UNIVERSITAT DE LLEIDA

Institut Nacional d'Educació Física de Catalunya

INSTITUTO POLITÉCNICO DE SANTARÉM

Escola Superior de Desporto de Rio Maior

Fonaments Metodològics de la Recerca de l'Activitat Física i l'Esport

TESI DOCTORAL

Effects of a Physical Activity and Dietary Education Intervention in a Population with type 2 Diabetes *Mellitus*

Félix Luís de Lima e Cunha Hopffer Romero

Director: Pedro Manuel Marques Vidal PhD

LLEIDA, 2010

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RESUM

RESUM

Antecedents: la diabetis tipus 2 és cada vegada més freqüent en la població general. L'activitat física adequada i els hàbits alimentaris són les pedres angulars per al tractament de la diabetis i per tant els programes d'intervenció de millora de l'estil de vida poden ser de valor, però l'impacte d'aquests programes necessita més estudi.

Mètodes: 43 persones diagnosticades amb diabetis tipus 2 van ser assignades a un grup de control (12 homes i 12 dones, 68,9 ± 11,3 rang 46-84 anys) i altre grup a una intervenció (6 homes i 13 dones, 69,5 ± 8,9 rang 52-81 anys), en funció de la seva voluntat. El grup d'intervenció va rebre un programa d'estil de vida incloent classes d'activitat física i d'assessorament dietètic per a un període de 9 mesos. El grup control va rebre l'atenció habitual. Van ser avaluats els canvis en els hàbits d'activitat física i alimentaris i les seves conseqüències en les variables biològiques (pes, composició corporal, pressió arterial, perfil lipídic, HbA1c i glucèmia), de fitness (força física, resistència aeròbica, flexibilitat i agilitat), psicològiques (Profile of Mood States) i econòmiques (despeses individuals i els de l´Estat en referència als medicaments).

Resultats: Els participants del grup d'intervenció tendeixen a augmentar la seva activitat física en general (p = 0,020), i a adoptar millors patrons en la dieta (p = 0,050). No obstant això, els canvis en l'estil de vida van ser lleus: l'increment de l'activitat física general fora del programa va ser no significatiu i els canvis en la conducta alimentària no van ser suficients per a, de forma significativa, modificar el percentatge de participants que complien les recomanacions dietètiques per a la població portuguesa. Canvis significatius van ser trobats en la força de l'extremitat inferior (p = 0,014), de les extremitats superiors (p = 0,001), la resistència aeròbica (p = 0,001) i la flexibilitat de les extremitats superiors (p = 0,040). Per altra banda, no es van trobar canvis significatius en la composició corporal, pressió arterial, perfil lipídic, o el control glucèmic. El perfil dels estats d'ànim va mostrar una disminució significativa en el factor fatiga-inèrcia (p=0,002). Les despeses de la medicació va incrementar substancialment per a l'Estat (p = 0,028) però no per als individus.

Conclusions: Els subjectes sotmesos al programa d'intervenció de millora de l'estil de vida van obtenir un èxit moderat en relació al canvi de comportament, però no suficient per a obtenir un impacte significatiu en la majoria de les variables clíniques i biològiques. Gràcies al programa de fitness van millorar i la fatiga percebuda es va reduir. Els nostres resultats suggereixen que per a ser més efectius, la intervenció ha de començar tan ràpid com sigui possible, ja que la seva implementació en persones grans resulta més complicada. Això permetria una resposta major al programa i una implicació en l'activitat física més intensa.

RESUMEN

RESUMEN

Antecedentes: la diabetes tipo 2 es cada vez más frecuente en la población general. La actividad física adecuada y los hábitos alimentarios son las piedras angulares para el tratamiento de la diabetes y por lo tanto los programas de intervención de mejora del estilo de vida pueden ser de valor, pero el impacto de estos programas necesita más estudio.

Métodos: 43 personas diagnosticadas con diabetes tipo 2 fueron asignadas a un grupo de control (12 hombres y 12 mujeres, 68,9 ± 11,3 rango 46-84 años) y otro grupo a una intervención (6 hombres y 13 mujeres, 69,5 ± 8,9 rango 52-81 años), en función de su voluntad. El grupo de intervención recibió un programa de estilo de vida incluyendo clases de actividad física y el asesoramiento dietético para un período de 9 meses. El grupo control recibió la atención habitual. Fueron evaluados los cambios en los hábitos de actividad física y alimentarios y sus consecuencias en las variables biológicas (peso, composición corporal, presión arterial, perfil lipídico, HbA1c y glucemia), de fitness (fuerza física, resistencia aeróbica, flexibilidad y agilidad), psicológicas (Profile of Mood States) y económicas (gastos individuales y los del Estado con los medicamentos).

Resultados: Los participantes del grupo de intervención tienden a aumentar su actividad física en general ($p = 0,020$), y a adoptar mejores patrones en la dieta ($p = 0,050$). Sin embargo, los cambios en el estilo de vida fueron leves: el incremento de la actividad física general fuera del programa fue no significativo y los cambios en la conducta alimentaria no fueron suficientes para, de forma significativa, modificar el porcentaje de participantes que cumplían las recomendaciones dietéticas para la población portuguesa. Cambios significativos fueron encontrados en la fuerza de la extremidad inferior ($p = 0,014$), de las extremidades superiores ($p = 0,001$), la resistencia aeróbica ($p = 0,001$) y la flexibilidad de las extremidades superiores ($p = 0,040$). Por otra parte, no se encontraron cambios significativos en la composición corporal, presión arterial, perfil lipídico, o el control glucémico. El perfil de los estados de ánimo mostró una disminución significativa en el factor fatiga-inercia ($p = 0,002$). El coste de la medicación incrementó substancialmente para el Estado ($p = 0,028$) pero no para los individuos.

Conclusiones: El programa obtuvo un éxito moderado en relación al cambio de comportamiento, pero no suficiente para obtener un impacto significativo en la mayoría de las variables clínicas y biológicas. El fitness mejoró y la fatiga percibida se redujo. Nuestros resultados sugieren que para ser más efectivos, la intervención debe comenzar tan pronto como sea posible, ya que su implementación en personas mayores resulta más complicada. Esto permitiría una respuesta mayor al programa y a una intervención de actividad física más intensa.

ABSTRACT

ABSTRACT

Background: Type 2 Diabetes is becoming increasingly prevalent worldwide at an alarming rate. Physical activity and adequate dietary patterns are cornerstones for the treatment and prevention of diabetes. Lifestyle intervention programs can be effective, but their application to the elderly needs further study.

Methods: overall, 43 individuals with diagnosed type 2 diabetes were assigned to control (12 men, 12 women; age 68.9 ± 11.3, range 46- 84 years) or intervention (6 men 13 women; age 69.5 ± 8.9, range 52-81 years) groups based on their own choice. The intervention group received a lifestyle program including physical activity classes and dietary counseling for a 9 month period. The control group received the usual care. Improvement in physical activity and dietary patterns was assessed as well as changes in biological (weight, body composition, blood pressure, lipid profile, HbA1c, glycemia), fitness (strength, aerobic endurance, flexibility, agility), psychological (profile of mood states) and economic variables (individual and state cost of medications).

Results: participants in the intervention group tended to increase their overall physical activity (p=0.020) and to adopt better dietary patterns (p=0.050). However changes in lifestyle were mild: changes in overall physical activity outside the program were non-significant and no significant changes were found in the percentage of compliers with the dietary recommendations for the Portuguese population. Significant changes were found in lower limb strength (p=0.014), upper limb strength (p=0.001), aerobic endurance (p=0.001) and upper limb flexibility (p=0.040). Conversely no significant changes were found for body composition, blood pressure, lipid profile or glycemic control. The profile of mood states showed a significant decrease in the Fatigue-Inertia factor (p=0.002). The cost of medication increased substantially for the State (p=0.028) but not for individuals.

Conclusions: The program achieved moderate success in relation to behaviour change, but not enough to have a significant impact on most clinical and biological variables. Fitness was improved and perceived fatigue reduced. Our results suggest that in order to be more effective, intervention should begin as early as possible, as its implementation among elderly subjects is difficult. This would lead to a larger response to the program and to a more intense physical activity intervention.

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LIST OF ABREVIATIONS

BMI – Body Mass Index

CHD – Coronary Heart Disease

CVD – Cardio Vascular Disease

DBP – Diastolic Blood Pressure

DSME – Diabetes Self-Management Education

IFG – Impaired Fasting Glucose

IGT - Impaired Glucose Tolerance

IPAQ – International Physical Activity Questionnaire

MET - Metabolic Equivalent

POMS – Profile of Mood States

SBP – Systolic Blood Pressure

1. INTRODUCTION

The considerable increase in a sedentary lifestyle worldwide, as a consequence of technological development in the last century, has had a substantial impact on health. This is particularly the case among western populations, where the considerable decrease in physical activity levels has led to a parallel increase in obesity and obesity-related diseases (Blair, 2003).

Physical activity, through structured exercise programs, has been shown to be an efficient method of preventing sedentary-related diseases. Well structured physical activity programs may have leisure, biological, psychological and social goals. Such programs, when targeting particular populations, should be tailor-made to the specific needs and pathologies of those populations and be provided by multidisciplinary teams.

Subjects with type 2 diabetes can benefit the most from an increase in physical activity through structured exercise programs. Indeed, an increase in physical activity represents one of the main treatment options for this disease. Unfortunately physical activity is seldom prescribed to prevent or treat type 2 diabetes (American College of Sports Medicine, 2000; Hawley, 2004; Praet & van Loon, 2008). Furthermore several co-morbidities associated with type 2 diabetes can limit the structuring of physical exercise programs, particularly the duration and intensity of sessions, which may have an impact on their effectiveness. Several recommendations regarding the design of exercise programs for diabetics have been issued

(American Diabetes Association & American College of Sports Medicine, 1997) covering in particular the training loads to be applied. It is however important to assess whether interventions with lower training loads, possibly easier to implement and with lower dropout rates, show similar levels of effectiveness.

Large changes in populations' dietary patterns are another decisive aspect that over the 20th century contributed to an increase in the prevalence of diabetes. Economic globalization and the success of the fast food industry have led to high energy density food choices now becoming not only available, but often the lowest cost option to the consumer (Darmon, Ferguson, & Briend, 2002). This trend was also noted in Portugal where people are moving away from the traditional Mediterranean diet at a faster rate than in other Mediterranean countries (Chen & Marques-Vidal, 2007).

These changes in the environment make it more important that the population is educated towards healthy lifestyle choices and there is more responsibility on health departments to provide and promote the adoption of these choices.

It was in this line of action that the program "Saúde em Movimento" was implemented in a primary health care unit - the S. João Health Center. This program aims to grant type 2 diabetic patients free access to a structured physical exercise and nutritional educational program. Currently, this program is being used by elderly subjects (mean age 69 years).

The present study aims to characterize their physical activity and dietary habits as well as to determine their profile regarding clinical and biological variables related to parameters of diabetic control and to fitness. A psychological profile - the profile of mood states was also established and an economic analysis was done regarding costs with medications. Changes occurred in these variables after 9 months participation in the program were assessed and compared with a control group following a conventional treatment.

2. REVIEW OF THE LITERATURE

2.1. CONCEPTS

Throughout this work the following concepts will be used:

- Adherence – the extent to which a person's behaviour in terms of taking medications, following diets or making lifestyle changes corresponds with the agreed recommendations of the health care provider. Adherence connotes a willingness of the patient to follow the physician's recommendations (World Health Organization, 2003b);

- Compliance – the degree to which an individual's behaviour (taking pills, following diets or changing lifestyle) is congruent with medical or health advice (Falk, 2001).

- Exercise – a type of physical activity, is defined as planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness (American College of Sports Medicine, 2009a);

- Health – a complete state of physical, mental and social well being (World Health Organisation, 1947);

- Health behaviour – a behaviour adopted with the objective of preventing illness (Ogden, 2004);

- Health-related physical fitness – the ability to perform daily activities with Vigor, and the possession of traits and capacities that are associated with a low risk of premature development of hypokinetic diseases. Health-related components of fitness include cardio-vascular endurance, muscular strength and endurance, flexibility and body composition (American College of Sports Medicine, 2009a);

- Hyperglicemia – abnormally increased glucose in the blood such as in diabetes *mellitus* (Dorland, 2007);
- Incidence – the number of new cases arising in a given period in a specified population (Beaglehole, Bonita, & Kjellström, 1993);
- Lifestyle – the set of habits and customs that are influenced, changed, encouraged or restricted by a process of socialization throughout life. It includes the use or consumption of substances such as alcohol, tobacco, tea or coffee, eating habits, exercise, etc., which have important implications on health and are the subject of epidemiological investigations (Last, 1995).
- Physical Activity – a type of bodily movement that is produced by the contraction of skeletal muscles and that substantially increases energy expenditure (American College of Sports Medicine, 2009a);
- Physical Fitness – a set of attributes that people possess or achieve that relates to the ability to perform physical activity (American College of Sports Medicine, 2009a);

- Prevalence – the number of cases in a defined population at a specified point in time (Beaglehole et al., 1993);
- Primary Prevention – set of measures aimed to limit the incidence of disease by controlling causes and risk factors. Primary prevention targets the total population, selected groups and healthy individuals (Beaglehole et al., 1993);
- Relative Risk – risk of an event (or of developing a disease) relative to exposure. Relative risk is a ratio of the probability of the event occurring in the exposed group versus a non-exposed group (Last, 1995);
- Secondary prevention – set of measures aimed to cure patients and reduce the more serious consequences of disease through early diagnosis and treatment. Secondary prevention targets patients in the early stages of the disease (Beaglehole et al., 1993).
- Tertiary prevention – set of measures aimed at reducing the progress or complications of established disease (Beaglehole et al., 1993). Tertiary prevention targets patients with established disease and tries to get them to the pre-morbid condition (Stone, Armstrong, Macrena, & Pankau, 1999).

2.2. DEFINITION AND AETIOLOGY OF TYPE 2 DIABETES

Diabetes mellitus can manifest over different clinical types. Type 2 diabetes results from a relative lack of insulin with a higher or lower degree of insulin resistance and is the most common type of diabetes mellitus. It is mainly due to a decrease in the number of insulin receptors among peripheral cells, leading to a decreased glucose uptake and increased levels of glycaemia. In order to compensate for this decreased insulin sensitivity, the pancreatic beta cells increase insulin excretion, leading to hyperinsulinemia. This process worsens with age, because the pancreas progressively fails to produce enough insulin to compensate cells resistance (Bonen, 2001; Hornsby & Albright, 2003; Steinberger & Daniels, 2003).

The criteria for the diagnosis of diabetes mellitus are based on the glycemic level above which specific complications arise, rather than from deviation from population normal parameters (A. Powers, 2006):

1 - Symptoms of diabetes (polyuria, polydipsia, unexplained weight loss) plus fasting (defined as no caloric intake for at least 8 hour) or nonfasting plasma glucose ≥ 200 mg/dl.

or

2 - Fasting plasma glucose ≥ 126 mg/dl.

or

3 - Plasma glucose ≥ 200 mg/dl, 2 hours after an oral glucose tolerance test with a 75 g load.

If hyperglycaemia is not unequivocal, the diagnosis should be confirmed by a second test performed on a different day (American Diabetes Association, 2004a; A. Powers, 2006).

Some individuals have glycemic levels that, although not reaching the above mentioned criteria, are too high to be considered as normal. This group is defined as having:

- Impaired Fasting Glucose (IFG) if fasting plasma glucose is between 100 mg/dl and 126 mg/dl;
- Impaired Glucose Tolerance (IGT) if plasma glucose is between 140 mg/dl and 200 mg/dl 2 hours after an oral glucose tolerance test.

These individuals have a 40% risk of developing diabetes within a 5 year period (A. Powers, 2006) and, for this reason, are referred as having “pre-diabetes” (American Diabetes Association, 2004a).

The causes of diabetes can be separated into genetic and environmental, with possible interactions between them (Pratley, 1998). The genetic component of diabetes has been shown through family (A. Powers, 2006; Weires et al., 2007), or twins studies (Kyvik, Green, & Beck-Nielsen, 1995; Medici, Hawa, Ianari, Pyke, & Leslie, 1999; A. Powers, 2006). The higher prevalence of diabetes in some specific populations is other evidence of the genetic component. The fact that populations sharing the same genetic background but living in different environments have distinct diabetes prevalence shows the importance of the environmental component(Liao et al., 2002).

The causes of the epidemic growth of diabetes prevalence must thus be looked for in the environmental component because, as stated by Roberts and Barnard (2005): “100% of the increase in the prevalence of Type 2 Diabetes and obesity in the United States during the latter half of the 20th century must be attributed to a changing environment interacting with genes because 0% of the human genome has changed during this time period". Some evidence of an environmental component is provided by history - two hundred years ago diabetes was a rare disease that affected a privileged minority that could afford to be physically inactive and had access to a rich diet (Lehmann, 1998).

In the last century the decrease in physical activity due to technological progress associated with changes in dietary patterns resulted in an unbalanced energy state leading to obesity, a strong risk factor for type 2 diabetes (Blair, 2003; Swinburn & Egger, 2004).

Evidence of the role played by inappropriate dietary habits and sedentary behaviour in the development of diabetes has been accumulating over the past few years:

- The incidence of obesity and type 2 diabetes among Pima Indians living in two different cultural environments was compared. Individuals living in rural Mexico with their traditional lifestyle of heavy physical activity and a low fat diet showed lower incidence rates than individuals living in Arizona with a more sedentary life and a more westernized diet (Kriska et al., 1993; Kriska et al., 2003; Ravussin, Valencia, Esparza, Bennett, & Schulz, 1994). Similarly the higher prevalence of type 2 diabetes among American Japanese than among Japanese residing in Japan can be explained by different lifestyles, with lower levels of physical activity and a higher caloric intake from fat (Liao et al., 2002).

- In a prospective study covering 42,504 male health professionals a higher risk of type 2 diabetes was found among subjects who reported high intakes of red meat, high-fat dairy products, refined grain, sweets and desserts, compared to subjects who had a diet based on vegetables, fruit, fish, poultry and whole grains (Roberts & Barnard, 2005).
- G. Hu et al(2004) found 120 new cases of diabetes when analyzing the results of 2,017 men and 2,352 women without a history of known or newly diagnosed diabetes in a prospective study with an average duration of 9.4 years. The conclusion was that there is a higher risk for obese, inactive and normoglycemic subjects of becoming diabetic, compared to subjects with IGT, but active and with a normal Body Mass Index (BMI).
- In another study, 5,159 men aged 40 to 59 years, without a history of diabetes, and with no recall of physician diagnosis of stroke or coronary heart disease (CHD), were followed during an average of 16.8 years. During this period 196 new cases of diabetes occurred (Wannamethee, Shaper, & Alberti, 2000). Again an inverse relationship between incidence of type 2 diabetes and physical activity was found, and persisted after adjusting for age, smoking, alcohol intake, social class, BMI and pre-existing undiagnosed CHD (measured through responses to a World Health Organization questionnaire indicating angina or

possible myocardial infarction, or electrocardio-graphic evidence of definite or possible myocardial ischemia or myocardial infarction).

- G. Hu et al.(2003) followed 6,898 men and 7,392 women without history of diabetes, CHD or stroke for an average of 12 years. During this period, 373 new cases of diabetes appeared. Again the protective effects of exercise were found: 0.70 and 0.74 for moderate and active work respectively; similarly the relative risks for diabetes were 0.67 and 0.61 for moderate and high leisure time physical activity. The benefits were independent of the age, sex, arterial tension, smoking habits or education. However, when adjusted to the BMI, the results were not significant.

- F. B. Hu et al.(1999) conducted a prospective study that included 70,102 female nurses and found that greater physical activity level is associated with substantial reduction in risk of type 2 diabetes, including physical activity of moderate intensity and duration. the relative risks of developing type 2 diabetes across quintiles of physical activity (least to most) were 1.0, 0.77, 0.75, 0.62, and 0.54 (P for trend <.001)

Until the 20th century individuals performed most physical activity as part of their occupations or in subsistence activities. With the progress and the search for city life, occupation-related physical demands have declined, and the availability of leisure time has grown. Some studies on the effects of physical activity are focused only on leisure time:

- When comparing, throughout 10 years, the diabetic risk for 1,340 men and 1,500 women with high, moderate and low leisure time physical activity, Haapanen, Miilunpalo, Vuori, Oja, and Pasanen, (1997) found, respectively, relative risks of 1,0;1,17 and 2,64 for women and 1,0;1,21 and 1,54 for men. In this study evidence was found that increased activity intensity had a role in the reduction of the risk of diabetes.

- F. B. Hu, Leitzmann et al. (2001) used indirect measures of leisure time physical activity noting the time spent watching TV. They followed 37,918 subjects over a 10 year period. Those who watched TV for over 21 h/week had a relative risk for type 2 diabetes of 2.16 when compared to the control group (≤1 hours/week of TV). The relative risk was further increased to 2.87 in the group that watched TV for over 40 hours a week.

- The combined effect of diet and physical activity on the relative risk for type 2 diabetes was assessed in a study that followed 84,941 nurses for a period of 16 years (F. B. Hu, Manson et al., 2001). A low risk group was defined according to a set of five variables considered to have a protective effect against the occurrence of diabetes: BMI <25 kg/m^2; a diet rich in cereal fibre and polyunsaturated fat, low in trans fat and with a low glycemic load; at least 30 minutes of moderate to vigorous physical activity per day; no smoking; moderate consumption of alcohol. During the study 3,300 new cases of diabetes were diagnosed. Participants from the low risk group had a relative risk for diabetes of 0.09 (95% CI: 0.05-0.17) compared to the added risk group.

These studies have identified the variables that possess predictive value relative to the risk of diabetes, which has allowed the construction of instruments for risk stratification used in clinical practice (Lindstrom & Tuomilehto, 2003).

2.3. CO-MORBIDITIES OF DIABETES

Diabetes is strongly associated with other metabolic disorders which are, of themselves, hazards for death and premature morbidity.

Most patients with insulin resistance or type 2 diabetes are overweight or obese (Hawley, 2004; Hornsby & Albright, 2003; Steinberger & Daniels, 2003), and 60% to 90% of type 2 diabetes cases develop in obese subjects (Kelley & Goodpaster, 2001; Shephard, 1997). In young populations, the increase in the prevalence of type 2 diabetes seems to parallel the increase in the prevalence of obesity (Steinberger & Daniels, 2003; Rena R. Wing et al., 2001).

Hypertension and a degraded lipid profile are also related to type 2 diabetes and insulin resistance (American Diabetes Association, 2008b; American Diabetes Association & American College of Sports Medicine, 1997; Buse et al., 2007; Steinberger & Daniels, 2003). Hypertension is considered one the most critical aspects in the care of the patient with diabetes (Buse et al., 2007) because it represents an independent risk factor for cardiovascular disease (CVD), the major cause of morbidity and mortality among diabetic patients (American Diabetes Association, 2008b). The prevalence of CVD can be as high as 40% among middle-aged patients with type 2 diabetes and over 60% in older patients (Kesavadev, Short, & Nair, 2003). It is estimated that the risk of cardiovascular events starts at a blood pressure higher than 115/75 mmHg, and doubles for every 20 mmHg systolic or 10 mmHg diastolic increase.

Dyslipidemia is also an independent risk factor for CVD. A lipid profile characterized by a low HDL cholesterol, a high LDL cholesterol and high triglycerides has been reported in obese and non obese adults with type 2 diabetes, in non obese adults with IGT and in obese normoglycemic adults (Kesavadev et al., 2003; Steinberger & Daniels, 2003). Lowering LDL cholesterol is considered the primary objective of lipid lowering therapy by both the American Diabetes Association and the American Heart Association (Buse et al., 2007).

In the early stages, type 2 diabetes is asymptomatic and may stay so for about 10 years (American Diabetes Association, 2008b; Bonen, 2001). As a consequence, many individuals are unaware of the disease, resulting in about 50% of undiagnosed cases (American College of Sports Medicine, 2000; Kim, Rolland, Cepeda, Gammack, & Morley, 2006). Many diabetics seek medical advice only when symptoms or other conditions associated with diabetes arise and compromise daily well-being. In the final stages the consequences of diabetes include blindness, kidney failure, neuropathy, and tissue necrosis as a result of deterioration of blood vessels (American Diabetes Association, 2008b; American Diabetes Association & American College of Sports Medicine, 1997; Booth & Winder, 2005).

Finally, the consequences of diabetes are not limited to biological issues(Stanton, Revenson, & Tennen, 2007). According with these authors, an important psychological burden may be present. The very definition of chronic disease – “illnesses that are prolonged, do not resolve spontaneously, and are rarely cured completely” – carries with it a sense of inevitability.

2.4. DIABETES: A PUBLIC HEALTH ISSUE

Diabetes is the most frequent metabolic disease and is now one of the main public health problems worldwide. The prevalence of diabetes is between 1 and 5% , but due to the asymptomatic characteristics of the early stages of the disease it is estimated that actually only 50% of cases are diagnosed(Bonen, 2001; Wild, Roglic, Green, Sicree, & King, 2004). Thus the true prevalence of diabetes may be as high as 10%, and type 2 diabetes accounts for 80 to 95% of all cases (Bonen, 2001; Eichner, 2002; Heyward, 1991; Hornsby & Albright, 2003; Miller & Dunstan, 2004; Steinberger & Daniels, 2003; Strine et al., 2005).

The prevalence of diabetes is growing fast. Hawley (2004) reported a six fold increase in type 2 diabetes between

1958 and 1993 in the American adult population, while McGinnis (2002) reported an increase from 4.9 to 6.5% between 1990 and 1998 for the same population. Booth and Winder (2005) reported diabetes as being the fifth leading cause of death in the United States. In a study aimed at estimating the prevalence of diabetes worldwide for years 1995, 2000 and 2025, King et al. (1998) predicted a further increase in diabetes prevalence from 4.0% in 1995 to 5.4% in 2025. Overall an estimated 300 million persons worldwide will be suffering from diabetes in 2025. In that study different trends were noted between developed and develop-ping countries: a 42% increase is expected in developed countries (51 to 72 million individuals), whereas in developing countries this increase is much steeper (170%, from 84 to 228 million individuals). Furthermore, in the same study, some interactions arose between country development and other factors: for instance in developed countries there are more diabetic women than men, while in developing countries the prevalence of diabetes is similar in both genders. These authors also point that in developing countries the major increment will occur in the 45-64 years age group, while in developed countries it will occur in the over 65 year group. Once those were the age groups that already had the largest proportion of diabetes subjects in 1995, this trend will therefore be accentuated. It has been estimated that, even if obesity were to stay the same until 2030, which is not likely, diabetes prevalence in the world will double because of ageing and the search for an urban lifestyle (Wild et al., 2004). Furthermore differences in diet, physical activity and other socioeconomic factors result in a higher prevalence of diabetes in urban compared with rural areas (H. King et al., 1998). The current population migrations from a rural to an urban environment could thus be a contributing factor to an increase in diabetes prevalence.

Based on data from the National Health Survey it is estimated that diabetes prevalence in Portugal increased from 4.7% in 1999 to 6.7% in 2006 and then to 8.2% in 2007. Estimates for 2025 point to 9.8% prevalence(Direcção Geral de Saúde, 2008).

Diabetes is not just getting more prevalent; it’s growing across the lifespan too. For a long time type 2 diabetes was considered to be a disease of adults, mostly because most cases usually occurred after the age of 40 (Bonen, 2001; Hornsby & Albright, 2003; H. King et al., 1998). However the increase in the prevalence of diabetes is no longer restricted to this age group; indeed diabetes is increasingly affecting younger individuals (Bonen, 2001; Lehmann, 1998; Sinha et al., 2002; Steinberger & Daniels, 2003). Between 1982 and 1994 the prevalence of diabetes increased tenfold in adolescents and currently about 30% of newly diagnosed cases occur in subjects aged between 10 and 19 years (Kabadi, 2004). The increasing prevalence amongst young subjects was reported by Sinha (2002)who found in a study of 167 children and obese adolescents that 25% of the children aged between 4 and 10 years and 21% of adolescents aged between 11 to 18 years old had IGT, while 4% of the adolescents were diabetics.

The current prevalence of pre-diabetic individuals is also high. In the United States 34% of the total adult population have IFG, while 15% have IGT and 40% have one or both of these conditions (Centers for Disease Control and Prevention, 2003). The situation is particularly serious among the elderly, and it has been reported by Lehmann (1998) that a quarter (25%) of subjects aged over 70 have IGT. In Portugal IGT prevalence is estimated at 10.1% (Direcção Geral de Saúde, 2008).

2.5. ECONOMIC BURDEN OF DIABETES

When analysing the economic burden associated with diabetes, different kinds of costs may be considered (International Diabetes Federation, 2006a):

- Direct costs to patients with diabetes and their families. Living with diabetes leads to the patient and his/her family carrying a significant economic burden through the cost of medications and frequent medical visits. Diabetic patients also have a higher probability of being admitted to a hospital (Bo et al., 2004), a greater risk of disability (American Diabetes Association, 2003), and their family income is frequently reduced when diabetes interferes with their work (International Diabetes Federation, 2006b). The economic impact of the disease can thus be considerable, especially in the poorest countries, where diabetic patients and their families bear almost the entire cost of whatever medical care they can afford. In those countries insulin is not subsidized by governments (who instead tax it heavily), and it is often not available at any price, which results in high rates of premature death (International Diabetes Federation, 2006b). For instance in India the poorest individuals with diabetes spend an average of 25% of their income on private care, whereas in Latin America 40 to 60% of diabetes care costs are paid for directly by patients (International Diabetes Federation, 2006b). In Portugal the expense of drugs directly associated with diabetes is borne entirely by the healthcare system. However the treatment of co-morbidities is supported according to specific policies for each pathology.

- Direct costs to healthcare systems. Since diabetes is associated with multiple diseases (neurological, peripheral cardiovascular, endocrine/metabolic, renal, vascular and ophthalmological), part of the costs related to those diseases can be attributed to diabetes. That amount is calculated by comparing the health care use pattern between subjects with and without diabetes. In the United States of America the direct costs attributable to diabetes amounted to $91.8 billion in 2002. Diabetes accounts for about 10% of acute hospitalizations (Shephard, 1997), and it has been estimated that the 4.5% of Americans with confirmed diabetes represent 14.6% of United States of America care expenditures (Eichner, 2002). Hospitalisation (43.9%) and nursing home care (15.1%) were the major expenditure groups (American Diabetes Association, 2003). Also in the United States of America the *per capita* annual healthcare costs reached $13,243 for diabetic vs. $2,560 for non-diabetic patients; when corrected for age, ethnicity and gender, diabetic patients still had 2.4 times higher healthcare costs than non-diabetic (American Diabetes Association, 2003). These results are in line with estimates done by Rubin, Altman, and Mendelson (1994) or by Nogueira (1999) who found, respectively, a 3 and a 2.5 times increase in *per capita* health care expenditures among diabetics. In Spain it is estimated that 6.3 to 7.4% of total public health expenditure is attributable to diabetes (Oliva, Lobo, Molina, & Monereo, 2004) and hospitalization (35-39%) and drugs (31-36%)were the most important items. In this study p*er capita* annual expenditure was €1,290 to €1,476 for diabetics and €860 for non-diabetics. In Portugal, the direct healthcare costs attributable to diabetes for the year 1998 were estimated at €510 million (Nogueira, 1999). The abovementioned sums are actually underestimated, because in all studies subjects with undiagnosed diabetes were considered as non-diabetics. Also this value does not take into account the cost of informal caregivers, dental care, optometry or licensed nutritionists to whom individuals with diabetes apply more frequently. Finally it should be stressed that inadequate diabetic control and the presence of CVD (stroke) considerably increase treatment costs (Gonçalves, 2001).

- Indirect costs. Diabetes leads to increased work absenteeism and premature retirement, thus reducing productivity (Gonçalves, 2001; Nogueira, 1999). The stress and anxiety of daily living and, in some situations, the pain, are costs that are intangible and therefore unquantifiable.

CVD is the major cause of morbidity and mortality among individuals with diabetes, and it is also the largest contributor to both the direct and indirect costs of diabetes (American Diabetes Association, 2009). In the United States of America direct and indirect expenditure associated with diabetes reached $132 billion in 2002 (American Diabetes Association, 2003), and the then forecast $156 billion expenses by 2010 were actually surpassed by the $174 billion spent in 2007 (American Diabetes Association, 2008a). Lifestyle changes could help in attenuating this situation but in most modern societies pharmacological interventions are preferred, and this leads to an increased economic burden (Bonen, 2001).

The economic analysis of programs designed to encourage the adoption of healthier lifestyles has proved their efficiency; however the programs usually imply short term expenses and long term benefits(Cefalu, 2004). This author points that these studies are generally made in respect of a specific disease but, because some risk factors for type 2 diabetes, such as obesity, smoking, hypertension or hyperlipidemia, are also risk factors for other diseases and seem to be correlated to each other, these studies may underestimate the actual economic effectiveness of such programs.

Several economists and public health experts have tried to identify strategies to achieve population-wide lifestyle changes (Hill, Sallis, & Peters, 2004). In this study the main conclusions were that psycho-social models aimed at changing individual behaviours are worthwhile, but only reach a small number of participants and have low maintenance rates. To these authors, individual behaviour will change only if there is concerted action across the work of individuals, social environments, physical environments and policies, producing a synergistic effect. It is essential that a study be made of market driving forces especially in the food business and also in a varied set of industries that relate to physical activity and sedentary behaviours, perhaps without being conscious of their role in this problem.

2.6. PREVENTION OF DIABETES

2.6.1. PRIMARY/SECONDARY PREVENTION

Due to the long period of development of the illness, the majority of the studies on diabetes prevention are conducted on samples with high-risk participants (usually with IFG or IGT), as in such cases about 30 to 50% of the participants will develop diabetes within 10 years time (Tuomilehto, 2005).

Three large randomized controlled trials assessed the efficiency of lifestyle changes in diabetes prevention: The Diabetes Prevention Program(The Diabetes Prevention Program Research Group, 1999), the Finnish Diabetes Prevention Study(Tuomilehto et al., 2001) and the Da Quing Prevention Study(Pan et al., 1997).

Since 1999 the Diabetes Prevention Program Research Group implemented a randomised clinical trial in order to test strategies to prevent and delay the development of type 2 diabetes. This program (The Diabetes Prevention Program Research Group, 2002b) randomly assigned 3,234 individuals with IGT aged 25-85 years, with a wide distribution of obesity and ethnic backgrounds (The Diabetes Prevention Program Research Group, 2000), to three groups: a control group that received a placebo, a diet and exercise group (moderate exercise for 150 min /week) and a pharmacotherapy group that received metformin (The Diabetes Prevention Program Research Group, 1999). Lifestyle intervention included a 16 session core curriculum where basic information regarding nutrition, physical activity and behavioural self-management was taught; maintenance sessions following the core curriculum were also scheduled (The Diabetes Prevention Program Research Group, 2002a). Dietary advice was focused on reducing total fat, and participants were taught and asked to self monitor fat and calory intake and to keep a log of their physical activity. Supervised physical activity was provided twice a week but attendance was voluntary. Both control and metformin groups received standard lifestyle recommendations, i.e. written information and an annual 20 to 30 minutes individual session that emphasized the relevance of a healthy lifestyle. After 3 years of follow-up, the diet and exercise group lost 5 to 7% of body weight and had a risk reduction of 58% (95% CI: 48-66%) compared with the control group. Metformin was also effective, but in this group only a 31% (95% CI: 17-43%) risk reduction was achieved (The Diabetes Prevention Program Research Group, 2002b). These interventions were estimated to delay the development of diabetes by 11 years (lifestyle) and 3 years (metformin) and to reduce the incidence of diabetes by 20% and 8% respectively (Herman et al., 2005). The impact of these interventions on CVD risk factors such as hypertension, dyslipidemia was also assessed (The Diabetes Prevention Program Research Group, 2005a). Reduction in hypertension was statistically significant for the lifestyle and metformin groups for both systolic and diastolic pressures. Among hypertensive individuals at baseline, control was achieved for the lifestyle group with a 5% additional hypertensive therapy, while in the control and metformin groups a 15% increase was necessary. Total cholesterol and LDL showed no statistical differences between groups. Triglycerides fell in all groups but significantly more in the lifestyle group. HDL levels increased significantly in the lifestyle group compared to metformin or control groups. Conversely, there were too few CVD events for an adequate statistical analysis. Finally, the cost–effectiveness of these interventions was compared both from a societal perspective including direct (medical and non-medical) and indirect costs, and from a health care perspective that considered only direct medical costs (The Diabetes Prevention Program Research Group, 2003). The lifestyle intervention was the most cost–effective in both analyses, followed by the metformin intervention: from a societal point of view the lifestyle and metformin intervention had respectively costs of $24,400 and $34,500 per case of diabetes delayed or prevented. From a health care point of view those costs were $15,700 for the lifestyle and $31,300 for the metformin interventions.

In the Finnish Diabetes Prevention Study, (Tuomilehto et al., 2001) a study was made of 522 middle-aged individuals with impaired glucose tolerance, randomly assigned to a control group (general oral and written information about diet and exercise) or to an intensive lifestyle intervention that included individualised dietary advice by a nutritionist (7 sessions in the first year and every three months afterwards) and exercise for at least 30 minutes a day (supervised aerobic activities and circuit training). After the 3.2 years follow-up, the risk of type 2 diabetes was 58% (hazard ratio 0.4; 95% CI: 0.3-0.7; $p < 0.001$) lower in the intervention group than in their control counterparts. Compared with the control group, the intensive lifestyle intervention group had a significantly greater reduction in weight, waist circumference, fasting and 2 hours glycaemia after oral glucose challenge, total cholesterol and triglycerides, systolic blood pressure (SBP), diastolic blood pressure (DBP) and HbA1c, and higher HDL cholesterol levels (Lindstrom et al., 2003; Tuomilehto et al., 2001).

Also in the Finnish Diabetes Prevention Study, Laaksonen et al (2005) followed 487 individuals for 4.1 years with impaired glucose tolerance. The purpose of the study was to determine the role of leisure time physical activity (LTPA) in the prevention of diabetes. Individuals who had increased their levels from moderate to vigorous LTPA had a 63 to 65% risk reduction. Walking and low intensity LTPA increases were also effective, but in a more modest way. Results were attenuated when corrected for changes in diet and body weight. A follow-up of the participants was performed 3 years after discontinuation of active counselling (Lindström et al., 2006). A relative risk reduction of 36% was still found in the intensive lifestyle intervention group. This reduction was related to achieved goals for weight loss, reduced intake of total and saturated fat, increased intake in dietary fibre and increased physical activity.

The Da Qing Prevention Study (Pan et al., 1997) followed 577 middle-aged individuals for 6 years. Participants were randomized to one of four groups: control, diet only, exercise only and diet plus exercise. Compared to the control group, significant reductions in the risk of developing type 2 diabetes were obtained (31%, 46% and 42% for the diet only, exercise only and diet plus exercise groups respectively), after adjustment for baseline BMI and fasting glucose.

The findings of these three seminal studies were further confirmed by others. In the Malmö Preventive Trial, Eriksson & Lindgärde (1998) followed 6,956 men and compared mortality rates among 4 different groups: normoglycemic individuals (control group), a “usual care” IGT group, an IGT lifestyle intervention group and a type 2 diabetes lifestyle intervention group including systematic dietary advice and exercise. After 12 years follow-up, the mortality rate in the diabetes group was the highest - 22.6 per 1,000 person years (95% CI: 15.6-31.5) followed by IGT routine treatment group - 14.0 per 1,000 person years (95% CI: 8.7-21.4). The lowest mortality rates were found in the IGT lifestyle group - 6.5 per 1,000 person years (95% CI: 4.1-9.9) and in the normoglycemic group - 6.2 per 1,000 person years (95% CI: 5.7-6.8). These groups showed no significant differences between them. In that study BMI, SBP, smoking or cholesterol failed to predict mortality among individuals with IGT.

Lower reductions in diabetes risk were found in the Indian Diabetes Prevention Program where 531 individuals with IGT were followed during 3 years (Ramachandran et al., 2006). Participants were randomly distributed into 4 groups: control (usual care), metformin alone, lifestyle alone and lifestyle plus metformin. Lifestyle intervention consisted of dietary and physical activity advice. Compared with the control group significant risk reductions were found for the lifestyle (-28.5%), metformin (-26.4%) and the lifestyle plus metformin groups (-28.2%). Interestingly the combination lifestyle plus metformin did not provide additional protection relative to each intervention alone.

These results do not confirm those obtained in the Diabetes Prevention Program, the study of Da Quing or the Finnish Diabetes Prevention Study. The fact that the intervention was limited to counselling, did not have supervised physical activity and that the population studied had different characteristics (the participants were younger and leaner) compared to the participants analyzed in those studies, might partly explain those findings.

Mensink, Feskens, Saris, de Bruin, and Blaak, (2003) evaluated the effect of a lifestyle intervention program in 102 both gender individuals with IGT. 30 minutes of daily physical exercise were recommended to the intervention group, and free access was granted to physical activity lessons integrating aerobic and resistance components. Personal nutrition advice was also given to this group, aimed at a weight loss of between 5 and 10% over a one-year period. The control group was informed of the benefits of exercise and of a healthy diet. The results confirmed the intervention efficiency: a mean weight loss of 2.7Kg, improved tolerance to glucose (-0.8 mmol/l) and improvement of cardio-respiratory capacity (0.1 l/min in VO_2max).

Kosaka, Noda, and Kuzuya (2005) conducted a randomized trial assigning 458 individuals with IGT to a control and an intervention group. Subjects from the control group received standard information, were advised to take 5-10% smaller meals and to increase their physical activity. Those recommendations were explained again every 6 months. The intervention group received individual counselling regarding adequate food consumption and 30 to 40 minutes walking each day was recommended. The intervention group also had their physical activity and usual dietary patterns assessed every 2-3 months. After 4 years diabetes incidence was 9.3% in the control group and 3.0% in the intervention group, which represents a risk reduction of 67.4% ($p<0.001$). The authors noted that the reduction in incidence of diabetes in the intervention group was steeper than expected simply on the basis of the reduction of BMI.

Also Liao et al. (2002) showed a lifestyle intervention directed at patients with IGT to be effective. In that study 64 subjects were randomized to a control or intervention group. The intervention included diet (less than 30% of total calories as fat, less than 7% saturated fat, 55% carbohydrate and 200 mg cholesterol daily) and endurance exercise for 1 h three times a week. The control group was also prescribed a diet (less than 30% of total calories as fat, less than 10% saturated fat, 50% carbohydrate and 300 mg cholesterol daily) and a stretching exercise for 1 h three times a week. After 6 months the intervention group showed significantly greater reduction in BMI and percent body fat and an increase in cardio respiratory fitness (VO_2max).

In a meta-analysis regarding efficiency of lifestyle based interventions on subjects with a high risk for type 2 diabetes (Yamaoka & Tango, 2005), 9 randomized controlled trials were found. From a combined analysis their authors concluded that it is possible to reduce risk for type 2 diabetes by about 50%. This reduction seems to be effective for different BMI levels as proven by the American Diabetes Prevention Program and the Finnish Diabetes Prevention Study that reach the same conclusions about populations with different BMIs. However lifestyle interventions might have effects that are not mediated by weight reduction (F. B. Hu, Manson et al., 2001; G. Hu et al., 2004; Kosaka et al., 2005; LaMonte, Blair, & Church, 2005; Pan et al., 1997; Wannamethee et al., 2000).

In short, and despite the considerable heterogeneity in the content and the way the interventions in these studies were implemented, it was possible to identify some similar results such as increased insulin sensitivity (Carr et al., 2005; Mayer-Davis et al., 1998; Perseghin et al., 1996; R. R. Wing, Venditti, Jakicic, Polley, & Lang, 1998), improved glycemic control (J. Eriksson et al., 1999; Galani & Schneider, 2007; Kosaka et al., 2005; Lindstrom et al., 2003; Tuomilehto et al., 2001) better lipid profile (Galani & Schneider, 2007; Lindstrom et al., 2003; Petrella, Lattanzio, Demeray, Varallo, & Blore, 2005; Stefanick et al., 1998; The Diabetes Prevention Program Research Group, 2005a; Tuomilehto et al., 2001; R. R. Wing et al., 1998), weight/ BMI reduction (Carr et al., 2005; J. Eriksson et al., 1999; Galani & Schneider, 2007; Kosaka et al., 2005; Liao et al., 2002; Lindstrom et al., 2003; Mensink, Feskens, Saris, de Bruin, & Blaak, 2003; The Diabetes Prevention Program Research Group, 2005b; Tuomilehto et al., 2001; R. R. Wing et al., 1998), lowered blood pressure (J. Eriksson et al., 1999; Galani & Schneider, 2007; Petrella et al., 2005; Stefanick et al., 1998; The Diabetes Prevention Program Research Group, 2005a; Tuomilehto et al., 2001; R. R. Wing et al., 1998) and better cardio respiratory fitness (Carr et al., 2005; Mensink et al., 2003; Petrella et al., 2005; R. R. Wing et al., 1998).

2.6.2. TERTIARY PREVENTION

The impact of lifestyle change programs in individuals with diagnosed type 2 diabetes has equally been studied. **Table 1** presents a summary of these studies.

Improvements identified in secondary prevention trials are confirmed in tertiary prevention: lifestyle interventions directed to type 2 diabetic patients tend to improve glycemic control. For HbA1c, improvements can reach as much as 10-20% of baseline (American Diabetes Association & American College of Sports Medicine, 1997).

The influence of the type of exercise was analysed in a meta-analysis (Snowling & Hopkins, 2006) that found that small to moderate reductions in HbA1c occur as a result of either resistance, aerobic or combined training in programs of at least 12 weeks duration. Combined training appeared to be the most effective, with decreases in HbA1c comparable to those obtained through diet or insulin (0.6-0.8%).

Using continuous glucose monitoring, Macdonald, Philip, Harrison, Bone and Watt (2006) concluded that moderate exercise improved glycemic control for a 20 hours period in obese individuals with type 2 diabetes. Periods of 24 to 72 hours are also referred (Horowitz, 2007; Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006). This acute effect of exercise depends on exercise intensity and duration and can be increased in trained individuals (Colberg, 2006). Regularity in exercise is therefore important, because this acute effect is the most important effect of exercise on glycemic control (A. Kirk, N. Mutrie, P. MacIntyre, & M. Fisher, 2004; Miller & Dunstan, 2004).

Regarding exercise intensity, there is some evidence that more intense exercise has an increased effect on glycemic control. American Diabetes Association recommendations (Sigal et al., 2006) encourage type 2 diabetic individuals who are already exercising to increase their exercise intensity in order to achieve better glycemic control and improved aerobic fitness.

In their meta-analysis of the effects of aerobic exercise interventions on cardio-respiratory fitness in adults with type 2 diabetes, Boulé, Wells, Sigal, Kenny and Haddad (2003) selected only interventions that lasted for over 8 weeks. They found larger reductions in HbA1c in studies with more intense exercise interventions, but they also noted that these more intense interventions were done with younger samples and therefore an age effect might be present. Interventions resulted in an overall increase in VO_2max of 11.8% versus a 1% decrease in the controls. Considering only intervention groups submitted to moderate intensities, an increase of 9.5% of VO_2max was achieved.

Even if trainable, exercise capacity may be compromised in diabetic or even pre-diabetic patients (Fang, Sharman, Prins, & Marwick, 2005). In older individuals with type 2 diabetes exercise capacity may be seriously limited and the ability to increase exercise intensity may be very low(Kesavadev et al., 2003).

Besides that, in these individuals, the effect of exercise over insulin sensitivity may be much milder(Kesavadev et al., 2003).

Table 1 – Tertiary lifestyle interventions according to country, sample, age, intervention and results

Reference	Country	Sample	Age (years)	Intervention	Results
(Tessier et al., 2000)	Canada	39 (20C; 19I)	69.5 ± 5.1 (Control) 69.3 ± 4.2 (Intervention)	For 16weeks- three times a week 1 hour aerobic, strength, stretching session	↑ Exercise capacity, Glycemic control (Intervention group)
(F. B. Hu, Stampfer et al., 2001)	US	5,125 female nurses	30 to 55	Follow up	↓risk of cardiovascular events with increase in hours of moderate to vigorous PA
(Castaneda et al., 2002)	US	62 (31C; 31I)	66.2 ± 2	16 weeks with a 3 times a week 45 minutes PRT	=Total cholesterol, triglyceride (borderline),HDL,LDL, DBP ↓ HbA1c, FPG, and SBP for intervention group
(Maiorana, O'Driscoll, Goodman, Taylor, & Green, 2002)	Australia	16 (group A 6-trained first 8 weeks; group B 10-trained last 8 weeks)	52 ± 2	8 week circuit training combining aerobic and resistance exercise (24 sessions)	↑ Cardio respiratory fitness; muscular strength and ↓ HbA1c FPG, HR for trained group =BP;HDL;LDL;triglycerides

(A. Kirk et al., 2004)	**Scotland**	**70 (35C; 35I)**	**57.6 ± 7.9**	Physical activity counselling	**↑ HbA1c, Total Cholesterol and SBP for control group** **↓ HbA1c, Total Cholesterol and SBP for intervention group**
(Alam et al., 2004)	**UK**	**18 (9C; 9I)**	**55.3 ± 3.2 (C-unsupervised)** **59.5 ± 2.5 (I-supervised)**	For 6 months 20 to 40 minutes sessions 4 times/week.	**=BW;BF;HbA1c,FPG, VO2max for control group** **↑VO2max and** **↓BW;BF;HbA1c,FPG for intervention group**
(Wolf et al., 2004)	**US**	**147 (73C; 74I)**	**53.3 ± 8.4**	Individual and group education dieticians advice	**↓ HbA1c, weight ,waist circumference, prescription medications for intervention group**
(Tokmakidis, Zois, Volaklis, Kotsa, & Touvra, 2004)	**Greece**	**9**	**55.2 ± 6.7**	4 months strength and aerobic training twice a week	**↑ upper and lower body strength** **↓ HbA1c, FPG**

(Ibanez et al., 2005)	**Spain**	**9**	**66.6 ± 3.1**	4 week control period followed by 16 week PRT supervised	**No change after 4 weeks control period. After PRT: ↑ leg and arm maximal strength; insulin sensitivity =BMI; ↓subcutaneous abdominal fat**
(Fritz, Wandell, Aberg, & Engfeldt, 2006)	**Sweden**	**52 (26C; 26I)**	**59.3 ± 6.2 (Control) 60 ± 7.3 (intervention)**	For 4 months - 45 minutes brisk walking 3 times/week.	**↑HDL and ↓SBP, DBP, BMI, Total cholesterol, LDL for intervention group = HbA1c, FPG for both groups**
(Krousel-Wood et al., 2008)	**US**	**76 (39C; 37I)**	**56.6 ± 9.6**	For 3months-30minutes videotape guided home based exercise 5 days/week	**= HbA1c,;SBP; DBP for both groups ↓BMI for intervention**

BF – Body Fat; BMI -Body Mass Index; BW – Body Weight; C-Control; DBP –Diastolic Blood Pressure; FPG – Fasting Plasma Glucose; HR – Heart Rate; I – Intervention; PA –Physical Activity; PRT – Progressive Resistance Training; SBP Systolic Blood Pressure.

Tessier et al. (2000) studied the effect of aerobic exercise in 39 type 2 diabetics, aged over 65 years, submitted to a supervised exercise program 3 times a week. Each 60 minute exercise session comprised a 10 minute warm–up phase, a cardiovascular phase consisting of a 20 minute rapid walk, a 20 minute strength/endurance phase comprising 2 sets of 20 repetitions involving major muscle groups, and a 10 minute stretching/relaxation phase. After 16 weeks, significant improvements were found in cardio-respiratory fitness for the experimental but not in the control group. However no significant decreases were found in HbA1c, neither in the control nor in the intervention group.

Although these results point to a limited effect of exercise in older individuals regarding glycemic control, they also stress its importance in the improvement of respiratory fitness and thus in the reduction of CVD risk factors. This is an important goal in tertiary prevention, because CVD is one of the major complications of diabetes.

F.B. Hu, Stampfer et al. (2001), followed 5,125 diabetic women for 14 years and found a significantly lower risk for cardiovascular events in individuals with increased physical activity, including walking. Indeed walking is the exercise of choice for many diabetics because it is simple to do and does not require a formal structured exercise program (Bonen, 2001; Laffrey, 2000). For instance a two-fold reduction in all-cause mortality risk and a five-fold reduction of non-CHD CVD was found in older adults with type 2 diabetes who walked over a mile per day (Tyler, Deborah, Besa, Kritz-Silverstein, & Barrett-Connor, 2006).

2.7. TREATMENT OF DIABETES

Glycemic control is the major objective of diabetic treatment. Glycemic levels can be monitored through capillary glycaemia, but the control of glycosylated haemoglobin (HbA1c) is considered the primary goal of diabetes therapy because it expresses the average glycemic control achieved in the last 2-3 months (Eichner, 2002; A. Powers, 2006). Target values for HbA1c may vary according to patient functional status and co-morbidities, but in a healthy individual or in an adequately treated type 2 diabetic, HbA1c should stand below 7% (American Diabetes Association, 2009; A. Powers, 2006).

Three main distinctive intervention areas are cornerstones in fighting diabetes: pharmacotherapy, diet and physical activity.

2.7.1. DRUG TREATMENT

Pharmacotherapy is beyond the scope of this study, and, therefore, we will refer to this subject only marginally. Oral antidiabetic drugs include sulfonylureas, biguanides and alpha glucosidase inhibitors, which can be taken isolated or combined. In more severe cases, and despite adequate compliance with diet, exercise and oral agents, glycemic control is still poor. In those cases insulin administration is mandatory.

2.7.2. DIET

Diet is a key element for the management and prevention of diabetes. Diets should be planned taking into account the usual eating habits and preferences of the patient (Klein et al., 2004) and, whenever possible, should be tailored to increase compliance. Albeit the fundamental principle is a nutritionally balanced diet (Kesavadev et al., 2003), a reduction in fat intake is commonly recommended. Indeed most successful diets are usually low fat diets, where fat intake represents 25-30% of total calories (Klein et al., 2004). Further due to the high prevalence of overweight and obesity among diabetics, most diets are also designed to achieve weight control. Beattie (2001) refers to different kinds of diets:

- Individualised moderate energy deficit diet: daily energy requirements are estimated taking into account age, sex, weight and physical activity level. A diet is established based on a 600 calories deficit relative to this value. This diet should allow a loss of 0.5-1 kg/week.

- Fixed moderate energy diet: standardized diets with 1200-1300 calories per day. This kind of diet allows a weight loss of about 1 kg/week but has a high dropout due to restricted food choice that leads to monotony.

- Calory-counting diets: these diets are rarely used in the clinical setting; they are more flexible regarding food choices but they also imply a good knowledge of food calory contents and the ability to control portion sizes. The lack of professional advice may lead to undesirable results.

- Very low calorie diets (250-800 calories/day) are not effective in the long term (P. Powers, 2005). Usually liquid based they lead to substantial weight loss due to severe energy depletion. Weight rebound and loss of lean mass are common and medical complications may arise.

If weight control is the objective, an appropriate goal setting is fundamental. Unattainable objectives usually lead to treatment failure and decreased compliance. Indeed a 5% weight loss may have a significant effect on health and is an attainable and reasonable initial goal (Klein et al., 2004).

2.7.3. PHYSICAL ACTIVITY

The role of physical activity and exercise in the prevention and treatment of type 2 diabetes is recognized by the American Diabetes Association, the American College of Sports Medicine, the North American Association for the Study of Obesity or the American Society for Clinical Nutrition (American Diabetes Association & American College of Sports Medicine, 1997; The American Diabetes Association, the North American Association for the Study of Obesity, & American Society for Clinical Nutrition, 2005).

It is consensual that moderate intensity physical activity provides an adequate protective effect, and guidelines from the American College of Sports Medicine, the American Diabetes Association (American Diabetes Association & American College of Sports Medicine, 1997), the North American Association for the Study of Obesity or the American Society for Clinical Nutrition (Klein et al., 2004) recommend moderate intensity physical activity for about 30 minutes most days of the week (U.S. Department of Health and Human Services, 1996).

In each session a 5 to 10 minutes warm up period is required before progressing to moderate intensity exercise (American College of Sports Medicine, 2009b). In the core part of the session, activities that use large muscles in a rhythmic and continuous way should be emphasized (American College of Sports Medicine, 2009b). Exercise intensity should correspond to 50 to 80% of the heart rate reserve, corresponding to a rating of perceived exertion of 12 to 16 on a 6 to 20 scale(American College of Sports Medicine, 2009a). If the exercise intensity is too high, the release of epinephrine and norepinephrine will be exaggerated, leading to an increased glucose production, which may result in transient hyperglycaemia in a diabetic patient (Colberg, 2006). A cool down period is required to prevent a sudden reduction in venous return and to allow a gradual redistribution of blood from the extremities to other tissues(American College of Sports Medicine, 2009b).

During exercise insulin production is decreased due to the action of catecholamines and glucagon, two hormones that increase the release of glucose by the liver. This action is intended to compensate the increase in glycogen depletion by exercising muscles, thus avoiding hypoglycaemia. Exercise duration is therefore important, because muscles' carbohydrate stores are limited, and even in a healthy individual hypoglycemia may arise (Colberg, 2006). In exercising type 2 diabetic patients this decrease in insulin production may not be enough. In this case, the production of an adequate blood glucose level (over 65 mg/dl) may be compromised and the risk of hypoglycaemia rises substantially (Colberg, 2006).

During the process of restoration of muscle glycogen after physical activity, glucose is taken up from the blood in an insulin-independent process (Kesavadev et al., 2003). Exercise enhances tissue glucose uptake for a period that may last for 24 to 72 hours(Sigal et al., 2006), and is the most important effect of exercise in glycemic control (Colberg, 2006; Horowitz, 2007). There is some doubt about how much of the benefit is due to a training effect and how much is due to replenishment of glycogen stores, but after exercise the muscle is more sensitive to insulin action (Bonen, 2001; Shephard, 1997). Thus regularity of exercise is important, not because of its long term effect, but in order to ensure the continuous acute effect of exercise.

Exercise planning for individuals with type 2 diabetes should take into account the following points:

- Before engaging in an exercise program, type 2 diabetes patients should have an extensive medical evaluation where the cardiovascular, nervous, renal and visual systems should be screened for related diabetic complications (American College of Sports Medicine, 2009a);

- Sports that involve intense body contact should be avoided due to the increased risk of retinal detachment (Sigal et al., 2006);
- Isolated sports practice should also be prevented, especially if it occurs in hazardous environments (such as diving or parachuting) due to the potentially fatal consequences of a hypoglycaemia (Barata, 1997);
- Competitive exercises that lead to exhaustion might cause excessive levels of stress. Moderate exercise is associated with more desirable personality characteristics, with the promotion and keeping of self-esteem, with satisfaction with life and with a better quality of life (Cruz, Machado, & Mota, 1996);
- Aerobic training appears to be associated with better glycemic control while high intensity exercise may result in transient hyperglycemia and may not be appropriate especially for older people (Colberg, 2006);
- Glucose monitoring before and after exercise is required (American College of Sports Medicine, 2009b);
- Exercise should be avoided if fasting glucose levels are over 250 mg/dl or if non-fasting glucose levels are over 300 mg/dl (Albright, 1997; Sigal et al., 2006);
- Participants should be aware of hypoglycaemia symptoms. In older people these symptoms may be less

intense than in younger people (Kesavadev et al., 2003; Williamson, 2011);

- A supervised environment is recommended until individual metabolic responses to exercise are characterised;
- Quantifiable and reproducible ways of exercise are desirable, because exercise prescription and load dynamics are easier to adjust (American College of Sports Medicine, 2009b);
- Proper footwear is required and special attention should be paid to foot–gel or air mid-soles. Polyester socks are recommended (Albright, 1997; American Diabetes Association & American College of Sports Medicine, 1997);
- A diabetes identification bracelet or shoe tag should be clearly visible when exercising (American Diabetes Association & American College of Sports Medicine, 1997);
- A source of rapidly acting carbohydrate must be available during exercise (Albright, 1997; Colberg, 2006; Williamson, 2011);
- Exercise should include proper warm-up and cool-down periods (American Diabetes Association & American College of Sports Medicine, 1997; Williamson, 2011);
- Proper hydration is required during exercise (Albright, 1997; American Diabetes Association &

American College of Sports Medicine, 1997; Williamson, 2011). Physical Activity in the heat needs special attention (American Diabetes Association, 2004b);

- Prolonged exercise (over 1 h) may cause hypoglycaemia. This situation is enhanced by the use of insulin or oral hypoglycemic agents, therefore, a pre-exercise carbohydrate ingestion may be needed, aiming at a blood glucose level of 100 mg/dl. Adjustments in therapy might also be needed(Kesavadev et al., 2003);
- High-resistance exercise using weights may be acceptable for young people with diabetes, but not for older people or those with long-standing diabetes(American Diabetes Association, 2004b);
- Individuals with neuropathy in the legs and feet may experience balance and gait problems and should avoid exercises that include quick changes in foot patterns(Williamson, 2011);
- Exercise should be done daily. If that is not possible, the maximum interval between exercise bouts should be minimized (Sigal et al., 2006).

2.8. IMPLEMENTATION OF LIFESTYLE CHANGES

Exercising regularly as well as keeping a proper diet, requires, in the vast majority of cases, a fundamental change in lifestyle. The problem is not so much the effectiveness of lifestyle changes but how to promote these changes in a sustainable manner. In this chapter strategies to implement lifestyle changes and factors related to compliance will be briefly reviewed.

Compliance with diabetes treatment implies a wide set of health behaviours: continuous control over diet, increasing physical activity, taking pills, daily assessment of glycaemia, daily checking of feet and periodical clinical exams. The degree of involvement of the patient is very high, as it demands not only knowledge about the disease, but also a considerable compliance effort (Eichner, 2002). Very often patients do not adhere to the prescribed treatment plan (Eichner, 2002). Lifestyle changes regarding diet and exercise may be complex and are aimed at the long term, leading to reduced compliance.

Diabetic patients require continuing medical care and self-management education in order to prevent both acute and long term complications. Due to the complexity and diversity of the areas involved in the treatment, the constitution of a multidisciplinary, physician coordinated team, that prepares, guides and supports the diabetic patient on his treatment, is more effective (Kim et al., 2006; Mensing et al., 2006). This team might integrate professionals from distinct disciplines such as physicians, nurses, psychologists, social assistants, dieticians or exercise physiologists.

It is difficult to achieve long term adherence to diabetic treatment. A rebound is common in weight control programs after one year, and typically 30% of initial weight loss is put back on in that period. After 3 to 5 years most patients are back to the baseline (Lindstrom et al., 2003;

Rena R. Wing et al., 2001). Drop-out rates of 50% within 6 months (Resnick, 2000) and 75% within 2 years are common (A. Kirk et al., 2004) in physical activity programs.

Compliance with diet recommendations is also difficult to achieve. Hsia et al. (2002) studied the compliance of 13,777 participants with hypercholesterolemia with dietary recommendations from the National Cholesterol Education Program. Only 20% of the participants followed those recommendations about total fat and saturated fat intake. Lower compliance was associated with high BMI, sedentary lifestyle and smoking.

Studying 1,480 adults with type 2 diabetes Nelson, Reiber and Boyko (2002) found that almost two thirds of the sample got over 30% of their daily calories from fat and 10% of total calories from saturated fat. Likewise 62% of the sample did not follow guidelines in respect of fruit and vegetables.

It is imperative that patients with diabetes see themselves as playing an active role in their care (Clark, 2003). Diabetes Self-Management Education (DSME) is an integral part of diabetes care and specific and detailed information about the disease must be provided to patients (Mensing et al., 2006). After assessment of the particular needs of individuals with diabetes DSME might include information on the following topics (Funnell et al., 2007):

- Description of the diabetes disease and treatment options;
- Inclusion of nutritional management into lifestyle;

- Using medication safely and with maximum therapeutic effectiveness;
- Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making;
- Preventing detecting and treating acute complications;
- Preventing detecting and treating chronic complications;
- Developing personal strategies to address psychosocial issues and concerns;
- Developing personal strategies to promote health and behaviour change.

Studying 22,682 patients with type 2 diabetes, Strine et al. (2005) found that about 48% of them never received DSME and estimated that 50 to 80% of patients with diabetes knew little about the management of their disease. Those subjects were less likely to have benefited from ophthalmologic examination, to have regularly checked their feet for sores or their blood sugar and HbA1c levels.

Information about the disease may be essential, but it is not enough to guarantee compliance. Albarran et al.(2006) studied 48 diabetic patients and 38 relatives divided into six discussion groups (6 to 8 members each). During the intervention period 5 meetings took place to discuss lifestyles and knowledge about diabetes. After 8 months the knowledge about diabetes had increased significantly, but no significant risk-reduction was observed. Also Ogden

(2004) notes the importance of keeping patients informed about the disease as a way of increasing compliance with the treatment, but the author also points that in some cases the relationship between information about the benefits of physical activity and compliance is very weak.

Patient empowerment is defined as helping patients develop the capacity to be responsible for one's own life. The role of the patients is to be well informed active partners in their own care. The role of the health professionals is to help patients make informed decisions and through education help them to overcome barriers (Funnell & Anderson, 2004). Goal setting should be a negotiated process between professionals, experts about diabetes and its treatment, and patients, experts about their own personal goals (Funnell & Anderson, 2004; Lerman, 2005). Goals should preferably be expressed in a way that is most related to the patient's personal goals (Clark, 2003).

Thus an intervention based on a partnership between physician and patient is recommended. The use of a linguistic level appropriate to the patient is critical, so that the patient is able to negotiate and take part in the decision-making process. The patient's ideas, fears, expectations and health-beliefs are crucial in the design of therapies so that they can be accepted and accomplished (Falk, 2001). Falk (2001) considers that the term "adherence" should replace "compliance" as the latter term feels paternalistic and is associated with obedience, whereas the former relates to a fundamental part of the process: the agreement and commitment of the patient to the prescribed treatment.

Adherence to treatment depends on a large number of factors, and over 200 variables might influence adherence to treatment (Silva, Pais-Ribeiro, & Cardoso, 2005) but adherence studies are difficult due to the lack of adequate standardized methods to measure adherence. Most studies used patients' self reports, but it is probable that this procedure overestimates compliance because patients tend to answer what the interviewer wants, due to social desirability. Therefore reports of non-compliance are more trustworthy than those of compliance. Adherence is a dynamic event: it may happen in different degrees, and behaviour can change considerably over a short period of time (Lerman, 2005).

Four main clusters of correlates of adherence behaviours in diabetes were proposed by the World Health Organization (2003a): treatment and disease characteristics, intrapersonal, interpersonal and environmental factors.

2.8.1. TREATMENT AND DISEASE CHARACTERISTICS

According to the psychosocial typology of the illness the adaptation of the subject to the illness is related to the following variables (Rolland, 1994; Steinglass, 1987):

- Beginning of the illness (sudden or sharp, insidious or gradual, mainly focusing on the perception that the subject has of the illness, and not so much on its physical symptoms).
- Evolution: gradual, constant or episodic (associated with how quickly the illness progresses, with the

necessity of care, with the role and task/function changes in the personal, family and social life of the person).

- Result: death, gradual and/or fatal damage, or other expected result which will vary from time to time (according to the prognosis for the illness, to information about the illness and to clarification of patient’s fears).
- Incapacity: degree of damage from the cognitive, sensorial and motor point of view, which also involves the disseminated social constructions of the illness (i.e estimates that the several levels of damage and its combinations can provoke different types of incapacity - none, average, moderate, severe).
- Other factors, such as the visibility of the symptoms, severity of the crises, genetic contribution, type of treatments and the age of appearance are also prominent in the process of psychological and psycho-social adaptation to the illness and are associated with treatment adherence.

Disease characteristics will influence expectancies about disease control, therefore changing the locus of control. Commitment to health behaviours and to medical treatments doesn’t always assure control over the disease’s outcome (Stanton et al., 2007).

For type 2 diabetes the study of adherence to the different components of its treatment must be made in an independent form (World Health Organization, 2003). In the World Health

Organization report (2003) adhesion rates varied from 23% to 33% for glucose monitoring, from 70 to 80% for taking pills, from 37 to 70% for diet and from 26 to 52% for prescribed physical activity.

Some aspects of the treatment influence adherence. Paes, Bakker, and Soe-Agnie (1997) found a 79%, 65% and 38% adherence for a once, twice and three-daily regime respectively of oral hypoglycemic drugs. Complexity of treatment and treatment length are thus important issues to consider. Short term treatments have higher adherence than long term therapies (Lerman, 2005; World Health Organisation, 2003).

2.8.2. INDIVIDUAL FACTORS

Once diabetes is diagnosed, an adjustment process occurs. There is evidence of adjustment processes' heterogeneity whether from individual to individual or within the same individual across time (Stanton et al., 2007). Individual coping abilities will greatly influence behaviour towards the disease. Referring to an individual's perception about the underlying main causes of events in his/her life, the locus of control is a key element(Rotter, 1966). If it's external, the individual will consider the disease as being out of his/her control. Adherence to treatment will then be compromised. If it's internal responsibility over his/her health will then lay on future behaviour, and adherence to treatment is more likely.

Willis and Campbell (1992) analysed the general population and found fatigue, lack of time, lack of facilities and lack of knowledge about fitness as the main barriers affecting adherence to exercise programs. These authors considered that fatigue is often a psychological issue more than a physical one. Lack of time may be due to spending time on other behaviours not related to health (like watching TV) and lack of facilities or equipment may mean lack of pleasant facilities or equipment.

Psychological aspects may indeed be highly relevant in the success or failure of adjustment and disease management (Rolland, 1994; Steinglass, 1987). There is some evidence that high self-concept and self-esteem are associated with high levels of diabetes self management (Laffrey, 2000; Silva et al., 2005).A low self-esteem is associated with comfort eating, excess alcohol intake or physical activity reduction, thus inducing lethargy and lack of motivation (Swinburn & Egger, 2004). Mood states also influence treatment outcomes through changing adherence (Silva et al., 2005; Rena R. Wing, Phelan, & Tate, 2002). Its analysis will be made in a subsequent chapter.

2.8.3. INTERPERSONAL FACTORS

One of the most influential aspects on adherence to treatment seems to be social support (Lerman, 2005). The adjustment process requires emotional and practical support. Family and social support systems may help treatment compliance for example by their reminding patients to take medications on time or by their calling attention to a larger than usual meal. On the other hand, if interpersonal relationships are poor, well intended advice may be regarded as criticism, generate stress and anxiety and contribute to an even poorer relationship.

Sluzki (1996) identifies a recursive relationship between personal social network (in the several types of aid and support made available) and health/illness. He concludes that the quality of the personal social network, and the way that its elements function, have a relevant impact on the promotion of healthy lifestyles. Equally the personal social network is also fundamental to the aid given to patients, particularly in the way that they can adapt to the illness, and people from the network can assume an active and collaborative role in the treatment.

The quality and frequency of contact between the patient and care providers are correlated with adherence. Compliance with healthy lifestyles may be accomplished more easily if the contact with health team members is more frequent (Eichner, 2002; Miller & Dunstan, 2004; Rafferty, Anderson, McGee, & Miller, 2002; Trento et al., 2001). Tuomilehto et al.(2001) report an increase in health–related behaviours among intervention group participants during the follow-up examinations. This group had frequent contacts with health team members, especially nutritionists and exercise monitors.

Working with groups of patients seems to be a valid way to intervene: it allows the patient to meet other individuals with the same problem and on the other hand it increases contact time with health care providers (Gucciardi, DeMelo, Lee, & Grace, 2007; Trento et al., 2001).

Studying compliance with dietary programs in 2,532 individuals, Rafferty, Anderson, McGee and Miller (2002) found that compliance was higher among subjects who were told by their clinician that they had high blood pressure. The perceived threat might be an important element in the adoption of health behaviours.

2.8.4. ENVIRONMENTAL FACTORS

Environmental factors that condition adherence to treatment differ according to culture and lifestyle. Exposure to unhealthy environments, such as to an environment that favours low physical activity or to one with easy access to high caloric food, is a major obstacle to lifestyle modification.

In a diabetes intervention program conducted in Mexico most individuals complied with the minimum recommended physical activity despite the lack of government effort to promote physical activity. The levels of physical activity found in this study were higher than those in the USA for both healthy Mexican-Americans and adults with type 2 diabetes (Bacardí, Rosales, & Jiménez, 2005). In Greece a meta-analysis of participation in physical activity and exercise found low levels of participation (Tzormpatzakis & Sleap, 2007), and Parks, Housemann and Brownson (2003) found differences between urban and rural areas.

The heterogeneity of the cultural characteristics of the environment may therefore influence adherence to one or other components of the treatment, such as physical activity recommendations.

Other environmental aspects that influence behaviour change include access to healthy food or to facilities for exercise. Socioeconomic factors play here a crucial role (Weinberg & Gould, 1995).

A higher quality diet is associated with a low–energy-density food choice and to higher diet costs (Darmon, Briend, & Drewnowski, 2004; Drewnowski, Monsivais, Maillot, & Darmon, 2007). Sugars, refined grains and fats often represent the lowest cost option to the consumer, increasing the percentage of total energy intake from this kind of food and consequently decreasing the percentage of energy from the more expensive fruits and vegetables (Darmon et al., 2002). This pattern of choices is representative of those made by low income groups (Drewnowski & Specter, 2004). The availability and affordability of foodstuffs may also depend on the type and number of grocery stores in a particular area (Block & Kouba, 2006).

A low socio economic status may directly affect adherence to treatment by conditioning access to health care or, indirectly, by making depression and anxiety more common. In fact individuals with low socio-economic status find life events more stressful and at the same time have fewer social and psychological resources to manage them (Everson, Maty, Lynch, & Kaplan, 2002; Stanton et al., 2007).

The patient’s educational level is another factor that influences adherence to treatment. Higher education levels were found to be associated with higher levels of physical activity as well as with increased compliance with dietary advice (Drewnowski & Specter, 2004; Hsia et al., 2002; A. King et al., 2000; Lerman, 2005; Rafferty et al., 2002; Strine et al., 2005).

In western societies the concept of an ideal (thin) body leads to body dissatisfaction and even guilt feelings towards one's body in obese and overweight individuals. Still in this case some activities might be discretely introduced into daily life in order to increase physical activity, such as getting out of the bus one stop in advance and walking a little more or using the stairs rather than the lift (Beattie, 2001). Increased body weight may be a disincentive for exercise and physical activity: overweight individuals tend to do fewer and less demanding activities, generating further weight gain (Swinburn & Egger, 2004). Overweight individuals also have more mechanical problems like arthritis, lower back pain or obstructive sleep apnoea that precludes them from exercising adequately(Swinburn & Egger, 2004).

2.9. MOOD STATES AND PHYSICAL ACTIVITY

Despite the fact that physical activity is part of the recommended treatment in type 2 diabetes, there is a considerable lack of data regarding the psychological benefits of participation in physical activity programs (Biddle & Mutrie, 2001). Indeed in their joint position statement the American Diabetes Association and the American College of Sports Medicine consider exercise to be a first line measure against diabetes. Nothing is said however about the psychological advantages of exercise or about compliance or dropout rates in exercise programs (American Diabetes Association & American College of Sports Medicine, 1997).

Exercise can play an important role in fighting depression because exercise can reduce stress and increase the sense of control that leads to a positive attitude about life, as referred to by Mutrie (2001). Exercise may enhance perceptions of well-being which are important predictors for staying active in older ages. These effects might be explained by the larger release of endorphins - natural brain opiates - that occurs during exercise, as well as by the more intense social activity usually associated with exercise (Ogden, 2004).

A meta–analysis of 39 studies and 20,218 subjects over comorbid depression in adults found a double likelihood of depression amongst individuals with diabetes (Anderson, Freedland, Clouse, & Lustman, 2001).

Other meta–analysis of the psychological advantages of exercise were done by Biddle and Mutrie (2001) and Leith (1994). Both of these studies found an inverse relationship between exercise and depression. These findings are in line with those of Ruuskanen and Ruoppila, (1995) who found a relationship between a higher prevalence of depression and no regular exercise. The Surgeon’s General Report (U.S. Department of Health and Human Services, 1996) notes the role of exercise in relieving anxiety symptoms, promoting well-being and reducing the risk of depression. This seems to be a consensual conclusion.

Blumenthal et al. (1999) conducted a study of patients with depression who were aged over 50 years. Three groups were compared: one group did moderate intensity aerobic exercise, another had pharmacotherapy and the last one received both treatments. The authors concluded that all three methods were effective in fighting depression. The pharmacotherapy group got quicker results but the exercise group achieved the same results after 16 weeks. Furthermore exercise interventions are also associated with better quality of life than pharmacotherapy interventions (The Diabetes Prevention Program Research Group, 2003).

Aikens, Aikens, Wallander, and Hunt (1997) studied 72 retired individuals, aged 59 or older, with type 2 diabetes. They found a strong association between stress and poor glycemic control among individuals with low levels of physical activity. These individuals are consequently more vulnerable to daily undesirable events.

In order to access changes in mood states as a consequence of exercise a large variety of studies used the Profile of Mood States Questionnaire (POMS) (McNair, Lorr, & Droppleman, 1971), a 42 item questionnaire grouped in six factors of mood states: Tension - Anxiety, Depression - Dejection, Anger – Hostility, Vigor – Activity; Fatigue – Inertia and Confusion – Bewilderment. Physical activity appears to promote an “iceberg profile” (Alves, 2005; Biddle & Mutrie, 2001; Leith, 1994) – an increase in Vigor – Activity and a decrease in every other factor considered.

2.10. MOTIVATION THEORIES

The research about the reasons why people adhere to healthy lifestyles, and the barriers that prevent that adherence, are of great importance. Only by understanding what motivates individuals is it possible to promote well designed programs, adapted to their needs.

In a meta-analysis Biddle and Mutrie,(2001) identified 6 main theories that try to explain human behaviour related to exercise adherence:

- Theory of reasoned action(Ajzen & Fishbein, 1980; Fishbein & Ajzen, 1975): based on the assumption that intention is a determinant of behaviour. Individuals will, before adopting a given behaviour, evaluate positive and negative consequences of that particular behaviour, developing an attitude towards it. External variables will exert their influence over what is perceived as positive or negative in a particular environment. Subjective normative factors will work as a social regulator of attitudes. Both subjective normative factors and attitude may explain and forecast intention;

- Theory of planned behaviour (Ajzen, 1985): not very different from the previous, but rather a remodelling, this theory introduces the concept of “Perceived Behavioural Control” as a factor influencing intention. In fact the theory of reasoned action failed to explain the lack of volitional control that occurs in the adoption of some behaviours. The perceived ease or difficulty of performing a specific behaviour might influence intention to perform that behaviour or the behaviour itself. Opportunities and resources, as well as perceived power over behaviour, are included in this construct. Some health behaviours such as quitting smoking or engaging in a weight control program may not be adopted because individuals belief to have poor control over their own behaviour and don't even try to adopt them as habits;

- Health belief model(Rosenstock, 1974): this model predicts that people will not adopt health protective behaviours unless they: see their condition as threatening, have minimal levels of health motivation and knowledge, find themselves as vulnerable, believe in the efficacy of the behaviour and find the behaviour easy to adopt;
- Protection motivation theory(R. W. Rogers, 1975): similar to previous puts emphasis on the perceived threat to health, which depends on the perceived severity and the perceived probability of threat. The coping appraisal depends on the perceived efficacy of the preventive behaviour and the perceived self-efficacy of the individual. The threat appraisal and the coping appraisal determine the intention to protect and thus the adoption of the protective behaviour;
- Self-determination theory(Deci & Ryan, 1985; Ryan & Deci, 2000): incorporating four theories, this is a macro-theory of human motivation and personality,

focusing on the dialectic between the active organism and the social context on the one hand, and the degree to which human behaviours are determined by personal choice on the other. The theory states that there are three innate, essential and universal psychological needs - competence, autonomy and relatedness – that, when met, will improve intrinsic motivation, mental health and well-being. Conversely, when not met, a person will function sub-optimally and will show evidence of low motivation and ill-being;

- Self Efficacy Theory(Bandura, 1977): the rationale behind this model is that individuals tend to choose activities where they perceive themselves as competent. These situations allow positive emotions, low anxiety and an internal locus of control. According to this theory, past experiences with a particular behaviour will influence the adoption of that behaviour in the future. Perceived self efficacy may also be enhanced by comparison with others, if the individual finds him/herself more competent than others in a particular behaviour, or through social inducement.

These 6 theories overlap considerably, and different attempts to form an integrated model have been made, usually based on the theory of planned behaviour. This transtheoretical model of behaviour change considers different stages of adherence to a behaviour adoption:

- Pre-contemplation: there is no intention to adopt the behaviour;

- Contemplation: a behaviour change is considered;
- Preparation: small changes occur in behaviour;
- Action: a new behaviour is adopted for less than a 6 month period;
- Maintenance: the adoption of the new behaviour is sustained over a 6 month period.

This theory has supported the work of A. Kirk et al. (2004) who analysed changes in stages of behavioural adoption after 12 months of physical activity counselling. The objective was the adoption of 20 minutes of moderate to hard exercise three times a week (American College of Sports Medicine guidelines in 1990). The intervention included 30 minute consultations every 6 months and follow-up phone calls one and three months after each consultation. The stage of exercise behaviour changed over the intervention period for the experimental group, while no changes occurred in control group (A. Kirk, N. Mutrie, P. MacIntyre, & M. Fisher, 2004). The experimental group also had significantly better results than the control group in glycemic control, blood pressure and total cholesterol.

A counselling strategy to promote the adoption and maintenance of physical activity by type 2 diabetic patients was proposed by Di Loreto et al (2003). The strategy comprised an initial 30 minute session where 7 keys points were made:

- Motivation: the benefits of regular exercise were explained;
- Self-efficacy: the patient was asked to collaborate in designing a program the patient felt was accomplishable. Realistic goals were established;
- Pleasure: previous experiences with exercise were asked about. Several activities (outdoor/indoor) were proposed;
- Support: The patients' partners were also invited to engage in the program;
- Comprehension: Patients were asked about the established program to ensure they had understood it.
- Lack of impediments: potential obstacles to exercise were identified and the patient suggested ways to overcome those barriers.
- Diary: patients were asked to keep a log of their performed Physical activity. This way self-efficacy was enhanced, and barriers to exercise were identified.

This intervention group was followed up with a phone call after the initial session and with a 15 minute session every 3 months. In this study the intervention group was compared with a control group that received standard counselling. The results showed a significant improvement in physical activity for the intervention group after a two year intervention. Significant improvements in BMI and HbA1c were also found.

Some strategies based on these theories have been proven to have some positive effect on adherence and should be adopted in future programs:

- Physical activity programs should have a pedagogical scope, where the benefits of increased physical activity are taught to participants, especially psychological ones. Participants' knowledge about such benefits should never be taken for granted. (Willis & Campbell, 1992);
- The program must ensure that the participants have understood the given information (Di Loreto et al., 2003);
- Adequate goal setting (particularly about weight or accomplishable physical activity) (Rena R. Wing et al., 2001);
- Look for social support – a group or a partner committed to the same objective (Di Loreto et al., 2003; Lerman, 2005);
- Program participation must be as simple as possible (Lerman, 2005);
- The program should provide frequent contacts with health team members (Eichner, 2002; Miller & Dunstan, 2004; Trento et al., 2001; Tuomilehto et al., 2001);

- Patients should keep logs to track eating and physical activity habits in order to identify situations that trigger unhealthy eating or non-compliance with physical activity objectives, and should develop strategies to avoid them (Di Loreto et al., 2003);
- Patients should be taught that default from a diet or from a physical activity program should not be seen as an irreversible failure but as part of the process. Patients should be able to cope with small lapses. (Beattie, 2001; P. Powers, 2005).

3. OBJECTIVES

The objectives of this study were:

- To characterize the daily physical activity of a population with type 2 diabetes *mellitus*, and particularly the time spent in vigorous and moderate physical activity as well as the time spent walking.

- To characterize the dietary habits of the same population, and particularly the degree of compliance with the dietary recommendations for the Portuguese population.

- To assess the effectiveness of a 9 month lifestyle intervention consisting of a low workload physical activity program and a nutritional education program aimed at the adoption of a more active lifestyle and better nutritional habits.

- To assess the impact of such a program on:

    - clinical and biological variables: parameters of diabetic control;

    - fitness: progress achieved in different physical qualities such as strength, aerobic endurance, flexibility and agility;

    - psychological: evolution of mood states;

    - economic: cost of medication.

The rationale for those objectives was that physical activity and diet are the cornerstones of diabetes management and that intervention programs targeting these areas should look to help bring about a synergistic effect between them.

Guidelines from major international organizations recommend moderate physical activity for 30 minutes most days of the week (American Diabetes Association & American College of Sports Medicine, 1997; Klein et al., 2004; U.S. Department of Health and Human Services, 1996). However research on the effectiveness of physical activity programs with lower intervention loads is needed (LaMonte et al., 2005). Intervention programs providing supervised physical activity with lower workloads may be easier to implement, with increased adherence and lower dropout rates, and might have reduced costs. When applied to type 2 diabetic patients, supervised classes should be seen as “centres for behaviour change”, providing information about the disease and helping patients to adopt healthier lifestyles.

4. MATERIALS AND METHODS

4.1. SÃO JOÃO HEALTH CENTRE

This interventional study took place at São João Health Centre, a primary health care unit located in central Lisbon, which covers about 40,000 people (**Figure 1**). The area where this unit is located has a low socio-cultural level and a rather elderly population.

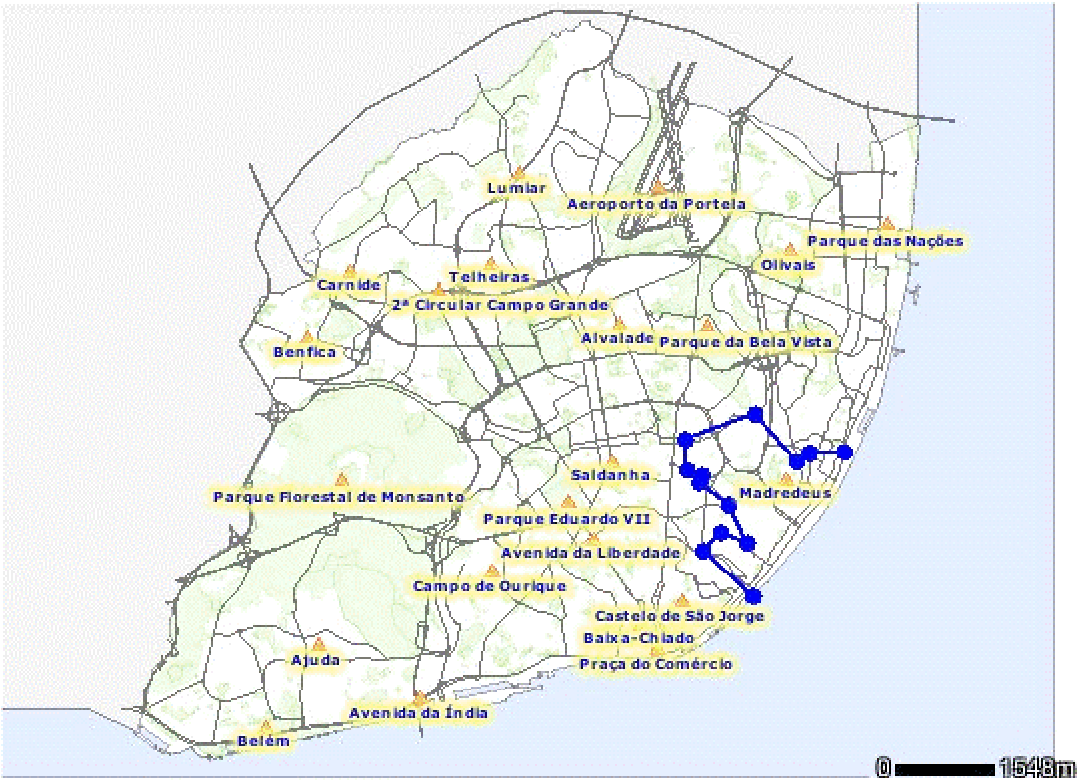

Figure 1 – S. João Health Centre and its intervention area.

At the São João Health Centre about 1,900 individuals are registered as diabetics, and they are regularly followed by the health centre physicians and specialized nurses. Out of those, only about 300 diabetic patients come to a specialized nurse consultation regularly, despite these consultations being advised by physicians and free of charge. The history of the diabetic patient is recorded here and his/her ability for disease self management is evaluated. Instructions on self-glycaemia control and about the disease are given as well as general lifestyle counselling, including nutrition and physical activity. Specific patients' problems are also discussed. Patients attend the consultation with a periodicity of between 15 days and 4 months depending on the nurse's evaluation of the achieved control.

This health unit has recently implemented a program named "Saúde em Movimento" – Health in Motion – directed at type 2 diabetic patients. This program was the result of the cooperation between S. João Health Center, Escola Superior de Desporto de Rio Maior - Instituto Politécnico Santarém and the Centro de Nutrição e Metabolismo - Instituto de Medicina Molecular.

The main purpose of this program is to provide, apart from the already mentioned care services, individual dietary advice as well as physical activity classes. Both activities occur in the unit's facilities. With this in mind, a multi-disciplinary team was set up including a physician, a nurse, a nutritionist and a physical activity instructor.

After being launched, the program and its objectives were presented to the health centre´s physicians. Their cooperation was asked in order to advise all diabetic patients with no contraindication to exercise to attend the specialized nurse consultation and join the program.

It was expected that the regular and frequent contact between patients and members of this multi-disciplinary team would help patients to adopt better health behaviours.

To ensure a coordinated work, several meetings took place between the health centre director, specialized nurses, nutritionists and the physical activity instructor. In these meetings the work of every member was described and analysed in order to allow each one to have a complete knowledge of the program and to make sure that no contradiction would be found in the information provided to the patient. The channels of communication were established and the specialised nurse was appointed as the one responsible for reporting to each patient’s physician. During the program the specialized nurse met the nutritionists every fortnight and the physical activity instructor monthly.

4.2. SAMPLING AND STUDY DESIGN

The S. João Health Centre has around 1.900 diabetic patients registered and out of those, only about 300 diabetic patients regularly attend specialized nurse consultations. Invitations to participate in the study were made to these 300 patients.

The inclusion criteria were:

- Diagnosed type 2 diabetes;

- Absence of contraindication to exercise;
- Agreement to participate in the experiment (written consent).

Exclusion criteria included:

- contraindication to exercise;
- pregnancy or lower limb amputation;
- inability to follow the program regularly - a minimum of 75% attendance was set.

Initially, only 47 subjects complied with these criteria but during the study period 4 individuals dropped out resulting in a final sample of 43 subjects. Data confidentiality was assured and written consent was requested from each participant in the study. Data was gathered between February 2005 and July 2006 with a 9 month period between each subject observation. The sample was then divided into two groups according to the participant’s choice. Those who were willing to participate in the experiment but not to engage in physical activity classes or nutritionist consultations were assigned to the control group (n=24, 12 men and 12 women, age 68.9±11.3). The control group wasn’t submitted to any additional treatment apart from the regular medical and specialized nurse consultations already mentioned.

Those who were willing to participate fully in physical activity classes and nutritionist consultations engaged in the “Saúde em Movimento” program and were assigned to the intervention group (n=19, 6 men and 13 women, age 69.5±8.9).

Figure 2 summarizes the sampling process.

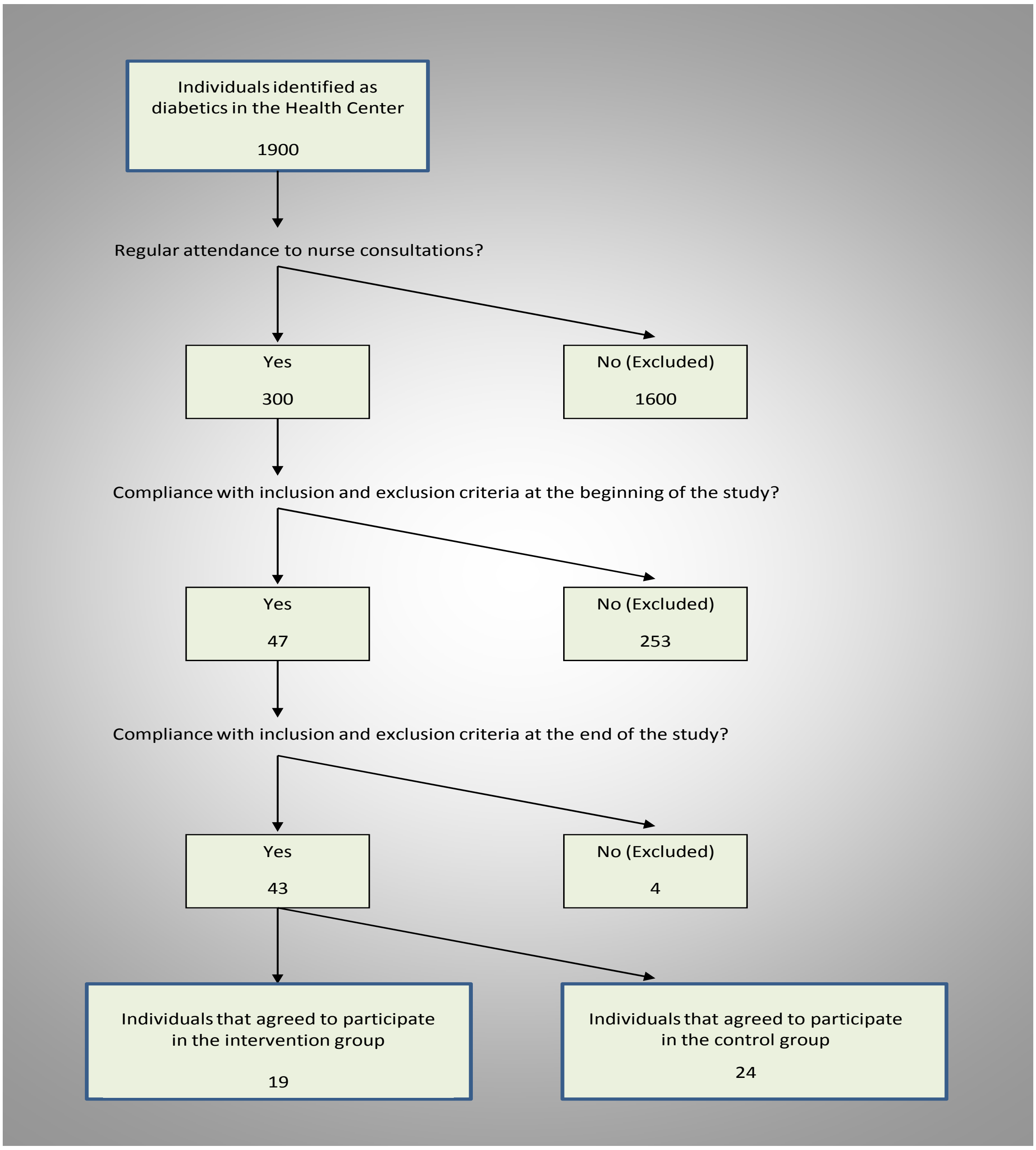

Figure 2 – Flow chart showing recruitment and affiliation to groups of study subjects

The intervention group was given dietary advice and physical activity classes. Dietary advice was provided in monthly consultations by trainee nutritionists under the supervision of the Centro de Nutrição e Metabolismo - Instituto de Medicina Molecular. This advice was adapted to specific needs and individual preferences. The main dietary guidelines included:

- Eat every 2.5 hours with a special focus on breakfast and evening meal.
- Increase vegetable and fruit consumption (max 3 pieces/day)
- Reduce food with a high glycemic index such as sweets, sodas, etc.

During the nutritional consultation, recommendations to increase physical activity were also provided.

Physical activity classes of 50 minutes each were provided twice a week in the Health Centre facilities by a Health and Fitness trainee under the supervision of Escola Superior de Desporto de Rio Maior. A typical class included a 10 minutes warm-up period, a 30 minutes core part and a 10 minutes cool down period. The physical activity classes were low impact and had a high percentage of aerobic exercises which required the use of large muscles in a rhythmic and continuous fashion. Exercise intensity was moderate according to both the American College of Sports Medicine (ACSM) recommendations and criteria (American College of Sports Medicine, 2006). Borg's scale of perceived exertion was taught to participants, and an intensity target value of 12-13 on a 6-20 scale was sought(Borg, 1970). Walks and outdoor classes occasionally took place in order to allow a change of environment. Apart from providing extra physical activity, the program had the additional goal of promoting the increase of individual daily physical activity. Various simple strategies to raise daily activity were taught:

- Elevators should be avoided and stairs should be used as much as possible.
- Leaving the bus one stop before destination and walk the remaining distance.
- Participants were given a list of physical activity homework.

The role of physical activity classes as "behaviour modification centres" was enhanced by the physical activity instructor, not only in relation to physical activities but also in relation to dietary compliance. Also whenever significant changes occurred in a patient's health a physician consultation was advised.

4.3. DATA COLLECTED

4.3.1. PHYSICAL ACTIVITY HABITS

Physical activity was measured through the International Physical Activity Questionnaire (IPAQ) - short form. This questionnaire, originally created by Booth et al (1996), is now validated in 12 countries including Portugal (Craig et al., 2003). Its short form evaluates the time spent in a week doing physical activity. For this purpose three different kinds of physical activity were considered:

- Vigorous activity - Activities considered as being within this category imply intense physical effort such as lifting heavy objects, digging, taking aerobic or step classes, fast cycling, running, swimming, playing soccer or basketball. Activities were considered if practised for at least 10 minutes. An average Metabolic Equivalent (MET) of 8 was given to these activities("Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) – Short and Long Forms," 2005).

- Moderate activity - This category includes activities which promote breathing adaptation such as carrying light objects, cycling, hunting, gardening, playing table tennis, domestic activities like scrubbing or cleaning. A minimum of 10 minutes is necessary for it to count in the calculation of physical activity. An average MET of 4 was given to these activities("Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) – Short and Long Forms," 2005).

- Walking time – All the walking time should be included in this category, covering: travel to home or work, walks done for leisure, sports or just moving around. As in the other categories, walking time should be included if it lasted for at least 10 minutes. An average metabolic equivalent (MET) of 3.3 was given to these activities("Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) – Short and Long Forms," 2005).

In order to estimate the questionnaire reliability in this population, intra-class correlation coefficient was used with a test-retest applied to 10 subjects with a 2 week interval. Relative reliability was 0.99 for vigorous and moderate activity and 0.98 for walking time.

4.3.2. DIETARY HABITS

Dietary intake was assessed by a nutritionist using the 24 hour recall method. The participant had to indicate and provide approximate sizing of all foodstuffs and drinks he/she consumed in the 24 hours prior to the interview. Each participant was subsequently classified as complier or non-complier according to the dietary recommendations for the Portuguese population (**Table 2**). For example if the consumption of a single average sized fruit in one day is reported, and considering that the recommended consumption is between 3 and 5 portions per day, this subject would be classified as a non-complier.

Table 2 – Categories and Dietary recommendations for the Portuguese population. Units are portions.

	Cereals and equivalents	Vegetables	Fruit	Dairy products	Meat/Fish /Eggs	Pulses	Fats and Oils
Min	4.0	3.0	3.0	2.0	1.5	1.0	1.0
Max	11.0	5.0	5.0	3.0	4.5	2.0	3.0

Also a dietary score was computed for each participant for each evaluation time according to the number of categories where that individual is a complier. Hence a participant with a healthy dietary score of 4 had a better dietary intake according to the Portuguese recommendations than a participant with a dietary score of 2. The changes in the subject’s dietary habits were subsequently classified. All individuals with negative scores were classified as having worsened their dietary patterns, those who had 0 has having no change, and all with positive scores as having improved their dietary habits.

However any favorable change in dietary behaviour (even if the desired outcome was not reached) could be considered as relevant. This analysis was made leaving out of account whether or not the changes were enough *per se* to change the classification as complier or non-complier. Three categories were defined: negative (-1) when moving away from the reference interval; maintenance (0) when no changes happened in dietary patterns or when both observations were inside the reference interval; improvement (1) when the change was towards the interval reference, independently of reaching it or not. Another score (Dietary Habits Evolution) was computed as the sum of dietary evolutions of the different categories. Thus a subject that kept his dietary behaviour in two categories, got closer to reference values in 4 categories and worsened in 1 category would have a score of 3.

4.3.3. CLINICAL AND BIOLOGICAL ASSESSMENT

Weight and height were measured on a SECA scale and a stadiometer according to Norton and Olds (1996) recommendations. The body mass index (BMI), defined as the ratio between weight and height (in meters) raised to the square was then calculated. Subjects were classified according to the American College of Sports Medicine criteria (Going & Davis, 2001): underweight if BMI<18.5 kg/m^2; normal weight if BMI between 18.5 and 24.9 kg/m^2; overweight if BMI between 25.0 and 29.9 kg/m^2 and obese if BMI≥30 kg/m^2.

Body composition was determined through bipolar manual bioimpedance with an OMRON BF-300 Body fat monitor (OMRON, Japan) and the results were expressed as a percentage of body weight.

Blood pressure was measured by a certified nurse, with a manual sphygmomanometer, in resting conditions, prior to physical tests. Hypertension was considered as SBP≥140 mmHg and/or DBP≥90 mmHg (American College of Sports Medicine, 2009a), or if the patient took antihypertensive drugs.

The prevalence of hypertensive patients was assessed and, among these, the percentage taking antihypertensive drugs and the percentage of patients with controlled blood pressure, defined as SBP<140 and DBP<90 mmHg. The *treatment rate* was defined as the ratio between the number of individuals receiving antihypertensive treatment and the total number of hypertensives. The *control rate* was obtained by dividing the number of treated and controlled hypertensives by the total number of hypertensives (Macedo et al., 2007).

As there are no laboratory facilities in the health unit, blood analyses were performed in different laboratories external to the health unit. In order to avoid bias due to different calibration processes, participants were asked to use the same laboratory throughout the study period. Total cholesterol levels were considered as adequate if below 200 mg/dL; intermediate risk was defined as values between 200 and 240 mg/dL and high risk for values >240 mg/dL. Triglyceride levels were considered high when they were >150 mg/dl, and a minimum of 40 mg/dl was set to define adequate HDL cholesterol levels ("Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report," 2002). LDL concentration was estimated through the formula proposed by Friedewald, Levy and Fredrickson (1972): LDL = Total Cholesterol – HDL – (Triglycerides/5). A maximum of 130 mg/dL was adopted as the cut value to define a low risk zone for LDL ("Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report," 2002).

In relation to diabetes, hyperglycaemia was defined as glucose values >126 mg/dL (A. Powers, 2006), and inadequate diabetic control was defined as glycated haemoglobin (HbA1c) levels above 6.5% (Direcção Geral de Saúde, 2008).

4.3.4. FITNESS ASSESSMENT

Physical fitness was evaluated through Rikli and Jones (2001) battery of test items. These battery tests are presented in **table 3**.

Table 3 - Parameters and tests included in Rikli and Jones (2001) battery of test items

Parameters evaluated	Tests	Description
Lower limb strength	- standing and sitting in a chair	Stand–ups in 30s, without arm help
Upper limb Strength	- forearm flexion	Arm flexions in 30s with weight (Women - 2.27 Kg, Men – 2.63 Kg)
Aerobic Endurance	- 2 min stepping in place	Completed steps in 2 min
Lower Flexibility	- Sit and Reach	Distance between middle fingers and toes.
Upper Flexibility	- reaching behind back	Distance between middle fingers behind back
Agility/dynamic balance	- Sit, walk 2.44 m and sit again	Time needed to stand up from a chair, walk 2.44m and return to chair.

4.3.5. PSYCHOLOGICAL ASSESSMENT

Mood States – Mood states were evaluated through the short version of the Profile of Mood States Questionnaire – (McNair, Loor & Droppleman, 1971), which was translated into Portuguese and validated by Viana (2001). It includes 42 items grouped in six factors of mood states: Tension - Anxiety, Depression - Dejection, Anger – Hostility, Vigor – Activity; Fatigue – Inertia and Confusion – Bewilderment. In each item the respondent, in relation to a particular mood, must mark the word that best describes his or her feelings in the last seven days: nothing; a little; moderately; much; very much.

For each factor, the mean of the composing items was found,

Tension - Anxiety items nº 1;12;16;20;29;31

Depression – Dejection items nº3; 7; 11; 15; 17; 21; 23; 30; 33; 36; 38; 42

Anger – Hostility items nº 2; 9; 14; 25; 28; 37

Vigor – Activity items nº 5; 8; 10; 27; 32; 39

Fatigue – Inertia items nº 4; 13; 19; 22; 34; 41

Confusion – Bewilderment items nº 6; 18; 24; 26; 35; 40

Ten individuals were subjected to a test-retest situation with a 2 week interval in order to estimate test reliability. The intra-class correlation coefficient was calculated for each factor. The results were:

Tension - Anxiety – 0.84

Depression – Dejection - 0.93

Anger – Hostility - 0.96

Vigor – Activity - 0.93

Fatigue – Inertia - 0.97

Confusion – Bewilderment - 0.83

It was considered to be an iceberg profile if the Vigor – Activity factor was higher than any other factor(Leith, 1994).

In order to confirm the data collected on physical activity and dietary changes a small directed interview was conducted in the 2nd observation. This interview was also intended to assess hospitalization time during the intervention period and to get a final opinion about the benefits of the program. An *a posteriori* categorization was done considering the answers to the following questions:

- "What do you yourself consider your degree of compliance with the dietary advice that was given to you?" Answers were categorised as "High Compliance" or Low Compliance";
- "In the last 9 months did you significantly change your dietary pattern?" Answers were categorised as "Steady dietary pattern" or "Changed dietary pattern". If the answer was affirmative the next question was "in which way?" and the answers were categorised in

"yes" or "no" as to the occurrence of quantitative changes and qualitative changes.

- "In the last 9 months did you significantly change your physical activity habits?" Answers were categorised as "Unchanged physical activity habits" or "Changed physical activity habits". If the answer was affirmative the next question was "in which way?" and the answers were categorised as "increased physical activity" or "reduced physical activity".
- "How many days have you been hospitalized in the last 9 months?"

Two more questions were added for the intervention group:

- "What are the greatest benefits you've got from participating in the program?"

Dimensions that arose from the answers given were:

- o Biological Advantages

  In this dimension 3 categories were considered:

  ⇒ General Health Control - "I feel better" or "My blood pressure is lower"

  ⇒ Diabetes Control – "I have better glycaemias"

  ⇒ Physical Fitness – "I have improved my balance" or "Now I move better"

- o Psychological Advantages

⇒ Dietary Habits - “It’s easier to control my food intake”

⇒ Physical Activity Habits - “I walk more”

⇒ Mood States - “After classes I’m in a good mood” or “ I’m not so tired” or “ I used to spend too much time alone”

- o Social Advantages

⇒ Acquaintanceship - “ I’ve met interesting people”

- “Would you recommend the program to your friends?”

The answers were categorised as “yes” or “no”.

4.3.6. ECONOMIC ASSESSMENT

The cost of treatment was assessed by summing up the costs of all prescribed medicines and treatment for each participant. In short, for each drug the total number of units (pills) consumed per month was calculated based on the physician prescription, and the corresponding costs were computed using the cheapest versions. If the prescription allowed a generic drug, the cheapest alternative was considered. The cost of treatment was further split into:

- Direct costs for participants: the percentage of medication cost not covered by the Portuguese health system. The Portuguese health system divides people into two different kinds according to income: 1) regular users and 2) pensioners with an annual *per* *capita* income of less than 14 times the minimum monthly wage (385.90€). Pensioners pay less for medicines and they pay no treatment charges. As the coverage of medicines varies according to the socio-economic characteristics of the subjects, this was also taken into account in the calculations. It should be noted that patients with chronic diseases, such as diabetes, can obtain their treatment for free.

- Costs for the State: equals the difference between the public sale price of medicines and the cost to individuals.

Hospitalization days – the self-reported days hospitalized during the intervention period.

4.4. PROCEDURES

Figure 3 schematizes the intervention study after inclusion in the control and intervention groups.

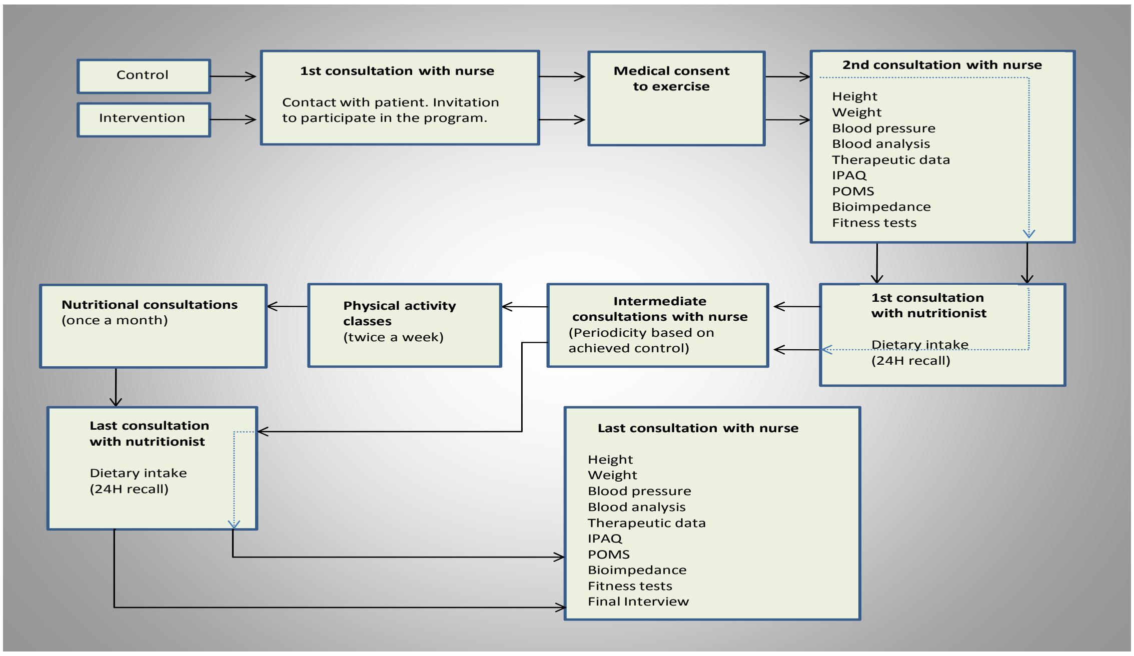

Figure 3 – Scheme of the intervention study after inclusion in the control and intervention groups

In a first specialized nurse consultation the program was presented to the patient and its objectives and associated tasks were explained. If the patient agreed to participate, a medical authorization to exercise was asked. In a second consultation, if medical consent was given, data was collected.

All variables were collected at the beginning (baseline) and at the end of the study.

The first collection was made during the regular nurse consultation following medical consent was given. Height, weight, blood pressure, blood analysis and therapeutic data were gathered by the nurse during the consultation. These elements are part of the regular clinical record of each individual.

The patient then moved to a contiguous individual cabinet where he/she was submitted to IPAQ and POMS questionnaires, bioimpedance and the Rikli and Jones battery of tests, in that order. Those tests were performed by the study coordinator. A trial period for each test was allowed in physical tests until the correct performance was achieved. After a small rest period each test was performed. In the same week dietary data was collected by a nutritionist during a nutritional consultation.

The second data collection was scheduled according to the 9 month period defined.

4.5. STATISTICAL PROCEDURES

Statistical analysis was conducted using SPSS version 17(SPSS Inc, USA) and Excel 2007 (Microsoft Corporation). Descriptive statistics were expressed as median, 1st and 3rd quartiles for quantitative, and as percentages for qualitative data. Comparisons between first and second observations stratifying for group were made using Wilcoxon’s sign rank test. Comparisons between the intervention and control groups were made using Mann Whitney‘s U and Chi-square tests. Fisher’s exact test was used whenever the conditions to apply Chi square were not present. Non-parametric statistics were preferred due to the skewed distribution of most variables. Statistical significance level was set at $p \leq 0.05$.

5. RESULTS

5.1. DROP-OUT ANALYSIS

Four out of the 47 subjects (8.5%) who initially agreed to participate in the study dropped out and their initial data were therefore excluded from the analysis. The reasons for dropping out were: 1 control and 1 intervention moved away; 1 control was too ill to be tested and 1 control refused to be tested again.

5.2. LIFESTYLE DATA

5.2.1. PHYSICAL ACTIVITY DATA

The average attendance rate for the physical activity program was 81%. Physical activity at baseline and at the end of the study was analyzed for each IPAQ's level and the results are summarized in **table 4**. Overall no difference was found between groups at the beginning or at the end of the study period. Still pairwise analysis showed that the intervention group significantly increased walking time and overall physical activity, although this latter increase was mainly due to the physical activity classes (**Table 5**).

Table 4 - Physical activity at baseline and at the end of the study. Results are expressed as medians and (1st quartile, 3rd quartile). PA, physical activity. Comparison between control and intervention groups by Mann Whitney's U test.

	Control (n=24)	Intervention (n=19)	U	P-value
Baseline				
Walking (min/week)	195 (105; 390)	210 (105; 240)	217.0	0.787
Moderate PA (min/week)	225 (0; 720)	420 (0; 840)	204.0	0.553
Overall PA (Met-min/week)	2021 (749; 6005)	2253 (1188; 4053)	225.5	0.951
End				
Walking (min/week)	210 (125; 233)	210 (180; 420)	164.5	0.115
Moderate PA (min/week)	180 (0; 1395)	540 (120; 940)	194.0	0.404
Moderate PA (min/week) a)	180 (0; 1395)	440 (20; 840)	227.0	0.980
Overall PA (Met-min/week)	1691 (691; 6100)	2952 (1573; 5039)	188.5	0.334
Overall PA (Met-min/week) a)	1691 (691; 6100)	2552 (1173; 4639)	213.5	0.723

a) Leaves out of account time spent at PA classes

Table 5 - Evolution of each type of physical activity, by group. PA, physical activity. Statistical analysis by Wilcoxon signed rank test.

	Control		Intervention	
	W	p-value	W	p-value
Walking	0.211	0.833	2.054	0.040
Moderate PA	0.672	0.502	1.208	0.227
Overall PA	0.657	0.511	2.334	0.020
Overall PA a			1.288	0.198

a) Leaves out of account time spent at PA classes.

No differences were found between the control and the intervention group regarding the amount of time spent walking at baseline or at the end of the study. But pairwise analysis showed that the intervention group significantly increased the amount of walking time, while no such increase was found in the control group (**Figure 4**). The median change in the time spent walking was 0 and 105 min per week in the control and intervention groups respectively (Mann Whitney's U=153, p=0.066), and excluding the outliers did not change the results (Mann Whitney's U=117; p=0.065). Finally the percentage of subjects that increased the amount of walking time was 46% and 74% in the control and the intervention groups respectively (X^2=3.38; p=0.066).

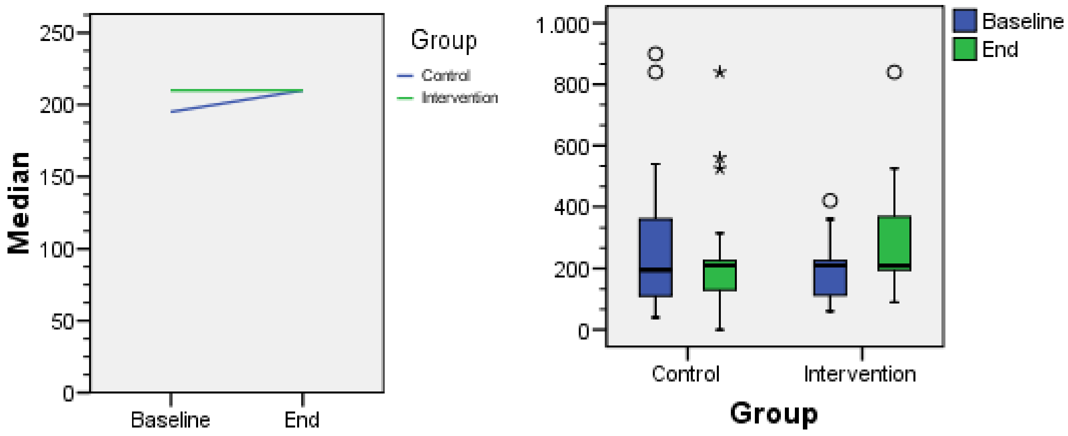

Figure 4 - Time spent in walking at baseline and at the end of the study, by group. Results are expressed in minutes per week.

Regarding moderate physical activity, no significant differences were found between groups either at baseline or at the end of the study. Interestingly the control group showed a 45 min median decrease, whereas the intervention group showed a two-hour median increase in the time spent doing moderate PA per week, although these changes were not statistically significant (**Figure 5**).

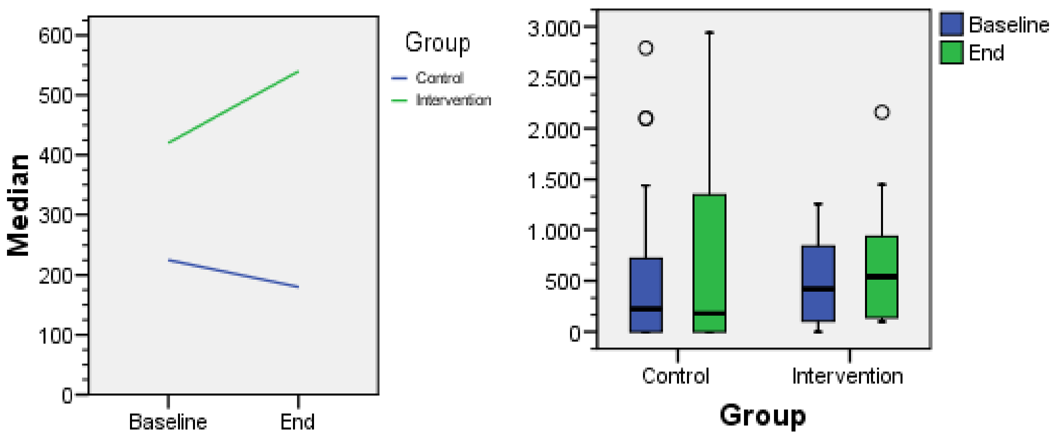

Figure 5 - Time spent in moderate physical activity at baseline and at the end of the study, by group. Results are expressed in minutes per week.

Considering that the physical activity classes provided for the intervention group were mostly of moderate intensity and that the study goal was to increase physical activity on a daily basis, we also compared moderate physical activity levels between groups after excluding class time in the intervention group. Again no significant differences were found. The median change in moderate physical activity levels was a 45 min/week decrease and a 20 min/week increase in the control and the intervention groups respectively (Mann Whitney's U=200, p=0.493), and excluding potential outliers did not change the results (Mann Whitney's U=140, p=0.190). Finally, the percentage of subjects that increased the amount of moderate physical activity was 42% and 63% in the control and the intervention groups respectively (χ^2=1.61; p=0.223).

Very few subjects reported performing vigorous physical activity: 3 at baseline (2 control, 1 intervention) and 2 (both intervention) at the end of the study period. It is worth noting that the two subjects from the control group who reported vigorous physical activity at baseline decreased their levels during the study period.

Overall physical activity was calculated by adding up the different types of physical activity (walking, moderate and vigorous physical activity). At baseline 20.8% of the control group and 10.5% of the intervention group did not comply with the 3.5 hours/week of physical activity. The contributions of each type of physical activity at baseline and at the end of the study for each group are summarized in **figure 6**. Overall physical activity in both groups was mainly due to moderate physical activity, with walking being less important and there being virtually no vigorous physical activity.

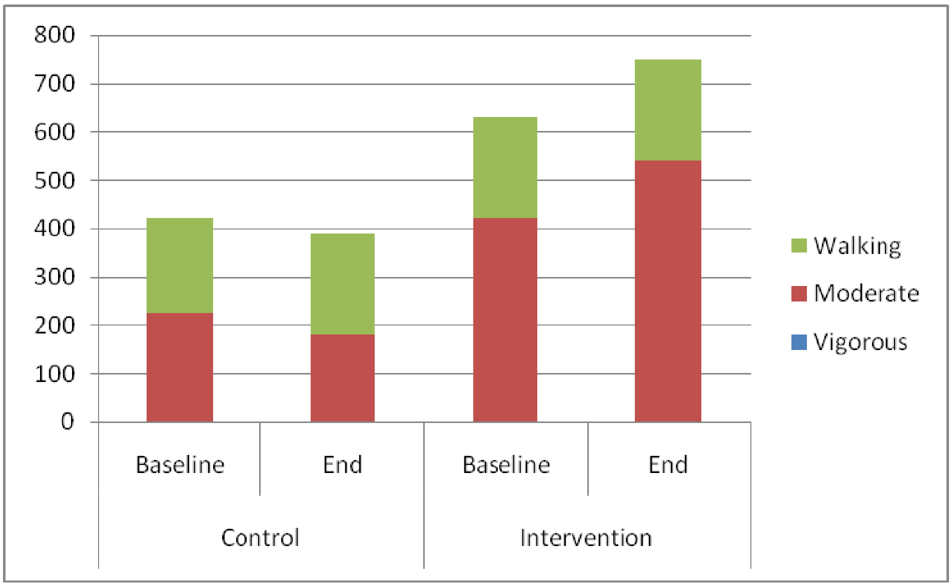

Figure 6 - Median contribution of walking, and moderate and vigorous physical activity to overall physical activity at baseline and at the end of the study, by group. Results are expressed in minutes per week.

When Met-min per week was calculated, no significant differences were found between groups, neither at baseline nor at the end of the study. However pairwise analysis showed a significant increase in metabolic equivalents (METs) in the intervention group, while no such increase was found in the control group (**Table 5**). The individual changes in overall physical activity levels by group are summarized in **figure 7** The median changes in overall physical activity was a 116.3 Met.min/week decrease and a 711 Met.min/week increase in the control and the intervention group respectively (Mann Whitney's U=159; p=0.09), and excluding potential outlier values led to somewhat different results, the increase being greater in the intervention group (Mann Whitney's U=118; p=0.05).

Finally the percentage of subjects that increased their overall physical activity was 33% and 74% in the control and intervention groups respectively (χ^2=6.9; p=0.009).

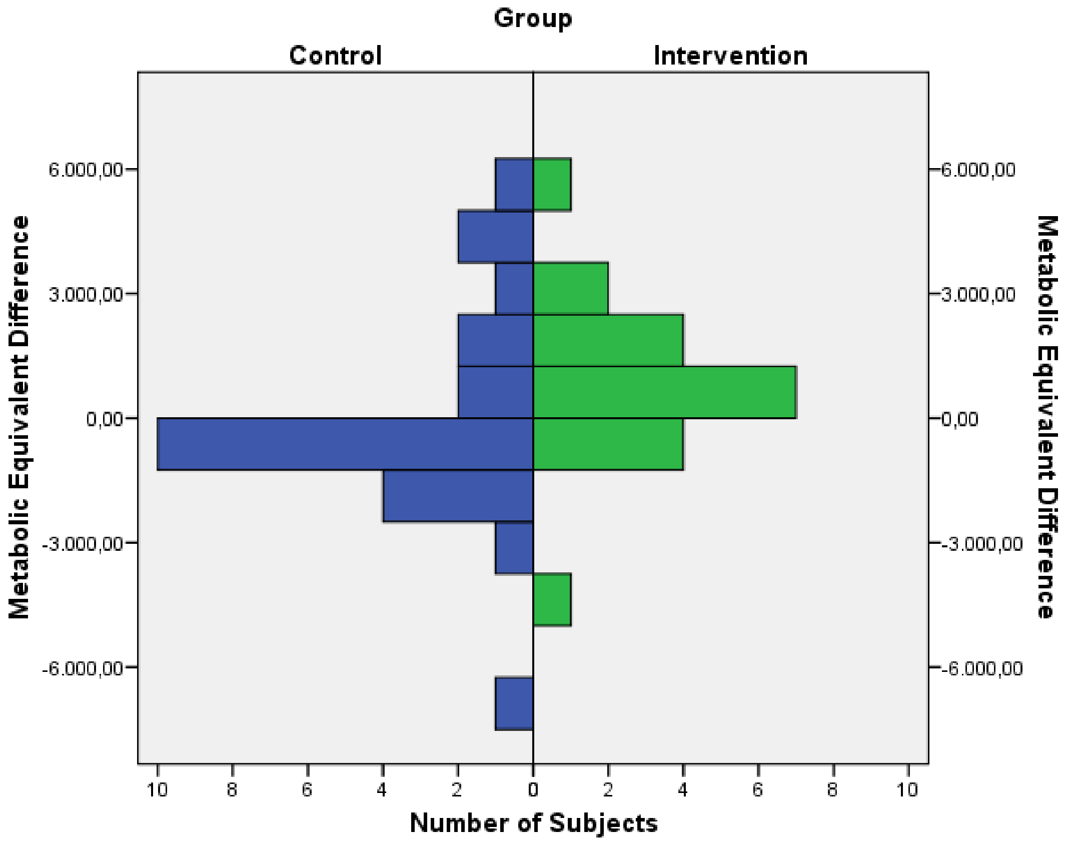

Figure 7 - Differences in overall physical activity, by group. Results are expressed in Met-min per week.

The results of the interview conducted on the second observation are summarized in **table 6.** In order to allow statistical inference, the categories "reduced" and "unchanged" were aggregated. Overall 74% of the intervention group reported an increase in physical activity levels, compared with only 17% in the control group (χ^2=13.11; p=0.001).

Table 6 - Reported changes in physical activity levels. Results are expressed in number of subjects and (percentages).

	Control (n=23)	Intervention (n=19)
Reduced	3 (13)	0 (0)
Unchanged	16 (70)	5 (26)
Increased	4 (17)	14 (74)

Finally cross tabulation of changes in overall physical activity levels as assessed by IPAQ with those assessed by the interview showed a good agreement (χ^2=8.12, p<0.01).

5.2.2. DIETARY DATA

The percentages of participants complying with the Portuguese dietary recommendations for each food group are shown in **table 7**. The statistical results within each group are summarized in **table 8** (next pages).

Table 7 - Percentage of compliers with Portuguese population dietary recommendations within each group. Comparison between control and intervention groups by Fisher's exact test.

	Control (n=18)	Intervention (n=19)	Fisher's exact test
Baseline			
Cereals and equivalent	27.8	42.1	0.495
Vegetables	22.2	10.5	0.405
Fruit	27.8	26.3	1.000
Dairy products	27.8	47.4	0.313
Meat/Fish/Eggs	33.3	42.1	0.737
Pulses	11.1	5.3	0.604
Fats and oils	83.3	73.7	0.693
End			
Cereals and equivalent	44.4	46.8	0.743
Vegetables	5.6	5.3	1.000
Fruit	16.7	26.3	0.693
Dairy products	27.8	68.4	0.020
Meat/Fish/Eggs	38.9	52.6	0.515
Pulses	0.0	15.8	0.230
Fats and oils	83.3	89.5	0.660

Table 8 – Statistical results of the evolution of compliance with the Portuguese dietary recommendations within each group (Wilcoxon sign ranks test).

	Control		Intervention	
	W	p-value	W	p-value
Cereals and equivalent	1.134	0.257	0.378	0.705
Vegetables	1.732	0.083	1.000	0.317
Fruit	1.000	0.317	0.000	1.000
Dairy products	0.000	1.000	1.633	0.102
Meat/Fish/Eggs	0.378	0.705	0.707	0.480
Pulses	1.414	0.157	1.000	0.317
Fats and oils	0.000	1.000	1.342	0.180

The recommendations on fats and oils are the most frequently achieved in both groups and in both assessment times. Conversely the recommendations on vegetables and pulses were less implemented (**Figure 8**).

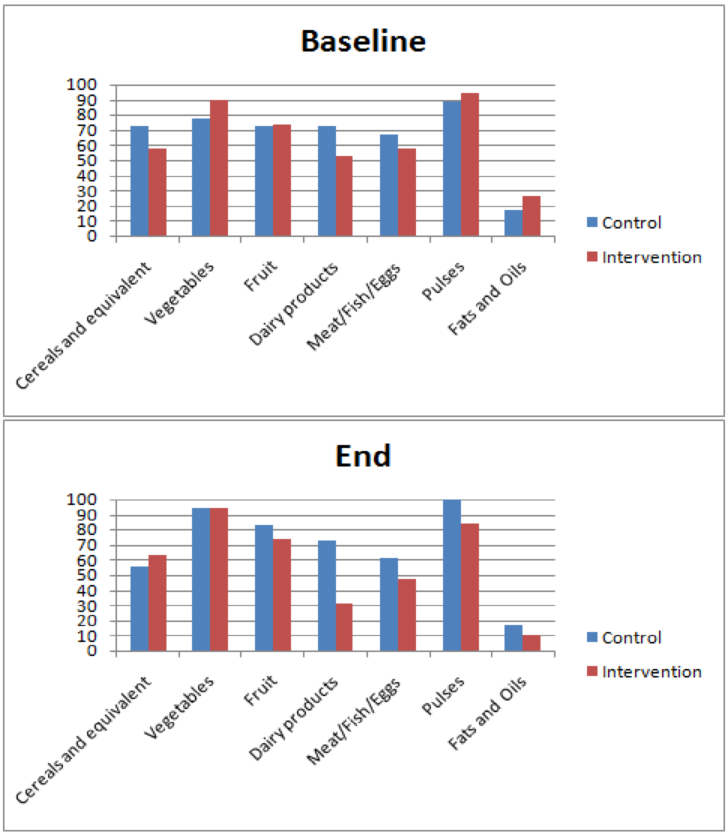

Figure 8 – Percentage of non-compliers for each dietary recommendation at baseline and at the end of the intervention, by group.

There were no significant differences between groups at any time in the percentages of participants meeting the dietary recommendations, with the exception of dairy products at the end of study. This is due to the increased number of individuals in the intervention group who met the recommendations. Similarly no significant differences were found for compliance with dietary recommendations between the first and the second evaluation periods, in both the control and intervention groups.

The results for the dietary score are shown in **figure 9.** At baseline there were no significant differences between groups (Mann Whitney's U=163.5; p=0.822), but at the very end the intervention group showed significantly higher dietary scores compared to the control group (Mann Whitney's U=100.5; p=0.031). An improvement in those in the intervention group with lower levels of compliance was also noted: the lowest compliance rate was 2/7 at the end of the study.

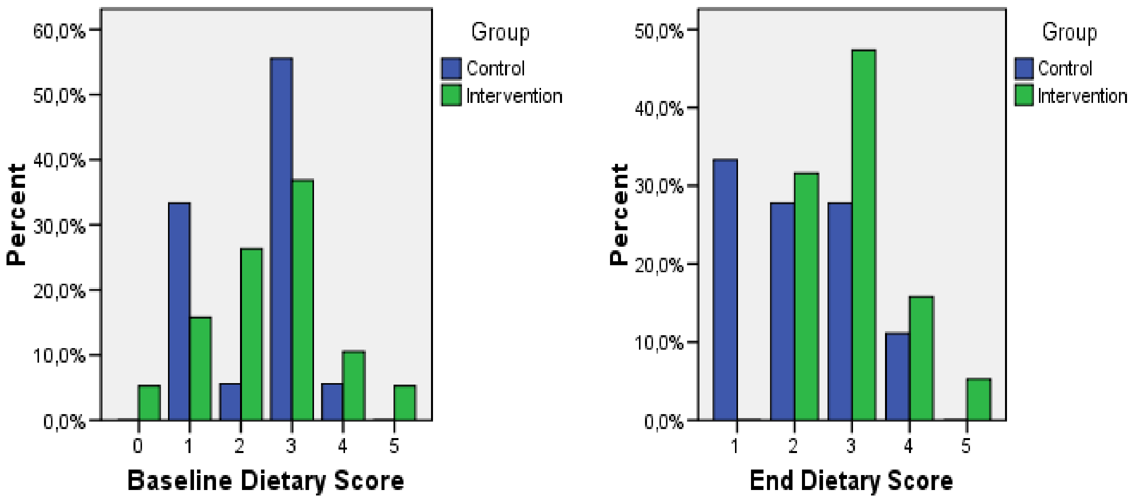

Figure 9 – Dietary scores at baseline and at the end of the study (%)

The evolution of dietary behaviour was compared, regardless of whether or not the subjects were complying with the Portuguese dietary recommendations. The rationale for this analysis was that there could be an improvement in dietary habits even without achieving the recommended dietary level for each food category. Therefore when changes in dietary habits were classified into better, maintained or worsened (**Figure 10**), significant differences were found, the control group showing a higher percentage of worsening dietary habits (X^2=6.005; p =0.05).

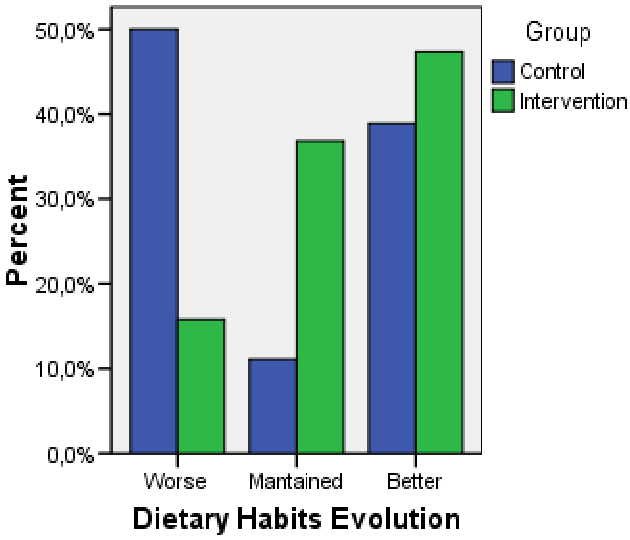

Figure 10 – Trends in dietary habits, by group. The results are expressed as a % of the participants.

From the 23 participants interviewed in the control group, 17 (74%) were classified as having maintained their dietary behaviour during the study period. Among the remaining 6 (26%) who were classified as having made significant changes during the study period, all reported qualitative changes, and 4 also reported quantitative changes. Among the 17 participants who didn’t change their dietary patterns, 8 were classified as already compliant with the dietary recommendations.

From the 19 participants in the intervention group interviewed, 8 (42%) were classified as having maintained their dietary behaviour during the study period, while the remaining 11 (58%) were considered to have made significant changes: 8 reported qualitative and quantitative improvements, 2 only qualitative and one only quantitative improvements. Among the 8 participants who didn’t change their dietary patterns, 7 were considered to have already been compliant with the dietary recommendations at baseline.

Between-group comparisons showed that the increase in compliance with the dietary recommendations was higher in the intervention compared with the control group (X^{2}=4.369; p=0.037). Because participants with a high compliance at the beginning of the study had a low margin to improve their dietary habits, it is also important to look at the final outcome about compliance, independently of behaviour change. At the end of the study about 26% of the control group and 60% of the intervention group reported that they were high compliers (Fisher's exact test, p=0.038).

5.3. CLINICAL AND BIOLOGICAL DATA

The clinical and biological data according to intervention group and assessment period are summarized in **table 9**.

Table 9 - Clinical and biological data at baseline and at the end of the study, according to intervention group. The results are expressed as medians and (1st quartile, 3rd quartile). Comparison between control and intervention groups by Mann Whitney's U test.

	Control	n	Intervention	n	U	p-value
Baseline						
Weight (Kg)	69.0 (63.1; 79.5)	24	76.5 (67.5; 82)	19	188.5	0.334
Body Fat (%)	35.2 (29.5; 41.2)	23	36.9 (31.5; 41.5)	18	184.0	0.546
BMI (Kg/m2)	28.4 (23.6; 29.9)	24	27.7 (25.3; 32.8)	19	195.0	0.420
SBP (mmHg)	135.0 (123.0; 150.0)	24	130.0 (120.0; 140.0)	19	187.0	0.311
DBP (mmHg)	70.0 (61.0; 78.0)	24	80.0 (70.0; 80.0)	19	172.5	0.159
Total Cholesterol (mg/dl)	221.0 (196.0 ; 240.0)	19	192.0 (158.0; 207.0)	19	79,5	0.003
HDL (mg/dl)	46.0 (41.0; 58.0)	15	51.0 (44.0; 61.0)	14	80.0	0.274
LDL (mg/dl)	150.7 (127.0; 173.0)	14	102.0 (73.0; 120.0)	12	23.0	0.002
Triglycerides (mg/dl)	134.0 (105.0 ; 226.0)	17	124.0 (97.0; 146.0)	17	106.0	0.185
Glycaemia (mg/dl)	155.0 (123.5 ; 200.5)	21	141.0 (123.5; 171.5)	17	150.5	0.411
HbA1c (%)	6.7 (6.3; 8.4)	16	6.6 (6.0; 8.2)	15	115.5	0.859

End						
Weight (Kg)	70.0 (63.3; 78.8)	24	75 (68.0; 82.0)	19	178.0	0.221
Body Fat (%)	36.3 (30.4; 43.3)	23	39.6 (34.5; 44.0)	18	165.5	0.276
BMI (Kg/m2)	28.0 (25.6; 30.4)	24	28.0 (26.0; 33.1)	19	186.0	0.304
SBP (mmHg)	140.0 (120.0 ; 150.0)	24	140.0 (110.0; 160.0)	19	221.5	0.872
DBP (mmHg)	70.0 (61.0; 80.0)	24	70.0 (60.0; 80.0)	19	223.0	0.901
Total Cholesterol (mg/dl)	198.0 (170.0 ; 228.0)	19	175.0 (152.0; 197.0)	19	115.5	0.057
HDL (mg/dl)	48.0 (43.0; 54.0)	15	55.0 (46.0; 60.0)	14	83.0	0.336
LDL (mg/dl)	122.5 (96.0; 145.0)	14	94.0 (75.0; 116.0)	12	37.0	0.016
Triglycerides (mg/dl)	109.0 (83.0; 160.0)	17	103.0 (82.0; 170.0)	17	134.0	0.718
Glycaemia (mg/dl)	135.0 (114.5 ; 165.5)	21	130.0 (104.5; 166.0)	17	163.5	0.660
HbA1c (%)	6.6 (6.2; 8.2)	16	6.5 (6.0; 8.0)	15	120.0	1.000

The results of the statistical analysis of the changes within each group are summarized in **table 10**.

Table 10 - Clinical and biological data, by group. Statistical analysis by Wilcoxon signed rank test.

	Control		Intervention	
	W	p-value	W	p-value
Weight	0.762	0.446	0.817	0.414
Body Fat	2.306	0.021	2.548	0.010
BMI	0.897	0.370	1.079	0.281
SBP	0.191	0.849	0.636	0.525
DBP	0.475	0.635	1.347	0.178
Total Cholesterol	2.516	0.001	1.136	0.256
HDL	1.480	0.139	1.015	0.310
LDL	3.107	0.002	0.533	0.594
Triglycerides	3.124	0.002	1.603	0.109
Glycaemia	1.886	0.001	1.293	0.350
HbA1c	0.000	1.000	0.350	0.726

There were no significant differences between groups in relation to weight, BMI and percentage of fat mass, either at the beginning or at the end of the study. It should be noted that only 29.2% of participants in the control and

21.1% in the intervention group had a normal BMI at the initial evaluation (**Table 11**). A median increase of 1 kg in weight in the control group was noted, versus a 1.5 kg median decrease in the intervention group; still the differences were not statistically significant. Similarly no significant changes were found regarding the evolution of BMI in the control and intervention groups. In relation to body composition, there was a significant increase in the percentage of fat mass in both groups: the median increase was 1.1% for the control and 2.4% for the intervention group. The percentage of participants who presented an increase in body fat was 21% of the control and 10% of the intervention group (X^2=0.827, p=0.36).

Table 11 - Percentage of individuals in each of the American College of Sports Medicine’s categories, by group.

	Control		Intervention	
	Baseline	End	Baseline	End
Normal	29.2	20.8	21.1	15.8
Overweight	45.8	41.7	36.8	36.8
Obese	25.0	37.5	42.1	47.4

The percentages of individuals with hypertension, having treatment for hypertension and with controlled hypertension are given in **table 12**.

Table 12 – Percentage of individuals with hypertension, treated hypertension and controlled hypertension at baseline and at the end of the study, by group. Comparison between control and intervention groups by Fisher exact test.

	Control (n=24)	n	Intervention (n=19)	n	Fisher Exact Test
Baseline					
Hypertension	83.3	20	68.4	13	0.295
Treated Hypertension	70.0	14	84.6	11	0.431
Controlled Hypertension	35.0	7	46.2	6	0.717
End					
Hypertension	79.2	19	78.9	15	1.000
Treated Hypertension	73.7	14	73.3	11	1.000
Controlled Hypertension	21.1	4	33.3	5	0.462

The individuals taking anti-hypertensive medication were the same at baseline and at the end of the study.

At baseline, although most hypertensive subjects were treated, less than half were adequately controlled. Changes regarding prevalence of hypertension during the period of the study were non-significant both for the control group (X^2=0.295, p=0.59) and for the intervention group (X^2=0.978, p=0.32). Likewise changes in treatment rate were not significant for the control (X^2=0.798, p=1.0) and intervention (Fisher's exact test p=0.655) groups. Changes in control rate were also non-significant in control (X^2=0.936, p=0.48) and intervention (X^2=0.480, p=0.70) groups. No between-group differences were found regarding blood pressure values, either at the beginning or at the end of the study. Similarly, no differences were found regarding trends in blood pressure levels within groups over the study period.

Regarding total cholesterol, the median reductions were 23 mg/dl in the control and 17 mg/dl in the intervention group. But this reduction is statistically significant only in the control group. It should be noted that at baseline 68.5% of the participants in the intervention group were already within the desired values, while the figure was only 26.4% in the control group. The result is that, although at the beginning of the study the intervention group had significantly lower total cholesterol values than the control group, this difference was only borderline significant (p=0.06) at the end of the study.

No between group differences were found regarding HDL cholesterol at the beginning or at the end of the study. Similarly no within group differences were found in respect of the median increases in HDL cholesterol: +2 mg/dl in the control and +4 mg/dl in the intervention group. Also no differences were found regarding the trends in the percentage of participants with adequate HDL cholesterol levels: increase of 13.3 to 20.0% in the control (X^2=0.577 p=0.448) and no change (7.1%) in the intervention group.

Both at the beginning and the end of the study LDL cholesterol levels were significantly lower in the intervention group, which also had a lower percentage of subjects with high LDL cholesterol (16.7% vs. 71.4% of the control group). During the study period reductions in LDL cholesterol levels occurred in both groups, but only in the control group was this reduction statistically significant. At the end of the study period 57.2% of the participants in the control group had adequate LDL cholesterol levels (X^2=5.600 p=0.018), while in the intervention group all participants had adequate levels. At the end of the study both groups remained significantly different.

As for triglycerides the groups had no significant differences at baseline or at the end of the study. Both groups showed a reduction of triglycerides median value, but only in the control group did that reduction have statistical meaning. The conclusions did not change after correction for hypolipidemic drugs. The percentage of subjects presenting with high lipid levels at baseline and at the end of the study is summarized in **figure 11**.

At the beginning of the study, 71% of both the control and the intervention group presented hyperglycaemia. At the end of the study both groups reduced their blood glucose values, but this reduction was only statistically significant in the control group. At the end of the study 62% of the control (X^2=0.933 p=0.334) and 65% of the intervention group (X^2=0.283 p=0.595) still presented hyperglycaemia.

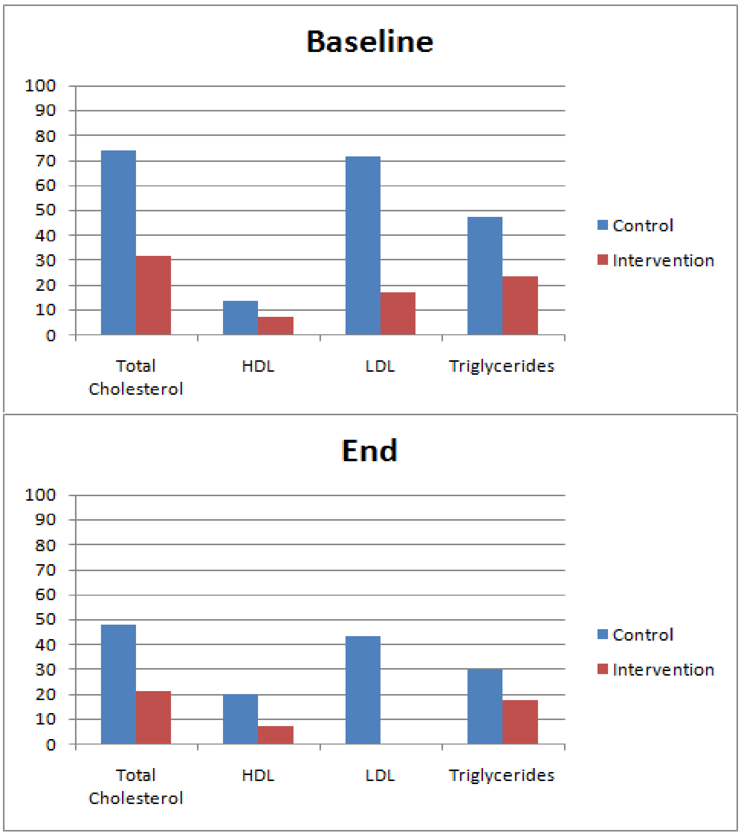

Figure 11 - Percentage of subjects at risk for lipid profile at baseline and end of the study, by group

Also the HbA1c values showed a reduction in both groups, but this reduction was not statistically significant. In the control group the percentage of participants with high HbA1c values was 63% at the beginning and at the end of the study, while in the intervention group there was a non-significant reduction from 60 to 53% (χ^2=0.278 p=0.598).

5.4. FITNESS DATA

The results of the fitness tests according to group and evaluation period are summarized in **table 13**.

Table 13 - Fitness data at baseline and at the end of the study. Results are expressed as medians and (1st quartile, 3rd quartile). Comparison between control and intervention groups by Mann Whitney's U test.

	Control	n	Intervention	n	U	p-value
Baseline						
30 second chair stand	14.0 (12.0; 15.0)	21	16.5 (13.5; 19.0)	18	116.5	0.040
Arm curl	11.5 (9.8; 14.0)	22	14.0 (11.0; 15.0)	18	134.5	0.083
2 minute step in place	83.0 (57.3; 92.0)	20	96.0 (69.3; 104.0)	18	122.0	0.093
Chair sit and reach	-9.5 (-17.0; -1.0)	22	-1.0 (-6.3; 4.3)	18	101.5	0.009
Back scratch	-24.5 (-32.0; -13.8)	22	-21.5 (-30.0; -14.3)	18	177.0	0.581
2,44 m up and go	6.7 (6.1; 8.5)	22	6.2 (5.5; 7.4)	18	142.0	0.132

End						
30 second chair stand	16.0 (14.0; 18.5)	21	18.0 (15.0; 22.5)	18	121.5	0.055
Arm curl	14.0 (12.0; 17.0)	22	18.0 (17.0; 21.0)	18	69.0	<0.001
2 minute step in place	93.0 (77.8; 111.5)	20	110.0 (99.8; 116.0)	18	107.5	0.033
Chair sit and reach	-9.0 (-15.0; 0.0)	22	2.5 (-8.3; 8.3)	18	108.5	0.014
Back scratch	-25.0 (-38.3; -20.8)	22	-23.0 (-29.3; -3.0)	18	129.0	0.062
2,44 m up and go	6.4 (5.7; 8.6)	22	5.9 (5.4; 6.7)	18	138.5	0.106

The results of the paired analysis (baseline – end) for each group are presented in **table 14.**

Table 14 - Evolution of fitness data, by group. Statistical analysis by Wilcoxon signed rank test.

	Control		Intervention	
	W	p-value	W	p-value
30 second chair stand	2.123	0.034	2.458	0.014
Arm Curl	2.775	0.006	3.630	<0.001
2 minute step in place	2.912	0.004	3.288	0.001
Chair sit and reach	1.778	0.075	1.823	0.068
Back Scratch	2.472	0.013	2.049	0.040
2,44m up and go	0.925	0.355	0.544	0.586

Lower limb strength was assessed by the 30 second chair stand test, while upper limb strength was assessed by the arm curl test. At baseline the intervention group fared significantly better than the control group in respect of lower limb strength. (**Tables 13 and 14**). A similar difference, albeit non-significant (p=0.08), was found for upper limb strength. During the study a significant increase in upper and lower limb strength was found in both groups but this increase was greater in the intervention group.

Aerobic endurance was assessed by the 2 minute step in place test. No differences were found between the two groups (p=0.093) at the beginning of the study, but at the end of the study the differences were significant (p=0.033) with the intervention showing better results than the control group (**Table 13**).

Lower flexibility was assessed by the chair sit and reach test, while upper flexibility was assessed through the back scratch test. At the beginning of the study the intervention group showed significantly better results than the control regarding lower flexibility. On the other hand the difference was no longer significant at the end of the study, probably due to a large intra-group variability in the intervention group. In both groups flexibility increased, although the trend was not significant (**Table 12**). No differences were found between the two groups at baseline in respect of upper limb flexibility. During the study period a significant worsening was found in the control group, whereas in the intervention group a significant improvement was noted. Even so at the end of the study the between-group differences were only borderline significant (p=0.068).

Agility was assessed by the 2.44 m up and go test. At baseline no significant differences were found between the two groups. During the study period a trend towards a fall in the median time was noted in both groups, but in the end there was still no significant differences between the two groups.

5.5. MOOD STATES DATA

Data regarding the profile of mood states is presented in **table 15**.

Table 15 - Profile of Mood States data at baseline and at the end of the study. Results are expressed as medians and (1st quartile, 3rd quartile). Comparison between control and intervention groups by Mann Whitney’s U test.

	Control (n=24)	Intervention (n=19)	U	p-value
Baseline				
Tension – Anxiety	2.7 (2.5; 3.5)	2.8 (2.7; 3.5)	198.0	0.460
Depression – Dejection	2.0 (1.7; 2.7)	2.1 (1.5; 2.7)	219.0	0.826
Anger – Hostility	2.3 (1.8; 3.1)	2.2 (1.7; 3.3)	224.0	0.922
Vigor – Activity	2.7 (2.0; 3.8)	3.3 (2.8; 4.0)	177.0	0.212
Fatigue – Inertia	2.9 (2.2; 4.0)	2.7 (2.2; 3.7)	208.0	0.624
Confusion – Bewilderment	2.5 (2.2; 2.8)	2.8 (2.2; 3.2)	181.5	0.252

End				
Tension – Anxiety	2.8 (2.3; 3.2)	3.0 (2.5; 3.3)	191.5	0.369
Depression – Dejection	1.7 (1.6; 2.8)	1.9 (1.4; 2.4)	219.0	0.826
Anger – Hostility	2.3 (1.8; 3.1)	2.5 (1.8; 2.8)	224.5	0.932
Vigor – Activity	2.9 (2.3; 4.0)	3.7 (3.0; 4.5)	150.5	0.058
Fatigue – Inertia	2.5 (2.2; 3.4)	2.0 (1.5; 3.0)	160.5	0.098
Confusion – Bewilderment	2.7 (2.0; 3.0)	2.5 (2.3; 3.2)	219.0	0.825

The statistical significance of the changes which occurred within each group is shown in **table 16**.

Table 16 - Profile of Mood States data, by group. Statistical analysis by Wilcoxon signed rank test.

	Control		Intervention	
	W	p-value	W	p-value
Tension – Anxiety	0.825	0.409	0.200	0.842
Depression – Dejection	0.251	0.830	0.721	0.471
Anger – Hostility	0.350	0.727	0.285	0.775
Vigor – Activity	1.293	0.196	1.742	0.081
Fatigue – Inertia	1.297	0.195	3.067	0.002
Confusion – Bewilderment	1.043	0.297	0.482	0.630

There are no significant differences between groups in any of the factors that make up the POMS, either in the initial or in the final evaluations. However borderline values were found at the end of the study: the intervention group scored higher than the control in the Vigor – Activity factor, whereas the opposite result (lower score) was found in the Fatigue – Inertia factor.

At baseline, the control group (**Figure 12**) scored higher in the Fatigue-Inertia factor and the intervention group (**Figure 13**) for Vigor-Activity.

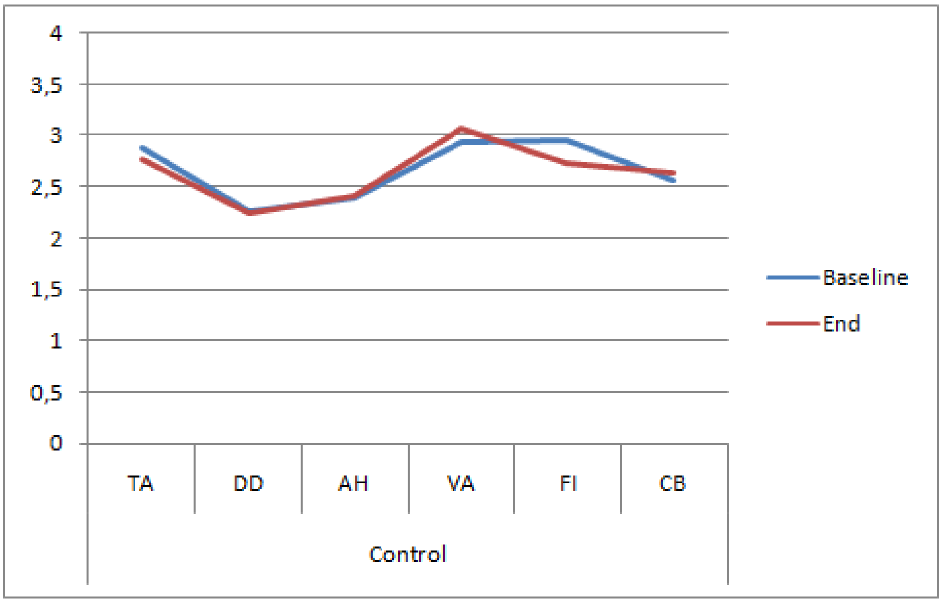

Figure 12 - POMS at baseline and at the end of study for the control group. Data are means in each factor. TA -Tension - Anxiety, DD-Depression-Dejection, AH -Anger – Hostility, VA -Vigor – Activity; FI - Fatigue – Inertia and CB -Confusion – Bewilderment.

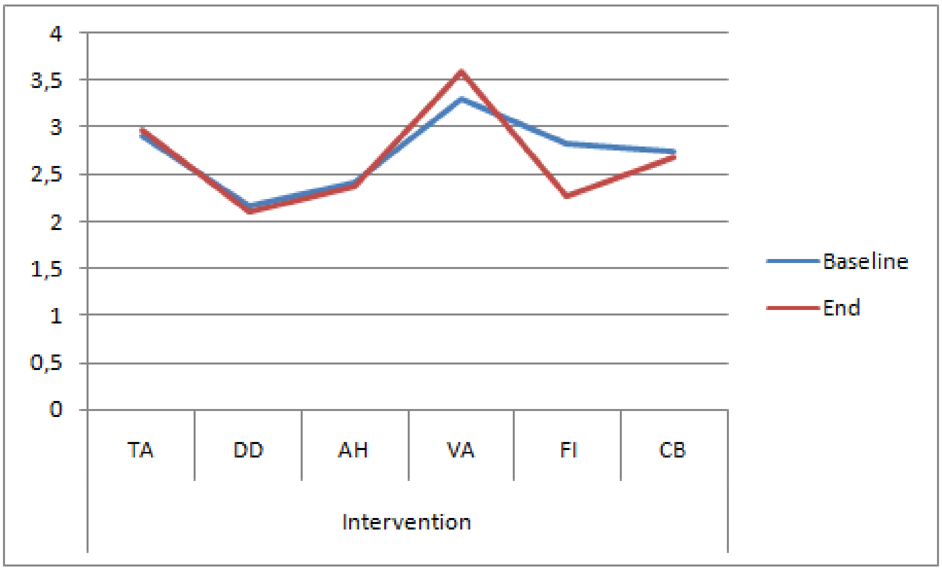

Figure 13 - POMS at baseline and at the end of study for the intervention group. Data are means in each factor. TA -Tension - Anxiety, DD-Depression-Dejection, AH -Anger – Hostility, VA -Vigor – Activity; FI -Fatigue – Inertia and CB -Confusion – Bewilderment.

At the end of the study, the highest median scores were for the Vigor-Activity factor in both groups. In both groups and for both evaluation times, the lowest median scores were for the Depression-Dejection factor. The only change with statistical significance, from the initial to the final moment, occurs in the intervention group, in the Fatigue-Inertia factor, with a median fall from 2.7 to 2.0 ($p=0.002$).

The analysis of **figures 12** and **13** indicates that the control group evolves to an iceberg profile, while the experimental group increases its iceberg profile that already existed at baseline.

For illustrative purposes three cases will be addressed:

- Case 1: a woman in the control group. At baseline her POMS had an iceberg profile, but this was no longer the case at the end of the study (**Figure 14**). The decrease in the Vigor-Activity factor is clear, as well as the increase in the Tension-Anxiety, Depression-Dejection and Anger- Hostility factors.
- Case 2: a woman in the intervention group. At baseline her POMS had an iceberg profile, which was maintained at the end of the study with improvements in all factors (**Figure 15**).
- Case 3: a man in the intervention group. His initial POMS did not have an iceberg profile (**Figure 16**). But over the course of the intervention it improves in all factors, except in Confusion-Bewilderment. As a result, at the very end it already has an iceberg profile.

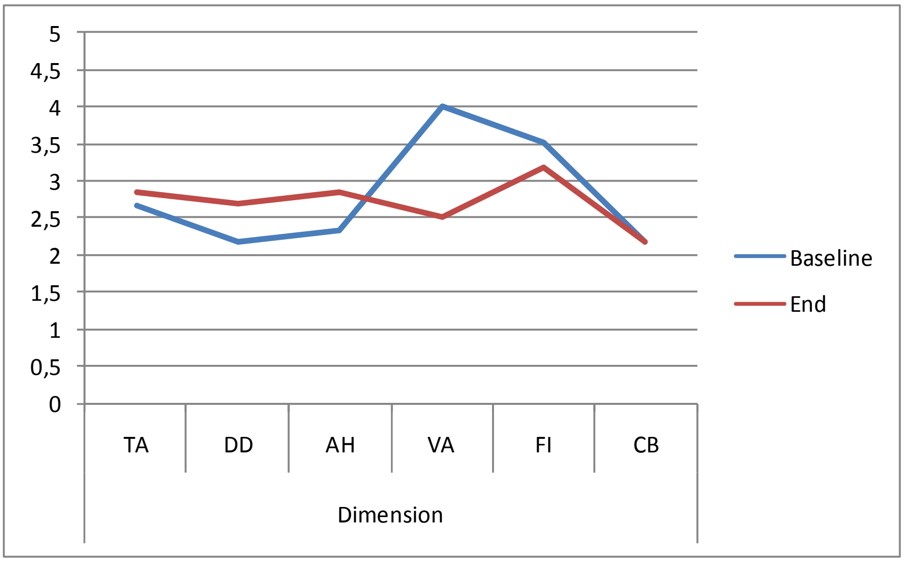

Figure 14 - POMS at baseline and at the end of study for subject nº 20. Data are means in each factor. TA, Tension–Anxiety; DD, Depression-Dejection; AH, Anger–Hostility; VA, Vigor–Activity; FI, Fatigue–Inertia and CB, Confusion–Bewilderment.

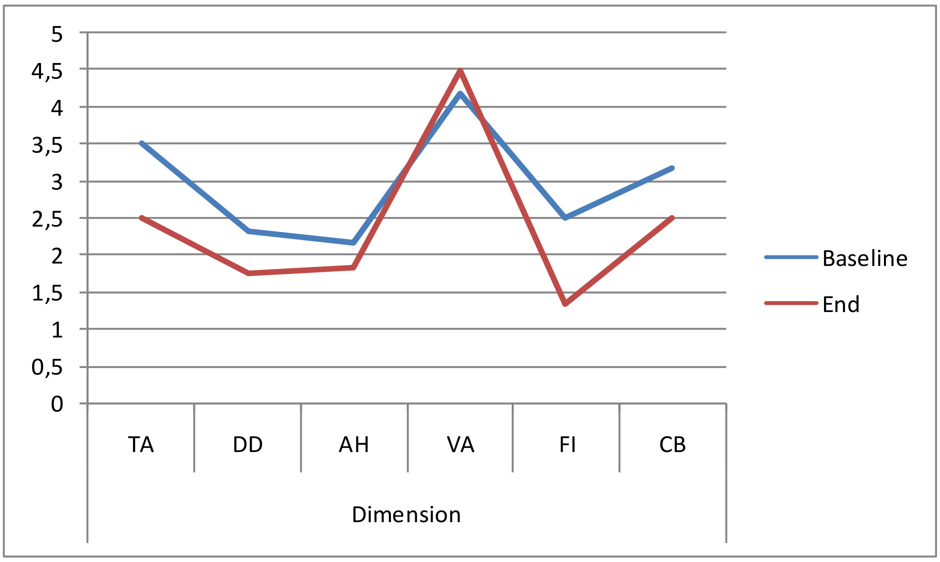

Figure 15 - POMS at baseline and at the end of study for subject nº 6. Data are means in each factor. TA, Tension–Anxiety; DD, Depression-Dejection; AH, Anger–Hostility; VA, Vigor–Activity; FI, Fatigue–Inertia and CB, Confusion–Bewilderment.

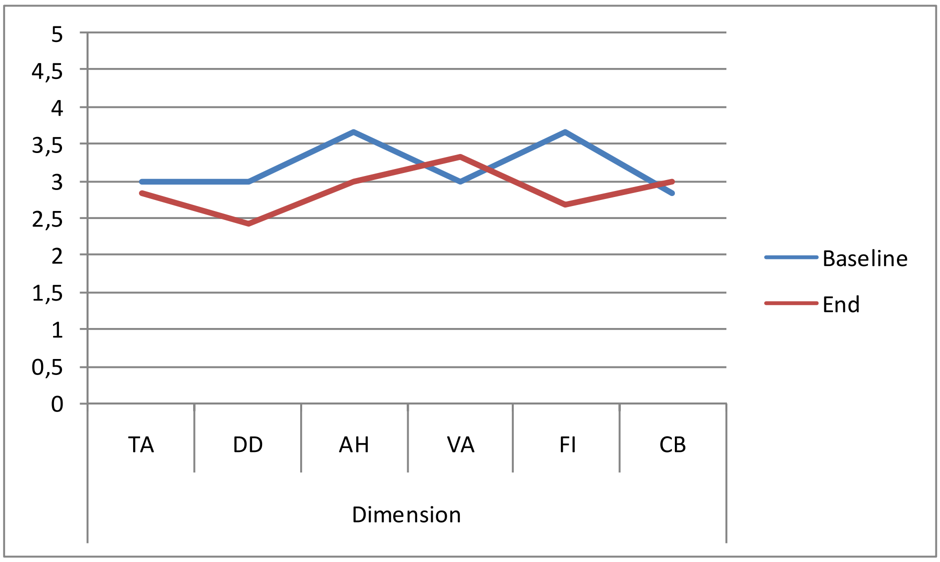

Figure 16 - POMS at baseline and at the end of study for subject nº 24. Data are means in each factor. TA, Tension–Anxiety; DD, Depression-Dejection; AH, Anger–Hostility; VA, Vigor–Activity; FI, Fatigue–Inertia and CB, Confusion–Bewilderment.

When the results were analysed for the presence/absence of an iceberg profile, at the beginning of the study 10 (42%) of the control group presented an iceberg profile, versus 7 (37%) participants of the intervention group (χ^2=0.103; p=0.748). At the end of the study the values were 10 (42%) and 13 (68%) in the control and intervention groups respectively (χ^2=3.051; p=0.081).

5.6. ECONOMIC DATA

Most participants had serious economic limitations. For instance, 44% of them had an annual income below 14 times the minimum monthly wage (385.90€), 37.5% in the control and 52% in the intervention group. The monthly cost of medications during the study period is summarized in **table 17.**

Table 17 – Medication costs (€) at baseline and at the end of the study. Results are expressed as medians and (1st quartile, 3rd quartile). Comparison between control and intervention groups by Mann Whitney's U test.

	Control (n=24)	Intervention (n=18)	U	p-value
Baseline				
Individual costs (€/month)	4.5 (0; 14.0)	14.5 (0; 25.9)	178.5	0.335
State Costs (€/month)	16.9 (7.2; 39.0)	45.4 (3.5; 64.0)	164.5	0.190
End				
Individual costs (€/month)	9.2 (0; 27.4)	17.6 (3.6; 31.0)	182.5	0.391
State Costs (€/month)	20.2 (6.1; 53.4)	54.2 (10.4; 67.8)	165.0	0.195

The comparison of the cost of treatments at baseline and at the end is shown in **table 18**.

Table 18 – Medication costs (€), by group. Statistical analysis by Wilcoxon signed rank test.

	Control		Intervention	
	W	p-value	W	p-value
Individual costs	2.429	0.015	1.352	0.176
State Costs	2.499	0.012	2.191	0.028

There were no significant differences between groups at baseline in regard to medication costs either incurred by the participants or borne by the State (**Figure 17**). It was the same at the end of the study. But when the changes in costs within each group are analyzed, the control group had a median increase of 4.70€ in monthly individual expenses and of 3.30€ in monthly charges for the government, these increases being statistically significant. In the intervention group the 3.10€ monthly median increase in individual charges is not statistically significant, whereas the increase in 8.80€ in relation to government costs is statistically significant.

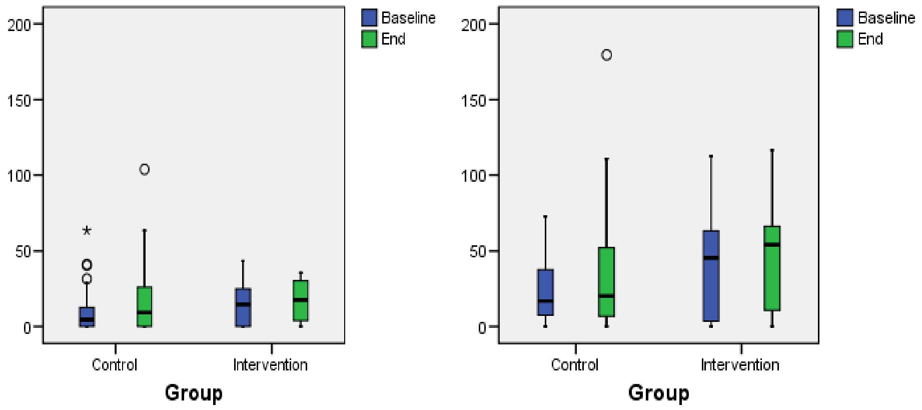

Figure 17 - Costs at baseline and at end of study, by group. Results are expressed in €/month for participants (left) and the government (right)

Finally 5 hospitalizations occurred in the control group during the study, as opposed to 3 in the intervention group. Again those findings were not statistically significant (Fisher exact test p=0.493)

5.7. FINAL INTERVIEW DATA

The perceived advantages of program participation were found from the answer to the question "what are the main benefits you've found from program participation?”. The data obtained by interview is summarized in **table 19**.

Biological advantages were referred to the most and, among them, the general health control category, which included imprecise and vague statements like “I feel better”.

Table 19 – Interview data regarding the intervention group.

Perceived Advantages		Percentage
Biological		89.4
	General health control	68.4
	Diabetes control	21.0
	Physical fitness	57.8
Psychological		78.9
	Dietary habits	36.8
	Physical activity habits	52.6
	Mood states	47.3
Social		68.4
	Acquaintanceship	68.4

Changes in physical activity habits were the most valued advantages among the psychological benefits from program participation. On the other hand changes in dietary habits were referred to less as advantages linked to program participation.

More than two thirds of the intervention group stated that the development of their social network through acquaintanceship provided by the program was a relevant advantage.

All members of the intervention group declared they would recommend the program to their friends.

6. DISCUSSION

The implemented program was an important change to usual care practices provided by the health centre to the diabetic population. The integration of new elements (dietician and physical activity instructor) in the health care team demanded preparation and coordination and the dissemination of their work to the team made it possible for common goals to be defined and knowledge of the complete program to be shared.

Despite a low adherence to the program (only 1% of the 1900 registered diabetic patients adhered to the program in the intervention group), physical activity habits among those who have engaged in the program improved. This improvement, however, was mainly due to participation in supervised physical activity classes. Metabolic expenditure in unsupervised physical activity did not increase. Positive changes in dietary behaviour occurred, but compliance with recommendations was not increased. Body fat rose and there were no significant changes in blood pressure, lipid profile or glycemic control. On the other hand significant improvements were found in most variables relating to fitness, especially aerobic endurance, upper and lower strength and flexibility. Most factors in the profile of mood states showed no significant alterations, but fatigue-inertia was significantly reduced and vigor-activity increased (borderline). Over the 9 months intervention period there was a significant increase in the cost of medications for the State, but not for the people in the program.

An unexpected finding was that a considerable number of diabetic patients do not seek treatment or counselling. Indeed out of the 1,900 patients with type 2 diabetes identified by the Health Centre, only 300 (16%) actually benefited from free specialized care consultations. Furthermore out of the 300 subjects that benefited from these consultations, only 47 (16%) agreed to participate in this study, and only 20 agreed to be included in the intervention group. Despite our efforts it was not possible to reach the initially planned sample size (n=60). These 20 subjects represent approximately 1% of the above-mentioned 1,900 patients with type 2 diabetes. In some cases physical inability or logistical constraints might justify this non-adherence. The health centre limitations in providing these consultations (mainly human resources and facilities) results for example in long waiting times for the consultations and such delays may deter patients from attending. In other cases non-adherence might reveal the little concern that diabetics have with their health. This situation is in agreement with the literature (Bonen, 2001) and it has been suggested that this low adherence to treatment might be due to the lack of physical symptoms (i.e. pain) in the early stages of the disease (World Health Organisation, 2003). According to the transtheoretical model of behaviour change, the benefits of a healthy behaviour are low in the early stages of change but increase when the stages of change also increase (World Health Organisation, 2003). Most of these individuals are in a pre-contemplation phase and therefore perceived gains from a possible change to a healthier behaviour are low. This represents a challenge to secondary and tertiary prevention programs because individuals should engage in those programs as early as possible, in order to prevent or delay disease progression. In diabetic individuals the consequences of late intervention might be the early development of chronic major complications that diminish quality of life and are hardly reversible. In these conditions treatment efficacy is limited (U.S. Department of Health and Human Services, 1996).

A question therefore remains about how to increase healthy behaviours among the vast majority of diabetics, i.e. those who do not look for advice.

6.1. LIFESTYLE

One of the objectives of this study was to induce sustained lifestyle changes, particularly regarding physical activity and diet, and to develop a greater awareness of individual health responsibility, thus enhancing patient empowerment. During program participation information about the disease was provided either individually or in groups. Contact with the healthcare team members was substantially increased, mainly due to participation in physical activity classes twice a week.

The program was well accepted: after 9 months of intervention there was only one dropout in the intervention group, and for a reason unrelated to the program itself. Other indicators of the good acceptance of the intervention were the high attendance rate and the fact that all the elements of the intervention group have, in their final interview, answered that they would recommend the program to their friends.

6.1.1. PHYSICAL ACTIVITY

The participants had adequate levels of physical activity at baseline, both in the control and the intervention groups. The sum of the median time spent walking and performing moderate physical activity for instance was 7 and 10 hours per week for the control and intervention groups respectively. Only 20.8% of the control and 10.5% of the intervention group did not meet the recommended 3.5 hours/week of physical activity. This should be compared to data indicating that about 70% of the Portuguese population aged over 55 years has no physical activity at all, and 78% do not meet this recommendation of the National Program for Obesity Control (Direcção Geral de Saúde, 2005).

The characteristics of the physical activity program were not in accordance with the recommendations from the literature in relation to the workload provided. Most guidelines recommend 30 minutes of physical activity at least 5 times per week (American Diabetes Association, 2004b; American Diabetes Association & American College of Sports Medicine, 1997; U.S. Department of Health and Human Services, 1996). But the objective of this study was to assess the effectiveness of intervention programs with lower workloads, as little is known whether such interventions, possibly easier to implement and with lower dropout rates, are also effective (LaMonte et al., 2005). Our program included only two sessions of 50 minutes and was more designed as a "centre of behaviour change" aimed to promote an increase in physical activity levels outside classes. Hence throughout the intervention the participants were urged to adopt strategies that would maximize their increase in daily physical activity so as partly to offset the missing workload recommended in the above mentioned guidelines.

Although no significant differences between groups were found at the end of the study regarding physical activity levels, a significant increase in walking time was noted in the intervention group. It must be emphasized that the hilly and steep terrain around the health centre is an obstacle to this particular behaviour change. So this change in behaviour denotes an intention to comply with the advice given. This is an important result because physical activity tends to decline with ageing (Direcção Geral de Saúde, 2005).

Despite the fact that the physical activity classes were reported as "moderate physical activity”, no differences between the two groups were found for this category. A possible explanation lies in the diversity of situations found in the control group, especially at the end of the study. The slight but non significant increase in moderate physical activity levels in the intervention group contributed to the increase in total energy expenditure at the end of the study. The fact that this did not happen in the control group makes us believe that the program was effective in increasing the total energy expenditure in the intervention group. However two considerations are relevant: first the program did not increase physical activity in the intervention group so as to be significantly higher than in the control group. Probably the high initial physical activity level from both groups prevented any further substantial increase. Further the increase in total energy expenditure in the intervention group was achieved only through direct intervention with the physical activity classes, because, if this activity is not taken into account, the change in total energy expenditure in the intervention group is no longer significant. The increase in walking time in the intervention group was not sufficient by itself to have a significant impact on total energy expenditure. The objective of increasing total energy expenditure outside physical activity classes was therefore not achieved in this study. These findings highlight the importance of exercise supervision as reported by Alam (2004). Comparing a group submitted to supervised exercise with another submitted to unsupervised exercise, these authors found significant improvements in weight, body composition, lipid profile and glycemic control in the supervised compared to the unsupervised group.

6.1.2. DIETARY HABITS

At baseline, more than half of the subjects did not meet the dietary recommendations for the Portuguese population for each food category. The highest rates of non-compliance both at the beginning and at the end of the study were in vegetables and pulses. This could be related to the cost of those foods, and also to the fact that they are perishable (Darmon et al., 2004; Darmon et al., 2002, Drewnowski et al., 2007; Drewnowski & Specter, 2004). Our results are thus consistent with the literature (Hsia et al., 2002; Nelson et al., 2002) that also found over two thirds of individuals with inadequate dietary intakes in respect of vegetables and fruits.

Despite being a more motivated group, and having access to specialized dietician consultations, the dietary pattern of the intervention group was far from optimal. The reasons for such a finding can only be speculated, but lack of comprehension by the participants or economic difficulties in buying selected foodstuffs are most likely. Indeed, a sizeable fraction of the participants lived on less than

400€ a month, which considerably reduces their food budget. This might also explain the difficulties in changing dietary habits when strong economic constraints exist.

Also no significant improvements were noted for both the control and intervention groups regarding compliance with the dietary recommendations for the Portuguese population. Despite this at the end of the study the intervention group had significantly more compliers than the control group in the category of milk and derivatives, and also a better dietary score. This indicates that, despite a statistically non-significant progress in each food category, the overall dietary pattern improved in the intervention compared to the control group. These findings suggest that it might be more important to assess the overall effect of dietary intervention rather than the effect on selected foodstuffs. Further if we consider the changes in dietary behaviour irrespective of agreement with guidelines, the intervention group achieved a significant improvement in dietary behaviour (**figure 10**). These findings suggest that even if the participants fail to comply fully with the dietary recommendations their dietary intake tends to improve. Conversely a bi-modal trend was found in the control group with about half of the subjects improving and the other half decreasing the quality of their dietary behaviour. The reasons for such a trend are currently unknown. Overall our results are consistent with those reported in the literature (Hsia et al., 2002, Nelson et al., 2002) that describe the difficulty of achieving changes in eating behaviour in the long term.

6.2. CLINICAL AND BIOLOGICAL VARIABLES

At baseline over two thirds of participants were either overweight or obese. Such results are consistent with the literature: data from the National Health Survey (INSDRJ, 2009) indicates that for individuals aged over 55 years the prevalence of overweight and obesity is around 64.1%. This value is further increased among subjects with diabetes. Data from the Third National Health and Nutrition Examination Survey (NHANES III), 1988-1994, and the NHANES 1999–2002, shows a prevalence of 85.2% for overweight and obesity among individuals aged over 20 years with diabetes, (Centers for Disease Control and Prevention, 2004).

The increased fat mass percentage found in both groups may be caused by a reduction in fat-free mass due either to sarcopenia (American College of Sports Medicine, 2009b; Kesavadev et al., 2003; Short & Nair, 2001), or to the reduction of bone mineral density, both characteristics of the ageing process (American College of Sports Medicine, 2009b). Contrary to the literature, that showed reductions in weight and percentage of fat from physical activity (Alam et al., 2004, Fritz et al., 2006; Krousel-Wood et al., 2008), our results suggest that a low intensity intervention is not adequate to improve BMI or body composition. However, the previous studies were conducted in younger subjects and an age effect might be present. Also it is likely that younger individuals might be able to exercise at higher intensities.

At baseline hypertension was present in 83.3% and 68.4% of the control and intervention groups respectively. Such values are in line with the literature and match those of the general population of the same age group. In a sample of 5,023 adults aged 18 to 90 years representative of the general Portuguese population (Macedo et al., 2007), the prevalence of hypertension was 42.1% for the total sample and 79% for the group aged over 64 years. In our study treatment rates (70.0% and 84.6% at baseline for the control and intervention groups respectively), were slightly higher than in the referred study for the same age group: 55.9% for men and 69.6% in women. Usually treatment rates increase with age due to the more frequent health monitoring of elderly people. The same process also applies to diabetics and may explain the differences between our study and the one referred to. Finally the rates of controlled hypertension (35.0% in the control and 46.2% in the intervention group) were higher than in the referenced study, albeit no data is available regarding the control levels for age, but it is noted that individuals with controlled hypertension are younger. Indeed, the median baseline SBP and DBP values in our study (140 mmHg and 70 mmHg for both groups) were lower than those found in the cited article for individuals over 74 years (150 mmHg and

85 mmHg), probably due to the higher rate of controlled individuals. Another study that included 1,031 Portuguese aged over 55 of both genders reported similar results: a hypertension prevalence of 67.6% (95% CI: 64.6-70.5%), with 41.6% of treated individuals and 27.4% of treated and controlled subjects (Clara, Macedo, & Pego, 2007). Still no clinical effect of the intervention on blood pressure levels or on hypertension control was found. Again the results suggest that, in order to achieve adequate blood pressure control, more stringent conditions should be implemented.

As for the lipid profile, the groups differed significantly at baseline regarding total cholesterol and LDL, the intervention group presenting lower values. The total cholesterol values at baseline of the intervention group were comparable to those from the literature, namely for subjects aged over 60 years in the NHANES study (Schober, Carroll, Lacher, & Hirsch, 2007), and those found by Castaneda (2002) in a sample with the same age profile than our study. The baseline LDL cholesterol levels for the intervention group were also in agreement with the literature (Castaneda et al., 2002; Fritz et al., 2006; A. Kirk et al., 2004; Maiorana et al., 2002). A possible explanation might be a lower dietary compliance among the control group. The triglyceride values at baseline were similar to those found by Castaneda (2002) but lower than those referred to by other authors (Fritz et al., 2006; A. Kirk et al., 2004; Maiorana et al., 2002). The control group presents a median 10mg/dl higher values than the intervention group but the differences are not statistically significant.

The reduction in total and LDL-cholesterol, and of triglyceride values, was statistically significant only in the control group, probably due to the greater progression margin in this group. It is noteworthy that the intervention group completed the study without any subject with high LDL-cholesterol values. This is an important result because elevated LDL cholesterol is the primary target of lipid-lowering therapy according to the American Diabetes Association and the American Heart Association (Buse et al., 2007). The fact that the dietary category "Fats and oils" has one of the highest percentage of compliers in both groups might partly explain these results, as a reduction in saturated fat leads to a decrease in LDL cholesterol levels (Hsia et al., 2002). Non-significant improvements in median values for total, LDL and HDL cholesterol, and triglycerides were found in both groups. This could be due to the lack of statistical power caused by the small sample size and high data variability. In general, these results are in line with the literature (Castaneda et al., 2002; Fritz et al., 2006; A. Kirk et al., 2004; Maiorana et al., 2002) where non-significant trends were found. One exception is the work of Fritz et al.(2006), where significant differences were found for LDL and HDL levels, but those trends were found in both the control and the intervention group.

At baseline the percentage of participants with a HbA1c under 6.5% was 37% for the control and 40% for the intervention group. Compared with the literature (Castaneda et al., 2002; A. Kirk et al., 2004; Krousel-Wood et al., 2008; Maiorana et al., 2002; McDonald, Hertz, Unger, & Lustik, 2009; Tokmakidis et al., 2004; Wolf et al., 2004), our results indicate a relatively good glycemic control among the diabetic subjects. Further both groups had reductions in both glycaemia and HbA1c over the study period. However those changes were significant only for glycaemia in the control group. These findings are in agreement with some studies (Castaneda et al., 2002; A. Kirk et al., 2004, Maiorana et al., 2002; Tokmakidis et al., 2004, Wolf et al., 2004), but not with others (Baynard, Franklin, Goulopoulou, Carhart, & Kanaley, 2005, Fritz et al., 2006; Krousel-Wood et al., 2008). Possible explanations for this lack of improvement in the intervention group include the already low values found at baseline as well as the age of the sample. Indeed it has been shown that in older individuals the improvement of glycemic control is considerably more difficult (Kesavadev et al., 2003). According to Boulé (2003), interventions with more intense physical activity are more effective in glycemic control. This is thus a limitation of the program, because it was not appropriate to increase the intensity of the sessions of physical activity in our study sample. In the case where significant differences were found, they ranged between 0.2%(A. Kirk et al., 2004) and 1.1%

(Castaneda et al., 2002). The work of Wolf et al. (2004) points to a relevant issue: a possible rebound effect. After 4 months the intervention group presented significant lower HbA1c than the “usual care” group, but at 12 months, differences were no longer significant, neither from baseline values nor from the “usual care” group. It is of relevance that in this study there was a weight regain in the last 4 months of intervention, a rebound effect that can also happen regarding glycemic control.

Overall, the clinical and biological results of our study may be explained by the characteristics of the program. Regarding physical activity, the program was below the recommendations of international organizations regarding the frequency of sessions. This was due to the difficulty in increasing total metabolic expenditure outside classes and thus the program fell short of the recommended total workload. Furthermore, the high age of the participants conditioned not only the intensity of the sessions, but also the magnitude of the results, because the effects of intervention tend to decrease with age (Kesavadev et al., 2003).

6.3. FITNESS

A significant rise, both in upper and lower strength, was found in the intervention group; and the significance of the rise in upper was greater than that in lower strength.

The fact that a significant improvement was verified also in the control group may be explained by an adaptation to the test itself. Despite the time given to adapt to the test doing a specific warm up, and the large period between test applications (9 months), it is possible that individuals have learned to manage their effort more efficiently. Differences between baseline and the end of study were however more significant in the intervention group both for lower and upper strength.

These results are in line with those found in the literature:

Maiorana et al.(2002) found after an 8 weeks circuit training program a significant increase in strength in 16 both gender subjects with type 2 diabetes. In this study maximum isotonic voluntary contractile strength was assessed as a sum of strength measures on each of 7 different exercises.

Tokmakidis et al.(2004)found a significant upper (13%) and lower(14%) strength improvement in 9 women with type 2 diabetes after an exposure to a 4 months combined strength and aerobic exercise program.

Ibanez et al. (2005)exposed 9 subjects with type 2 diabetes to a program that included two sessions per week of progressive resistance training at an intensity of 60% of 1 repetition concentric maximum (1RM), without a concomitant weight loss diet. Significant improvements in upper (18%) and lower (17%) strength were found.

The abovementioned results were obtained with younger samples than in our study, but the fact that those results can be reproduced in older individuals is an important result, because in that case deficits in strength can affect autonomy and, particularly in lower limb strength, may contribute to impaired balance, thus increasing the risk of falls (M. Rogers, Rogers, Takeshima, & Islam, 2003).

This problem is especially important among older adults with diabetes, who have a two-to threefold increased risk of physical disability (Kesavadev et al., 2003; Park et al., 2006) and tend to be weaker. Andersen, Nielsen, Mogensen and Jakobsen (2004) compared type 2 diabetic patients with control subjects matched for sex, age, weight, height, and physical activity. They found a significant strength reduction in ankle flexors (17%) and extensors (14%) and also in knee flexors (7%) and extensors (14%).

Our results confirmed that it is possible to resist the strength loss that comes with age, even in an elder and diabetic population.

Aerobic endurance also improved in the control and intervention groups. At baseline the intervention group had a better performance than the control group, but differences were of borderline significance. At the end of the study those differences became statistically significant, i.e. the improvement was steeper in the intervention group.

These results are in line with those obtained by several authors (Alam et al., 2004; Maiorana et al., 2002; Tessier et al., 2000) which found an increase in cardio respiratory fitness as a result of intervention programs. In all of these studies, the program included, at least partially, aerobic exercise.

Considering that low cardio respiratory fitness is a risk factor for cardiovascular events (F. B. Hu, Stampfer et al., 2001) and an independent predictor of all cause mortality in individuals with type 2 diabetes (Wei, Gibbons, Kampert, Nichaman, & Blair, 2000), these results point towards a risk reduction as a consequence of participation in aerobic exercise.

Our results indicate a non significant (borderline) improvement in both groups in relation to lower flexibility. In upper flexibility there was a significant decrease for the control group and a significant increase for the intervention group.

The importance of flexibility is sometimes undervalued among fitness variables. It can be determinant of the quality of life, particularly in elderly subjects. In diabetic patients this might be an important issue, because joint structures may be affected, and complaints of “frozen shoulders” are common (Herriott, Colberg, Parson, Nunnold, & Vinik, 2004).

In the intervention group upper limbs had a steeper evolution compared with the lower limbs, in relation to strength and flexibility. This fact may signify that in this population daily physical activity does not make equal demands on lower and upper limbs. Thus the applied program might represent a substantial increase in physical activity for the upper limbs, but not for the lower limbs.

The overall improvement in fitness variables is an important outcome of the program because, in elders, these variables affect autonomy. By delaying the loss of autonomy, this effect is not confined to be a biological one but its implications may be extended into the psychological, social and economic areas, and have a profound impact on the quality of life of the patients and their relatives.

6.4. MOOD STATES

At baseline the intervention group had an iceberg profile in relation to mood states, and that profile increased during the study due to the decrease shown in the Fatigue-Inertia factor and the borderline increase in Vigor-Activity. Changes in these factors are significant and had no parallel in the control group. At the end of the study individuals in the intervention group perceived themselves more active and less tired than at baseline. These results are probably related to the improvements found in aerobic endurance and in upper and lower strength for this group. This was also an important result from the psychological point of view. In order to keep individuals motivated and committed to their treatment, it is important to value, and to make the patient value every little progress achieved, because it enables the patient to find himself as having a say in his own fate. This change in the locus of control over the disease from external to internal is a crucial step towards compliance with treatment and towards patient empowerment. If the patient has an external locus of control he will see the disease as a fate, as something he is not able to control. In this situation the commitment to a treatment plan will be very hard to achieve. On the other hand if the patient has an internal locus of control he will see himself as having a good level of control over the disease, and will, hopefully try to improve it. The interest in acquiring knowledge about the disease and the commitment to a treatment plan is therefore, more likely (Stanton et al., 2007).

The reduction in the subjective perception of fatigue is a change that can easily be valued by the patient because it has an impact on his/her quality of life, especially in more aged individuals. This effect can be used to promote a change towards an internal locus of control, which should be a target for every lifestyle intervention program.

Despite no reductions having been found in most factors of profile of mood states, the above mentioned changes were enough to increase the percentage of individuals in the intervention group with an iceberg profile which rose from 37 to 68%. In the control group this percentage remained unaltered at 42%. These results are in agreement with the literature (Biddle & Mutrie, 2001; Leith, 1994) concerning the appearance of an iceberg profile following an increase in physical activity.

6.5. ECONOMIC ANALYSIS

In order to be implemented lifestyle programs must also prove to be cost-effective (Imai & Zhang, 2005). In this research the cost of medications to the individual and the State were assessed. Inflation in the 9 months period during which the research was implemented was not taken into account, and therefore increments in costs must be interpreted as higher doses or more expensive medication prescriptions. The figures obtained may be underestimated, as the calculations were made based on the cheapest drugs allowed in the prescription. Overestimation may also be possible due to lack of compliance with the prescribed intakes.

No national data is available to compare but, at baseline, the cost of medication per individual could reach as much as 103.84€ per month. Thus the economical constraints diabetes imposes on individuals can be substantial, considering that 44% of the sample had an income of less than 385.90€ per month.

From the individual point of view, both groups increased their expenses, but the increase was statistically significant only in the control group. The State expenses rose significantly in both groups. The explanation for the different evolution of individual and State expenses may lie in the healthcare system itself: albeit antidiabetic medications are entirely supported by the Portuguese health system, medications for its co-morbidities are not. Therefore, it is possible that in the intervention group the program delayed some co-morbidities of diabetes thus keeping individual expenses stable. The chronic complications of diabetes are responsible for more than one third of diabetic health expenses (Oliva et al., 2004) and postponing them is one of the main objectives of tertiary prevention, as stated in the Portuguese national program for diabetes prevention and control (Direcção Geral de Saúde, 2008). Therefore this result is encouraging.

A higher number of hospitalizations and a longer period of hospitalization were reported in the control group, but those differences did not reach statistical significance. It was likely that this was due to the sample size and to the low number of hospitalizations which occurred within this period.

The economic burden of antidiabetic medication is generally low for individuals but high for society. The cost-effectiveness of lifestyle programs is difficult to assess because the modelling used for pharmacological interventions does not apply to lifestyle interventions. In pharmacological interventions the costs are linked with adherence to the treatment, while in lifestyle interventions costs are upfront and cost-effectiveness depends largely on the long term maintenance of health benefits and on adherence to treatment. The large variability of health outcomes found in different lifestyle programs further complicates the economic analyses (Jacobs-van der Bruggen et al., 2009).

6.6 FINAL INTERVIEW ANALYSIS

Data obtained in the final interview confirms the one gathered about physical activity and dietary habits by the IPAQ questionnaire and by the 24 hour recall respectively.

The questions asked to the intervention group regarding program participation revealed that perceived advantages were mostly biological. Only 10.6% of participants do not refer this kind of outcome. Diabetes’ control was the less referred biological category which is consistent with the lack of significant improvements found amongst the intervention group in the clinical and biological variables. On the other hand, the high percentage of participants that reported “general health control” and “physical fitness” advantages might have based their answers on the improvement this group had on most fitness variables and also in the profile of mood states in what regards to “fatigue-inertia” and to “vigor–activity” categories.

A change in dietary habits was the least referred psychological advantage of program participation. This seems to reveal that the participants were aware that their efforts to improve compliance with dietary recommendations were not enough.

Physical Activity habits was the most referred category amongst psychological advantages. In fact the participation in the structured physical activity classes represented to this group a significant change in physical activity habits. Participants may however have considered this change as sufficient and have neglected the advice to increase its unstructured daily physical activity. The significant raise in the time spent walking and the unchanged moderate physical activity were not sufficient to promote significant differences in the overall physical activity, leaving out of account the time spent at physical activity classes.

The perceived changes regarding mood states are also in line with changes found in POMS questionnaire namely regarding the “fatigue-inertia” and “vigor–activity” categories.

Data gathered by interview was therefore consistent with data collected from the other sources.

The fact that 68.4% of the subjects in this group referred that acquaintanceship was a significant advantage from program participation, highlights the importance for the individuals of the enlargement of their social network. This might be related with the age of the sample since in older ages it is common to witness a substantial reduction in the social network (Findlay, 2003; Victor, Scambler, Bond, & Bowling, 2000).

The contribution that participation in this kind of programs has in the extension of the social network is an aspect to be held in account in future researches especially in elder populations because there is some evidence of relation between social support and personal coping resources with chronic diseases(Auslander & Litwin, 1991; Penninx et al., 1997).

The last question “would you recommend the program to your friends?” would reflect a final judgment about program participation. All things considered, all participants found the program participation as an experience they would recommend. Despite the unanimous response, it is to consider a possible bias due to the social desirability of the answer.

7. CONCLUSIONS

Daily life self-reported levels of physical activity were higher than expected considering the age of the sample. Vigorous physical activity is avoided by most individuals and the core part of the energy expenditure is reached through moderate physical activity and walking.

Dietary habits were poor and recommendations for the Portuguese population were not followed for most individuals on most of the food categories. Cultural, social and economic reasons may help explain this non-compliance amongst a population that has on dietary habits one cornerstone in the treatment of their disease.

The program achieved a moderate success in changing behaviours. Structured physical activity was well accepted but the increase of unstructured physical activity in daily life is more difficult to achieve. This stresses the importance of supervised physical activity classes.

Improvements in dietary habits took place but were tenuous and insufficient to significantly change the compliance with recommendations for the Portuguese population.

The above mentioned improvements in both physical activity and dietary habits had no significant impact on most clinical and biological variables, namely blood pressure and lipid profile.

Fitness was improved and perceived fatigue diminished. This can have a direct impact on the quality of life but can also be an important point to keep individuals motivated.

The program may help to control individual costs of medications, and it probably delays the occurrence of the chronic complications of diabetes.

This study was useful to identify some barriers that hinder the development of this kind of program, and the experience gained will be important for the future implementation of similar (and hopefully more efficient) interventions.

Our results suggest that in order to be more effective, intervention should begin as early as possible, as its implementation among elderly subjects is difficult. This would lead to a larger response to the program and to a more intense physical activity intervention.

This was a quasi-experimental pilot study. The fact that participants were affiliated to groups based on their own choice rather than randomly is a limitation because the probabilities for the two groups were not equivalent. It is plausible that individuals in the intervention group were more motivated and had a higher commitment to their health.

Adherence to the program conditioned sample size, leading to a low statistical power. Despite our efforts it was not possible to reach the initially planned sample size (n=60).

Another important aspect in the interpretation of the results is the mean age of the sample (69.1 years), which is considerably older than most studies. The comparison of our results with those of other studies must thus consider a possible age effect.

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