

Physical Activity and Quality of Life in People with Type 2 Diabetes Mellitus: A Randomized Controlled Trial

Abstract

Background: Chronic diseases such as diabetes have an adverse effect on the quality of life (QOL) of patients. It has been shown physical activity can improve the quality of life. **Aims:** The aim of current study was to determine the effectiveness of Physical activity package (PAP) on the quality of life (QOL) of individuals with type 2 diabetes. **Methods:** Using a randomized controlled trial, 100 individuals with type 2 diabetes were studied. The patients were selected from endocrine clinic of a teaching hospital of Iran University of Medical Sciences. Subjects were randomly assigned to intervention (PAP and routine care), and control (just education and routine care) groups. The WHO Quality of Life- brief (WHOQOL - BREF) Questionnaire was completed by all patients at the beginning and after three months. The IPAQ (long form) physical activity questionnaire was completed at the beginning, 1.5 and 3 months follow-up for all subjects. The Mann-Whitney U, Chi-square and repeated measure of analysis of variance (ANOVA) tests were used to analysis of data. The significant level was considered as 0.05. **Results:** Average of age was 46.22 ± 6.10 years. The scores of physical, psychological and environmental domains of WHOQOL - BREF were 27.42 ± 3.34 , 21.44 ± 3.24 and 27.02 ± 4.68 in intervention group versus 22.58 ± 3.71 , 17.29 ± 3.46 , and 24.41 ± 3.92 , in control group respectively. These differences were statistically significant ($P < 0.0001$). There was not any significant difference for social relations domain across two groups. **Conclusions:** Physical activity package had a significant effect on all aspects of QOL just social relations of individuals with type 2 diabetes. It seems social relations activities needs more time to change.

Keyword: Diabetes type 2, exercise prescription, physical activity, quality of life

Introduction

The trend of type 2 diabetes (T2D) as the most common disease of metabolic disorders has been increasing in recent years.^[1] By 2035, 592 million general public will have T2D.^[2] A systematic review on the prevalence of T2D in Iran reported a wide range from round 3% up to 20%. Also the risk of T2D was 1.7% higher in women than men.^[3] Individuals with T2D have insulin resistance, and usually have relative (rather than absolute) insulin deficiency and often associated with impaired function and organ failure, especially peripheral nerves, heart, eyes, kidneys and blood vessels.^[4] Type 2 diabetes and its complications are major causes of illness, disability and early death.^[5] Inadequate physical activity is a key risk factor for non- communicable diseases such as T2D. Universally, 1 in 4 adults do not have enough activity, and more than 80% of

the adolescent population in the world has insufficient physical activity.^[6] According to World Health Organization (WHO) statistics for 2016, the prevalence of diabetes in women and men with physical inactivity is 41.6% and 22.3%, in Iran respectively.^[7] Diabetes mellitus leads to increased mortality, disability and loss of quality of life, and high social and economic costs.^[8] The chronic nature of T2D affects the body, the psyche, the individual and social functioning of the person.^[9] Physical activity offers many benefits in preventing and managing T2D, which includes better control of blood glucose; reduced co-morbidities such as high blood pressure, dyslipidemia and cardiovascular disease, and also reduces mortality and improves quality of life.^[10] Regarding the high prevalence of diabetes in the world and Iran, the incidence of short and long term complications and the direct and indirect costs for the treatment of its complications, it seems that one of the major goals in this

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disease is to minimize complications and maximize the quality of life for people with T2D. Therefore, considering the importance of the issue, we decided to train diabetics to exercise and increase physical activity in leisure time with an exercise prescription. The aim of current study was to determine the effect of Physical Activity Package (PAP) on the quality of life of individuals with T2D.

Methods

Participants and sampling

Using a randomized controlled trial, individuals with T2D who referred to Endocrine Research Center of Iran University of Medical Sciences were enrolled into the study. The method of sampling was convenient (each patient who referred to the clinic and was eligible recruited) from September to October 2016.

The inclusion criteria included men ≤ 45 and women ≤ 55 years old, having type 2 diabetics who were treated with low sugar oral medications or insulin-based drugs with HbA1C ≤ 8.5 . Patients with debilitating diabetic complications who are not able to perform physical activity were excluded.

Randomization was done using function = RAND () the software Excel. We created table of random numbers generated by 100 cells. We assigned even and odd digits for intervention and control groups respectively. Then the type of intervention was written on a paper and placed in the opaque envelopes. Outside of each envelope was labeled Person 1, Person 2, and Person 3, and so on to match the person's entry sequence. Then the door packs closed. Assignment was done by a person who has no role in entering the participants in the research, data collection and data analysis.

The sample size was calculated to detect 30% difference in QOL score between the two groups (based on Gehan table). The significance level and power were considered as 0.05 and 80% for detecting the difference respectively. There are about 40 individuals with T2D were considered for each group. To handle the loss to follow-up, $NW = N/(1-W)$ was used,^[11] (in which W is the proportion of prediction withdrawal and N is the number of samples). The final sample size was 100 including 50 individuals with T2D for each group.

Participants received comprehensive information about the aims of the research, including the benefits, results and confidentiality of the information before participating in the research. Informed consent was obtained from all participants before beginning the study.

Measurements and interventions

A medical history and risk factor assessment was done for each patient at the beginning of the study by a physician. Thereafter, World Health Organization Quality of Life-brief

Questionnaire (WHOQOL - BREF) and International Physical Activity Questionnaire (IPAQ) (long form) were completed by all participants. The intervention group was received both PAP and life style education. The control group just received the life style education.

The PAP included a prescription and a table that advises 150 minutes moderate physical activity a week such as fast walking, for example, 30 minutes per day, 5 days a week, to increase physical activity which causes sweating and heavy breathing.^[12] Moreover, in order to assess the activity, and practice recommended by the physician for each person in the intervention, weekly tables were set up for 12 weeks (3 months). In these tables, the rows were sorted by days of the week (7 days) and the columns show the physical activities, such as fast walking, swimming, water sports, physical exercises, gardening, on foot shopping, walking from the taxi or bus station to one's house, walking 10 to 30 minutes around one's home every day. Individuals were asked to write down the activities carried out, and bring it on his next visit to the physician. Life style education included simple oral advice on healthy eating and physical activity for 150 minutes per week, and the cases listed in the table above.

Meanwhile, the follow-up, telephone training and the formation of a separate telegram group for men and women for sending educational messages on a daily basis and answering the questions of participants in the research throughout the follow-up period were actively conducted by the doctor.

After 1.5 months, the participants were revisited, and completed the IPAQ (the long form).

Then, three months after the first visit, the WHOQOL - BREF questionnaire was completed in order to assess the quality of life and the IPAQ (the long form) in each group. In addition, the completion of IPAQ (long form) was done face-to-face by one person.

Questionnaire WHOQOL - BREF examines the quality of life in four domains related to health, including: (1) Physical health (2) Psychological field (3) Social relationships (4) environmental. The domains have 7, 6, 3, 8 questions respectively. The first two questions in each domain do not belong to any of the fields and generally assess the health status, and the quality of life, so the questionnaire has a total of 26 questions. The items of physical health were pain, energy, sleep, work and activities. For psychology domains the items were about positive and negative emotions and body image. Items of personal relationships and social protection were for social relationship domain. Home and work environment and satisfaction with amenities like transportation, health, life, and financial issues were items of environmental domain. Items of questionnaires had a 5-point scale. The higher score was for the most positive answer. Therefore, 4 to 20 score was described the worst

and best condition respectively. These scores converted to a score of 0-100. The reliability of this questionnaire using correlation coefficients for physical health, psychological level, social relations and environment domains were 0.77; 0.77, 0.75 and 0.84 respectively. The validity and reliability of the Persian version of WHOQOL - BREF was confirmed by Dr. Najat *et al.*^[13]

International Physical Activity Questionnaire (the long form) is divided into five sections: 1. Physical activity associated with work 2. Physical activity associated with moving in different direction 3. Home tasks, home and family care activities 4. Leisure, sports and entertainment activities 5. Sitting down time. Questions were asked about the activities in the last 7 days. Each of the sections included 7, 6, 6, 6, 2 items respectively (a total of 27 questions). Validity and reliability of the Persian version of this questionnaire was confirmed by Dr. Vasheghani -Farahani *et al.*^[14]

Fasting blood glucose (FBS) was measured at the beginning and end of the study.

Ethical approval

The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences, with the code "IR.IUMS.REC1395.9411220005", which is in compliance with Helsinki declaration. The clinical trial was registered in the Iranian Clinical Trial Registry with the identification number of "IRCT2016082029372N4"

Statistical analysis

Data analysis was performed using SPSS version 23. To assess the normal distribution of variables, the Kolmogorov-Smirnov (KS) test was used. Mann-Whitney *U* test was used in case of non-normal distribution of numeric variables. Chi-square and Fisher's exact tests were used to compare categorical variables across two groups. Friedman test was used to compare the scores of the IPAQ as an ordinal scale during different times. Repeated measurement of analysis of variance (ANOVA) was used to compare the IPAQ as a numeric measure of metabolic equivalent of task (MET) during the follow-up. The significance level was considered as 0.05.

Results

In current study, 100 individuals with T2D were included and randomized into intervention, and control groups. After starting the study, 5 persons were excluded during the follow-up (three in intervention and two in control group). Causes of withdrawal in intervention group were due to breast cancer, abnormal uterine bleeding and loss to follow-up. In control group two persons were lost during the follow-up. Finally, 95 individuals with T2D, (47 in the intervention and 48 in control groups) were analyzed at the end [Figure 1].

The mean age of participants was 46.22 ± 6.10 years old. Table 1 illustrates gender, age, level of education, marital status, number of children, menopause, and BMI across two groups. There was not any meaningful difference across two groups for demographic variables and BMI.

The distribution of physical, psychological, social relationships and environmental domains of WHOQOL - BREF were not normal. Mann-Whitney *U* test showed all domains of quality of life (QOL) were identical across two groups before intervention. Physical, psychological and environmental scores were different significantly after intervention across two groups ($P < 0.01$). Although social relationships was not different after 3 months follow-up across two groups ($P = 0.53$) [Table 2].

The IPAQ (the long form) physical activity questionnaire was completed before, 1.5, and 3 months after intervention.

Table 1: Comparison of two groups based on demographic variables

Variable	Total number=95		P
	Control group n=48	Intervention group n=47	
Sex (%)			0.55
Male	7 (14.6%)	9 (19.1%)	
Female	41 (85.4%)	38 (80.9%)	
Age (mean±SD) (year)	46.58±5.31	45.85±6.85	0.59
Marriage status (%)			0.48
single	3 (6.2%)	5 (10.6%)	
married	45 (93.8%)	42 (89.4%)	
Education level (%)			0.058
Elementary	10 (20.8%)	12 (25.5%)	
high school	20 (41.7%)	9 (19.1%)	
Diploma and higher	18 (37.5%)	26 (55.4%)	
Menstruation			0.58
Menopause	20 (48.8%)	15 (39.5%)	
No menopause	21 (51.2%)	23 (60.5%)	
BMI (mean±SD) (kg/m ²)	29.24±4.10	27.92±3.48	0.09
Number of children (mean±SD)	2.75±1.15	2.25±1.39	0.06

Table 2: Comparison of the two groups based on statistical significance of the WHOQOL questionnaire before and 3 months after the intervention

Domain	Control (mean/SD)	Intervention (mean/SD)	P*
Physical before	22.06±3.89	23.78±3.17	0.82
Physical after	22.58±3.71	27.42±3.34	0.0001
Psychology before	17.38±3.69	17.76±2.72	0.80
Psychology after	17.29±3.46	21.44±3.24	0.0001
Social relationships before	9.20±2.56	8.70±2.10	0.09
Social relations after	9.12±2.66	9.46±2.70	0.53
Environment before	24.70±3.71	24.24±3.15	0.35
Environment after	24.41±3.92	27.02±4.68	0.01

*Using Man-Whitney Test

There was not any significant difference for IPAQ at the beginning of the study across two groups ($P = 0.89$). This difference was significant after 1.5 and 3 months follow-up ($P = 0.0001$) [Table 3].

The repeated measurement of ANOVA showed the IPAQ (long form) score, was changed significantly during the follow-up for all participants (within group comparison) based on the MET calculation ($P = 0.0001$). Also, there was a significant difference after the follow-up across two groups (between group comparison) ($P = 0.0001$) [Figure 2].

It was shown FBS was changed significantly after intervention ($P = 0.009$). At the beginning of the study, there was not any significant difference of FBS across two groups ($P = 0.07$) [Table 4].

Discussion

The current study showed PAP has a significant effect on all domains of quality of life just social relations.

A study was conducted by Danielle M. Thiel *et al.* (2017) in Canada, in adults with T2D, was shown a significant association between physical activity and health related quality of life, especially physical health.^[4] They assessed quality of life using the short-form Health survey V.2 (SF V.2) and the 5th level (EQ-5D) questionnaires.

Rodger L *et al.* (2016), using a observational study in Sweden, demonstrated that physical activity and quality of life in people who received physical activity as a physical activity prescription improved during a follow-up period of 2 years.^[15] They showed an association between physical activity and QOL in non-diabetic patients for an almost long time.

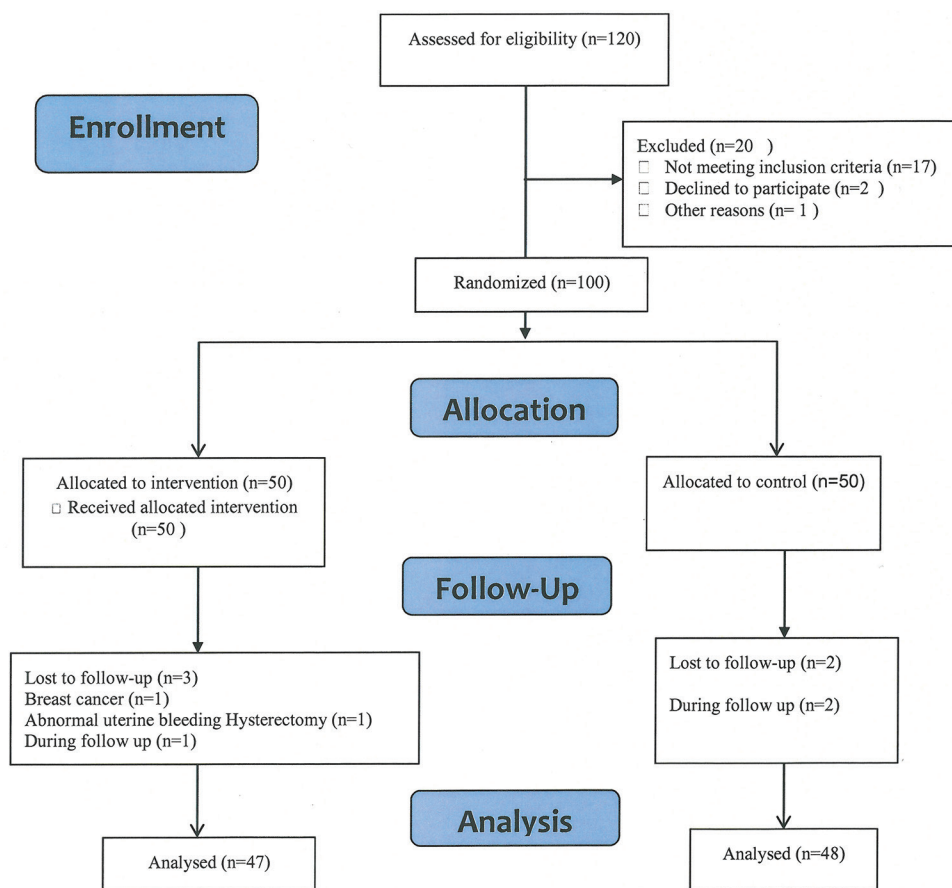


Figure 1: Participant flow diagram

Table 3: Comparison of the two groups based on physical activity as a qualitative scale before, 1.5, and 3 months after intervention

IPAQ	Control (%)			Intervention (%)			P*
	Low	Moderate	High	Low	Moderate	High	
Before intervention	28 (58.3%)	18 (37.5%)	2 (4.2%)	27 (57.4%)	17 (36.2%)	3 (6.4%)	0.89
1.5 months later	23 (47.9%)	21 (43.8%)	4 (8.3%)	2 (4.3%)	34 (72.3%)	11 (23.4%)	0.0001
3 months later	23 (47.9%)	21 (43.8%)	4 (8.3%)	0 (0.0%)	24 (51.1%)	23 (48.9%)	0.0001

*Using Chi-square test

Table 4: Comparison of two groups based on fasting blood glucose level at the beginning of the study and 3 months after

Fasting blood glucose (FBS)	Control (mean/SD)	Intervention (mean/SD)	P*
At the beginning of the study	151.27±27.58	152.55±17.68	0.07
After 3 months of study	151.06±26.80	136.63±16.86	0.009

*Using Man-Whitney Test

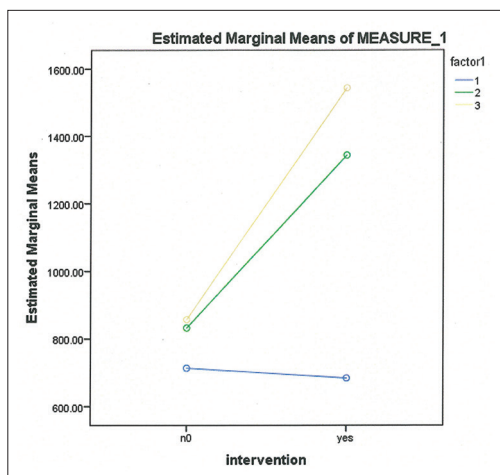


Figure 2: Diagram of physical activity rate to MET in intervention and control groups

Eljedial *et al.* (2006) compared quality of life in a sample of diabetic patients in refugee camps living in the Gaza Strip to the non-diabetic control subjects of the same camp in which the two groups were matched for gender and age. They concluded that diabetes and its complications negatively affected all domains of QOL using the WHOQOL - BREF questionnaire. However, the strongest effect was on the physical and psychological health and the least one was on the social relations and the environmental domain.^[16]

In the study of Pragma Kumar *et al.* (2016), QOL of individual with diabetes was poor compared to non-diabetic subjects for all domains of WHOQOL - BREF. The physical activity of individuals with diabetes were less than non-diabetics significantly.^[17]

In our study, we showed physical activity can improve physical, psychological and environmental aspects of QOL in individuals with T2D. However, our results were as the same as the mentioned studies and confirmed that physical activity has a significant effect on QOL.

Hong cai *et al.* (2017) using a systematic review study showed the effect of aerobic exercise on the QOL of individuals with type 2 diabetes is safe and effective.^[18] In our study, the physical activity prescription included aerobic exercise too.

Using a randomized controlled trial by Ajediran I Bello *et al.* (2011) the effect of 8 weeks of aerobic exercise on

physiological parameters and quality of life in individuals with T2D was assessed in Ghana. They showed recovery of patients after 8-week aerobic exercise. Fasting blood sugar (FBS), lipid profile and quality of life of patients improved significantly.^[19]

In our study, the follow-up period was longer (12 weeks), and decreasing of FBS was shown.

We could not show any significant improvement of social relations in current study. Items of social relations according to the WHOQOL - BREF questionnaire included three questions: 1. How satisfied are you with your private relationships? 2. How satisfied are you with your sexual relationship? 3. How satisfied are you with the support you receive from your friends? It seems that changing social relations needs more time. The other explanation could be that exercise may be has not any effect on the social relations. Although the first one is more probable.

Grandes G *et al.* (2009), in a RCT study, showed that family physicians are effective in on promoting physical activity in primary care. It has been shown clinical status is better in patients who received physical activity as a prescription.^[20] Our study also indicated that exercise counseling included in physical activity prescription in individuals with T2D can increase physical activity and improve QOL.

Limitations

The most important limitation of current study was short follow-up period. With longer follow-up time we were able to assess the longevity of effect and also the effect of physical activity on social relations. We did not measure HbA_{1c} that could be the other limitation of current study.

Conclusions

We showed physical activity could improve QOL of individuals with T2D significantly. The effect of physical activity on social relations needs more time. We suggest evaluating the effect of physical activity on social relations with a long time follow-up in future studies.

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Conflicts of interest

There are no conflicts of interest.

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