

Changing illness perceptions: a randomised controlled trial of a psychological, family-based intervention to improve outcomes in type 2 diabetes

Submission date

28/02/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

27/04/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/05/2019

Condition category

Nutritional, Metabolic, Endocrine

☐ 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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Contact details

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Additional identifiers

Protocol serial number

RP/2005/178

Study information

Scientific Title

Changing illness perceptions: a randomised controlled trial of a psychological, family-based intervention to improve outcomes in type 2 diabetes

Study objectives

To examine the effects of a psychological, family-based intervention to improve biophysical, psychosocial and behavioural outcomes for patients with poorly controlled type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Joint Research Ethics Committee of St. James's Hospital and the Federated Dublin Voluntary Hospitals, approved on the 8th February 2006.

Primary study design

Interventional

Study design

This study is a randomised controlled trial with an intervention group and a control group.

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

The study is a psychological intervention, designed to change peoples cognitions about their diabetes, with a view to improving diabetes self-management behaviours, and ultimately diabetes outcomes. The intervention is aimed at changing any negative or misperceptions about diabetes, and improving, in a positive direction, the degree of similarity between patient and family members cognitions in relation to diabetes.

The intervention will be delivered by a health psychologist who is trained in using motivational interviewing techniques. The intervention also incorporates a family member of the person with diabetes, and will also focus on the family members cognitions about diabetes. The participants in the control group receive the usual care.

The intervention will be delivered over three sessions, one session a week. Participants will be followed up at 6 months from time of randomisation.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcomes will be collected at baseline and at 6-month follow up.

1. HbA1c

2. Illness perceptions
3. Psychological well-being

Key secondary outcome(s)

Secondary measures will be collected at baseline and at 6-month follow up.

1. Biomedical outcomes
 - a. Blood pressure
 - b. Body mass index
 - c. Cholesterol
2. Diabetes self-efficacy
3. Social support
4. Daily activities
5. Self-care activities

Completion date

30/03/2009

Eligibility**Key inclusion criteria**

1. Have type 2 diabetes for more than one year, and at least two out of their last three HbA1c readings have been 8.0% or over, in order to identify patients with persistent poor control
2. Over 18 years of age
3. Have fluency in English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Total final enrolment

121

Key exclusion criteria

Patients with a significant mental or physical illness, as determined by the patients clinician, will be excluded. Significant mental or physical illness is defined as any illness that is thought likely to impair the patients capacity to change their lifestyle behaviour or assimilate new information.

Date of first enrolment

01/04/2006

Date of final enrolment

30/03/2009

Locations

Countries of recruitment

Ireland

Study participating centre

Department of Public Health and Primary Care

Dublin 24

Ireland

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Sponsor information

Organisation

Health Research Board (Ireland)

ROR

<https://ror.org/003hb2249>

Funder(s)

Funder type

Government

Funder Name

Health Research Board, Research Project Grant - General 2005 (RP/2005/178) (Ireland)

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 article	results	01/02/2011	16/05/2019	Yes	No
Protocol article	protocol	27/06/2007		Yes	No