ISRCTN45031143 https://doi.org/10.1186/ISRCTN45031143

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

Submission date	Recruitment status
10/08/2005	No longer recruiting
Registration date	**Overall study status**
10/08/2005	Completed
Last Edited	**Condition category**
15/02/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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?
Results article	results	01/08/2011		Yes	No