

Staged Nutrition and Activity Counselling (SNAC) interventions that prime targeted antihypertensive therapy to prevent cardiovascular outcomes in the primary care setting

Submission date 11/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/12/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Staged Nutrition and Activity Counselling (SNAC) interventions that prime targeted antihypertensive therapy to prevent cardiovascular outcomes in the primary care setting

Acronym

SNAC

Study objectives

Improved lifestyle behaviour would enhance cardiac function, vascular elastic properties, and conduit vessel endothelial function with important benefits to clinical outcome measures and exercise perturbations to the cardiovascular system.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Research Ethics Board of The University of Western Ontario on the 22nd April 2003 (review #: 09572).

Study design

Randomised prospective design.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

High-normal blood pressure and/or impaired glucose regulation.

Interventions

Subjects were randomly assigned to either the SNAC intervention group or the usual care group.

The SNAC intervention group received the SNAC lifestyle intervention that combined the STEP test and exercise prescription with a version of Canadas Food Guide adapted to suit a Mediterranean-style diet. The SNAC lifestyle intervention was delivered according to Procheska and Declementes Transtheoretical Model, and delivered by each subjects family physician. To optimise familiarisation with the diet and facilitate long-term adherence, during first 8 weeks, subjects received one dinner meal per day (5 meals per week) from the laboratory as well as sample menus for breakfast and lunch. From the week 9, subjects received only sample menus for all meals.

The usual care group received "usual care" blood pressure and plasma glucose management from their family physician (for example, family physicians in this group delivered lifestyle advice to subjects as the way they normally did).

All assessments were conducted at baseline (V1), week 8 (V2), week 16 (V3), week 24 (V4), and week 52 (V5).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Improvements in exercise capacity, left ventricular diastolic function (E/A ratio), and brachial artery endothelial function, measured at V1 - V5 (see interventions).

Secondary outcome measures

1. Caloric profile and anthropometrics, measured at V1 - V5 (see interventions)
2. Resting blood pressure and 24-hour ambulatory blood pressure, measured at V1 - V5
3. Blood chemistries (glucose, lipids, catecholamines, HbA1c, etc), measured at V1 - V5
4. Muscle sympathetic nerve activity, measured at V1 - V5
5. Geometry and elastic properties of the carotid artery, and geometry of left ventricle, measured at V1 - V5

Overall study start date

01/01/2004

Completion date

30/06/2006

Eligibility

Key inclusion criteria

1. Men and women aged 40 - 85 years who are able to provide informed consent
2. Presence of high-normal blood pressure, impaired fasting glucose, impaired glucose tolerance, or all of them

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Unstable cardiovascular or metabolic disease
2. Previous diagnosis of hypertension or type 2 diabetes
3. Myocardial infarction, coronary artery bypass, or cerebrovascular ischaemia/stroke (including Transient Ischaemic Attack [TIA]) within 3 months prior to study
4. History of alcoholism, drug abuse, or other emotional, cognitive or psychiatric problems that are likely to limit compliance to the study
5. Pacemaker
6. Already enrolled in a clinical research trial

Date of first enrolment

01/01/2004

Date of final enrolment

30/06/2006

Locations

Countries of recruitment

Canada

Study participating centre

Parkwood Hospital, Room B3002

London

Canada

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Sponsor information

Organisation

Lawson Health Research Institute (Canada)

Sponsor details

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info@lhrionhealth.ca

Sponsor type

Research organisation

Website

<http://www.lhrionhealth.ca/LHRI/index.html>

ROR

<https://ror.org/051gsh239>

Funder(s)

Funder type

Research organisation

Funder Name

Heart and Stroke Foundation of Ontario (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	16/02/2011		Yes	No