

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

Submission date 10/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/02/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00182026

Protocol serial number
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

Study type(s)

Treatment

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(s)

HbA1c Levels

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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	01/08/2011		Yes	No