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A patient decision aid to improve decision quality and health outcome in type 2 diabetic patients

Submission date
24/06/2010

Recruitment status
No longer recruiting

Registration date
24/06/2010

Overall study status
Completed

Last Edited
29/01/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). A large number of sufferers have poorly controlled blood sugar despite lifestyle changes and glucose lowering drug. This can lead to serious complications such as problems with the eyes (retinopathy), nerves (neuropathy) and kidneys (nephropathy), as well as significantly increasing the risk of heart problems. To control the blood sugar, a patient needs to either take insulin or another medication (e.g. glitazone). Patients often find it difficult to decide whether or not to start insulin for many reasons, such as lack of understanding or reluctance to inject themselves. Patient decision aids (PDAs) are specially designed resources which provide information to help people to make decisions. They have been shown to improve knowledge, help patients to understand treatment risks and benefits, address their values and roles in decision making. Few studies, however, have been able to show the impact of PDAs on patient's health. The aim of this study is to find out whether a specially designed PDA for patients with T2DM can help more patients to make informed decisions about whether to start insulin therapy.

Who can participate?
Adults with poor blood sugar control, who are taking the maximum dose of anti-diabetic tablets.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive usual care from their doctors, and are not given access to the PDA. Those in the section group are given a run through of how to use the PDA, which is then available for them to use. At the start of the study and then again after 6 months, all participants have their blood sugar tested to find out if their control over their blood sugar (glycaemic control) has improved. Participants are also asked to complete questions in order to find out whether their current treatment is different to when the study started.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Northern General Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2008 to May 2015

Who is funding the study?
1. National Institute for Health Research (UK)
2. South Yorkshire Collaborative Local Research Network (UK)

Who is the main contact?
Professor Nigel Mathers

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
4677

Study information

Scientific Title
The development and evaluation of the effectiveness of a patient decision aid to improve decision quality and health outcome in type 2 diabetic patients making treatment choices

Acronym
DRN150 (PANDAs)

Study objectives
Current study hypothesis as of 23/07/2012:
The use of the PANDAs patient decision aid improves decision quality in patients with type 2 diabetes mellitus who are making a decision whether or not to start insulin in General Practice. PANDAs is a cluster randomised controlled trial which has been carried out to evaluate the clinical effectiveness of a patient decision aid (PDA) in general practice. The PDA has been developed by the researchers to help people with type 2 diabetes make an informed decision about starting insulin treatment.

Previous study hypothesis as of 26/06/2012:
PANDAs is a cluster randomised controlled trial which will be carried out to evaluate the clinical effectiveness of a patient decision aid (PDA) in general practice. The PDA has been developed by the researchers to help people with type 2 diabetes make an informed decision about starting insulin treatment.
This study was conducted in South Yorkshire, UK, involving 49 general practices. Participants in the intervention group used the PDA followed by the usual consultation; the control group received the consultation (usual care).
The main outcome measures were improvement in participants decision quality (immediate) and HbA1c level (6 months later).

Original study hypothesis:
PANDAs is a cluster randomised controlled trial which will be carried out to evaluate the clinical effectiveness of a patient decision aid (PtDA) in general practice. The PtDA has been developed by the researchers to help people with type 2 diabetes make an informed decision about starting insulin treatment.
This study will be conducted in Sheffield and surrounding areas, involving 30 general practices. Participants in the intervention group will use the PtDA followed by the usual consultation; the control group will only be receiving the consultation (usual care).
The main outcome measures are improvement in participants' decision quality (immediate) and HbA1c level (6 months later).

On 26/06/2012 the following changes were made to the trial record:
1. The public title was updated. The previous public title was 'The development and evaluation of the effectiveness of a patient decision aid to improve decision quality and health outcome in type 2 diabetic patients making treatment choices'.
2. The anticipated end date was changed from 01/10/2010 to 28/02/2011.
3. The target number of participants was changed from 1440 to 440.
4. The sources of funding field was updated. The previous text was 'National Institute for Health Research (NIHR) (UK) - Service Delivery and Organisation (SDO)'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield Research Ethics Committee, 19/06/2007, ref: 07/Q2308/53

Study design
Single-centre randomised interventional process of care and treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2, Not Assigned; Disease: Diabetic Control, All Diseases, Not Applicable, Education, Insulin Initiation

Interventions
Current interventions as of 26/06/2012:
Control Group: No PDA used by patients or doctors (usual care)
Intervention Group: Brief training of clinicans pre-consultation, familiarisation of PDA by participants, use of PDA by patients and clinicians
Follow-up length: 6 months
Study entry: other
Details: randomised according to clusters of practices

Previous interventions until 26/06/2012:
Control group: No PtDA for patients or doctors
Intervention group: PtDA, for doctors and patients

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measure(s) as of 26/06/2012:
Decisional conflict as an indicator of decisional quality post-consultation and glycaemic control after 6 months (HbA1c).

Previous primary outcome measure(s) until 26/06/2012:
Baseline and six-month clinical data will be provided by the practices from the medical records.

Key secondary outcome(s))
Current secondary outcome measure(s) as of 26/06/2012:
Knowledge and realistic expectations of risks and benefits, post consultation.

Previous secondary outcome measure(s) until 26/06/2012:
1. The outcome of decision making will be glycaemic control (HbA1c) and persistence with chosen option
2. The process of decision making will be measured using decision quality indicators

Completion date
28/02/2011

Eligibility

Key inclusion criteria

1. Type 2 diabetes mellitus
2. Aged 21 years and above, either sex
3. HbA1c greater than 7.4%
4. On maximum dose of oral anti-diabetic drugs
5. Advised by the doctor or nurse to start insulin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Taking insulin currently
2. Difficulty reading or understanding English
3. Chronic debilitating illness (e.g., visual, hearing or cognitive impairment)
4. Active mental illness
5. Participated in a clinical trial in the past 6 months

Date of first enrolment
01/08/2007

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern General Hospital
Academic unit of Primary Medical Care
Samuel Fox House
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Health and Social Research Consortium

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
South Yorkshire Collaborative Local Research Network (SY CLRN)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/11/2012		Yes	No

Results article	results	07/06/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes