

The effect of virtual reality on a home-based cardiac rehabilitation programonbodycomposition,lipidprofileandeatingpatterns: A randomized controlled trial^{\$}

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ABSTRACT

Introduction: Subjects with cardiovascular diseases are referred to cardiac rehabilitation, with a possibility of using virtual reality environments. The study aimed to analyze the effect of a home-based specific exercise program, maintenance phase, with a six months period, performed in a virtual reality (Kinect) or conventional (booklet) environment, on the body composition, eating patterns and lipid profile of subjects with coronary artery disease.

Methods: A randomized controlled trial was conducted with subjects from a hospital in Porto, Portugal. Subjects were randomly assigned to either intervention group 1 (n = 11), whose program encompassed the use of Kinect; or intervention group 2, a booklet (n = 11) or a control group, only receiving education concerning cardiovascular risk factors (n = 11) during 6 months. Beyond the baseline, at 3 and 6 months the body composition was assessed with a bioimpedance scale and a tape-measure, eating patterns with the semi-quantitative food frequency questionnaire and three months later, the lipid profile with laboratory tests. Descriptive and inferential statistical measures were used with a significance level of 0.05.

Results: The intervention group 1 revealed significant improvements in the waist-to-hip ratio after 6 months (p = 0.033) and, between the baseline and third month, when compared with the control group (p = 0.041). The intervention group 1 also decreased their ingestion of total fat (p = 0.032) after six months and increased the high-density lipoprotein cholesterol (p = 0.017) 3 months after the program's conclusion. Conclusions: The virtual reality format had a positive influence on body composition, specifically on the waist-to-hip ratio, in the first three controls.

1. Introduction

Cardiovascular diseases are still the main cause of death in Europe, with coronary artery disease responsible for nearly 20% of the annual deaths [1]. These subjects are usually referred to cardiac rehabilitation (CR) programs. A multidisciplinary CR program is an

 $\label{lem:abbreviations: CG, control group; CR, cardiac rehabilitation; HR, heart rate; IG1, intervention group 1; IG2, intervention l group 2.$

essential component of cardiovascular diseases prevention and management [2], as the case of the coronary artery disease, that aims to optimize the reduction of cardiovascular risk, facilitate the adoption and adherence to healthy behaviors, reduce disability, promote an active lifestyle [3] and so improve the functional capacity and quality of life [4].

Obesity is a controllable risk factor and able to influence many other factors, so anthropometric assessments and the identification of excess weight may help to identify and provide early control of cardiovascular risk. The occurrence of heart-related complications is linked not only to the excess weight, but also to fat distribution, since the accumulation of fat in the abdominal region increases the risk of developing metabolic disorders associated

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with heart disease, and visceral fat seems to have great influence on metabolic risk [5,6]. An unhealthy diet and a sedentary lifestyle might have an impact on energy balance and contribute to put on weight [7]. Several eating patterns can influence the risk of developing coronary artery disease, as well as its main risk factors [8].

CR programs are linked to improvements in obesity indexes and on the levels of plasma lipids (lipid profile) [9,10]. Regular physical activity can contribute to disrupt the vicious circle between inactivity and excess weight, leading to improvements in the body composition and lipid profile, and reducing the cardiometabolic risk [7]. However, despite the known benefits of CR, participation and adherence are still lower than what practitioners aim for, due to significant barriers [2,9]. Several barriers to CR still exist in hospital settings, such as long distances and uneasy access [9].

Home-based CR programs are one way to fight some causes of low adherence [11]. Appropriately prescribed home-based programs have been reported to be acceptably safe and effective when compared with conventional, medically supervised group programs [2]. The implementation of home-based programs has been increasingly suggested, as a way to lessen the dropout rates and promote the setup of the maintenance phase (the last phase of CR) [12], that focuses on long-term prevention, representing the long-term outpatient supervision of patient compliance to prescribed lifestyle [13]. Nevertheless, according to Clark et al. [14], only the community and telehealth based individualized, multifactorial models were associated with improvements in the risk profile for cardiovascular diseases similar to hospital-based programs.

In the study of Brubaker et al. [15] the data indicate that the home-based program, maintenance phase, was as effective as the hospital-based CR program at improving/maintaining blood lipids, and body weight/composition. These authors suggested that a home-based program with a maintenance component could be offered as a low-cost alternative to hospital-based programs. This was based on similar success being achieved in the group that had no contact with the CR program. This was likely to be due to their prior experience in CR program and knowledge of follow-up testing [15]. According to Pinto et al. [16], in a group of participants that received a home-based intervention (a six month program of exercise counseling after the training phase of CR delivered via telephone, print materials and feedback reports) and a contact control group, this intervention, in their patient population, could help maintain exercise. In addition it prevents regression and increased motivational readiness for exercise, and improve physical functioning.

Nowadays, there are still a lack of long-term studies focusing on new approaches to home-based CR however, resorting to technology has been suggested as a potential tool [11]. In this context, new technologies might contribute to increasing the amount of innovative intervention strategies, as well as the levels of motivation and predisposition of patients [17]. There has been interest in the use of virtual reality technology for developing tools for rehabilitation as a physical therapy. The idea of virtual realitybased rehabilitation is to use sensing devices [18]. Industrial motion sensors and, in particular, entertainment oriented ones are useful as physical rehabilitation tools. One of the possible resources is the Microsoft Kinect that is a webcam-style add-on peripheral intended for the Xbox 360 game console [19] and is composed of several sensors that is able to act as a tracking device [20]. Microsoft Kinect has a video camera, along with a depth sensor (which allows to measure the distance between an object and the Kinect) [21], providing a full-body 3D motion capture and joint tracking capabilities without markers or handheld controllers [18]. Using the Kinect, the virtual exercise programs, are becoming increasingly popular in rehabilitation [17].

So, the goal of this study was to analyze the effect of a specific exercise program which was designed to be performed at home during the maintenance phase of CR, over a six-month period. The study compared a virtual reality format (Kinect) to a conventional format (booklet) and measured changes in body composition, lipid profileandeating patterns, for subjects with coronary artery disease.

2. Methods

2.1. Sample

The sample for this randomized controlled trial, using a three arm, parallel group over 23 months, was obtained from the *Centro Hospitalar do Porto* (Porto Healthcare Center in Portugal). The target population was composed of subjects who had just completed the training phase of CR at the Cardiovascular Prevention and Rehabilitation Unit and having been individually invited to participate in this study. The enrollment and assignment was conducted by the research coordinator, with the support of the responsible of the Unit, according to the inclusion and exclusion criteria.

Eligible subjects were men and women, aged between 40 and 75 years, with coronary artery disease, diagnosed and stabilized, with no unstable angina and complex ventricular arrhythmias [22-25] with or without percutaneous coronary intervention and a final diagnosis of acute myocardial infarction or stable angina pectoris, that completed training phase of CR at the Cardiovascular Prevention and Rehabilitation Unit; and had access to a computer with Microsoft Windows 7 (minimum). The exclusion criteria included heart surgery, non-completed stress test due to maximum fatigue, pregnancy or planning to get pregnant, cardiovascular high risk [22,24,25] according to Pescatello et al. [26], pacemaker, severe neurological, musculoskeletal or pulmonary diseases, and, uncompensated metabolic disorders, reported dementia [24-26], cardiomyopathies and previous cardiorespiratory arrest non-associated with acute myocardial infarction or heart procedures. Additionally, those who had significant and uncompensated visual [24] and auditory deficits, those who were uneducated and/or with no fluency in Portuguese and those who had attended or planned to attend gym or regular physical exercise programs were excluded.

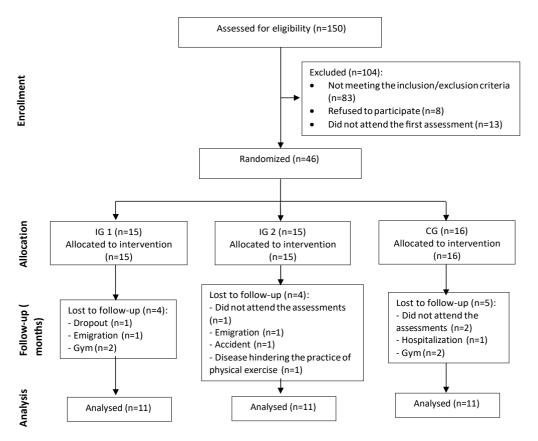
The flow diagram is presented in Fig. 1. The participants were randomly assigned to one of three groups: Intervention group 1 (IG1) – allocated to a home-based CR program, using a computer and Kinect (virtual reality format) (n = 15); Intervention group 2 (IG2) – allocated to a home-based CR program using a paper booklet (conventional format) (n = 15); and a Control group (CG), only subjected to education regarding the cardiovascular risk factors (n = 16). A randomization by blocks was used, and an allocation sequence based on a fixed block size of 3 was generated with a computer random number generator by an investigator not involved in the trial.

Throughout the follow-up 4 subjects were excluded from IG1 and from IG2, and 5 from CG. Therefore, the final sample was composed of 33 subjects: IG1 n = 11, IG2 n = 11 and CG n = 11.

2.2. Instruments and Procedures

The study was approved by the Ethics Committee of the *Centro Hospitalar do Porte*-Teaching, Coaching and Research Department N/REF.ª-212/12 (165-DEFI/157-CES) and by the Ethics Committee of the Health School, Polytechnic Institute of Porto — 1489/2012.

All procedures were conducted according to the Declaration of Helsinki and the study is registered at ClinicalTrials.gov (NCT02753829). Data collection took place at the Cardiovascular Prevention and Rehabilitation Unit and the Health School of Porto.



 $Fig.\ 1.\ Flow\ diagram\ patients\ (Assessed\ for\ eligibility\ n=150).\ CG,\ Control\ Group;\ IG1,\ Intervention\ Group\ 1;\ IG2,\ Intervention\ Group\ 2.$

A pilot study was conducted among 10 subjects whose characteristics resembled the ones from the target population, with the aim of assessing the feasibility of the exercises, the reliability of the instruments and to improve the time management of data collections. The assessment of the study encompassed four moments: a baseline/initial moment (M0), right after the termination of the training phase and before the beginning of the program; an intermediate moment (M1), three months after the beginning of the program; a final moment (M2), six months

after the beginning of the program; and a moment nearly three months after the conclusion of the program (M3) (Fig. 2).

2.2.1. Measurements

The participants filled in a sample selection and characterization questionnaire, made up of demographic questions and questions regarding medical history and CR.

Bioimpedance, body mass index and calculation of ratios were used to assess the body composition. At M0, the researchers started

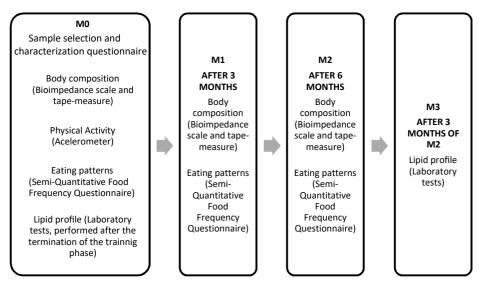


Fig. 2. Time management of the study and respective collections and instruments. M0, baseline/initial moment; M1, intermediate moment; M2, final moment; M3, three months after the program's completion.

by making three measurements of height and considering the mean value. To that effect they used an inelastic tape-measure with a precision of 0.1 cm to a maximum of 2 m [27], measured in the final moment of inspiration at tidal volume, during apnea, with the participants in a standing position, barefooted and with their heels, buttocks and posterior side of the head against a wall [28].

Shortly after that, they proceeded to the assessment of the bioimpedance using a Tanita InnerScan bioimpedance scale, model BC-545 TM (EUA), weight and lean mass in kg, total body fat percentage and body fat at the trunk percentage, with the participants undressed, barefooted, and with their heels aligned with the electrodes of the platform, with no metallic objects [29]. The participants were told to avoid alcohol, caffeine and heavy meals in 24 h before, urinating half an hour before weighing and not carry out intense physical activity 4 h before [28,29]. The bioimpedance scale had a capacity of 150 kg, with a precision of 0.1 kg for weight and 0.1% for fat mass percentage [29], as well as a criterion validity with dual-energy X-ray absorptiometry of r = 0.89 [30]. The intra-observer reliability of the pilot study was remarkable (ICC=0.94) [31].

Height and ratio were used to calculate the body mass index = $\frac{\text{Bodymass}0\text{KgP}}{\text{Height}^2\text{omb}}$. Each participant was classified as having: Normal Weight –18,5-24,9; Excess weight –25-29.9; and

Normal Weight -18,5-24,9; Excess weight -25-29.9; and Obesity $-2:30 \text{ kg/m}^2$ [26].

The tape-measure was also used to assess perimeters and subsequently to calculate ratios, which had presented an excellent intra-observer reliability in the pilot study (ICC = 0.90) [31]; three non-consecutive measurements were performed in each part midpoint between the lowest rib and the iliac crest (waist) and the great trochanters (hip) — at the end of inspiration at tidal volume, using the mean value. The participants were placed with their arms hanging loosely at both sides and feet shoulder width apart [28,32]. Midpoint between the lowest rib and the iliac crest was divided by the great trochanters perimeter, in order to obtain the waist-to-hip circumference [28], and the midpoint between the lowest rib and the iliac crest perimeter was divided by height to obtain the waist-to-height circumference ratio [33,34].

Later on, and only for sample characterization purposes, physical activity was measured with an ActiGraph accelerometer, model GT3X (head office at 49 East Chase Street Pensacola, FL 35502, USA), with the support of a record sheet. The accelerometer was placed vertically over the anterosuperior iliac crest, being removed only before sleep and prior to under-water activities [35]. Troiano's accelerometry cut points for different counts were considered to classify physical activity, as well as the sedentary (:99), light (2t00 and 2019) and moderate to vigorous (2: 2020) [36]. Participants were requested to use it during seven days running, having been included at least four valid days (a minimum of 600 min of gatherings), with at least one day at the weekend [36,37]. The ActiLife software was used to register data at every 5 s (epoch).

With the goal of assessing the participants' eating habits and patterns over the last twelve months, each participant took home the Semi-Quantitative Food Frequency Questionnaire, validated for the Portuguese population [38], to be filled in. The intra-observer reliability of the pilot-study was fair (ICC = 0.54 for calorie intake, ICC = 0.58 for total fat and ICC = 0.55 for carbohydrates) [31]. Later on, Food Processor Plus (ESHA Research, Salem, Oregon) was used to convert food into the nutrients chosen for analysis (calories, total fat and carbohydrates) [38].

In addition, data from the laboratory tests performed at *Centro Hospitalar do Porto* were gathered, total cholesterol levels in blood, high-density lipoprotein and low-density protein cholesterol, and triglycerides, obtaining the lipid profile.

2.2.2. Intervention

The researchers delivered pamphlets with information on the risk factors for cardiovascular disease, which focused on eating habits, smoking and physical activity. The pamphlets were presented and questions regarding the pamphlets were answered. A leaflet with a brief presentation of the study was also distributed. Before moving on to the exercise protocol and respective instructions, the subjects of the intervention groups attended three classes of teaching and demonstration (namely regarding the preparation of home space), with at least a one-day break between them [24,25]. IG1 was also taught on how to use Kinect.

Heart rate (HR) training for each participant was determined using the Karnoven's formula, with the HR reserve, based on the maximum HR of the stress test and obtaining the basal HR with the participant in a sitting and relaxed position. A Polar Wearlink Coded cardiofrequencimeter, model FT7 with watch, with an excellent precision (error of $\pm 1\%$ or $\pm 1\%$ bpm) [39] was used to determine the HR training, as well as the number of repetitions.

The exercise protocol was adapted to the characteristics of the home context in the form of a self-monitoring system, presenting two progressive levels, so as to meet the principles of overcharge, specificity and reversibility, being performed at moderate intensity. At level 1 of the exercise protocol, the exercise intensity was 65% of the HR reserve. Three months passed, participants moved to level 2, with an intensity of 70% HR reserve [26,40]. Exercise progression was made by increasing the number of repetitions, series and/or with modifications in the way how the exercise was performed.

The exercise intensity and the number of repetitions were also monitored with the Borg scale of perceived exertion (ratings between 6 and 20), so as to achieve an interval between 12 and 13 [25,26,40]. The scale presents a criterion validity of r = 0.62 when compared with HR and r = 0.64 when compared with VO2 max [41]. The exercise protocol was performed three times a week [42], over six months [24,25], in the most suitable time for each participant. In addition, in the remaining days, a daily walk of 30 min was recommended [42].

The exercise protocol (Table 1), designed by a certified expert in Physical Therapy with five years of experience in the field and adapted from Noites et al. [43], was made up of 10 exercises: a warm up exercise; seven exercises of conditioning workout aimed at enhancing muscular endurance and/or strength, and two exercises to increase limb flexibility. Additionally, exercises 1, 4, 6 and 7 were also aimed at improving balance, as well as exercise 5 and progression of exercise 3 were aimed at improving thoracic curve.

IG2 performed the home-based program with paper booklets for consultation. IG1's program included the use of Kinect (Microsoft) and a computer, having the system been installed at each participant's home. The Kinect-RehabPlay project, developed in the Faculty of Engineering, University of Porto [20], relies on software to monitor and evaluate the rehabilitation exercises, which have to be performed by the user and captured by the Kinect sensor, providing him/her with real time feedback about the given challenge. This system provides a virtual physical therapist performing the exercise and providing indications concerning the quality of execution. The participant is also represented as a second avatar, which interactively follows the physical therapist [20]. The software uses the Microsoft Kinect to track individual movement and making a match with a pre-defined pattern. This feature monitored the number of repetitions for each exercise, according to the pre-calculated value, and set it to the individual exercise profile. The same was referenced in the program along with the respective exercise.

Table 1 Presentation of the exercise protocol.

Session pha	ase	Exercise	Description
Warm up 10 min		1—Marching in place	Hip flexion, below the waist level, with flexion of the contralateral glenohumeral joint, always in the same place.
			After 3 months perform hip flexion up to the waist level.
Workout	Strength 20-25 min	2—Squats	With feet shoulder width apart, perform knee flexion, without going over the toes, with bilateral flexion of the glenohumeral joint to 90° .
	(to each individual repetitions		After 3 months perform 2 series with a 1 min break.
	calculated by 65-70% of the HR reserve)	1—Crossing	Keep marching in place throughout the exercise; perform the 1st proprioceptive
			neuromuscular facilitation diagonal for bilateral upper limb flexion
			(glenohumeral flexion, adduction and external rotation).
			After 3 months perform 2 series with a 1 min break the 2nd proprioceptive neuromuscular facilitation diagonal for bilateral upper limb flexion
			(glenohumeral flexion, abduction and external rotation).
		4—Ankle movement	Dorsiflexion/plantar flexion of the ankles while standing.
			After 3 months perform 2 series with a 1 min break.
		5—Backward movements	Keep marching in place throughout the exercise; perform extension, abduction
		of the arms	and external rotation of the glenohumeral for the complete range. At the end of
			the movement forcefully increase range of movement 10 times.
			After 3 months perform 2 series with a 1 min break.
		6—Sit and stand	Sitting in a chair with the upper limbs crossed over the chest. Sitting should be performed in a controlled movement.
			After 3 months down seat height.
	Endurance 35-	7—Step forward,	Perform forward and backward half-step with bilateral upper limb flexion, and
	45 min	Sideways and	sideways half-step with bilateral upper limb abduction and external rotation.
	(to each individual repetitions	Backward 8—	After 3 months perform 2 series with a 1 min break.
	calculated by 65-70% of the HR reserve)	Walk (30 m	After 3 months, if possible, increase to 60 min.
	,	inutes)	1
Stretching		9—Calf muscle stretching	Stretch the triceps surae
6 min		0	4 repetitions/maintain 15 s
		10—Anterior forearm	Stretch the wrist flexors
		muscle stretching	4 repetitions/maintain 15 s

HR, Heart Rate.

The CG was only subjected to education on the cardiovascular risk factors; daily walks were also encouraged, similar to what happened with the intervention groups.

Throughout the study, the subjects in IG1 and IG2 added the HR values, Borg rating and eventual comments on an 'Exercise Diary' during sessions and in this way proving their assiduity to the exercises and so their adherence to the program. Phone contacts were scheduled for the weeks 4, 10 and 22, as well as home visits or in-person meetings (aimed at reevaluating and readjusting the

exercises) for weeks 6 and 18 [24,25]. E-mails and/or phone messages were sent on a weekly basis, emphasizing the importance of adhering to the program.

2.3. Statistics

Assuming a power of 80% with a 5% significance level, the power calculation revealed a training effect of 0.65 on triglycerides

Table 2 Sample characteristics in M0.

Variable		IG1 (n = 11)	IG2 (n = 11)	CG (n = 11)
Age (years)		55 ±9.0	59 ±11.3	59 ±5.8
Body mass index (kg/m ²)		27.4 ± 3.0	26.9 ± 4.7	28.0 ± 3.6
Counts (Counts/min)		355.4 ± 144.6	365.1 ± 138.5	424.9 ± 82.6
Professional situation	Active	7 (64%)	2 (18%)	5 (45%)
	Inactive	4 (36%)	9 (82%)	6 (55%)
Reason for hospitalization	ACS without ST elevation	6 (55%)	6 (55%)	5 (45%)
	ACS with ST elevation	5 (45%)	3 (27%)	6 (55%)
	Stable Angina Pectoris and post-angioplasty	0	2 (18%)	0
Cardiovascular	Dyslipidemia	10 (91%)	9 (82%)	8 (73%)
Risk factors	Obesity	2 (18%)	2 (18%)	4 (36%)
	Diabetes Mellitus	2 (18%)	3 (27%)	1 (9%)
	Hypertension	5 (45%)	6 (55%)	8 (73%)
	Smoking	5 (45%)	5 (45%)	4 (36%)
	Family history	1 (9%)	1 (9%)	2 (18%)
Pharmacology	Blood Platelet Antiaggregants	9 (82%)	11 (100%)	10 (91%)
	Beta blockers	8 (73%)	9 (82%)	8 (73%)
	Statins	9 (82%)	11 (100%)	11 (100%)
	Antihypertensive drugs	4 (36%)	4 (36%)	6 (55%)
	Vasodilators	1 (9%)	3 (27%)	5 (45%)
	Calcium channel blockers	0	1 (9%)	1 (9%)
Cardiovascular	Low	7 (64%)	7 (64%)	8 (73%)
Risk	Moderate	4 (36%)	4 (36%)	3 (27%)

Data are expressed as mean values and standard deviation or n (%). The cardiovascular risk was classified according to Pescatello et al. [26]. ACS, Acute Coronary Syndrome; CG, control group; IG1, intervention group 1; IG2, intervention group 2.

indicating a need for 27 participants to ensure statistical power to detect differences between the 3 groups in M3.

The statistical analysis was accomplished using the IBM SPSS 22 software (Statistical Package for the Social Sciences) for Windows, with a significance level of 0.05 and a confidence interval of 95%. Normal data distribution was verified by Shapiro-Wilk test. The sample was characterized through descriptive statistics using mean as measure of central tendency and standard deviation as a measure of dispersion. For the inter-group analysis, in the several moments (M0, M1, M2 and M3) and in the variables difference between the different assessment moments (M0-M1, M1-M2, M0-M2 and M0-M3), whenever the distribution was normal the oneway analysis of variance (Anova) test was used for the rational and nominal variables, and whenever the distribution was not normal the Krustal-Wallis test and the Fisher test for independent samples were used for rational and nominal variables, respectively. The ttest for independent samples was used to compare adherence rates between the intervention groups. In the intra- group analysis, to compare the M0, M1 and M2, the Anova test for repeated measures or the Friedman test were used, respectively, in case the variables followed the normal pattern or if they didn't. For the laboratory tests variables, to compare the M0 and M3, the t-test for paired samples was used whenever the distribution was normal and the Wilcoxon test whenever it was not [44].

3. Results

As present in the flow diagram (Fig. 1), from the 150 subjects assessed for eligibility, 46 were recruited to participate in the study and randomized to the IG1, IG2 or CG. During the enrollment 104 subjects were excluded, 83 for not meeting the inclusion/exclusion criteria, 8 for refused to participate and 13 for did not attend the first assessment. Nonetheless, only 33 subjects were included in

the analysis. During the follow-up 13 subjects were lost to follow-up, 4 in the IG1 for dropout (n = 1), emigration (n = 1) and decision to join a gym (n = 2), 4 in the IG2 for did not attend the assessments (n = 1), emigration (n = 1), accident (n = 1) and disease hindering the practice of physical exercise (n = 1) and 5 in the CG for did not attend the assessments (n = 2), hospitalization (n = 1) and decision to join a gym (n = 2). The final sample was composed of 33 subjects, all men.

At M0, no significant differences were found between the 3 groups (p > 0.05) in the demographic and clinical characteristics, and medication (Table 2) and its respective change throughout the study. As far as the body mass index is concerned, the 3 groups presented values classified as having excess weight of 63.6% in IG1, 45.4% in IG2 and 36.4% in CG. The physical activity was considered to be light in the 3 groups.

Concerning the percentage of subjects adhering to the program, for three sessions a week, IG1 presented a mean of 82% in the first three months and 70% in the last three, with a mean of 77% over the six months period. IG2 presented a mean of 90% in the first three months and 75% in the last three, with a mean of 83% for the whole six months. No significant differences were found between the 2 groups.

At M0, no significant differences were observed between the 3 groups in the variables under study. The same was observed with the body mass index and the data obtained from the bioimpedance scale during the inter-group analysis (Table 3). In the intra-group analysis of the lean mass, significant differences were found in IG1 (F = 4.702 for p = 0.023); however, using the Bonferroni's post-hoc correction, no significance was found.

Examining the ratios, in the waist-to-hip ratio, in the intergroup analysis of the variable difference M0-M1 significant differences were found between the groups (F = 3.445 for p = 0.046) with a significant decrease in IG1 compared with CG

Table 3 Inter-group analysis at different moments (M0, M1 and M2) and of the variables difference (M0-M1, M1-M2 and M0-M2) of the Bioimpedance scale and Body mass index.

Variable		Group	M0 X ± SD	M1 X±SD	M2 X±SD	Variable difference		
			X ± 3D	XISD	X±3D	M0-M1	M1-M2	M0-M2
Bioimpedance	Total body fat	IG1	25.5 ± 4.3	22.8 ± 5.8	25.7 ± 5.4			
scale	percentage (%)		(n = 11)	(n = 10)	(n = 10)			
		IG2	23.5 ± 5.1	21 ± 6.1	23.5 ± 6.0			
			(n = 11)	(n = 11)	(n = 11)			
		CG	22.5 ± 4.9	21.9 ± 6.2	24.1 ± 5.2			
			(n = 11)	(n=10)	(n = 11)			
		р	NS	NS	NS	NS	NS	NS
	Body fat at the	IG1	28.7 ± 5.4	25.3 ±6.3	28.7 ±5.9			
	trunk percentage (%)		(n = 11)	(n = 10)	(n = 10)			
	• 0 . ,	IG2	25.7 ± 5.9	23.0 ± 6.6	25.8 ± 5.7			
			(n = 11)	(n = 11)	(n = 11)			
		CG	24.0 ± 5.9	23.6 ± 7.1	25.8 ± 6.3			
			(n = 11)	(n=10)	(n = 11)			
		р	NS	NS	NS	NS	NS	NS
	Lean mass (kg)	IG1	55.0 ± 6.4	56.1 ± 5.2	54.0 ± 6.0			
	(0)		(n = 11)	(n = 10)	(n = 10)			
		IG2	54.8 ± 9.5	55.9 ± 8.2	54.7 ± 9.0			
			(n = 11)	(n = 11)	(n = 11)			
		CG	58.6 ± 7.0	58.0 ± 6.6	57.5 ± 6.5			
			(n = 11)	(n=10)	(n = 11)			
		p	NS	NS	NS	NS	NS	NS
	Body mass	IG1	27.4 ± 3.0	27.3 ± 3.6	27.4 ± 4.2			
	index (kg/m²)		(n = 11)	(n = 10)	(n = 10)			
	(6/ /	IG2	26.9 ± 4.7	25.6 ± 2.8	25.9 ± 3.0			
			(n = 11)	(n = 10)	(n = 10)			
		CG	28.0 ± 3.6	27.7 ± 3.5	28.1 ± 3.5			
			(n = 11)	(n=10)	(n = 11)			
		p	NS	NS	NS	NS	NS	NS

Data are presented as mean values (X) and standard deviation (SD). CG, control group; IG1, intervention group 1; IG2, intervention group 2; M0, baseline/initial moment; M1, intermediate moment; M2, final moment; NS, non-significant; p, significance level.

Table 4
Inter-group analysis at different moments (M0, M1 and M2) and of the variables difference (M0-M1, M1-M2 and M0-M2) of the Ratios.

Variable		Group	M0 X ±SD	M1 X ±SD	M2 X ±SD	Variable difference		
			X 13D			M0-M1	M1-M2	M0-M2
Ratios	Waist-to-hipratio	IG1	$0.95 \pm 0.04 \text{ (n = 11)}$	0.93 ± 0.04 (n = 11)	0.93 ± 0.04 (n = 11)			
		IG2	0.94 ± 0.08 (n = 11)	0.96 ± 0.05 (n = 10)	0.94 ± 0.05 (n = 11)			
		CG	0.94± 0.04 (n=11)	0.95 ± 0.06 (n=10)	0.95 ± 0.06 (n = 11)			
		p Post-hoc	NS	NS	NS	$0.046*^{a}$ IG1 # CG $p = 0.041*^{b}$	NS	NS
	Waist-to-height ratio	IG1	0.56 ± 0.04 (n=11)	0.56 ± 0.04 (n = 11)	0.56 ± 0.06 (n = 11)			
		IG2	0.55± 0.07 (n=11)	0.54 ± 0.07 (n = 11)	0.56 ± 0.06 (n = 11)			
		CG	0.57 ± 0.06 (n = 11)	0.57± 0.06 (n=10)	0.57 ± 0.06 (n = 11)			
		p	NS	NS	NS	NS	NS	NS

Data are expressed as mean values (X) and standard deviation (SD). CG, control group; IG1, intervention group 1; IG2, intervention group 2; M0, baseline/initial moment; M1, intermediate moment; M2, final moment; N5, non-significant; *p*, significance level; *significant value; a exercise value with the Anova test; exercise value for Tukey's post-hoc.

(p = 0.041) (Table 4). In the intra-group analysis, significant differences were found in IG1 (F = 7.013 for p = 0.005) with a significant decrease from M0 to M2 (p = 0.033).

In the inter-group analysis for the Semi-Quantitative Food Frequency Questionnaire, no significant differences were found between the 3 groups. However, for IG1, in the intra-group analysis, significant differences were found regarding the values of total fat ($X^2 = 6.545$ for p = 0.038) with a significant decrease from M0 to M2 (p = 0.032) and carbohydrates (F = 4.862 for p = 0.045), nevertheless, using the Bonferroni's post-hoc correction, no significance was found.

The results of the laboratory tests did not reveal any significant difference in the inter-group analysis, except in the triglycerides at M3 (F = 4.056 for p = 0.034); however, in Tukey's post-hoc no

significance was found (Table 5). The intra-group analysis revealed significant differences, with a significant increase, in high-density lipoprotein cholesterol in IG1 (t = -3.281 for p = 0.017).

4. Discussion

Excess weight and obesity are linked to a greater risk for cardiovascular disease, and the assessment of the body composition is useful to detect and control this risk [32]. According to Koning et al. [45], an increase of 0.01 in the waist-to-hip ratio is associated with an increase of 5% in the risk of going through cardiac-related events, being the cardiovascular risk in men stronger when the waist-to-hip ratio i£:1 [28]. In addition the waist-to-height ratio has been increasingly used to measure the

Table 5
Inter-group analysis at different moments (M0 and M3) and of the variable difference (M0-M3) of the Laboratory tests.

Variable		Group	M0 X ±SD	M3 X ±SD	Variable difference M0-M3
Laboratory tests	Total cholesterol (mg/dl)	IG1	144.6 ± 59.1 (n=10)	141.6 ± 26.5 (n = 8)	
	(8))	IG2	147.7 ± 36.1 (n = 11)	175.4 ± 45.4 (n=8)	
		CG	$147.1 \pm 42.5 \ (n = 11)$	168.9 ± 22.8 (n=8)	
		p	NS	NS	NS
	High-density lipoprotein cholesterol (mg/dl)	IG1	42.2 ± 6.3	45.3 ± 6.4	
			(n = 10)	(n = 8)	
		IG2	40.6 ± 8.2	39.7 ± 6.1	
			(n = 11)	(n = 7)	
		CG	43.5 ± 8.0	48.6 ± 10.1	
			(n = 11)	(n = 8)	
		p	NS	NS	NS
	Low-density protein cholesterol (mg/dl)	IG1	78.4 ± 37.4 (n = 10)	71.4 ± 28.2 (n = 8)	
		IG2	$78.9 \pm 18.5 \ (n = 11)$	98.9 ± 34.4 (n=7)	
		CG	85.3 ± 38.8	97.7 ± 21.5	
			(n = 11)	(n = 7)	
		p	NS	NS	NS
	Triglycerides	IG1	105.5 ± 38.6	104.1 ± 38.2	
	(mg/dl)		(n=10)	(n = 8)	
		IG2	$124.5 \pm 56.8 \text{ (n = 11)}$	156.0 ± 65.2 (n=8)	
		CG	$92.0 \pm 16.8 (n = 11)$	100.6 ± 14.0 (n=8)	
		p	NS	0,034* ^a	NS

Data are expressed as mean values (X) and standard deviation (SD). CG, control group; IG1, intervention group 1; IG2, intervention group 2; M0, baseline/initial moment; M3, three months after the program's completion; NS, non-significant; p, significance level; *significant value; *aexercise value with the Anova test.

adipose tissue in older adults, due to its high validity. It is also a good predictor of the vulnerability to risk factors for cardiovascular diseases and metabolic syndromes [46], although there's no consensus regarding the cut point that represents a trigger for the increase of metabolic risk, a point of 0.5 has been suggested [33,34].

The present exercise protocol was composed of strength and endurance exercises, which have remarkable effects on the loss of fat mass and on the increase of lean mass [47]. These effects are boosted when they're accompanied by a controlled diet [47] an aspect that was not neglected in the course of the study. According to Mandic et al. [48], studies that have examined the effects of long-term (> 1 year) CR programs found favourable changes in body composition and lipoprotein profile, with less deterioration in body weight control.

According to Noites et al. [8], whenever a specific regimen is changed to introduce healthier eating habits, a decrease in the body composition values can be acknowledged, therefore being important to monitor food consumption. A strong motivation to exercise might bring about some changes in eating patterns, resulting in the adoption of healthier eating habits [8], being one of the benefits of CR programs the improvement of the lipid profile [10].

The results of this study suggest that, in this sample, starting a specific exercise program during the maintenance phase of CR, in a virtual reality format, led to improvements in the waist-to-hip ratio in the first three months. The participants in the study had already completed a training phase, in which the outcomes studied would have been presumably promoted, being important not to forget that these subjects were also under the control of the medication. Overall, the values were close to being the recommended ones at the beginning of the present experiment. However, it is important to remember that one of the main objectives of the maintenance phase of the CR is the maintenance, and so no loss, of the gains obtained in the training phase [4], and, whenever possible, the promotion of gains.

As stated above, the waist-to-hip ratio underwent a significant decrease in the virtual reality group between the baseline/initial and final moments of the study, compared with CG in the first three months. The GC, considering the mean values, confirmed an increase of 5% in the risk of going through cardiac-relates events. At the baseline/initial moment of the study, 9.1% of the subjects from CG had a waist-to-hip ratio 2:1, and that percentage had increased by the end, moving to 27.3%. On the other hand, the subjects of IG1 and IG2 presented percentages of 9.1% and 18.2% respectively, with a waist-to-hip ratio 2: nevertheless, at the end of the program that percentage remained unchanged. This allows us to affirm that the program contributed to prevent a worsening of the cardiovascular risk.

In this study, even though no significant changes were found in the waist-to-height ratio, it should be highlighted that, in IG2 and CG, 18.2% and 9.1% of the subjects respectively had a waist-to-height ratio < 0.5, and by the end of the program this percentage stayed the same. In turn, IG1 had 0% of subjects with a waist-to-height ratio < 0.5, and this percentage increased and improved to 9.1% by the end of the program.

Regarding the mean values of the body mass index, the three groups maintained an 'excess weight' classification throughout the study. However, as far as the bioimpedance data are concerned, the intervention groups presented some improvements in the body composition in the first three months, even if they were not significant, when compared with CG, since there was an increase of lean mass and a decrease of total body fat percentage and body fat at the trunk percentage. Regarding the laboratory tests, even though no significant differences between the groups were found, it was possible to observe a significant increase, but only in the

group subjected to the virtual reality format in the high-density lipoprotein cholesterol levels however, it should be highlighted the almost invariable upkeep of the reference values for the remaining parameters, according to the European Society of Cardiology and the European Atherosclerosis Society.

All participants had access to generic information concerning eating habits through the pamphlets and information delivered however, it is important to note that, as part of this study, this same information was not personalized and/or accompanied by a specialized professional such as a nutritionist. Despite having been noticed a decrease in the consumption of total fat in the three groups (as visible in the Semi-Quantitative Food Frequency Questionnaire), this decrease was significant only in the virtual reality format, between the baseline/initial and final moments of the study, which means that the Kinect might have been an added value, however no significant differences between the groups were found. These results regarding eating patterns are in accordance with the results attained in the lipid profile, which were more positive in the group subjected to the virtual reality format, as well as with the results in body composition. Nonetheless, it should be highlighted that, in the three moments, the three groups were, by average values, within the reference values for total fat and as a rule for calories, but below the reference values for carbohydrates. The daily consumption of the studied nutrients was therefore disproportionate to the recommended, at least in part [49].

In this study, the results of the first three months were better than those of the last three months. This can be explained by a decrease in adherence after three months. In this study, as in the study of Grace et al. [50], adherence was defined as the number of sessions attended (in the case of this study according to the registration in the 'Exercise Diary') divided by the number of sessions prescribed (three sessions a week during 6 months in the case of this study). According to Chatzitofis et al. [51] the application of home-based exercise programs in the context of CR carried the possibility of providing much higher adherence rates. Throughout the study/program, the adherence to the three weekly sessions was always higher than 65% in the two formats [43], a good adherence in both groups [43,50] however, with a noticeable decline in the last three months. No significant differences were found between the groups, what proves that the adherence rate did not influence the results. In this study, as in the study of Noites et al. [43], the home-based CR program was monitored, accompanied and encouraged by remote supervision and by meetings. The decline in adherence over time may mean that participants had difficulty maintaining the habits of physical exercise or that the protocol is not sufficiently motivating for a long

The sample size can be pointed as a limitation of this study, preventing the results from being extrapolated. For further studies, we believe that it would be important to focus on methods to increase motivation, as well as on the possibility of integrating a specific and personalized nutritional program guided by a nutritionist, the analysis of the physical activity levels throughout the study and, taking into consideration the stratification by ages and the body mass index, and the conduction of these studies in the training phase of CR. It would also be important to take into account, in the process of randomization, aspects such as the initial values of the laboratory tests.

5. Conclusions

In this sample, composed of subjects with coronary artery disease, the home-based specific exercise program, prescribed for a period of six months to be performed during the maintenance phase of CR, showed benefits in the group that completed the program in a virtual reality format, in the first three months

compared with CG, on body composition, specifically on the waist-to-hip ratio, which can reveal the potential of virtual reality with the Kinect, at least in the first three months.

Conflict of interest

The authors declare that they have no conflict of interest.

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