The Effect of Implementation Intention on Improving Physical Activity Level and Cardiovascular Fitness in Patients with Type 2 Diabetes: A Randomized Control Study

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Abstract

Objective: Regular physical activity (PA) is one of the most effective recommendations to prevent diabetic complications. However, the reported level of PA is low in this group. This study evaluates intervention based on the implementation intention (II) theory, to improve the level of PA and the health of patients with diabetes.

Materials and Methods: This randomized control study was conducted on 124 patients with type 2 diabetic. The participants were randomly assigned in to two groups. PA level was measured by using International Physical Activity Questionnaire (IPAQ). The Rockport test was used in order to measure Maximal oxygen consumption volume (vo2max). In the intervention group, Individuals were asked to identify details of the behavior of PA and their own strategies for removing the barriers of exercise. Post-tests took place 3 month later. Normal distributed data were analyzed using two independent and paired sample T-test. Wilcoxon, Mann Whitney tests were used to compare PA level.

Results: The results showed that although the median level of PA after the intervention (396) had increased. This difference was not statistically significant ($P$-value= 0.12). Also, after three months vo2max score (19.91) was not significantly different from before ($P$-value= 0.30).

Conclusion: Intervention based on II had no significant effect on level of PA in patients with type 2 diabetes. Using multiple methods, as well as incorporating it with motivating interventions should be investigated to increase the level of PA in this group.

Keywords: Implementation intention, Physical activity, Cardiovascular fitness, Patients, type 2 diabetes

Introduction

Diabetes is known as a worldwide health problem, globally 12% of total health costs are attributed to diabetes (1). In Iran, the prevalence of diabetes is increasing, as it is estimated that by the year 2030, the population of diabetes in Iran will...
increase to about 9 million (2). Diabetes is known as a disease of lifestyle, so healthy lifestyle is the main factors of preventing and controlling the complications of type 2 diabetes mellitus (T2DM) (3). In addition to therapeutic approaches, behavioral interventions are also necessary to prevent and reduce the complications of diabetes (4). Regular physical activity (PA) is one of the most effective behaviors in controlling the complications of diabetes (5). PA reduces blood glucose and cardiovascular risk (6). The regular PA has positive effects on the metabolic status and cardiovascular fitness (7).

In terms of PA, diabetic patients are recommended to exercise at least 30 minutes of moderate exercise in five days a week (8). Although diabetic patients are encouraged to increase their total daily PA, but they usually are not successful in this task. So that some patients cannot maintain their motivation to continue their PA, and there are numerous personal and environmental barriers that cause instability in their PA (9). Some studies showed that over 50% of patients with T2DM do not have enough PA (10-12).

One of the theories which are helpful in changing behaviors is the theory of action phases and implementation intention strategy. This strategy distinguishes between motivating development stages and acting (13). In fact, this strategy actually establishes a subjective relationship between the existence of a position (if this situation exists) and the individual's response (then I will do it), which facilitates the conducting behavior (14). In addition, this strategy affected the sustainability of behavior by predicting obstacles during the conduction of the action and presenting an approach to adapt to those conditions (15-17). This study evaluates intervention based on the implementation intention (II) theory, to improve the level of PA and the health of patients with diabetes.

Materials and Methods
This study was conducted in 2018 on 124 patients with T2DM who were covered by Rafsanjan city health centers. To collect the samples, two health centers were selected randomly from eight centers. One was considered as the control group and another intervention group. According to their file number and random sampling method, the eligible individuals were entered the study to reach the sample size. People with a history of at least one year of T2DM as well as the ability to performing the recommended PA, were recruited. Patients who had blood glucose above 250 mg/dl before the test, and who did not complete the cardiorespiratory fitness test have been excluded from the study.

In order to determine the level of PA, the IPAQ short form was used. This standard questionnaire has been approved by the World Health Organization in different countries (18). In Iran, the Persian version of this questionnaire is approved (19). The self-report questionnaire examines three types of PA, including walking activity, moderate activity and high intensity activity. Calculation of the total score with the sum of the time duration and number of days of the week, which were spent with moderate and high intensity activities, and their conversion in to metabolic equivalents (METs).

Another assessment was cardiorespiratory fitness determination. One of the simple methods of checking cardiorespiratory fitness is the using of the Rockport test to calculate vo2 max. In this test, a person should walk fast for 1 mile (1.6 km). Before the test, 5 minutes of stretching exercises were performed to warm up the body. After passing the way, heart rate of the patient was controlled and recorded by a pulse oximetry device. Finally, considering the changes in heart rate, the age and gender vo2max of the participant were calculated by using the formula (20).
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At this stage, after organizing a training session on the necessity of identifying the details of PA behavior and its impact on the success of exercise, individuals were asked to plan for exercising in the next three months. They were asked to determine the exact time and place and the type of sport which they want to do. Then, individuals have completed their program in special forms.

At this stage, patients were asked to think and discuss about issues and barriers that they thought they will face in exercising. Then they set out their strategies to overcome these barriers and express their own personal form.

The use of the prescribed schedule for exercising was reminded to patients during the follow-up period by telephone. These reminders were performed once a month. The control group did not receive any special intervention. In both groups, the level of PA and vo2max levels were compared before and after the three month intervals. Descriptive statistics and also two independent and paired sample T-test were used to compare the groups to analyze the data. Non-parametric statistical equations were used when the data were not normal distributed. All analyses were performed using Statistical Package for Social Sciences (SPSS) software (version 19).

Ethical considerations
The present paper is a research project registered with ID number of 95066 and the ethics code of (IR.RUMS.REC.1395.72) in Rafsanjan University of Medical Sciences.

Results
The demographic characteristics of the study showed that the majority of participants in both group were women. The majority of the individuals were in the range of 50-60 years old and with less than the diploma education. There was no statistically significant difference between two groups in demographic characteristics (Table 1).

The PA level and the Vo2 max level comparison showed that there were no significant differences between two groups before the intervention. The results showed that although the level of PA and vo2 max was increased in the intervention group, but the differences between two groups were not statistically significant. The use of statistical paired and Kruskal–Wallis tests showed that there was no significant difference in the level of PA and in both groups after intervention in comparison with the pre-test (Table 2).

Although vo2 max in the intervention group had increased, paired T-test results showed that this increase was not statistically significant.

Table 1. Demographic characteristics of participants of patients in both groups

| Variable          | Control Group N (%) | Intervention group N (%) | p-value* |
|-------------------|----------------------|--------------------------|----------|
| Gender            | Female               | Male                     |          |
|                   | 48 (78.7)            | 14 (22.2)                 | 0.74     |
| 25-39             | 3 (4.9)              | 9 (14.75)                 |          |
| Age               | 9 (14.75)            | 43 (70.5)                 | 0.54     |
| 50-59             | 4 (6.5)              | 5 (7.9)                   |          |
| 60-65             | 6 (9.83)             | 3 (4.8)                   |          |
| Education         | Elementary school    | Middle school            |          |
|                   | 18 (29.50)           | 28 (45.90)                | 0.38     |
|                   | 21 (33.3)            | 27 (42.9)                 |          |
| Income            | Poor                 | Moderate                 |          |
|                   | 24 (39.34)           | 36 (59.01)                | 0.24     |
|                   | 17 (27)              | 44 (69.9)                 |          |
| Diabetes History  | 1-3 year             | 3-5                      |          |
|                   | 4 (6.5)              | 27 (44.26)                | 0.12     |
|                   | 8 (12.7)             | 20 (31.7)                 |          |
|                   | 5-10                 | 30 (49.18)                |          |
|                   | 35 (55.5)            |                          |          |

*Chi Square
significant (Table 3).

**Discussion**

The findings showed that, despite the necessity of PA to control diabetes, the level of PA was low in these patients. In total, the PA level was lower than the minimum recommended level for this group. In the present study, based on the questionnaire, the total PA level was calculated which included the total number of walking and various types of sports with different severity, which it was less than the recommended level (495 MET). Also, the results of this study showed that the level of cardiovascular fitness in patients with type II diabetic was not in desirable condition. On average, according to the age of the participants, the recommended vo2max level was recommended at least 25, which in the present study; the mean score was less than this level. However, this lack of readiness is justifiable due to the low level of mobility and the physiological changes in diabetes. This is consistent with the previous studies which were showing the low level of vo2 max in diabetic patients (21). One of the most important findings of this study was the incompatibility of the II intervention to improve the level of PA in patients with T2DM. This finding is not consistent with some of the studies performed in this area. As the study of Ziegelmann showed, the process of implementing intention was able to predict exercise in orthopedics patients (22). Also, the results of the Prestwich study showed that the II was able to increase the level of PA in a group of students (17). Individuals with the implementation of complex health behaviors, such as PA, are facing two challenges. The first delaying factor is in the onset of behavior and the second one is the problem of leaving the behavior or returning to the previous state. In the strategy of implementing intention, the probability of starting behavior and non-forgetfulness will be increased by specifying the implementation details (23). On the other hand, in this process, a mental relationship is created between the predicted position and the behavior that cause to increase the probability of implementation of behaviors. The implementation strategy also aims to predicting barriers during the acting and providing a solution to be consistent with those conditions. Therefore, it is expected that this intervention will also affect the PA behavior. However, the following reasons may be effective as regards the ineffectiveness of the II in this study. The first point is that the process of II is primarily intended to act as an intermediary intervention, and this intervention will be more effective if the intention and motivation is high (14). It seems, the training and recommendations of the medical staff have failed to provide sufficient motivation and intention to start PA in diabetic patients. The study of Morowati

| Table 2. Pre and post intervention -intervention changes in PA score (MET) in two Groups |
|---------------------------------|---------------------------------|-------------------|
| Variable | Physical activity | Physical activity | P-value |
| Group | Median (IQR) | Median (IQR) |
| Control group | 396 (396) | 396 (495) | 0.89 |
| Intervention Group | 297 (396) | 396 (396) | 0.12 |
| P-value | 0.55 | 0.51 |
| IQR: interquartile range |
*Kruskal-Wallis test, **Mann–Whitney U test |

| Table 3. Pre and Post Intervention changes in vo2max in two Groups |
|---------------------------------|-------------------|-------------------|
| Variable | Vo2 max | P-value |
| Group | Mean (SD*) | Mean (SD*) |
| Before intervention | After intervention |
| Control Group | 20.21 (8.69) | 20.77 (8.88) | 0.59 |
| Intervention Group | 19.10 (7.95) | 19.91 (7.22) | 0.30 |
| P-value | 0.40 | 0.56 |
*Paired Sample T-test, **Independent-Sample T-test
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showed that motivation is a determining factor in the PA of diabetic patients (24). Rutter's study on the effect of the II on mammography behavior showed that this process was effective on people who had a high intention for the desired behavior (16). On the other hand, the procedure of implementing intention can also be more effective in the outcome of the intervention. In the present study, the individuals themselves determined how to behave, and the researcher did not interfere in their regulation. Perhaps the situations and plans that patients have planned for them are not very consistent with reality and in practice have not been successful in their implementation. It seems that self-regulation process, which is one of the necessities of the process of implementing intention, requires the skills and training which the individuals do not possess in present study due to the level of their education and the absence of such courses. However, some studies have shown that the process of implementing intention has not been able to increase the level of PA (25). Finally, the chronic and complex nature of diabetes seems to play an important role in the results of this study. Studies show that the diabetic patients face multiple challenges such as exercise, diet and treatment, and on the other hand, each of these cases needs planning and self-regulation (26). It is possible that, people with diabetes have fewer capacities and resources to plan, self-control and self-regulation in PA (27). Also, the prevalence of stress, anxiety and depression is high in T2DM in comparison with the usual population (28), and these disorders can also effect on self-regulatory and management capabilities such as PA in T2DM patients. (29)

A limitation of this study is the lack of accurate monitoring of the level of PA during the intervention period. In addition, the high age and low level of literacy of the majority of participants Interferes with accurate planning. Therefore, future studies are recommended in more diverse groups of diabetic patients to evaluate the effect of II. However this study was the first study which investigated the effect of the II to improve PA among T2DM in Iranian population. Other strengths of this study include measuring vo2max index in addition to assessment the level of PA.

Conclusions
The present study showed that II strategy, alone, do not seem to increase adherence to PA in patients with T2DM. Given the chronic nature of diabetes, it seems that more attention should be paid to improve motivation for recommended PA. Therefore, it is suggested to study the effects of II with more supervision and use of more family participation, adding skills such as self-regulation and self-control especially in the case of illiterate and elderly groups to enhance levels of PA in T2DM.

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Conflict of Interest
The authors declare that they have no conflict of interests.

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