

# 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

☐ Prospectively registered

☒ Protocol

**Registration date**

20/01/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

17/08/2018

**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 Jackie Sturt

**Contact details**

NHS R&D Lecturer in Social Sciences  
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Warwick Medical School  
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Coventry  
United Kingdom  
CV4 7AL

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Quality of life

## Participant information sheet

## 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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

08/06/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

424

**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**

England

United Kingdom

**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

**Sponsor details**

Warwick Medical School

University of Warwick

Coventry

England

United Kingdom

CV4 7AL

**Sponsor type**

University/education

**Website**

<http://www.warwick.ac.uk>

ROR

## Funder(s)

### Funder type

Charity

### Funder Name

Diabetes UK (UK)

### Alternative Name(s)

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

### 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	17/07/2006		Yes	No
<a href="#">Results article</a>	results	01/06/2008		Yes	No