

# 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

**Registration date**

30/03/2009

**Overall study status**

Completed

**Last Edited**

26/02/2016

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Melanie Davies

**Contact details**

Leicester Diabetes Centre (Broadleaf)  
Leicester General Hospital  
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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  $\mu\text{mol/l}$
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**

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?
<a href="#">Results article</a>	results	01/09/2011		Yes	No