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#### ABSTRACT

Aims: To compare the feasibility of high intensity interval exercise (HI-IE) versus moderate intensity continuous exercise (MI-CE) in patients with type 2 diabetes (T2D), and to investigate the preliminary efficacy of HI-IE and MI-CE for improving glycated hemoglobin  $A_{1c}$  (Hb $A_{1c}$ ) and body composition.

*Methods*: Individuals with T2D were recruited and randomly assigned to HI-IE and MI-CE. Exercise training was performed 5 days per week for 12 weeks. Recruitment, retention, adherence, feeling states and self-efficacy were analyzed for feasibility. Changes in  $HbA_{1c}$  and percent body fat from baseline were investigated at 12 weeks to determine the preliminary efficacy.

Results: Of 126 participants showing interest to join the study, 15 individuals were randomized and completed the program. No participants dropped out from the study after enrollment. Adherence rates were high and did not differ between HI-IE and MI-CE (p > 0.05; >97.2% of the eligible exercise sessions for both groups). Feeling states and self-efficacy did not differ between the groups. Percent trunk fat decreased in both HI-IE and MI-CE (p = 0.007and 0.085, respectively). Total percent body fat, percent leg fat, and subcutaneous fat width were significantly reduced in both groups (p < 0.05), whereas HbA<sub>1c</sub> did not change from baseline (p > 0.05). The degree of improvement was similar between the interventions (p > 0.05).

Conclusion: In individuals with T2D, implementing a 12-week structured HI-IE training can be as feasible as MI-CE training. Both interventions are equally effective in lowering total body fat but have little impact on HbA<sub>1c</sub> in relatively well controlled participants with T2D. © 2012 Elsevier Ireland Ltd. All rights reserved.

# 1. Introduction

Current physical activity or exercise recommendations for patients with type 2 diabetes (T2D) suggest a minimum of 150 min per week of moderate to vigorous aerobic exercise [1].

However, data are conflicting as to whether or not individuals with T2D benefit more from participating in high intensity exercise. Recent meta-analyses have highlighted the variability in the response to various exercise protocols and have suggested that a greater exercise dose predicts greater decreases in glycated hemoglobin  $A_{1c}$  (Hb $A_{1c}$ ) [2]. Conversely,

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greater exercise intensity per se has been shown to lead to greater improvements in  $HbA_{1c}$  in some meta-analyses [3] but not others [2,4].

Similarly, while high intensity exercise has been indicated to improve insulin sensitivity [5–7], the mechanisms by which exercise intensity affects insulin sensitivity are not well understood. Acute increases in non-oxidative glucose disposal [8-10] or chronic preferential reduction in intra abdominal adipose tissue (IAAT) [11], just to name a few, may be more prominent following high intensity exercise and contribute to enhanced insulin sensitivity. Recently, more attention has been directed toward the effect of high intensity exercise on IAAT due to its role in the pathogenesis of insulin resistance and T2D. Nonetheless, studies have shown conflicting results with some studies showing preferential reductions in IAAT with higher intensity exercise irrespective of energy expenditure [12-14] while others report no differences [15,16]. Thus, whether exercise intensity can be tailored to favor preferential reductions in IAAT and HbA<sub>1c</sub> remains inconclusive.

While the benefits of high intensity exercise requires further research, there are several concerns regarding the feasibility of implementing high intensity exercise, particularly in older, sedentary or overweight participants with comorbidities such as T2D. Primary perceived barriers include concerns over the risk of injury [17], poor adherence [18], and low self-efficacy in the ability to implement exercise [19]. One approach to minimizing the barriers to high intensity exercise may be the use of interval exercise training which alternates between high intensity exercise bouts and lower intensity recovery periods. Interestingly, while only a few previous studies [20-22] have prescribed interval training in people with T2D, all demonstrated preferable effects with one study [20] reporting greater reductions in HbA<sub>1c</sub> and IAAT than other studies identified in a meta-analysis [2]. Unfortunately, this latter study did not have a moderate intensity exercise comparison group and it is unknown whether the greater than expected benefits were due to the intervention itself or to some characteristics of the participants.

As recently suggested by Hawley et al., high intensity interval training may be a potent therapeutic intervention to improve blood glucose concentrations and body composition [23]. Nonetheless, to our knowledge there has not yet been a randomized trial that compares the feasibility and chronic effects of high intensity interval exercise (HI-IE) and moderate intensity continuous exercise (MI-CE) interventions in T2D. The objective of this pilot study was to compare the feasibility (recruitment, adherence and retention) of HI-IE versus MI-CE in patients with T2D. Secondary outcomes of interest included investigation of the preliminary efficacy of HI-IE and MI-CE in improving HbA<sub>1c</sub> and estimates of IAAT. Compensatory changes in daily steps and energy intake throughout the study were also investigated.

# 2. Methods

### 2.1. Design

This was a 12-week, single center, parallel-group randomized trial (ClinicalTrials.gov registration number: NCT01144078) conducted in Edmonton, Alberta, Canada. Ethical approval was obtained from the University of Alberta Health Research Ethics Board.

## 2.2. Participants

Initial recruitment was conducted through newspaper advertisement and websites. These recruitment strategies briefly outlined the inclusion criteria: (1) men and women between 55 and 75 years (y) of age; (2) diagnosed with T2D; (3) able to exercise 5 days per week; and (4) non-smokers. Other recruitment procedures were conducted through word of mouth and by contacting the individuals with T2D who expressed interest in participating in research studies.

The study coordinator conducted a brief telephone interview to confirm the potential eligibility of participants, answered questions regarding the study, and scheduled a first meeting. In the first meeting participants responded to questionnaires to further screen for the following criteria: (1) post-menopausal for more than 5 y; (2) <150 min of structured exercise per week; (3) <3 kg body weight change within the last 6 months (mo); (4) absence of diabetes-related complications and limitations to regular exercise; and (5) self-reported absence of alcohol or substance abuse within last 12 mo. Blood pressure (BP) was measured at rest to ensure the participants were safe to perform exercise intervention (cutoff criteria < 140/90). The use of prescription medications that might affect body fat distribution (i.e., insulin and thiazolidinedione) was considered a contraindication to participation. Participants meeting the inclusion criteria provided a baseline fasting blood sample measured at a local accredited diagnostic laboratory (DynaLIFE $_{\mbox{\scriptsize DX}}$ , Edmonton, AB). Individuals with  $HbA_{1c}>9\%,\ LDL>3.5\ mmol/l\ or\ total\ cholesterol\ to\ HDL$ ratio > 5.0 were excluded. The fasting blood sample was used to determine baseline lipids, lipoproteins, fasting blood glucose and HbA<sub>1c</sub> concentrations. All participants provided written informed consent.

#### 2.3. Initial assessment

Participants performed a graded exercise stress test on a treadmill (stress test) under the supervision of a trained physician, and reported to the University of Alberta on a separate day to assess baseline anthropometric characteristics, body fat, peak oxygen consumption (VO<sub>2peak</sub>) and ventilatory threshold (VT). Height was measured with a wallmounted stadiometer. Waist and hip circumferences and sagittal diameter were measured as previously described [24]. Briefly, waist and hip circumferences were measured with a flexible tape measure (Almedic, Saint-Laurent, QC) in standing with feet together at the end of a normal expiration (endtidal). Waist circumference was measured midway between the costal arch and the iliac crest and hip circumference was measured as the maximal circumference over the buttocks at the level of the trochanters. For sagittal diameter, while participants were lying supine on the floor, a sliding-beam caliper was used to measure the vertical distance between the floor and the abdomen at the level of umbilicus. All measures were performed in duplicate to the nearest 0.1 cm. Where the difference exceeded 0.5 cm, measurements were repeated and the average of the closest two was calculated.

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