

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

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

### Contact name

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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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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