



**Effects of bariatric surgery and an exercise intervention on
physical activity in severe obese patients**

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List of abbreviations

AACE - *American Association of Clinical Endocrinologists*

AFMV - atividade física moderada a vigorosa

ANOVA - analysis of variance

ANCOVA – analysis of covariance

ASMBS - *American Society of Metabolic and Bariatric Surgery*

AF – atividade física

AFL – atividade física ligeira

BMI - body mass index

BS – bariatric surgery

CB – cirurgia bariátrica

CG - control group

EG - exercise group

FDA – *Food and Drug Administration*

GC – grupo controle

GE – grupo de exercício

IFSO - *International Federation for the Surgery of Obesity and Metabolic disorders*

IMC – índice de massa corporal

ITT - intention-to-treat

LGS - gastrectomia em manga

LPA – light physical activity

MPA – moderate physical activity

MVPA – moderate to vigorous physical activity

OMS – organização mundial de saúde

OS - *Obesity Society*

PA – physical activity

PP – per-protocol

RYGB - roux-en-Y gastric bypass

SB – sedentary behaviour

SG – sleeve gastrectomy

US – United States

VLED – very low energy diets

VPA – vigorous physical activity

Resumo

Objetivos: o estudo desta dissertação teve como principais objetivos avaliar, em doentes com obesidade severa submetidos a cirurgia bariátrica (CB), i) as repercussões da CB na atividade física diária e em variáveis antropométricas e ii) avaliar as repercussões de um programa de exercício físico realizado entre 1 a 6 meses após a CB na atividade física (AF) diária. **Métodos:** Trinta doentes com obesidade severa com idade >18 e <65 anos, índice de massa corporal (IMC) $> 40 \text{ kg.m}^{-2}$ ou $> 35 \text{ kg.m}^{-2}$ com comorbilidades associadas à obesidade, referenciados para realizar Bypass Gástrico em Y-de-Roux (RYGB) ou Gastrectomia Vertical, foram randomizados em dois grupos: i) grupo de intervenção ($n = 20$) ou ii) grupo de controlo ($n = 10$). Os doentes alocados ao grupo controlo (GC) receberam o acompanhamento médico habitual após a CB sem prescrição estruturada sobre exercício físico. Os doentes alocados ao grupo de exercício (GE), além do acompanhamento médico habitual participaram, durante 5 meses consecutivos, num programa de treino multicomponente, 3x/semana em dias alternados, com sessões de duração de 75 minutos. Todos os pacientes foram avaliados entre 1 a 3 meses antes da CB e novamente aos 1 e 6 meses após a CB para avaliação do padrão de AF habitual e de um conjunto de variáveis antropométricas (Peso, IMC, perímetros da cintura e da anca). **Resultados:** Foram identificadas diferenças significativas no tempo passado em AF ligeira (AFL; $p = 0.038$), em AF moderada a vigorosa (AFMV; $p = 0,004$) e na circunferência da anca ($p = 0.039$), quando comparados antes e 1 mês após a CB. A análise das variáveis antropométricas e AF dos doentes divididos em GC e GE aos 1 e 6 meses após a CB não demonstrou qualquer efeito significativo de grupo (todos $p > 0.05$) para qualquer uma das variáveis em estudo, pese embora todas as covariáveis tenham mostrado significância estatística (todos $p < 0,05$). **Conclusão:** O efeito da cirurgia, como esperado, resultou na diminuição significativa dos valores médios de todas as variáveis antropométricas analisadas, não sendo, contudo, identificado nenhum efeito clinicamente relevante em relação à AF. Ausência de efeito do programa de exercício regular multicompetente, não mostrando eficácia na modificação significativa do tempo passado em AF ou em comportamentos sedentários.

Palavras-chave: OBESIDADE, CIRURGIA BARIÁTRICA, ATIVIDADE FÍSICA

Abstract

Objectives: The aim of this dissertation was to evaluate, in patients with severe obesity that underwent bariatric surgery (BS) i) the repercussions of BS on daily physical activity and anthropometric variables and ii) to evaluate the repercussions of a physical exercise program performed between 1 to 6 months after BS, on the daily physical activity (PA) pattern. **Methods:** Thirty subjects with ages between 18 and 65 years, body mass index (BMI) $>40 \text{ kg.m}^{-2}$ or $>35 \text{ kg.m}^{-2}$ with obesity-related comorbidities, referenced to perform Roux-en-Y Gastric Bypass (RYGB) or Sleeve Gastrectomy were randomized in two groups: i) one intervention group (n=20) and ii) one control group (n=10). Patients allocated to the control group (CG) received the usual medical follow up following BS with no structured recommendations about exercise. Patients allocated to the exercise group (EG), in addition to the usual medical follow up participated in a supervised multicomponent exercise-training program, for 75 minutes, 3x/week in alternative days, for 5 consecutive months. All patients were assessed at between 1 to 3 months before BS and again 1 and 6 months after BS for determination of the PA pattern and anthropometric variables (body mass, body mass index (BMI), waist and hip circumference). **Results:** Significant differences were detected in light PA (LPA; $p = 0.038$), moderate to vigorous PA (MVPA; $p = 0.004$) and hip circumference ($p = 0.039$) when patients were compared before and 1 month after BS. The analysis of anthropometric and PA variables of patients divided in CG and EG at 1 and 6 months after BS showed no significant group effect (all $p > 0.05$) for any of the studied PA variables. **Conclusion:** BS, as expected, resulted in a significant decrease in the mean values of all anthropometric variables assayed, however no clinically relevant effect related to PA was observed. A multicomponent regular exercise program had no effect, showing no efficacy in modifying PA and sedentary time variables.

Keywords: OBESITY, BARIATRIC SURGERY, PHYSICAL ACTIVITY

General introduction

Obesity is a highly prevalent chronic metabolic disease with an increasingly higher incidence. These increasing trends are worrisome, particularly in developed countries, in which they are now approaching epidemic proportions. Alongside, obesity is a main risk factor (Beamish et al., 2016) for the development of other clinical conditions such as arterial hypertension, dyslipidemia, ischemic heart disease, stroke, and type 2 diabetes mellitus (Jensen et al., 2014). Since it is a public health problem, current concerns focus on ensuring effective and timely prevention and treatment. The most common strategies to tackle this problem are lifestyle modification such as diet and engaging in physical exercise programs, pharmacological treatments, and, in selected severe cases, bariatric surgery (BS) (Castañeda-González et al., 2010; Parretti et al., 2016; Wu et al., 2009). In the last few years BS has proven to be the most effective treatment for patients with severe obesity with body mass index (BMI) $\geq 40\text{Kg/m}^2$ or BMI $\geq 35\text{Kg/m}^2$ with two or more significant obesity related comorbidities such as hypertension, type 2 diabetes, obstructive sleep apnea, pulmonary hypertension, and non-alcoholic steatohepatitis. This is the reason why it is an increasingly performed treatment worldwide. Two surgical procedures are the most frequently employed: sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB) (Angrisani et al., 2017). The choice for one procedure in detriment of the other is usually influenced by several clinical factors, specific local settings, and surgical team expertise.

Despite the well-known effects of BS on the loss of excessive body mass, prevention of body mass regain after surgery is a matter of concern, and should be prevented (Busetto et al., 2017), inasmuch a non-neglectable percentage of these patients recover a significant portion of the excess body mass initially lost. Regular physical activity (PA) is frequently encouraged after BS, starting after the post-surgical recovery period (Busetto et al., 2017) given the evidence that physically active subjects have lower BMI, achieve greater body mass loss, and that exercise prevents body mass regain in patients undergoing diet for body mass loss (Herring et al., 2016). Nevertheless, a considerable amount of patients with severe obesity have low levels of PA prior to surgery which are maintained postoperatively in addition to presenting large amounts of time spent in sedentary behaviors (King et al., 2015). Therefore,

interventions aiming to increase PA levels following bariatric surgery are needed for the optimization of surgery derived health benefits and to prevent body mass regain in these patients.

The present dissertation investigates: i) the effects of bariatric surgery on daily PA levels, and, ii) the effects that the participation in a structured exercise intervention program specially designed for patients with severe obesity that underwent bariatric surgery has in increasing daily PA.

Based on the above mentioned, this dissertation is organized into six chapters. First, in this introduction, we aimed to contextualize the object of the dissertation and guide the reader through the research problem. In the second chapter a literature review was performed, aiming to frame essential concepts such as obesity and to describe the state of the art about therapeutic strategies to treat and manage obesity (pharmacotherapy, very-low energy diets and BS), and report the existing knowledge about the associations of PA, obesity and BS. On the third and fourth chapters, we present the methodological features of our experimental study, as well as the results, respectively. In the fifth chapter, we discuss our results, and provide cues of future research directions for conducting intervention programs after BS. Finally, in the sixth chapter the main conclusions are summarized.

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Literature review

Obesity epidemiology

Considered by the World Health Organization (WHO) as an epidemic, obesity is a growing public health problem, affecting longevity and quality of life with significant economic and social consequences (Rennie & Jebb, 2005). Considered as chronic disease, its aetiology is multifactorial, resulting from physical, social, genetic and behavioral factors (Kopelman, 2000). Obesity is characterized by excess body mass as a result of a body composition with high and abnormal proportion of subcutaneous and visceral fat, which results from a long lasting positive energy balance (Krebs et al., 2007; Pulgarón, 2013). Due to the fact that it is considered a chronic condition with a growing impact on public health, WHO (1997) recommends continued surveillance. To this end, WHO advises the use of a ponderal index, the Quetelet's Index, more commonly known as BMI, for monitoring and controlling population overweight and obesity. Although it is an indicator that does not directly quantify the amount and proportion of body fat relative to total body mass, and it is known that there may be factors affecting the measurement of the ratio of weight to height squared, there is a sufficiently strong association of this indicator with body composition components at different age and gender (WHO, 2014). Obesity is clinically defined as $\text{BMI} \geq 30 \text{ kg.m}^{-2}$ with values between 30-35 kg.m^{-2} classified as obesity grade I, between 35-40 kg.m^{-2} obesity grade II, 40-50 kg.m^{-2} obesity grade III and $\text{BMI} \geq 50 \text{ kg.m}^{-2}$ as super obesity (Livhits et al., 2010; Quintas-Neves et al., 2016).

A lifestyle characterized by high-energy consumption and comparatively low energy expenditure due to physical inactivity is one of the main factors associated with excessive body mass gain and obesity (Krebs et al., 2007; Pulgarón, 2013). One of the important phenomena to consider when analyzing the issue of obesity is the globalization process, which, even though it is related to the improvement of quality of life and food safety and, in addition, is a factor associated with the significant reduction in the level of poverty in many countries it also had a set of negative consequences that should not be ignored. For example, the international commerce growth has facilitated the massive intake, particularly in sugary drinks and foods with low nutritional value and significant energy density, which in parallel with the decreases in PA reported seem to be contributing to the rising obesity epidemic worldwide (Kelly et al., 2013).

Several studies in the United States (US) have shown the continued rise in obesity prevalence between 1980 and 2010, a phenomenon that, even with varying prevalence and frequency values, has spread worldwide (Ogden et al., 2012). In fact, according to data from the study by Finucane et al. (2011), between 1980 and 2008 the prevalence of obesity increased globally from 4.8% to 9.8% in the male population and from 7.9% to 13.8% in the female population (Finucane et al., 2011). In addition, another study showed that in 2013 about 2.1 billion individuals worldwide were overweight, while in 1980 the figure was just 857 million. (Ng et al., 2014). Also, according to data reported by the WHO (2014) in reference to the year 2014, 11% of men and 15% of women, aged 18 years or older, were obese. Currently, it is estimated that the number of overweight people is 2.5 times higher than the number of undernourished people (Haddad et al., 2015).

In Portugal, the literature reports that approximately 1 in 6 Portuguese are considered obese, with prevalence increasing regularly since 1995 (Marques-Vidal et al., 2011). This increase has been most prominent in women and in young ages (Carreira et al., 2012). Indeed, educational inequalities in women associated with social stereotypes seem to underlie this fact. Thus, women with higher socioeconomic positions appear to be under greater social pressure to be thin and to control their body mass compared to women with lower educational levels (Williams et al., 2011). Additionally, physically more demanding jobs are usually performed by men, and that may explain gender differences in energy expenditure by PA in less privileged socioeconomic groups and the impact on the likelihood of occurrence of a positive energy balance. We can also consider other non-behavioral factors that may be at the root of this phenomenon of rising obesity, such as, when compared with the opposite sex, women from lower economic classes appear to be more vulnerable to unfavorable psychosocial exposures throughout their lives, what may influence adiposity due to stress-related psychological disorders, which is associated with a tendency to BMI and waist circumference increases, which is a strong indicator of visceral fat. (Rosmond & Bjorntorp, 2000; Tenk et al., 2018). Furthermore, women with poorer social conditions tend to earn lower wages than men, which may amplify these mechanisms (Ferreira, 2010). In fact, when compared to men, women in many countries, complete fewer years of schooling and, consequently, have lower wages and higher household poverty ratios (Conley & Glauber, 2006). Investigations also indicate that overweight in adolescence and early adulthood can trigger more severe socioeconomic

consequences for women than for men. Thus, as a woman, belonging to disadvantaged socioeconomic group has increased likelihood of being obese and, as a result, becoming pregnant can lead to children who are at greater risk of becoming equally obese (Whitaker et al., 2010).

In the case of the young, childhood obesity was considered by the WHO as one of the most serious public health problems of the 21st century, and one of its main predictors may be parental body mass. Thus, a child with an overweight or obese parent has a 48% increased risk of being overweight or obese at 9.5 years, while in a child whose parents are not obese this risk drops to 13% (Agras et al., 2004). Data from 2013 shows that, worldwide, 42 million of children under the age of five were overweight (WHO, 2015). In Europe, this figure is around 14 million children, to which over 400 000 children are added annually (Abela et al., 2014). In Portugal, over 30% of the child population is overweight. In addition to parental obesity, other predictors that enhance childhood obesity development have been reported, which include low socioeconomic status, high birth body mass, sedentary lifestyle and inadequate eating patterns (Krebs et al., 2007; Pulgarón, 2013). In addition to the above factors, and although the body has excellent physiological defenses against the depletion of its energy reserves, it also has fragile means of fighting excessive accumulation of energy reserves in situations of overeating (Hill & Peters, 1998). This phenomenon seems to potentiate overweight during childhood and acts as a risk factor for the development of obesity in adulthood. It is estimated that about 60% of children who are overweight or obese before puberty will maintain this condition as young adults with short and long-term adverse effects such as increased risk of morbidity and premature mortality (Beja et al., 2014; Krebs et al., 2007; Pulgarón, 2013). In the US, about 6% of children and adolescents suffer from severe obesity, which means that one or more children in every primary, secondary, or high school in the country is affected by this epidemic. In addition, there is an indication that the prevalence of severe obesity is increasing faster than the prevalence of overweight or moderate obesity (Skinner & Skelton, 2014). This disturbing rise in BMI and BMI percentiles in adolescence have attracted crescent interest, as childhood obesity is closely linked to serious medical and psychological consequences (Kelly et al., 2013). In fact, severely obese children and adolescents when compared to overweight or obese youths have higher levels of blood pressure, triglycerides, inflammation and oxidative stress markers, lower levels of high density lipoprotein, signs of subclinical atherosclerosis and a high prevalence of impaired

glucose tolerance and pre-diabetes (Kelly et al., 2013). Besides that, longitudinal studies suggest that adiposity excess and its associated comorbidities prevail into adulthood. Thus, the long-term prognosis for most of these young people becomes very delicate, and it is estimated that approximately 90% of severely obese children will be at least level 2 obese adults ($\text{BMI} \geq 35 \text{ kg.m}^{-2}$) (Freedman et al., 2007). In Portugal, over 30% of the child population is overweight. These figures have tripled in many European countries since 1980 for the general population, and in children are up to 10 times higher than in 1970 (Gaio et al., 2018). In conclusion, childhood is considered to be a priority period of prevention and action to struggle against overweight and obesity (communities, 2017). Healthy lifestyles promotion, when implemented during childhood, seems to be determinant in the effective reduction of adiposity when compared to their implementation in adolescence and adulthood. (Danielsson et al., 2012).

Speaking about comorbidities, obesity is largely related to the onset of pathologies and diseases such as type 2 diabetes, sleep apnea, high blood pressure, coronary heart disease, strokes, oncological diseases, osteoarthritis and neurodegenerative diseases. Moreover, this epidemic seems to affect equally and negatively the performance of reproductive function (Lim et al., 2012). For example, it is estimated that hypertension is 2.5 times more common in obese individuals compared to people with normal body mass (cardiologia, 2019).

Considering the epidemic dimensions of obesity, as well as severe obesity ($\text{BMI} \geq 35 \text{ kg/m}^2$), innumerable health agents, aided by the scientific community, have sought to develop treatment strategies to handle obesity.

WHO (2014) reports that obesity treatment should include a combination of a balanced diet with reduced sedentary behavior and physical inactivity, to which pharmacological therapy may have to be added.

Therapeutic Strategies

Pharmacological

In recent decades, the only pharmacological agents available for the treatment of obesity were only approved for short term use (<12 weeks) by the Food and Drug Administration (FDA). However, in recent years, several drugs have been approved for the long-term use in the treatment of obesity. This data highlights the evolution of

the importance that society has given to this phenomenon, and the complexity of obesity as a disease (Velazquez & Apovian, 2018). The FDA wants these drugs to be used for health improvement and are indicated for people with a BMI ≥ 27 kg/m² (overweight) or a BMI ≥ 30 kg/m² (obesity). Simultaneously with the body mass overload criterion, the use of pharmacological therapy is indicated when some types of comorbidity co-exists, such as hypertension, type 2 diabetes or dyslipidemia (Fujioka, 2015).

There are currently three major groups of FDA approved pharmacological therapies to treat obesity: a) drugs that impair dietary intake such as the combination of phentermine and topiramate, and the combination of bupropion and naltrexone; b) medications that act peripherally to impair dietary absorption such as Orlistat, and c) medications used for the treatment of type 2 diabetes, such as GLP-1 agonists. However, pharmacological therapies are still rarely used in clinical practice (Thomas et al., 2016). *The Endocrine Society Clinical Practice* guidelines on pharmacological manipulation of obesity recommend close monitoring of the effectiveness of drug use in body mass loss, and for a drug to be effective, is required a $\geq 5\%$ loss of the total body mass. If this efficacy and patient safety are verified, the guidelines recommend continuous medication; otherwise, the medication is considered ineffective and has to be discontinued and alternative therapies should be considered (Obesity Medicine Association, 2016).

A systematic review of randomized controlled trials evaluating the long-term efficacy of pharmacological treatments in body mass loss appears to demonstrate the low efficacy of this therapeutic strategy (Castañeda-González et al., 2010). In addition, eleven other randomized trials were found, seven with orlistat, two with sibutramine, and two with rimonabant. The results of these studies were consistent to demonstrate the low retention percentage and the presence of a significant group of non-body mass loss subjects. These results are associated with the regain of excess body mass loss after discontinuation of treatment and the frequent adverse effects associated with drugs coupled with their high costs, factors that often make this type of treatment unfeasible (Castañeda-González et al., 2010).

Very low energy diets

Very low energy diets (VLED) are considered as one of the best therapeutic strategies for non-surgical and non-pharmacological treatment of obesity (Parretti et

al., 2016). VLED typically involve replacing all meals and snacks with pre-packed and nutritionally complete shakes, soups (to which water or milk are added), bars, or other prepackaged substitutes. The total energy content of a meal in these VLED is usually less than 800 Kcal.d⁻¹ (Delbridge & Proietto, 2006). These VLED are considered safe in the short term and have been reported to be used for up to 5 months without any associated health problems (Sumithran & Proietto, 2008). Three studies using VLED diets investigated three indicators: a) previous attempts at body mass loss, b) the experience of living with obesity, and c) what is the influencing agent of the desire for body mass loss in participants who had already performed multiple body mass loss attempts (namely commercial program diets, nutritional appointments, physical exercise, and drug use). The failure of these attempts was due to internal and external factors such as stress, slow body mass loss, boredom over the intervention program, lack of time, feeling depressed, seeking comfort and rewarding eating (Ostberg et al., 2011). After the intervention, positive changes in PA habits and improvements in participants psychological health were reported in all studies. One of the studies reported a positive change in physical and psychological levels during the intervention immediately after the completion of the VLED, however it is unknown whether these changes persisted over time (Rehackova et al., 2017). In the same study, participants reported increased sensitivity to hunger, understood how the body responds to a calorie restriction, and perceived their relationship with food. Additionally, many of these participants reported improvements in mood, confidence, work, and dietary management. Thus, VLED are known to induce fast body mass loss which, when combined with physical and psychological improvements promote their adherence and gains. However, the transition period from a replacement diet to a regular diet has not yet been explored, and there is still no clear way to make this period more effective. This lack of data makes it difficult to understand the permanence of these changes perceived by the participants. A meta-analysis compared a diet program with a diet program combined with exercise. The results of this analysis clearly show that the greatest long-term body mass loss is reached with diet combined with exercise, compared with diet alone. Despite this data, both programs are associated with significant body mass loss regain (Wu et al., 2009). These results seem to demonstrate that VLED are not effective in the long term.

Bariatric Surgery

Diet and exercise are the most common treatment options for obesity. However, both are rarely enough for effective long-term body mass loss, especially in severely obese patients. In view of this BS, which results in sustained body mass loss, has gained increasing popularity as a treatment option for severe obesity. This surgery consists, in general terms, in either in a reduction of gastric volume or a change in gastrointestinal anatomy in which food bypasses a portion of the gastrointestinal tube, or both. BS has the ability to produce better long-term results compared to traditional obesity treatments, both in terms of magnitude of changes in body mass and improvement in comorbidities and in durability (Stefater et al., 2012). In fact, BS produces long-term body mass loss, resulting frequently in a 50% reduction in an individual's excess fat, and a significant improvement in the comorbidities that are associated with this condition (Buchwald & Oien, 2009; Sjöström et al., 2007).

The two most common BS procedures are Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (LGS). There is also a third procedure consisting of biliopancreatic deviation with duodenal switch, however, this carries a higher risk of developing complications and is therefore performed less and less frequently (Kushner et al., 2013). The RYGB consists on the creation of a small gastric pouch, whose primary aim is to limit the ingestion capacity of food. This pouch is anastomosed to the small intestine in the jejunum region, thus extending beyond the duodenum, preventing the contact between food and the digestive action of pancreatic and biliary secretions. Individuals undergoing this procedure need vitamin and mineral supplements, and periodic nutritional monitoring due to the significant modification that occurs in the digestive tract (Abdelrazek et al., 2017). In sleeve gastrectomy (LGS), the patient experiences volume reduction in the largest curvature of the stomach by 80 to 85%, leaving only a narrow sleeve formed by the lesser gastric curvature (Carlin et al., 2013). The removal of a large portion of the stomach has significant implications in the amount of food digested, gastric acid production, and the absorption of vitamin B12 and iron. These patients also require continuous vitamin and mineral supplementation.

Selection criteria for BS were established by the *American Association of Clinical Endocrinologists* (AACE), *The Obesity Society* (OS), and the *American Society of Metabolic and Bariatric Surgery* (ASMBS) (Mechanick et al., 2009) and in Portugal are defined by specific clinical orientation norms provided by health

administration. According to these eligibility criteria, BS may be indicated for adult patients with a BMI $\geq 40 \text{ kg.m}^{-2}$ without obesity associated comorbidities; or patients with a BMI $> 35 \text{ kg/m}^2$ with obesity-derived comorbidities and a history of failure in non-surgical body mass loss attempts. To be eligible to BS, patients must also be able to commit to postoperative medical and nutritional care, which includes medical follow-up and compliance with recommendations, the use of dietary supplements, and following the instructions regarding procedures or tests required. This impairment should be assessed after surgery by examining the patient's ability to keep a food diary, to regularly attend appointments, the history of adherence to other therapies, and the analysis of disruptive life events that may compromise this follow-up and consequently the final result (Kushner et al., 2013).

A study conducted in patients with severe obesity (BMI $> 40 \text{ kg/m}^2$; n = 29; 18-65 years), mostly female, who underwent RYGB and were analyzed postoperatively showed that, one year after surgery the subjects had lost on average $44.3 \pm 10.2 \text{ kg}$ of body weight, and that 80% of the lost weight occurred in the first 6 months after surgery. Average pre-surgery body weight was $128.5 \pm 16.1 \text{ kg}$ while six months after surgery was $92.9 \pm 13.3 \text{ kg}$ and 12 months after surgery was $84.2 \pm 13.3 \text{ kg}$ (Tamboli et al., 2010). Results from another study also shows that patients that underwent were, after surgery, less hungry, less expectant about the amount of food they could eat, and increased their satisfaction and satiety during the postoperative meal test, even consuming 50% less calories than normal (Shankar et al., 2017). Another study showed that the success rate of diseases such as type 2 diabetes, dyslipidemia, hypertension and hyperuricemia increased significantly after surgery, and the incidence rate of these diseases was significantly lower 10 years after surgery when compared with a control group (Sjöström et al., 2004). Additionally, following these bariatric interventions, there has been an improvement in the low-grade chronic inflammatory status that characterizes obesity and diabetes (Fenske et al., 2013).

In 2014 data published by the *International Federation for the Surgery of Obesity and Metabolic Disorders* (IFSO) has reported that, in North America, 198.442 bariatric surgeries were performed, in Latin America about 160.636, in Asia / Oceania around 59.744 and, in the Europe, approximately 149.276. In Portugal, last published numbers report that around 2.892 surgeries are performed annually, mostly RYGB (around 45% of the total number of BS) (Angrisani et al., 2017). Currently, bariatric procedures are considered the most effective option for the treatment of severe

obesity and its comorbidities when compared to non-surgical interventions (Colquitt et al., 2014). As the number of surgical care centers specialized in BS increase, the number of patients having access to this treatment also becomes easier and the reflect of this is the increasing number of bariatric surgeries performed, both globally and in Portugal, from year to year.

Physical Activity Associated with Obesity and Bariatric Surgery

Physical inactivity, defined as noncompliance with PA volume and intensity recommendations, which are associated with bad health outcomes, is one of the top ten factors for global mortality, and it is associated with about 3.2 million deaths per year (Lim et al., 2012). Thus, it is estimated that insufficiently active adults have an increased mortality risk of 20-30% compared with those who engage in at least 150 minutes of moderate PA per week, or the equivalent, as recommended by the WHO (2010). In fact, regular PA practice is crucial for adequate energy expenditure to balance energy intake, control body weight and prevent excess adipose tissue accumulation and the development of obesity (WHO, 2010).

According to public health guidelines, virtually all patients recommended for BS are inactive in the preoperative period, accumulating <150 minutes per week of MVPA for periods lasting ≥ 10 minutes (Bond et al., 2015; Haskell et al., 2007). Approximately two thirds of BS patients do not perform any daily MVPA (Bond, Jakicic, Unick, et al., 2010). Considering that most of these patients find it difficult to make substantial changes in the amount of MVPA performed after BS (King et al., 2015), it is recommended that an increased effort to increase MVPA in the preoperative period should be made. (Haskell et al., 2007; King et al., 2012). Several studies suggest that increasing PA before and after BS is directly associated with improved surgical outcomes/responses, including effective excess body mass loss (Jacobi et al., 2011; Livhits et al., 2010). In addition, practicing regular PA allows an improvement in flexibility, strength and balance, contributes to mitigate bone mass and bone strength losses, reduces the risk of cardiovascular disease, stroke, type 2 diabetes, breast and colon cancer, improves immunity, promotes psychological well-being, improves or maintains some aspects of cognitive function, increases sleep quality and decreases sleep mortality risk (The Secretary of Health and Human Services, 2008). However, the ability of many BS patients to reverse inactivity and to engage in structured PA

may be impaired by other health problems (Physical Activity Guidelines Advisory Committee, 2008). Among the health-related barriers that hamper the practice of PA and exercise performance in patients undergoing BS, cardiometabolic complications of obesity are one of the main found (Poirier et al., 2011) as well as psychosocial issues such as body image and self-efficacy (Napolitano et al., 2011). Another barrier that often complicates adherence to PA is the feeling of chronic or acute pain (Cote & Bement, 2010).

Studies that incorporate patient self-reports regarding PA habits seem to suggest that patients become more active after surgery (Jacobi et al., 2011). However, studies using objective measures to assess PA using accelerometers or pedometers do not usually show any significant increase in PA during the postoperative period (Berglind et al., 2015; Bond, Jakicic, Vithiananthan, et al., 2010; Liu et al., 2012). Thus, it is unclear whether the self-reported increase in PA can be explained by poor perception (e.g., improvements in functional capacity after surgery may lead the patient to believe he or she is more active) or because there is a bias in the report (e.g., knowing that they are expected to be more active, patients may feel more pressure to report greater PA practice after surgery). Specifically, in a study using questionnaires and accelerometers in 20 patients undergoing RYGB or LAGB, MVPA reported by patients was four times higher between preoperative and 6 months postoperatively, however, changes in MVPA (or low intensity PA) measured by accelerometer were not significant, suggesting that patients overestimated their postoperative PA (Bond, Jakicic, Vithiananthan, et al., 2010). In another study, changes in objective PA measurements between the preoperative and postoperative moment were examined in a sample of 310 adults subjected to BS. Essentially, it was intended to evaluate the number of steps performed daily (which can be accumulated in light, moderate or vigorous PA intensities), the high cadence minutes (an indirect measure for ambulatory MVPA) and the active minutes (the inverse of sedentary time). In general, the participants in this study were more active 1 year after surgery compared to the preoperative period. Considering the cutoff points of $\geq 10,000$ steps / day or ≥ 150 high cadence min / week to define individuals as active, it was found that approximately 20% of participants were active preoperatively and 35% postoperatively. Similarly, the percentage of individuals reporting ≥ 150 min / week of exercise increased from 30% to 46% from the preoperative to the postoperative period. However, when changes from objective PA measurements were assessed on

a continuous scale, about a quarter of participants decreased their PA by $\geq 5\%$, indicating a considerable number of patients who became less active 1 year after surgery (King et al., 2012). In a different study, using objective and subjective measures of PA assessment, we observed changes in PA 6 months before and after BS. The aim of this study was to quantify changes in PA and SB after surgery-induced weight loss, and to evaluate the agreement between objective and subjective measures of PA. The results showed that 22 of the 38 recruited participants completed the Physical Activity and Lifestyle Questionnaire and submitted valid accelerometer data, and that only 4 of these 22 were 'active' in the pre-surgery period (remaining 2 of them 'active' after surgery). The major finding of this study was the absence of significant changes in PA and SB (objective measures or access through a questionnaire) from 6 months before to 6 months after surgery, despite of a reduction in body mass of 27 kg. There was also poor agreement between objective and subjective measures of PA (Afshar et al., 2017).

Conclusion

Obesity is currently one of the main public health problems worldwide, being considered a disease of concern due to its social, psychological and metabolic repercussions. It is associated with the development of several serious comorbidities and substantially increases the risk of premature death. In particular, individuals with a BMI above 40 m.kg^{-2} have a high risk of developing cardiovascular disease, diabetes, several types of cancer, arterial hypertension, obstructive sleep apnea, locomotor disorders, dyslipidemia and depression (Livhits et al., 2010; Pinheiro et al., 2004).

Effective treatment options for obesity are currently scarce and rely mostly on pharmacological strategies, low energy diets and exercise programs. Due to their lack of efficacy, especially in severe cases of obesity, BS has emerged in the last decade as the most effective strategy for reducing excess body mass in a substantial and long-lasting way. Nevertheless, PA habits have been established as an important predictor of BS effectiveness and durable body mass losses (Welch et al., 2008) and therefore patients are frequently recommended to increase their PA levels following BS in order to optimize BS-associated health outcomes. PA provides numerous physiological and psychological benefits for both adults (Warburton et al., 2006) and children (Poitras et

al., 2016) . Since there is strong evidence indicating that a sufficient amount of MVPA (Arem et al., 2015), and to some extent the reduction of SB (Biswas et al., 2015), are associated with a positive set of health outcomes, reduced mortality and increased longevity. Higher PA levels after BS are associated with additional body mass losses (Egberts et al., 2012) and improvements in motor functions (de Souza et al., 2009). Considering the importance that PA has on the improvement of health and particularly on the optimization of BS-associated health outcomes, it is crucial to determine to what extent post-BS patients adhere to lifestyle and PA recommendations following surgery as well as to what extent the participation in structured exercise programs following surgery contribute to the increase in total PA and sedentary behavior. Answering to these questions will allow us to determine if BS *per se* is enough to induce a significant change in PA patterns or if further behavioral measures are needed.

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Methodology

Patients recruitment, selection and randomization

This study was conducted as a single-center randomized controlled trial (*BaSEIB Clinical Trial - Bariatric Surgery and Exercise Intervention Bone Trial*), with two parallel arms: one intervention and a control group. Inclusion criteria were: i) age between 18-65 years; ii) body mass index (BMI) $>40 \text{ kg/m}^2$ or $>35 \text{ kg/m}^2$ with obesity-related comorbidities; iii) referral to undergo Roux-en-Y Gastric Bypass (RYGB) or Sleeve gastrectomy. Exclusion criteria were: i) use of drugs that interfere with bone metabolism (i.e. bisphosphonates, teriparatide, calcitonin, hormone replacement therapy, chronic use of glucocorticoids); ii) health condition that hinders the ability to exercise (e.g. severe gonarthrosis) and/or that can be aggravated by physical exercise (e.g. uncontrolled arterial hypertension, severe kidney disease, class III-IV NYHA heart failure); iii) known metabolic bone disease (i.e. Osteogenesis Imperfecta, Paget bone disease); iv) peri-menopausal status (amenorrhea > 3 months but last menses <1 year); v) pregnancy or breast-feeding; vi) revisional bariatric surgery; and vii) inability to integrate any of the study groups.

Recruitment was performed based on the patients waiting list for BS of the General Surgery Department of the São João Medical Center. After being identified on the list, medical records were analyzed to determine if inclusion and exclusion criteria were met. Afterwards, an invitation letter with a summary of the study was mailed to all eligible patients (supplementary material 6.1 - 6.3). Thereafter, patients were contacted by phone call to provide more details about the study design. After confirming eligibility criteria with the patients and if they were interested in participating, a visit to the laboratory was made to provide further details about the study, sign the informed consent forms (supplementary material 6.4) and to perform pre-bariatric surgery (BS) measurements. All evaluations were conducted at the Faculty of Sport from the University of Porto. Patients participating in this study were recruited between January 2016 and October 2017.

Randomization was conducted by minimization, which is a covariate adaptive randomization method that ensured that each study group was always balanced regarding the number of patients and a set of predefined covariates (Scott et al., 2002). Factors selected to balance groups were: i) sex, ii) age, iii) BMI class, iv) type 2 diabetes mellitus, v) menopausal status, vi) current thiazide diuretics use and vii)

smoking status.

Initially, equal allocation was conducted in both groups, but after a midpoint interim analysis randomization was changed from balanced (1:1) to imbalanced (3:1) favoring the intervention group, to compensate the higher than expected dropouts and low attendance to the exercise training classes in the intervention group (Altman D; Peckham et al., 2015). The minimization process was conducted with the MinimPy software (Saghaei, 2011), with a 80% random component using the biased coin probability method. Imbalance measure between groups for each covariate was calculated according to the marginal balance method (Saghaei & Saghaei, 2011). The allocation sequence conducted in the minimization process was generated by Research Randomizer (www.randomizer.org) to prevent selection bias. The minimization of RYGB and Sleeve patients was done separately, but the criteria used were the same (factors selected to balance groups and allocation ratio). The research protocol was approved by the São João Medical Center Ethics Committee (reference: CES 192-14) and is registered at ClinicalTrials.gov (identifier: NCT02843048).

Study design

After being recruited and after performing all baseline measurements, participants were randomized to either the control or intervention group. Patients allocated to the CG received the usual medical follow-up care following BS which included prescription of dietary supplements at the time of hospital leave together with the standard nutritional recommendations and were followed at 6 months' intervals during hospital visits. Participants in the CG were informally advised to increase PA but received no structured exercise prescription. Patients allocated to the EG, in addition to the usual medical follow-up participated in a multicomponent exercise-training program, 3x/week in alternative days, 75 minutes, for 5 consecutive months.

Exercise intervention protocol

The exercise-training program started one month after BS due to the need for post-surgical recovery. Each training session consisted of: 1) warm-up (5 min); 2) high impact component (10 min); 3) balance component (10 min); 4) high impact component (10 min); 5) strength component (35 min); and 6) cool down (5 min). Impact training was organized in a circuit composed of 4 to 5 exercises performed in

moderate-to-high intensity measured by accelerometers. Exercises included multi-directional jumps, slaloms and walk/run series, using materials such as steps, cones, poles, agility ladders, jump ropes, jump boxes and treadmills. The training protocol encompassed two alternative blocks: a) circuit of exercises lasting 3 minutes interspersed with 1 min rest; or b) circuit of exercises with 30s duration interspersed with 10s for rest.

Balance component included i) 1 to 2 traditional balance exercises (i.e. support base manipulation, vision and proprioception), ii) 1 or 2 perturbation balance exercises (reaction to external stimulus) and, iii) 1 or 2 multitask balance exercises (performing balance tasks while simultaneously doing a cognitive and/or motor task). Each exercise had 2 sets, lasting 30-45s each with 15-30s rest between sets and 45-60s rest between exercises. Variables used to prescribe the exercises were: base of support, feet position, surface type, sensory input, movement speed, equipment (i.e. mattresses, ankle disks, poles, Swiss balls and beams), perturbation and motor and/or cognitive multitasks. Strength component consisted in 7 to 8 exercises per training session, and encompassed trunk (2 exercises), lower limbs (2 exercises), upper limbs (1 or 2 exercises) and core (2 exercises) muscle groups. Two to three sets were performed in each exercise. The periodization of intensity and rest intervals between sets varied from 10-12, 8-10, 6-8 and 4-6RM with 30, 60, 90 and 120s, respectively. Agonist/antagonist muscle groups were trained in alternate training sessions. Free weights (bars, dumbbells, weight grip plates) and elastic bands were the main equipment's used for the strength exercises. All training sessions were performed as group sessions and supervised by a member of the research team. Further details regarding the intervention program are described in the supplemental material.

Measurements and outcomes

All patients were assessed between 1 to 3 months before BS and reassessed at 1 and 6 months after BS for determination of PA and anthropometry.

Anthropometry

Anthropometric features were assessed with the patient standing and wearing light clothing. Height was measured to the nearest 0.1 cm using a mounted stadiometer (Seca, model 213) with heels together, buttocks and shoulder blades

against the column scale and head positioned in the Frankfurt horizontal plane. Weight was measured to the nearest 0.1 kg using a digital scale (Seca, model 899). Waist circumference was measured as the largest circumference between the top of the iliac crest and the lowest rib at the end of normal expiration with a tape positioned parallel to the floor. Hip circumference was determined as the point of largest circumference over the buttocks with a tape positioned parallel to the floor. Waist and hip circumference were measured to the nearest 0.1 cm. All anthropometric evaluations were measured twice, and the mean was calculated. BMI was calculated as weight (kg) divided by squared height (m^2).

Physical activity evaluation

Daily life PA and sedentary behavior (SB) were objectively measured by accelerometers (GT9X Link, 3.5 X 3.5 X 1.0 cm, 14g, ActiGraph, Pensacola, FL, USA). Participants were asked to wear the accelerometer at the lower back (at the midpoint between the two posterior superior iliac spines) for seven consecutive days during all awake hours, except during activities involving water. The software supplied by the manufacturer was used to initialize the accelerometers at 100 Hz sampling frequency and to download the data (ActiLife version 6.13.3; Actigraph, Pensacola, FL, USA). Vector magnitude activity counts summarized in 60 seconds epochs were used for the data analysis. Data were considered valid when the accelerometer was worn for at least 3 weekdays and 1 weekend day, during at least 10 hours each day. Non-wear time was considered when the accelerometer registered no signal for at least 90 minutes and was excluded from the analysis.

Based on previous literature (Matthews et al., 2008; Troiano et al., 2008), cut-points that identify SB and light (LPA), moderate (MPA) and vigorous (VPA) intensities were determined as follows: ≤ 99 counts per minute – SB; 100-2019 counts per minute – LPA; ≥ 2020 counts per minute – MPA and ≥ 5999 counts per minute - VPA. Average time (in minutes) spent per day in SB and in each PA intensity category, as well as the average number of steps per day were the variables used in the PA data analysis.

Statistical analysis

Data analysis was conducted according to both intention-to-treat (ITT) and per-protocol (PP) approach excluding data from patients who had been non-compliant with the exercise intervention program (defined as attendance of less than 50% of the training sessions). In both analyses, PA variables were obtained from the whole wear time period. A final analysis was also made excluding the time corresponding to the training sessions for all subjects from both groups included in the per-protocol analysis at 6 months post-BS. Data distribution was determined by the Shapiro-Wilk test and it indicated that MVPA and steps had a non-normal distribution and that all other variables had a normal distribution. Log transformations were applied to the non-normal variables prior to statistical analysis with resolution of non-normality distribution. Paired T-tests were used to compare the variables before and one month after BS. Analysis of covariance (ANCOVA) was performed to assess whether there was a group effect on the follow-up values (6 months after BS), using the baseline values as covariate. Differences were considered significant when $p < 0.05$. All analyzes were conducted with the Statistical Package for Social Sciences (IBM Corp., Version 26.0).

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Results

Table 1 shows results from the comparison between 1 month before and 1 month after BS for the anthropometric and PA data. All anthropometric variables significantly decreased (all $p < 0.001$) at 1 month after BS, while for the PA variables, time in LPA significantly decreased ($p = 0.038$), and time in MVPA significantly increased ($p = 0.004$). Time in SB, LPA and MVPA at 1 month before and 1 month after BS are also shown in Figure 1.

Table 1. Anthropometric and physical activity parameters at one month before and one month after BS

Parameters	1 month before BS	1 month after BS	<i>p</i> value
Anthropometric			
Age (years)	44.2 ± 8.0	—	—
Height (cm)	159.1 ± 9.7	—	—
Body mass (kg)	113.8 ± 19.3	102.9 ± 17.4	< 0.001*
BMI (kg·m ²)	44.8 ± 5.1	40.8 ± 4.8	< 0.001*
Waist circumference (cm)	125 ± 14.4	117.5 ± 13.2	< 0.001*
Hip circumference (cm)	132.3 ± 9.0	126.6 ± 10.0	< 0.001*
Physical activity			
SB (min/day)	591.8 ± 80.7	605.2 ± 79.4	0.299
LPA (min/day)	255.1 ± 75.8	229.4 ± 63.1	0.038*
MVPA (min/day)	7.0 (11.5)	10.8 (13.8)	0.004*
Steps (steps/day)	4791.1 (2868.4)	4858.6 (2325.4)	0.419

Data is presented as mean ± standard deviation or median (interquartile range). A p value < 0.05 (indicated by *) is considered significant.

BMI, body mass index; BS, bariatric surgery; LPA, light physical activity; MVPA, moderate to vigorous physical activity; SB, sedentary behaviour.

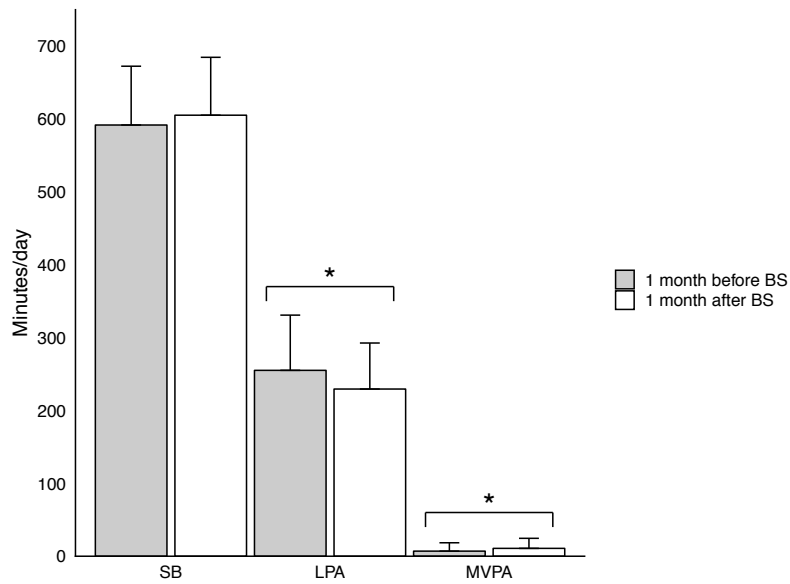


Figure 1. Average time per day spent in SB, LPA and MVPA at 1 month before and 1 month after BS. Data are presented as mean and standard deviation for normally distributed variables (SB and LPA) and as median and interquartile range for non-normally distributed variables (MVPA). Abbreviations: BS, bariatric surgery; LPA, light physical activity; MVPA, moderate to vigorous physical activity; SB, sedentary behavior.

Anthropometric and PA baseline parameters are shown in Table 2 for the ITT and PP analyses. In the ITT and PP analysis, the EG have an average attendance rate of 51.7% and 70.3%, respectively. There were significant baseline differences between groups for both ITT and PP analyses regarding BMI ($p = 0.009$ and $p = 0.002$, respectively) and SB ($p = 0.001$ and $p = 0.005$, respectively). Significant differences for ITT were also detected in LPA ($p = 0.038$) and MVPA ($p = 0.004$), and for PP in hip circumference ($p = 0.039$).

Table 2. Anthropometric and physical activity parameters at one month after BS

Parameters	CG (n = 10)	EG (intention-to-treat, n = 20)	<i>p</i> value	EG (per-protocol, n = 13)	<i>p</i> value
Anthropometric					
Age (years)	47.2 ± 7.4	43.5 ± 8.3	0.230	45.2 ± 8.6	0.547
Height (cm)	156.8 ± 10.0	159.5 ± 9.4	0.489	159.7 ± 9.9	0.512
Body mass (kg)	107.3 ± 15.2	100.7 ± 18.3	0.307	98.5 ± 13.8	0.170
BMI (kg·m ²)	43.5 ± 43.5	39.4 ± 5.0	0.009*	38.6 ± 3.7	0.002*
Waist circumference (cm)	121.5 ± 8.4	115.5 ± 14.8	0.173	114.4 ± 11.3	0.099
Hip circumference (cm)	129.6 ± 7.9	125.1 ± 10.8	0.204	122.3 ± 7.8	0.039*
Physical activity					
SB (min/day)	544.5 ± 59.2	635.6 ± 71.2	0.001*	632.6 ± 76.8	0.005*
LPA (min/day)	248.9 ± 48.2	219.7 ± 68.4	0.038*	225.2 ± 72.4	0.358
MVPA (min/day)	9.1 (9.0)	13.9 (18.8)	0.004*	19.0 (16.9)	0.164
Steps (steps/day)	4631.0 (1859.4)	4858.6 (1955.9)	0.419	5041.3 (1899.0)	0.499

Data is presented as mean ± standard deviation or median (interquartile range). The *p* values refer to the comparison between control group and exercise group (intention-to-treat or per-protocol, with a minimum of 50% attendance in the training sessions). A *p* value < 0.05 (indicated by *) is considered significant.

BMI, body mass index; BS, bariatric surgery; CG, control group; EG, exercise group; LPA, light physical activity; MVPA, moderate to vigorous physical activity; SB, sedentary behaviour.

Analysis of the anthropometric and PA variables of the patients divided in CG and EG at 1 and 6 months after BS for the ITT and PP analysis are presented in Table 3. ANCOVA showed no significant group effect (all $p > 0.05$) for any of the variables, although all covariates showed a significant effect (all $p < 0.05$).

Table 3. Anthropometric and physical activity parameters of control and exercise groups, at one and six months after BS, for ITT and PP analysis

Parameters	CG (n = 10)		EG (intention-to-treat, n = 20)		<i>p</i> value	EG (per-protocol, n = 13)		<i>p</i> value
	1 month after BS	6 months after BS	1 month after BS	6 months after BS		1 month after BS	6 months after BS	
Anthropometric								
Body mass (kg)	107.3 ± 15.2	85.5 ± 10.2	100.7 ± 18.3	79.8 ± 15.9	0.763	98.5 ± 13.8	77.8 ± 14.2	0.744
BMI (kg·m²)	43.5 ± 43.5	34.9 ± 2.8	39.4 ± 5.0	31.1 ± 4.8	0.637	38.6 ± 3.7	30.3 ± 4.6	0.953
Waist circumference (cm)	121.5 ± 8.4	104.1 ± 8.0	115.5 ± 14.8	97.5 ± 17.1	0.752	114.4 ± 11.3	95.8 ± 16.8	0.609
Hip circumference (cm)	129.6 ± 7.9	111.6 ± 8.6	125.1 ± 10.8	106.8 ± 9.7	0.333	122.3 ± 7.8	107.5 ± 9.1	0.427
Physical activity								
SB (min/day)	544.5 ± 59.2	513.0 ± 83.5	635.6 ± 71.2	588.4 ± 104.5	0.707	632.6 ± 76.8	579.6 ± 96.0	0.511
LPA (min/day)	248.9 ± 48.2	297.9 ± 70.9	219.7 ± 68.4	269.0 ± 83.7	0.706	225.2 ± 72.4	271.9 ± 73.8	0.626
MVPA (min/day)	9.1 (9.0)	22.6 (22.4)	13.9 (18.8)	16.0 (22.5)	0.632	19.0 (16.9)	20.2 (18.3)	0.898
Steps (steps/day)	4631.0 (1859.4)	7233.2 (4658.6)	4858.6 (1955.9)	5819.6 (3715.3)	0.467	5041.3 (1899)	5859 (3240)	0.532

Data is presented as mean ± standard deviation or median (interquartile range). The *p* values refer to the analysis of covariance group effect between control group and exercise group (intention-to-treat or per-protocol, with a minimum of 50% attendance in the training sessions). A *p* value < 0.05 (indicated by *) is considered significant. BMI, body mass index; BS, bariatric surgery; CG, control group; EG, exercise group; LPA, light physical activity; MVPA, moderate to vigorous physical activity; SB, sedentary behaviour.

Table 4 shows PA variables analysis at 1 and 6 months after BS, excluding the time corresponding to the training sessions for all subjects from both groups included in the per-protocol analysis at 6 months post-BS. As occurred to the anthropometric and PA variables obtained from the whole wear time period for the ITT and PP analyses, ANCOVA exhibited no significant group effect (all $p > 0.05$), and all covariates showed a significant effect (all $p < 0.05$).

Table 4. PA parameters of CG and EG, at one and six months after BS, PP analysis, removing the training sessions time from the analysis

Parameters	CG (n = 10)		EG (per-protocol, n = 13)		p value
	1 month after BS	6 months after BS	1 month after BS	6 months after BS	
SB (min/day)	544.5 ± 59.2	481.7 ± 81.5	632.6 ± 76.8	554.1 ± 92.7	0.629
LPA (min/day)	248.9 ± 48.2	280.2 ± 68.7	225.2 ± 72.4	252.1 ± 72.0	0.548
MVPA (min/day)	9.1 (9.0)	22.4 (21.8)	19.0 (16.9)	11.7 (15.1)	0.355
Steps (steps/day)	4631.0 (1859.4)	6889.0 (4719.7)	5041.3 (1899)	5553.4 (3362.5)	0.366

Data is presented as mean ± standard deviation or median (interquartile range). The p values refer to the analysis of covariance group effect between control group and exercise group (per-protocol, with a minimum of 50% attendance in the training sessions), removing the training sessions time from the analysis. A p value < 0.05 (indicated by *) is considered significant.

BMI, body mass index; BS, bariatric surgery; CG, control group; EG, exercise group; LPA, light physical activity; MVPA, moderate to vigorous physical activity; SB, sedentary behaviour.

Time in SB, LPA and MVPA at 1 and 6 months after BS are shown in Figure 2, for both groups in all analyses: ITT, PP and excluding the time corresponding to the training sessions.

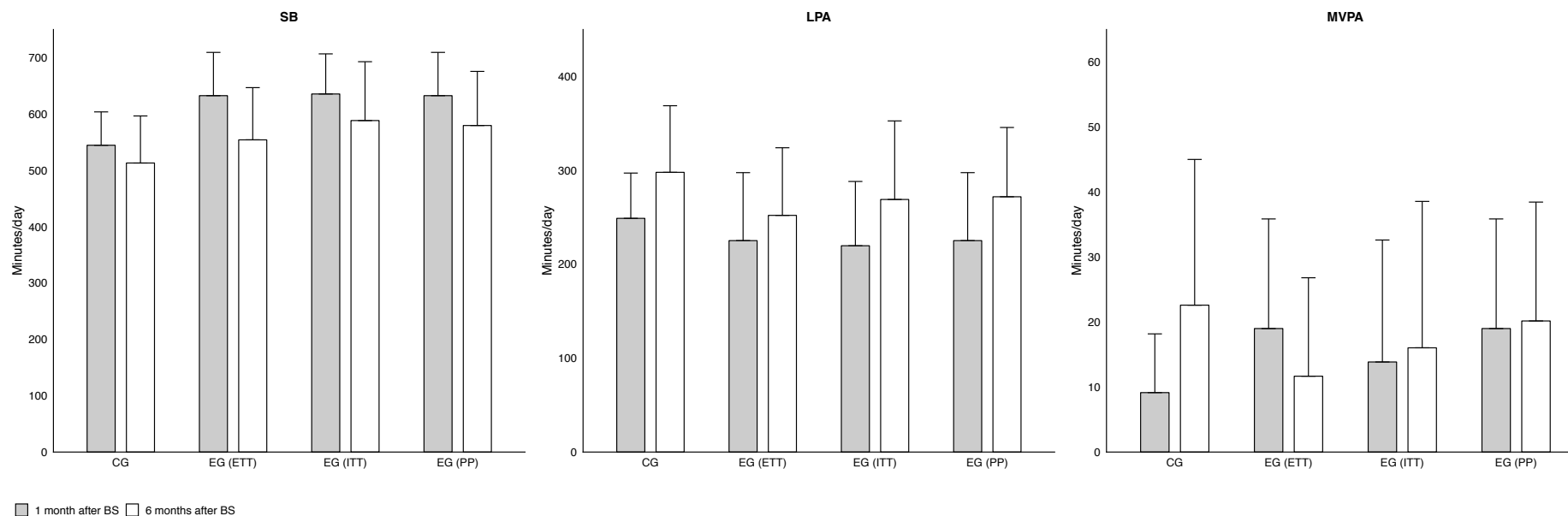


Figure 2. Average time per day spent in SB (left panel), LPA (middle panel) and MVPA (right panel) at 1 and 6 months after BS with the subjects divided in CG and EG for ITT, PP and ETT analyses. Data are presented as mean and standard deviation for normally distributed variables (SB and LPA) and as median and interquartile range for non-normally distributed variables (MVPA). Abbreviations: BS, bariatric surgery; ETT, excluding the time corresponding to the training sessions; ITT, intention-to-treat; LPA, light physical activity; MVPA, moderate to vigorous physical activity; PP, per-protocol; SB, sedentary behavior.

Discussion

The original study supporting this dissertation (BaSEIB clinical trial) aimed to identify the role and value of a structured physical exercise intervention in modulating body composition in patients undergoing BS. Regarding our particular research that supports the present dissertation, we aimed to analyze the effects of BS and the participation in a structured exercise intervention program in the daily PA pattern of these patients and to determine if they adhere to the international guidelines regarding time spent in PA and SB. First, we analyzed the short-term effects of BS comparing the pre- to post-surgery changes in objectively measured PA and anthropometric variables. When compared, 1 month before and 1 month after BS, we found that there were significant differences in all anthropometric values, namely body mass, BMI, waist circumference and hip circumference, as well as in LPA and MVPA. As expected and in accordance with previous studies (Berglind et al., 2015; Crisp et al., 2018), the postoperative anthropometric results revealed a trend for substantial body mass losses after surgery. Nevertheless, regarding the PA patterns at the postoperative moment (1 month after surgery), we can observe that there was a decrease in the time spent in LPA, that went from an average of 255.1 ± 75.8 min/day to 229.4 ± 63.1 min/day, and an increase of the average time spent at MVPA from 7.0 ± 11.5 min/day to 10.8 ± 13.8 min/day. However, this increase, even though being statistically significant has most certainly almost no clinical significance as it is still far below the recommendations of the *American College of Sports Medicine*, which advises a minimum of 30 minutes of moderate intensity daily PA for general health maintenance and disease prevention or $200\text{--}300 \text{ min.wk}^{-1}$ for long-term body mass loss (Donnelly et al., 2009).

As we expected, there were no statistically significant differences in both SB and the number of steps per day since subjects are still within the recovery period. This is possibly because of the short time frame in analysis and the need of recovery from the surgical procedure don't give room to change considerably the PA behavior.

One month after BS, the participants were randomly allocated into CG and EG. Afterwards, the two groups were compared concerning anthropometric and PA baseline parameters at 6 months post-BS follow-up. In order to ensure the validity of our research findings we performed an ITT analysis and found between groups statistically significant differences in BMI, SB, LPA and MVPA. These differences

could be explained by the ITT method itself since it analyses the groups exactly as randomised – including patients without an observed outcome and those who did not take all the projected treatment, or received a different treatment or no intervention (Herman et al., 2009; Moher et al., 2010). We also performed a PP analysis and found statistically significant differences in BMI, hip circumference and SB. This methodology excludes participants who did not adequately adhere to the exercise training protocol being just an observational comparison (Abraha et al., 2007).

When comparing patients of the CG and EG at 1 and 6 months after BS for PA, we found a decrease in SB, and an increase in LPA, MVPA and number of steps. However, the contribution of the exercise was not as desired. Individuals allocated to EG, when compared to CG, due to the fact of being inserted in an intervention of regular exercise training, were expected to have higher values of total PA regardless the intensities, as well as to have higher daily PA beyond that one performed during the exercise-training timetable, and to significantly reduce their SB. At first sight, one could state that the intervention plan was unsuccessful.

Our findings are in agreement with those reported by several authors. Berglind et al. (2015) studied 56 women that underwent RYGB, and examined pre-to post-surgery changes in objectively measured PA. The results have shown that there were no significant changes in MVPA, MVPA in 10-min bouts, LPA, or sedentary time from 3 months pre-surgery to 9 months post-surgery, despite substantial body mass losses.

Afshar et al. (2017) also reported results similar to our findings in a group of 22 individuals, whose daily PA was measured by accelerometer and did not reached the recommended PA levels, either pre and post-surgery. Yet, they had a mean reduction in body mass of 27 kg from before to 6 months after BS.

Herring et al. (2017) studied the effects of a supervised exercise training program 12–24 months after bariatric surgery, in which twenty-four inactive adult patients that underwent BS and whose BMI remained $\geq 30 \text{ kg}\cdot\text{m}^{-2}$ 12 to 24 months after BS, were randomized to an exercise intervention ($n = 12$) or control group ($n = 12$). Supervised exercise consisted of three 60-minute exercise sessions of moderate intensity aerobic and resistance training for 12 weeks. The control participants received only the usual care.

Significant improvements in physical function, anthropometry, cardiovascular health, self-efficacy and PA outcomes were observed directly after 12 weeks of exercise training compared with routine care. After a further 12-week follow-up period,

the exercise group had maintained an advantage over the control participants in terms of physical function, anthropometry and cardiovascular outcomes. Objective measurements indicated that MVPA time was 7.5 min higher per day at baseline in the exercise group and step count and self-reported activity also remained higher at baseline. However, increases in some of these results were also observed in the control group after the counselling session received at the end of the intervention period.

Overall, our findings corroborate observations from others suggesting that after BS changes in PA are modest, and that exercise training seems not to influence this behaviour at a desirable extent, given that there are no significant differences in comparison with controls, and that the mean values of PA at the different categories of intensity, specially MVPA are substantially below the recommended, and SB remains mostly unchanged.

Our findings recall our attention to the known barriers to behavioural change in patients with obesity. Although the self-reported perception of individuals with class II/III obesity of the need to change their life-style and to be more likely to declare they should do something to improve their physical health than other individuals, a study that has examined the barriers to behavior change found that regardless of the obesity class the most reported barrier were the lack of willpower, followed by work schedule and health problems (Bastin et al., 2019). Although the patients in our study received clinical counseling from surgeons, endocrinologists and exercise physiologists regarding the importance to change their lifestyle and PA behaviours, it is possible that interventions with the participation of health providers specialized in behavioral counseling could be more effective, particularly using techniques targeting key drivers of change in beliefs and motives.

In a second data analysis, the per-protocol analysis, we excluded the time corresponding to the training sessions timetable for all subjects in both groups. An approach that did not yield results to much different from the ITT approach. However, if we look more closely at the results, we can see that the EG, which has PA levels below the recommended by international guidelines, without the intervention plan would have even lower values, being even more inactive. This shows that the patients that attended to the exercise-training program have their PA positively influenced. Indeed, we found that the individuals allocated to the EG who had higher adherence presented a higher MVPA. This shows that these individuals performed most of their

total MVPA at exercise training sessions, and that the rest of the day was mostly filled with sedentary behaviours. This can be explained by several factors: a greater sense of vigour due to body mass loss and being resigned with PA periods in the exercise sessions, feeling tired after class, and therefore avoiding exertional activities in other periods of their daily life.

Although the absence of statistically significant differences between groups, we found a gradual reduction in the mean values of anthropometric variables (BMI, waist circumference, hip circumference). This presupposes that body mass losses continue over the first 6 months, in accordance to what has been described in previous studies (Wolfe et al., 2018). However, it is known that the body mass losses after bariatric surgery are due to decreases both in fat and lean mass. This is a matter of concern because excessive loss of lean mass can adversely influence neuromuscular function and bone health (Boppre, 2017). Therefore, exercise training and habitual PA could be of importance in preventing or mitigating loss of lean mass during periods of body mass loss related to bariatric surgery.

The present study has some limitations that must be mentioned. The first one is that we cannot ensure that the subjects allocated into the CG group were not exercising regularly. Indeed, for ethical reasons all patients that undergo bariatric surgery are advised to become more physically active and motivated to be involved in structured exercise. The second one, is the fact that the subjects of each group were not paired according to age, which is an important predictor in the body mass loss process and that older adults find it difficult to meet moderate and vigorous exercise targets, as previously described by (Sparling et al., 2015). Another limitation is related with the removal of the 3 hours of intervention time in both groups, given the fact that we do not know if the CG performed any kind of PA in the meantime. Regarding the two types of data analysis, ITT and PP, it appears that PP itself is a limitation, once it should be properly labelled as a non-randomized, observational comparison (Moher et al., 2012).

Besides the above-mentioned limitations, this study has an important set of strengths. We believe that its added value because of the rigorous and meticulous methodology used - it followed the international guidelines for conducting clinical trials (Moher et al., 2012; Ranganathan et al., 2016). Also, it allowed a group of patients to have access to an intervention treatment protocol, supervised by well qualified professionals with no financial cost to the patient, that otherwise they would not have

access to. Third, it encompasses a condition that has never been tested, which is the removal of the 3 hours of intervention time in both groups, allowing to see the effective benefits of the treatment itself.

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Conclusion

In the present investigation, we can see a brief literature review and an experimental study. Based on this study we can take five capital conclusions: i) BS had no major effect on the PA pattern despite a significant increase in MVPA. Given the interindividual variability expressed by standard deviation, this outcome is clinically irrelevant; ii) BS, as expected, resulted in a significant decrease of the mean value of all anthropometric variables assayed; iii) absence of effect of the multicomponent regular exercise program, showing no efficacy regarding the alteration of the PA and sedentary time variables; iv) despite the absence of the difference between groups on the PA alterations at 6 months follow-up after BS, for the EG the program allowed its average PA values not to be even lower than the recommended; and v) for both groups, a decrease in the average values of anthropometric variables over the 6 months follow-up was observed, however without differences between groups.

This study made an important contribution to understand the effect of surgery on the PA pattern and the impact that participating in a structured exercise program has on several PA variables. However new strategies, new training proposals, and maybe longer interventions, aiming to reach increased PA levels should be developed in the future.

Supplemental Material

Exercise training program – BaSEIB

The intervention program began one month after BS and was extended for 22 weeks. The exercise training program started one month after the surgery due to post-surgical recovery needs. The exercise-training program was divided into two periods: an adaptation phase, with 1-month duration and a 4-month intermediate/advanced phase. The adaptation phase was planned due to the low participant's physical fitness, decreased motor skills and post-surgical care (i.e. avoid excessive intra-abdominal pressure) that should be considered until the second month after surgery.

The exercise training program aimed to develop three fundamental components: impact, balance and strength. Each training session was designed according to Figure 3, with a 75min duration and in 3 alternated week days always supervised by physical exercise experts in Faculty of Sport, University of Porto.

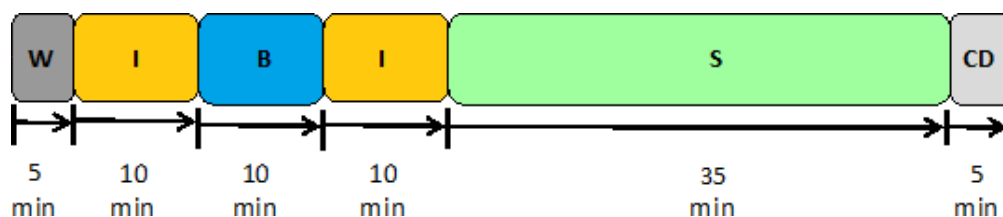


Figure 3. Representation of training sessions structure (W - Warm up; I - Impact component; B - Balance component; S - Strength component; CD - Cool down).

Table 5 presents the characteristics of training components. Impact was composed by 4 to 5 exercises according to a circuit training regime. Balance comprised 4 to 5 exercises working postural control in static and dynamic conditions. The last component, strength was composed by 7 to 8 exercises focusing on muscular groups of the trunk, upper and lower limbs.

Table 5. Characteristics of training components.

Components	Exercises	Work regime	Time/ Repetitions	Rest
Impact	- 3 to 4 multidirectional jumps - 1 to 2 run/slalom exercises	Circuit	3min or 30s	1min or 10s
Balance	- 1 to 2 basic balance exercises - 1 to 2 external perturbation exercises - 1 to 2 multitask exercises	2 series	30-45s	15-30s
Strength	- 4 exercises for large muscle groups - 1 to 2 exercises for small muscle groups - 2 core exercises	2 to 3 series	4 to 12 repetitions	30s-2min

Impact

This training component aimed to manipulate 4 variables: magnitude (amount of mechanical stimuli), direction (antero-posterior, medio-lateral and vertical) and frequency (number of stimuli/time) (Guadalupe-Grau et al., 2009; Kohrt et al., 2004). In each session the circuit training was composed by multidirectional jumps and run/slalom exercises with different times of execution and rest (Table 5). Two approaches were used to prescribe impact exercises to the intermediate/advanced phase: a) 3min of continuous execution of all exercises of the circuit interspersed with 1min rest; or b) 30s continuous execution in each exercise station followed by 10s rest. These two options of impact protocol were applied alternatively among training sessions. The two impact blocks together promoted 20min of moderate to vigorous physical activity (Figure 4). To exercise performance were used materials such as steps, agility ladders, jump ropes, jump boxes, poles, cones and treadmills. Adaptation phase comprised low impact exercises in treadmill gait with speed varying between 3 to 6 km/h according to participants' skills and physical fitness.

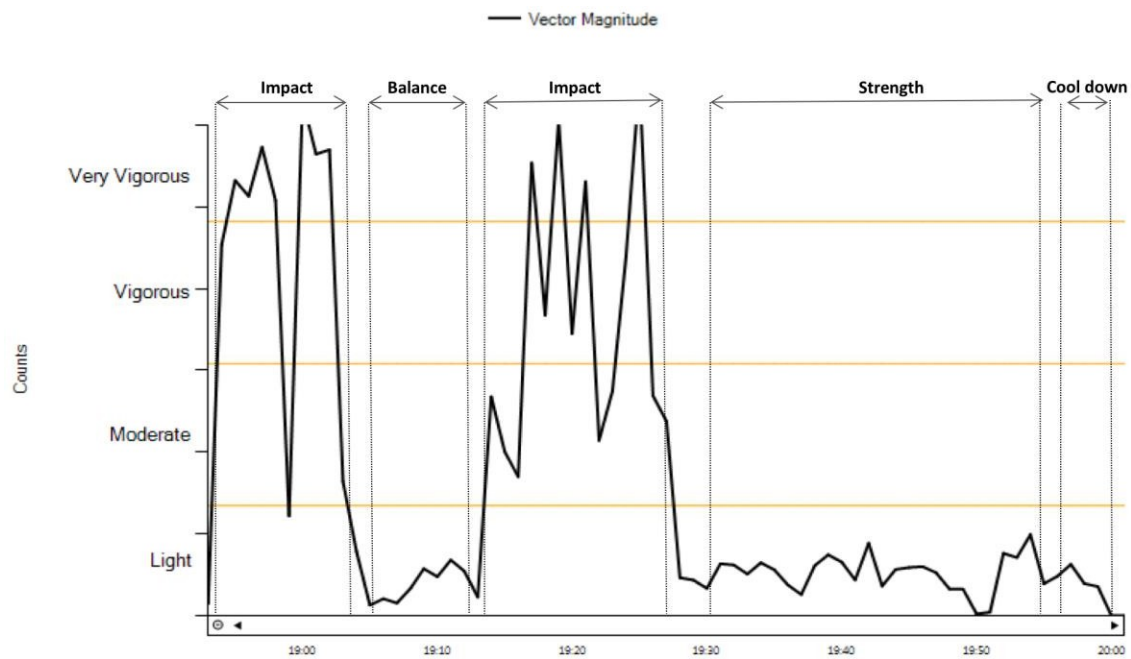


Figure 4. Representation of one training session intensity through accelerometer output obtained from the ActiLife software.

Balance

The exercise training program tried to improve balance capacity both in the static and dynamic conditions. In the intermediate/advanced phase, static condition includes exercises to sustain balance in the bipodal or unipodal base support, whereas dynamic condition includes tasks that involve space progression (e.g. gait). Balance component was composed by 1 to 2 exercises focusing in improving basic balance skills (e.g. manipulation of base support, vision and proprioception), 1 to 2 external perturbation exercises and 1 to 2 multitask exercises (Table 5). Each exercise comprised 2 series with 30 to 45s of execution time each and 15 to 30s rest (Table 5). Table 6 and 7 show balance prescription variables and an example of progressive difficulty increment is exhibited in Figure 5. In the adaptation phase, exercise prescription aimed to execute correctly basic tasks to posteriorly facilitate the progression of balance exercises. In this phase variables such as base of support, feet position, alternated surfaces and vision are manipulated. To perform exercise, we used materials such as ankle disks, swiss balls, balls, bars, cones, beams, rackets and gymnastic mattresses.

Table 6. Static balance exercise prescription.

Exercise variables	Examples
Base of support	Stable to unstable: bipedal – semi-tandem – tandem – one leg stance
Position of feet	i.e., lateral or medial weight shift on heels or toe angle in or out
Surface	i.e., from soft to hard (e.g., grass to concrete), from stable to unstable (e.g., concrete to sand)
Sensory input	Impede vision or hearing
Speed of movement	Decrease or increase of execution speed (e.g., upper arm movements)
Equipment	Use of free weight, elastic bands, balls...
Perturbation	Reaction to external stimulus applied varying in speed, amplitude and direction on ankle, hip, trunk or shoulder level
Multitask - Motor tasks	Involves doing a primary task (e.g., maintaining postural control) while performing a secondary task (e.g., a manual task such as carrying an item)
Multitask - Cognitive tasks	Involves doing a primary task (e.g., maintaining postural control) while performing a secondary task (e.g., naming objects or arithmetic task)

Adapted from Gschwind et al. (2013)

Table 7. Dynamic balance exercise prescription.

Exercise variables	Examples
Base of support	Stable to unstable: normal gait – narrow gait – overlapping gait – tandem gait
Position of feet	i.e., lateral or medial weight shift on heels or toe angle in or out
Surface	i.e., from soft to hard (e.g., grass to concrete), from stable to unstable (e.g., concrete to sand)
Sensory input	Impede vision or hearing
Speed of movement	Decrease or increase of execution speed (e.g., upper arm movements)
Equipment	Use of free weight, elastic bands, balls...
Perturbation	Reaction to external stimulus applied varying in speed, amplitude and direction on ankle, hip, trunk or shoulder level
Multitask - Motor tasks	Involves doing a primary task (e.g., maintaining walking speed) while performing a secondary task (e.g., a manual task such as carrying an item)
Multitask - Cognitive tasks	Involves doing a primary task (e.g., maintaining walking speed) while performing a secondary task (e.g., a cognitive challenge such as counting backwards)

Adapted from Gschwind et al. (2013)

**Figure 5.** Example of balance exercise progression. Adapted from Gschwind et al. (2013)

Strength

Strength component was composed by 2 exercises focused in large trunk muscle groups (anterior or posterior trunk region), 2 exercises in large lower limb muscle groups (anterior or posterior thigh region) 1 or 2 exercises in small lower limb muscle groups (anterior or posterior arm region) and 2 exercises in core (abdominals and/or lumbar). Strength training session was split in two ways: A) anterior trunk region muscle groups + anterior thigh region muscle groups + posterior arm region muscle groups + core; B) posterior trunk region muscle groups + posterior thigh region muscle groups + anterior arm region muscle groups + core. Training A and B were performed intercalated between sessions (table 6). Strength training was composed by a mesocycle that englobes eleven microcycles (Table 8). Microcycle characteristics are described in table 5. Microcycle A (adaptation phase) was performed in a circuit regime to increase participant's muscle and joint resistance and to acknowledge basic strength training techniques (e.g. squat or push) always avoiding high intra-abdominal pressures. The intermediate/advanced phases include microcycles H1, H2, S1 and S2 with the purpose of optimizing muscle mass and maximal strength (Schoenfeld, 2010). In these microcycles training was performed in a series regime following the next order: 1) anterior or posterior trunk region muscle groups; 2) anterior or posterior thigh region muscle groups; 3) anterior or posterior arm region muscle groups; 4) core (abdominals and/or lumbar). In microcycle R, participants executed a low intensity strength training to promote a recovery period. We used materials such as: free weights (weight bars, dumbbells, weight grip plates, fitness balls and elastic bands.

Table 8. Strength training periodization.

Training type	Mesocycle - 5 training months (22 weeks)										
	A	H1	H2	S1	S2	R	H1	H2	S1	S2	R
Weeks	4	2	2	2	2	1	2	2	2	2	1

Adapted from Boppre (2017)

Table 9. Strength microcycle characteristics.

Phase	Exercises	Number of exercises	Series	Repetitions	Rest between series	Rest between exercises	Execution velocity
H1	Trunk	2	3	10 - 12 RM	30"	1'	1:3
	Lower limbs	2	3				
	Upper limbs	2	2				
H2	Trunk	2	2	8 - 10 RM	1'	1'30"	1:3
	Lower limbs	2	3				
	Upper limbs	2	2				
S1	Trunk	2	2	6 - 8 RM	1'30"	2'	1:1
	Lower limbs	2	3				
	Upper limbs	1	3				
S2	Trunk	2	2	4 - 6 RM	2'	2'30"	1:1
	Lower limbs	2	2				
	Upper limbs	1	3				

Abbreviations: RM - maximal repetition.

Adapted from Boppre (2017)

Table 10. Example of an **annual** strength training plan.

Year	Month	Week	Days	Micro	Training		Year	Month	Week	Days	Micro	Training
2017	July	10 — 16	10				2017	October	23 — 29	23	A	
			12							25	A	
			14							27	A	
		17 — 23	17				2017	November	30 — 5	30	H1	A
			19							1	H1	B
			21							3	H1	A
		24 — 30	24						6 — 12	6	H1	B
			26							8	H1	A
			28							10	H1	B
2017	August	31 — 6	31						13 — 19	13	H2	A
			1							15	H2	B
			3							17	H2	A
		7 — 13	7						20 — 26	20	H2	B
			9							22	H2	A
			11							24	H2	B
		14 — 20	14						27 — 03	27	S1	A
			16							29	S1	B
			18							1	S1	A
		21 — 27	21				2017	December	4 — 10	4	S1	B
			23							6	S1	A
			25							8	S1	B
2017	September	28 — 3	28						11 — 17	11	S2	A
			30							13	S2	B
			1							15	S2	A
		4 — 10	4						18 — 24	18	S2	B
			6							20	S2	A
			8							22	S2	B
		11 — 17	11						25 — 31	25	R	A
			13							27	R	B
			15							29	R	A
		18 — 24	18				2018	January	1 — 7	1	H1	B
			20							3	H1	A
			22							5	H1	B
		25 — 1	25						8 — 14	8	H1	A
			27							10	H1	B
			29							12	H1	A
2017	October	2 — 8	2	A					15 — 21	15	H2	B
			4	A						17	H2	A
			6	A						19	H2	B
		9 — 15	9	A					22 — 28	22	H2	A
			11	A						24	H2	B
			13	A						26	H2	A
		16 — 22	16	A				February	29 — 4	29	S1	B
			18	A						31	S1	A
			20	A						2	S1	B

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