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# The Effect of Progressive Muscle Relaxation on Glycated Hemoglobin and Health-related Quality of Life in Patients with Type 2 Diabetes Mellitus\*



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#### ABSTRACT

*Aim:* This study aimed to evaluate the effect of Jacobson's progressive muscle relaxation (PMR) on *glycated hemoglobin* (*HbA1c*) levels and health-related quality of life (HRQoL) in patients with type 2 diabetes mellitus (DM). *Background:* Due to relatively *poor* HRQoL in patients with type 2 DM, different stress reduction techniques was applied to improve physical and mental health in these patients.

*Methods*: This randomized controlled clinical trial was conducted at the Diabetes and Endocrinology Institute of Firoozgar Hospital, Tehran, Iran, between June and December 2015. Sixty-five patients with type 2 DM were randomly divided into the control (n=35) and PMR (n=30) groups. The patients of the control group only received the conventional care. The PMR group practiced Jacobson's PMR at home for 12 weeks and were monitored by the researcher's phone calls and patient's self-report list. For both groups, Iranian Diabetes Quality of Life Brief Clinical Inventory (IDQoL-BCI) questionnaire was completed and HbA1c levels were measured before and 12 weeks after study entry.

*Results:* The results showed that there were no significant differences in terms of *HbA1c levels and* HRQoL scores between the PMR and control groups 12 weeks after intervention. However, in the PMR group, the intervention led to a significant reduction in *HbA1c levels* (P=0.04) *and* a significant increase in total HRQoL score (P=0.045) and its psychosocial dimension (P=0.019).

*Conclusion*: PMR had no significant impact on *HbA1c* levels and HRQoL in patients with type 2 DM. Further studies with larger sample size and longer follow-up are needed to improve QoL in patients with type 2 DM.

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#### 1. Introduction

Diabetes mellitus (DM) as one of the most common chronic diseases is the leading cause of death and disability worldwide, suggesting DM imposes a substantial burden on society and healthcare system (Sajadi et al., 2012). In Iran, it has been estimated that more than 4,581,600 individuals *had DM* in 2014, while the approximate number of undiagnosed *diabetes* in adults were 2,290,800 individuals, among whom 90% of individuals had type 2 DM (International Diabetes Federation Middle East and North Africa, 2015; International Diabetes Prevention and Control Foundation, 2015).

Major fluctuations in blood glucose, diet and *exercise restrictions*, *physical disability and development of* vascular disorders are known as

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the factors affecting *diabetes*, *indicating this disease is closely associated with stress level* (Safavi, Samadi, & Mahmoodi, 2013). Furthermore, the daily management of DM can cause high level of stress, and continuous stress leads to anxiety and depression in these patients (Australian Diabetes Council, 2013). It is noted that the body responds to stress by releasing various hormones that neutralize the effects of insulin, resulting in insulin resistance. Stress causes to eat more and exercise less (Mcculloch, 2008) and is related to low quality of life and health perception (Morewitz & Goldstein, 2007).

Health-related quality of life (HRQoL) refers to social, physical and emotional well-being levels in a patient undergoing medical treatment (Fairclough, 2010). A number of studies have reported lower HRQoL in patients with type 2 DM as compared to healthy people (Acton, 2013; Saadatjoo, Rezvanee, Tabyee, & Oudi, 2012). One of the major factors affecting HRQoL in these patients is psychological stress due to continuous self-management. Therefore, *reducing diabetes*-related *distress* is most likely to be an important predicting factor for improving HRQoL in patients with type 2 DM (Tol et al., 2015). High percentatge of patients with DM affected by depression and less attention was paied to

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their psychological issues (Nejati Safa, Larijani, Shariati, Amini, & Rezagholizadeh, 2007). A study *has also showed that it is important to improve* HRQoL level in patients with type 2 DM (Javanbakht, Abolhasani, Mashayekhi, Baradaran, & Jahangiri Noudeh, 2012). One of the duties of nurses is to improve the stress responses in these patients through the appropriate and effective interventions (Yoost & Crawford, 2015). Understanding of complementary therapies and application of relaxation techniques are a part of comprehensive nursing care, for which all nurses should be trained and educated. There are various relaxation techniques to reduce muscle tension in the body (Snyder & Lindquist, 2010). Relaxation techniques for diabetes are based on the fact that stress stimulates liver cells to release glucose that leads to increased insulin resistance, so these methods can reduce stress and create a state of relaxation *in diabetes* (Dunning, 2007).

Progressive muscle relaxation (PMR) is a technique to relax the muscles by regulating muscle tension throughout the body (Seaward, 2011). Edmund Jacobson described the PMR technique in 1935. He believed that the body responds to disturbing thoughts and stressful events by increased muscle tension. In Jacobson' PMR, it is trained to tighten a group of muscles and then slowly releases while focusing on the feeling of muscle tightness and relaxation. In original model of PMR, a patient learns how to tighten gradually the sixteen muscle groups of body, then exhales slowly before relaxing each muscle group (Dossey, Keegan, Barrere, & Helming, 2015). This method is simple and requires neither special training nor prior experience.

In a study, touch massage therapy and PMR technique have been compared in patients with type 2 DM, and it has been showed that both methods had no effects on HRQoL of these patients (Wandell, Carlsson, Gafvels, Andersson, & Tornkvist, 2011). However, another study on 158 black women with type 2 DM living in South Africa has reported that PMR improved the QoL of these patients (Van Rooijen, Rheeder, Eales, & Becker, 2004). In addition, a study has indicated that both massage therapy and PMR had positive effect on reducing blood sugar and glycated haemoglobin (HbA1c) levels in children with type 1 DM as compared to the control group (Ghazavi, Talakoob, Abdeyazdan, Attari, & Joazi, 2008). However, the combination of relaxation method (such as muscle relaxation, deep breathing exercises and guided imagery) and music had no effect on HbA1c levels, whereas there was a significant reduction in fasting blood sugar (FBS) (Khoshkhou, Bakhshipoor, Dashipour, & Keramati, 2010). Also, it has been found that PMR caused a significant decrease in anger and FBS among patients with types 1 and 2 DM as compared to the control group (Asadi, Tirgari, & Hasanzadeh, 2013).

In a systematic review on 25 articles, the results of 12 studies have showed that cognitive-behavioral techniques (CBT) may reduce HbA1c levels and psychological distress in patients with type 2 DM; however, there are a lot of weak evidences in this regard (Ismail, Winkley, & Rabe-Hesketh, 2004). A meta-analysis has indicated that CBT as a psychosocial intervention has been recently developed and is still in the beginning stages. This technique may slightly reduce blood glucose in children and adolescents but shows no effects on adults (Winkley, Landau, Eisler, & Ismail, 2006). However, it is essential to conduct more randomized clinical trials (RCTs) based on standards for high quality researches in order to examine the effect of various complementary interventions on different groups of people with diabetes (Alam, Sturt, Lall, & Winkley, 2009; Winkley et al., 2006). The results of a recent systematic review showed that CBT may be effective on the care of patients with DM. Also limited studies was investigated the effect of CBT on HRQoL in patients with DM and few studies were conducted in United Kingdom, and Africa and Asian countries, indicating more research is necessary for increasing the generalizability of findings (Uchendu & Blake, 2016).

This study aimed to evaluate the effect of Jacobson's PMR on *HbA1c* levels and HRQoL in patients with type 2 DM.

#### 2. Materials and Methods

#### 2.1. Type of study

This study was a *randomized controlled clinical trial* that was conducted at the *Diabetes* and *Endocrinology Institute* of Firoozgar Hospital, Tehran, Iran, between June and December 2015.

#### 2.2. Ethical consideration

This study was approved by the Ethics Committee of Iran University of Medical Sciences (93/D/105/5864). *The purpose of the study* was fully explained to all participants before they signed a written informed consent form, in which they granted permission for taking blood samples. Furthermore, the *confidentiality* of their *information* was *protected*, and the results of the study were then released to them. Also, it was emphasized that if the participants were not willing to cooperate, *their decisions* would not affect the treatment process.

#### 2.3. Study population

The subjects in this study were patients with type 2 DM who were referred to the Diabetes and Endocrinology Institute of Firoozgar Hospital. The inclusion criteria were as follows: (i) age between 35 and 65 years, (ii) literacy skills, (iii) definitive diagnosis of type 2 DM by a doctor, (iv) history of taking oral anti-diabetic drugs for at least 1 year, (v) absence of chronic complications of DM (such as cardiovascular disease, retinopathy, chronic renal failure, and diabetic foot), (vi) no signs of mental illness (not taking psychiatric drugs), (vii) no sensoryperceptual and communication problems, (viii) no movement disorders and injuries of the extremities, (ix) no addiction and (x) no history of PMR training. Furthermore, the exclusion criteria were as follows: (i) failure to attend in one of the training sessions, (ii) lack of ability and skill to learn the technique, (iii) failure to complete 10 sessions of the PMR technique during a week at home (failure to complete the self-report list), (iv) change in the drug regimens, (v) use of other complementary therapies during the research, (vi) presence of severe complications of DM, and (vii) facing stressful events during the study (like death of family member). The sample size was calculated with *a* 95% confidence interval and 80% power, assuming that relaxation method could improve HRQoL score in the PMR group as compared to the control group at the effect size of d = 6. A sample size of 28 patients in each group was then estimated using the following formula:

$$x = \frac{\left(Z_{1-\frac{a}{2}} + Z_{1-\beta}\right)^2 \times 2S^2}{d^2}$$

With a 25% drop-out rate, a sample of 35 patients in each group was considered (a total sample size of about 70 individuals). The standard deviation (SD) of 8 was also considered according to the studies by Dudzinska et al. (2012) and Ghazavi et al. (2008). Of 70 patients participating in this study, 5 patients were excluded from the PMR group for missing the second educational session (2 patients) and increasing drug dose (3 patients). Therefore, the data of 65 patients were analyzed. The flow chart of study population selection is shown in Fig. 1.

#### 2.4. Random allocation

The samples (n=65) were allocated into the PMR (n=30) and control (n=35) groups using fixed blocked randomization with block size of 4 in ratio of 1: 1. Therefore, different possible combination of groups were written on the separate cards, placed in sealed envelopes and kept in a box. Then a sealed envelope was removed from the box and opened to determine the *patient's group*. A nurse who was blinded to the study took the sealed envelopes out of the box. After all the sealed envelopes

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