Original article

Effectiveness of a customised, unsupervised 4 month exercise programme, on exercise tolerance, perception of fatigue and anthropometric variables in sedentary patients with cardiovascular risk factors

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Summary

Introduction: Improving the physical condition is related to health benefits. The objective of this study is to assess the effectiveness of an individualized unsupervised exercise program on anthropometric variables, the perception of fatigue and physical effort tolerance (6 minutes walking test) in sedentary patients with cardiovascular risk factors.
Material and Methods: We studied 119 sedentary patients with cardiovascular risk factors, aged between 21 and 77 years old. Only 75 patients completed the study (45 women and 30 men). Before beginning the exercise program a medical examination was conducted, including: medical history, physical exam, blood pressure measurement (BP), rest-electrocardiogram (rest-ECG), anthropometrical measurements (weight, height, body mass index (BMI) and impedanciometry. The six minutes walk test was performed at the beginning and end of the study. The distance, BP, heart rate, oxygen saturation and perceived effort were measured.
The 4 month exercise program included: walking for about 30-60 minutes/day, cycloergometer: 3 days/week, 30 minutes each session, intensity of 40-60% of individual maximum functional capacity, isometric abdominal and static stretching.
A descriptive statistical study and a comparison of means for paired data were realized.
Results: The data at the beginning *versus* the end of the exercise program were:
Weight: 100,63 (24,29) *vs.* 99,6 (23,32) (p<0,05) kg; BMI: 36,62 (8,47) *vs.* 36,23 (8,12) (p <0,05) kg/m^2. Fatigue perception, Borg Scale: 4,15 (2,37) *vs.* 2,93 (1,81) (p <0,001). The distances covered were: 474 (61) *vs.* 514,6 (69,2) (p <0,001) meters.
Discussion and Conclusions: The results of the study confirm that the exercise program implemented in our center improves exercise tolerance, reduces the perception of fatigue and even slightly decreases the weight and the BMI, in sedentary patients with cardiovascular risk factors.

Key words:
6 minutes walk test.
Cardiovascular risk factors.
Aerobic endurance.
Effort tolerance.
Physical condition.
Fatigue perception.

Efectividad de un programa de ejercicio físico individualizado no supervisado, de cuatro meses de duración, sobre la tolerancia al esfuerzo, percepción de fatiga y variables antropométricas en pacientes sedentarios con factores de riesgo cardiovascular

Resumen

Introducción: La mejora de la condición física se relaciona con beneficios para la salud. El objetivo de este estudio es valorar la efectividad de un programa de ejercicio físico individualizado no supervisado sobre variables antropométricas, la percepción de fatiga y la tolerancia al esfuerzo (test de los 6 minutos) en pacientes sedentarios con factores de riesgo cardiovascular.
Material y métodos: Se estudiaron 119 pacientes, de los cuales terminaron el estudio 75 (45 mujeres y 30 hombres), con edades comprendidas entre los 21 y 77 años, sedentarios con factores de riesgo cardiovascular. Previo al inicio del programa de ejercicio físico se sometieron a un examen médico-deportivo que incluyó: anamnesis, exploración por aparatos, toma de tensión arterial (TA), electrocardiograma de reposo (ECG), estudio antropométrico (peso, talla, IMC e impedanciometría). Al principio y final del estudio se realizó el test de lo 6 minutos que mide la distancia recorrida y se valoró al inicio y final del test: TA, la frecuencia cardiaca, la saturación de oxígeno y solo al terminar, la percepción de esfuerzo.
El programa de ejercicio físico, de 4 meses de duración, incluyó: caminar 30–60 minutos /día, bicicleta estática: 3 días/semana, 30 minutos/sesión, con una intensidad del 40-60% de la capacidad funcional individual máxima, abdominales isométricos y estiramientos estáticos.
Se realizó estudio estadístico descriptivo y comparación de medias para datos apareados.
Resultados: Los datos al comienzo *versus* el final del programa de ejercicio físico fueron los siguientes: Peso: 100,63 (24,29) *vs.* 99,6 (23,32) (p <0,05) kg; IMC: 36,62 (8,47) *vs.* 36,23 (8,12) (p <0,05) kg/m^2; Percepción de fatiga. Escala de Borg: 4,15 (2,40) *vs.* 2,93 (1,81). (p <0,001). Las distancias recorridas fueron: 474 (61) *vs.* 514,6 (69,2) metros. (p <0,001).
Discusión y conclusiones: Los datos del estudio confirman que el modelo de programa de ejercicio físico individualizado no supervisado aplicado en nuestro centro en pacientes sedentarios con factores de riesgo cardiovascular mejora, de forma estadísticamente significativa: la tolerancia al esfuerzo, la sensación de fatiga y, aunque discretamente, el peso y el IMC.

Palabras clave:
Test de los 6 minutos.
Riesgo cardiovascular.
Resistencia aeróbica.
Tolerancia al esfuerzo.
Condición física.
Percepción de fatiga.

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Introduction

Current scientific evidence highlights that the most important health benefits gained from physical exercise are focused in cardiovascular or metabolic illnesses, those affecting the locomotive apparatus, certain types of cancer and psychiatric illnesses[1-3].

Healthy physical exercise must have some determined characteristics, both in the type of activity as well as the frequency, duration and intensity, and should be orientated towards improving some of the qualities of the health-related physical condition, in particular with cardiorespiratory resistance.

In clinical practice, it can be observed how primary illnesses, such as those presented by patients that are attended frequently in our health care centres, can give rise to a deficit that leads to a sedentary lifestyle of the patient and a subsequent physical de-conditioning that will lead to a worsening of the pathology.

On a physiological level, in patients with moderate-level pathologies, modifications occur to the peripheral muscle, including in particular, the decrease of muscle mass and strength, more marked in the lower extremities, a reduction of type I and IIa fibres, of myoglobin and capillarisation, of oxidative enzymes and energy substrates, which will lead to a decrease in endurance (cardiorespiratory resistance)[4].

A lack of training results in a peripheral myopathy in these patients, due to the reduction of the aerobic metabolic pathway and the development of the anaerobic metabolic pathway.

Thus, once the illness has appeared, and faced with a lack of appropriately applied physical exercise as one of the therapeutic strategic pillars, there is a reduction in the degree of physical activity performed, an increase in sedentary lifestyle habits and a progressive loss of functional capacity, closing a perpetual vicious circle of decline and a progressive worsening of the state of health[5].

Performing regulated physical exercise on a regular basis (correctly prescribed depending on medical and physiological criteria), this process can be reversed.

Prescribing exercise should be based on customisation, i.e. adapting the prescription as far as possible to the characteristics of each patient[6,7].

When prescribing physical exercise, the frequency and duration are still generally accepted standards, but there should be a more in-depth analysis of physiological customisation in the re-training programme (intensity). There are different approximations of this physiological customisation, including: the ventilatory threshold (these adjust very well to the characteristics of each patient: age, pathology they have, metabolic situation, and there is a strong link between the work load requested and the comfort shown by the patient), lactate, dyspnoea, visual analogical scale, among others[6].

In addition to the physiological perspective, the prescription should also be customised taking into account the associated pathologies presented in the patient, the medical treatment being followed, and the social-cultural and economic level.

Given the scientific evidence that links improvement to cardiovascular resistance with health benefits and a reduction of the cardiovascular risk factor in sedentary patients, the aim of this study is to assess whether or not an unsupervised customised physical exercise programme improves physical condition parameters, such as cardiovascular resistance - tolerance to exertion and some anthropometric variables - that could be used to improve cardiovascular and metabolic disorders presented in the patients, as well as enhancing their physical well being.

Material and method

Sample

The sample studied is made up of 119 patients moved from other services at the Sant Joan de Reus University Hospital to the Sports Medicine Unit at the same hospital. 44 subjects were excluded for not performing the physical exercise indicated or for not attending the final evaluation, with which the result assessment was performed using a total of 75 patients: 30 men and 45 women.

All the patients aged between 21 and 77 years old were visited in the Clinical Physiology consultancy of the Sports Medicine Unit, and as well as being sedentary (less than 30 minutes a day of regular exercise, less than 3 days a week), they had one or two of the following cardiovascular risk factors: excess weight, type 1 obesity, dyslipemia, type 2 diabetes mellitus, arterial hypertension, and they did not have any psychiatric illnesses, drug dependencies, oncological illnesses or diagnosed heart diseases.

Procedure

The calculation of the sample size was performed using the main variable, a 6-minute Test in which, with a minimum of 371 metres per participant, a better prognosis was obtained if the participant improved the distance by 40 metres. For this, the sample must include at least 35 participants[8-12].

Informed consent was requested from each patient to participate in the study voluntarily and in order to use their biomedical data.

This study was carried out in accordance with the Helsinki Declaration and the *International Conference of Harmonization* (ICH) Good Clinical Practices Guideline.

Before starting the exercise programme, a sports-medical examination was performed which included:

- H-Net Digitalised Clinical History: Anamnesis, exploration with apparatus, blood pressure reading and resting ECG.
- Anthropometric study with the measurement of weight, height, BMI, impedanceometry (percentage of fat [% of fat])[13].
- 6-minute Test following the procedures indicated in the scientific literature, in a marked walkway of over 30 metres[14-17]. The distance covered was measured. Before and after the test the following were assessed: blood pressure, heart rate, oxygen saturation, and after the test, perceived exertion (Borg scale)[18].

Throughout the 4-month long exercise programme, monthly reviews were arranged to assess adherence to the exercise programme and to motivate the participants, whilst checking that no significant medical problems had arisen.

On these visits, compliance with the indicated exercise programme was assessed by giving each patient a customised interview. In the case of failure by the patient to complete the prescribed exercise (not attaining the energy expenditure proposed on any of the weeks included in the assessment period), the patient was removed from the study.

Upon finishing the study, after the four months of physical exercise programme, the anthropometric study was repeated, as well as the 6-minute test using the same methodology.

Material

- Anthropometric: Anó-Sayol weighing scale and height rod (0-150 kilograms; precision of 100 grams and 55-200 centimetres, precision of 1 mm respectively). Impedanceometry: *body composition analyzer, type* BC-418 MA III (Tanita).
- 6-minute test: Riester blood pressure cuff. Casio stopwatch. Vital signs monitor *Suresigns VS3 Philips* (Pulse oximeter, heart rate). Analogical-visual scale.
- The 4-month Exercise Programme included: walking for 30 to 60 minutes each day in series of 10-15 minutes, exercise bike 3 days/week, 30 minutes/session with an intensity of 40-60% of the individual maximum functional capacity (reserve heart rate), isometric abdominals and static stretches. The aim was to increase the energy expenditure between 1,300 and 2,000 kilo-calories (Kcal) each week[19-21].
- To compare the evolution of the parameters of each sample, the data was handled via the "Student t" to compare the averages of the matching data. To compare the parameters in different samples (men vs. women); "Student t" to compare the unmatched data averages, and the two controls were checked using the Wilcoxon test for non-parametric matching data. The statistic package used was SPSS[19].

Results

The tables presented reveal the results of this work and are compared with results from a previous study performed in 2012 in our centre, using the same methodology and a sample with similar characteristics but on a smaller scale: 30 patients (14 men and 16 women). The objective of presenting them in this way is to assess the behaviour of the data studied upon increasing the sample size.

Table 1 reveals the demographic and anthropometric characteristics of the sample.

Tables 2 and 3 display the evolution of the values for weight, BMI, % of fat before and after the exercise programme with a slight reduction of these being statistically significant in the case of total weight and BMI.

Tables 4 and 5 respectively display the improvement in the distance covered (in metres), assessed using the 6-minute test and the evolution

Table 1. Sample characteristics (Averages ± Sd).

Year	2012 All n=30	2014 All n=75
Males	14	30
Females	16	45
Age (years)	48.5 ± 12.7	47.6 ± 13.3
Height (cm)	166 ± 6.97	166 ± 7.4
Weight (kg)	96.4 ± 21.8	100.6 ± 24.2
BMI (kg/m³)	35.3 ± 8.27	36.6 ± 8.4
Fat (%)	38.3 ± 10.1	39.3 ± 10.3

Sd: standard deviation, cm: centimetres, kg: kilograms, BMI: Body mass index; %: percentage; m: metres.

Table 2. Evolution of anthropometric values. 2012 study ("student t" test comparison of averages, matched data).

Year 2012 (n=30)		Before	After	P
Weight (kg)	average	96.4	96.1	P = ns
	Sd	21.7	21.7	
BMI	average	35.3	34.8	P = ns
	Sd	8.3	7.9	
Fat (%)	average	38.3	37.4	P = ns
	Sd	10.1	10.1	

Weight in kilograms; BMI: Body Mass Index (kg/m²); % fat: fat percentage; Sd: standard deviation.

Table 3. Evolution of anthropometric values. 2014 study ("student t" test comparison of averages, matched data).

Year 2014 (n=75)		Before	After	P
Weight (kg)	average	100.6	99.6	P <0.05
	Sd	24.3	23.3	
BMI	media	36.6	36.2	P <0.05
	Sd	8.5	8.1	
Fat (%)	media	39.3	38.9	P = ns
	Sd	10.3	10.2	

Weight in kilograms; BMI: Body Mass Index (kg/m²); % fat: fat percentage; Sd: standard deviation.

Test 4. 6-minute test. Evolution of the distance and perceived exertion. 2012 study ("student t" test comparison of averages, matched data).

Year 2012 (n=30)		Before	After	P
Distance	average	471	505	P<0.001
	Sd	66.9	78.7	
Borg	average	3.8	2.9	P<0.002
	Sd	2.2	1.8	

Distance in metres; Sd: standard deviation; Borg: perceived exertion scale.

Table 5. 6-minute test. Evolution of the distance and perceived exertion. 2014 study ("student t" test comparison of averages, matched data).

Year 2014 (n=75)		Before	After	P
Distance	Average	474	514.6	P <0.001
	Sd	61	69.2	
Borg	Average	4.1	2.9	P <0.001
	Sd	2.4	1.8	

Distance in metres; Sd: standard deviation; Borg: perceived exertion scale.

of the perceived fatigue test assessed using a visual analogue scale. Both with statistical significance.

Via the indirect calculation of the maximum oxygen consumption (VO_2max), using the formulas from the 6-minute test, variations in metabolic equivalents were studied (METs) at the start and end of the exercise programme[14-17]: METs at the start (n=75): average of 5.2 (0.52) *versus* METs at the end: average of 5.55 (0.59). Increase: average of 0.35 (0.39) METs. Statistical significance $p<0.001$. No differences were found by sex.

The distances covered differentiated by sex were:

Women (n=45): start 471.2 (58.05) metres average *versus* 505.2 (64.14) metres average at the end. A difference of 34.02 (37.39) metres average, 7.22% increase in the distance covered. Statistical significance of $p<0.001$.

Men (n=30): start 478.1 (66.07) metres average *versus* 528.6 (75.15) metres average at the end. A difference of 50.47 (54.8) metres average, 10.55% increase in the distance covered. Statistical significance of $p<0.001$.

Overall, we can see that the anthropometric variables studied improve slightly: reduction in total weight ($p<0.05$), BMI ($p<0.05$) and % of fat, this latter without statistical significance. An increase occurs in the distance covered, with an average improvement of 40.6 metres $p<0.001$, with marked differences between men and women in the distances covered, though they are not statistically significant, and a reduction in the perceived exertion on the Borg Scale, average of 4.05 (2.37) to 2.93 (1.81) and a significance of $p<0.001$.

We can also observe an improvement in the physical condition expressed in METs, which despite being slight, is statistically significant.

Discussion

As in previous studies carried out in our centre on patients with similar characteristics, it has been observed that a large number of the subjects recruited for the study drop out - 44 subjects from a total of 119, some 37% of the initial sample. Given that this is a clinical study, it reflects the importance of patients adhering to a regular therapeutic physical exercise routine, and becomes a hugely significant problem to take into account[22].

In any case, this study revealed a lower number of drop outs compared to the 2012 study (45 subjects dropped out in 2012 - 60% of the total, whilst in this 2014 study, 44 subjects dropped out - 37% of the total), this figure may be due to the increase of controls performed (monthly) to ensure adherence over time to the exercise programme.

Therefore, it would seem plausible to deduce from the results obtained that undertaking monthly controls to review compliance with the exercise and to give motivational support will reduce the number of drop outs by 60%, or, likewise, increase adherence to the exercise programme planned for these patients by 40%.

A recent study undertaken in 2014 focuses on this aspect and proposes the use of the 6-minute test as a simple tool that can be used to improve the motivation of overweight patients[23].

The physical exercise programme proposed is intended to be easy to prescribe, without the need for complicated or complex complementary tests, easy for the targeted patients to follow, both in terms of the type of exercise to perform as well as their intensity (note that they are sedentary patients). It also aims to achieve a weekly calorie consumption increase of between 1,300 and 2,000 Kcal.

Scientific evidence acknowledges that physical condition is an excellent predictor of life expectancy and quality of life. Over recent years, numerous studies reveal an inverse association between physical condition and morbi-mortality in the population, very marked in patients with cardiovascular risk factors[24-29]. Improvements in both physical and mental health are observed: self-image, self-control, anxiety[30].

Physiological values such as maximum consumption of oxygen (VO_2max.), which can be estimated either directly or indirectly, constitutes an excellent marker of the maximum cardiovascular capacity[31,32], observing an almost linear relationship between the reduction of mortality and the increase of physical condition (METs). Therefore for each MET of improvement, there is a 12% increase in life expectancy in men and 17% in women[31,33,34].

These figures indicate that poor physical condition is an added risk factor, as well as a morbi-mortality predictor.

The 6-minute test fundamentally assesses endurance or cardiorespiratory resistance, i.e. tolerance to exertion, which is perhaps of greater interest in the patients used in this study, because it defines the aptitude that requires regular work at a sub-maximum percentage of the VO_2max.

From a functional perspective, the qualities of endurance (aerobic resistance) in patients are more useful than performance qualities, as they allow for a better adaptation to the energy demands of daily life. In any case, it should be noted that the VO_2max. measurement and the 6-minute test are complementary.

In this study, the initial distance covered in metres, average of 474 (61), is considerably lower than the values taken from literature regarding healthy people in the same age-range, average of 698 (96) metres. Even with the improvement that the patients displayed following the re-training period, the distance attained in metres - average of 514 (69), is still far removed from these values[35-37], though they are close to the theoretical benchmark distance considered as normal in patients, average of 531 (71) metres[9].

In the studies consulted, there are clear differences in the distances covered by men and women, with values that oscillate between 59-84 metres of difference in favour of men[35-37].

In this study, the initial distance covered is low and similar for men 478.1 (66) metres and women 471.2 (58) metres, whilst after the exercise period both subgroups improved, in particular men, with an average of 50.47 (55) metres, whilst women showed less improvement, with an average of 34 (37) metres.

Though both sexes reveal an improvement that is within the theoretical range considered optimum for patients: 31-75 metres[9,12], in women there should be a reinforcement of recommendations, motivation and follow-up. Note that these figures are from studies on pneumology patients and cannot therefore adjust completely to the characteristics of the sample studied, but they are the only ones that have been included, at least those that were accessible at this time.

There was also a slight yet significant improvement in the maximum METs calculated (increase of 0.35 (0.39) METS average). The figures show that both aerobic power (slightly) and endurance (in greater measure) would improve.

This increase of the aerobic power and endurance is reflected very clearly in the improvement of perceived exertion measured using the Borg Scale.

The improvement in the tolerance of the physical exertion-condition observed is not so clearly marked when analysing the anthropometric data, in which a considerably less notable improvement trend has been observed. Recent studies highlight that improving physical condition is more important for the health and for the reduction of cardiovascular risk than improving anthropometric values[28,29].

In this study, the abdominal girth measurement was not included - a measurement which in these particular patients, would quite possibly provide a better reflection of the modifications that occur to the intra-abdominal fat and body composition. In this respect it should be noted that the patients studied claimed that despite the minor change in their overall weight, they observed clear changes in the size of clothes they used and in particular around their waist.

Current studies reveal the prognostic value of the results obtained in the 6-minute test. Subjects that covered shorter distances have a greater risk of mortality across the board, in particular from cardiovascular illnesses, heart failure and dementia. The risk increases significantly when the distance covered is less than 400 metres, remaining high with distances of less than 460 metres. These authors promote the use of this test to assess the overall exercise capacity and to discover the evolution of cardiorespiratory aptitude following intervention programmes, as is the case in this study, and not only to assess the cardiovascular performance of heart and respiratory patients[38,39].

Thus, according to these studies, poor physical condition (measured using the 6-minute test), such as that revealed in the patients used in this study at the very beginning, is an added cardiovascular risk factor, as well as a morbi-mortality predictor.

Comparison of the data gathered in this study with that taken from the 2012 study reveals the same trend of improvement in the distance covered, perceived fatigue, total weight and BMI, but with greater strength upon increasing the sample. All of this reinforces the impression that it would be very interesting to implement a programme of these characteristics in a clinical-hospital environment, though clearly with necessary alterations.

The experience acquired over these years along with the data gathered and the bibliography consulted, lead us to consider that it is necessary to systematically include an evaluation of the physical condition and the prescription of physical exercise in the overall treatment of patients with cardiovascular risk factors, alongside clinical follow-up.

An assessment of physical condition is the foundation for the prescription of exercise and its developmental control. Clinical practice in sedentary patients with metabolic syndrome and cardiovascular risk factors should include: the 6-minute test to assess aerobic resistance and to calculate the VO_2max. indirectly, anthropometric measurements: weight, height, BMI, abdominal girth, as well as strength tests such as the hand dynamometer and/or isokinetic tests on the lower extremities.

Despite not being included in this study, strength is another related physiological variable, and seems to be a good morbi-mortality predictor and a reliable marker of the state of health. We therefore feel it should be included in the habitual assessment[40].

In terms of prescribing exercise to patients, the aim is to improve the physical condition qualities that are linked to the reduction of cardiovascular risk and morbi-mortality risk: VO_2max, tolerance to aerobic exertion-resistance, muscle strength[41,42].

We feel that there should be reference values for the distances achieved and possibilities for improvement in the 6-minute test in these patients. The findings discovered are aligned with this action.

Finally, negative effects should be avoided: dropping out, locomotive system injuries, increased cardiovascular and metabolic risk, for which the periodical supervision of these patients by medical specialists in clinical physiology is required.

In future studies the intention is to include: a abdominal girth measurement, a hand dynamometer reading, to increase the sample size, the re-training time and the supervision measures. Also include a control group and even ensure that the group is more homogeneous. However this latter factor is more difficult as it is a clinical study.

Conclusions

The inclusion of monthly controls, as well as the supervision and motivation measure, seem to increase adherence to the physical exercise programme in the study group.

The unsupervised customised physical exercise programme lasting for four months, proposed for the patients participating in the study (all of them sedentary patients with cardiovascular risk factors), has slightly improved their aerobic power (METs) and clearly improved their aerobic-tolerance resistance to exertion and their perceived fatigue. All these improvements are statistically significant.

The modifications detected in the anthropometric variables studied reveal discrete significant improvements to the weight and BMI.

As a result of these modifications, the cardiovascular risk reduces and the morbi-mortality and quality of life of these patients improves.

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