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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

Registration date
18/08/2003

Overall study status
Completed

Last Edited
08/09/2009

Condition category
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

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
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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