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An innovative model for changing the lifestyles of persons with obesity and/or Type 2 diabetes mellitus

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ABSTRACT. Aim: To describe the multidisciplinary lifestyle intervention model used in an experimental CURIAMO (Centro Universitario Ricerca Interdipartimentale Attività Motoria) project designed to validate the short- and long-term efficacy of the model in obesity and Type 2 diabetes. Research design and methods: Over a 3-yr period, about 1000 adults (70% diabetes-free and overweight or obese; 30% with Type 2 diabetes and overweight or obese). Inclusion criteria: Age range 18-80 yr, body mass index >27 kg/m² with or without Type 2 diabetes mellitus; participants will be divided into three age groups (18-45, 45-65, 65-80 yr). The study duration will be from 5 to 6 yr: 1 yr of intervention followed by a mean follow-up period of 4 yr. In the first years, after a 4-month intensive lifestyle intervention, subjects will follow a maintenance programme. The intervention, which includes seven steps, involves the following experts: endocrinologists, sport medicine doctors or cardiologists, psychologists, dietitians, educators, nurses, exercise physiologists, and promoters of outdoor activities. Results: The main endpoint of the study is to measure the efficacy of the lifestyle improvement intervention, defined as a loss of at least 7% of body weight combined with an increase of at least 10 MET/h·week⁻¹ of energy expenditure by physical activity, after 1 yr and during the follow-up. A cost/utility analysis of the model will be made in participants with diabetes. Conclusions: We expect that the CURIAMO model will be highly effective, and that the aim of the intervention will be achieved in more than 70% of cases.


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INTRODUCTION

It is stated in the website of the World Health Organization (WHO), which is concerned about the rising incidence of obesity and diabetes worldwide consequent to the current sedentary lifestyle, that: “Each year, at least 1.9 million people die as a result of physical inactivity; without action to address the causes, deaths from non-communicable diseases will increase by 17% between 2005 and 2015” (1). In a recent joint document produced by the WHO and the World Economic Forum it is estimated that approximately 80% of cases of heart disease, stroke, Type 2 diabetes and 40% of cancers could be prevented through inexpensive and cost-effective interventions addressing the primary risk factors (2).

Lifestyle modifications involving changes to diet and exercise are effective in reducing the incidence of Type 2 diabetes in subjects with impaired glucose tolerance by ~60% (3, 4). The demonstration that physical activity counseling can motivate most diabetic patients to increase their levels of voluntary energy expenditure (5, 6) underlines the importance of instituting physical activity programs as an essential part of therapy for patients with Type 2 diabetes mellitus. In the Diabetes Prevention Research Group study (4), a goal of 150 min/week of physical activity was recommended, and 74% of the patients achieved this level by the 24th week of undergoing the intervention programme. This type of success in lifestyle modification has been made possible in research protocols thanks to intensive counseling (7). At present, there is a need for validated multidisciplinary models designed to deliver healthy lifestyle interventions to people at risk of, or already suffering from, Type 2 diabetes, research on this aspect being limited. According to the American Diabetes Association (ADA) 2010 Standards of Care, diabetics should receive medical care from a physician-coordinated team. Such teams may include, but are not limited to, physicians, nurse practitioners, physicians’ assistants, nurses, dieticians, pharmacists, and mental health professionals with expertise and a special interest in diabetes (8). The aim of the present paper is to describe an innovative multidisciplinary model for intensive lifestyle intervention in obesity and Type 2 diabetes based on the ADA principle of an integrated team approach. The model, theoretically grounded on social cognitive (9) and group empowerment (10) theories, is to be validated at the Healthy Lifestyle Institute of Perugia University (CURIAMO: Centro Universitario Ricerca Interdipartimentale Attività Motoria). The CURIAMO model involves the following health care professionals: endocrinologists, sport medicine physicians or cardiologists, psychologists, dieticians, educators, nurses, exercise physiologists, and a manager for outdoor leisure time activities. The philosophy of the CURIAMO model is the active involvement of the patient, who is considered the main character in achieving change.
MATERIALS AND METHODS

The aim of the project is to validate the short-term (1 yr) and long-term efficacy (3-5 yr) of the CURIAMO model, and to estimate its cost/utility ratio in the management of obesity and Type 2 diabetes. The primary endpoint/outcome is the efficacy of the intervention in improving lifestyle. A significant improvement in lifestyle is defined by a loss of at least 7% of body weight combined with an increase in weekly energy expenditure of at least 10 MET/h·week⁻¹, by physical activity (4). We postulate that by the end of the study period (6 yr), more than 70% of the enrolled participants will have improved their lifestyle. Secondary outcomes for Type 2 diabetes participants are: reduction in glycosylated hemoglobin (HbA₁c) levels and in the risk of cardiovascular disease [United Kingdom Prospective Diabetes Study (UKPDS) risk engine model]. Furthermore, in Type 2 diabetes participants, a cost/utility analysis of the model will be made. The CURIAMO trial has been registered in the Australian New Zealand Clinical Trials Registry (a Primary Registry in the WHO registry network) with the number: ACTRN12611000255987.

Study design (Fig. 1)

Over a 3-yr time period (Enrolment Phase or PHASE 1), about 1000 patients will be enrolled: ~700 male and female adult participants with body mass index (BMI) > 27 kg/m², and ~300 male and female participants with Type 2 diabetes (overweight or obese). Inclusion criteria are: age between 18 and 80 yr, BMI > 27 kg/m² with or without Type 2 diabetes mellitus. Exclusion criteria are: concomitant diseases contraindicating physical exercise. Participants will be equally divided by sex into the following age groups: 1) young people (18-45 yr), 2) middle age (46-65 yr), 3) elderly people (66-80 yr), in order to evaluate whether the impact of the intervention is the same in different age groups. Socio-economic status, education levels, work/reirement status or living conditions will be recorded for subsequent analysis of the impact of these variables on the outcome of the intervention.

The estimated number of enrolments is 40 to 50 participants every 2 months, the aim being an annual accrualment of 200 to 250 obese/overweight patients and 100 to 125 Type 2 diabetics. Following Enrolment Phase (Phase 1), the intervention program (Phase 2) will be initiated; the entire program lasting no more than 6 yr, this Phase will consist of 1 yr of intervention program and a mean follow-up in the region of about 48 (range 36-70) months. In the first year (Intensive Program Phase), following the initial 4-month period of intensive lifestyle intervention, all participants will follow a maintenance program and undergo medical examinations at CURIAMO, every 3 months during the first year of follow-up, and every 4 months thereafter, until the end of the study period.

The intensive lifestyle intervention (Table 1) (Fig. 1) of the first 4 months includes the following steps: 1) initial medical examination by an endocrinologist; 2) interview by a psychologist; 3) assessment by a specialist in nutrition; 4) examination by a specialist in sport medicine; 5) a supervised program of 24 sessions (2 per week) of structured indoor exercise with an exercise physiologist; 6) group therapy sessions with other patients (12 patient in each group) organized by an educator (a doctor of pedagogic sciences) and a nurse; 7) daily Nordic walking activity combined with weekend walking excursions planned by a manager for outdoor leisure time activities. For step 7, attendance by participants is optional, the choice to be made by participants being left open until the end of the study.

Steps 1 to 4 are designed for achieving a clinical assessment, and promoting behavioral changes in the participants. Steps 5 to 7 are designed to improve physical fitness and to use group power to support long-term lifestyle change.

Step 1

The first medical examination with the endocrinologist is designed to clinically evaluate the disease and any complications, and to establish whether the subject meets the enrolment criteria. During the 40-min examination, the endocrinologist will help patients develop an awareness of the causes of their disease, and explain ways in which they can improve their health. During the visit, the CURIAMO model of lifestyle intervention is explained, blood tests and drugs are prescribed according to

![Fig. 1 - Design of intensive 4-month intervention.](image-url)
Table 1 - Clinical and psychological steps of the CURIAMO (Centro Universitario Ricerca Interdipartimentale Attività Motoria) model toward established lifestyle change.

<table>
<thead>
<tr>
<th>Step</th>
<th>Professional in charge</th>
<th>Main clinical goal</th>
<th>Main psychological goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Endocrinologist</td>
<td>Evaluation and treatment of the disease and its complications</td>
<td>To increase patient’s awareness</td>
</tr>
<tr>
<td>Step 2</td>
<td>Psychologist</td>
<td>Assessment of mental health status</td>
<td>To increase patient’s motivation to change</td>
</tr>
<tr>
<td>Step 3</td>
<td>Dietitian or physician specialized in nutrition</td>
<td>Assessment of nutritional status, correction of nutritional errors</td>
<td>To increase patient’s consciousness</td>
</tr>
<tr>
<td>Step 4</td>
<td>Sports medicine physician or cardiologist</td>
<td>Evaluation of aerobic capacity and muscle strength</td>
<td>To increase patient’s consciousness</td>
</tr>
<tr>
<td>Step 5</td>
<td>Exercise physiologist</td>
<td>Improvement of aerobic performance and muscle strength</td>
<td>To increase patient’s self-esteem and pleasure</td>
</tr>
<tr>
<td>Step 6</td>
<td>Doctor in pedagogic sciences and educator nurse</td>
<td>Therapeutic group education to promote motivation to change</td>
<td>To increase patient’s adherence to established lifestyle change</td>
</tr>
<tr>
<td>Step 7</td>
<td>Instructor of Nordic walking, Manager for leisure time activities</td>
<td>To improve aerobic performance, recommend attractive trails and offer new opportunities to exercise in group</td>
<td>To promote patient’s autonomy and pleasure through exercising in an enjoyable environment</td>
</tr>
</tbody>
</table>

Step 2
The interview with a psychologist at the beginning of the therapeutic program aims to increase the subject’s motivation to change and to assess his/her psychological status. In our model, the psycho-motivational interview is specifically focused on assessing therapeutic compliance and the subject’s motivation to change. The psychologist listens to the subject’s personal history, coping strategies and expectations regarding the rehabilitation program. Moreover, during the psycho-motivational interview a test is administered in order to identify patients at risk of dropping out. A meta-analysis of 42 studies demonstrated that 11.4% of patients with diabetes meet the criteria for comorbid major depression and 31% have significant symptoms of depression (13). In our model, participants with psychological disorders with a potentially negative impact on behavioral change are invited to attend a program of 12 sessions of group psychotherapy. Psychotherapy groups, limited to a maximum of 25 people, are intended to promote the personal growth and psychological health of participants (14). In fact it has been observed that patients with both diabetes and depression have worse adherence to multiple components of self-care regimen with a consequently compromised clinical outcome (15). If necessary, during the psychological interview, participants will receive counseling for smoking cessation.

Step 3
The assessment with a nutritionist and/or a dietician (duration, 30-45 min) is intended to assess the nutritional behavior of the subject, help raise his/her awareness about correct nutrition and plan a strategy to optimize nutrient intake. A dietary intake questionnaire for the quantitative estimation of adherence to the cardioprotective “Mediterranean diet” is administered (16). Body composition for total lean body mass, upper and lower limbs lean mass (BC-420 S MA, and Segmental Body Composition Analyzer, Tanita Europe), is measured by non-invasive multi-frequency bioimpedance analysis. Nutritional counseling, based on the Mediterranean diet principle for both obese/overweight patients and diabetics, aims to reduce saturated and trans-un-saturated fatty acids to under 10% of the total daily energy, to promote the consumption of fish, vegetables, legumes, fruit and whole grain cereals, of “natural” (organic?) foods rich in dietary fibers, and to reduce calorie intake by preventing frequent nutritional pitfalls (17). During the intensive intervention period, all participants are invited to attend 6 group educational sessions (15-20 people and 2 dieticians) planned to discuss issues about correct nutrition and weight loss and to a laboratory of taste and healthy recipes.

Step 4
The examination with the medical specialist in sport medicine is intended to measure aerobic capacity and muscle strength. The protocol test for maximal aerobic capacity, an incremental treadmill, starts with a 5-min warm-up at a speed of 2-3 km/h; the load is then increased by 1 km/h, every 5 min until exhaustion. At the end of each step, the participant is given 20-sec rest and capillary blood is drawn from the ear lobe for the determination of blood lactate using a lactate meter (Lactate Pro, Arkay, Tokio, Japan). The heart rate, continuously monitored by electrocardiogram, is used for obtaining the values corresponding to lactate concentrations of 2, 3, and 4 mM. These parameters are used to plan training and to monitor its effects. The maximum dynamic force of extensor muscles of the leg and the flexor and extensor muscles of the arms is determined by means of the indirect method of extrapolation to 1, using one maximal repetition test on the leg press, and the lat chest press machines. Tests of aerobic capacity and muscle strength are also used to heighten the participants’ awareness of their physical status and to show them how to improve upon it.

Step 5
The exercise physiologist aims to achieve improvement in the participants’ aerobic performance and muscle strength, and in their self-esteem, an indoor exercise program being used. The indoor exercise program has been designed using international guidelines for patients with Type 2 diabetes (18-20). Training consists of two sessions a week (3-day interval) at the gym for a total of 12 weeks (3 months). Each session, which lasts 90 min, is divided into 60 min of aerobic workout and 30 min of circuit training to enhance muscle strength and also to provide flexibility exercises. The aerobic workout is performed using er-
gometers for cardiovascular exercise (treadmill, bike, step and arm ergometers). The intensity of the workout is gradually increased (4 steps) from 50 to 65% of the heart rate reserve. The workout for muscular strength uses machines and isotonic free weights for the training of the lower and upper limbs; intensity is gradually increased, starting with 50 to reach 65% (there is one lower and one upper limit) of 1 repetition maximum (RM). Before and after each session, the resting heart rate, blood pressure and capillary blood glucose (participants with Type 2 diabetes) are measured. Training sessions are monitored by real-time heart rate telemetry (Hosand Technologies, Verbania, VR, Italy) and data are fed into a computer for subsequent analysis. The intensity of the training sessions is increased in four steps (50%, 55%, 60%, 65%) every 6 sessions.

Step 6
This step, conducted by a specialist in patient education (PhD in pedagogic sciences) and by a nurse with experience in therapeutic education for diabetic patients, is designed to stimulate the subject’s motivation to establish a lifestyle change. Patients are invited to attend 4 to 5 group meetings, once a week, for an hour and a half. The meetings focus on self-reflection, self-narration and self-writing. A disease cannot be seen only in the light of its organic features: subjective aspects and implications must also be taken into account (7). The narrative-autobiographical approach (21) is thus an effective tool in patients to reveal their needs and feelings in relation to their condition, and to gain an awareness of their own history and disease. It also represents a safety valve, “outlet” for the distress and sorrow that accompany the disease. In a straight-forward and clear way, patients are asked to narrate and, in particular, write about themselves and about some key aspects which represent the daily challenges of living with diabetes and obesity (21) (i.e. difficulties, fears, needs and limits related to the disease); they are asked to write about their relationship with food, with their own body, with others and with self-care. Moreover, the possibility of sharing one’s stories within a group of peers is of added value, providing patients with the opportunity to make comparisons and interact with their fellow group members, thus helping them overcome feelings of loneliness and separation, typical of sufferers of this disease; it also helps them address any difficulty (often related to their educational status) that they experience in writing essays.

Step 7
The outdoor walking activity is designed to increase energy expenditure, aerobic performance and long-term adherence to exercise. The participants are given an opportunity to attend daily group sessions of Nordic walking (with heart rate monitoring) in a pleasant environment, and weekend walking excursions are organized; this enables patients to discover the pleasant surrounding areas in the region. From a physiological point, this strategy supports lifestyle change, enhancing the pleasure gained by taking part in an outdoor activity within a group setting. In addition, once the treatment has been completed, participants who need a continuing challenge can take part in an annual trek: a walking trip across Italy from coast to coast for a total of 250 miles in 14 days.

Maintenance period
All participants are required to undergo medical examinations every 3 months for the first year, and subsequently every 4 months; steps 2, 3 and 4 are repeated every 6 months until the end of the study period. Examinations are performed to evaluate the effects of the intervention and to reinforce the achieved results. Attendance for step 7 is unplanned, the opportunity being made available throughout the study period in order to promote the subject’s spontaneous choice to do physical exercise. Weekly meetings are arranged, which allow the health care professionals involved in the project to discuss the cases calling for special attention.

Measurements
Before starting the program and every 3 to 4 months thereafter, all participants undergo measurement of the following: weight, waist circumference, changes in body composition for total lean body mass, upper and lower limb lean mass (BC-420 S MA, Segmental Body Composition Analyzer, Tanita Europe), blood pressure (2 measurements in clino-statism), resting heart rate, test for aerobic capacity and muscle strength, HbA1c, blood glucose, insulin, total cholesterol, LDL, HDL, triglycerides, as described elsewhere (22). Cardiovascular disease risk is estimated using UKPDs tables for coronary events and ischemic stroke (23); energy expenditure due to physical activity is estimated using the International Physical Activity Questionnaire (12). Cost analysis includes registration of health-related (drugs, biochemical analyses, hospital admittances) and social (loss of working days) costs incurred during the study period. All changes in national health system and social costs are recorded every 3 to 4 months to calculate the cost/utility ratio for the intervention using UKPDs outcomes model (24).

Statistical analysis
Discrete survival analysis will be used for primary outcome, and longitudinal data analysis (mixed models) will be used for secondary outcomes (25).

DISCUSSION
The CURIAMO model is theoretically grounded on socio-cognitive (8) and group empowerment (9) theories. The main aim of the multidisciplinary approach used by us to address obesity and diabetes is to actively involve the patient, who is considered as the main protagonist in achieving change. For this reason, the intervention is characterized by counseling centered on each patient’s needs, by promoting the involvement of patients in educational group sessions, by tailoring (to suit each patient) the intensity of work during exercise sessions and by allowing patients to freely organize their physical activity on completing the four month intensive program of lifestyle change. The primary outcome of the study is to verify the efficacy of the model in improving lifestyle (i.e. the percentage of participants who maintain a healthy lifestyle at 1 yr and after 4 yr) following the intervention. The improvement (i.e. loss of at least 7% of body weight combined with an increase of at least 10 MET·h·1·week·1 of energy expenditure by physical activity), validated for diabetes prevention in the Diabetes Prevention Programme (4), was considered a significant improvement in lifestyle in our patients. The analysis results in relation to sex, age, groups and diseases (obesity or Type 2 diabetes) will yield relevant data on the efficacy of the model in these subgroup categories. We anticipate that dropouts in
obese people will be greater than in those with Type 2 diabetes, but we do not expect gender- or age-related differences in results. The fundamental feature of the CURIAMO model is the multidisciplinary approach that it uses, which is designed to promote participants’ growth in three parallel fields: exercise, nutrition and psychological well-being. Motivation to change is based on promoting decisional balance and auto-efficacy (8), motivation to long-term stable lifestyle improvement is based mainly on several group empowerment strategies (9); educational group sessions for nutrition and for motivation to change, indoor group exercise sessions and outdoor excursions and activities. The seven steps of the model are designed to promote a progressive maturation of participants toward a stable lifestyle change, a key role being played by the physical exercise intervention, which, in agreement with international guidelines (18-20), includes both resistance and endurance training since there is evidence that the decrease in HbA1c is enhanced more when two types of exercise are combined (26, 27). According to the model, for 3 months participants should attend two indoor sessions per week, together with elective open air walking activities on the other 5 days of the week. This choice is based on several considerations: 1) patients usually do not have enough time to exercise; 2) available data show that two structured sessions of indoor exercise are sufficient to ameliorate several parameters of the metabolic syndrome in participants with Type 2 diabetes (28); 3) the strategy to give patients the option to exercise during the other five days of the week increases their autonomy in choosing pleasant physical activities during their leisure time.

The psychological growth proposed by the CURIAMO model is based on numerous aspects that sustain a behavioral change, including consciousness, self-esteem, pleasure, support, and reinforcement as shown (5) and discussed in detail (7) elsewhere. The present model of lifestyle intervention represents an advancement in our previous physical activity counseling strategy (5); the personal experience gained in our approach to patients with obesity and/or Type 2 diabetes who have a sedentary lifestyle has led us to believe that physicians are more successful in promoting healthy behavior patterns when they work together with fellow health care professionals as a coordinated team. In our view, the strengths of our model lie in its structured multidisciplinary approach and the attention that is paid to patients with psychological problems, who receive specific support through group psychotherapy. For these reasons, we expect that the efficacy of the CURIAMO model will be high and that more than 70% of patients will achieve the primary outcome of the study. It is expected that the cost/utility analysis will demonstrate that the model is also cost-effective; this finding should promote its incorporation in the National Health System.

The burden of diabetes and its related complications has an impact not only on the quality of life of individuals and their families, but also on the country socioeconomic structure (2). The WHO and the World Economic Forum estimate that this ‘epidemic’ will lead to an enormous loss of national income in different countries throughout the world (2). With respect to our investment in understanding the causes and consequences of health issues, we believe that an adequate investigation into the best possible ways of organizing, managing and financing health promotion has not yet been adequately undertaken (29). Yet we trust that the description of our multidisciplinary model for promoting healthy lifestyles and its future validation will lead to the diffusion of structured models of intervention encompassing the experience and the skills of different health professionals. Patients and personnel receive direct benefits when the multidisciplinary approach is used. The former perceive the effort and the support provided by a team focusing on improving their psychological and clinical conditions and are therefore strongly motivated to change. The latter are reinforced in their motivation to conduct a multidisciplinary approach that underlines their specific competences, by benefiting from the positive feedback given by patients, and in the weekly operational meetings.

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