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

Submission date	Recruitment status	[X] Prospectively registered
19/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
D-6

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

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 measure
Change in HbA1c (glycaemic control) at 18 months

Secondary outcome measures
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

Overall study start date
15/10/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 432

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^2 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
England

United Kingdom

Study participating centre
Department of Psychological Medicine
London
United Kingdom
SE5 9RJ

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Department of Research & Development
34 Love Walk
London
England
United Kingdom
SE5 8AD

Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	01/10/2016	Yes	No