

A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with type 1 diabetes mellitus and suboptimal glycaemic control

Submission date 18/08/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/08/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/09/2009	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 01/17/05

Study information

Scientific Title

Acronym

ADaPT

Study objectives

1. To test whether brief computer assisted motivational interviewing (MI) is more effective than usual medical care in improving glycaemic control in a population based sample of younger adults with type 1 diabetes
2. To test whether cognitive behaviour therapy (CBT) is more effective than usual medical care in improving glycaemic control in a population based sample of younger adults with type 1 diabetes and persistent suboptimal glycaemic control after brief MI
3. To examine cognitive, behavioural and biological predictors of outcome after MI and after CBT
4. To examine the cost effectiveness and cost utility of each intervention
5. To examine factors which may modify or mediate the process of change
6. To assess whether training and supervision can lead to a change in the consultation behaviour of nurses

Please note that, as of 17 January 2008, the start and end date of this trial were updated from 1 January 2002 and 31 December 2004 to 1 February 2003 and 31 May 2007, respectively.

Please note that the target number of participants was added as of 17/12/2008.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Diabetes

Interventions

1. Brief therapy: motivational interviewing (MI)
2. Intensive therapy: motivational interviewing followed by cognitive behaviour therapy (CBT)
3. No therapy

All patients will continue to receive their usual diabetes care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Added as of 17/12/2008:

12-month change in haemoglobin A1c levels

Secondary outcome measures

Added as of 17/12/2008:

1. Hypoglycaemic events
2. Depression
3. Quality of life
4. Fear of hypoglycaemia
5. Diabetes self-care activities
6. Body mass index

Overall study start date

01/02/2003

Completion date

31/05/2007

Eligibility

Key inclusion criteria

Patients who have had glycated haemoglobin values of 8.2% and greater in the past 12 months and currently, will be defined as having persistent sub-optimal glycaemic control and are eligible for the study.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

344

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/02/2003

Date of final enrolment

31/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Clinical Trials Unit

London

United Kingdom

SE5 8AZ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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:	18/11/2008		Yes	No