

# Diabetes Intervention in the community to help achieve reduced glucose elevation: Diabetes IN-CHARGE

**Submission date**  
10/08/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
10/08/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
15/02/2019

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## 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

NCT00182026

## Secondary identifying numbers

MCT-68786

# Study information

## Scientific Title

A randomised trial of diabetes intervention in the community to help achieve reduced glucose elevation: Diabetes IN-CHARGE

## Acronym

Diabetes IN-CHARGE

## Study objectives

This trial will determine if supplementing a community-based diabetes program with an automated system that generates specific evidence-based tailored recommendations to individuals/MDs based on responses to a self-administered questionnaire lowers hemoglobin A1c levels (A1c) more than the community-based program (i.e. Diabetes Hamilton) alone.

As of 15/01/2008, this record was updated to include an extended anticipated end date due to recruitment taking longer than anticipated; the initial end date at the time of registration was 31/07/2007 was updated to 30/06/2009.

As of 26/02/2009 this record was updated to include another extension to the anticipated end date to allow for completion of all follow-ups. The previous end date was 30/06/2009 and this has now been updated to 31/12/2009.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

McMaster University Research Ethics Board gave approval on the 31st August 2004.

## Study design

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**

Type 2 diabetes

**Interventions**

Participants in the community with type 2 diabetes will be enrolled in Diabetes Hamilton, fill out a questionnaire, and have regular information regarding diabetes management sent to them and their MD. Allocation will be to either receive or not receive automated recommendations and reminders based on the questionnaire response, interpretation of their HbA1c, a customised list of resources, and simple tools to track glucose control, HbA1c and related variables.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

HbA1c Levels

**Secondary outcome measures**

1. Self-care behaviours
2. Drug use (i.e. angiotensin-converting enzyme [ACE]-inhibitor, cholesterol-lowering aspirin, angiotensin 2 receptor blocker, beta blocker, diuretic, influenza immunisation)
3. Clinical outcomes
4. Hospitalisations
5. Quality of life
6. Incremental cost per quality-adjusted life-year (QALY)

**Overall study start date**

01/04/2005

**Completion date**

31/12/2009

**Eligibility****Key inclusion criteria**

500 participants with type two diabetes, both sex, 30 years and older

1. Type 2 diabetes of 1 or more years duration
2. Ontario Health Insurance Plan (OHIP) coverage
3. Registered in, or willingness to register in Diabetes Hamilton
4. English fluency
5. Provide consent
6. Have home access to either mail, email or the internet
7. Have a baseline HbA1c level greater than 7%

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

500

**Key exclusion criteria**

1. Current pregnancy
2. Institutionalised
3. Cohabiting first degree relative of a participant in the study
4. Inability to read or understand English
5. Inability or unwillingness to consent or comply with the protocol
6. Residence outside the city of Hamilton

**Date of first enrolment**

01/04/2005

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

Canada

**Study participating centre**

**McMaster University**

Hamilton, Ontario

Canada

L8N 3Z5

## Sponsor information

**Organisation**

McMaster University Health Sciences Centre (Canada)

**Sponsor details**

1200 Main Street West

Hamilton, Ontario

Canada

L8N 3Z5

**Sponsor type**

University/education

### Website

<http://fhs.mcmaster.ca/main/index.html>

### ROR

<https://ror.org/02fa3aq29>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-68786)

## 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?
<a href="#">Results article</a>	results	01/08/2011		Yes	No