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

Submission date	Recruitment status
23/03/2009	No longer recruiting
Registration date	**Overall study status**
30/03/2009	Completed
Last Edited	**Condition category**
26/02/2016	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] 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

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
Other non-profit organizations

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

Not provided at time of registration

Study outputs

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