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Community Cardiovascular Health Awareness Program

Submission date 15/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2007	**Overall study status** Completed	
Last Edited 09/03/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.chapprogram.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06-205

Study information

Scientific Title

Acronym
C-CHAP

Study objectives
Community-based volunteer-operated, Cardiovascular Health Awareness Program (CHAP), with assessment of Blood Pressure (BP) and other Cardiovascular Disease (CVD) risk factors at pharmacy sessions, that are linked with Family Physicians (FPs) and pharmacists, can improve the cardiovascular health of older adults in Ontario communities, yielding a statistically and clinically significant reduction in the mean rate of hospital admissions (mean rate of change from the year preceding the program) for acute myocardial infarction, congestive heart failure, and stroke (composite end point), for the entire population of residents 65 years and older during the year following implementation of CHAP, compared to control communities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Final approval received from the Hamilton Health Sciences/McMaster University Faculty of Health Sciences Research Ethics Board on the 11th July 2006 (ref: 06-205).

Study design
C-CHAP is a prospective stratified cluster randomised controlled trial to evaluate the effectiveness of CHAP in medium-sized communities across Ontario

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
Cardiovascular disease risk factors

Interventions

The community pharmacy sessions are weekday three-hour morning sessions over a ten-week period, which entail volunteer Peer Health Educators ensuring that accurate BP recordings and risk factor data are collected for delivery to FPs, pharmacists, and session participants, and providing patient-specific cardiovascular disease risk factor education. Older adult residents of the program communities are invited to attend at least two sessions over the course of the program. Multiple strategies are used to invite older adults to the CHAP sessions, including letters and hand-outs from their FPs, flyers and posters distributed throughout the community, and direct advertising through local media.

Participants' FPs receive immediate notification of BPs exceeding 180/120 mmHg (previously shown to occur in about 3% of cases), and a toll-free fax-to-database system is used to forward all other session results to FPs and pharmacists at the end of the ten-week program in the form of reports listing their patients by BP, treatment status, and cardiovascular risk. Pharmacists will be involved in consulting with patients as needed both during and outside of sessions about their medication (e.g. adherence, side effects) or related concerns. Pharmacists will document their interactions, assessments and recommendations for physicians using structured documentation forms. FPs will also receive aggregate-level comparative feedback six months later. Individual and aggregate session data and cardiovascular health resources will be available to participants and their FPs and pharmacists via a secure, password-protected website (see www.chapprogram.ca).

The study is powered to detect a 21% reduction in the mean rate of hospital admission for acute myocardial infarction, congestive heart failure, and stroke (the composite primary end-point) for residents 65 years of age and older during the year following implementation of CHAP in program compared to control communities, using routinely-collected, population-based data held at the Institute for Clinical Evaluative Sciences (ICES).

This trial is also being sponsored by:
Elisabeth Bruyere Reserach Institute (EBRI) (Canada)
c/o Larry W Chambers
SCO Health Service
43 Bruyère Street
Ottawa, Ontario
K1N 5C8
Canada

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure will look at change in the composite outcome for one year prior to the program to one year following the program, in intervention compared to control communities, using administrative data.

Secondary outcome measures
Process data will inform evaluation of the success of community mobilisation and program delivery in the intervention communities.

Process measures in the program communities include:
1. Assessment of the success of community mobilisation
2. Surveys of volunteers, family physicians, and pharmacists
3. Interviews with coordinators
4. Final reports from lead organisations
5. Learning from a debriefing workshop with all program community partners

This data is being collected during the six months following the ten-week program.

Overall study start date
01/03/2006

Completion date
01/03/2009

Eligibility

Key inclusion criteria
The 39 eligible communities vary in population size from 10,000 to 60,000, and were stratified by population aged 65+ and geographic location, and randomly allocated to CHAP or control. The community mobilisation model aims to involve all family physicians, local pharmacies and relevant organisations in the program communities. The program targets all residents 65 years of age or older through community-wide advertising and invitation via family physicians.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30% of seniors in program communities

Key exclusion criteria
1. Communities of less than 10,000 residents
2. Fewer than five family physicians and two pharmacies in community

Date of first enrolment
01/03/2006

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
Canada

Study participating centre
Primary Care & Community Research at the Child & Family Research Institute
Vancouver
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Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
c/o Janusz Kaczorowski
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Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Government

Funder Name
Canadian Stroke Network (CSN) (Canada)

Funder Name
Ministry of Health Promotion, Government of Ontario (Ontario Stroke System) (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?
Results article	results	07/02/2011		Yes	No