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Mixed effects of a six-month supervised exercise program in overweight and moderately obese adults with Type 2 diabetes mellitus

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Abstract

Type 2 Diabetes Mellitus (T2DM) is often associated with overweight or obesity. Clinical practice guidelines recommend that people with T2DM should regularly perform aerobic and resistance exercise and reduce the amount of time spent sitting. However, most adults with T2DM remain inactive and those who start a program are not willing to maintain exercise for the long run. To evaluate the relationship between supervised exercise, glycemic control, fitness and potential body image a longitudinal study with intervention was conducted. Twenty-three T2DM adults were assessed on Body Mass Index, glycosylated haemoglobin A_{1c} (HbA_{1c}), Fitness Index (FI) and Potential Body Image (PBI) at baseline and after completing a six-month supervised exercise program. BMI and Fitness Index were modified by exercise. No group differences were found on HbA_{1c} and PBI. However, significant individual differences in BPI were detected by means of mixed-effects models. A six-month exercise program can affect some biological and clinical parameters as BMI and Fitness Index. High inter-individual variability was observed in

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PBI. Mixed-effects models should be preferred to the traditional ANOVA's and personalized supervised intervention should be implemented for long-term maintenance of exercise.

Keywords: Type 2 diabetes mellitus; Exercise; Intervention.

1. Introduction

Most people with type 2 diabetes mellitus (T2DM) are overweight or obese, therefore weight control is of great importance for the success of any treatment. A 5-10 percent weight loss among obese subjects with T2DM may lead to improvements in glucose control, blood pressure and favorable changes in lipid profile (Baptiste-Roberts, Gary, Bone, Hill, & Brancati, 2006). The American Diabetes Association (2018) recommends that people with T2DM achieve at least 150 minutes/week of moderate-intensity exercise, 2-3 sessions/week of resistance exercise and break up bouts of sedentary activity (30 min) by briefly standing, walking or performing other light activities. Light-to-moderate resistance training combined with moderate aerobic exercise (three times/week) can improve metabolic and lipid profiles, adiposity and blood pressure after one year (Balducci, Leonetti, Di Mario, & Falluca, 2004) and can reduce cardiovascular risk and other complications in people with T2DM (Umpierre, Ribeiro, Kramer, Leitão, Zucatti, Azevedo *et al.*, 2011; Balducci, Sacchetti, Haxhi, Orlando, D'Errico, Fallucca *et al*., 2014). Since T2DM requires more than adherence or self-care management (Settineri, Frisone, Merlo, Geraci, & Martino, 2019) a lack of emotional and psychological support in the long run can impact the ability of people to effectively manage their disease (Marchini, Caputo, Napoli, Balonan, Martino, Nannini *et al.*, 2018). As negative thoughts about physical activity are often reported by people suffering from T2DM (Guicciardi, Lecis, Anziani, Corgiolu, Porru, Pusceddu *et al.*, 2014a), it is necessary to point out that smaller but still substantial benefits are achieved with moderate intensity training exercises or other physical activities that can reduce sedentary behavior (Hu, Jousilahti, Barengo, Qiao, Lakka, & Tuomilehto, 2005; Armstrong & Sigal, 2015): in T2DM and obese elderly, low-grade leisure activity can ultimately reduce all-cause mortality (Centis, Trento, Dei Cas, Pontiroli, De Feo, Bruno *et al*., 2014).

Middle-aged obese individuals with T2DM underestimate their obesity degree more than non-affected overweight people (Bjerggaard, Philipsen, Jørgensen, Charles, Witte, Sandbæk *et al*., 2015). Obese women who perceive themselves as obese are more likely to lose weight than those who do not rate themselves as having a weight problem (Lynch, Liu, Wei, Spring, Kiefe, & Greenland, 2009). Consequently, a more accurate perception of body could motivate obese women to undertake some weight reduction program, as exercise.

Body image specifically refers to an individual's perception of his or her own physical appearance in terms of height, weight, and shape (Heiss & Petosa, 2014) and must be considered as a multidimensional construct that represents the feelings, thoughts and behaviors which individuals develop about their physical appearance. Body image can result as a significant and independent predictor of weight reduction, before and after adjustment for baseline weight, particularly in obese women (Teixeira, Palmeira, Branco, Martins, Minderico, Barata *et al*., 2004; Lynch *et al*., 2009). Body image can be assessed by means of various forms of figure rating scales or silhouette-based matching task (SMT). These instruments are composed by some gender-specific body figures of increasing size, ranging from thin to fat, with monotonic increments in overweight percentage.

Overweight individuals with T2DM, compared with overweight individuals without diabetes mellitus, often select different body figures. Particularly, women with T2DM had a significantly higher BMI compared with women without diabetes mellitus who had selected the same body figure. Similar results were reported by men, only for the extreme figures (Bays, Bazata, Fox, Grandy, Gavin, & SHIELD Study Group, 2009). If overweight individuals with T2DM perceive their body image closer to their actual BMI, they will be more prone to adopt a program for weight reduction. Thus, both BMI and SMT must be considered useful to assess the relationship of body weight to adverse clinical outcomes (Bays *et al*., 2009).

Clinical disorders in body image, like body dissatisfaction, are already investigated in T2DM subjects (Anderson, Janes, Ziemer, & Phillips, 1977; Baptiste-Roberts *et al*., 2006).

However, they are often reported as a difference score between figures representing the actual and the ideal body silhouette (Marsh, Hau, Sung, & Yu, 2005). Despite its large use, this procedure has been criticized for collapsing distinct constructs (e.g., actual and ideal body figure) into a single difference score, losing relevant information and providing less reliable estimates of the constructs being assessed (Vartanian, 2012). For example, the same difference score can be achieved in two different conditions: if body images remain stable over time or if both change in the same direction with similar strength. Therefore, a difference score may be not very sensitive in monitoring a desirable change in body image, as achievable by means of health behaviors (e.g. diet and exercise).

Conversely, although less used, the body image connected to potential self, named Potential Body Image (PBI), could solve previous measurement problems and be more sensitive to expected changes.

The potential selves reflect an individual's perceptions of what might be (Vartanian, 2012), with reference to different health-related behavior, such as exercise and diet, which are important components of diabetes treatment. The potential body image can reduce the issues of difference scores, making a positive characteristic more concrete and tangible. Only few instruments based on silhouette matching task include potential selves as frame of reference, and issues related to body image in overweight or obese people are more frequently assessed as difference scores between actual and ideal self (Bays *et al*., 2009; Bjerggaard *et al*., 2015). Moreover, most of the studies investigating the psychological determinants of lack of exercise in people with T2DM used correlational and cross-sectional design (Guicciardi, Lecis, Anziani, Corgiolu, Porru, Pusceddu *et al.*, 2014b). There are very few longitudinal studies with intervention: often the length of the intervention is less than five weeks, because T2DM adults and older people are unwilling to maintain exercise for an extended period of time (Kirk, Mutrie, Macintyre, & Fisher, 2004; Centis *et al*., 2014). Thus, a period of six months appears to be a challenging threshold for assessing the effectiveness of exercise programs in overweight and moderately obese adults with T2DM.

2. Aims and hypothesis

The aim of the present study was to examine, by means of a longitudinal study, the changes on BMI, HbA_{1c}, Fitness and Potential Body Image in a sample of overweight and moderately obese adults with T2DM. Particularly, we hypothesized that after a six-month supervised exercise program: a) Fitness Index should increase, while BMI, HbA_{1c} and Potential Body Image should decrease; b) Fitness Index should correlate more with BMI, than with HbA_{1c} and PBI; c) Potential Body Image should correlate more with BMI before the intervention than after, motivating overweight and obese adults and older with T2DM to adopt a program for weight reduction.

3. Methods

A single arm, pre-post study design was carried out, in which all participants completed a six-month supervised exercise program. This study was carried out in accordance with the recommendations of the Italian Psychology Association Code of Ethics for Research in Psychology. The protocol was approved by the local Ethical Committee. Informed consent

was obtained by all subjects in accordance with the Declaration of Helsinki and its later amendments.

3.1. Sample

The study involved a convenience sample of 23 participants with T2DM, recruited from the Centre of Diabetology, San Giovanni University Hospital, Cagliari (Italy). Inclusion criteria were limited to a diagnosis of T2DM since at least 1 year and age > 24. The only exclusion criteria was the presence of underlying ischemic heart disease, screened by means of a maximal exercise tolerance test on a motorized treadmill according to the Bruce Protocol standard (Bruce, 1971).

Participants were both males (12) and females (11), with a mean age of 60.22 ± 8.99 years and mean diabetes duration of 6.04 ± 5.67 years. Type 2 Diabetes Mellitus was defined according to the American Diabetes Association (2018), as a progressive insulin secretory defect on the background of insulin resistance. T2DM was controlled by diet (n = 5), oral hypoglycemic agents (n = 11), insulin (n = 6), or a combination of oral hypoglycemic agents and insulin (n = 1).

3.2. Instruments

Demographic data, including gender, age, education, and marital status were self-reported. Disease-related information about duration and treatment of diabetes were self-reported, too.

Body Mass Index (BMI), calculated as ratio between weight and height, and reported in units of kilogram/ square meter (kg/m^2), was obtained from the Hospital Information System.

Glucose levels were assessed by estimation of glycated hemoglobin (HbA_{1c}) obtained from the Hospital Information System.

Fitness Index (FI): all participants performed a 2 km UKK Walk Test, developed by the Urho Kaleva Kekkonen Institute for Health Promotion Research (the UKK Institute). The test consists in a 2-km brisk walking pace on a flat surface. The results of the test are recorded as a fitness index, which takes into consideration the subject's age, gender, height, weight, time taken to walk the 2 kilometers, and heart rate (Ojala, 2013). The index is used to form five "fitness classes", which can be used to compare the individual result with the fitness of others of the same age: > 130 ("very good"), 111 – 130 ("good"), 90 – 110 ("medium"), 70 – 89 ("weak"), and < 70 ("very

weak"). This method enables a quick and reliable estimation of the performance level (Oja, Laukkanen, Pasanen, Tyry, & Vuori, 1991).

Potential Body Image (PBI) was measured with the Silhouette-Matching Task (Marsh & Roche, 1996; Marsh, 1999), which is composed of different body silhouette images, ranging from 1 to 12, with 1 being the thinnest body shape and 12 being the largest, most fat shape. Different series of body silhouette images were presented for men and women. Participants were asked to identify which of the figures fit better their body, in relation to three different questions regarding potential body images: "How would you feel if you exercised regularly?"; "How would you feel if you followed a healthy diet?"; "How would you feel if you followed a healthy diet and exercise regularly?". An overall index, named Potential Body Image, was calculated as mean score of the three figures selected. Cronbach's alpha reliability coefficient at baseline for the scale in the present study was .97.

3.3. Procedure

Participants were randomly assigned to sequential groups and participated in a six-month supervised exercise program of aerobic and strength activities, performed once a week. The exercise program was performed in two times: the first based on Fit walking (45 minutes), the second (30 minutes) focused on improving strength and muscular endurance (stretching, balance exercises, etc.). After 6 months, all outcome measures carried out at baseline were repeated using the same procedures.

4. Data analysis

Preliminary analyses were conducted on outcome measures to check if there were gender differences at baseline.

The effects of exercise program on BMI, Fitness Index, and Potential Body Image were analyzed using mixed-effects models, fitted by the Package Lme4 (version 0.999999-0) (Bates, Maechler, Bolker, & Walker, 2015) and by multilevel library (version 2.4) of the R software (R Core Team, 2015). For each dependent variable, subjects were considered as random factor and the time as fixed factor (two levels). To test the differences between the end and the beginning of program, we compared the model including the fixed factor "time", against the "null" model, including the intercept as single fixed parameter. The comparison was performed by using the likelihood ratio test (chi-squared statistics) and the Akaike

Information Criterion (AIC; Akaike, 1974). If the model including the fixed factor presents a smaller AIC than the null model, the "time" factor can be considered as a good predictor of the dependent variable. We expressed the difference in AIC between the two models as ΔAIC. The individual differences were quantified using the Intraclass Correlation Coefficient (ICC (1), which provides an estimation of the effect of individual variability on the total variability (Bartko, 1976; Bliese, 2000). The relationships between variables were calculated at the start and the end of the program, by means of the Spearman's rank correlation coefficient. The comparison between two Spearman's rank correlation coefficients was done after a Fischer's r-to-z transformation (Siegel, 1956).

5. Results

Preliminary analyses show no gender differences at baseline for all outcome variables. Therefore, the data of the males and females were collapsed together.

Descriptive statistics for the complete sample are presented in Table 1. After the intervention, the mean body mass index (BMI, kg/m^2) decreased from 30.79 ± 4.84 to 29.58 ± 4.88. Conversely, the Fitness index increased from 59.19 ± 34.7 to 77.44 ± 33.89. Potential Body Image scores do not change from baseline to 6 months.

Table 1 - *Descriptive statistics*

Measures	Baseline	6 Months
BMI	30.79 (4.84)	29.58 (4.88)
Fitness Index	59.19 (34.75)	77.44 (33.89)
HbA_{1c}	7.04 (1.01)	6.91 (1.32)
Potential Body Image	6.43 (2.50)	6.42 (1.50)

The relationships between variables computed at baseline and the end of the exercise program (6 months), by means of Spearman's rank correlation coefficient, were reported respectively in Table 2 and Table 3.

Table 2 - *Relationships between variables at baseline*

	Fitness Index	HbA_{1c}	Potential Body Image
BMI	-.446 *	.108	.583**
Fitness Index		-.242	-.423 *
HbA_{1c}			.273

* $p < .05$, two tailed tests
** $p < .01$, two tailed tests

Table 3 - *Relationships between variables at 6 months*

	BMI	Fitness Index	HbA_{1c}
Fitness Index	-.591**		
HbA_{1c}	.212	-.154	
Potential Body Image	.118	-.162	.179

* p < .05, two tailed tests
** p < .01, two tailed tests

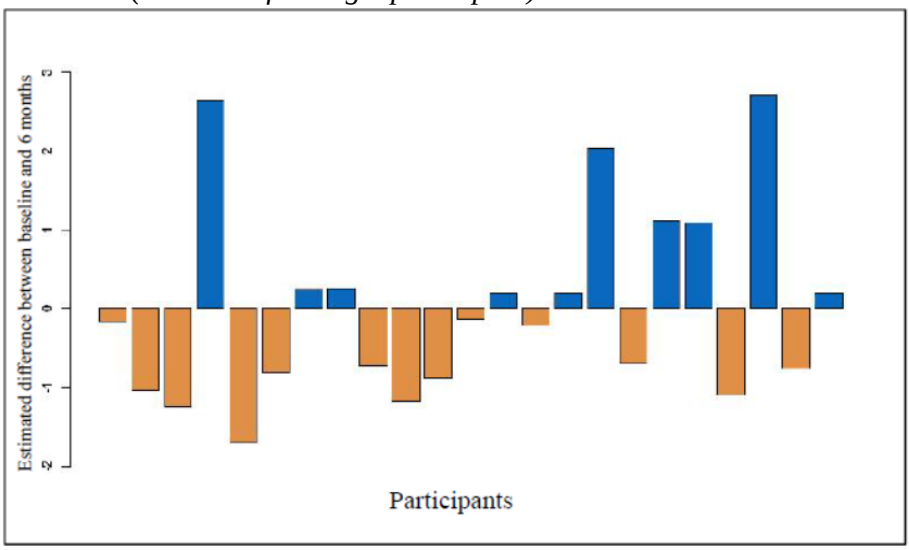
Only the relationship between PBI and BMI show a significant decrease after the six-month intervention ($z = -2.48$, $p = .01$), changing from *rho* = .58 to *rho* = .12.

The models' comparison performed using the likelihood ratio test (chi-squared statistics) and the Akaike Information Criterion show significant changes for BMI ($\chi^2_{(1)} = 12.42$, $p < .001$, $\Delta AIC = -10.42$) and for Fitness Index ($\chi^2_{(1)} = 15.55$, $p < .001$, $\Delta AIC = -23.55$). However, both significant results have a small effect size ($\eta^2 = .02$ and $\eta^2 = .07$, respectively).

No significant differences emerged for Potential Body Image ($\chi^2_{(1)} = .02$, $p = .88$, $\Delta AIC = 1.98$). However, as the analysis outline the 52% of total variance in PBI can be explained by individual differences ($ICC_{(1)} = .52$). Therefore, in a subsequent analysis we included a further parameter that expresses the variability of the angular coefficient among the participants. This model showed a better fit than the model that includes only the angular coefficient ($\chi^2_{(2)} = 7.82$, $p < .05$, $\Delta AIC = -3.83$), indicating a strong component of individual variability in the fluctuations of the beta parameters. As reported in figure 1, after the intervention some participants

show an increase of beta parameters, related to PBI, while others show a decrease.

Figure 1 - *Random beta parameter changes in Potential Body Image (estimated for single participant)*



6. Discussion

This study examined the group and individual changes on BMI, Fitness Index and Potential Body Image in a sample of overweight and moderately obese adults with T2DM, after completing a six-month supervised exercise program.

Our first hypothesis that all outcome measures (BMI, FI, HbA_{1c} and PBI) should show a significant change at the end of the program (6 months) has not been fully supported. In particular, after the intervention, only BMI and Fitness Index showed significant changes: as expected BMI decreases, while Fitness Index increases. Both results confirm previous findings that show the beneficial effect of exercise, in reducing weight and enhancing fitness, in overweight and obese adults with T2DM (Balducci *et al*, 2014; Armstrong & Sigal, 2015). These results appear even more interesting considering that the supervised exercise program was performed once a week, while most of clinical trials evaluating the effects of intervention with T2DM people, have used a three-time per week frequency (Boulé, Haddad, Kenny, Wells, & Sigal, 2001), as recommended by guidelines. The differences reported on BMI and Fitness Index are remarkable, even if their effect sizes were small.

However, also larger clinical trials, conducted with greater statistical power, found small but clinically significant changes in a variety of important outcomes (Balducci *et al*., 2004; Armstrong & Sigal, 2015).

Our results do not support a change in HbA_{1c} and Potential Body Image levels at the end of the program (6 months). Indeed, while the expected declines in Hb_{A1c} were not found, significant differences on PBI occurred only at an individual level, where parameters analyzed showed opposite trends into the sample investigated. These null results can be attributed to different pitfalls as, for example, the exercise duration and the high individual variability of participants. Both conditions were recently taken into account as potential confounding variables in assessing how stability or variability in daily physical activity can have some implications for the mental health of obese adults (Maher, Huh, Intille, Hedeker, & Dunton, 2018). Moreover, it must be remembered that previous research indicates that structured exercise duration of more than 150 minutes per week was associated with greater benefits, as a relevant reduction in HbA_{1c} (Umpierre *et al*., 2011).

The results on correlation analysis supported our hypotheses. In particular, a significant inverse relationship was found both at baseline and at 6 months between Fitness Index and BMI. This relationship increases in strength after the intervention. This finding is consistent with the results of previous researches which demonstrate that Fitness Index correlates more with BMI, than with other variables (i.e., HbA_{1c} and PBI) (Murano, Asakawa, Mizukami, Takihara, Shimizu, & Imai, 2014). Moreover, an inverse relationship was found between Fitness Index and Potential Body Image, which is significant only at baseline. As was already outlined, individuals with T2DM who perceive themselves as overweight or obese were less active, regardless of actual BMI (Heiss & Petosa, 2014). The hypothesis that Potential Body Image should correlate more with BMI at baseline than after exercise program, has been supported. Indeed, women who perceive themselves as overweight or obese are more likely to lose weight than those who did not rate themselves as having a weight problem (Lynch *et al*., 2009). After the six-month intervention, as was reported for obese younger people, the three silhouettes here used are nearly unrelated to continuous measures of body composition (Marsh *et al.*, 2005).

We acknowledge that the study has some limitations. First, participant in the study consist of a convenience sample recruited only from a University Hospital, limiting the generalizability of the study findings. An additional limitation concerns the single arm, pre-post study design, that in the absence

of a non-treatment control group, does not allow to rule out that the obtained results could be due to some methodological artefacts (i.e., regression toward mean). Additionally, we acknowledge that the small sample size of our study would have required repeated measurements of parameters, intermediate between the baseline and 6 months. Future researches should monitor sedentary behavior or physical activity performed at work or during leisure time by means of objective measurements devices (e.g. accelerometers or pedometers). Moreover, the SMT, as other silhouette-based matching task, suffers some limitations due to scale coarseness, restriction of range and constant height across the different figures (Gardner, Friedman, & Jackson, 1998). However, this scale was already used as assessment tools in body image research and intervention and its psychometric properties are reported to be valid and reliable, particularly with high school and college students (Marsh, 1999; Marsh *et al*., 2005; Zappas & Granger, 2017).

A specific consideration requires the wide inter-individual variability that was detected in Potential Body Image. Inter-individual variability must be best controlled increasing the inclusion criteria or introducing some moderator variables, that account for individual variability in the outcome variables, as for example, stage of change (Kraemer, Wilson, Fairburn, & Agras, 2002; Centis *et al*., 2014; Guicciardi *et al*., 2014b). The individuation of moderator variables spurs interventions characterized by a higher level of individualization and cost-effectiveness (Teixeira *et al.*, 2004), targeting specific areas of concern in selected participants or homogeneous groups.

In summary, notwithstanding the limitations previously reported, this study shows that a six-month supervised exercise program is feasible for a small sample of overweight and moderately obese adults with T2DM.

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