ISRCTN75070242 https://doi.org/10.1186/ISRCTN75070242

Diabetes Intervention for Agenda Trial: study of the efficacy of a patient-orientated agenda (produced by the PACE-D tool) for use in a diabetes clinical consultation

Submission date
12/06/2013

Recruitment status
No longer recruiting

Registration date
12/06/2013

Overall study status
Completed

Last Edited
18/06/2020

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
Diabetes is a condition associated with many long-term complications. It affects a large number of people and its management is costly to the NHS. People with diabetes need to be actively involved in managing their condition and self management of diabetes is sometimes complex. Patients receive advice in consultations with healthcare professionals. However, patients do not always discuss things which concern them in these consultations, perhaps because of perceived limited time or embarrassment. PACE-D is a tool which has been developed for this study. It is designed to help people with diabetes to identify any areas that they think are important to discuss in their routine consultation. We want to test whether using the PACE-D tool to produce an agenda helps people to play a more active role in their consultation, and whether this in turn helps people to manage their diabetes.

Who can participate?
Adults with type 1 or type 2 diabetes are eligible to participate (excluding women with gestational diabetes and people with insulin pump).

What does the study involve?
Participants are randomly allocated to one of two groups. One group will complete the PACE-D questionnaire and the other will attend their routine appointments as normal (control group). After completion of the PACE-D questionnaire, a list of the participants main concerns (agenda) is produced and this is taken into consideration. On three occasions (prior to the consultation, three months and six months later), each participant will complete a standard postal questionnaire and provide a blood sample (as a measure of glucose control). To analyse the content of the sessions and clinical encounters, a small number of these sessions will be audio recorded with the permission of all relevant parties.

What are the possible benefits and risks of participating?
It is possible that there may be slight distress to some individuals. There are questions in the

questionnaire booklet that may cause slight distress or embarrassment. We will minimise the impact on participants by providing those who experience such distress with the contact details of appropriate organisations that can provide support.

Where is the study run from?
This study is conducted at the Royal Devon and Exeter NHS Foundation Trust, UK and Plymouth Hospitals NHS Trust, UK. The study takes place at routine outpatient appointments with a consultant diabetologist with 60 participants per site.

When is study starting and how long is it expected to run for?
The study started in May 2013 and will continue for two years.

Who is funding the study?
This research is funded by the National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Julia Frost
J.Frost@exeter.ac.uk

Study website
https://penctu.pcmd.ac.uk/diat/

Contact information

Type(s)
Scientific

Contact name
Dr Julia Frost

ORCID ID
http://orcid.org/0000-0002-3503-5911

Contact details
University of Exeter Medical School
Veysey Building
Salmon Pool Lane
Exeter
United Kingdom
EX2 4SG
+44 1392 722970
j.frost@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14573

Study information

Scientific Title
A pilot randomised controlled study of the efficacy of a patient-orientated agenda (produced by the PACE-D tool) for use in a diabetes clinical consultation

Acronym
DIAT

Study objectives
The aim of this study is to investigate the efficacy of a 'preconsultation' intervention in which the patient is supported by a healthcare assistant to complete a web-based intervention aimed at producing an agenda to help them identify important areas for discussion in the consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 04/04/2013, ref: 13/NW/0123

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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: Both; Disease: Diabetic Control

Interventions
Interventions as of 08/07/2016:
The intervention has been designed to facilitate the articulation of patients’ often unvoiced agendas which arise from their continual efforts to manage their conditions. Discussion of these agendas enables patients to manage their condition more effectively, which includes better

adherence. The PACE intervention has been modified specifically for diabetes (as PACE-diabetes or PACE-D) by the DIAT Project Team. PACE-D is a web-based tool, designed to be completed by a patient before a clinic appointment. In this study, the appointment is with a consultant diabetologist.

A trained healthcare assistant (HCA) will facilitate the use of the PACE-D tool, with the aim of assisting patients to identify the things that they wish to discuss with the diabetologist (ie, their 'agenda') in the clinical consultation. The intervention takes approximately 20 min to complete, and consists of a series of open and closed questions, prompts and a list of possible concerns that people with diabetes have identified (eg, 'increased thirst' or 'depression'). On completion, a concise agenda will automatically be produced, which the patient will take into their consultation with a diabetologist, and which may be used subsequently (ie, in discussions with the general practitioner (GP) or practice nurse, and to guide self-management). PACE-D aims to enable patients to identify their agenda for discussion with the diabetologist, improving communication and empowering patients to be more proactive at managing their diabetes, potentially leading to improved clinical and quality-of-life outcomes. The intervention appears to be a simple and relatively inexpensive tool but requires a rigorous test of its efficacy and cost-effectiveness. Piloting the PACE-D intervention and agenda with people with diabetes could provide improvements in communication, blood glucose management, enablement, self-care, medication use and quality of life, with little impact on cost or clinic time.

An independent statistician based at the Peninsula Clinical Trials Unit (PenCTU) will generate the randomisation list, using computer-generated random numbers. Randomisation will be stratified by clinic session. Randomisation will be achieved by means of an automated web-based system created by a PenCTU data programmer in conjunction with the independent statistician and accessed by a separate member of the PenCTU staff on receipt of the completed consent form. Consenting participants will be allocated with equal probability to receive PACE-D or usual clinical care, using randomly permuted blocks of varying size to generate the allocation sequence and achieve balance in the numbers of participants allocated to each group.

Following randomisation, PenCTU will notify participants by standard letter about the arrival time for their clinic appointment. Those in the intervention arm will be notified that they are required to arrive 30 min early, while those in the control arm will be notified that they are not required to arrive early.

Original interventions:
PACE-D: PACE-D is a bespoke online intervention (administered on an internet-enabled computer). PACE-D is designed to be completed by the participant immediately before a clinic appointment with a consultant diabetologist. A designated facilitator (i.e. an outpatient department healthcare assistant, trained in specific study procedures) is present to facilitate the participant to use the PACE-D tool.
The objective of PACE-D is to assist the patient to identify the things that they wish to discuss.
Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Blood glucose is measured by measuring glycosylated haemoglobin (HbA1c) at baseline and 6 months.

Secondary outcome measures
1. Quality of life is measured using the Audit of Diabetes-Dependent Quality of life at baseline and 6 months
2. Resource use is measured using the Client Services Receipt Inventory at baseline and 6 months
3. Empowerment is measured using the Diabetes Empowerment Scale at baseline and 6 months
4. Self care activities are measured using the Diabetes Self-Care Activity Questionnaire at baseline and 6 months
5. Treatment satisfaction is measured using the Diabetes Treatment Satisfaction Questionnaire ('status' and 'change' versions) at baseline and 6 months
6. Quality of life is measured using the EuroQol-5L at baseline and 6 months
7. Enablement is measured using the Patient Enablement Instrument at baseline and 6 months
8. Communication is measured using the Patient Report of Communication at baseline and 6 months
9. Use of medication is self-reported by patients at baseline and 6 months
10. Qualitative interviews will be conducted with participating staff and patients in order to capture patient and staff perspectives

Overall study start date
23/05/2013

Completion date
22/05/2015

Eligibility

Key inclusion criteria
1. People with type 1 or type 2 diabetes mellitus
2. Due to attend for hospital outpatient appointment
3. Aged 18 and over
4. Basic written and spoken English (to complete outcome measures)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria

1. People with gestational diabetes
2. People receiving insulin pump therapy

Date of first enrolment
28/05/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Royal Devon and Exeter NHS Foundation Trust (UK)

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03085z545

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

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2013

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	31/07/2013		Yes	No

Results article	qualitative results	14/06/2019	18/06/2020	Yes	No
HRA research summary			28/06/2023	No	No