

BMJ Open Development and evaluation of self-care intervention to improve self-care practices among people living with type 2 diabetes mellitus: a mixed-methods study protocol

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ABSTRACT

Introduction The management of diabetes mellitus (DM) depends on medication adherence, self-care and regular follow-up to prevent complications and premature mortality. This study aims to develop and implement the behavioural change theory and model based diabetes self-care intervention package to improve self-care practices among people living with type 2 DM.

Methods and analysis An exploratory sequential mixed-method study design wherein, quantitative follows qualitative will be used to develop, implement and evaluate the effect of diabetes self-care intervention package among people living with type 2 diabetes. The qualitative research method will be used to identify barriers and facilitators for self-care practices among people living with type 2 DM and will also provide the basis for the development of the diabetes self-care intervention package. The quasi-experimental with control study design will be used to evaluate the developed intervention package among 220 randomly selected people living with type 2 diabetes in both intervention and control arms. Baseline, follow-ups and endline data will be collected using same prevalidated and structured questionnaire for each self-care activity. Difference-in-difference analysis will be used to measure for changes in the proportion of people living with type 2 DM doing different component of self-care practices, preintervention and postintervention in both arms.

Ethics and dissemination Permission for conducting the study has been taken from Institutional Ethical Committee of PGIMER, Chandigarh (Ref no. NK/4538/PhD/226, Dated 18.08.18). The findings of the trial will be disseminated through publication in peer-reviewed journals.

Trial registration number CTRI/2018/10/016108; Pre-results.

INTRODUCTION

Diabetes mellitus (DM) is a global health emergency and top killer among all the non-communicable diseases (NCDs).¹ It has been estimated that 463 million people are living with diabetes in the world and 700 million globally are expected to be effected by the

Strengths and limitations of this study

- The major strength of the proposed study is the mixed-method study design.
- The intervention will be implemented with the help of existing healthcare system which will ensure the future sustainability of behavioural change process among people living with type 2 diabetes after the completion of active follow-up period proposed for 1 year.
- The major limitation of this study is evaluation of the intervention package through quasi-experimental study design. It has inherited weakness of selection bias.
- As the intervention area of the proposed study is northern state of India, generalisation of the study findings for the other parts of the country may not be feasible.

end of 2045.² Followed by China, India too has become diabetes capital of the world and has estimated to overtake it by the end of 2040.² More than half of the premature mortality are attributed to NCDs of which diabetes and its related complications are on the forefront in India.³ The increasing prevalence of the type 2 DM (T2DM) is mainly due to transition in socio-economic condition in both urban and rural areas of India.⁴

Ominous octet is a complex disease that requires sustainable medical support and self-care practices in order to avert or slow down the chance of complications and their subsequent impact on quality of life. Diabetes self-care behaviour is of utmost importance as treatment of diabetes and its related complications contributes huge proportion of out-of-pocket expenditure among people living with T2DM and for the public health services.⁵ It is evident that diabetes self-management does not solely depend on knowledge and

awareness about diabetes but also require skills for self-care management along with support of health care staff, family, peer group, positive mental attitudes and optimal utilisation of available resources.^{6–15} Therefore, without addressing these factors among people living with T2DM, knowledge about disease hardly predicts self-care behaviour.

In India, National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular disease and Stroke (NPCDCS) was launched in 2010 with objectives of opportunistic screening, health education and health promotion activities of people >30 years of age¹⁶ but due to lack of specific intervention strategies it could not achieve the desired goals. Thus, there is a need to develop an approach to strengthen the existing programme and policies for NCDs especially for diabetes that can also be implemented through existing healthcare setup.

The use of behavioural change models and theories for the diabetes self-care intervention implementation predicated better glycaemic control and sustained self-care behaviour among people living with diabetes.^{17–20}

Systematic review and meta-analysis of behavioural change theories based self-care intervention studies have shown that the theory of self-efficacy and transtheoretical model are effective in successful management of diabetes by adopting and learning skills through setting tailor made preventive and therapeutic goals and to overcome barriers in a day to day life with the assistance of healthcare professionals and different support groups^{21–23} but there is no such study from Indian subcontinent.

Therefore, there is a need to develop and evaluate the effectiveness of behavioural change theories based diabetes self-care intervention package for people living with T2DM. In this study, the readiness to change model guided tailor made intervention will be implemented using framework of self-efficacy theory.

METHODS AND ANALYSIS

Study design and study setting

The study will be conducted in district Fatehgarh Sahib of Punjab. Due to socioeconomic transitions there is a visible increase in the trend of diabetes prevalence.^{3 24} In 2016, the prevalence of diabetes was 8% among population aged 18 years and above.²⁵ The district Fatehgarh Sahib, Punjab has been selected purposively as an intervention district for the study as there is an existing Memorandum of understanding for strengthening of public health system and field practice area of the Department of Community Medicine and School of Public Health, PGIMER, Chandigarh. An exploratory sequential mixed-method study²⁶ will be carried out in three phases (figure 1).

Inclusion and exclusion criteria

Participants recruitment inclusion criteria will be as following: person living with T2DM based on available medical records and on antidiabetic medications for >6

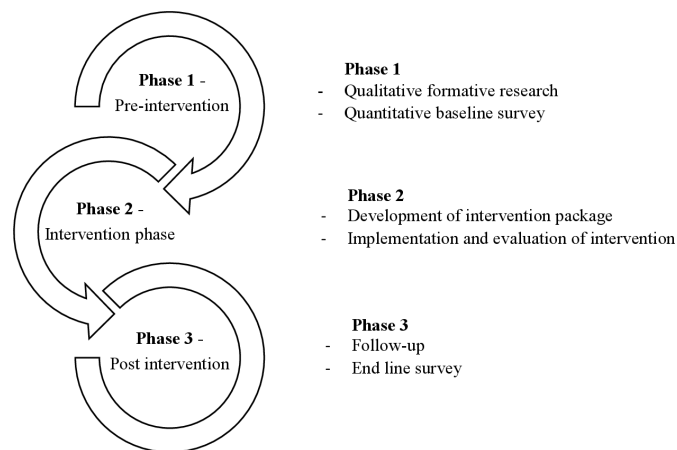


Figure 1 Summary diagram of the study design.

months, males and females age >30 years and willing to give consent to participate in study. The participants who meet the all the above mentioned criteria will be recruited in the study.

Those individuals with severe complications like heart problem, kidney disease, cognitive impairment, who could not communicate and pregnant women will be excluded from the study.

PHASE 1: PREINTERVENTION

Qualitative formative research

Sampling technique

Purposive sampling technique will be employed for the recruitment of study participants.

Participant's recruitment and sample size

The study participants will be recruited with the help of list of target population available from the villages of the selected subcentres. Individuals who will fulfil the study inclusion criteria will be recruited for focus group discussions (FGDs) and the primary healthcare staff who have work experience of at least 6 months or more, will be selected from the subcentres for in-depth Interview (IDIs). All the study participants will be recruited with help of existing health staff and separate team for the study. The sample size of participants will be six to eight for each FGD.

Interview technique

FGDs among people living with type 2 diabetes and IDIs of healthcare providers will be conducted to achieve the objective of formative research.

Interview administration

Each FGD and IDIs will be moderated by the researcher and another accompanying person will help in taking the notes. Before starting FGDs and IDIs researcher will undergo exhaustive training for collecting and conducting qualitative study. The duration of FGDs and IDIs will be ranged from 30 to 45min. The venue of FGD will be a community centre located in the village of selected subcentres.

Basic sociodemographic information and the duration of diabetes from participants will also be collected from participants before the start of FGDs. A topic guide will be used by moderator to conduct the sessions of FGDs and IDIs. FGDs and IDIs will be recorded with the help of audio device after taking informed consent, a notes will also be made by the notes taker. FGDs and IDIs will be conducted until data saturation is achieved.

Data Analysis

The recorded interviews will be transcribed in vernacular language (Punjabi) and translated into English and then will backtranslated to vernacular language (Punjabi) to check content accuracy before actual data analysis. Data will be analysed using narrative thematic analysis approach. FGDs and IDIs will be explored to identify emergent codes which will be added to the list of codes and used for further coding of the data. Codes will be finalised after discussion and consensus of qualitative research experts.

Quantitative baseline study design

Study design

A cross-sectional study design will be used to ascertain level of self-care practices among people living with T2DM.

Sample size estimation for the baseline data

A sample size of 700 is estimated for the baseline assessment of self-care practices. The sample size is calculated on the basis of estimated prevalence of healthy diet and physical activity practices to be 30% with precision/ absolute error 5%, design effect 2 at 95% CI.

Sampling technique and study participants

Multistage random sampling will be used to select the subcentres from where the study sample will be recruited. Initially, two health blocks of district Fatehgarh Sahib, Punjab will be selected randomly and assigned as intervention and control arm respectively. In each health block four subcentres will be chosen randomly. Prior to the data collection, with the help of health workers of selected subcentres a list of people living with T2DM will be prepared from the ongoing diabetes screening

programme and will be approached for the enrolment with written consent. Take all approach technique will be used to enrol eligible participants from each village of selected subcentres. The study participant's enrolment will be carried out starting from subcentre which have highest number of villages among the selected subcentres and then proceed to next subcentre in descending order and so on till the required sample size of 350 is achieved from each arm (total 700).

Data collection

Baseline assessment tool

Data will be collected using pre-validated, structured questionnaires (table 1), which will be including details of sociodemographic data, medical history, specific questionnaire (for detail assessment) related to each self-care activity to tailor the intervention plan along with assessment of diabetes management self-efficacy.

Anthropometric measurements and estimation of biomarkers

Height will be measured through calibrated anthropometric rod using to nearest 0.1 cm. Weight will be measured on a portable weighing scale with minimal clothing and bare foot using to the nearest 0.1 kg. Waist circumference will be measured wearing minimal cloth midway between last ribs and iliac crest at the level of umbilicus in mid expiratory position and hip circumference will measured at level of widest point over the greater trochanters using inelastic centimetre tape. Body mass index (BMI) in kg/m² and waist and hip ratio (WHR) will be calculated using these values and will be categorised according to classification for Asian population.

Blood pressure measurement will be taken two times with the help of a standard blood pressure machine using to nearest 2mm Hg. Random blood sugar measurement will be measured through capillary blood using calibrated glucometer.

PHASE 2: DEVELOPMENT OF INTERVENTION PACKAGE AND IMPLEMENTATION

Development of intervention packages

The existing guidelines and interventions published globally will be reviewed and findings from the formative

Table 1 List of the assessment tools

Sl. no	Prevalidated and structured data collection tools	Assessment of the component
1.	STEPs survey questionnaire ²⁵	To assess habit of smoking and alcohol
2.	Global Physical Activity Questionnaire ⁶⁰	For assessing Physical activity
3.	Food Frequency Questionnaire ⁶¹	To assess dietary habit
4.	Brief Medication Questionnaire ⁶²	To assess medication adherence
5.	Revised Summary of Diabetes Self Care Activity ⁶³	To assess the diabetes self-care activity including Self-Monitoring Blood Glucose
6.	Nottingham Assessment of Functional Foot care ⁶⁴	To assess foot care
7.	Diabetes Distress Scale ⁶⁵	To assess diabetes related distress
8.	Diabetes Self-Management self-efficacy scale ⁶⁶	To assess diabetes self-care efficacy

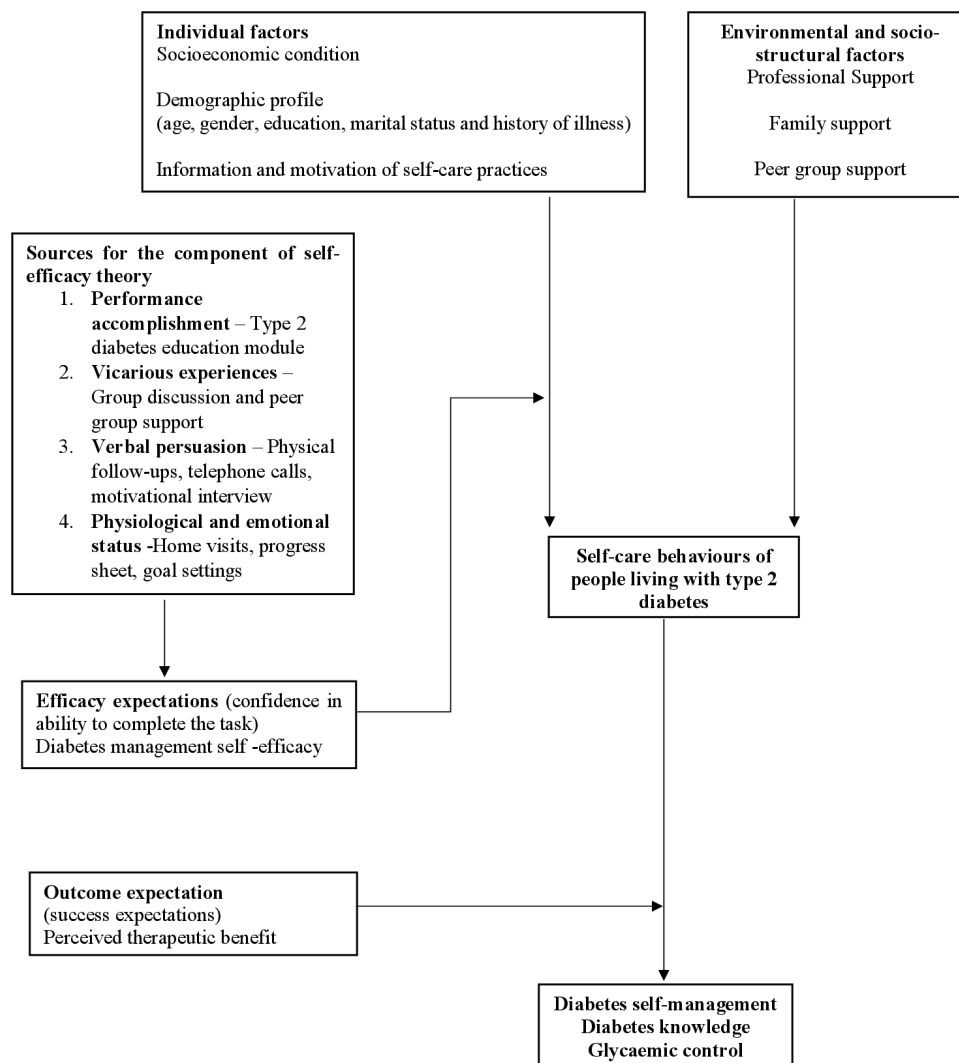


Figure 2 Proposed behavioural change framework based on self efficacy theory.

research using qualitative study design will be used to develop interventions for all seven components of T2DM self-care. To make intervention more effective, self-efficacy theory of behavioural change will be used as a guide for behavioural change framework (figure 2). The intervention package will be finalised on the basis of pilot study and experts' feedback.

Implementation and evaluation process (quasi-experimental study)

Study design and sample size estimation

A quasi-experimental with control arm study design will be used to implement the developed intervention package. A total sample of 440 persons living with type 2 diabetes will be recruited; 220 in each arm (Intervention and control). Proportion of population are doing self-care assumed to be 30% based on prior study.^{27 28} The sample size is calculated by using the formula of changes in two proportion with the assumption is that improvement for self-care after intervention to be 50% with 5% α , 80% power and design effect of 2 with 10% attrition rate.

Recruitment of the participants and healthcare staff

Eligible participants will be recruited for intervention implementations. Though the intervention will be provided to all 700 participants (350 from each arm) recruited during the cross-sectional study but the effect of implemented intervention will be evaluated only among randomly selected 220 participants in each arm. The intervention implementation will start from largest subcentre in terms of number of village among the selected subcentres and then proceed to next largest subcentre in descending order till the desired sample size is achieved.

The intervention will be implemented at the randomly selected subcentres. Already available healthcare staff at existing healthcare setup under the ongoing national health programme will implement the diabetes self-care intervention package. Currently, government of India is converting existed subcentres into health and wellness centre for providing comprehensive primary healthcare services to make sure universal health coverage, which covers wide range of health services and national health

programme such as screening, prevention and treatment facility for the various NCDs including diabetes along with maternal and child health services and management of communicable diseases.

Characteristics of existed healthcare staff at selected subcentres will be matched in term of their knowledge and experiences of handling people living with T2DM. Each healthcare staff who will be involved in intervention implementation will be trained before actual implementation of diabetes self-care intervention. Any potential confounder will be adjusted during data analysis.

Components of intervention

The intervention for improving self-care will have two components:

Information and education

Information and education about all seven diabetes self-care activity will be provided through pictorial leaflet, group discussion, model demonstration and short video in local language to the people living with T2DM.

Behavioural change

For behavioural change component various approaches such as demonstration of different diabetes self-care skills, counselling, motivational interview and goal settings will be adapted. To add in monitoring the behavioural changes, the behaviour tracking sheet will also be provided to the participants.

Intervention implementation among intervention group

Depending on the baseline characteristics and readiness to change (figure 3) of each participant, a tailor-made plan will be implemented using self-efficacy theory (table 2) by taking into consideration their occupation, socioeconomic status, physical and social environment

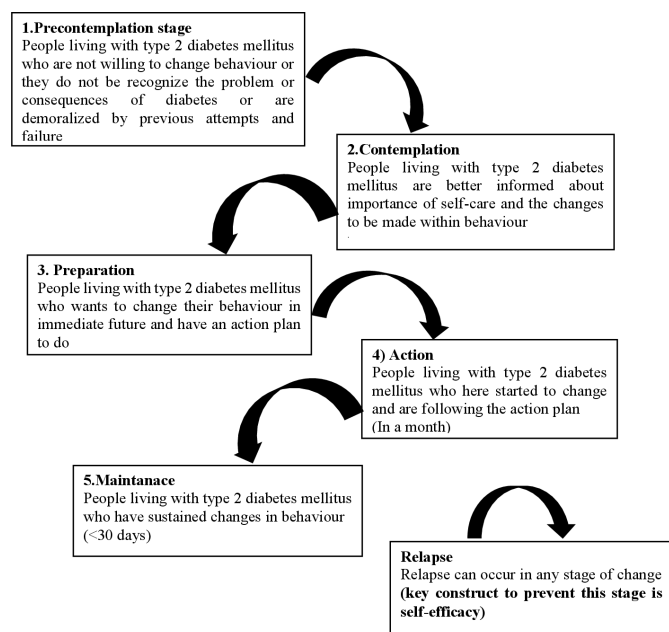


Figure 3 Stage of change in self-care behaviour of person living with type 2 diabetes.

where the patient resides and works. Participants of intervention area will receive the initial part of the intervention in the subcentres nearest to their residence. The details of the implemented intervention and goals of the participants will be shared with the trained healthcare staff of the village for regular follow-up. In addition, they will also help the participants in case of any difficulty in understanding and following the prescribed plan.

Implementation among control group

Control group participants will be provided routine healthcare services as per the existing healthcare norms along with educational material such as pamphlets and flipchart of diabetes self-care management. All blood test reports will be also shared with the control group participants.

Study outcomes measures

Primary outcome

Changes in proportion of people living with T2DM performing different component of self-care, preintervention and postintervention.

Secondary outcome

Changes in proportion of people living with T2DM having glycated haemoglobin <7% (HbA1c), mean changes in fasting blood sugar (FBS), lipid levels, self-efficacy for doing self-care, BMI and WHR.

Data collection

Adherence assessment tool

All eligible participants will be assessed by trained healthcare staff in detail regarding all the seven components of self-care using a prevalidated structured questionnaire along with diabetes self-management efficacy. List of the assessment tools has been summarised in table 1.

Anthropometric measurements and estimation of biomarkers

Height will be measured through calibrated anthropometric rod using to nearest 0.1 cm. Weight will be measured on a portable weighing scale with minimal clothing and bare foot using to the nearest 0.1 kg. Each instrument will be calibrated before each measurement. Waist circumference will be measured wearing minimal cloth midway between last ribs and iliac crest at the level of umbilicus in mid expiratory position and Hip circumference will measured at level of widest point over the greater trochanters using inelastic centimetre tape. BMI in kg/m^2 and WHR will be calculated using these values and will be categorised according to classification for Asian population.

Blood pressure measurement will be taken two times with the help of a standard blood pressure machine using to nearest 2 mm Hg. A 5 mL blood sample (1 mL-sodium fluoride vial, 1 mL-EDTA vial and 3 mL-plain vial) will be withdrawn from each participant to estimate biomarkers such as HbA1c (%), fasting plasma glucose (mg/dL) and lipid profiles (mg/dL) by applying standard laboratory methods. Participants will be instructed 1 day before to

Table 2 Proposed diabetes intervention implementation based on theory of self-efficacy

Sl. no.	Main content	Mode of intervention	Constructs of self-efficacy theory	Time for each session (min)
1	General overview about diabetes and diabetes self-care	<ol style="list-style-type: none"> 1. Educational classes 2. Model presentations 3. Group discussions 4. Providing pictorial reading material in vernacular language (pamphlets and flip chart) 	Performance accomplishment, Verbal persuasion and Vicarious experiences	45–60 min
2	Overview about component of self-care and Assessment of diabetes self-care practices	<ol style="list-style-type: none"> 1. Educational classes 2. Group discussions 3. Providing pictorial reading material in vernacular language (pamphlets and flip chart) 4. Demonstration of model having healthy life style and self-care practices 	Performance accomplishment, vicarious experiences and verbal persuasion	45–60 min
3.	Identify barriers and enabling them for making healthy choices and goal settings	<ol style="list-style-type: none"> 1. Motivation and Counselling sessions 2. Booklets, pamphlets and video for enhancing self-care skills 3. Person goal setting sessions 	Performance accomplishment, Verbal persuasion and Vicarious experience	45–60 min
4.	Follow-ups for encouraging problem solving, and reinforcing in behavioural change towards healthy lifestyle choices and self-care	<ol style="list-style-type: none"> 1. Motivation and Counselling session. 2. Personal goal setting sessions 3. Telephonic calls and reminder through short messages services 4. Group problem solving sessions and discussions 5. Model demonstrations 	Performance accomplishment, Verbal persuasion, Vicarious experience and Physiological Feedback	30–45 min

blood sample collections for overnight (at least 8 hours) fasting. Reports of blood tests for various proposed biomarkers will also be shared with the participants.

PHASE 3. POSTINTERVENTION PHASE

Follow-up and end line assessment

The study participants will be followed up for the period of 1 year, at an interval of every 6 months. Assessment of intervention will be done on randomly selected 220 participants in each arm by using same questionnaire to assess each self-care and its correlates, as used in the baseline assessment of the study.

Data analysis

Data will be analysed using done in SPSS V.21 (IBM). Quantitative continuous data will be presented as means and SD. χ^2 test will be used to compare the categorical variables. Paired t-test will be used to analyse changes within group and student t-test will be used to compare between-group changes from baseline to end line at 12 months (from baseline to end line). Multivariable regression analysis will also be used to investigate potential differences between socioeconomic, age group etc. DID analysis will be used to measure the for changes in

proportion of population with different component of self-care between preintervention and postintervention in intervention and control arms. Secondary outcome will be measured through DID of mean changes in FBG, lipid profiles, BMI and WHR. Statistical significance will be adjusted at $p < 0.05$. generalised estimating equation models will be applied to explore the outcomes of intervention after adjusting for confounders.

DISCUSSION

In this study, the intervention outcomes will be obtained through complex exploratory sequential mixed-methods study design approach. We assume that findings of this study can guide the effective implementation of the ongoing national programme to reduce the mortality and morbidity due to complications of diabetes, in India.

The proposed study will address all the seven components of self-care as described by American Diabetic Association (ADA). ADA recommends seven essential self-care behaviours namely sensible eating behaviour, being physically active, self-monitoring of blood glucose, medications adherence, good problem-solving skills, healthy coping skills and risk-reduction behaviours (foot care)

for managing optimal blood glucose and to decrease the chance of getting complications.^{29,30} In spite of the being aware of the importance of diabetes self-care the level of self-care practices has been reported from very low to moderate in India. It ranges from 17% to 88% for adherence to medications, 20% to 70% for physical activity, 15% to 68% for foot care, 40% to 92% for monitoring of blood glucose, 23% to 76% for adherence to diet plan and 83% have good problem solving skills among people living with T2DM.^{28,31–37}

Though, there is paucity of intervention studies to provide evidence on improvement in self-care practices from India.^{38–43} These studies provide only limited post intervention effect on glycaemic control which range from 0.5 to 2 mg/dL for FBS, 0.5%–1% reduction in HbA1c level and inconsistent results for other health outcomes such as body weight, lipid profile, fruits and vegetables intake and sustainable behavioural change. Most of the interventions for diabetes self-care from the Indian subcontinent targeted towards selected component of the self-care behaviour namely diet, physical activity, foot care and medication adherence. None of the intervention studies have looked in to behavioural change theories and frameworks. Furthermore, these studies have shown significant methodological weaknesses, small sample sizes, short duration of intervention, lack of appropriate measures and inconsistent in the results obtained. These limitations greatly limit the scope for transferring trial results in to practices. Therefore, this study will aim to bridge this very gap.

A meta-analysis shows that educational and behavioural interventions were successful in lowering HbA1c by approx. 0.50%, 24mg/dL in fasting blood glucose and weight by 2kg.⁴⁴ Many studies have also reported that primary healthcare staff/community health worker have capability to enable this change especially among rural population.^{45–48} However, implementation at the individual level in the community is a challenging task but involvement of primary healthcare staff may help to reduce the burden on the public health system and may reduce the problem of trained personal staff in rural areas.

There are evidences from across the globe that intervention strategies using behavioural change theories successfully increases adherence to self-care practices and also improve the quality of life among people living with diabetes by significantly controlling HbA1c.^{49–51}

Self-efficacy theory developers define self-efficacy as the confidence in one's own skills to successfully complete the action required to meet given situational demands.⁵² This theory is also a construct of the social cognitive theory which assert that human behaviour is outcome of cognitive process that develops through the knowledge a person gains from day-to-day life actions, society and environment. An individual efficacy build on four main sources are: Mastery experience (past successful experiences), vicarious experience (success and failure of the role model), verbal persuasion (verbal motivation) and physiological state (emotions of the individual).

Whereas transtheoretical model (TTM) specifies stages of behavioural changes in a time dimension are: precontemplation stage (individual is not considering behavioural change in the next 6 months), contemplation stage (considering behavioural changes in the near future, between 1 and 6 months), preparation stage (planning for behavioural change in the next 30 days), action stage (individual has made meaningful behavioural changes in the past 6 months), maintenance stage (individual has maintained behavioural change for 6 or more months).⁵³ The TTM is an unifying framework of behavioural change that consists process oriented variables to describe and anticipate when and how an individual change behaviour.

However, there are certain limitations of the chosen self-efficacy theory to implement that can affect the outcome of the intervention are individual past experiences, multiple setbacks or failure on previous task, variation in individual beliefs about their efficacy to performing given task, environmental factor, availability of resources and distorted memories of the previous performance and huge variation among individual's self-efficacy.^{54,55} Studies have shown that stage-based tailor-made intervention plan helps in better sustainability of changes in self-care behaviour.^{56–59} Thus, TTM can act as add on self-efficacy theory.

To the best of our knowledge to date, there are no diabetes intervention studies conducted in India that have addressed the problem of self-care practices based on theory of behavioural change through the primary healthcare staff among people living with T2DM. Therefore, the present study will add new scientific evidence on effectiveness of T2DM self-care management programmes in India as well as other lower-income and middle income countries, where this part of research has been less discovered. This study may also help target population reducing unnecessary treatment cost due diabetes related complications and improve overall quality of life.

ETHICS AND DISSEMINATION

Ethical consideration

Permission for conducting the study has been taken from IEC committee of PGIMER, Chandigarh (Ref no. NK/4538/PhD/226, Dated 18 August 2018). Any changes in proposed protocol will be informed to institutional ethics committee before implementation.

Informed consent

Participant interview and clinical examination will be done only after obtaining informed consent. Confidentiality of participant's data will be ensured during study.

Dissemination

Results of the research will be published in peer-reviewed journals.

Strengths and limitations of this study

The major strength of the proposed study is the mixed-method study design. The intervention will be implemented

with the help of existing healthcare system which will ensure the future sustainability of behavioural change process in community after the completion of active follow-up period proposed for 1 year. The major limitation of this study is evaluation of the intervention package through quasi-experimental study design. Quasi-experimental study has inherited weakness of selection bias. Any confounders which may be associated with both intervention and outcome will be addressed during data analysis.

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