

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	☐ Prospectively registered
Registration date 18/08/2003	Overall study status Completed	☐ Protocol
Last Edited 08/09/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

Added as of 17/12/2008:

12-month change in haemoglobin A1c levels

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Clinical Trials Unit

London

United Kingdom

SE5 8AZ

Sponsor information

Organisation

Department of Health (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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:				

[Results article](#)

18/11/2008

Yes

No