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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

Protocol serial number
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)

Primary study design
Interventional

Study design
Open-label blinded-adjudication randomised controlled trial

Study type(s)
Treatment

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(s)
Difference between the 12-month and the baseline systolic blood pressure (SBP).

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

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
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Sponsor information

Organisation
London Health Sciences Centre (Canada)

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary