



Intensive lifestyle intervention is particularly advantageous in poorly controlled type 2 diabetes

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Abstract *Background and aims:* It is unknown whether lifestyle change is effective in people with type 2 diabetes with inadequate glucose control. The aim of this study was to assess, in a group of people with type 2 diabetes, the impact of baseline values of glycosylated haemoglobin (HbA1c) on the effects of an intensive lifestyle intervention on metabolic, clinical and strength parameters.

Methods and results: 222 people with type 2 diabetes with mean \pm standard deviation baseline HbA1c of $7.50\% \pm 1.27$ (range 5.1–12.7%), were enrolled in a 3-month structured multidisciplinary lifestyle intervention. Anthropometric, biochemical, clinical and fitness measurements were collected at baseline, at the end of the lifestyle intervention program and at two-year follow-up visit. Significant improvements in glycometabolic control (HbA1c: $p \leq 0.0001$); anthropometric parameters (BMI $p \leq 0.0001$; waist circumference: $p \leq 0.0001$); and systemic blood pressure ($p \leq 0.0001$) were observed both at the end of the three month intensive lifestyle program and at the two-year follow up visit. In addition, defined daily doses of hypoglycaemic treatment significantly decreased ($p = 0.001$).

Fitness measures exhibited significant increments in the whole sample at the end of the intensive intervention program ($p \leq 0.0001$). When patients were divided into tertiles considering the baseline value of HbA1c, the most marked improvements in HbA1c, blood glucose and triglycerides were observed in the group with inadequate glucose control (HbA1c $\geq 7.71\%$), both at the three-month and two-year follow-ups.

Conclusion: These results demonstrate that an intensive lifestyle intervention should be recommended for people with type 2 diabetes, particularly those with the most inadequate glycaemic control.

Registration number: CURIAMO trial was registered in the Australian New Zealand Clinical Trials Registry, (ACTRN12611000255987).

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Abbreviations: DM2, Type 2 diabetes; WHO, World Health Organization; ADA, American Diabetes Association; HHR, Heart Rate Reserve; 1RM, One repetition maximum; BMI, Body Mass Index; DDD, Defined Daily Doses; SD, Standard deviation; ACTRN, Australian New Zealand Clinical Trials Registry; HbA1c, Glycosylated haemoglobin.

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Introduction

The WHO reported the global prevalence of diabetes for 2014 as 9% among adults [1]. In 2012, diabetes was directly responsible for an estimated 1.5 million deaths [2], and is predicted to be the 7th leading cause of death in 2030 [3]. Type 2 diabetes (DM2), that accounts for about 90% of all diagnosed cases of diabetes worldwide [4], is largely the result of excess body weight and physical inactivity. According to position statements published by the American Diabetes Association, American College of Sports Medicine and American Health Association, structured lifestyle intervention should be the first approach to diabetic disease [5,6]. The lifestyle intervention CURIAMO trial (Australian New Zealand Clinical Trials Registry, ACTRN12611000255987) performed at the Healthy Lifestyle Institute of Perugia University (C.U.R.I.A.M.O., *Centro Universitario di Ricerca Interdipartimentale Attività Motoria*) is designed to promote participants' growth in three parallel fields: exercise, nutrition and psychological well-being [7]. The multidisciplinary approach involves multiple health care professionals (exercise physiologist, endocrinologist, sports medicine physician, psychologist, dietician, educator, nurse) who work together to support patients in achieving long-lasting lifestyle change.

Despite the clinical guidelines of scientific societies considering lifestyle change as a basic therapeutic option for DM2 prevention or treatment, there are no data on the efficacy of lifestyle intervention in relation to the degree of baseline glucose control. To the best of our knowledge there is one study that demonstrated, in a subgroup analysis limited to participants with a baseline HbA1c value > 7%, greater improvement in glycaemic control following an exercise program among persons with higher baseline haemoglobin A1c values over a six-month period [8].

Thus, the aim of this study was to assess the impact of patients' baseline value of glycosylated haemoglobin on the effects of an intensive lifestyle intervention on metabolic, clinical and strength parameters in a group of people with type 2 diabetes.

Methods

Subjects

Among 1464 subjects enrolled in the CURIAMO trial from 2010 to 2014, 222 subjects (122 males and 100 females) with type 2 diabetes mellitus (according to the diagnostic criteria for diabetes from American Diabetes Association (ADA) guidelines [9]) participated and completed a three-month intensive lifestyle intervention program of the CURIAMO trial.

This model included follow-up visits performed annually for 5 years. We report data from baseline (T0), control visit after intensive intervention (T1 - three months), and two-year follow-up visit (T2). Analyses were limited to participants with baseline (T0) and control (T1) data on all

measurements (n = 222). 142 subjects participated at the two-year follow-up visit (T2).

The study was approved by the local Ethics Committee (CEAS Umbria Region, HREC number 1/10/1633). Full informed consent was given by all participants at the beginning of the treatment. Inclusion criteria were: age between 18 and 80 years, BMI >27 Kg/m² and type 2 diabetes. Exclusion criteria were orthopaedic or other medical conditions that would contraindicate exercise testing or the practice of physical activity.

Baseline characteristics of the study population with diabetes are shown in Table 1.

Lifestyle intervention

The intensive phase of the three-month lifestyle intervention program involved different qualified personnel, as previously described in detail [7]. Briefly, during the intervention, patients underwent: 1) an initial medical examination; 2) an interview by a psychologist; 3) an assessment by a dietician and nutritional intervention; 4) a physical examination by a sports medicine specialist; 5) an individualized program (groups of five to six patients) of 26 sessions (two per week) of structured indoor exercise, described elsewhere [7]; and 6) eight sessions of group therapeutic education conducted by a doctor of pedagogical sciences.

The initial interview with a psychologist was aimed at increasing the subject's motivation to change and to assess his/her compliance and psychological status [7].

The exercise program was performed in a gym twice a week for three months (total 26 sessions) and supervised by an exercise physiologist. Each session lasted 90 min. These were divided into 60 min of aerobic workout and 30 min of circuit training for muscular strength. The aerobic workout was performed using ergometers for cardiovascular work with a gradual increase of the workout intensity (5% every 3 weeks) up to 70% of Heart Rate Reserve (HHR), established by Karvonen's formula [10]. Muscular strength was assessed using isotonic machines starting with a load corresponding to 50% of one repetition maximum (1-RM); 1-RM is defined as the maximum weight that can be lifted by a subject for a single repetition in a specific exercise. The load was gradually increased every three weeks, if possible. In conjunction with the beginning of physical activity sessions, patients were invited to attend 8 focus groups, conducted by a doctor in pedagogic sciences, in which participants were given the opportunity through self-narration and self-writing to express and free themselves of difficulties, fears and problems related to their disease which prevented their achieving lifestyle change [11]. During the intensive phase of the lifestyle intervention program, patients underwent a nutritional intervention that consisted of periodic individualized nutritional visits and four sessions of nutrition education, performed by dieticians. The aim of these visits was to support the change in nutritional habits based on national recommendations [12].

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