

# Diabetes 6 (D-6) trial: psychologically enhanced diabetes care, delivered by nurses

<b>Submission date</b> 19/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/06/2017	<b>Condition category</b> 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

**Protocol serial number**  
4299

## Study information

**Scientific Title**  
A randomised controlled trial of 'Psychologically Enhanced Diabetes Care, delivered by nurses' (D-6) for people with Type 2 diabetes and sub-optimal glycaemic control

**Acronym**

## **Study objectives**

Some people with type 2 diabetes (T2DM) have problems reaching ideal blood glucose levels that will prevent a worsening of their condition. They may need to make significant lifestyle changes to do this which can be very difficult. Often it may be a question of being unsure whether they can make the changes not that they don't know what changes to make. Talking therapies such as motivational interviewing and cognitive behavioural therapy can help people talk through their difficulties within a supportive relationship and help foster their own self confidence in their ability to make changes. These therapies have increasingly been used in health settings although usually delivered by psychologists but the skills involved can be taught to non-psychologists such as practice nurses.

The aim of this study is to train practice nurses (for intervention GP practices) in talking therapy for diabetes and compare their patients with those from practices where nurses have not had the training. We would invite approximately 24 GP practices from the London boroughs of Lambeth, Southwark and Lewisham to participate and these would be randomised and nurses in the intervention practices would receive training. Nurses working in the non-intervention (control) GP practices would receive additional training in diabetes education. If this study shows that training nurses in talking therapy helps their patients to get better control of their diabetes this training could be offered to other practice nurses working in the NHS.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. South East Ethics Committee 3, 30/11/2009, ref: 09/H0808/97
2. Research & Development Centre for South East London NHS, 05/05/2010, ref: RDLSL 534/CSP 20423

## **Study design**

Multicentre randomised interventional treatment trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Hypertension, Dyslipidaemia, Diabetic Control, Obesity, Prevention/screening

## **Interventions**

Baseline blood tests are taken in both the treatment and control groups. Patients are randomised to:

1. D-6 treatment group: face to face psychological diabetes care sessions. Maintenance psychological diabetes sessions, specified by patient, may be telephone/e-mail/face to face.
2. Control group: Face to face diabetes education sessions. Maintenance education sessions specified by patient, may be telephone/e-mail/face to face.

Follow-up blood tests are then taken in both the treatment and control groups.

Total duration of intervention: 12 months

Total duration of follow-up: 6 months

### **Intervention Type**

Other

### **Phase**

Phase II

### **Primary outcome(s)**

Change in HbA1c (glycaemic control) at 18 months

### **Key secondary outcome(s)**

1. Total cholesterol, taken at baseline and at end of study
2. Blood pressure, taken at baseline and at end of study
3. BMI, taken at baseline and at end of study
4. Quality of life, measured before and after intervention
5. Depressive symptoms, measured before and after intervention
6. Economic evaluation, measured before and after intervention

### **Completion date**

30/11/2016

## **Eligibility**

### **Key inclusion criteria**

1. People with Type 2 diabetes for more than 2 years
2. Resident in south London boroughs of Lambeth Southwark and Lewisham
3. Aged 18 - 79 years, either sex
4. Persistent suboptimal glycaemic control defined as HbA1c above or equal to 8% on occasions in the past 12 months despite 2 appointments with a diabetes health professional

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Severe mental disorders
2. Terminal illnesses and severe end stage diabetes complications
3. Morbid obesity with a body mass index (BMI) greater than 50 kg/m<sup>2</sup> as there is usually comorbid psychiatric morbidity
4. No telephone or mobile phone access as telephone contact is part of the intervention

**Date of first enrolment**

27/09/2010

**Date of final enrolment**

11/10/2011

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Department of Psychological Medicine**

London

United Kingdom

SE5 9RJ

## Sponsor information

**Organisation**

King's College Hospital NHS Foundation Trust (UK)

**ROR**

<https://ror.org/01n0k5m85>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Programme Grants for Applied Research (ref: RP-PG-0606-1142)

# Results and Publications

## 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	01/10/2016		Yes	No