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Guildford HyperTension 2000: Exercise interventions to increase levels of physical and sporting activity

Submission date	Recruitment status	[X] Prospectively registered
07/06/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/09/2020	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Physical activity is known to convey a number of health benefits but many people are effectively inactive and thus at risk of coronary heart disease and other cardiovascular conditions. Currently, people with hypertension (high blood pressure), suspected hypertension, pre-hypertension or high-normal blood pressure can be referred by their general practitioners (GPs) for a programme of gym-based activity and we want to see if we can find ways of improving the effectiveness of these referrals. Our goal is to find the best possible combination of activities that will promote continued increases in peoples activity levels.

Who can participate?
The study aims to recruit about 2000 people aged 18-74 years with hypertension, suspected hypertension, pre-hypertension or high-normal blood pressure.

What does the study involve?
People will be invited to attend a 12-week programme of exercise either with a gym focus or a more sporting focus. Some people will also be invited to use a new web-based self-help tool that will help them plan and record their activities. Which intervention(s) a participant is allocated to will be decided by a process called randomisation, which is like a coin toss. At the end of the study, which will be a year after the person first goes on the exercise programme, we will compare the amount of activity people engage in and also look at indicators of their cardiovascular health like blood pressure and body mass index (BMI) to see which interventions produce the most beneficial changes.

What are the possible benefits and risks of participating?
Participants will get a supervised programme of activity that will help them improve their cardiovascular fitness. They will also get advice on how to build activity into their daily lives. There are few risks in taking part since your GP will have already decided that a programme of activity would be good for you. Trained exercise professionals will be on hand to ensure your safety throughout the exercise programme.

Where is the study run from?
The study is being run by the University of Surrey in GP practices in the Guildford and Waverly CCG area.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in the autumn of 2013 and run until mid summer 2015.

Who is funding the study?
Funding has been provided by Sport England with in kind support from partners Surrey County Council, Active Surrey, Surrey Sports Park, Spring Street Surgery, Isostasy.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Guildford Hypertension 2000: randomised trial of exercise interventions to increase levels of physical and sporting activity

Acronym
GHT2000

Study objectives
To test the independent and synergistic efficacy of a 12-week sports oriented exercise referral intervention and a self-help web-based intervention intended to promote sustained and

increased levels of physical activity over a period of 12 months. Do these interventions separately and in combination improve these indicators and do they improve them above that expected by existing gym-based GP referral alone?

Do these interventions improve other clinical indicators of cardiovascular health [e.g. body mass index (BMI), waist and hip measures, blood pressure and other measures that contribute to the QRisk2 risk indicator) above that expected by existing gym-based GP referral? Do these interventions increase participation in sporting activity over a period of 12 months?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bloomsbury NHS REC, 19/9/2013, ref: 13/LO/1170

Study design
Four-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Currently inactive 18-74 year old people with hypertension, suspected hypertension, pre-hypertension or high-normal blood pressure.

Interventions
1. The first intervention is a web-based behaviour change support tool, that allows users to easily find out about outlets for organised activity, form and store plans to carry out the activities and to form a log of what they have achieved. The tool provides educational material and easy access to existing health maintenance sites. The user can set up the site to give alerts when events relating to their preferred sports/activities are available and to provide prompts to log the activities that they have completed.
2. The second intervention is a 12-week sports oriented exercise programme intended as a direct substitute for existing gym-based GP exercise referral. As with the latter this will be supervised by qualified exercise specialists but participants are given a choice of entry-level sports to pursue. Sports offered will include squash, badminton (Badmintone), netball (Netfit), tennis, swimming, walking football, bowls, athletics (AthleFIT), Cardio Tennis and a new Healthy Cycle Ride.
3. The control will be standard care which is referral of a 12-week for gym-based exercise programme.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

The interventions individually will be regarded as successful if they lead to an average increase in activity of 100 Metabolic Equivalents (MET) -minutes per week as measured by the IPAQ-S. This equates to engaging in an extra moderate intensity activity, say brisk walking (3.3 MET) for 30 minutes per week. The new interventions will be regarded as superior to the standard gym-based referral if they increase activity levels above those of the standard care gym-based exercise by 20 MET-minutes per week. Activity will be measured at baseline, 12 weeks, 6 months and 12 months.

Key secondary outcome(s))
1. We will assess changes in indicators relating to cardiovascular health including blood pressure, weight and waist and hip circumference at baseline, 6 weeks, 12 weeks and 12 month. In terms of blood pressure the interventions will be regarded as successful if they lead to an average decrease in blood pressure of 2.5mmHg. We will assess the proportion of the sample reducing their blood pressure by more than 10 mmHg and an intervention will be regarded as a success if more than 20% of the members of that study arm achieve a reduction greater than this.
2. The interventions will be deemed to have been successful in promoting sports participation if they increase sports related activity by 100 MET-minutes per week.

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. The patient is aged 18 to 74 years at randomisation
2. The patient has been diagnosed as having hypertension, suspected hypertension and pre-hypertension
3. The patient is screened as being less than active on the General Practice Physical Activity Questionnaire (GPPAQ)
4. The patient has access to the internet and an e-mail account
5. The patient is able to understand the Informed Consent Form (ICF), and understand study procedures
6. The patient has signed the ICF

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. The patient is pregnant
2. Inability to freely consent to take part in the study
3. Inability to understand the study materials
4. The patient is unable to access the internet/email
5. Current participation in another clinical trial relating to physical activity or exercise
6. Any condition that, in the GPs opinion, compromises the subjects ability to meet protocol requirements or to complete the study
7. The patient is referred out of the trial by the exercise professional on the grounds that the programme is, in their judgement, is likely to cause harm

Date of first enrolment
01/09/2013

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Psychology
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Government

Funder Name
Sport England (UK) - (Get Healthy, Get in to Sport project no. 2012021353) with in kind support from partners Surrey County Council, Active Surrey, Surrey Sports Park, Spring Street Surgery, Isostasy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/08/2014		Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes