

Effectiveness of an Educational Intervention via Health Belief Model in Promoting Self Care Behavior in Type II Diabetes Mellitus Patients in Lucknow Province of Uttar Pradesh, India: Randomized Controlled Trial

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ABSTRACT

Introduction: Diabetes is the most prevalent disease worldwide, resulted from metabolic disorders. The aim of the study was to investigate the effectiveness of health belief model (HBM) on promoting self care behavior in patients having type II diabetes mellitus in Lucknow city, India.

Methods: This study was a single blinded randomized controlled trial on patients who visited the OPD of a medical college and having type II diabetes. 200 patients were involved in the study and they are assigned into 2 groups by using stratified randomization i.e. control (N = 100) and intervention (N = 100), later on few participants were excluded from the study so the subjects in each group was 92 (control group) & 88 (intervention group). The data collection tool was a questionnaire based on Health Belief Model and self care behavior and it was completed by both groups before the intervention. After that the intervention group received 4 sessions of educational program based on HBM in one month at 7 days interval, and the same questionnaire was again completed by them after 2 months of intervention and the data were analyzed through SPSS version 20, Chi square, paired t test & Unpaired t test was used for data analysis.

Results: The scores of intervention and control groups before the educational intervention was lower in both the groups but after the educational intervention the mean score of each HBM construct and the self-care behaviors showed a significantly increase in intervention group.

Conclusion: Our results suggest that educating patients with diabetes based on HBM promotes the self-care behaviors.

Keywords: Type II Diabetes Mellitus, Health Belief Model, Self Care Behavior, India

INTRODUCTION

Diabetes Mellitus also known as 'diabetes'. It was derived from Greek word '*Diabetes*' means 'siphon - to pass through' and Mellitus is a Latin word means "Sweet". Diabetes is a metabolic diseases and it is a multifactorial disorder that is characterized by a chronic rise in the blood sugar level. The main broad categories are Type 1 Diabetes Mellitus (T1DM) and Type 2 Diabetes Mellitus (T2DM), which occur because of defective insulin secretion (T1DM) and/or action (T2DM). T1DM occur in children or adolescents, while T2DM affect middle-aged and older adults who have prolonged hyperglycemia due to poor lifestyle and dietary choices.¹

Diabetes accounts for 9% of all deaths worldwide.² Experts expect the prevalence of DM to increase from 415 to 642 million by 2040, with the most significant increase in populations transitioning from low to middle-income levels.³ More than 90% of people with diabetes are individuals with a form of type 2 diabetes.⁴ More than 60% of the world's diabetic population resides in Asian countries.⁵ Indeed, the prevalence of diabetes in India is expected to rise from 8.8% (in 2017) to 11.4% by 2045.⁶

Its complications are undoubtedly on the rise in India. It is considered the leading cause of retinopathy, neuropathy, nephropathy, and 60 % of foot amputations.⁷ In addition, the risk of heart attack and stroke and death from cardiovascular diseases is two to four times greater than other patients in patients with diabetes.⁸ Patients having uncontrolled diabetes have oral complications such as increased dry mouth, burning mouth and periodontal diseases.⁹

One of the methods of preventing or delaying the acute and chronic complications is early detection and patients proper care in order to effectively control and prevent the progression of the disease.¹⁰ The successful control of diabetes is dependent upon the patients self-care because more than 95 % of care associated with diabetes is observed by the patients themselves.¹¹ Self-care is learned, based on the ability of individuals to perform caring practices on their own;¹² it can be defined as a strategy to cope with life affairs that promote health and independence, including special activities to alleviate the symptoms of the disease.¹³ This process is composed of having a healthy nutrition, on-time

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How to cite this article: Singh A, Niranjana AS, Singh A, Meena S, Sial S. Effectiveness of an educational intervention via health belief model in promoting self care behavior in type II diabetes mellitus patients in Lucknow province of Uttar Pradesh, India: randomized controlled trial. International Journal of Contemporary Medical Research 2021;8(2):B22-B27.

DOI: <http://dx.doi.org/10.21276/ijcmr.2021.8.2.21>



medication use, blood glucose or urine self-testing, regular exercises, and foot care.¹⁴

Studies indicate that adherence to self-care activities improves not only the life quality of patients and their families, but also plays an important role in reducing health care costs because of repeated hospitalizations.¹⁵ The improvement of self-care behaviors is the first step to help patients control their disease, making the importance of factors affecting self-care behaviors more obvious.¹⁶ One of the main tasks of diabetes care providers is supporting patients to perform their self-care behaviors via giving recommendations for effective self-care diets and providing education to patients.¹⁷ Health practitioners encourage patients with diabetes to develop many self-care behaviors.¹⁸ Thus, the purpose of the education is for the disease to be managed by the patient and to improve the patients' quality of life.¹⁹

To reduce the complications of diabetes, some studies emphasize that healthcare workers should not merely provide knowledge to people, but take into account the perception of the risk as a central concept for understanding healthy behaviors and making changes in behavior. So, patients with diabetes need to properly understand the risk of diabetic complications and the structure of the Health Belief Model (HBM) with respect to constructs appropriate for intervention.²⁰ HBM is one of the most effective models of health education since it mainly focused on prevention of diseases and adoption of behaviors to avoid illness and disease chains and it is one of the important precise models which is used to determine the relationship between health beliefs and behaviors.²¹ The HBM Model about type 2 diabetes patients' self-care problems has been considered in the variety of studies.^{19,22,23}

Diabetes is one of such diseases in which patients have a major role in its control and it is not possible to have the patients under the supervision of healthcare professionals at all hours of the day, it is necessary to teach these patients in terms of self-care.

Considering the lack of a theory-based study regarding the self care behavior based on HBM construct in patients with type II diabetes in India, the current study was conducted to design and evaluate an educational intervention to promote self care behaviors in patients with T2DM. The null hypothesis of the study was that there is no difference with the educational intervention among intervention and control groups.

MATERIAL AND METHODS

This study was a single blinded randomized controlled trial of an educational intervention on type II diabetic patients who visited the OPD of Department of medicine, in a medical college in Lucknow city, India from August 2019- October 2019. From a total of 1988 diabetic patients visiting the OPD, 200 patients who met the inclusion criteria of the study were randomized into 2 groups by stratified randomization with an allocation ratio of 1:1.(Figure 1)

A sample of 79 was obtained for each groups by using the OpenEpi software considering $\alpha = 5\%$, $\beta = 0.1$, power of the

study 90%, $z=1.96$, effect rate=0.6. To avoid attrition in the study sample size was increased to 25%, so the final sample size for each group was 100.

Inclusion criteria: Patient having type II diabetes aged in between 40 to 60 years, literate and having smart phone, residing in Lucknow province of Uttar Pradesh, having no other co-morbidity and signing an informed written consent.

Exclusion criteria: Illiterate, not having smart phone, having no desire to participate in the study, not attending the training sessions regularly, and suffering from any other systemic disease.

Ethical clearance was obtained from the Institution Ethical Committee of Medical College before the start of the study and the principles of the Declaration of Helsinki were applied throughout the study. 200 selected patients were randomized to intervention ($n = 100$) and control ($n = 100$) groups via stratified randomization (age and gender).

After randomizing each patients to respective group, pre-tested questionnaire was administered to both the groups so as to record the baseline level. After that the intervention group received trainings based on Health Belief Model (HBM) and the control group received routine cares. Then these patients were followed up for a period of 2 months. After that the post-test was administrated to both the groups and finally the effect of education on self care behaviors was re-evaluated.

In this study the primary outcomes were constructs of HBM (perceived susceptibility, severity, benefits, barriers and self efficacy) and secondary outcomes was self care behaviors.

The data collection tool in this study was a valid and reliable researcher-made questionnaire consisting of questions on demographic information, awareness, constructs of the Health Belief Model, and self care behavior in patients with T2DM. The validity of questionnaire was approved by a panel of experts (2 General physician, 2 endocrinologist, 1 Dentist, 1 health educator, 1 MD PSM expert) and those questions with a Content Validity Ratio (CVR) >0.62 and a Content Validity Index (CVI) >0.79 were included in the study.

Pilot study was conducted on 26 diabetic patients having similar demographic profile. Reliability was measured by a test-retest correlation. The reliability was assessed using Cronbach's alpha coefficient and it was found reliable (0.992).

The questions were designed in three parts. The first part included 8 questions on patient's demographic information. In the second part, questionnaire were designed according to HBM construct and it includes 6 questions on perceived susceptibility, 5 question on perceived severity, 6 question on perceived benefits, 7 question on perceived barriers, and 10 question on self efficacy.

Rating in the HBM questionnaire was in a way that the score range for each item of perceived susceptibility and severity, perceived barriers, and self-efficacy was from 1 to 5, [1= never, 2= low, 3= medium, 4=, high, and 5= very high]. Accordingly, the range for the perceived susceptibility scores

(6 to 30), perceived severity (5 to 25), perceived barriers (7 to 35) and self-efficacy (10 to 50).

The score range for the perceived benefits is 6 to 30. Regarding perceived benefits, the scores of 5, 4, 3, 2, and 1 are awarded to strongly agree, slightly agree, neutral, slightly disagree, and strongly disagree, respectively.

Third section include questionnaire that are Hindi translated version of Summary of Diabetes Self-Care Activities (SDSCA)²⁴ and 1 question was added regarding oral health and so in total it now include 11 questions.

The reliability of the questionnaire was also verified and its validity was checked by forward- backward- forward translation from English to Hindi. This questionnaire is employed to assess self-care activities in six main areas: having a diet, doing physical activities, taking medications, monitoring blood sugar, maintain proper oral hygiene and taking care of the feet.

The answers of this questionnaire were designed in such a way that the patient may report the amount of his/her activity during the past week, and the answers are scored from 0 to 7, in which zero stands for no self-care activities during the past week and seven represents performing self-care behaviors in all seven days.

As much as the score of model constructs goes up, the amount of self-care behavior increases as well.

Study intervention

Before performing the educational intervention, the questionnaires were completed by both groups and entered into the computer so as to determine patients educational needs and to determine the need for training of different structures in educational sessions.

Then, according to Health Belief Model and based on the results of the need assessment, the training program was prepared for 30 min every week for 1 month so in total there was total four session targeted at the intervention group. All the participant in experimental group were added in an online group, on every Sunday a link was posted for a uploaded video so that each participants can watch the video and download power point presentation and this also helps us to had a look on watch time (duration) of video watched by every participants. Also a feedback link for any query was also provided and along with that on every Wednesday from 5-7pm there was an online group discussion regarding the topic of video that was posted on previous Sunday. The timing 5-7 pm was chosen by a survey among the selected participants and this timing suits majority of the participants. The first session contained an introduction on diabetes, symptoms, complications, and the ways to prevent it. The second session was composed of knowledge of self-care aspects (foot care, regular drug use, oral care, quitting smoking, and physical activities, particularly walking). The third session was on healthy diet and proper nutrition. In the fourth session, the patients became familiar with testing blood sugar through practical demonstrations and modified bass technique for brushing was also shows by the researchers, and the patients were asked to practice this activity.

The control group was abstained from educational intervention on HBM. To maintain the blinding in the study the patients in control were also added in an online group were they can also discuss with general physician, dentist, nutritionist and health educator appointed in the study and the post-test was administered after two months to both the groups.

STATISTICAL ANALYSIS

The data were analyzed using SPSS version 20, chi square was applied for comparing the demographic variables, paired and unpaired t test for the HBM constructs and self-efficacy data. A p value of <0.05 was considered as statistically significant.

RESULTS

The average age of the diabetic patients in the control and intervention groups was 52.36 ± 3.64 and 53.24 ± 4.28 years, respectively. Table 1 shows the demographic characteristics of the patients in both intervention and control groups. 12 participants (8 females and 4 males) from intervention group were excluded since the total duration of video's watch time by them was less. From the intervention group 5 females and 3 males also left the study. So, the sample size in intervention group is 88 and in control group it was 92.

Table 2 represents the variations of mean in each HBM construct (perceived susceptibility, perceived severity, perceived benefits, perceived barriers and self-efficacy) and self-care behaviors before and after intervention. According to the results of Table 2 unpaired samples t-test indicates that there was statistically no significant difference between both the groups before the educational intervention

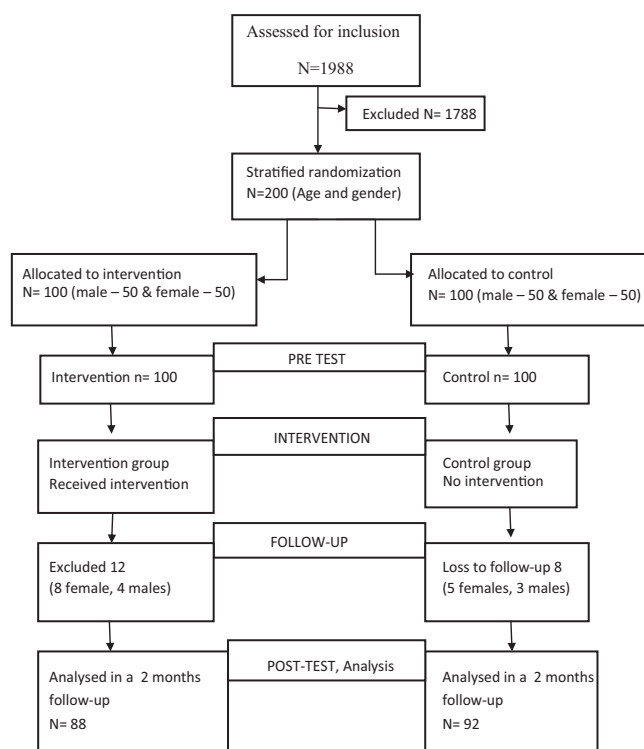


Figure-1: Flow diagram of RCT

Group Variable		Control Frequency (N)	control Percentage (%)	Intervention Frequency (N)	Intervention Percentage (%)	P Value (Chi sq)
Gender	Male	47	51.09	46	52.27	0.99
	Female	45	48.91	42	47.72	
Marital status	Married	82	89.13	76	86.36	0.73
	Single	10	10.86	12	13.64	
Education level	10 th or below	23	25	20	22.72	0.95
	12 th	31	33.69	32	36.36	
	Diploma	16	17.39	18	20.45	
	Graduate	14	15.21	12	13.63	
	Post-graduate	8	8.69	6	6.81	
Socio- economic status	Low	22	23.91	17	19.31	0.43
	Middle	64	69.56	68	77.27	
	High	6	6.52	3	3.40	

Table-1: Comparison of the intervention and control groups, concerning the demographic variables

Group Variable		Control Mean	SD	Intervention Mean	SD	p value ^{##}
Perceived susceptibility	Before	13.86	2.87	13.54	4.455	0.56
	After	14.78	3.65	23.78	2.785	0.001
	P value [#]	>0.05		<0.001		
Perceived severity	Before	12.10	3.84	11.82	4.170	0.64
	After	12.30	3.345	18.65	2.349	0.001
	P value [#]	>0.05		<0.001		
Perceived barrier	Before	19.65	4.895	19.92	4.738	0.78
	After	17.56	1.876	13.20	2.566	0.001
	P value [#]	>0.05		<0.001		
Perceived benefit	Before	11.10	2.86	11.21	3.642	0.822
	After	12.23	1.56	28.25	1.287	0.001
	P value [#]	>0.05		<0.001		
Self-efficacy	Before	28.48	4.42	28.29	6.541	0.81
	After	29.20	3.46	38.12	5.126	0.001
	P value [#]	>0.05		<0.001		
Self-care	Before	31.86	5.78	32.52	8.89	0.55
	After	32.12	4.52	49.45	5.586	0.001
	P value [#]	>0.05		<0.001		

^{##} unpaired t test; [#]paired t test

Table-2: Comparison of the intervention and control groups, concerning the HBM and self-care behaviors in type 2 diabetic patients before and after the intervention.

but after the educational intervention was applied there is statistically significant difference between the mean scores of HBM constructs and self-care ($p < 0.05$). By increasing the perceived susceptibility, severity, benefits, barriers and self-efficacy, the self-care behaviors increased as well.

DISCUSSION

Education can be considered as cornerstone for diabetes management, so finding a suitable method to improve self behaviour is of great importance for type II diabetic patients. Since there have been no study on HBM-based studies on self-efficacy in diabetic patients in India, this study was conducted to examine the effect of Health Belief Model on the self behaviour of patients with type 2 diabetes.

The Health Belief Model is a psychological health behavior change model that was developed by social psychologists in 1950 to explain and predict health-related behaviors particularly in regard to the uptake of health services.^{25,26} It

is one of the best known and most widely used theories in health behavior research.²⁷ It suggests that people's beliefs about health problems, perceived benefits, barriers to action, and self-efficacy explain in health-promoting behavior.²⁸

Preparing training classes suitable for the audience features is one of the necessary principles of any training program as this study tried to present the training session in a such a way that it is suitable according to age and education level of the participants also its easier for them to follow the training session according to their convenience.

In this study, perceived susceptibility of diabetic patients increased after the educational intervention, while the average score of perceived susceptibility shows a little changed in the control group. This increase can be attributed to the training video lectures and group discussions aiming to sensitize the participants.

In this study there were 88 patients in intervention group and 92 patients in the control group belonged to the age group

of 40-60 years. Also to avoid any confounding factors in the study all the parameters were completely match. During the start of the study there were no significant differences between the distribution of demographic variables in both case and control groups ($p > 0.05$).

The results of this study showed that there was an increase in the mean scores of perceived susceptibility, perceived benefits, perceived severity, and self-efficacy and also a decrease in the mean score of perceived barriers after the implementation of the education based implementation of HBM model on the experimental group.

As shown by the results of this study participating in the educational program on HBM increased the mean score of perceived susceptibility and perceived severity in the intervention group in 2 months intervals ($p < 0.05$). Baghianimoghadam et al. in 2010 conducted a study on 80 patients to examine the effect of current education and peer-education on walking in patients having type II diabetes based on HBM. The results of their study showed a significant increase in the mean scores of perceived susceptibility and perceived severity in the peer education group after intervention, which matched with the results of our study.²⁹

The mean scores of perceived severity and perceived benefits in the experimental group increased two months after the educational intervention ($p < 0.05$). The results of study conducted by Shamsi et al on type 2 diabetic mellitus patients also showed an increase in the scores of perceived susceptibility, perceived severity and perceived benefits and a decrease in perceived barriers after 3 months after the intervention.³⁰

Similar study conducted by Mardani et al on educational program for patients, that increased the mean score of the benefits construct and led to a decrease in the mean score of the perceived barriers construct.³¹ Aghamolai et al. in 2006 examined the effects of Health Belief Model application on modifying the self-care behaviors in type II diabetic patients. The results of his study showed that after the educational intervention was applied there was a significant increase occurred in all the constructs of the model and the perceived barriers construct decreased significantly.³² The similar results were obtained from another study performed by Sharifirad et al. in 2008 on 88 patients having type-2 diabetes.³³ Similar study conducted by Fatemeh Bayat et al in 2013 showed a positive and significant impact on extended health model belief constructs in experimental group at 3 & 6 months after the intervention which was similar to the results of our study.³⁴

In 2011 in Patrick's conducted a study to assess the effect of diabetic patient's education and self-management education in type-2 diabetes, the results of his study shows a significant increase in the mean score of self-efficacy 6 months after the educational intervention, which is in accordance with the results of our study.³⁵ Heijden et al. in 2012, tests the effects of an exercise intervention, based on self-efficacy for inactive patients with type-2 diabetes, showed a significant improvement in the self-efficacy of the experimental group.³⁶

One of the limitations in conducting this study was face to face interaction during the training was not there, sample size is small, and it was a single center study, so further studies must be conducted involving larger population and comparing differences in outcome via face to face training and online training.

CONCLUSION

The educational training intervention on HBM model showed a significant increase in self care behaviors in the intervention group as compared to the control group. In fact, this enhanced behavior can be attributed to the training method that was used in the study. If diabetic patients can be educated and motivated, then this self realization can help them in preventing the secondary complications & this can leads to an increase in the level of care among diabetic patients.

ACKNOWLEDGMENTS

Authors wants to thanks Megha Aggarwal (software engineer) for creating a software that help us to had a look on duration of videos watched by study participants.

Author's contributions: 1 designed the study protocol and conducted the trial, 2,4 frame the questionnaire, 3,4 supervised data collection, 1,4 entered and analyzed the data and 1,2,3,4,5 wrote the manuscript. Then, all authors read and approved the final manuscript.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 01-01-2021; **Accepted:** 26-01-2021; **Published:** 28-02-2021