

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

Submission date 23/03/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/03/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/02/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Quality of life

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(s)

HbA1c at 18 months.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 $\mu\text{mol/l}$
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

United Kingdom

England

Study participating centre

Leicester Diabetes Centre (Broadleaf)

Gwendolen Road

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust

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

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