Improving diabetes care through professional behaviour change

Submission date	Recruitment status	Prospectively registered		
04/04/2013	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/04/2013	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/05/2018	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Background and study aims

The aim of this study is to evaluate the effectiveness and costs of training for GPs and practice nurses to improve the care they provide for people with type 2 diabetes. We are targeting six areas that were found in our previous study to require improvement: prescribing medicine for high blood pressure and blood glucose control, providing self-management and weight advice, general education, and foot examinations.

Who can participate?

GPs and practice nurses who provide diabetes care in 44 general practices in north east England.

What does the study involve?

Practices are randomly allocated to either the intervention or the control group. GPs and primary care nurses in the intervention group practices attend a single training session about providing the best diabetes care. The control group do not receive any training during the study, but will be provided with access to the training materials after the study is over. We survey the GPs and practice nurses in both groups before the training and again 12 months later. We also conduct interviews with GPs and practice nurses to see what they thought of the training, what they liked, what they didn't like, and how it could be improved. At the 12-month follow-up, patients with type 2 diabetes will be randomly selected from practice lists and asked about their care.

What are the possible benefits and risks of participating?

GPs and practice nurses will receive training to help them to provide better care for patients with type 2 diabetes. There are no risks involved in this study.

Where is the study run from?

Institute of Health and Society, Newcastle University (UK).

When is the study starting and how long is it expected to run for? March 2013 to March 2015.

Who is funding the study? Diabetes UK.

Who is the main contact? Joan Mackintosh joan.mackintosh@ncl.ac.uk

Study website

http://www.ncl.ac.uk/ihs/research/project/4385

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 14053

Study information

Scientific Title

The Improving Diabetes care through Examining, Advising, and prescribing (IDEA) trial: A theory-based cluster randomised controlled trial of a multiple health professional behaviour change intervention in primary care

Acronym

DRN 782

Study objectives

Moving clinical research findings into routine care is recognised as an inconsistent process with implications for the quality of care offered to people with Type 2 diabetes. Providing evidence

based care often requires clinicians to change their behaviour. Based on findings from a UK wide study of theory based factors associated with high quality diabetes care, this study will evaluate the effectiveness and cost of an intervention targeting primary care clinicians to improve the behaviours involved in providing high quality type 2 diabetes care. We will conduct a theory based two armed cluster randomised controlled trial in 44 general practices in the north east of England. We will target improvement in six underperformed clinical behaviours highlighted in NICEs quality standards: prescribing for hypertension and glycaemic control, providing self management and weight advice, general education and foot examinations. The intervention will be delivered within a group session by a community diabetologist, patient representative, GP, a psychologist and a nurse. The main outcomes will be the proportion of patients prescribed (using anonymised computer records) and advised (using anonymous patient surveys) after 12 months. We will also investigate whether the intervention was delivered as designed (fidelity) and operated as hypothesised (process evaluation) by analysing responses to theory based surveys before and after the trial, and by conducting qualitative interviews with relevant primary care clinicians.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14053

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Riverside, 17/10/2012, ref: 12/LO/1742

Study design

Theory-based two-armed cluster randomised controlled trial Design type: Process of Care

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Hypertension, Diabetic Control, Diabetic foot, Education, Nutrition, Prevention/screening, Service delivery

Interventions

IDEA training session: The intervention will consist of a single training session for GPs and primary care nurses involved in providing care for patients with type 2 diabetes. The training

sessions will look at providing optimal care and will include role identification, discussion with colleagues, goal setting and barriers elicitation with the aim of identifying relevant solutions, reinforced through practice, planning and case studies using scenarios.

We plan to oversample our intervention group by four practices in order that we can conduct some qualitative interviews with practice staff to see what they thought of the intervention, what they liked, what they didn't like, how it could be improved etc. We will randomly select four practices from the intervention group after the intervention has been received and these practices will be excluded from the main trial outcomes.

Follow Up Length: 12 month(s)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Clinician advising, prescribing and examining behaviours collected via patient questionnaires and electronic queries; Timepoint(s): 12 months

Secondary outcome measures

We will collect QOF data for diabetes mellitus and practice organisation for each participating practice; we will also conduct a process evaluation (using quantitative and qualitative methods), a cost analysis and fidelity of delivery assessment.

Overall study start date

04/03/2013

Completion date

31/03/2015

Eligibility

Key inclusion criteria

- 1. Male & Female; Lower Age Limit 18 years
- 2. Primary health care professionals delivering care to people with type 2 diabetes within their practice.
- 3. People with type 2 diabetes registered with participating practices.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 2002; Description: 242 GPs and primary care nurses 1,760 patients with type 2 diabetes

Key exclusion criteria

- 1. Health care professionals providing care to patients with type 2 diabetes from more than one GP practice, e.g. district nurses and podiatrists
- 2. GP registrars
- 3. Patients for whom the questionnaire would not be appropriate (decided by practice staff)
- 4. Patients aged under 18 years

Date of first enrolment

04/03/2013

Date of final enrolment

01/06/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

21-23 Claremont Place

Newcastle Upon Tyne United Kingdom NE2 4AA

Sponsor information

Organisation

NHS North of Tyne (UK)

Sponsor details

Bevan House 1 Esh Plaza Sir Bobby Robson Way Great Park Newcastle upon Tyne England United Kingdom NE13 9BA

Sponsor type

Hospital/treatment centre

Website

http://www.northoftyne.nhs.uk/

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK); Grant Codes: 11/0004367

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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?
<u>Protocol article</u>	protocol	24/05/2014		Yes	No
Results article	results	02/05/2018		Yes	No