

Looking for study participants to study the effects of diet/exercise on plaque in coronary arteries

Researchers at St. Paul's Hospital's Healthy Heart Program are studying whether diet coupled with exercise, can reduce hardening of the arteries, also known as atherosclerosis, which can lead to heart disease and stroke.

The five-year study of 200 people will take place in Vancouver, Toronto and Quebec City. St. Paul's will enrol 50 people in Vancouver who can participate in the study for three years.

The study follows the hospital's 2011 Portfolio Diet study, which looked at whether it could be as effective as cholesterol-lowering medications in combating heart disease. That study found that the diet reduced bad levels of cholesterol (LDL) by 13 per cent on average.

The new study will use the same Portfolio Diet, which is mainly a vegetarian diet rich in plant sterols, high in soluble fibre, nuts, and soy proteins – each of them known to decrease bad cholesterol. This study will differ from the 2011 study by adding exercise to determine the impact of diet/exercise on atherosclerosis.

Dr. Jiri Frohlich, lead investigator at the St. Paul's site and head of the hospital's Healthy Heart Program Clinical Trials, said: "This study will look deeper to see if this particular diet, plus exercise, will affect not only risk factors such as LDL cholesterol but also the disease itself." Researchers will measure plaque size in participants' carotid (neck) and coronary (heart) arteries with magnetic resonance imaging (MRI) three times during the study.

Benefits to participants throughout the study:

Extra monitoring of heart health including: medical imaging (ultrasound and MRI's) and blood pressure, cholesterol and blood sugar will be followed closely during the study.

Some free study foods will be given to participants and their family that will supplement their family's grocery expenses.

Participants will be divided into two groups. Both will be provided with nutrition counselling by a Registered Dietitian. One group will get regular exercise counselling.

Recruiters are looking for:

Men aged 21 and over and postmenopausal women, with each group having a body mass index (a measure of height and weight), of between 25 and 40 who have minor atherosclerosis measured at screening. See the portfolio study inclusion and exclusion criteria for more details (below).

Portfolio Study: Inclusion Criteria details:

Men aged over 21

OR

Post menopausal woman

And BMI (body mass index), which is a measure of fitness, between 25 and 40 kg/m² (body weight stable over 3 months before starting the study)

Additional Requirements (one or more of the following):

1. Type 2 Diabetes
2. Heart disease (heart attack/stroke/undergone angioplasty) more than 6 months prior and treated with a cholesterol-lowering medication
3. High cholesterol (LDL > 3.5, non HDL-C ≥ 4.3 mmol/L if untreated)
 - Treated with a statin (LDL can be <3.5)
 - Treated with a statin but intolerant to it
 - Prescribed statin but refused to take it

In addition, a Cardiologist will be performing a carotid ultrasound (test) in potential participants to see if there are any plaque deposits. Presence of plaque deposits in the carotid arteries are needed to qualify for the study.

Exclusion Criteria:

Having cancer, hepatitis, food allergies to soy, nuts, plant sterols, oats, and/or psyllium, or having other medical problems such as chronic infections will disqualify people from being enrolled in the study. Being claustrophobic as this study requires MRI tests will

disqualify potential participants. Body weight changes in the past 3 months will also disqualify participants.

Contact Information:

If you or someone you know could qualify for and wants to be part of this study, please contact the researchers by email combinedportfolio@providencehealth.bc.ca or by phone at: **604 806 9624**.

Questions and Answers:

How long will I be in the study?

You will be in the study for 3 years plus a 4 month “run in” and screening period. If you qualify after screening, you will start the 3 year study.

How often will I need to come in for a visit?

About every 3 months and there are a total of 18 visits, some are by telephone and most are in-person.

Will I be paid for this study?

Unfortunately, not, but free study foods, diagnostic testing, nutrition counselling by a Registered Dietitian and exercise counselling by an Exercise Specialist.

Will the study cost me anything?

No, except transportation costs of getting to St. Paul's Hospital's Healthy Heart Program and part of it will be reimbursed.

How much will I be reimbursed for transportation?

You will receive \$6 per study visit once you start the study (not included is the screening and run-in period)

How much exercise do I need to do?

If you're assigned to one of the exercise groups you will be asked to gradually increase your activity to achieve 10,000 steps per day. As part of this step goal we

will support you in including 150 minutes per week of moderately vigorous activity (for example 30 minutes, 5 days per week).

Can I choose which study arm I will be placed in?

No, all participants will be randomized into 4 groups so you have a 25% chance of being placed into the groups: 1) portfolio with exercise, 2) portfolio no exercise, 3) DASH with exercise, 4) DASH no exercise

Can I eat meat while I am in this study?

Red meat, such as beef, pork and lamb is discouraged, but fish and chicken are allowed in moderation.

Can I eat in restaurants or enjoy other social occasions with food while I am in the study?

Yes, you can in moderation. You are encouraged to eat your recommended foods as often as you can and ideally choose these foods while you are dining out, if possible. You can discuss this with your Dietitian.

I heard that consuming soy foods increases risk of cancer: is this true?

Overall, soy foods do not increase cancer risk in humans and in fact, consuming soy foods actually may lower cancer risk. See the link for the American Institute of Cancer Research for more information. Link:

<http://www.aicr.org/foods-that-fight-cancer/soy.html>

Can I have any alcohol while I am in the study?

If you drink alcohol, do so in moderation: Moderation for those who choose to drink is considered two drinks/day for men and one drink/day for women.

