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Primary care research into diabetes evolution (PRIDE)

Submission date
29/11/2011

Recruitment status
No longer recruiting

Registration date
30/11/2012

Overall study status
Completed

Last Edited
30/03/2023

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
The prevalence of diabetes, in particular type 2 diabetes, is increasing at an alarming rate. It is expected that the current obesity epidemic will result in the rapid growth of the number of patients with diabetes and subsequently result in greater treatment costs. Diabetes is associated with a number of health complications including blindness, heart disease, stroke, kidney problems, amputation, nerve damage, pregnancy complications and birth defects. This is a particular concern for Birmingham and the West Midlands as not only do the West Midlands have one of the highest levels of obesity in the country, but Birmingham also includes several population groups at high risk of diabetes and its complications. Despite the surge in research into the disease, there are still many gaps in our knowledge and understanding of type 2 diabetes. There is insufficient information about the following factors in diabetes and their impact on quality of life: stress levels, obstructive sleep apnoea, sleep duration and quality, physical activity levels, and diabetes-related distress and mental health. This study aims to understand the health status of patients with diabetes across one primary care trust serving a population of 300,000, one of the largest primary care trusts in the UK. The three phases of the study (PRIDE 1, PRIDE 2 and PRIDE 3) have specific aims.

PRIDE 1 aims to approach a large number of patients with type 1 and type 2 diabetes across the South Birmingham Primary Care Trust (SBPCT). This phase aims to gather:
1. Demographic data including age, sex, ethnicity, level of education and social background
2. Lifestyle data including alcohol intake, smoking status, dietary intake and physical activity
3. Anthropometric data including height, weight, and neck and waist circumference
4. Healthcare utilization data
5. Co-morbidity data including retinopathy, nephropathy, neuropathy, cerebrovascular disease, ischaemic heart disease and peripheral arterial disease
6. Medications
7. Sleep data including daytime sleepiness, sleep quality
8. Quality of life
9. Mental health risks

PRIDE 2 aims to approach a sub-population within the cohort with type 2 diabetes for further detailed study and assessment of:

1. Diabetic microvascular complications including diabetic neuropathy, diabetic nephropathy and diabetic retinopathy
2. Obstructive sleep apnoea
3. Sleep quality and duration
4. Diet and physical activity
5. Stress
6. Quality of life
7. Depression and anxiety
8. Coping styles
9. Perceived control of health
10. Readiness to change health behaviour
11. Impulsivity and cognitive function

PRIDE 3 aims to recruit up to 40 patients for an in-depth interview to explore patients experiences living with type 2 diabetes. Interviews will be carried out at study entry, 12 and 24 months.

Who can participate?
Adults aged 18 or over who have registered with a GP practice within South Birmingham Primary Care Trust and have been diagnosed with diabetes. PRIDE 1 will include type 1 and type 2 diabetes patients. PRIDE 2 and 3 will only include type 2 diabetes patients.

What does the study involve?
PRIDE 1: Patients with type 1 and 2 diabetes across South Birmingham Primary Care Trust will be approached through primary care. Patients attending their local GP surgery for their annual diabetes visit will receive a recruitment pack from their diabetes specialist nurse containing: patient information sheet, consent form, first questionnaire booklet, current anthropometric measurements form (to be completed by the nurse), a contact details form, and a return envelope. Patients will be asked to return their completed questionnaire, consent form and biomedical results slip in the pre-paid business envelope provided if they would like to participate. Patients will also be asked to provide optional contact details if they would like to participate in future research.

PRIDE 2: A sub-cohort of 1000 patients who took part in PRIDE 1 will be randomly selected and invited to PRIDE 2. They will receive a patient information leaflet, consent form and second questionnaire booklet. Patients who provide consent and are eligible will be invited to two measurement sessions with a team of researchers at a local community centre. Session 1 will include: blood sampling, urine sampling, blood pressure measurement, foot screening, height /weight and hip/waist measurements, administration of wrist-worn actigraphy device, administration of ApneaLink device, administration of sleep diary and instructions for saliva sampling. Session 2 will include: morning awakening cortisol via saliva sampling, dietary interview and readiness to change interview.

PRIDE 3: Up to 40 eligible patients who consented in PRIDE 2 will be invited to undergo three home interviews over a 2-year period. Interviews will explore the following issues: patients current priorities in their lives; impact of unemployment; impact on self-esteem; perceived risk of diabetic complications; perspectives on sleep and understanding of available health services.

What are the possible benefits and risks of participating?
PRIDE will identify patient-specific factors which contribute to diabetes and could aid patient

care and wellbeing. The study will address important gaps in our understanding of diabetes on health and will aid development of more tailored and effective interventions to improve health outcomes in patients with diabetes. Only the blood sample poses a minor risk.

Where is the study run from?
South Birmingham Primary Care Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in May 2012 and will run for 2 years.

Who is funding the study?
National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR - CLAHRC) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Vrs 1.1

Study information

Scientific Title
Prospective study of the long-term outcomes of diabetes and its complications. [Primary care Research Into Diabetes Evolution (PRIDE)]

Acronym
PRIDE

Study objectives
This is an exploratory, hypothesis-generating study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull

Study design
Prospective cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Diabetes, Sleep disorders

Interventions
This is observational research and does not include any interventions.

The study will be conducted in three phases.
PRIDE 1: patients will be asked to complete a comprehensive questionnaire that aims to find out health status and behaviours.

PRIDE 2: A subset of 1000 consenting patients with type 2 diabetes from PRIDE 1 will be randomly selected and invited to come for additional tests for a more comprehensive data collection and characterisation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
In PRIDE 1 a questionnaire booklet will be issued to all patients willing to take part. It contains the following measures: EQ5D, stanford presenteeism scale, Mental Health Inventory (MHI5), Problem Areas in Diabetes (PAID) score, International Physical Activity Questionnaire (IPAQ), Pittsburgh Sleep Quality Index (PSQI), Berlin Questionnaire, Epworth Sleepiness Scale (ESS), Food Frequency Questionnaire (FFQ) and some healthcare utilisation measures. The questionnaire also includes the following descriptive variables: age at diabetes diagnosis, ethnicity, marital status, education level, dependents, family history, employment, smoking status, alcohol intake, comorbidities, and whether
someone has accessed online health information. Further descriptive data on the participants will be gathered from their GP records. These will include: height, weight, waist circumference, blood pressure, blood glucose.

In PRIDE 2 the following additional measurements will be taken from those selected to be part of this phase: variety of medication intake, sleep duration, ApneaHypopnea Index (AHI), cortisol, renal impairment stage, physical activity level, diabetic neuropathy stage, amount of dietary intake, past weight, past waist and neck circumference, past blood pressure, past albumin creatinine ratio, coping strategies level, depression and anxiety level, locus of control, impulsivity and cognitive function, readiness to change and the Functional Outcomes of Sleep Questionnaire (FOSQ) score.

In PRIDE 3 the main outcomes will be: patients current priorities in their lives, patients account of the impact of unemployment on selfmanagement, patients account of the impact of diagnosis on selfesteem, identity, candidacy, and stigma, patients perceptions of risk regarding the complications of type 2 diabetes, patients views and perspectives on sleep and patients views, understanding and perceptions of current service provision, including diabetes self management education, and preferences for future diabetes care.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/08/2013

Eligibility

Key inclusion criteria
1. Diabetes mellitus
2. Adults >18 years old
3. Men and women
4. Ability to give informed consent, and complete study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current or concomitant illness that would interfere with the individuals ability to perform the study or confound the study results.

For PRIDE 2 and 3, type 1 diabetes patients will be excluded.

Date of first enrolment
18/01/2012

Date of final enrolment
01/08/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B12 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) for Birmingham & Black Country - Theme 8 (UK)

Funder Name
ResMed (UK)

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2018	30/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes