

Effectiveness of Mobile Application for Promotion of Physical Activity Among Newly Diagnosed Patients of Type II Diabetes – A Randomized Controlled Trial

Abstract

Background: Mobile health intervention shows the positive effects on the management of chronic diseases. Therefore, the study was planned to study the effectiveness of a mobile-based application promotion of physical activity among newly diagnosed patients with type II diabetes. **Methods:** The present study was a parallel-design randomized controlled trial conducted over 2 years. The participants were type II diabetes patients between 18 and 60 years within 3 months of diagnosis who attended the endocrinology outpatient department having knowledge of using smart phone. The sample size was calculated to be 66 and 33 for each arm. The block random design method was adopted for allocation into different arms. A pretested interview schedule was used for the collection of data. Outcomes included body mass index, waist circumference, body fat percentage, and changes in the physical activity was obtained by global physical activity questionnaire (GPAQ). The information thus collected were processed and analyzed using SPSS v 20. **Results:** The study included 66 patients aged between 18 and 60 years, out of which 33 were enrolled into control and 33 into intervention group. The mean age of the participants was 42.29 ± 9.5 years ranged from 25 years to 59 years, 65.2% were males and 34.8% were females. It was observed that a higher proportion of intervention participants met WHO recommendations of physical activity level. Total metabolic equivalent of task (MET) value per minute (Mean \pm SD) was 1347.27 ± 1028.5 in the control group and 1223.03 ± 584.87 in intervention group at baseline and was not different ($P = 0.538$). The total MET value per minute was found to be higher among the intervention group in all follow-ups. There was a significant decrease in weight, BMI, waist circumference, hip circumference, body fat percentage, and systolic blood pressure (SBP) in the intervention group. **Conclusions:** Cost-effective, simple mobile applications may help in routine clinical practice to encourage the patients for the promotion of physical activity.

Keywords: Diabetes mellitus, diabetic patients, life style, mobile app, physical activity

Introduction

Diabetes mellitus is a global epidemic, WHO projects that diabetes will be the seventh leading cause of death in 2030.^[1] The prevalence of diabetes has been rising more rapidly in middle and low-income countries. It is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India.^[2] As per the International Diabetes federation, the prevalence of diabetes among Indian adults is 8.9%.^[3] Diabetes can be treated, and its consequences can be avoided or delayed with a healthy diet, regular physical activity, weight management, smoking cessation,^[4] compliance with medication, and regular medical check-up. Lifestyle modification is found to be

effective in preventing, delaying the onset, and managing type II diabetes mellitus. There is an increasing amount of evidence that patient education is the most effective way to lessen the complications of diabetes and its management.^[5]

India, the second-most populous country in the world and is the second-highest smartphone using country in 2017 followed by China.^[6] Health information browsing on the internet has become a popular activity, patients access health care-related information, learn more about their queries, and make healthcare-related decisions. According to the report of Akerkar *et al.* in a developing country like India, 32% of the patients attending a private tertiary care center in an urban setting were surfing the

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internet and 75% of them accessing the internet for seeking medical information.^[7]

Several recent studies show the positive effects of a mobile health intervention on the management of chronic diseases.^[8,9] A smart phone is one of the most promising tools with a wide user base and easy utility.^[9,10] Android applications have been developed to increase the awareness among diabetic patients and its effectiveness studies were conducted. Applications run on smart phones helped patients to monitor meals and medication for the management of chronic diseases including diabetes and also improved communication with medical staff as well as the patient's compliance.^[9] In a study by Kim YJ *et al.*, smartphone-based application was developed, which had shown positive changes in diabetes-related self-care activities and increase user satisfaction.^[9] There is a need for the development of android application and checking its effectiveness for monitoring and guiding the patients for their self-management of the disease in this part of India. As the prevalence of diabetes in Odisha is quite high, and a large number of patients were attending this tertiary care hospital for their diabetes management situated in the urban area of Odisha. So this study was planned to be carried out in this hospital to study the effectiveness of a mobile-based application promotion of physical activity among newly diagnosed patients with type II diabetes.

Methods

The present study was a parallel-design randomized controlled trial conducted over 2 years from 01.10.2016 to 31.10.2018 after clearance by the institutional ethics committee. The ethics committee code was DMR/IMS/-SH/SOA/16006. The trial was registered in the Clinical Trial Registry of India and the registration number was CTRI/2017/02/007911.

Type II diabetes mellitus (T2DM) patients aged between 18 and 60 years within 3 months of diagnosis, who attended the endocrinology outpatient department during the study period, able to read and write in English, and having knowledge in using smart phone and computer were selected for the study purpose. Patients registered on the day of the interview were selected using a simple random sampling method. The recruited patients randomly allocated to the two arms. The sample size was calculated to be 66, 33 for each arm. The block random design method was adopted for the selection of patients into different arms. The intervention group was the mobile interactive platform, an android-based application. The application proposes to take the following inputs, record them, and synchronize with the server established at the institute/university. The control group was an online platform on the website. It included options for recording data similar to that of the mobile application except for the provisions like reminders.

The study subjects were interviewed using a predesigned, pretested, and semi-structured interview schedule. Those

patients who were reluctant and refused strictly were excluded from the study. The collection of data was done in a friendly atmosphere after obtaining informed consent. Anthropometric parameters like height, weight, body mass index, waist circumference, waist-hip ratio, skinfold thickness, etc., and blood pressure were recorded. All patients were contacted by phone at 3 months' interval and motivated to come for follow-up at 3, 6, 9, and 12 months. The patients were interviewed by a follow-up schedule and all anthropometric measurements were done in all follow-ups.

Height was measured by a stadiometer to the nearest centimeter without shoes. Weight was measured by an electronic weighing machine. Weight was measured with light clothing and without footwear to the nearest 100 g. BMI was calculated as weight in kg divided by height in meter square. Waist circumference was measured at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest to the nearest 0.1 cm. Hip circumference was measured around the widest portion of the buttocks, with the tape parallel to the floor to the nearest 0.1 cm. Blood pressure was measured with a standard clinical sphygmomanometer, using a stethoscope placed over the brachial artery pulse.

Outcomes included anthropometric measurements for the weight (kg), body mass index (kg/m^2), waist circumference (cm), and body fat percentage collected at baseline and in all follow-ups at 3, 6, 9, and 12 months. Changes in physical activity were obtained by a global physical activity questionnaire (GPAQ) of the World Health Organization, which was a validated tool.

The information thus collected were processed and analyzed using SPSS v 20 licensed to the institute. Intention to treat (ITT) analysis was adopted. Repeated measures analysis of variance (ANOVA) test was done for analyzing continuous data and Cochran Q test was done for categorical data.

Results

The study included 66 patients aged between 18 and 60 years, out of which 33 were enrolled into control and 33 into intervention group. They were contacted telephonically at 3 months' interval and motivated to come for follow up at 3, 6, 9, and 12 months. Data so obtained were analyzed and interpreted accordingly.

Baseline characteristics like the mean age of the participants were 42.29 ± 9.5 years ranged from 25 years to 59 years, 65.2% were males and 34.8% were females. There is no difference observed between the control and intervention groups in socio-demographic characteristics [Table 1].

The physical activity of diabetic patients was assessed by using a global physical activity questionnaire of the World Health organization. The median of total physical

Table 1: Socio demographic profile

Variables		Overall (n=66) n (%)	Control (n=33) n (%)	Intervention (n=33) n (%)	Significance
Age in years (Mean±SD)		42.29±9.5	42.88±9.5	41.70±9.6	0.617
Gender	Male	44 (66.66)	23 (69.7)	21 (63.6)	0.601
	Female	22 (33.33)	10 (30.3)	12 (36.4)	
Religion	Hindu	63 (95.5)	31 (93.9)	32 (97)	0.500
	Minorities (Muslim, Christian)	3 (4.5)	2 (6)	1 (3)	
Caste	General	59 (89.4)	29 (87.9)	30 (90.9)	0.509
	Scheduled caste	3 (4.5)	1 (3)	2 (6.1)	
	Socioeconomically Backward	4 (6.1)	2 (6)	1 (3)	
Family Type	Joint	38 (57.6)	22 (66.7)	15 (45.5)	0.083
	Nuclear	28 (42.4)	11 (33.3)	18 (54.5)	
Marital status	Single	7 (10.6)	5 (15.20)	2 (6.1)	0.230
	Married	59 (89.4)	28 (84.8)	29 (87.9)	
Education level	Secondary and higher secondary	24 (36.4)	15 (45.5)	9 (27.3)	0.125
	Graduate and above	42 (63.6)	18 (54.5)	24 (72.7)	
Per Capita Income (Rs/month)	6261 and above	34 (51.5)	14 (42.4)	20 (60.6)	0.294
	3099-6260	23 (34.8)	14 (42.4)	9 (27.3)	
Occupation	1835-3098	9 (13.6)	5 (15.2)	4 (12.1)	0.536
	Professional	18 (27.3)	9 (27.3)	9 (27.3)	
	Semi-professional	17 (25.8)	9 (27.3)	8 (24.2)	
	Shop owner/farmer	7 (10.6)	3 (9.1)	4 (12.1)	
	Skilled Worker	4 (6.1)	2 (6.1)	1 (3)	
unemployed		2 (3.0)	1 (3)	0	
	Housewife	16 (27.3)	7 (21.2)	11 (33.3)	

activity MET-min/week was 1190 min/week, and it is not different between both groups ($P = 0.538$). As per World health organization recommendations, the physical activity cut off value in MET minutes per week is 600. Those who had MET minutes per week <600 were not meeting WHO recommendations of adequate physical activity. In our study, 27.3% of patients were not meeting WHO recommendations, and it is not significantly different in the control and intervention group ($P = 0.097$) [Table 2].

Among the study participants, it was observed that a higher proportion of intervention participants met WHO recommendations of physical activity level, but there was no significant difference across groups ($P = 0.782$) during all follow-ups. The total MET value per minute was also found to be higher among intervention group participants in all follow-ups [Tables 3 and 4]. The mean weight of the participants was 71.81 ± 12.78 kg. The mean waist and hip circumference were found to be 95.52 ± 10.07 and 98.58 ± 7.48 cm, respectively. The mean waist-hip ratio was 0.97 ± 0.62 . The mean SBP and diastolic blood pressure (DBP) were 128.79 ± 10.69 and 80.29 ± 8.08 , respectively. The difference between anthropometric parameters was not significant at baseline. Repeated measures ANOVA was conducted to see the significant changes both in the control group and intervention group. Wilk's lambda was significant for HC, body fat percentage, and SBP for the control group. There was a significant decrease in weight, BMI, waist circumference,

hip circumference, body fat percentage, and SBP in the intervention group [Table 5].

Discussion

The study was carried out in a tertiary care hospital to study the effectiveness of a mobile-based application for the promotion of physical activity among newly diagnosed patients with T2DM.

The median of total physical activity MET-min/week was 1190 min/week, and it was not different between both groups. As per WHO recommendations, the physical activity cut off value in MET minutes per week is 600. Those who had MET minutes per week <600 were not meeting WHO recommendations of adequate physical activity. In our study, 27.3% of patients were not meeting WHO recommendations, and it is not significantly different in the control and intervention group. Among the study participants, it was observed that a higher proportion of intervention participants met WHO recommendations of physical activity level, but there was no significant difference across groups during all follow-ups. The total MET value per minute was also found to be higher among intervention group participants in all follow-ups. The benefits of physical activity are widely known, but it continues to be the most prevalent (yet modifiable) risk factor for 51% of the Canadian adult population.^[11] Even a modest increase in physical activity, either aerobic or resistance training, can improve glycemia and overall

Table 2: Physical activity of patients as per global physical activity questionnaire (GPAQ) at baseline

GPAQ Scoring	Total (n=66) n (%)	Control (n=33) n (%)	Intervention (n=33) n (%)	Significance
Total physical activity MET-minutes/week	1190	1260	1120	0.538
Median (IQR)	(IQR: 420-1680)	(IQR: 0-1680)	(IQR: 780-1680)	
Meeting WHO recommendation	48 (72.7)	21 (63.6)	27 (81.8)	0.097
Not meeting WHO recommendation	18 (27.3)	12 (36.4)	6 (18.2)	

Table 3: Physical activity of patients as per global physical activity questionnaire - follow ups

Group	GPAQ Scoring	Baseline	1 st Follow up	2 nd Follow up	3 rd Follow up	4 th Follow up	Significance
Control	Meeting WHO recommendation	21 (63.6)	27 (87.1)	19 (76)	16 (72.7)	16 (80)	0.117
	Not meeting WHO recommendation	12 (36.4)	4 (12.9)	6 (24)	6 (27.3)	4 (20)	
Intervention	Meeting WHO recommendation	27 (81.8)	22 (75.9)	22 (84.6)	20 (87)	18 (81.8)	0.782
	Not meeting WHO recommendation	6 (18.2)	7 (24.1)	4 (15.4)	3 (13)	4 (18.2)	

Table 4: Total MET Value per minute (Mean±Standard Deviation)

Group	Baseline	1 st Follow up	2 nd Follow up	3 rd Follow up	4 th Follow up
Control	1347.27±1028.5	1667.27±1190.35	1304.84±785.00	1312.72±819.44	1260.00±740.89
Intervention	1223.03±584.87	1315.15±708.46	1469.69±724.03	1338.78±643.77	1343.63±703.82

diabetes control.^[12] A study by Tapehsari BS *et al.* found that increasing physical activity had a significant effect on the quality of life among individuals with type 2 diabetes.^[13]

There is a growing body of research that explores the benefits of frequent breaks in prolonged periods of sedentary behavior on glycemic control, specifically postprandial spikes. For example, reducing the time spent in sedentary positions (sitting or lying) can moderate the pathologic progression of type 2 diabetes.^[12] Sleep was adequate among 74.2% participants and not different between the control and intervention group. Among the study participants, it was observed that the proportion of participants with adequate sleep increased in both groups.

The mean waist and hip circumference were found to be 95.52 ± 10.07 and 98.58 ± 7.48 cm, respectively. The mean waist-hip ratio was 0.97 ± 0.62, which is very much similar to the study done by Gaidhane *et al.*^[14] as they found it 0.89. The mean SBP and DBP were 128.79 ± 10.69 and 80.29 ± 8.08, respectively. Repeated measures ANOVA was conducted to see the significant changes both in the control group and intervention group. Wilk's lambda was significant for HC, body fat percentage, and SBP for the control group. There was a significant decrease in weight, BMI, waist circumference, hip circumference, body fat percentage, and SBP in the intervention group. The mean BMI of the study participants was 27.47 ± 4.34 kg/m². Both control and intervention groups contain 2 (6.1%) normal patients while overweight patients were more in the control group (78.8%) than intervention group (69.7%). But the

intervention group contains more obese patients (24.2%) than the control group (15.2%). Forty-two (42%) patients were overweight and 17% were found to be obese. Our finding was higher than the results found from a similar study done by Das *et al.*^[15], which was 23.96 ± 3.51 kg/m². Then mean BMI found to be 24.4 ± 4.1 kg/m² from a study conducted by Fatema *et al.*^[16]

Physical inactivity is one of the top modifiable factors among type 2 diabetes. Low physical activity levels i.e., sedentary behavior is associated with obesity and further leads to complications. Achieving at least 150 min per week of moderate-intensity aerobic physical activity or 75 min per week of vigorous-intensity aerobic physical activity or a combination of the two with muscle-strengthening at least 2 days per week is important for your overall cardiovascular health.^[17] Increase of physical activity leads to a decrease in blood sugar level and prevent from the complications of diabetes. The total MET value per minute was also found to be higher among intervention group participants in all follow-ups, which reflects the success of intervention.

Conclusions

Mobile applications intervention program on healthy lifestyle significantly improves the weight, BMI, waist circumference, hip circumference, body fat percentage, blood pressure, and physical activity among the type II diabetes patients. So, cost-effective, simple mobile applications may help in routine clinical practice to encourage the patients for the promotion of physical

Table 5: Anthropometric measurements and blood pressure

Parameters	Control (Mean±SD)				Intervention (Mean±SD)					
	Baseline	1 st Follow up	2 nd Follow up	3 rd Follow up	4 th Follow up	Baseline	1 st Follow up	2 nd Follow up	3 rd Follow up	4 th Follow up
Weight (kg)	71.47±11.43	70.76±11.99	71.20±12.32	71.04±12.55	71.20±12.76	71.23±14.15	70.39±15.46	69.69±14.07	69.19±13.80	69.27±13.88
Body Mass Index (kg/m ²)	26.80±2.76	26.50±2.77	26.66±2.95	26.60±3.06	26.66±3.18	27.73±5.14	27.42±5.86	27.14±5.17	26.94±5.00	26.97±5.04
Waist circumference (cm)	96.48±9.34	94.63±9.54	94.48±9.65	93.69±10.48	94.24±10.70	94.84±9.89	93.33±9.43	92.81±9.75	92.42±9.59	91.96±9.75
Hip circumference (cm)	98.58±6.21	96.60±6.49	95.97±6.82	95.03±7.35	95.57±7.29	98.57±8.67	96.75±8.50	95.90±8.58	95.81±8.48	95.09±8.86
Waist Hip Ratio	0.977±0.057	0.978±0.058	0.983±0.057	0.984±0.060	0.984±0.063	0.962±0.055	0.964±0.052	0.967±0.051	0.964±0.053	0.967±0.050
Body Fat %	22.00±6.08	19.84±4.70	20.92±4.71	18.40±2.90	19.15±4.45	21.91±5.91	20.72±4.72	20.54±5.01	18.00±4.23	19.04±4.89
Systolic Blood Pressure	129.48±10.71	123.18±9.36	121.48±7.57	121.94±6.42	119.88±7.31	128.09±10.78	120.70±13.88	119.21±7.74	118.82±8.48	119.15±7.75
Diastolic Blood pressure	81.24±8.03	79.12±8.39	79.12±4.70	79.94±4.75	78.73±5.78	79.33±8.14	77.30±5.46	78.79±4.05	77.82±5.53	78.15±4.83

activity, which will further reduce complications of diabetes.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

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