Universitat Internacional de Catalunya
Facultat de Medicina i Ciències de la Salut

Treball Fi de Grau

Is Crossfit® (High intensity functional training) superior to continuous moderate exercise at reducing 10-year cardiovascular risk? A randomized clinical trial study Protocol.

Matt Corbett

END OF DEGREE DISSERTATION

3, 2, 1, GO!

Is Crossfit® (High intensity functional training) superior to continuous moderate exercise at reducing 10-year cardiovascular risk? A randomized clinical trial study Protocol.

Author: Matt CORBETT

Expected Duration: 3 Years

Keywords: High-Intensity Interval Training, Crossfit, Continuous moderate exercise, Cardiovascular Diseases/prevention and control

Date of presentation: 20/04/2018

Facultad de Medicina y Ciencias de la Salud - Degree in Medicine

ABSTRACT

Introduction: In 2015 cardiovascular disease (CVD) accounted for around 45% of the 40 million deaths due to non-communicable disease worldwide. A number of classical risk factors have been associated with increased risk of CVD and among these is physical inactivity. Inversely, the multiple health benefits of physical activity are well known, including, among others, improvements in blood pressure, serum cholesterol levels, body mass index, physical function and psychological wellbeing.

In addition to the pharmacological treatments aimed at correcting traditional risk factors (e.g., Statins for hypercholesterolemia), many efforts have been devoted to non-pharmacological interventions such as physical activity, and current recommendations to prevent CVD include the completion of continuous moderate exercise (CME). However, there has been limited success with regards to the acceptance and effectiveness of these recommendations. Little research has investigated which alternative modalities of physical activity are most effective at reducing CVD risk.

Crossfit® is a relatively new variation of high intensity interval training (HIIT), which combines powerlifting, Olympic lifting, gymnastics and metabolic conditioning at high intensity with little/no rest (Cf. HIIT). It is thought that this type of physical activity may yield improved reductions in CVD risk when compared CME.

Objectives: To assess any differences between the reductions of CVD risk (evaluated using HeartSCORE) achieved by a yearlong period of either Crossfit®, Continuous moderate exercise and a non-active-intervention group.

Participants: 360 participants aged from 40-65 will be recruited from 10 participating primary health care centers located within the central Barcelona healthcare region.

Methods: The participants will be randomized (stratified by sex, age and baseline HeartSCORE) into 3 groups before the 12-month intervention period. Group 1 will complete continuous moderate exercise for 60 minutes at 50-70% of their theoretical maximum heart rate, three times a week. Group 2 will complete three sessions per week of a group based Crossfit® class. Group 3, the non-active-intervention group, will only receive the standard recommendations from their primary care physician.

Data collection will be performed in an independent, centralized center, blinded to the objectives of the study and the participants group assignment. The primary outcome will be the reduction in HeartSCORE (an electronic version of the Systemic Coronary Risk evaluation tool) achieved following the intervention. Secondary outcomes will be changes in BMI, Blood pressure, baseline fasting glucose, glycated haemoglobin, blood lipid profile, diabetes status, smoking status and medication status (antihypertensive, antihyperlipidemic and antihyperglycemic agents). Data collection will be performed at 0, 3, 6, 9 & 12 months during the intervention period followed by a final data collection visit 6 months later (18m).

Expected results & Relevance: If the results were to show a clinically significant difference in favour of Crossfit®, physicians may be able confidently prescribe a Crossfit® based exercise regime as an alternative to the current physical activity recommendations, before the need to prescribe other pharmacological options that often have a range of adverse effects.

RESUMEN

Introducción: En 2015, las enfermedades cardiovasculares (ECV) suponían alrededor del 45% de los 40 millones de muertos por enfermedades no transmisibles. Existen factores de riesgo que se han asociado a un aumento del riesgo cardiovascular, entre ellos se encuentra la inactividad física. Por otro lado, los múltiples beneficios de la actividad física son conocidos, incluyendo, entre otros, mejorías en la tensión arterial, en la colesterolemia y en el índice de masa corporal.

Además de los tratamientos farmacológicos destinados a corregir los factores de riesgo tradicionales (por ejemplo, estatinas para la hipercolesterolemia), se han dedicado muchos esfuerzos a intervenciones no farmacológicas como la actividad física y las recomendaciones actuales para prevenir la ECV recomiendan el ejercicio moderado continuo (CME). Sin embargo, estas recomendaciones han tenido poco éxito a la hora de la aceptación y eficacia, y todavía hay menos investigaciones que hayan estudiado otras modalidades de actividad física y si son más eficaces en reducir el riesgo de ECV.

Crossfit® es una variación nueva de entrenamiento de alta intensidad que combina levantamiento de potencia, halterofilia, gimnasia y acondicionamiento metabólico a alta intensidad con poco/sin descanso. Se piensa que este tipo de actividad física podría producir mejores reducciones en el riesgo de ECV en comparación con ejercicio moderado continuo.

Objetivos: Demostrar una diferencia entre las reducciones de riesgo cardiovascular (evaluado utilizando HeartSCORE) conseguidas tras un año de tres sesiones semanales de Crossfit®, ejercicio moderado continuo y un grupo de intervención no activa.

Participantes: 360 participantes, entre 40-65 años, serán reclutados de 10 centros de atención primaria en el área básica de la salud de “Barcelona centro” que participan en el estudio.

Métodos: Se aleatorizarán los participantes (estratificados por sexo, edad y HeartSCORE) en 3 grupos (1, 2 o 3) antes del periodo de 12 meses de intervención. El Grupo 1 completarán ejercicio moderado continuo durante 60 minutos a 50-70% de su frecuencia cardiaca máxima teórica, 3 veces por semana. El Grupo 2 completarán 3 sesiones semanales de una

clase estructurada de Crossfit®. El Grupo 3 serán el grupo intervención no activa (control) que solo recibirá las recomendaciones estándares de su médico de atención primaria.

La recogida de datos se realizará en un centro independiente y centralizado, cegado a los objetivos del estudio y a la asignación de los participantes. El resultado primario será la reducción en la escala HeartSCORE (una versión electrónica de la herramienta de evaluación del riesgo coronario sistémico) conseguida después de la intervención. Los resultados secundarios serán cambios en el IMC, la presión arterial, la glucosa basal en ayunas, la hemoglobina glicosilada, el perfil lipídico, el control de la diabetes y la necesidad de medicación (fármacos antihipertensivos, antihiperlipidemiantes y antihiperglucemicos). La recogida de dataos se realizará a los 0, 3, 6, 9 y 12 meses durante el periodo de intervención, seguido de una visita final de recogida de datos 6 meses más tarde.

Resultados esperados: Si los resultados mostraran una diferencia clínicamente significativa que favoreciera Crossfit®, permitiría que los médicos pudiesen recomendar regímenes de actividad física basadas en el Crossfit® como alternativa a las recomendaciones actuales, sobre todo antes de recorrer a tratamientos farmacológicos, evitando así posibles efectos adversos.

RESUM

Introducció: El 2015, les malalties cardiovasculars (MCV) van suposar al voltant del 45% dels 40 milions de morts per malalties no transmissibles. Hi ha descrits factors de risc que s'han associat a un augment del risc cardiovascular, i entre aquests es troba la inactivitat física. Per altra banda, els múltiples beneficis de l'activitat física son coneguts, incloent millories en la tensió arterial, la colesterolèmia i l'índex de massa corporal.

A més dels tractaments farmacològics destinats a corregir els factors de risc tradicionals (per exemple, les estatines per l'hipercolesterolèmia), s'han dedicat molts esforços a intervencions no farmacològiques com l'activitat física, especialment amb recomanacions generals per prevenir la MCV, per exemple l'exercici moderat continu (CME). Tanmateix, aquestes recomanacions relacionades amb l'exercici han tingut un èxit limitat pel que fa a l'acceptació i l'eficàcia, i encara existeixen menys investigacions que hagin estudiat quina modalitat d'activitat física és més eficaç per reduir el risc de MCV.

El Crossfit® és una variant nova d'entrenament d'alta intensitat que combina aixecament de potència, halterofília, gimnàstica i condicionament metabòlic a alta intensitat amb poc o gens de descans. Es pensa que aquest tipus d'activitat física podria produir més reduccions en el risc de MCV en comparació amb CME.

Objectius: Avaluar la diferència entre les reduccions del risc de MCV (utilitzant HeartSCORE) assolit realitzant un període d'un any de Crossfit®, d'exercici moderat continu, o un grup control (intervenció no activa).

Participants: 360 participants d'entre 40-65 anys seran reclutats de 10 centres d'atenció primària en l'àrea bàsica de salut "Barcelona centre" que participen en l'estudi.

Mètodes: S'aleatoritzaran els participants (s'estratificaran per sexe, edat i HeartSCORE basal), en 3 grups (1, 2, o 3) abans del període de 12 mesos d'intervenció. El grup 1 completaran exercici moderat continu durant 60 minuts a 50-70% de la seva freqüència cardíaca màxima teòrica, 3 vegades a la setmana. El grup 2 completaran 3 sessions setmanals d'una hora, d'una classe estructurada de Crossfit®. El grup 3 seran el grup intervenció no activa (control) que nomes rebran les recomanacions estàndard del seu metge d'atenció primària.

La recollida de dades es realitzarà en un centre independent i centralitzat, cegat els objectius de l'estudi i l'assignació dels participants. El resultat primari serà la reducció en l'escala de HeartSCORE (una versió electrònica de l'eina d'avaluació del risc coronari sistèmic) aconseguit després de la intervenció. Els resultats secundaris seran canvis en l'IMC, la pressió arterial, la glucosa basal en dejú, l'hemoglobina glicada, el perfil lipídic, el control de la diabetis i la necessitat de medicació (agents antihipertensius, antihiperlipidèmics i antihiperglicèmics). La recollida de dades es realitzarà als 0, 3, 6, 9 i 12 mesos durant el període d'intervenció, seguit d'una visita final de recollida de dades 6 mesos més tard.

Resultats esperats: Si els resultats mostressin una diferencia clínicament significativa a favor del Crossfit®, permetria que els metges poguessin recomanar règims d'activitat física basades en el Crossfit® com a alternativa a les recomanacions actuals, sobretot abans de recórrer a tractaments farmacològics i d'aquesta manera evitar possibles efectes adversos.

ABREVIATIONS

BMI – BODY MASS INDEX

BP – BLOOD PRESSURE

CHD – CORONARY HEART DISEASE

CME – CONTINUOUS MODERATE EXERCISE

CVD – CARDIOVASCULAR DISEASE

HDL-C – HIGH DENSITY LIPOPROTEIN COLESTEROL

HIFT – HIGH INTENSITY FUNCTIONAL TRAINING

HIIT – HIGH INTENSITY INTERVAL TRAINING

LDL-C – LOW DENSITY LIPOPROTEIN COLESTEROL

METS – METABOLIC EQUIVALENTS

SCORE – SYSTEMIC CORONARY RISK EVALUATION

WHO – WORLD HEALTH ORGANIZATION

INTRODUCTION

In 2015 cardiovascular disease (CVD) accounted for around 45% of the 40 million deaths due to non-communicable disease, according to a report by the World Health Organization.[1] Although in high income countries the mortality rates have declined recently, they remain am important cause of mortality in the population. It is well established that lifestyle or environmental factors and a growing number of biochemical/physiological markers concur an increased risk of CVD. The Framingham Heart Study was initiated in 1948 by the American Public Health Service to investigate these possible risk factors of CVD. The study was one of the first to use the term "risk factor", defined as a measurable factor that is causally related to a difference in the risk of an outcome or condition, established on the basis of scientific evidence and causal inference.[2] Shortly after its initiation the Framingham study had already identified high blood pressure and high total cholesterol as potential factors in the development of CVD.[3] Subsequently, and in combination with multiple additional studies, a group of classical risk factors were established, including high serum cholesterol, hypertension, diabetes, smoking and physical inactivity. Detailed briefly below are the most well-established risk factors:

BLOOD LIPIDS:

The first study to demonstrate the association between high serum cholesterol was a 1957 continuation of the Framingham study.[4] It was then confirmed that these factors precede CVD and increase the risk of its development.[5] In 1979, research more specifically demonstrated the atherogenic role of increased Low-density lipoprotein cholesterol (LDL-C), while also revealing the protective role of High-density lipoprotein cholesterol (HDL-C). Since then, it has been estimated that for every 1mg/dL increase in HDL there is a resulting 2/3% decrease in coronary risk in men and women, respectively.

HYPERTENSION:

Results from the Framingham study showed that blood pressure (BP) was directly related to cardiovascular risk, and that isolated systolic hypertension (the commonest form of hypertension in the elderly) was an independent risk factor.[6] It has been estimated that for

every 20mmHg increment in systolic BP (or 10mmHg in diastolic BP) the risk of CVD doubles.[7]

HYPERGLYCAEMIA/DIABETES:

Both glucose intolerance and diabetes are associated with an increased risk of CVD, and patients with diabetes are also more likely to present low HDL-C, hypertension and obesity.[8]

As seen above the majority of the classical risk factors are biochemical or physiological parameters, however there are also a number of lifestyle and environmental factors that precede these biochemical alterations, such as smoking and physical activity. As such they provide an alternative strategy for reducing CVD risk at an earlier stage of the pathogenesis, either independently or via an ensuing reduction of the biochemical/physiological risk factor/s. In this way, it may be possible to reduce CVD risk without the use of costly pharmaceutical treatments (and their associated adverse effects) that target directly the biochemical alterations rather than the underlying causes (See Figure 1).

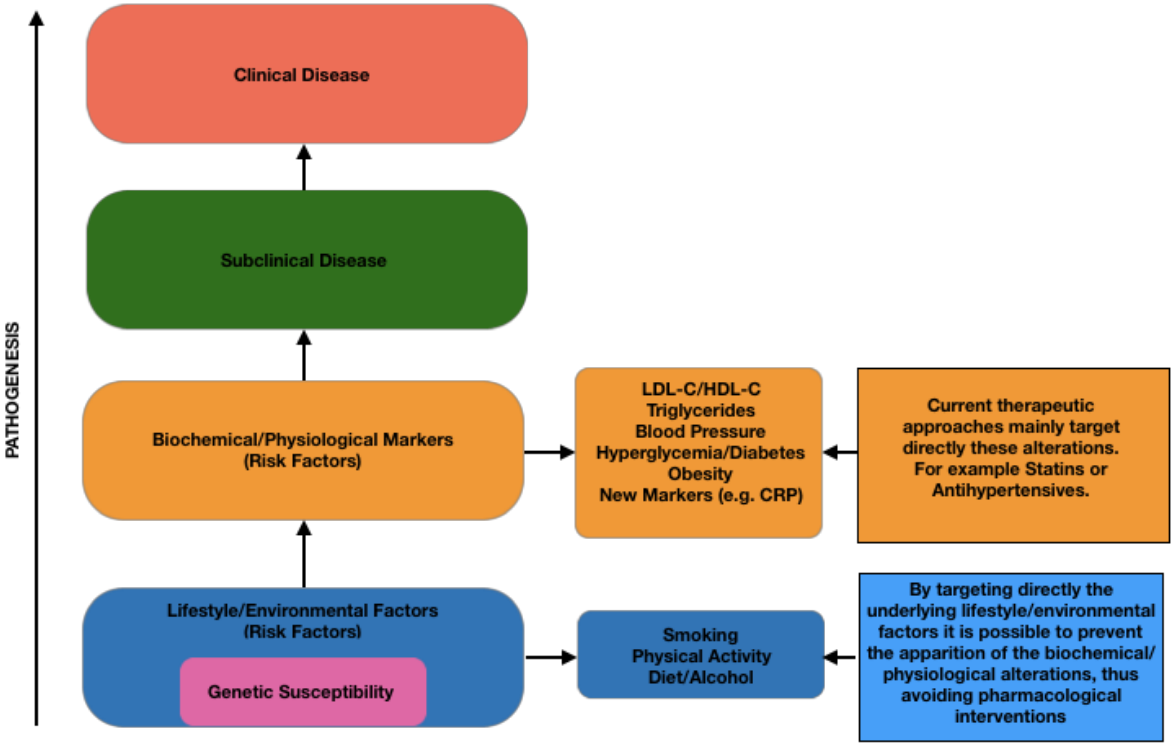


Figure 1. The stages that make up the pathogenesis of cardiovascular diseases. The boxes in blue illustrate that targeting the underlying lifestyle/environmental factors may allow prevention of CVD at an earlier point in the pathogenesis. Adapted from O'Donnell et al. *LDL-C = Low-density lipoprotein, HDL-C = High-density lipoprotein, PCR = C-Reactive Protein*.

SMOKING:

Smoking has been repeatedly shown to increase cardiovascular risk, and results from the Framingham study showed the risk to be proportional to the number of cigarettes smoked, and also that the risk decreased upon smoking cessation.[9] Given this evidence, smoking cessation initiatives and nicotine substitution therapy have become a mainstay of the preventative agenda.

PHYSICAL INACTIVITY:

The most relevant factor with regards to the current study are the long-term risks of physical inactivity, or conversely, the benefits of physical activity. In 1992, the American Heart Association named physical inactivity as an independent risk factor for cardiovascular disease.[10] Numerous studies have since demonstrated a correlation between physical inactivity and coronary heart disease (CHD), and the relative risk of death from CHD for sedentary individuals is 1.9 (when compared with active individuals).[11]

The multiple health benefits of physical activity are well known, for example aerobic exercise has been shown to improve a large number of biochemical variables (namely the classical risk factors for CVD) including blood pressure, HDL-C, Triglycerides, body weight and Insulin resistance, as well as improving physical function, psychological wellbeing and certain cardiovascular capacities (Max cardiac output, peripheral oxygen extraction, endothelial function etc.).[12] Physical fitness has been shown to reduce the risk of CVD to a similar degree as smoking cessation.[13] The mechanisms via which physical exercise is able to reduce CVD risk were previously unknown, until a 2007 study set to quantify the contribution of traditional and novel risk factors to the activity-related reduction in CVD risk. The results showed that the association between more activity and lower CVD risk can be explained in large part by changes in these known risk factors. Further examination revealed that these traditional risk factors were responsible for 59% of the risk reduction associated with physical activity, thus illustrating their upmost importance in the primary prevention of CVD.[14] However, it is important to point out that when these traditional risk factors are accounted for, the beneficial effect of physical activity partially persists supposedly via mechanisms not yet defined.

Given the multiple health benefits of physical activity (including reduced CVD risk), the Spanish ministry of health (based on the recommendations of the W.H.O) recommends either 150 minutes of moderate physical exercise, or 75 of vigorous exercise a week, in addition to muscular strengthening exercises at least twice a week. Moderate intensity refers to activity performed at 3.0-5.9 times the intensity of rest, and vigorous exercise 6 times the intensity of rest.[15]

The majority of worldwide recommendations regarding physical activity are based on the practice of continuous moderate exercise (CME), in other words, aerobic endurance exercise, supposedly due to the fact that the majority of randomized controlled trials that examine the effects of exercise on metabolic abnormalities and CVD risk have prescribed this modality. At this point in time there are very few studies that consider the benefits of alternative exercise intensities or modalities on CVD risk or its precursor metabolic abnormalities. It had been previously thought that changes in CVD risk factors and cardiovascular fitness were independent of exercise intensity, however a 2005 study that compared the effects of moderate intensity exercise with high intensity exercise showed that not only was high intensity exercise more effective at improving cardiovascular fitness, but also led to statistically significant improvements in total cholesterol and LDL-C not seen with the moderate exercise group.[16] In a separate study involving patients with clinically confirmed metabolic syndrome (altered blood pressure, dyslipidaemia, impaired glycaemic control, and abdominal obesity), the authors tested the efficacy of two different modalities of exercise (aerobic vs. High intensity interval training - HIIT) at reversing features of the metabolic syndrome. HIIT involves completing multiple cycles of short bursts (30 seconds – 1 minute) of high intensity exercise separated by longer periods of rest/low intensity work. The results showed that HIIT caused a greater reduction in fasting blood glucose, an increase in insulin sensitivity and β-cell function, while also increasing HDL-C by ~25% (unaltered in other groups).[17] Both of these studies suggest that there may be more efficient alternatives to CME that allow for equal or greater reductions in CVD risk factors.

In the 2005 study mentioned above the high intensity group was able to expend 1,200 kcal/week with 90-120 minutes of exercise per week, while to achieve the same energy expenditure walking briskly would take 30 minutes per day 7 days a week (210 minutes per week).[16] Given that a common reason for non-adherence to an exercise regime is lack of

time and that adherence is often less than half after 6 months[18], high intensity modalities could present an attractive alternative. Crossfit® is a new variation of HIIT which involves high-intensity resistance training using varied, multiple-joint movements, and may also offer increased aerobic fitness with minimal time commitment.[19] Crossfit® was originally designed to train police officers, military special forces, and is a form of high-intensity interval training with some differences, better defined as High intensity functional training (HIFT). According to its founder, Greg Glassman, Crossfit® consists of

"constantly varied functional movements performed at high intensity. All Crossfit® workouts are based on functional movements, and these movements reflect the best aspects of gymnastics, weightlifting, running, rowing and more… Intensity is essential for results and is measurable as work divided by time or power. The more work you do in less time, or the higher the power output, the more intense the effort. By employing a constantly varied approach to training, functional movements and intensity lead to dramatic gains in fitness."

In other words, Crossfit® combines powerlifting, Olympic lifting, gymnastics and metabolic conditioning at high intensity with little/no rest (Cf. HIIT) to promote muscle strength and cardiorespiratory fitness. A number of studies have already shown some of the benefits of Crossfit® , such as a 2013 study that showed decreased body fat percentages and increased VO_2 max (the maximum rate of oxygen consumption measured during incremental exercise, a reflection of the cardiovascular fitness of an individual) after just 10 weeks of study with a marked increase in VO_2 max seen in those with an already above average value (an improvement not seen with HIIT).[19]

It would therefore be reasonable to contemplate that Crossfit®, like other forms of HIIT, may also have favourable effects on CVD risk factors, and by combining various training methods at high intensity with little rest these effects may even be greater than those of CME. To date there have been no studies that examine Crossfit®'s effects on CVD risk and the associated biochemical/physiological risk factors. This study therefore aims to evaluate the effects of Crossfit® on traditional CVD risk factors and overall cardiac risk, and to determine if they are superior to the changes seen with CME.

HYPOTHESIS

Null Hypothesis (H0)

There is no difference between the cardiovascular risk reduction achieved by completion of a continuous moderate exercise program, and a group based Crossfit® exercise program.

Alternative/Operative Hypothesis (H1)

A yearlong Crossfit® based exercise program leads to a greater reduction in cardiovascular risk than a continuous moderate exercise program.

Secondary Hypothesis

Crossfit® based exercise programs produce greater improvements in blood sugar control (baseline fasting glucose and glycated haemoglobin), lipid profiles, systolic and diastolic blood pressure and body mass index than continuous moderate exercise programs.

OBJECTIVES

The primary objective of this study is to demonstrate a difference between the reduction of cardiovascular risk, evaluated using the HeartSCORE risk evaluation tool, achieved by a 12-month period of triweekly sessions of either Crossfit® or continuous moderate exercise, in participants aged between 40-65.

The secondary objectives aim to:

a) Demonstrate improvements in the following additional cardiovascular/metabolic risk factors following the intervention:

   - Systolic and Diastolic Blood Pressure
   - Blood lipid profile (Total cholesterol, LDL-C, HDL-C & Triglycerides)
   - Baseline fasting glucose
   - Glycated haemoglobin
   - Type II Diabetes status
   - Body mass index.

b) Analyse baseline differences in age, sex, baseline physical activity, alcohol intake and nutritional status, in order to determine any correlations between baseline characteristics and the outcomes.

METHODS

STUDY DESIGN

The present study consists of a three-arm, multicentre, randomized controlled trial analysing two different exercise modalities intended to reduce overall cardiovascular risk, and a non-active intervention group. This type of study was chosen in order to best demonstrate a causal relationship between the exposure (intervention group) and outcome (CVD risk), while also allowing statistical comparisons between intervention groups.

PARTICIPANTS, SETTING AND PROCEDURE

This multi-centre pilot project will be carried out in 10 primary care centres within the province of Barcelona, more specifically those within the region defined by the Spanish national health care system as “Central Barcelona” (319 primary care centres in total, Annex 1.).

Primary care physicians from the 319 centers will be asked if they would like to participate as participant recruiters in the trial, and those that agree will be included in the trial until a total of 10 centers/physicians have joined the study. The recruiting physicians in the participating centers, along with their corresponding nursing teams will be given in-depth training on the recruitment process and any follow-up actions required. Each physician will be responsible for recruiting a total 36 participants during the 6-month recruitment period.

The recruitment period will run from July-December 2018, during which the recruiters will screen for patients with any of the following risk factors:

- Systolic Blood pressure > 140mmHg / Diastolic blood pressure > 90mmHg
- Positive smoking status
- Type II Diabetes mellitus
- Impaired fasting glycaemia (Fasting plasma glucose: 110-125g/dL)
- Glycated haemoglobin >6.0%
- Total cholesterol >150mg/dL

- LDL-C >100mg/dL
- HDL-C <60mg/dL
- Body Mass Index (BMI) > 25

If a patient has any of the listed risk factors, the physicians will then calculate the patients cardiovascular risk using HeartSCORE, an electronic version of the SCORE (Systemic Coronary Risk Evaluation) risk evaluation (Full Version, Low Risk countries. See Annex 2). Any patient with a HeartSCORE between 1 - 5% (Moderate Risk) who meets the additional inclusion criteria will be asked if they would like to participate in a study designed to reduce their future cardiovascular risk.

The electronic version of SCORE was chosen as, unlike the original SCORE risk, it also takes into account values of HDL-C. This is important given that physical exercise is specifically associated with elevations in HDL-C[20], and its inclusion means a more complete evaluation of risk variation. The most useful characteristic of the SCORE risk chart when compared with the Framingham model is that it does not just estimate the risk of coronary heart disease, but also for all atherothrombotic cardiovascular manifestations, such as stroke, heart failure, peripheral arterial insufficiency and certain aneurysms.

INCLUSION & EXCLUSION CRITERIA

Participants will be **eligible** for the study if they meet the following criteria:

(1) aged >40 years

(2) HeartSCORE of 1-5% (risk of 10-year fatal CVD).

(3) are willing to commit to the time requirements of the study.

(4) agree to sign the informed consent forms for participation.

Participants will be **excluded** from the study If they meet any of the following criteria:

(1) Age >65 years.

(2) Established CVD (e.g. ischemic heart disease, peripheral artery disease or cerebrovascular incidents).

(3) Morbid Obesity (BMI >40).

(4) Suffer from a disease/illness that in the physician's medical opinion means it would be un-ethical to include them in the study/ask them to perform intensive physical exercise (e.g. Excessive hypertension, Alcoholism, Substance abuse).

(5) Diagnosed secondary origin for increased CVD risk.*

(5) Have any form of musculoskeletal injury or are recovering from such an injury that may impede their participation.

(6) Are unable to meet the physical demands of the exercise regime.

(7) Are cognitively or otherwise impaired.

(8) Life expectancy <10 years (subjective physician estimation)

(9) Are pregnant or lactating.

*Importantly, patients with a diagnosed secondary cause for their increased risk, such as familial hypercholesterolemia in the case of dyslipidaemia or pheochromocytoma in the case of hypertension will be excluded from the study, given that the aim of the study is to improve modifiable factors such as primary hypertension, dyslipidaemia or elevated blood glucose/diabetes.

Once the participants have shown interest in the study and have passed the selection criteria they will be asked to complete an informed consent form, where the aims, interventions, assessments and data collection process will all be explained in detail (Annex 3). They will be asked to read the consent form in full and given the option to opt out of the study if they wish. The intervention period will then run during an 18-month period, from January 2019 to January 2020.

RANDOMIZATION

Once a participant is accepted into the study and has signed the informed consent form, their baseline data (Table 1) from the first visit will be input into a computer program which will randomly assign them a number (1, 2 or 3) which will be their intervention group. In order to reduce confounding variables, this randomization process will be stratified by sex, age, baseline HeartSCORE. The randomization will also be blocked by recruiting center so that for every 36 patients recruited by a center 12 will end up in each of the 3 intervention groups, therefore reducing any variability between the types of patients in different centers.

BLINDING

The blinding of the participants and exercise supervision personnel will not be possible given the nature of the study. The primary care physicians responsible for recruiting the participants of the study will not be aware of a participants group assignment upon recruitment. Once recruited into the study and the randomization process complete, the participants will be informed via email as to their group assignment. The email will contain the appropriate information regarding where and when to begin the intervention and details of the follow up visits. This method is preferred to the use of sealed envelopes commonly used in other studies as they are prone to discovery.

In order to reduce variations between the data collected in the different primary care centers, the data collection visits during the intervention period will be conducted by a separate medical team in a single centralized independent medical center. The professionals in this center will not be aware of the objectives of the study or the participants group assignment. They will be instructed not to inquire as to a participants group assignment unless deemed strictly necessary for the wellbeing of the patient. The participants will also be asked to not reveal their group assignment in any of the data collection visits. In this way blinding of the individuals responsible for data collection will be achieved with minimal risk of breaking the blind.

The data analysis will be conducted by researchers in an additional independent center who will be unaware of both the aim of the study and the participants group assignment, while

also being blinded to any potential identifiers. Once the data analysis is complete they will send the results of the analysis to the lead investigators.

In summary, the recruiting primary care physicians, the data collectors, the data analysis experts and the lead investigators (until receiving final results after data analysis) will be blinded during this study, however given the nature of the study the participants will be aware of their group assignment.

VARIABLES

Principal independent variable: Continuous moderate exercise (1), Crossfit® (2) or non-active intervention control (3).

Principal dependent variable: HeartSCORE (%), an online version of the SCORE cardiovascular risk assessment tool that estimates the risk of 10-year fatal CVD. (Discrete quantitative variable).

Secondary dependent variables:

- Continuous quantitative variables: BMI, systolic and diastolic blood pressure (mmHg), baseline fasting glucose (mg/dL), glycated haemoglobin (%) & blood lipid profile (Total cholesterol, LDL-C, HDL-C & triglycerides mg/dL).
- Dichotomic qualitative variables: Diabetes status (Yes/No), Medication status (antihypertensive, antihyperlipidemic and antihyperglycemic agents; yes/no), Smoking status (Yes/No).

Additional variables of interest: for Descriptive analysis

To be measured solely at the initial visit

- Age: The decrease in HeartSCORE is unlikely to be the same in older participants and younger participants (Continuous quantitative variable).
- Sex: Male/Female (Nominal dichotomous variable)
- Baseline Physical Activity: Active, moderately active, moderately inactive, inactive (Ordinal qualitative variable, estimated using the General practice physical activity questionnaire, GPPAQ)
- Alcohol intake: UBE's (Standard alcoholic drink units) (Annex 5.)
- Nutritional evaluation: 16 item food intake questionnaire (16-FIQ)[21]

To be measured at the end of the study (18m visit)

- Reported musculoskeletal injuries

DATA COLLECTION & INSTRUMENTS

Data will be collected using a combination of clinical history, evaluation questionnaires, clinical examination and laboratory tests., explained in detail below. Throughout the duration of the study the data collection will be completed according the timetable below:

	Variable	***Baseline***	***Every 3 Months*** *(0-3-6-9-12m)*	***Follow up visit (18 months)***
Principal Dependent Variable	***HeartSCORE*** *(%)*	*X*	*X*	*X*
Secondary Dependent variables	***BMI*** *(weight in Kgs/Height in cm²)*	*X*	*X*	*X*
	Systolic + Diastolic Blood Pressure (mmHg)	*X*	*X*	*X*
	Baseline fasting glucose *(mg/dL)* ***Glycated Haemoglobin*** *(Hb1Ac, %)*	*X*	*X*	*X*
	Blood lipid profile (mg/dL) - Total Cholesterol - LDL-C - HDL-C - Triglycerides	*X*	*X*	*X*
	Diabetes status *(DM1/DM2)*	*X*	*X*	*X*
	Medication status (Yes/No) - Antihypertensive - Antihyperlipidemic - Antihyperglycemic	*X*	*X*	*X*
	Smoking Status *(Yes/No)*	*X*	*X*	*X*
Additional variables of interest (Descriptive analysis)	***Age*** *(40-65 years)*[+]	*X*		
	Sex (Male/Female)[+]	*X*		
	Baseline Physical Activity (GPPAQ)*[+]	*X*		
	Alcohol Intake (estimated during previous month, UBEs)**[+]	*X*		
	Nutritional Evaluation (16-FIQ)***[+]	*X*	-	-
	Musculoskeletal Injuries *sustained during exercise*[+]	-	-	*X*

Table 1. Data collection schedule illustrating which variables will be measured throughout the study.

* Baseline physical activity

- Calculated using the General practice physical activity questionnaire (GPPAQ, Annex 4).
- The questionnaire provides a simple, 4-level Physical Activity Index (PAI): Active, Moderately Active, Moderately Inactive, and Inactive. These levels are correlated to CVD risk.

** Alcohol intake (UBE = 10g pure alcohol). Annex 5.

*** Nutritional Evaluation: 16 item-Food Intake Questionnaire (16-FIQ)[21]

- A Validated evaluation tool (Annex 6) that includes:
  - 6 questions about the number of meals per day and frequency of consumption of fast foods, fruits, vegetables, sugar rich foods, and sweets.
  - 4 questions about fat or cream used for cooking & fat used on bread.
  - 6 questions on number of different dishes each week (fish, sausage, chicken, meat, vegetable), milk consumption, cheese, cold cut products, breakfast cereals, alcohol consumption.

†For descriptive analysis.

As seen in the above table, the data collection visits will be every 3-months and not more frequently. This is because certain variables such as blood lipids generally change at a relatively slow rate, and it is unnecessary to measure these parameters in smaller intervals. Similarly, glycated Haemoglobin (Hb1Ac) represents the mean plasma glucose concentration during the previous 120 days, thus 3-monthly measurements will suffice. This timing schedule also means a reduction in the number of blood extractions that the participant must undergo.

The measurement of blood pressure will be a mean value of the last 2 of 3 measurements taken. The measurements will be taken after 5 minutes of seated rest and to reduce variability, the blood pressure will be measured using a semiautomatic sphygmomanometer

(Omron M1 Plus (HEM-4011C-E). Omron Corporation, Kyoto, Japan) validated by both the Spanish and the British Hypertension Societies (EHS & BHS). The model has a function which allows mean calculation of the previous 2 measurements which will be used to report all data.

Body weight measurements will be conducted using the same standardized weighing scale (RGT 260468, Baxtran™, Vilamalla, Spain), and participants will be asked to empty their bladders and remove all outer clothing before being weighed. BMI (Weight in Kg/Height in meters squared) calculations will be made using an online BMI calculator provided by the National Institute of Health (Annex 7).

For the measurement of blood values, the extraction technique will be standardized. Following a 12-hour fasting period a sample of venous blood will be extracted preferably from an antecubital vein. The extraction should take place during the first few hours of the morning (between 08:00 and 10:00am). In order to avoid any interference from temporary variations following physical activity the extraction of all blood samples must be on days following a rest day, and not following an intervention day (e.g. On an intervention day, before completing any physical exercise or on a Sunday). After extraction into a sample tube containing EDTA, the samples will be quickly centrifuged to separate the blood plasma and will then be stored at 4^{o}C until the appropriate measurements can be made later that day. All samples will be processed and informed by the same laboratory.

SAMPLE SIZE CALCULATION

Given that the present study is a pilot study, and that no similar studies have been conducted previously, it is not possible to estimate effect-size. It was therefore calculated that in order to detect a 20% difference in HeartSCORE reduction between groups, with an 80% statistical power & a 5% significance level, that 103 participants per group would be needed.[22] Assuming a 20% dropout rate a total of 360 participants (36 participants per center) will be needed. These estimates should be considered approximations, but it is thought that a 20% difference would be both clinically relevant and possible to detect given the sample size, therefore warranting further investigation.

DESCRIPTION OF THE INTERVENTION

Participants who meet the inclusion criteria will be randomly assigned to an intervention group (1, 2 or 3) using the allocation process described above. The 3 groups are: The continuous moderate exercise group (Group 1), the Crossfit® group (Group 2), and the non-active intervention group (Group 3).

DIETARY MEASURES

Prior to the commencement of the intervention period patients in all 3 groups will be given dietary recommendations to follow throughout the duration of the study. The recommendations will be those stated in the European Guidelines on CVD Prevention in Clinical Practice.[23]

- Saturated fatty acids to account for <10% of total energy intake, through replacement by polyunsaturated fatty acids.
- Trans unsaturated fatty acids: as little as possible, preferably no intake from processed food, and <1% of total energy intake from natural origin
- <5 g of salt per day.
- 30–45 g of fibre per day, from wholegrain products, fruits and vegetables.
- 200 g of fruit per day (2-3 servings).
- 200 g of vegetables per day (2-3 servings).
- Fish at least twice a week, one of which to be oily fish.
- Consumption of alcoholic beverages should be limited to 2 glasses per day
    - (20 g/d of alcohol) for men and 1 glass per day (10 g/d of alcohol) for women.

GROUP 1 (CONTINUOUS MODERATE EXERCISE)

In an attempt to follow the recommendations of the Spanish Health System (150 minutes of moderate physical exercise/75 minutes of vigorous physical exercise per week), participants in this group will complete 60 minutes of continuous moderate exercise 3 times per week (Monday, Wednesday and Friday). Participants will complete a 10-minute supervised warm-up and stretching routine, followed by 40 minutes of continuous moderate exercise using aerobic exercise machines (Stationary bike, treadmill, cross-trainer or rowing machine: 20 minutes maximum per machine) at 50-70% (defined as moderate exercise by the American Heart Association) of their theoretical maximum heart rate (MHR: 220 – Age of participant., and finally a 10-minute supervised cool down. The participants will be given heart-rate monitors to wear during the activity and the exercise supervision personnel will aim to ensure that the heart rate remains within the desired limits during the 40-minute CME period (50-70% MHR). Participants will be asked to avoid all other types of structured physical activity during the study period.

GROUP 2 (CROSSFIT®)

Those in the Crossfit® group will also complete 3 x 60-minute sessions a week (Monday, Wednesday and Friday), but of a supervised group Crossfit® class. The classes will be completed at the participating Crossfit® boxes in the L'eixample area (Crossfit Les Corts, La Huella Crossfit and Max Grit Crossfit). Participants will be assigned to the gym location closest to their home residence in order to favour adherence. The 60-minute training sessions will be led by Crossfit® certified trainers, and will consist of combinations of powerlifting, Olympic lifting, gymnastics and metabolic conditioning performed at high intensity with little/no rest. The nine basic movements (air squat, front squat, overhead squat, press, push press, push jerk, deadlift, sumo deadlift high pull, and medicine ball clean. Annex 8) will be explained to the participants during the first 2 training sessions. The workouts themselves will last between 5 and 40 minutes, with the remaining time being occupied by warm-up/stretching, technique drills and warm-down/stretching. In order to reduce variability of trainer programming between the different gyms, all workouts used will be the corresponding "workout of the day" or "WOD" posted each day on the central Crossfit® website (www.Crossfit® .com). This will ensure that participants in the 3 different

gyms will be completing the same routines. Given the nature of the workouts it will be unfeasible to control the heart rate range achieved during the workouts, but the workouts will be completed at self-selected high-intensity and given the type of exercise it is assumed that participants will be mostly exercising at >80-90% of their predicted maximum heart rate (High Intensity). The workouts will be performed for time (as fast as possible), for repetitions (AMRAP style/As many repetitions as possible) or by maximum weight. Given the level of difficulty of some of the workout, a scaled option will be available for all workouts. The scaled option aims to reduce the load/difficulty of the movements while still allowing to exercise at high intensity. In this way, participants with a low physical fitness level may still benefit from the intervention. An example of a week's training program is shown in Table 1. As with the CME group, the participants will be asked to avoid all other types of structured exercise during the study. Descriptions of all movements and standards can be found on the Crossfit.com website.

Day	Monday	Wednesday	Friday
Workout	AMRAP 20 Minutes 8 Toes-to-bar 10 Dumbbell Power Clean & Jerk (22.5kg) 14 Calories Row	In 12 minutes complete: 1-2-3-4-5-6-7-8-9-10 reps for time of: Dumbbell squats (22.5kg) Bar-facing burpees Then 1 rep max clean	For time: 10 snatches (22.5kg) 15 burpee box jump-overs (24" Box) 20 snatches 15 burpee box jump-overs 30 snatches 15 burpee box jump-overs 40 snatches 15 burpee box jump-overs 50 snatches 15 burpee box jump-overs
Scaling options	Hanging leg raises 17.5kg Dumbbell	17.5kg Dumbbell	17.5kg Dumbbell 20" Box

Table 2. Example of the programming during a week of the Crossfit Intervention Group

GROUP 3 (NON-ACTIVE INTERVENTIONL)

The non-active intervention group will be given the same nutritional recommendations as the other intervention groups. Given the ethical issues regarding asking patients to abstain from physical activity, they will not be actively encouraged to exercise as part of the study (thus non-active intervention group), but their primary care physicians will be permitted to give them the standard advice on physical activity should the subject arise during a visit. It is assumed that this would reflect their lifestyle choices if the study were to not take place. It is understood that they will complete light physical activity such as walking and general household tasks as usual.

STATISTICAL ANALYSIS PLAN

The complete data will be input into an electronic data sheet. The analysis will be completed by intention to treat, meaning that all participant data will be analysed for each group, independently of whether they complete or not the entire protocol.

In order to achieve the primary objectives, the following statistical analysis plan will be implemented:

- A general descriptive analysis of the 3 samples will be performed, including the absolute (n) and relative (%) frequency distributions of the qualitative variables, as well as measurements of central tendency and dispersion (mean, standard deviation, median, minimum and maximum) of the quantitative variables.

- At baseline (first visit data), in order to assess the comparability of baseline characteristics between study groups:

    - Independent samples t-tests / One-way ANOVA (or U-Mann Whitney, if non-parametric tests are required) will be conducted for the quantitative variables (age, BMI, HeartSCORE, Blood pressure, baseline fasting glucose, glycated haemoglobin, blood lipid profiles, alcohol intake and 16-FIQ)

    - Chi-square analysis / Fishers exact Test will be used for the qualitative variables (sex, smoking status, diabetes mellitus status, medication status, baseline physical activity)

- To evaluate the evolution of the quantitative parameters (most importantly HeartSCORE) during the evolution of the study (at baseline, 3, 6, 9, 12 months and a final post 18 month follow up), a repeated measure analysis will be performed in the 3 groups.

- Levene's test will be used to assess homogeneity of variance and in the case of a homogeneity violation in any relevant variable of the study groups, a multivariate analysis will be performed (Multiple regression analysis).

- The overall reduction in HeartSCORE at the end of the study period, as well as changes in any other quantitative variable will be analysed using one-way random effects ANOVA.

- Analysis Post-hoc between: Crossfit® (2) & Non-intervention control (3) and Crossfit® (2) & CME (1) will be performed using a multiple testing procedure applying the Dunnett correction.

- Descriptive analysis of the additional variables (Age, Sex, Baseline physical activity, Alcohol intake and nutritional status) will be conducted in order to reveal any possible associations that may be the subjects of further studies (e.g., Are the benefits greater in men/women etc.)

- The 95% confidence interval will be estimated for all parameters and the level of significance will be set at 5%. The data analysis will be completed using the statistical analysis program SPSS version 25 (IBM Corp. Armonk, NY, USA) for Mac OS X.

Figure 2 summarizes the study design & protocol.

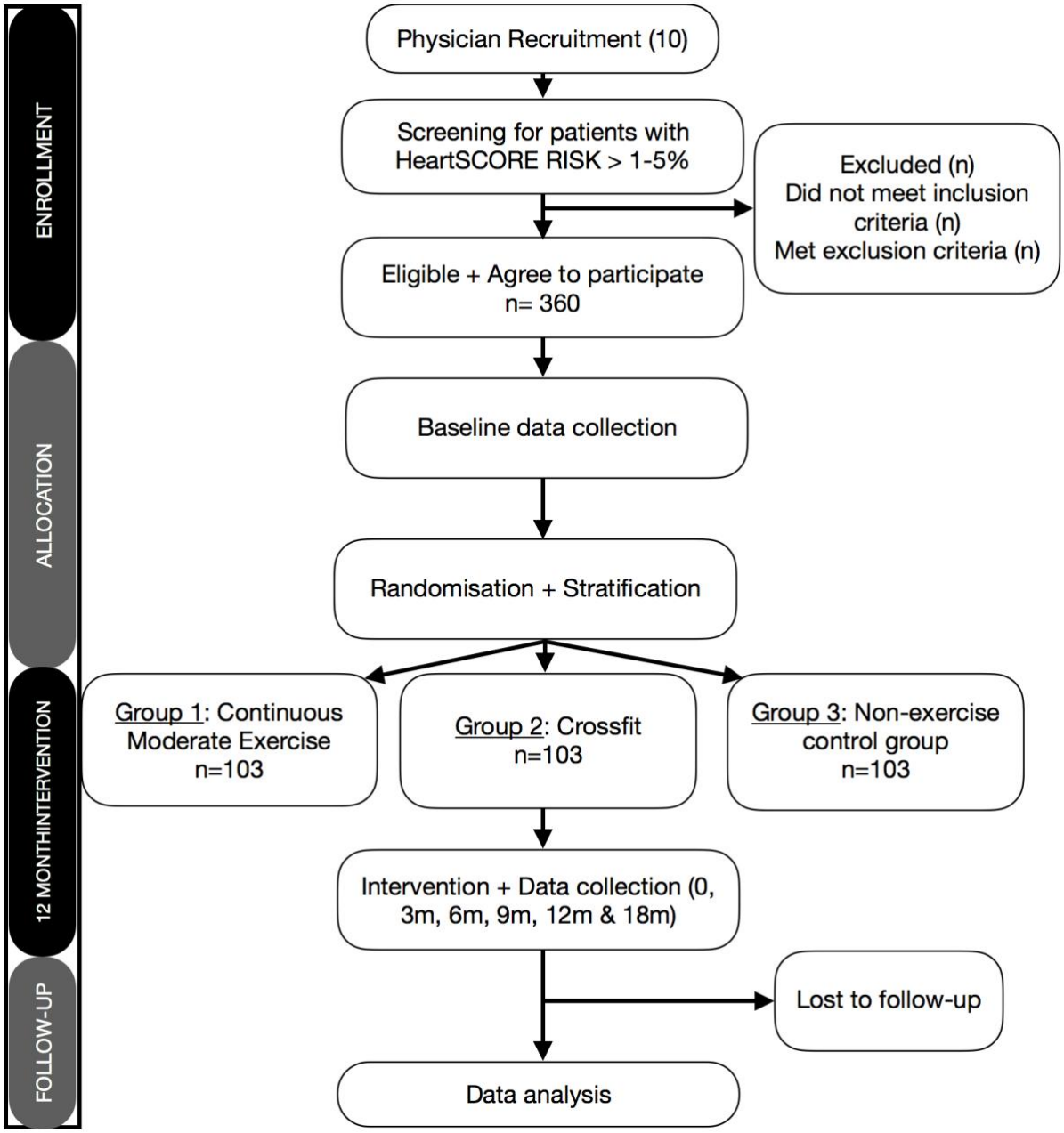


Figure 2. Study protocol flowchart

TIMETABLE

The predicted timetable is as follows: See Table 3 for a more detailed example.

July-December 2017: Creation of the Study Protocol

January-June 2018: Physician recruitment and training. Provisional approval by ethics committee.

July-December 2018: Recruitment period completed by primary care physicians participating in the study.

January 2019-January 2020: Intervention period & data collection.

July 2019: Final 18m follow up visit.

September 2019: Data analysis completed independently by external researchers unaware of group assignation and purpose of study. Results sent to lead investigators.

September 2019 (Post Data analysis): Interpretation of results and possible conclusions, drawbacks or ideas for further study.

October 2019: Submission of final report.

Activity																								
Time in months	-6	1	2	3	4	5	**0**	1	2	3	4	5	6	7	8	9	10	12	12	..	18	19	20	21	22
PLANNING + ENROLLMENT																									
Creation of Study protocol																									
Selection of 10 participating centers																									
Presentation of study to primary care physicians in selected centers																									
Physician recruitment and training																									
Approval by ethics committee																									
Participant screening and recruitment																									
INTERVENTION																									
Completion of 12-month intervention																									
Data collection																									
Follow-up Final visit																									
Introduction of results into central database and sent for analysis																									
EVALUATION																									
Data Analysis																									
Post Data Analysis																									
Discussion of results and final study report																									

Table 3. Predicted timetable of the study protocol

ETHICAL ASPECTS AND ADDITIONAL CONSIDERATIONS

The study will need approval from the ethics committee of the participating health centers, and the registration numbers from the ethical committee on clinical investigations will be indicated from the beginning of the study. The following procedures will be used to address any ethical aspects or additional considerations of the study.

DATA CONFIDENTIALITY & USE OF ELECTRONIC TECHNOLOGY

The study will be completed following the explanations given in this protocol. The study will endeavour to follow the recommendations given in the international guidelines on the completion of epidemiological studies and the "Declaration of Helsinki".[24,25]

In order to maintain the confidentiality of the participants, their identities will be protected during the following interventions: Data collection (only personal information strictly necessary will be collected, and will be stored in a secure location), Randomization (data dissociation, encryption of files, passwords) and publication of results. All personal information will be registered in the Spanish agency for the protection of data (AEP). All files and biological samples will be safely destroyed once no longer needed.

As mentioned above, all participants will be required to sign an informed consent form (Annex 3). The will receive both verbal and written explanations of the study design, and patient information. The consent process and form itself will follow the recommendations given in sections 25-32 of the Declaration of Helsinki.[25]

All participating health-care personnel, data analysts and investigators will have to sign an agreement in which they will accept the ethical and good practice guidelines of the study, as well as agreeing to adhere to the rules for the protection of patient data.

RISK-BENEFIT EVALUATION

If there is seen to be an abnormal number of musculoskeletal injuries in either group, then the trial will be put on hold to allow analysis of whether it would be ethical to continue the study. To facilitate this, patients will be asked to communicate any injuries sustained throughout the study in the data collection visits, although the total number of

musculoskeletal injuries per group will only be directly measured in the final control visit (18m).

PUBLICATION CONDITIONS

The publication of the study will be in scientific journals, with prior approval needed from the ethics committee of the participating centers. When published, the origin of all funding will be clearly stated. All information regarding the results of the study will be kept concealed until the data has been analysed and interpreted.

CONFLICTS OF INTEREST

The authors will be required to report any conflicts of interest and any funding from public/commercial or non-profit agencies that was received in support of the study.

STRENGTHS & LIMITATIONS

STRENGTHS

- This is an original pilot study, that looks to begin a novel branch of investigation into which forms of physical activity are most effective at reducing cardiovascular risk.
- This trial will provide new evidence regarding the effects of physical activity on cardiovascular disease risk, thus allowing for better patient advice in the clinical setting, and in the future possible reductions in fatal cardiovascular disease rates.
- The trial will take into account not only the risk factors that compose the HeartSCORE risk, but additional risk factors such as glycaemic control and BMI that are not only indicated as additional risk factors in CVD, but also in other diseases e.g. Breast cancer in the case of BMI.

LIMITATIONS

- The estimation of effect size may lead to results that do not reach statistical significance, however given the sample size selected it is thought that most clinically relevant differences will be detected.

- During the intervention there is little control over other lifestyle factors such as diet, alcohol intake or smoking. However, this likely reflects the real-life situation, thus allowing inferences as to the importance of combining physical activity with other lifestyle choices.

- The HeartSCORE evaluation is only able to assess risk for people between 40-65. Fortunately, people outside these age ranges do not require such strict control of their cardiovascular risk.

- A number of the variables measured are not exact measurements and may lack precision, only providing a general estimation (e.g. 16-FIQ, GPPAQ and UBEs), but these variables will only to be used for descriptive analysis and therefore will not reduce the power of the study or any conclusions made with regarding the primary outcome.

- In studies of a similar kind, the investigators have taken measures to ensure equal calorie usage in the different intervention groups. However, given that the aim of this study was to investigate whether 60 minutes of Crossfit®, or 60 minutes of CME was more effective at reducing cardiovascular risk, the number of calories burned during the sessions is not of paramount importance, and may be even be an indirect mediator of the effects observed.

- Given the important time commitments and intensity of the intervention, it is likely that there may not be 100% adherence to the intervention, and in the worst-case, abandonment of the study. This possible limitation is actually more likely to reflect the common habits of adherence to physical activity (i.e. not 100%).[18] To reduce the effect of this the data will be analysed by intention-to-treat.

- It is possible given the intensity of the interventions that there may be a number of injuries throughout the study. If patients are unable to attend all sessions their data will be analysed equally (ITT).

- There is a small chance of contamination between patients that attend the same primary care center, leading to participants that desire to change intervention

groups. However, this would only underestimate the effect size given the type of analysis used (ITT) therefore increasing the significance of any significant results.

- The participants will be asked to not do any additional structured physical activity during the study period, however some participants may not follow these recommendations, or may have active jobs. It is assumed that the risk of this additional physical activity is roughly equal between all intervention groups, thus minimizing any effect it may have on the end results.

- The study duration only allows evaluation of the effect during a short time period (12 months). To begin to correct this a post-intervention visit will be completed 6 months after finishing the intervention period. This will also allow examination as to whether a reduction in cardiovascular disease risk is maintained in time after finishing the intervention, and for how long.

- It is likely that if any statistical associations are discovered that further multi-centric investigations will be necessary.

EXPECTED IMPACT OF THE RESULTS

Given the prevalence of cardiovascular disease and its associated mortality, potential strategies to reduce the risk of its development should be extensively examined as they may allow for reductions in mortality rates, not forgetting the associated economic benefits for the national health service. Currently, the strategies with most success have been pharmacological treatments aimed to reduce risk factors (such as Statins in the case of hypercholesterolemia), however there has been less investigation into non-pharmacological interventions. The benefits of a significant CVD risk reduction without the need for regular medication are obvious and should not be taken likely. As to date, there are no studies that compare the reductions achieved using different exercise modalities. If the results were to show a clinically significant difference, physicians may be able prescribe a Crossfit® based exercise regime as an alternative to the current physical activity recommendations, before the need to prescribe other pharmacological options that often have a range of adverse effects. The ability to reduce not only cardiovascular risk but also other diseases influenced by metabolic alterations could mean an improved overall health at population level.

REFERENCES

1. WHO. WHO | World Health Statistics 2017: Monitoring health for the SDGs. WHO. 2017;

2. Porta MS, International Epidemiological Association. A dictionary of epidemiology. Oxford University Press; 2008. p289.

3. Dawber TR, Meadors GF, Moore FE. Epidemiological approaches to heart disease: the Framingham Study. Am J Public Health Nations Health. 1951 Mar;41(3):279–81.

4. Dawber TR, Moore FE MG. Coronary heart disease in the Framingham Study. Am J Public Heal. 1957;47:4–24.

5. Kannel, WB. Dawber, TR. Kagan, A. Revotskie, N. Stokes J. Factors of Risk in the Development of Coronary Heart Disease - Six Year Follow-up Experience. Ann Intern Med. 1961;55(1):33–50.

6. Kannel WB, Dawber TR, McGee DL. Perspectives on systolic hypertension. The Framingham study. Circulation. 1980 Jun;61(6):1179–82.

7. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R, Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet (London, England). 2002 Dec 14;360(9349):1903–13.

8. Kannel WB, McGee DL. Diabetes and glucose tolerance as risk factors for cardiovascular disease: the Framingham study. Diabetes Care. 2(2):120–6.

9. Doyle JT, Dawber TR, Kannel WB, Heslin AS, Kahn HA. Cigarette smoking and coronary heart disease. Combined experience of the Albany and Framingham studies. N Engl J Med. 1962 Apr 19;266:796–801.

10. Fletcher GF, Blair SN, Blumenthal J, Caspersen C, Chaitman B, Epstein S, et al. Statement on exercise. Benefits and recommendations for physical activity programs for all Americans. A statement for health professionals by the Committee on Exercise and Cardiac Rehabilitation of the Council on Clinical Cardiology, American Heart

associ. Circulation. 1992 Jul;86(1):340–4.

11. Berlin JA, Colditz GA. A meta-analysis of physical activity in the prevention of coronary heart disease. Am J Epidemiol. 1990 Oct;132(4):612–28.

12. Wise FM. Coronary heart disease--the benefits of exercise. Aust Fam Physician. 2010 Mar;39(3):129–33.

13. Blair SN, Kampert JB, Kohl HW, Barlow CE, Macera CA, Paffenbarger RS, et al. Influences of cardiorespiratory fitness and other precursors on cardiovascular disease and all-cause mortality in men and women. JAMA. 1996 Jul 17;276(3):205–10.

14. Mora S, Cook N, Buring JE, Ridker PM, Lee I-M. Physical Activity and Reduced Risk of Cardiovascular Events: Potential Mediating Mechanisms. Circulation. 2007 Nov 6;116(19):2110–8.

15. Ministerio de Sanidad, Servicios Sociales e Igualdad, Ministerio de Educación. Actividad Física para la Salud y Reducción del Sedentarismo: Recomendaciones para la Población. Estrateg Promoción la Salud y Prevención en el SNS Madrid. 2015.

16. O'Donovan G, Owen A, Bird SR, Kearney EM, Nevill AM, Jones DW, et al. Changes in cardiorespiratory fitness and coronary heart disease risk factors following 24 wk of moderate- or high-intensity exercise of equal energy cost. J Appl Physiol. 2005 Jan 20;98(5):1619–25.

17. Tjonna AE, Lee SJ, Rognmo O, Stolen TO, Bye A, Haram PM, et al. Aerobic Interval Training Versus Continuous Moderate Exercise as a Treatment for the Metabolic Syndrome: A Pilot Study. Circulation. 2008 Jul 22;118(4):346–54.

18. Thurston M, Green K. Adherence to exercise in later life: how can exercise on prescription programmes be made more effective? Health Promot Int. 2004 Sep 1;19(3):379–87.

19. Smith MM, Sommer AJ, Starkoff BE, Devor ST. Crossfit-Based High-Intensity Power Training Improves Maximal Aerobic Fitness and Body Composition [RETRACTED]. J Strength Cond Res. 2013 Nov;27(11):3159–72.

20. Durstine JL, Haskell WL. Effects of exercise training on plasma lipids and lipoproteins. Exerc Sport Sci Rev. 1994;22:477–521.

21. Hemiö K, Pölönen A, Ahonen K, Kosola M, Viitasalo K, Lindström J. A simple tool for diet evaluation in primary health care: validation of a 16-item food intake questionnaire. Int J Environ Res Public Health. 2014 Mar 4;11(3):2683–97.

22. Granmo Sample Size and Power Calculator GRANMO. Granmo Sample Size and Power Calculator GRANMO Version 7.12. http://www.imim.cat/ofertadeserveis/software-public/granmo/. 2012.

23. Perk J, De Backer G, Gohlke H, Graham I, Reiner Z, Verschuren M, et al. European Guidelines on cardiovascular disease prevention in clinical practice (version 2012). The Fifth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of nine societies and by invited experts). Eur Heart J. 2012 Jul 1;33(13):1635–701.

24. International guidelines for ethical review of epidemiological studies. Law Med Health Care. 19(3–4):247–58.

25. World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association [Internet]. [cited 2018 Apr 18]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

ANNEXES

1. **LIST OF THE PRIMARY CARE CENTERS WITHIN "CENTRAL BARCELONA" REGION (319 IN TOTAL**
2. **SCORE – SYSTEMATIC CORONARY RISK EVALUATION**
3. **INFORMED CONSENT FORM**
4. **GENERAL PRACTICAL PHYSICAL ACTIVITY QUESTIONAIRRE (GPPAQ)**
5. **UBEs OF COMMON ALCOHOLIC BEVARAGES**
6. **FOOD INTAKE QUESTIONAIRRE (FIQ-16)**
7. **BMI CALCULATOR**
8. **CROSSFIT'S 9 FOUNDATIONAL MOVEMENTS**

1. **LIST OF THE PRIMARY CARE CENTERS WITHIN "CENTRAL BARCELONA" REGION (319 IN TOTAL**

17 DE SETEMBRE	HORTA - BARCELONA 7D - 7F	ROGER DE FLOR - DRETA EIXAMPLE - MONUMENTAL
ABRERA	ISABEL ROIG - CASERNES DE SANT ANDREU	RONDA CERDANYA
ADRIÀ - MARC AURELI - SANT ELIES	ISIDRE BAGES	RONDA DE LA TORRASSA
AIGUAFREDA	JAUME I	RONDA PRIM - LA RIERA
ALAMEDA	JOAN MIRAMBELL I FOLCH DE CALDES DE MONTBUI	ROQUETES
ALELLA	JUST OLIVERAS	ROGER DE FLOR - DRETA EIXAMPLE - MONUMENTAL
ALT PENEDÈS	L'AMETLLA DEL VALLÈS	RONDA CERDANYA
AMADEU TORNER	LA BATLLORIA	RONDA DE LA TORRASSA
ANTÓN DE BORJA	LA BEGUDA ALTA	RONDA PRIM - LA RIERA
ANTONI CREUS - CAN PARELLADA	LA CRUÏLLA	ROQUETES
APENINS-MONTIGALÓ	LA FARIGOLA	ROGER DE FLOR - DRETA EIXAMPLE - MONUMENTAL
ARENYS DE MAR	LA FLORESTA	RONDA CERDANYA
ARENYS DE MUNT	LA FLORIDA	RONDA DE LA TORRASSA
AVINYÓ NOU	LA GARRIGA	RONDA PRIM - LA RIERA
BADIA DEL VALLÈS	LA GRANADA	ROQUETES

BAIX A MAR	LA GRANJA	ROGER DE FLOR - DRETA EIXAMPLE - MONUMENTAL
BARBERÀ DEL VALLÈS	LA LLAGOSTA	RONDA CERDANYA
BARCELONETA	LA LLÀNTIA	RONDA DE LA TORRASSA
BARRI COTET	LA MARINA	RONDA PRIM - LA RIERA
BARRI EL REMEI	LA MINA	ROQUETES
BELLVITGE	LA MÚNIA	ROQUETES
BESÒS	LA PALMA DE CERVELLÓ	ROSA DELS VENTS
BIGUES I RIELLS	LA PAU	SAGRADA FAMÍLIA - BAERCOLANA 2I - 2K
BÒBILA - CAN VIDALET - PUBILLA CASAS	LA RÀPITA	SANFELIÚ
BON PASTOR	LA RIERA DE MATARÓ	SANLLEHY
BORDETA - MAGÒRIA	LA SAGRERA	SANT ANDREU
BUFALÀ - CANYET	LA SALUT	SANT ANDREU DE LA BARCA
CA N'ORIAC	LA SERRA	SANT ANDREU DE LLAVANERES
CABANYES (LES)	LA SOLANA	SANT ANTONI DE VILAMAJOR
CABRERA D'ANOIA	LA TORRETA	SANT CELONI
CABRERA DE MAR	LARRARD - LA SALUT - LESSEPS	SANT CLIMENT DE LLOBREGAT
CABRILS	LAVERN	SANT CUGAT DEL VALLÈS
CALDES D'ESTRAC	LES CORTS	SANT CUGAT SESGARRIGUES
CAMPS BLANCS	LES FRANQUESES DEL VALLÈS	SANT ESTEVE DE

		PALAUTORDERA
CAN BOU	LES GUNYOLES	SANT ESTEVE SESROVIRES
CAN CARDEDEU	LES INDIANES	SANT FELIU DE CODINES
CAN MASSUET	LES MASUQUES	SANT FÈLIX
CAN MORITZ	LES PLANES	SANT FOST DE CAMPSENTELLES
CAN PANTIQUET	LES PLANES	SANT GENÍS
CAN RULL	LES PLANES	SANT ILDEFONS
CAN SANT JOAN	LLATÍ	SANT JOAN
CAN SERRA	LLEFIÀ	SANT JUST DESVERN
CAN TRIAS-ERNEST LLUC DE VILADECAVALLS	LLIÇÀ DE VALL	SANT LLÀTZER
CAN VILALBA	LLINARS DEL VALLÈS	SANT LLORENÇ D'HORTONS
CANALETES	LLUÍS MILLET	SANT LLORENÇ SAVALL
CANOVELLES	MANSO - POBLE SEC MONTJUÏC - SANT ANTONI - UNIVERSITAT - VIA ROMA	SANT MARÇAL
CÀNOVES I SAMALÚS	MARESME	SANT MARTÍ - VERNEDA SUD
CANYAMARS	MARÍA BERNADES	SANT MARTÍ SARROCA
CANYELLES	MARTÍ I JULIÀ	SANT MIQUEL
CARLES I	MARTORELL	SANT MIQUEL D'OLÈRDOLA
CARRERAS CANDI	MARTORELLVILA	SANT MIQUEL DEL CROS
CASANOVA - EIXAMPLE	MAS FONT	SANT OLEGUER

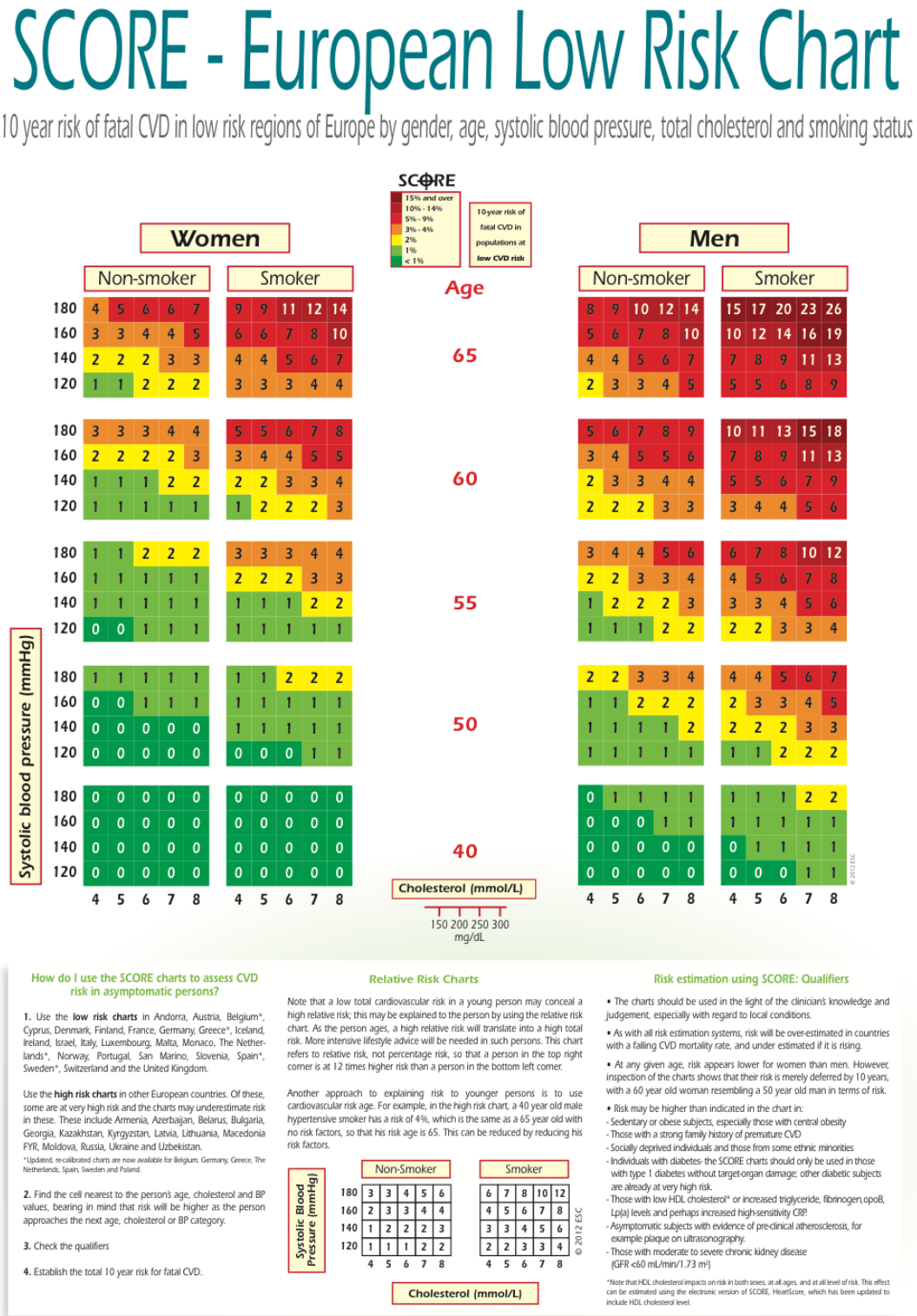
CASC ANTIC	MASNOU (EL)	SANT PAU D'ORDAL
CASTELLAR DEL VALLÈS	MASQUEFA	SANT PERE DE RIBES
CASTELLBISBAL	MATADEPERA	SANT PERE DE RIUDEBITLLES
CENTRE	MATARÓ-CENTRE	SANT PERE DE VILAMAJOR
CENTRE INTEGRAL DE SALUT COTXERES	MEDIONA	SANT PERE MOLANTA
CERDANYOLA-RIPOLLET	MERINALS	SANT QUINTÍ DE MEDIONA
CERVELLÓ	MOJA	SANT QUIRZE DEL VALLÈS
CHAFARINAS	MOLÍ NOU	SANT RAFAEL
CIRERA MOLINS	MONTALPARC	SANT ROC - EL GORG
CIUTAT MERIDIANA	MONTBAIG	SANT SADURNÍ D'ANOIA
COLLBATÓ	MONTCADA I REIXAC	SANT VICENÇ DE MONTALT
COLLBLANC	MONTCLAR	SANTA AGNÈS DE MALANYANES
COLONIA GÜELL	MONTGAT	SANTA COLOMA DE CERVELLÒ
COMTE BORRELL	MONTMELÓ	SANTA COLOMA DE GRAMENET
CONCÒRDIA	MONTNEGRE - LES CORTS PEDRALBES	SANTA EULÀLIA DE RONÇANA
CORBERA DE LLOBREGAT	MONTORNÈS DEL VALLÈS	SANTA FE DEL PENEDÈS
CORNELLÀ DE LLOBREGAT	MONTORNÈS DEL VALLÈS	SANTA MARGARIDA I ELS MONJOS
CORRÓ D'AVALL	MORERA POMAR	SANTA MARIA DE PALAUTORDERA

CREU ALTA	MOSSÈN CINTO VERDAGUER	SANTA MARIA DE VILALBA
CREU DE BARBERÀ	MÚTUA RUBÍ	SANTA PERPÈTUA DE MOGODA
CUBELLES	NORD	SANTA ROSA
DOCTOR BARRAQUER	NOVA LLOREDA - MONTIGALÀ	SANTS
DOCTOR CARLES RIBAS	NUMANCIA	SARDENYA
DOCTOR LLUÍS SAYÉ	OCATA	SARRIÀ
DOCTOR PUJOL ISADA	OLESA DE BONESVALLS	SENTMENAT
DOCTOR ROBERT	OLESA DE MONTSERRAT	SERRAPARERA
DOCTOR VICENÇ PAPACEIT	OLIVELLA	SINGUERLÍN
DOCTOR VILASECA (CAN MARINER)	ÒRRIUS	SITGES
DOSRIUSCENTRE	PACS DEL PENEDÈS	SUD
DR. BARTOLOMEU FABRÉS ANGLADA (GAVÀ 2)	PALAU-SOLITÀ I PLEGAMANS	TEIÀ
DR. CARLOS HERRÀIZ	PALAUDÀRIES	TERRASSA EST
DR. GONÇAL CALVO I QUERALTÓ	PALLEJÀ	TERRASSA NORD
DR. GUILLERMO MASRIERA I GUARDIOLA	PARE CLARET	TERRASSA OEST
DR. MARTÍ I JULIÀ	PARETS DEL VALLÈS	TERRASSA SUD -CAN JOFRESA-
DRASSANES	PASSEIG DE MARAGALL - CAMP DE L'ARPA - ENCANTS - CONGRÈS	TIANA

EL BRUC	PASSEIG DE SANT JOAN	TORRELAVIT
EL CARMEL	PINETONS	TORRELLES DE FOIX
EL CASTELL	PLA DE L'AVELLÀ	TORRELLES DE LLOBREGAT
EL CLOT	PLA DEL PENEDÈS (EL)	TORRELLETES
EL FONDO	PLANA LLEDÓ	TORRENT DELS LLOPS
EL PAPIOL	POBLE NOU	TRINITAT VELLA
EL PLA	POBLE SEC - LES HORTES	TURÓ - VILAPICINA
EL SERRAL DE SANT VIÇENS DELS HORS	POBLENOU	TURÓ DE CAN MATES
ESPARREGUERA	POLINYÀ	ULLASTRELL
FIGARÓ-MONTMANY	PONTONS	VALLCARCA - SANT GERVASI
FLORIDA NORD Y SUD	POU TORRE	VALLDOREIX
FONTETES	PREMIÀ DE DALT -NUCLI-	VALLÈS ORIENTAL
FONTSANTA	PREMIÀ DE MAR	VALLGORGUINA
GAVÀ 1	PROGRÈS-RAVAL	VALLIRANA
GELIDA	PUIGDÀLBER	VALLROMANES
GORNAL	PURA FERNÀNDEZ	VALLVIDRERA
GÒTIC	RAMBLA	VERDAGUER
GÒTIC ANNEX RULL	RAMBLA DE TERRASSA	VILA DE GRÀCIA - CIBELES
GRÀCIA	RAMBLA MARINA	VILA OLÍMPICA
GRAN SOL	RAMON TURRÓ	VILA VELLA

GUALBA	RAMONA VIA	VILANOVA DEL VALLÈS
GUARDIOLA DE FONT-RUBÍ	RÍO DE JANEIRO - PORTA - PROPERITAT - VERDUN	VILASSAR DE DALT
GUINARDÓ	RIPOLLET	VILLADECAVALLS
GUINEUETA	ROCAFONDA-PALAU	VILOBÍ DEL PENEDÈS
		VINYETS

2. SCORE – SYSTEMATIC CORONARY RISK EVALUATION



3. INFORMED CONSENT FORM

INFORMED CONSENT FORM FOR PATIENT

This Informed Consent Form is for men and women who have been invited to participate in a clinical trial aimed at reducing cardiovascular risk using different modalities of physical activity.

The title of our research project is: Is Crossfit® (High intensity functional training) superior to continuous moderate exercise at reducing 10-year cardiovascular risk? A Study Protocol.

Name of Principal Investigator: Matt Corbett

This Informed Consent Form has two parts:

• Information Sheet (to share information about the research with you)

• Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

We are doing research on the risk of cardiovascular disease, which is a major causa of mortality worldwide. The following information is designed to explain clearly the purpose and workings of the study. Once you have read the information you will be given time to decide whether or not you would like to participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them at any point).

Purpose of the research

Cardiovascular disease (CVD) is an important cause of mortality worldwide. A number of lifestyle factors and laboratory results can cause an increased risk of CVD, for example smoking or high cholesterol. Physical activity has been shown in previous studies to reduce these risk factors of CVD, but few studies have examined which types are exercise are more beneficial. This study aims to compare two types of exercise and a control group (that does not complete exercise) to find out which is more effective at reducing CVD risk.

Type of Research Intervention

The research will involve a year-long period where the participants will be asked to complete 3 sessions a week of 60 minutes (of 1 of the exercise types or the control group).

During the study there will be venous blood sample extractions every 3 months which are usually painless.

Participant selection

We are inviting all adults with the following characteristics to participate in the study:

(1) aged >40 years

(2) HeartSCORE of 1-5% (risk of 10-year fatal CVD).

(3) are willing to commit to the time requirements of the study.

(4) agree to sign the informed consent forms for participation.

Participants with any of the following characteristics will not be able to participate in the study:

(1) Age >65 years.

(2) Established CVD (e.g. ischemic heart disease, peripheral artery disease or cerebrovascular incidents).

(3) Suffer from a disease/illness that in the physician's medical opinion means it would be un-ethical to include them in the study/ask them to perform intensive physical exercise (e.g. Excessive hypertension).

(5) Have any form of musculoskeletal injury or are recovering from such an injury that may impede their participation.

(6) Are unable to meet the physical demands of the exercise regime.

(7) Are cognitively or otherwise impaired.

(8) Life expectancy <10 years (subjective physician estimation)

(9) Are pregnant or lactating.

Voluntary Participation

The participation in the study is 100% voluntary and there will be no consequences if you decide not to participate or if you leave the study at any a later point in time. Please feel free to discuss any concerns you may have with your doctor.

Procedures and Protocol

Once you have been assigned to one of the 3 groups (Crossfit, Continuous moderate exercise, or the control no-exercise group) you will receive an email containing the relevant information on where and when to begin the training.

The participants in the 2 exercise groups will be given in depth training on the corresponding training type, that will be completed in a small number of gyms in Barcelona. All 3 groups will be given standardized nutritional recommendations.

The control visits will take place in a separate medical center, and the professionals there will not be aware of the purpose of the study, or which group the participant has been assigned to. Participants will be asked NOT TO REVEAL THEIR GROUP ASSIGNMENT DURING THE CONTROL VISITS. In the first visit we will ask you a few questions about your general health and in the subsequent visits the physicians will record various details such as body weight, blood pressure, smoking status, medication status and will also take a venous blood sample every 3 month as explained above.

At the end of the 12 months the exercise classes will end. 6 months later there will be a final control visit where a final venous blood sample will be taken.

For any clinical study (if relevant):

We will take venous blood from your arm using a butterfly syringe. The process is usually painless and in general we will take about 6ml of venous blood. In total we will take 6 samples (every 3 months for 12 months and then a final sample 6 months later). At the end of the research any leftover blood samples will be destroyed).

B. Description of the Process

Duration

The research takes place over 2 years (6 months recruiting participants, 12 months of the exercise protocol and a final visit 6 months later).

Risks

Any risk can appear during the process. The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned, we will find out which group you have been assigned and will make any changes if appropriate.

Benefits

The benefits of this research are that you may achieve a reduction in your risk of cardiovascular disease in the following 10 years. There may not be any additional benefits but any illnesses during the study will be treated at no charge to you. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

Your participation is free. You will not be given any other money or gifts to take part in this research

Confidentiality

We will not be sharing the identity of those participating in the research with any 3rd parties.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and it we secured in a locked safe.

Sharing the Results

The results obtained from the study will be shared with you once available. At a later date the results may be published in scientific journals so that other researchers may benefit from our research.

Alternatives to Participating

If you do not wish to take part in the research, the care you receive will be the standard recommendations and treatment at the corresponding health-care center.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [Matt Corbett: 6811871723)

This proposal will have to be reviewed and approved by ethics committee of the participating centers before it is allowed to commence. This committee will evaluate whether the research participants are correctly protected from risk.

PART II: Certificate of Consent

I, Mr/Mrs _____ have read and understood the information given in part I of this informed consent form. I have been given the opportunity to resolve any questions and these questions have been answered satisfactorily. I consent voluntarily to participate as a participant in this research and understand that I may leave the study at any point in the future if I so wish.

Print Name _____

Signature _____

Date _____

Day/month/year_____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher _____

Signature of Researcher _____

Date _____

4. GPPAQ

General Practice Physical Activity Questionnaire

Date……

Name……

1. Please tell us the type and amount of physical activity involved in your work.

		Please mark one box only
a	I am not in employment (e.g. retired, retired for health reasons, unemployed, full-time carer etc.)	
b	I spend most of my time at work sitting (such as in an office)	
c	I spend most of my time at work standing or walking. However, my work does not require much intense physical effort (e.g. shop assistant, hairdresser, security guard, childminder, etc.)	
d	My work involves definite physical effort including handling of heavy objects and use of tools (e.g. plumber, electrician, carpenter, cleaner, hospital nurse, gardener, postal delivery workers etc.)	
e	My work involves vigorous physical activity including handling of very heavy objects (e.g. scaffolder, construction worker, refuse collector, etc.)	

2. During the *last week*, how many hours did you spend on each of the following activities? *Please answer whether you are in employment or not*

Please mark one box only on each row

		None	Some but less than 1 hour	1 hour but less than 3 hours	3 hours or more
a	Physical exercise such as swimming, jogging, aerobics, football, tennis, gym workout etc.				
b	Cycling, including cycling to work and during leisure time				
c	Walking, including walking to work, shopping, for pleasure etc.				
d	Housework/Childcare				
e	Gardening/DIY				

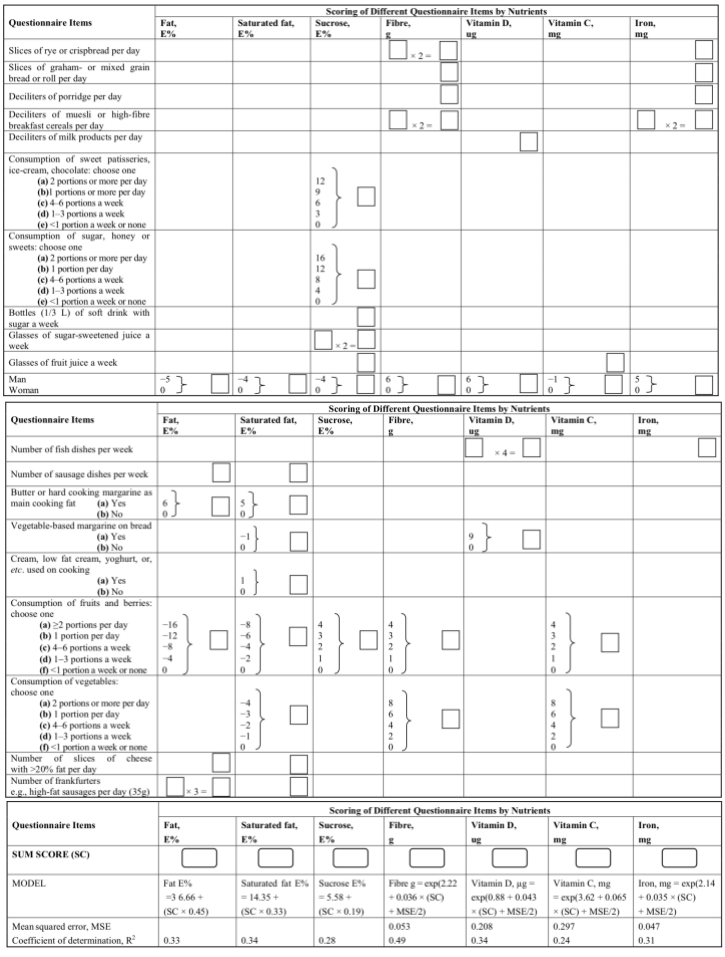
3. How would you describe your usual walking pace? Please mark one box only.

Slow pace (i.e. less than 3 mph)		Steady average pace	
Brisk pace		Fast pace (i.e. over 4mph)	

5. UBEs OF COMMON ALCOHOLIC BEVARAGES

Bebida	Graduación	Volumen	Alcohol puro contenido	Unidades de Bebida Estándar
Copa de vino o cava	12º	10 cl	9.6 gr	1
Vaso de calimocho	3.6º	20 cl	5.8 gr	0.5
Vaso de sangría	6.8º	20 cl	10.9 gr	1
Caña de cerveza	5º	25 cl	10 gr	1
Lata de cerveza	5º	33 cl	13.3 gr	1.3
Culín de sidra	6º	11 cl	5.2 gr	0.5
Botella de sidra	6º	70 cl	33.6 gr	3.4
Copa de aperitivo: vermouth, fino,...	17º	7 cl	9.5 gr	1
Copa de licor afrutado: melocotón,...	25º	6 cl	12 gr	1
Combinado: cuba libre,...	40º	6 cl de licor	19.2 gr	2
Copa de ginebra, ron, coñac	40º	6 cl	19.2 gr	2
Copa de whisky	42º	6 cl	20.2 gr	2

6. FOOD INTAKE QUESTIONNAIRE (FIQ-16)



Questionnaire Items	Scoring of Different Questionnaire Items by Nutrients						
	Fat, E%	Saturated fat, E%	Sucrose, E%	Fibre, g	Vitamin D, ug	Vitamin C, mg	Iron, mg
Slices of rye or crispbread per day				× 2 =			
Slices of graham- or mixed grain bread or roll per day							
Deciliters of porridge per day							
Deciliters of muesli or high-fibre breakfast cereals per day				× 2 =			× 2 =
Deciliters of milk products per day							
Consumption of sweet patisseries, ice-cream, chocolate: choose one (a) 2 portions or more per day (b) 1 portions or more per day (c) 4–6 portions a week (d) 1–3 portions a week (e) <1 portion a week or none			12 9 6 3 0				
Consumption of sugar, honey or sweets: choose one (a) 2 portions or more per day (b) 1 portion per day (c) 4–6 portions a week (d) 1–3 portions a week (e) <1 portion a week or none			16 12 8 4 0				
Bottles (1/3 L) of soft drink with sugar a week							
Glasses of sugar-sweetened juice a week			× 2 =				
Glasses of fruit juice a week							
Man Woman	−5 0	−4 0	−4 0	6 0	6 0	−1 0	5 0

Questionnaire Items	Scoring of Different Questionnaire Items by Nutrients						
	Fat, E%	Saturated fat, E%	Sucrose, E%	Fibre, g	Vitamin D, ug	Vitamin C, mg	Iron, mg
Number of fish dishes per week					× 4 =		
Number of sausage dishes per week							
Butter or hard cooking margarine as main cooking fat (a) Yes (b) No	6 0	5 0					
Vegetable-based margarine on bread (a) Yes (b) No		−1 0			9 0		
Cream, low fat cream, yoghurt, or, *etc*. used on cooking (a) Yes (b) No		1 0					
Consumption of fruits and berries: choose one (a) ≥2 portions per day (b) 1 portion per day (c) 4–6 portions a week (d) 1–3 portions a week (f) <1 portion a week or none	−16 −12 −8 −4 0	−8 −6 −4 −2 0	4 3 2 1 0	4 3 2 1 0		4 3 2 1 0	
Consumption of vegetables: choose one (a) 2 portions or more per day (b) 1 portion per day (c) 4–6 portions a week (d) 1–3 portions a week (f) <1 portion a week or none		−4 −3 −2 −1 0		8 6 4 2 0		8 6 4 2 0	
Number of slices of cheese with >20% fat per day							
Number of frankfurters e.g., high-fat sausages per day (35g)	× 3 =						

Questionnaire Items	Scoring of Different Questionnaire Items by Nutrients						
	Fat, E%	Saturated fat, E%	Sucrose, E%	Fibre, g	Vitamin D, ug	Vitamin C, mg	Iron, mg
SUM SCORE (SC)							
MODEL	Fat E% =3 6.66 + (SC × 0.45)	Saturated fat E% = 14.35 + (SC × 0.33)	Sucrose E% = 5.58 + (SC × 0.19)	Fibre g = exp(2.22 + 0.036 × (SC) + MSE/2)	Vitamin D, µg = exp(0.88 + 0.043 × (SC) + MSE/2)	Vitamin C, mg = exp(3.62 + 0.065 × (SC) + MSE/2)	Iron, mg = exp(2.14 + 0.035 × (SC) + MSE/2)
Mean squared error, MSE				0.053	0.208	0.297	0.047
Coefficient of determination, R^2	0.33	0.34	0.28	0.49	0.34	0.24	0.31

7. **BMI CALCULATOR**

- https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi-m.htm

8. **CROSSFIT'S 9 FOUNDATIONAL MOVEMENTS: For more information see: https://www.youtube.com/watch?v=f_lNO64zlSU**

THE **OVERHEAD SQUAT**

- Shoulder-width stance
- Wide grip on the bar
- Shoulders push up into the bar
- Armpits face forward
- Hips descend back and down
- Hips descend lower than knees
- Lumbar curve maintained
- Heels down
- Bar moves over the middle of the foot
- Knees in line with toes
- Complete at full hip and knee extension

THE **SHOULDER PRESS**

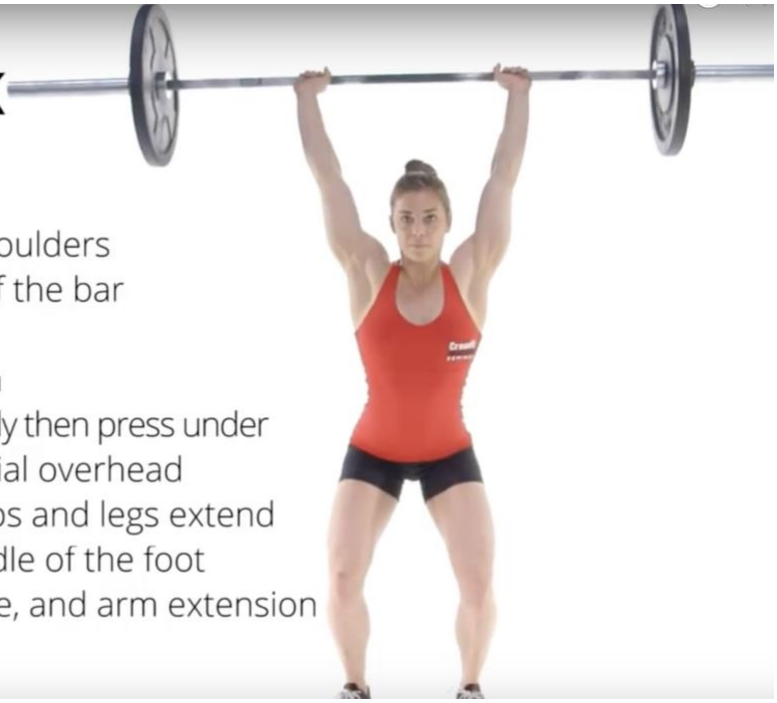
- Hip-width stance
- Hands just outside of shoulders
- Elbows slightly in front of the bar
- Full grip on the bar
- Bar moves over the middle of the foot
- Torso and legs static
- Heels down
- Shoulders push up into the bar
- Complete at full arm extension

THE **PUSH PRESS**

- Hip-width stance
- Hands just outside of shoulders
- Elbows slightly in front of the bar
- Full grip on the bar
- Bar rests on torso
- Torso dips straight down
- Hips and legs extend, then press
- Heels down until hips and legs extend
- Bar moves over the middle of the foot

THE **PUSH JERK**

- Hip-width stance
- Hands just outside of shoulders
- Elbows slightly in front of the bar
- Full grip on the bar
- Torso dips straight down
- Hips and legs extend rapidly then press under
- Receive the bar in a partial overhead
- Heels stay down until hips and legs extend
- Bar moves over the middle of the foot
- Complete at full hip, knee, and arm extension



THE **DEADLIFT**

- Hip-width stance
- Hands just outside of hips
- Full grip on the bar
- Shoulders slightly in front of the bar
- Lumbar curve maintained
- Hips and shoulders rise at the same rate
- Bar moves over the middle of the foot
- Heels down
- Complete at full hip and knee extension

THE **SUMO DEADLIFT HIGH PULL**

- Slightly wider than shoulder-width stance
- Hands inside legs with a full grip on the bar
- Knees in line with toes
- Shoulders slightly in front of the bar at set-up
- Lumbar curve maintained
- Hips and shoulders rise at the same rate
- Hips then extend
- Heels down until hips and legs extend
- Shoulders then shrug, followed by a pull of the arms
- Elbows move high and outside
- Bar moves over the middle of the foot
- Complete at full hip and knee extension with the bar pulled under the chin

THE **MEDICINE BALL CLEAN**

- Shoulder-width stance
- Ball between the feet with palms on the ball
- Knees in line with toes
- Shoulders over the ball at set-up
- Lumbar curve maintained
- Hips extend rapidly
- Then shoulders shrug
- Then arms pull under to the bottom of the squat
- Heels down until hips and legs extend
- Ball moves over the middle of the foot
- Complete at full hip and knee extension with the ball at the rack position