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Effectiveness of patient self-managed structured education for type 2 diabetes (The Diabetes Manual): a cluster randomised-controlled trial

Submission date
04/11/2005

Recruitment status
No longer recruiting

Registration date
20/01/2006

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] 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

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effectiveness of patient self-managed structured education for type 2 diabetes (The Diabetes Manual): a cluster randomised-controlled trial

Acronym
The Diabetes Manual Programme

Study objectives
Engagement with the Diabetes Manual will reduce HbA1c and cardiovascular disease (CVD) risk factors, improve self-efficacy and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Northern and Yorkshire Multi-centre Research Ethics Committee (MREC) on the 8th June 2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The Diabetes Manual Programme is administered to participants in the intervention group and compared to patients in the delayed intervention group who receive the intervention six months later.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
HbA1c.

Follow up for all measures is at six months post randomisation for both arms and 12 months post randomisation for the intervention arm to assess maintenance of effect on all measures.

Key secondary outcome(s))
1. Cholesterol
2. High Density Lipoprotein (HDL) cholesterol

3. Blood Pressure (BP)
4. Height, weight and Body Mass Index (BMI) calculated
5. Psychological distress, measured using a self-completion patient postal questionnaire
6. Quality of life
7. Self-efficacy

Follow up for all measures is at six months post randomisation for both arms and 12 months post randomisation for the intervention arm to assess maintenance of effect on all measures.

Completion date
31/05/2006

Eligibility

Key inclusion criteria
1. Less than 18 years
2. Confirmed clinical diagnosis of type 2 diabetes
3. Last clinical HbA1c not less than 7.0%
4. Ability to use the materials

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. People taking insulin
2. People with learning disabilities and dementia
3. People whose health care needs are met by others (e.g. carers/nurses)
4. Unable to attend the surgery

Date of first enrolment
08/06/2004

Date of final enrolment
31/05/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
NHS R&D Lecturer in Social Sciences
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK) - Centre for Primary Health Care Studies

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK)

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	01/06/2008		Yes	No
Protocol article	protocol	17/07/2006		Yes	No