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

	[X] Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Circulatory System	Record updated in last year
	Completed  Condition category

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Richard Chan

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#### Contact details

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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)

#### Study design

Open-label blinded-adjudication randomised controlled trial

# Primary study design

Interventional

# 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 Canada N6A 5A5

# 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, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes