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Promoting Adherence to a Regimen of risk factor modification by Trained Non-medical personnel Evaluated against Regular practice Study

Submission date 03/03/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 09/03/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/09/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-91025

Study information

Scientific Title
Promoting adherence to a regimen of risk factor modification by trained non-medical personnel evaluated against regular practice: a open-label randomised controlled trial

Acronym
PARTNERS

Study objectives
The study will examine the efficacy, durability, and cost-effectiveness of the volunteer-facilitated risk factor modification program, compared against regular practice in patients who have experienced recent ischaemic cerebrovascular events.

24/09/2015: Updated overall trial end date from 01/10/2013 to 30/09/2017 and recruitment end date from 01/10/2013 to 31/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Western Ontario Health Research Ethics Board gave approval on the 15th January 2009 (ref: 15516)

Study design
Open-label blinded-adjudication randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke/transient ischaemic attack (TIA)

Interventions

This is an open-label randomised controlled trial with equal number of subjects in both arms:
1. Regular practice (RP)
2. Regular practice plus volunteer-facilitated risk factor modification program (RV)

The RP arm will serve as the control group; subjects in this group will receive standard medical care. Subjects in the RV group will receive standard medical care and scheduled contact with a trained volunteer. The volunteers will serve as health information providers, lifestyle coaches, and peer supporters.

Total duration of both arms of the study is 2 years. For patients in the intervention group the volunteer phone contacts will occur over the first year. There will be a total of 10 contacts, one of which will be a face to face meeting at the outset to allow the volunteer and participant to meet. The telephone contacts will follow a script and time will depend on the participant. If there are no concerns or questions the call would generally take about 20 minutes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference between the 12-month and the baseline systolic blood pressure (SBP).

Secondary outcome measures
Efficacy outcome measures:
The difference between the 12-month and baseline values of the following:
1. Diastolic blood pressure (DBP)
2. Medication adherence rate
3. Body mass index
4. Cardiovascular risk score
5. Waist circumference
6. Low density lipoprotein cholesterol (LDL-C) concentration
7. Total cholesterol/high density lipoprotein cholesterol (HDL-C) ratio
8. HbA1c level
9. Cigarette smoking status
10. Alcohol consumption rate
11. Level of physical activities
12. Quality of life (SF-36)
13. Cognitive tests scores

The differences between the 24-month and baseline values of these same factors, plus the difference between the 24-month and baseline SBP, constitute the durability outcome measures

Other outcome measures:
14. Clinical outcome event (stroke, myocardial infarction [MI], all-cause death)
15. Estimated total healthcare expenditure

Overall study start date
01/04/2009

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Subjects aged 18 years or greater, either sex, who:
1. Experienced transient ischaemic attack or non-disabling stroke within 90 days of randomisation
2. Have hypertension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
316

Key exclusion criteria
1. Neuroimaging studies suggest other causes for presenting event (e.g., primary intracerebral haemorrhage, tumour, etc.)
2. Unable to communicate in English or French, or severe aphasia
3. Moderate to severe disability with modified Rankin Scale score greater than or equal to 3
4. Known dementia
5. Severe concomitant medical conditions with life expectancy of less than two years
6. Unable or unwilling to return for study-related scheduled follow-ups
7. Concurrent participation in other interventional studies

Date of first enrolment
01/04/2009

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Canada

Study participating centre

339 Windermere Rd., Rm B10-118
London
Canada
N6A 5A5

Sponsor information

Organisation
London Health Sciences Centre (Canada)

Sponsor details
339 Windermere Road
London, Ontario
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Sponsor type
Hospital/treatment centre

Website
http://www.lhsc.on.ca

ROR
https://ror.org/037tz0e16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Stroke Network (CSN) (Canada)

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) (ref: MCT-91025)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Publication in a peer reviewed journal.

Intention to publish date
01/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration