Tool was developed to measure patients' adherence to medication and self-management practices through a thorough process. This included a scoping review, focus group discussion, and in-depth interviews with healthcare professionals and patients. The tool underwent content validation and was refined into a 43-item questionnaire regarding adherence to insulin, diet control, and exercise. A pilot study confirmed the tool's internal reliability (test-retest reliability with Cronbach's alpha of 0.67) and construct validity (Cronbach's alpha of 0.67), with a five-dimensional factor structure accounting for 65.8% of the variance. Strong correlations were found between adherence in different domains, suggesting that higher adherence in one area generally correlates with higher adherence in others. This result aligns with research studies, where adherence in one domain is often linked with better adherence in other areas, enhancing overall disease management outcomes.[10,14,17] This developed tool integrates multiple adherence aspects into a single, culturally tailored, and locally translated instrument, offering a comprehensive assessment of adherence. This makes it more adaptable compared to existing tools, which often focus on specific aspects or lack regional customisation.

At present, there are no specific and validated questionnaires available to assess adherence to treatment for T1DM. Most existing questionnaires currently focus on quantifying pharmacological aspects and categorising patients as adherent or non-adherent based on established direct methods, such as HbA1c. However, these questionnaires do not consider other influential variables that may be

relevant at a specific time. For instance, there are few self-reported instruments such as the Self-Management of Type 1 Diabetes in Adolescents (SMOD-A)[17] and the Diabetes Behaviour Rating Scale (DBRS)[18]. However, these measures are generalised and are associated with challenges regarding the assessment of other areas of diabetes treatment. Whereas the adherence tool developed in this study offers a balanced and much more comprehensive approach that assesses all the dimensions of T1DM management.

Another tool known as Summary of Diabetes Self-Care Activities (SDSCA) assesses self-care activities in diabetes patients but is not ideal for T1DM patients.[19] This usually overemphasises the number and frequency of adherence behaviours across the 0s of diabetes, which may not exactly fit the T1DM patient population. Similarly, the Diabetes Self-Management Profile (DSMP) is one of the widely used tools; it is based on semi-structured interviews and hence seems to miss out on a range of behaviours in multiple domains of self-management of diabetes.[20] On the other hand, the developed adherence tool is easier to use and reliable for individuals with T1DM which makes it efficient for the management of the disorder.

Another very commonly used scale is the Morisky Medication Adherence Scale (MMAS) but this tool mainly targets medication adherence.[21] This would not make it possible to consider the details of T1DM management consisting of diet, exercise as well as other related aspects. Likewise, the Treatment Adherence Questionnaire developed by Mondaloo[22] is another prevalent adherence evaluation tool for T1DM patients. However, it mainly focuses on some of the treatment-related aspects. The designed adherence tool in the current study can offer all the requisite information regarding T1DM management. Furthermore, the tool has been properly translated and culturally customised which helps in gaining a better understanding of patients' adherence levels and improves the parameters of self-estimated information and patients' involvement.

Unlike other tools, this questionnaire is specifically developed for the assessment of the degree of adherence to the management in T1DM patients. Not only does it appraise adherence to the medications but also dietary behaviours, and physical activity which are imperative in managing T1DM. Because the tool is based on multiple dimensions of the patient's adherence behaviours, healthcare professionals can comprehend all of the patient's management activities.[23] This can help them in the better identification of the issues that require further attention and intervention. This comprehensive and diverse approach means that the tool not only provides a valid and reliable assessment of adherence but also provides strategies for improving patients' health in an appropriate way.

LIMITATIONS

Despite these strengths, the study has some limitations as well. The reliance on self-reported data introduces potential bias, such as over-reporting due to social desirability or recall bias, which may overestimate adherence and only partially identify non-adherence. Also, it has a small sample size which can raise generalisability concerns when compared with the general T1DM patients. For example, the participants who were attendants at the endocrinology appointments or education sessions might have been more inclined to manage their conditions, which may have equated to bias. Also, the study relied on the cross-sectional design which restricted the assessment of subjects' adherence at the single time point not considering potential changes to their behaviour. Additional longitudinal studies with greater sample sizes are required to verify the tool's applicability over long time periods and relevancy to patient outcomes. The tool also may fail to incorporate physical, mental, social and environmental variables that influence adherence. These limitations point clearly to the fact that more research and development need to be undertaken to increase the validity and generalisability of the tool.

CONCLUSION

The newly developed diabetes adherence tool provides a potential self-report measure for determining practical barriers towards adherence in T1DM. The study has also yielded a high internal consistency, test-retest reliability, and construct validity; thus, it has proved its effectiveness in measuring adherence to insulin, recommended diets and exercise regimes. The content of this tool corresponds to the main aspects of the T1DM treatment, which includes insulin administration, exercise and diet; its language and length were confirmed with T1DM patients. This makes it valuable for research and practice and represents a substantial advance toward individualised, problem-specific adherence improvement.

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AUTHORS' CONTRIBUTION

M J: Conceptualization, study design, data collection, data analysis, drafting of the manuscript, and project administration. S A: Supervision, methodological guidance, critical review, and substantial revisions of the manuscript. Z H: Supervision, critical review of findings, and intellectual input in manuscript refinement. S H: Data collection, coordination with participants, and assistance in literature review. F S: Data management, statistical support, and contribution to the results section. A H: Expert consultation, clinical validation of the tool, and critical revisions of the discussion section. M A: Support in literature review, referencing, and proofreading of the manuscript

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