Motivational interviewing to improve diabetes management for South Asian type 2 diabetic patients

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
31/03/2020	Nutritional, Metabolic, Endocrine	Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Motivational interviewing to improve diabetes management for South Asian type 2 diabetic patients

Study objectives

Around 1.3 million people in Britain are currently diagnosed with diabetes (85% with type 2 diabetes). Diabetes is a life-long condition and the treatment and care required will vary over time. Individuals with diabetes need the necessary knowledge and skills to enable them to improve their blood glucose control and to make the lifestyle changes necessary to reduce their likelihood of developing the complications of diabetes. Individuals with type 2 diabetes are not dependent on insulin injections. They can manage their diabetes with diet, exercise and oral medication. Compared with the white population, type 2 diabetes is up to six times more common in people of South Asian descent (www.doh.gov.uk/nsf/diabetes).

Therefore the aim of this study is:

How effective is motivational interviewing in improving self-management of diabetes for men and women of South Asian origin who have been diagnosed with type 2 diabetes?

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)

Not specified

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

Following ethical clearance and informed consent, a randomised-controlled trial will recruit two groups of Asian type 2 diabetic patients into:

- a. Normal nutritional and lifestyle support (control), and
- b. Motivational interviewing for nutritional and lifestyle support (treatment).

A sample size power analysis suggests that 28 participants per group will be adequate for the main outcome measures so at least 30 will be recruited per group to allow for attrition. The treatment group will engage in 20 to 30 minutes of motivational interviewing every two weeks. The control group will receive similar amounts of contact, but the total time allocation per patient will be less to concur with normal treatment. After three months the pre-treatment measures will be repeated and a two way analysis of variance design (P < 0.05) used to test the treatment effect.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Psychometric Measures: Symptom reduction as measured by Diabetes Impact Measurement Scales. Quality of Life as measured by Diabetes Impact Measurement Scales. Increase in self-efficacy as measured by Diabetes Management Self-Efficacy Scale for Type 2 Diabetes. Increase in perceived control as measured by Perceived Control Scales. Clinical parameters: blood glucose (HbA1c), waist measurement, weight, body mass index (BMI).

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/01/2003

Completion date

30/06/2003

Eligibility

Key inclusion criteria

People of South Asian descent with type 2 Diabetes.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

23/01/2003

Date of final enrolment

30/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Dietetics Department

High Wycombe, Bucks United Kingdom HP11 2TT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder typeGovernment

Funder Name

South Buckinghamshire NHS Trust (UK)

Results and Publications

Publication and dissemination planNot 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