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The effects of a diabetes pre-consultation booklet for patients with type 2 diabetes on patients and doctors communication during the consultation and on patient outcomes.

Submission date
14/02/2012

Recruitment status
No longer recruiting

Registration date
13/03/2012

Overall study status
Completed

Last Edited
21/01/2019

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
It is important that patients are given the opportunity to be involved in their diabetes care. Good communication between the doctor and the patient can help patients be more involved. The aim of our study is to explore if a pre-consultation booklet for people with type 2 diabetes can help patients and diabetes hospital doctors communicate better in the consultation and improve patient outcomes. The pre-consultation intervention booklet will encourage people to ask questions and provide them with their own personal clinical data and examples of questions they might like to ask during the consultation.

Who can participate?
People with type 2 diabetes aged 75 or under who are attending general diabetes outpatient clinics at the Diabetes Day Centre at the University Hospital Galway for review appointments will be approached to participate in the study.

What does the study involve?
Participants will be randomly allocated to one of three groups. The first group will receive an intervention booklet (containing personalised clinical information and prompt questions) at least 48 hours before their review appointment. The second group will receive a general information booklet (containing a glossary of diabetes topics usually discussed during a review visit) at least 48 hours before their review appointment. The third group will not receive a booklet. Those participating in the study will need to attend the Diabetes Day Centre 1-4 weeks before their review clinic appointment to have their HbA1c, cholesterol, blood pressure and Body Mass Index measured.
Participants will complete short questionnaires on a number of occasions including when they have their blood tests done at the beginning of the project, directly before and after their first and second review appointment, six weeks after their first and second appointment, and six

months after their second review visit. Data from patients in the control, general information, and intervention groups will be compared to see if there are any differences in patient outcomes and in how patients and doctors communicate during the consultation.

What are the possible benefits and risks of participating?
Findings from our research study may help improve the way we deliver diabetes care in the future.

Where is the study run from?
The Diabetes Day Centre, University Hospitals Galway (Ireland).

When is study starting and how long is it expected to run for?
The study ran from January 2011 to January 2014.

Who is funding the study?
This project is funded by the Health Research Board (HRB) (Ireland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Development and assessment of the feasibility, acceptability and potential effectiveness of a Patient Information Pre-consultation Package containing personalised clinical information for patients with type 2 diabetes attending an outpatient diabetes clinic for a review visit: a mixed methods approach (PIPP study)

Acronym
PIPP

Study objectives
The aim of this study is to design and evaluate a patient intervention to be given to type 2 diabetes patients prior to their outpatient review visit in order to facilitate their involvement in the consultation and to explore the effects of this information on clinical and psychosocial outcomes.

Specific objectives:
1. To develop a personalised clinical information sheet for patients with Type 2 diabetes informing them of the current status of their diabetes
2. To compare the administration of this personalised clinical information sheet during diabetes clinic attendance with administration of a non-personalised information sheet and with no administration (i.e. routine care)
3. To explore the feasibility of a large multi-centre trial evaluating this approach to diabetes care delivery in other diabetes clinics in Ireland

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Galway Regional Hospitals Research Ethics Committee, December 2010, ref: 11 January 2010
2. National University of Ireland Galway Research Ethics Committee, March 2011, ref: C.A.507

Study design
Exploratory randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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

Interventions
The intervention is a pre-consultation booklet that the intervention group will receive at least 48 hours before their review appointment. The intervention booklet will include personalised diabetes-related clinical information about their weight, body mass index, blood pressure and recent laboratory results including HbA1c and cholesterol levels. They will also receive prompt questions relating to their their personal clinical information and diabetes care. They will receive this intervention on two occasions at two consecutive clinic visits.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. HbA1c
2. Measure of diabetes self-efficacy

Secondary outcome measures
1. Patient anxiety
2. Patient satisfaction with the consultation
3. Weight
4. Cholesterol
5. Blood pressure
6. Self-care activities
7. Diabetes-related distress

Overall study start date
05/01/2011

Completion date
04/01/2014

Eligibility

Key inclusion criteria
1. People with type 2 diabetes of at least 12 months duration
2. People with type 2 diabetes attending general diabetes outpatient clinics
3. People with type 2 who have had their blood tests done (HbA1c, lipids) within 8 weeks of recruitment into the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 patients

Key exclusion criteria
1. People with Type 1 diabetes
2. People with type 2 diabetes whose English language ability, literacy or cognitive function will not enable them to participate in the study
3. People with type 2 diabetes who have not had blood tests (HbA1c, lipids) done within 8 weeks of their outpatient visit

Date of first enrolment
05/01/2011

Date of final enrolment
04/01/2014

Locations

Countries of recruitment
Ireland

Study participating centre
Clinical Science Institute
Galway
Ireland
-

Sponsor information

Organisation
Health Research Board (Ireland)

Sponsor details
73 Lower Baggot Street
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Sponsor type
Government

Website
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ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland), ref: HRA_HSR/2010/19

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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				

Results article	01/04/2016	21/01/2019	Yes	No