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Research Protocol paper: Development and utility of m-health enabled nutrition informatics intervention for self-care management of type 2 diabetes in home settings.

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Abstract

Background: Diabetes represents an important public health challenge in India and globally. It affects the quality of life and is one of the leading causes of death and disability. The burden on global health is huge, and about 463 million adults are currently living with diabetes. 77 million people in India in the age group of 20-79 years are affected by this pandemic, and the total cost of health expenditure is 8 billion US dollars. This is a huge burden and a great economic cost to public health. The research aims to explore the concept of diabetes self-management and major research questions would comprise asking what affects self-management in people with diabetes and how m-health applications and interventions can impact the self-management behaviors in development and the utility of the m-health apps in self-management of people with diabetes.

Objective: To design, develop, and assess the impact of an m-health-enabled nutrition informatics intervention for home-based type 2 diabetes self-management in an Indian setting.

Methods: The study is divided into three phases, in the first phase a systematic literature review of global and Indian literature using Scoping review method using PRISMA- SCR tool to report on various m-health interventions on Self-care management regimes on type 2 diabetes and Nutrition informatics will evaluate the effectiveness and utility of m-health application developed on Selfcare management with nutrition informatics will be reported. In the second phase m-health application on Selfcare management and nutrition informatics regime will be built in the third phase of the study evaluation of the m-health application will be done using System Usability Scale (SUS) usability and mixed research evaluation with end-users using Diabetes based management system (DBMS)questionnaire. A mixed research study between January 2023 and April 2023. A sample of approximately 250 individuals to be recruited online, enrolled in the m-health application using a non-probability complete enumeration sampling method from selected urban settings in Delhi & all over India. The inclusion and exclusion criteria for males and females aged 20–79 years old with Type 2 diabetes and access to a smartphone.

Results: A sample of 250 individuals will go through a pretested DBMS questionnaire. The data collection will be initiated in June 2022, and the initial results are planned for publication by July 2023. Out of n=250 individuals, at least 120 individuals will be retained in the study. A qualitative study using descriptive analysis of the gathered data will be performed using SPSS V11, and reporting of the results will be done at 95% CIs and *P*=.0.05.

Conclusions: The findings of the study using scoping review would inform the elements essential for the development of m-health to improve self-care management of diabetes at home settings in India and its wider application in the global framework.

KEYWORDS

Mobile Health, Type 2 Diabetes, Self-Management, Tele Health, m-Health, Chronic care management (CCM)

Introduction

Diabetes represents an important public health challenge in India and globally. It affects the quality of life and is one of the leading causes of death and disability. The burden on global health is huge, and about 463 million adults are currently living with diabetes. If a call to action is not taken on time for this,578 million people will have diabetes by 2030. With this overwhelming trend, 700 million will be affected by 2045 [1]. In the context of India and as per IDF atlas 2019, 1 in 6 diabetes comes from India and 1.2 million deaths are attributable to diabetes. This epidemic affects 77 million people in India between the ages of 20 and 79, with a total cost to health expenditure of $8 billion, representing a massive burden and significant economic cost to public health [1].
It is critical to self-manage type 2 diabetes mellitus; however, it is known to be one of the most difficult ailments to manage. The complications of diabetes and the amalgamation of complex self-management treatments into daily life led to high levels of distress, frustration, and discouragement, which impact a person's well-being [2]. Nonetheless, the management of diabetes is mostly done by patients and their families, and a self-management regime has turned out to be the backbone of diabetes care. The self-management regime is a method aimed at improving behaviors for actively engaging in self-care activities to achieve goals. Self-management comprises planning for meal nutrition and physical activity, monitoring blood glucose and diabetes medications, and dealing with high and low blood sugar levels during episodes of illness. Various healthcare specialists, such as doctors, nurses, dietitians, and pharmacists, have developed self-management action plans in consultation with individuals [3].

The overall complications of diabetes need to be managed well, which can reduce hospital admissions, morbidity, and mortality due to this epidemic. Through self-care management, m-health interventions can manage the complications, and it would contribute to universal health coverage [4]. The m-health diabetes self-care application can be developed for a better self-management regime with nutrition informatics recommended in the Indian population by the American Association of Physicians of Indian Origin (AAPI) for diabetes care [5]. Therefore, this study will be done to develop m-health applications and test nutrition informatics interventions (AAPI recommended) for self-care management of type 2 diabetes at home.

Identified Gaps in Research

A large variety of chronic disease models exist in the literature. Different models have different elements to consider. Some consider self-management; others have a health system approach, and few have a community participation approach [6]. In the literature review, it is evident that there are hundreds of applications available for diabetes and most of them are from the US and are not made in India for the Indian population. Self-care management of type 2 diabetes applications is mostly available in the US and not in India. Most of the applications are based on clinical approaches to glucose testing and exercise regimens. Therefore, better quality CCM model requires a well-designed m-health application, designed based on patient needs and connecting patients with other patient support groups and family doctor/s or clinicians. The mobile application review of applications (Annexure:

Table 1) mostly focused on lifestyle changes, and an integrated approach with self-care management and nutrition informatics in the context of the Indian population has not been tested in India. In a nutshell, several applications have been created, but none of them address the self-management chronic care model (CCM) regime with nutrition informatics in an Indian context.

Need of the study

It is very important to control sugar control through a self-management regime. It can purposely reduce problems and complications associated with diabetes. However, self-management of diabetes and strict sugar control is difficult to follow. It can become more complicated because of adherence to treatment plans. Various research done on diabetes has found that a substantial percentage of the population with diabetes fails to adhere to adequate self-management. Lack of adherence to a self-management regime is captured well in the literature review, and lack of adherence leads to poor health outcomes in people with diabetes [7]. The research priorities include exploring the concept of diabetes self-management and major research questions would comprise asking what affects self-management in people with diabetes and how m-health applications and interventions can impact the self-management behaviors in development and the utility of the m-health app in self-management of people with diabetes [8]. Therefore, this project research is of great significance and would bring an integrative approach to self-care management on the Chronic Care Model (CCM) and would also benefit patients having co-morbidities like patients having hypertension and diabetes together. M-Health intervention would provide a solution for interventions to adhere to the self-care management regime. In the future, this application can include a nutrition informatics module focusing on the local diet/regional diet of India [9]. Therefore, it would bring an integrated approach to diabetes self-management for people suffering from diabetes. The apparent control ability over their ailment seems likely to play a vital role in patient readiness for self-management and using m-Health for self-management of disease [10]

Table-1

SI	Author/ Year of study	Participants	Intervention	Comparator	Outcome	Significant intervention	Outcome results	Outcome Measurement details
1	Gong et al., (2020) [6]	Adults with type 2 diabetes	My Diabetes coach RCT	Control and intervention	The MDC program was successfully adopted	Potential for wider implementation of technology-enabled	Outcomes support diabetes self-care management	The intervention arm HbA1c was reduced by 0.30% and the control arm by 0.20% statistically not significant
2.	Nelson et al., (2020) [13]	Patients with type 2 diabetes	Mobile phone support, Hb 1AC test, text message 12 months		The patient's 50% adherence and improvement seen	Well-designed interactive text messages can engage diverse patients in self-care intervention	Frequency choice preference is important to consider	The median response rate
3	Young et al., (2020) [10]	Patients with Type 2 diabetes aged 18 and above	Nurse coaching and miHealth on diabetes self-management	Yes	The participants in the intervention group had significant improvement in self-efficacy	Significant improvement in physical activity	Increase in intervention diabetes self-efficacy in diabetes empowerment scale.no difference in other outcomes	Short-term effectiveness. however, by 9 months physical activity remained above the baseline

4	Yang et al., (2020) [22]	Type 2 diabetes patients in the clinic and 18 years and above	Intervention group, participants were required to upload. their daily self-monitoring of blood glucose (SMBG) results using the mobile phone app	Yes	The mobile phone-based glucose-monitoring and feedback system was. effective in glycemic control when applied in primary care clinic settings.	Yes	In 3 months, participants in the intervention group showed significantly more. improvement in HbA1c (adjusted mean difference to control -0.30%, 95% CI -0.50 to -0.11; *P*=.003) and fasting plasma glucose (-17.29 mg/dL, 95% CI -29.33 to -5.26. *P*=.005) than those in the control group	Baseline and 3 months, both groups had anthropometry and blood tests, including. hemoglobin A1c (HbA1c) and responded to questionnaires about treatment satisfaction. and compliance.

There are more than hundreds of global applications for diabetes, but very few on self-care management of type 2 diabetes and information at the outcome level (Table:1Applications review). The 'my diabetes coach application' supports self-care management of diabetes at the outcome level, in the intervention arm Hb1Ac was reduced by 30% and in the control, arms reduction was by 20%. In other interventions where daily self-monitoring of blood glucose (SMBG) using a mobile application significant improvement in Hb1Ac was observed. Most of the applications are US-based designed, and nutrition informatics does not cater to the needs of the Indian population. The AAPI has developed nutrition for diabetes based on research on the Indian population [11].

The need is to design a purposeful m-health-enabled nutrition informatics application to self-manage type 2 diabetes in an Indian context. Diabetes self-care management at home and control over the disease is likely to play a vital role in patient health outcomes, and education for the readiness to use m-health applications purposefully is important for better disease self-management. Type 2 diabetes self-care management enabled using an m-Health-enabled nutrition informatics platform has never been tested in homes in an Indian setting. This is an important study to examine the usefulness and effectiveness of self-care management in a home setting using the System Usability Scale (SUS tool) and the evaluation of patient-level outcomes.

Analysis of the Research Problem

The literature review on diabetes, self-care, and the Chronic Care Model (CCM) highlights the importance of m-health tools, which have made significant contributions to the chronic care model [12]. However, better quality CCM model intervention requires amendment in several key areas. Nonetheless, education and self-awareness are critical for m-health self-care. Mobile health interventions must be carried out in the community, and the benefits of virtual mobile support, community groups, and patient engagement must be ensured in the development of tools and applications which make self-care management work productively with virtual interactions between the patient and provider. The research on m-health suggests that features should be tailored to the needs of the patient. The expected benefits of using m-health should meet patients' requirements and it should be implemented in a manner to support the self-management regime [13]. The research on this topic, therefore, focuses on self-management regimes based on a theoretical model of investigation on chronic care management (CCM) [14]. It would be reasonable to know the underpinning of the m-Health intervention and develop an application for better self-care management of diabetes.

The problem necessitates multifaceted interventions based on theoretical frameworks, which must be applied to the causal contribution for the intervention to be effective. So, there is a need for research to identify and overcome barriers to self-care management to effectively develop self-management mobile applications. The study of the impact of m-health interventions on self-management regimes has the potential to make significant contributions to population health informatics (PHI), specifically nutrition informatics and self-care management for chronic care models (CCM).

This research area is unique to India; such work has never been attempted in India or

any other country before, and thus the research area would be of high scope and impact value in population health informatics (PHI) done in India and globally

Procedure Section of Research Proposal

Problem Statement

Diabetic patients face significant challenges at home in gaining access to the necessary knowledge on diabetes self-care and nutrition informatics to control these chronic diseases.

Overall Aim of the Study

Development and utility of m-health and nutrition informatics interventions in self-care and management of type 2 diabetes at home.

Research Questions

The study will address three research questions:

1. What is the scope and need for m-health intervention and nutrition informatics in type 2 diabetes self-care management at home?

2. How can the m-health application be developed for better self-management regimes and nutrition informatics as per the American Association of Physicians of Indian Origin (AAPI) recommended nutrition for diabetes care?

3. What will be the utility of the m-health application developed for diabetes care, nutrition regime, and evaluation of the application and effectiveness with end-users?

Specific Objectives

The specific objectives will be as follows:

- To understand the scope and need for m-health interventions and nutrition informatics in chronic care management (CCM)-Self-care of type 2 diabetes and management at home setting.

- To design and develop m-health on self-care management and nutrition informatics Indian regime (AAPI Type 2 diabetes recommended) intervention for type 2 diabetes.

- To evaluate the utility of the m-health application on self-care interventions, nutrition informatics (AAPI Type 2 diabetes recommended), patient outcomes, support groups, and health service provider linkage.

Methods

The study is divided into three phases and in the first phase, is a systematic literature review of global and Indian literature using Scoping review method using PRISMA- SCR tool to report on various m-health interventions on Self-care management regimes on type 2 diabetes and Nutrition informatics will evaluate the effectiveness and utility of m-

health application developed on Selfcare management with nutrition will be reported. In the second phase m-health application on Selfcare management and nutrition informatics regime will be made and in the third phase of the study evaluation of the m-health application will be done using System Usability Scale (SUS) usability and mixed research evaluation with end-users using Diabetes based management system (DBMS)questionnaire. mixed research design uses both qualitative and quantitative approaches. The qualitative approach will be major and exploratory, and the quantitative methodology will be done in sequence [15].

Exploratory, Sequential QUAL → Quan

The study would be exploratory and sequential, using a mixed-methods design. The mixed-methods design would answer both "what?" and "how." And from the perspective of diabetes and its association with self-care at home. In this concurrent design, the qualitative and quantitative components are both independent, and the data of each component would be investigated separately. The results would be merged to build explanations and draw inferences. However, for m-Health interventions, a self-care diabetes application and a global testing tool system usability score (SUS) will be used to evaluate a sufficient number of participants. Data will be collected using globally tested tools like the Diabetes Based Management System (DBMS) questionnaires. The collected data will be used to assess the use and utility of the mobile health application developed. The qualitative study is exploratory and sequential in nature. The exploratory study will be done using IDIs and FGDs, followed by a quantitative method.

Study Design and Population Study Aim (phase-wise)

The study is categorized into 3 phases to achieving its objectives, which are as follows:

Stage-1
To do a scoping review using the PRISMA tool to develop an understanding of various m-health interventions on chronic care management (CCM), and self-care management regime for type 2 diabetes.

Stage -2
In the Indian context, design and develop a human-centered design (HCD) mobile application on type 2 diabetes m-health and nutrition informatics regime (based on Chronic Care Management (CCM).

Stage-3
To assess the effectiveness and utility of a self-care management m-health application developed with nutrition informatics regime using System Usability Scale (SUS) usability and mixed research evaluation (concurrent design) with end-users using DBMS questionnaire.

Study Population

The study will be done in government hospitals/private clinics and on doctor’s referrals in this study we will have Telephone recruitment/online recruitment in community settings in Delhi and all over India through the developed m-health application.

Table 2 Target population: Male and female aged 20-79 years old with Type 2 diabetes and access to a smartphone.

	CATEGORY	CRITERIA
1.	**Populations**	**Include** Population 18 years to 75 years diagnosed with type 2 diabetes. **Exclude** Pregnant women, adolescents, Children, gestational diabetes, pre-diabetes or
2.	**Interventions**	**Include** Mobile device (i.e., phone, tablet, or watch) for diabetes self-management. Interventions must include at least one of the **Exclude** Medical devices that do not connect to a mobile phone or tablet (i.e., a blood glucose meter); artificial pancreas; texting interventions
3.	**Comparators**	**Include** Mobile-led m-health for diabetes self-management
4.	**Outcomes**	**Include** To include patient outcomes **Exclude** Health care and technology outcomes /Health provider outcomes, outcomes on
5.	**Timing/Setting**	**Include** Any setting; any study length; only studies published after 2010
6.	**Study design**	**Include** Randomized controlled trials, nonrandomized controlled trials, or another observational study with a comparator. **Exclude** Post studies without a comparator
7.	**Language**	English

Sampling

The sampling in the study for Qualitative study will be Purposive or Convenience sampling while in the Quantitative method study: Stratified random sampling will be used in this study

Sample Size n=250 (stratified random), at least the n=120 sample will be retained in the study and for the qualitative study, 15 IDIs and 6 FGDs will be done.

Study Tools: Outcome Measures: The outcome measurement will be done using a globally tested tool, the System Usability Scale (SUS).

Method of administration of study tools: The tools will be used for sharing online surveys (survey monkey) and through mobile-based application development.

SUS Tool

To evaluate the utility of m-health and nutrition informatics interventions in self-care and management of type 2 diabetes at home. As per ISO 9241-11, the measures of usability include:

a) Effectiveness
b) Efficiency
c) Satisfaction

The usefulness and acceptance of the proposed m-health intervention will be evaluated using the globally tested tool, System Usability Scale (SUS) for evaluation.
using IDIs and FGD will be done to understand knowledge, attitudes, practices, and beliefs regarding diabetes self-care management. Qualitative methods will be focus group discussion (FGD) and in-depth interviews (IDIs) in the study. Lastly, the study questionnaire system usability survey, a global tested tool (SUS), will be used to assess the usability of mobile applications for self-care management of diabetes.
The system usability scale (SUS) has been developed in response to the above-mentioned requirements. The System Usability Scale (SUS) is a simple, 10-item scale giving an international view of subjective assessments of usability. SUS is a Likert scale. The System Usability Scale (SUS) is certainly the most frequently used questionnaire. It was created by John Brooke in 1986. SUS is frequently used today to measure the usability of websites and apps. SUS can be used to test any system or application, including mobile apps, the Web, digital kiosks, laptops, and machinery [16].

The main reasons for SUS being used are that it is a quick, cheap, and reliable method. While participating in this study, you will fill out a questionnaire that measures the overall levels and utility of the m-health application. In other words, this questionnaire will use 5 points. The Likert scale will be used to assess whether the application's utility and effectiveness are satisfactory. In terms of effectiveness, efficiency, and usability performance, an overall SUS score can be provided [17].

Informed Consent

The institutional review board-approved informed consent form will be administered by the research team to the eligible individuals for the study. The research team will describe the study, the time required, and the benefits of the study results to the participants, and

those willing to participate and give their consent will be enrolled in the study.

The participants should be able to read and understand the questionnaire. If any participant is illiterate, ethical consent will be obtained with the help of a legally acceptable representative or an impartial witness. In addition, illiterate participants will be given the questionnaire in local Indian dialects to improve the study's usefulness and generalizability. Data gathered will be stored securely, ensuring data privacy and confidentiality. Written informed consent will be obtained in both English and the local Indian dialects. Participants in the study will be able to withdraw at any time, citing their reasons for doing so. All data, including those from study withdrawals, will be reported in the final analysis. No monetary compensation will be given, and those agreeing to participate will be offered snack meals. Every individual's time will be respected, and their voluntary participation will be appreciated. Nonmonetary forms of compensation would help to avoid coercion and undue inducement that might impact the results of the study.

Data Collection, Data Entry, and Quality Assurance

Data collection and data entry will be performed by a team of data collectors and data management personnel. The data will be collected at a one-time point by administering the study questionnaire to the eligible study participants. The researchers conducted a pilot study involving a sample of 275 individuals to design and standardize the questionnaire. Initial data will be gathered on paper and then entered on the computer using Microsoft Excel (Microsoft Corporation). For the main survey, the data will be recorded electronically using computer-based software. To ensure efficiency and high-quality data collection and processing, the following data management protocol is in place: a clearly defined study manual; a well-trained team of data collectors; weekly meetings with the research team; weekly data checks; maintenance of study participant contact; and maintenance of study participant data instrument logs. Security and privacy of data: data security will be ensured through regular backups, password-protected computers, and data files stored in a locked file cabinet in an office. The information will be accessible to members of the research team only. Data will be stored on a password-protected computer in a locked place by the principal investigator for 3 years from the point of study completion, at which time it will be destroyed.

Data Analysis Plan

The gathered data will be presented in tables comprising the recorded characteristics of all variables. These tables will serve the purpose of data quality control to find inconsistencies in the data patterns and outliers or any missing data. A descriptive analysis will be conducted to report the means and SDs of the continuous variables and frequency analysis of the categorical variables. A T-test will be performed to compare the means between the continuous variables and a categorical dependent variable, while a chi-square analysis will be performed for the categorical variables. Multivariate regression analysis will be performed to determine the predictors of the outcome variables of vaccine acceptance and hesitancy. All analyses will be carried out using the most recent version of SPSS.

Outcomes

The study outcomes would inform the elements essential for the development of m-

health to improve self-care management of diabetes at home. The authors of the study will also explore the usability, utility, and evaluation of mobile applications using global tools. System usability scales (SUS).

Research outcome dissemination:

The research outcome will be disseminated in seminars, and conferences, and will be published in journals and at least three publications are expected for the three phases of the study.

Limitations of the study

The limitation in the study is anticipated as it will be done on:

- Smartphone users
- Urban population

Variable Assessment

Socio-demographic Profile

This data will be gathered from study participants' age, gender, income level, education level, employment status, occupation, region of residence, marital status, parenthood, and religion.

Health Status Profile

This will include data on comorbidities, health insurance, diagnostic tests, and anthropometry measurements such as height and weight using a standard technique. The two measurements will aid in calculating the BMI of study participants.

History of Diabetes

This comprises questions related to individuals and their family members' history of diabetes.

Knowledge, Attitude, and Practices Related to Diabetes

This data collects participants' diabetes knowledge levels, as well as their attitudes and practices toward preventive practices for diabetes self-management at home. The information recorded will help to design targeted public health messaging to address knowledge, attitude, and practices related to diabetes.

Knowledge, Attitude, and Barriers Related to Diabetes self-care

This data would gather participants' knowledge, attitudes, and barriers related to diabetes self-care management at home so that appropriate.

Ethics and Dissemination

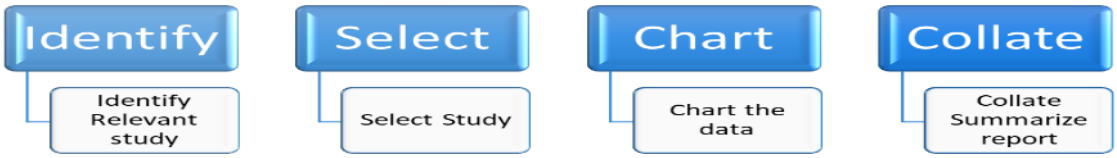
The study bearing the protocol number gained approval from the Dehradun Institute of Technology Research Ethics Committee (dated January 13, 2021). The study will be conducted according to the Declaration of Helsinki as it involves human participants (Protocol number DITU/UREC/2021/07/10). Findings from the survey will be disseminated through peer-reviewed publications and national and international conference presentations. The findings will also be shared with local community health

leaders, as well as other state officials and policymakers, to help them make data-driven, evidence-based, informed decisions.

Qualitative tools: Semi-structured interviews and FGDs will be done. Participants will sign up for individual blocks of time. Participants will be told that they are taking part in a study and will duly sign the consent form. They will be given a debriefing session and the consent form will be signed with the number of participants in the study.

Quantitative–Quasi-experimental case-control study and evaluation using System Usability Scale (SUS) tools and Score. The sample size is 275.

Scoping review: Methodological framework of Arksey and O'Malley



Results

A sample of 250 individuals will go through a pretested DBMS questionnaire. The data collection will be initiated in June 2022, and the initial results are planned for publication by July 2023. Descriptive analysis of the gathered data will be performed using SPSS V11, and reporting of the results will be done at 95% CIs and P=.0.05.

Self-care management of diabetes at home and control over the disease is likely to play a vital role in patient health outcomes. Therefore, education on the readiness to use m-health applications purposefully would be important for better self-management of disease. Nutrition informatics with a self-management care module in m-Health diabetic care management at home has never been tested. Therefore, this is a very purposeful study for self-care management regimes at home leveraging m-health and evaluating usability measures using the System Usability Scale (SUS) and patient-level outcomes. 250 people were chosen at random. The results would be merged to build explanations and draw inferences. However, for m-Health interventions on diabetes self-care management applications, a global testing tool is required. A sufficient approx. 10% of participants will be evaluated using the System Usability Score (SUS) and DBMS globally tested tools.

Discussion

Principal Findings

This research was conducted to explore the concept of diabetes self-management and how m-health applications and interventions can impact self-management behaviors in development and the utility of m-health apps in the self-management of diabetic people. Diabetes management at home and control over their disease is likely to play a vital role in patients' health outcomes, and education for the readiness to use m-health applications

purposefully is important for better disease self-management. Nutrition informatics with a self-management care module in m-Health diabetic care management at home would be very purposeful research. The self-management regime and follow-up with patients for better utilization of health care services and previous study and research recommendations are for testing in different and varied populations. The below tables capture fundamental studies with outcomes. The mobile application review for Type 2 diabetes is annexed in table 1.

Comparison to Prior Work

In the self-management of diabetes, the research priorities include exploring the concept of diabetes self-management and major research questions would comprise of asking what affects self-management in persons with diabetes and how m-health application and interventions can impact the self-management behaviors in development, the utility of the m-health app in self-management of a person with diabetes. Therefore, this study is of great significance and would bring an integrative approach to self-care management on the Chronic Care Model (CCM) and would also benefit patients having co-morbidities like patients having hypertension and diabetes together and m-Health intervention would provide solutions on interventions to adhere to self-care management regime and in future, this m-health application can include nutrition informatics module focusing on local diet/regional informatics on nutrition. In the literature review, it is evident that such an integrated approach has not been tested. Several mobile applications are developed but do not cover the self-management chronic care model (CCM) regime with the Nutrition informatics regime. To make self-care management work effectively, virtual interactions between the patient and provider and other patient support groups can improve adherence to the self-care management regime. The expected benefits of using m-health should meet patients' needs and requirements. It should be implemented in a manner to support feedback loops in the self-management regime [15].

Limitations

This research has some limitations as, firstly, it was conducted in the context of India. Secondly, it will be limited to a sample size of 278. The other limitation of the study is it will be limited to smartphone users and not to feature phones. The other limitation of this study is it will be done in an urban setting and not in a rural area.

Future Directions

Future research can be conducted on a large sample size. Moreover, future research can be conducted on other cities in India. Studies in the future can develop self-care management for feature phone users. An interactive voice response system (IVRS) can be tested in the future for feature phone users. The study in the future can be done in rural areas with a focus on primary health care (PHC) or private clinics in rural areas.

Conclusion

Self-care management of diabetes at home and control over the disease is likely to play a vital role in patient health outcomes, the education for the readiness to use m-health applications purposefully would be important for better self-management of disease. Nutrition informatics with a self-management care module in m-Health diabetic care

management at home has never been tested. The findings of the study would inform the elements essential for the development of m-health to improve self-care management of diabetes at home settings in India and its wider application in the global framework. The usefulness and acceptance of Mobile phone technology have presented a huge acceptance across different socioeconomic groups and ages and provide distinct prospects in healthcare that include the prevention of Type 2 Diabetes and self-management. The future appears to lie within the mobile health applications (mHealth) that utilize entrenched technology to showcase enhanced utilization of smartphones to help in preventing and managing chronic disorders like diabetes type 2. proposed m-health intervention will be evaluated using the globally tested tool System Usability Scale (SUS) for evaluation.

Table 5. Scheduled timeline of the tasks in the study.

Task	Month 1	2	3	4	5	6	7	8	9	10	11	12-24
Review of the literature, initial designing, and planningof the study	✓[a]	—[b]	—	—	—	—	—	—	—	—	—	—
Development of the study proposal and ethical approval of the study proposal	✓	—	—	—	—	—	—	—	—	—	—	
Development of survey items and the questionnaire	✓	—	—	—	—	—	—	—	—	—	—	—
Review and revision of the questionnaire by the research team	—	✓	—	—	—	—	—	—	—	—	—	—
Recruitment and training of the data collector team	—	✓	—	—	—	—	—	—	—	—	—	—
Pilot testing of the representative sample of the target population	—	—	✓	✓	—	—	—	—	—	—	—	
Initial data analysis results in the write-up, and disseminationof the pilot survey	—	—	—	—	—	✓	✓	—	—	—	—	—
Revision of the questionnaire based on the pilot testing	—	—	—	✓	—	—	—	—	—			—
Development of an electronic survey										—	—	
Recruitment of the target sample	—	—	—	✓	—	—	—	—	—			
Reviewing collected data by the research team	—	—	—	—	✓	✓	✓	✓	✓	—	—	—
Data analysis										✓	✓	
Results write-up and preparation of the manuscript	—	—	—	—	✓	✓	✓	✓	✓			
Dissemination	—	—	—	—	—	—	✓	✓	✓	✓	✓	—
indicates it will be done this month.										✓	✓	
	—	—	—	—	—	—	—	✓	✓			—
indicates it will not be done this month.	—	—	—	—	—	—	—	✓	✓	✓	✓	—

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Authors' Contributions

All authors have contributed to the design of the study, the development of the questionnaire, and the preparation of the manuscript, and have approved the manuscript for publication.

Conflicts of Interest

None declared

Multimedia Appendix

Appendix 1-5

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Abbreviation-

DBMS-Diabetes based management system
HCD-Human-centered design
SCR-Scoping reviews
SUS-System Usability Scale
FGDs- Focus group discussion
IDI- In-depth interviews