Effects of Pedometer Based Walking Program on Diabetes Treatment Satisfaction Scores in Patients with Type 2 Diabetes Mellitus

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Abstract: <u>Objective-</u> To determine the scores of patient satisfaction with two goal setting pedometer based walking program for people with type 2 diabetes, one employing supervised exercise group with pedometer and the other employing self reported group with pedometer. <u>Methodology</u>- A total of 102 type 2 diabetic outpatients (28 women, 74 men) between the age of 40-70 years were recruited and randomly allocated into 3 groups: supervised exercise group with pedometer (group A), self reported exercise group with pedometer (group B) and a control group (group C) for 16 weeks. Results- Group A participants started with low values on pre intervention observation (Current treatment, convenience, flexibility, understanding, recommend to others and continue with) and after 16 weeks of intervention, the mean values increased significantly. Similarly, there was an increase in the mean values of all the 6 items (Current treatment, convenience, flexibility, understanding, recommends to others and continues with treatment) in Group B after 16 weeks. Conclusion- Pedometer determined activity has the potential to improve the diabetes treatment satisfaction scores in Asian Indians with type 2 diabetes.

Keywords: type 2 diabetes, pedometer, diabetes treatment satisfaction and walking

1. Introduction

Type 2 Diabetes Mellitus (T2DM) is an epidemic affecting millions of people worldwide constituting nearly 90% of the diabetic population in any country [1]. India, the world's second populous country, now has more people with T2DM (more than 50 million) than any other nation [2]. The primary driver of the epidemic is rapid epidemiological transition associated with change in dietary patterns and decreased physical activity as evident from a higher prevalence of diabetes in the urban population [3].T2DM is preventable by lifestyle changes and to a lesser extent, medications [4]. Aerobic training has been promoted as the most effective mode of exercise for treating T2DM with improvements in lipid profiles and insulin sensitivity [5]. Older adults with T2DM are advised to undertake exercises that maintain or improve balance as a means of increasing joint range of motion and reducing risk of injury [6]. A well planned program will optimize the likelihood of a safe and effective response by addressing what types of exercise can be performed and how much exercise is recommended [7].

Walking appears to be the preferred activity among sedentary individuals taking up physical activity [8]. Tools to assist in the monitoring of physical activity and enhanced motivation may play an important role in changing exercise behaviours [9]. Many studies have been conducted that have used pedometers as a measurement tool of physical activity through walking [10] [11]. Pedometers are inexpensive, light weight and unobtrusive tools that measure physical activity by responding to vertical acceleration of the hip during gait cycles with acceptable accuracy [12] [13]. Researchers have reported that pedometer based walking programs have increased walking by an average of 3,000 steps per day [14]

as well as showing improvements in parameters of glycaemic control [10].. Taking 10,000 steps/day appears to be a reasonable target of daily activity for healthy adults and several studies have documented the health benefits of attaining these levels [15]. Regarding the efficacy of supervised walking program Negri et al, 2010 [16] reported that, supervised walking may be beneficial as it induces favourable changes and increases functional capacity in diabetic subjects but compliance remains a crucial issue. Dunn et al., 1999 [17] found both lifestyle and structured interventions produced significant and comparable beneficial changes in physical activity, cardiorespiratory fitness, blood pressure and percentage of body fat. Tully et al., 2007 [18] reported that adherence to unsupervised home based walking programmes using pedometers for self monitoring, is higher than levels of adherence previously reported for many research studies of other exercise programmes. Thus there has been a mixed response and conflicting results available regarding the efficacy of self reported and supervised physical activity programs.

Patient satisfaction has been shown to affect patients' healthrelated decisions and treatment-related behaviours, which in turn, substantially impact the success of treatment outcomes [19]. The Diabetes Treatment Satisfaction Questionnaire (DTSQ) has been specifically designed to measure satisfaction with diabetes treatment regimens in people with diabetes [20]. In focussing on satisfaction with treatment of diabetes, the present satisfaction questionnaire is able to include items concerned with satisfaction with perceived frequency of hyper- and hypoglycaemia which are important aspects of the short term outcomes of diabetes management [20]. Hypoglycemia is an unwanted complication of the treatment of patients with diabetes, and is particularly troublesome in patients with hypoglycaemia unawareness [21]. Early recognition of hypoglycemia risk factors, selfmonitoring of blood glucose, selection of appropriate treatment regimens with minimal or no risk of hypoglycemia and appropriate educational programs for healthcare professionals and patients with diabetes are the major ways forward to maintain good glycemic control, minimize the risk of hypoglycemia and thereby prevent long-term complications [22].

With continued increase in the growth of numbers of T2DM individuals, importance of physical activity has caught importance for the management of this disease. Performing walking using pedometer can help in quantification of the activity performed. Studies have shown the effectiveness of both physical activity protocols, like 30-40 minutes of moderate intensity walking [23] as well as the effectivess of achieving 10,000 steps/day in T2DM [24]. Many previous studies have focussed on physical activity responses on physiological parameters, but no attention has been paid on treatment satisfaction variables among type 2 diabetes individuals. However, there is scarcity of literature on the efficacy of achieving cumulative physical activity measured in step counts in the target range of 10,000 steps/day in T2DM irrespective of intensity in diabetic Asian Indians when used as a self reported activity. Therefore, the purpose of present study was to evaluate the effectiveness of supervised walking with pedometer on treatment satisfaction parameters in comparison with self reported walking with pedometer in individuals with T2DM.

2. Material and Methodology

The prospective randomized controlled trial study was conducted in the department of sports medicine and physiotherapy, Guru Nanak Dev University, Amritsar

2.1 Study Participants

A total of 102 outpatients with T2DM (28 women and 74 men) were recruited from Amritsar. Informed consent and measurements were completed before baseline randomization. The study was given approval by Institutional ethical committee of Guru Nanak Dev University, Amritsar (Ref. No.- 321/SMP). Subjects were recruited after the explanation of protocol and clearance from physician. Demographic information and health history were obtained from all the participants. Men and women between age of 40 to 70 years were included in the study. The inclusion criteria were as follows (i) \geq 1 year diagnosis of type 2 diabetes (ii) not taking insulin (iii) no physical activity limitation (iv) were not enrolled in any other physical activity program previously or simultaneously. Exclusion criteria were disease or condition e.g. any evidence of coronary artery disease, uncontrolled hypertension, diabetic complications and moderate-severe orthopedic/ cardiovascular/respiratory condition that would interfere with physical activity.

2.2 Procedure

Participants were randomly allocated into one of the three groups by the random lottery approach: supervised exercise group with pedometer (group A), self reported exercise group with pedometer (group B) and a control group (group C). A few initial sessions of familiarization with pedometer and the understanding of Borg scale [27] were given to all the participants in group A and group B. Similar instructions described by Tudor Locke et al (2002) [25] were given to all the subjects about handling and placement of the pedometer. Use of Borg scale (Rate of perceived exertion) with target perceived intensity of moderate, somewhat hard or hard is sometimes recommended as a possible alternative to heart rate based on maximal exercise testing. RPE scales are reported as valid and reliable for assessing the level of exertion during aerobic exercise [26]. RPE is a subjective measure which provides exertion rating and gives a fairly good estimate of actual heart rate during physical activity. Two initial sessions of physical activity for familiarization with RPE scales were given to the subjects in group A to let them understand the relation between capability of doing physical activity and required effort intensity. Subjects in group A were taught to adjust the intensity of the activity by speeding up and slowing down the speed of walking through RPE scale. No dietary modifications were advised while this intervention. Patients were advised to eat 1-2 hrs before exercise to avoid hypoglycaemia and maintain hydration levels. Baseline readings for all subjects were collected before randomization. Baseline data collection was conducted for 7 days to get an estimated number of steps for group A and group B. In group A, we found approximately 3000 steps for most of the subjects in 30 minutes while in group B there were approximately 5000 – 6000 steps/day.

2.2.1 Supervised Exercise with Pedometer (Group A)

In this group we aimed at achieving around 4000 steps/30-40 minutes under the supervision of physiotherapist. Participants walked using pedometer to achieve a target of 150 min/ week moderate intensity of physical activity. Intensity of exercise was increased gradually. Subjects in group A did warm up for at least 5 minutes, keeping their target RPE in the 'light' range on the borg scale, then they were instructed to increase intensity up-to their target heart rate range 'somewhat hard' (12-14) on RPE. Subjects in group A were encouraged to increase their step counts up-to 4000/ 30-40 minutes and maintain it till the end of 16 weeks. All the participants were asked to report for physical activity sessions as per their schedule and were instructed to walk with pedometer under supervision for 5 days a week. A log book was maintained for all the participants. Each session took 45 - 50 minutes which included warming up and cooling down.

2.2.2 Self Reported exercise group with pedometer (Group B)

In this group participants were instructed to wear pedometer for 5 days in a week from "morning to night till sleeping" for 16 weeks. Tudor-Locke et al [27], 2002 have proposed that daily steps in excess of 8000 may be roughly equivalent to the accumulation of 30 min of moderate-intensity activity on a single day. A diary was provided to all 2 the participants so that they can record their number of steps/day. Participants were taught about the handling/working of the pedometer and were instructed to report after 16 weeks for sharing experience on change in quality of life and well being. The investigator contacted the participants on phone for their step counts. They were told to achieve target of 10,000 steps/day during intervention period without any consideration to intensity and duration. Participants could contact the researcher at any point of time for any difficulty related either to exercise protocol or the handling of pedometer. Subjects were instructed to set the pedometer to zero early morning and record the steps before going to bed

2.2.3 Control group (Group C)

Participants were asked to maintain their lifestyle and were encouraged to walk. They were not enrolled in any other intervention throughout 16 weeks. Neither pedometers nor step count data were collected.

Trial was approved by Clinical trial registry India (CTRI) [CTRI/2012/10/003034)

2.3 Measurements

2.3.1 Diabetes Treatment Satisfaction Questionnaire (DTSQ)

The DTSQ was used to measure patient's satisfaction with treatment. It consists of a six item scale assessing treatment and two items assessing perceived frequency of hyperglycaemia and hypoglycaemia. As a part of our study, it was important for us to obtain feedback about the extent to which subjects were satisfied (or dissatisfied) with physical activity intervention. Intervention satisfaction was computed through six parameters 1, 4,5,6,7 and 8, which has a minimum of zero and a maximum of 36 on the scale. Item 2 (perceived frequency of hyperglycaemia) and 3 (perceived frequency of hypoglycaemia) are treated individually in data analysis.

2.4 Statistical Analysis

Paired t test were used within the groups to compare Mean±SD for all the parameters at baseline and at the end of 16 weeks. Differences between the groups were compared using analysis of variance (ANOVA). Statistical difference was further analyzed by Post hoc analysis using Bonferroni

method. STATA 11.0 statistical software was used for data analysis. In this study p-value less than 0.05 has been considered as statistically significant.

3. Results and Analysis

In the present study, majority of subjects aged 40 - 70 years reported having diabetes for more than 5 years. The mean of duration of diabetes (in years) for Group A (6.2±2.4), Group B (5.8±2.2) and Group C (5.5±2.1). DTSQ was administered to evaluate the success of intervention (self reported and supervised walking with pedometer). All the eight parameters of DTSQ were examined individually along-with monitoring of satisfaction from these parameters while interventional period.

Table 1 shows the adjusted means and post hoc (t) comparisons for all the DTSQ items. On multiple comparison using one way ANOVA statistically non significant differences were found in between all the three groups at baseline for DTSQ. This shows that groups were comparable. It is observed from the Figure 1 that the mean scores of all the items in Group A (Current treatment, convenience, flexibility, understanding, recommend to others and continue with) on pre intervention observation started with the low values and after 16 weeks of intervention, the mean values increased significantly. Similarly, there was an increase in the mean vales of all the 6 items (Current flexibility, treatment. convenience, understanding, recommends to others and continues with treatment) in Group B after 16 weeks. Insignificant outcome was observed in the control group, i.e., the average of all the six items (current treatment, convenience, flexibility, understanding, recommend to others and continue with treatment) was reduced after 16 weeks of the trial (Figure-3)



Figure 1: Effect of Supervised intervention (Group A) on treatment satisfaction score (differences between baseline and 16 weeks scores for all participants)

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Percentage frequency of hyperglycaemia and hypoglycaemia in both experimental groups was higher at baseline and decreased significantly after 16 weeks of intervention program, though reduction was significantly greater for subjects in supervised group (Figure 1 and Figure 2). Reduction in the percentage of hyperglycaemia and hypoglycaemia depicted better glucose control in Group A and Group B. Subjects in Group B found their intervention more convenient than the subjects in Group A, whereas, the overall improvement in total treatment satisfaction scores was greater in Group A than in Group B (Table 1) [Figure 4]. It can be observed from the Table 1, ANOVA results bring out that the F-value associated with the comparison was significant for all items except convenience after 16 weeks indicating that the group means differ significantly. Thus, we observed that participants in Group A and Group B were more satisfied in comparison to Group C (Table 1).

Items	Groups			Anova		Post Hoc (Bonferroni)		
1. Current treatment	Group-A	Group B	Group C	F	Р	A Vs B		B Vs C
Pre training	4.6±0.97	4.5±0.85		1.14	0.32	1.0	0.88	0.43
Post training	5.1±0.64	4.9±0.63	4.6±0.70	4.66	0.01**	0.74	0.01**	0.22
P Value	0.0002***	0.002**	0.011**					
2. Percentage frequency								
hyperglycaemia								
Pre training	1.57±1.11	1.51±0.95	1.3±0.64	0.70	0.49	1.0	0.77	1.0
Post training	0.86 ± 0.62	1.21±0.56	1.4±0.61	6.27	0.002**	0.09	0.002**	0.67
P Value	0.0001***	0.032*	0.183					
3. Percentage frequency								
hypoglycaemia								
Pre training	1.7±0.95	1.68 ± 0.71	1.56 ± 0.71	0.33	0.72	1.0	1.0	1.0
Post training	1.2±0.44	1.42±0.5	1.68 ± 0.64	4.76	0.01**	0.77	0.009**	0.20
P Value	0.005**	0.011**	0.16					
1. Convenience								
Pre training	4.6±0.79	4.5±0.85	4.7±0.55	0.86	0.42	1.0	1.0	0.59
Post training	4.9±0.66	4.9±0.63	4.6±0.65	2.78	0.06	1.0	0.13	0.14
P Value	0.031*	0.002**	0.05*					
2. Flexibility								
Pre training	4.6±0.73	4.54 ± 0.78	4.37±0.60	1.08	0.34	1.0	0.44	1.0
Post training	5±0.49	5.14 ± 0.44	4.21±0.60	28.6	0.01**	1.0	0.001***	0.001***
P Value	0.0001***	0.0002***	0.05*					
3. Understanding								
Pre training	4.3±0.63	4.3±0.68	4.28 ± 0.45	0.11	0.89	1.0	1.0	1.0
Post training	4.5±0.57	4.5±0.50	4.25±0.43	3.24	0.041*	1.0	0.09	0.09
P Value	0.043*	0.022*	0.32					
4. Recommend to others								
Pre training	4.3±0.87	4.4±0.60	4.2±0.49	0.83	0.43	1.0	1.0	0.63
Post training	4.9±0.60	5±0.38	4±0.59	29.63	0.001**	1.0	0.001***	0.001***
P Value	0.0002***	0.001***	0.031*					
5. Continue with								
Pre training	4.5±0.69	4.3±0.67	4.8±0.59	4.79	0.01**	0.31	0.41	0.008
Post training	5.1±0.64	4.9±0.63	4.6±0.7	4.66	0.01**	0.74	0.01**	0.22
P Value	0.0001***	0.0001***	0.022*					
Treatment Satisfaction								
Pre training	27.2±4.1	26.7±3.9	27.3±2.6	0.29	0.75	1.0	1.0	1.0
Post training	29.6±2.5	29.5±2.4	26.5±2.7	14.26	0.001***	1.0	0.001***	0.001***
P value	0.0001***	0.0001***	0.001***					

Table 1: Pre intervention and post intervention changes in Diabetes Treatment Satisfaction Questionnaire

Note: The abbreviations used in the tables appearing in this chapter mean as under: SD-Standard Deviation, P-Probability value, ***- $p \le 0.001$, **- $P \le 0.01$, *- $P \le 0.05$

4. Discussion

Diabetes has emerged as a major healthcare problem in India and it is only next to China which leads world in number of diabetics [28]. In the Diabcare Asia Study (1998) it was observed that, of all the patients with diabetes who were taking treatment from specialized centres, more than 50% of patients were on diet therapy, 59.9% were receiving oral antidiabetic agents, 22% of patients were taking insulin and 19% were on both insulin and oral drugs [29]. The focus on physical activity for control of diabetes and its complications is lacking in India.

The aim of the present study was to determine the effectiveness of two different pedometer based ambulatory protocols, one supervised and other self reported on treatment satisfaction parameters, among T2DM individuals. To the best of our knowledge, no other study has shown the impact of pedometer based walking intervention on treatment satisfaction in Asian Indians.





Figure 2: Effect of self reported intervention (Group B) on treatment satisfaction score (differences between baseline and 16 weeks score for all participants)



Figure 3: Changes in the treatment score of Control group (Group C)

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Figure 4: Changes in the treatment satisfaction scores after 16 weeks in all the three groups

DTSQ has been specifically designed to measure satisfaction from diabetes treatment regimens in people with diabetes. In this study, treatment satisfaction levels significantly improved after addition of walking with pedometer in both the experimental groups. Treatment satisfaction improved significantly from baseline to 16th week in both experimental groups as it improved by 8.8 % in Group A and 10.4 % in Group B. However, in control group treatment satisfaction scores declined by 2.93% [Table 1]. Though Group B improvement scores have been better for overall treatment satisfaction but the frequency of perceived hyperglycaemia and hypoglycaemia showed better improvement in Group A than that of Group B. Group A experienced 45% and 29% decrease respectively in perceived frequency of hyperglycaemia and hypoglycaemia, whereas Group B showed only 19 % and 15% decrease respectively in perceived frequency of hyperglycaemia and hypoglycaemia. In addition to this, patients in Group B also reported 8.8% improvement in treatment convenience, 13.2% in flexibility and 13.9% in satisfaction with continuing treatment. This suggests that use of pedometer in self reported interventions invite greater acceptance and ease for subjects compared to pedometer based interventions of supervised groups. However for important parameters like reduction in the perceived frequency of hyperglycaemia and hypoglycaemia, supervised group displayed better results than that of self reported group. Saatci et al, 2010 [30] reported that hypoglycaemia and hyperglycaemia perceptions were not significantly related to the type of treatment. In absence of literature advocating the thought of reduced perceived levels of hyperglycaemia and hypoglycaemia due to pedometer based interventions and also other unknown factors outside purview of our study, it is difficult to support with proper reasoning, why Group A experienced better benefits in these two outcomes (Perceived frequency of hyperglycemias and hypoglycaemia). Patients should be supported for being active participants in the management of their condition and balancing the biomedical and psychosocial outcomes [31].

It may be concluded on the basis of observation that both self reported and supervised program were effective depending upon personal inclination, time and social factors. This will serve as evidence in establishing benefits from achieving 10,000 steps per day irrespective of intensity. It has been concluded that whatever be the nature of intervention (supervised or self reported), the use of a pedometer may lead to more realistic assessment and motivation to T2DM individuals in everyday physical activity. Our findings confirm that there is a association in physical activity and T2DM patient satisfaction.

5. Future Scope

The findings of this study would help clinical practitioners, diabetologists and physical therapist to have a better idea, how physical activity is affecting type 2 diabetes individuals in improving different aspects of treatment satisfaction.

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Access to questionnaires:

www.healthpsychologyresearch.com

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