

# 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**

Dr Susan Smith

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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.

### Study design

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

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### 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 measure**

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

1. HbA1c
2. Illness perceptions
3. Psychological well-being

**Secondary outcome measures**

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

**Overall study start date**

01/04/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

122

**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

-

**Sponsor information****Organisation**

Health Research Board (Ireland)

**Sponsor details**

73 Lower Baggot Street

Dublin 2

Ireland

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**Sponsor type**

Government

**Website**

<http://www.hrb.ie/>

**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

**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?
<a href="#">Protocol article</a>	protocol	27/06/2007		Yes	No
<a href="#">Results article</a>	results	01/02/2011	16/05/2019	Yes	No