Medication, Education and Medication Optimisation: improving glycaemic control and blood pressure in patients with microalbuminuria from a mixed ethnic population

Submission date	Recruitment status No longer recruiting	Prospectively registered	
23/03/2009		Protocol	
Registration date	Overall study status	Statistical analysis plan	
30/03/2009	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
26/02/2016	Nutritional, Metabolic, Endocrine		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Leicester Diabetes Centre (Broadleaf) Leicester General Hospital Gwendolen Road Leicester United Kingdom LE5 4PW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Integrated care-based education intervention to improve glycaemic control and blood pressure in patients with microalbuminuria from a mixed ethnic population: a randomised controlled trial

Acronym

MEMO

Study objectives

This four-year study will examine the benefits of combining medication optimisation with structured self-management education in a multi-ethnic community, for individuals with microalbuminuria and type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire Research Ethics Committee, 05/09/2005, ref: 05/Q2501/34

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus/nephropathy

Interventions

Intervention arm:

Participants attend group education sessions. Initially they are offered a basic programme of 6 hours around basic diabetes. They then attend a 3-hour session on diabetes and the kidney - they

are then given the opportunity to opt into sessions depending on the risk factors they wish to target such as blood pressure, weight management, lipids, blood glucose. In addition to this participants are seen on a one to one basis with a clinician/nurse who titrates medications for glucose, blood pressure and lipids if necessary and sets individualised goals with the participants. Participants are seen at 3, 6, 9 and 12 months and then 6-monthly thereafter.

Control arm:

Patients receive usual care but attend the research centre for clinical measurements at 6, 12, 18, 24 months and yearly thereafter.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

HbA1c at 18 months.

Secondary outcome measures

- 1. Cardiovascular events at 4 years
- 2. Mortality at 4 years
- 3. Biochemical measured at baseline and 6, 12, 18, 24, 36, 48 months
- 4. Blood pressure measured at baseline and 6, 12, 18, 24, 36, 48 months
- 5. Blood lipids measured at baseline and 6, 12, 18, 24, 36, 48 months
- 6. HbA1c measured at baseline and 6, 12, 18, 24, 36, 48 months
- 7. Medication use measured at baseline and 6, 12, 18, 24, 36, 48 months
- 8. Urinary albumin excretion measured at baseline and 18, 24, 36 and 48 months
- 9. Serum creatinine and urea levels measured at baseline and 6, 12, 18, 24, 36, 48 months
- 10. Smoking status measured at baseline and 6, 12, 18, 24, 36, 48 months
- 11. Physical activity measured at baseline and 6, 12, 18, 24, 36, 48 months
- 12. Quality of life measured at baseline and 6, 12, 18, 24, 36, 48 months
- 13. Medication beliefs measured at baseline and 6, 12, 18, 24, 36, 48 months
- 14. Depression measured at baseline and 6, 12, 18, 24, 36, 48 months
- 15. Personality measured at baseline

Overall study start date

01/09/2005

Completion date

30/09/2011

Eligibility

Key inclusion criteria

- 1. Aged 25 80 years, either sex
- 2. A confirmed diagnosis of type 2 diabetes on diet, tablets or insulin
- 3. Microalbuminuria or proteinuria

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

189

Key exclusion criteria

- 1. A malignancy
- 2. Liver disease
- 3. An autoimmune disease
- 4. Any life threatening condition with a life expectancy of less than 5 years
- 5. Immobility (difficult to attend sessions)
- 6. Learning disability or mental incapacity
- 7. Serum creatinine greater than 180 µmol/l
- 8. Patients taking part in another research study

Date of first enrolment

01/09/2005

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Leicester Diabetes Centre (Broadleaf)

Gwendolen Road Leicester United Kingdom LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust

Sponsor details

Leicester General Hospital Gwendolen Road Leicester England United Kingdom LE9 8HZ

Sponsor type

Hospital/treatment centre

Website

http://www.uhl-tr.nhs.uk/

ROR

https://ror.org/02fha3693

Funder(s)

Funder type

Charity

Funder Name

Kidney Research UK

Alternative Name(s)

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

Planned publication in a peer reviewed journal.

Intention to publish date

31/12/2011

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No