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Norfolk Diabetes Prevention Study

Submission date
13/04/2016

Recruitment status
No longer recruiting

Registration date
14/04/2016

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a condition where the concentration of glucose (sugar) in the blood is high, which may over time increase the risk of heart disease and damage to the blood vessels, nerves, eyes and kidneys. There are two types of diabetes - type 1 (which usually develops before the age of 40) and type 2 (adult onset, which is usually diagnosed over the age of 40). There are now more than 3 million people with type 2 diabetes in the UK, and many people with this condition pass through a stage where their blood sugar levels are elevated, but not quite to the level that means they have diabetes. This stage is sometimes called 'pre diabetes', and the aim of this study is to see if the risk of progressing from 'pre diabetes' to full diabetes can be reduced.

Who can participate?
We plan to check about 10,000 people for 'pre diabetes' with a blood test, and to find about 950 people with pre diabetes and about 300 people who have diabetes without knowing it.

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group attend a single dietary and lifestyle education session which will last for 2 hours. Participants in the second group attend about 21 sessions over 4 years, including both education sessions and exercise classes. Participants in the third group attend the 21 sessions and also receive extra help and support from people with diabetes who have been trained to give diet and lifestyle advice. All participants provide blood samples to measure blood glucose levels at the start of the study and after 6, 12, 24, 36, 40 and 46 months. We also record the views of all participants on the value of this programme.

What are the possible benefits and risks of participating?
Detecting diabetes or ‘pre-diabetes’ in this way could offer some medical benefits as early detection allows early treatment and intervention. There are minimal risks associated with taking part in this study. Some people will be diagnosed with diabetes or ‘pre-diabetes’, which can be a shock, but the study team will be available to provide support and their GP will also be informed. There may be some discomfort from the needle prick when the blood samples are taken but this should ease almost immediately after the blood test. There may be a small bruise at the site of the needle prick but again this should fade quite quickly. Anyone who takes part in

physical exercise can be at risk of common injuries. This risk can be reduced by gradually building up your levels of activity their own pace and patients will be guided by qualified fitness facilitators.

Where is the study run from?
The project is being run from the Clinical Research and Trials Unit (CRTU) at the University of East Anglia (UEA) in Norwich, and is running at several sites NHS hospitals and general practices in the East of England.

When is the study starting and how long is it expected to run for?
April 2011 to April 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Mike Sampson

Study website
www.norfolkdiabetespreventionstudy.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Mike Sampson

Contact details
Norfolk and Norwich University Hospital
Norwich
United Kingdom
NR9 4HN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 13.0 2nd September 2014

Study information

Scientific Title

Delivering a realistic diabetes prevention programme in a UK community: the Norfolk Diabetes Prevention Study (Norfolk DPS)

Acronym
NorfolkDPS/NDPS

Study objectives
The primary hypothesis which this programme will test is that the novel diet and lifestyle intervention programme that we have developed will significantly reduce the risk of developing type 2 diabetes (T2DM) compared to standard care in participants with impaired fasting glucose (IFG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 1 RES, 13/01/2011, ref: 10/H0301/55

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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, non-diabetic hyperglycaemia, impaired glucose regulation (IGR)

Interventions
The study design involves an NHS primary care based screening programme to detect and screen 10,000 subjects at increased risk of Type 2 diabetes, with randomisation of 'pre diabetes' groups into three arms (3:7:7 ratio):
1. A control group
2. An intervention group
3. An intervention group supplemented with additional support from lay trainers

Subjects with screen-detected Type 2 diabetes are also randomised into these intervention groups. The programme is coordinated from CRTU@UEA Norwich and the Norfolk and Norwich

University Hospital, Norwich. Recruitment and intervention takes place at multiple sites across the East of England

Participants randomised into the intervention group(s) will initially attend 6 x 2 hour education session run by one Diabetes Prevention Faciliator (DPF). These 6 sessions are group sessions with randomised participants and will include:
1. An introduction to the programme, and to introduce the definitions of IFG and T2DM
2. The importance of diet and physical activity
3. Information session about exercise
4. Behavioural change
5. A review and evaluation of what participants have achieved, and whether their expectations have been met
6. How to plan to go forward after the programme ends
7. Explanation of future intervention sessions

Each education session will last 2 hours (12 hours total) and will take place every two weeks at the University of East Anglia (UEA) or at an alternative assessed site. After completing the education sessions, participants will attend up to 15 less intensive maintenance sessions which include exercise classes run by one DPF and one physiotherapist, over a follow-up period of up to 3.25 years. Each maintenance session will last for 2.5 hours and will take place every 8 weeks (total 37.5hrs) at the UEA or an alternative assessed site.

Staff called 'Diabetes Prevention Facilitators' (DPFs), will be recruited from multidisciplinary backgrounds to run the lifestyle part of the intervention and will work alongside specialised physical activity facilitators who will lead exercise sessions. More detailed information on the content of these sessions is given below, but overall we aim to encourage people to lose up to 7% of their body weight through a reduced fat intake and increased physical activity (largely walking).

A unique part of the Norfolk DPS will involve the recruiting and training of members of the public already diagnosed with T2DM to be lifestyle mentors, known as Diabetes Prevention Mentors (DPMs). In the intervention group with DPM, each participant also receives a 15-minute semi-structured telephone call from the DPM every 4 weeks during the education session phase (first twelve weeks of programme) and then every 8 weeks in between their maintenance and exercise sessions.

The control group will receive a single dietary and lifestyle education session which will last for 2 hours and which will take place at the UEA, NNUHFT or an alternative assessed site.

The participants in both intervention groups will have blood samples taken for FPG and HbA1c at: baseline (0) , 6, 12, 24, 36, 40 and exit (46 months). We will record the views of all participants in the Norfolk DPS using qualitative and quantitative methods on the value of this programme which will be used as part of the evaluation process.

Added 12/03/2021:
In the main trial programme we also undertake a smaller observational two - arm controlled trial (Control group vs Standard intervention group) in participants with non - diabetic hyperglycaemia [NDH; paired HbA1c≥42 to<48 mmol/mol] , and a normal fasting plasma glucose [<5.6 mmol/l]. The primary end point in this small observational trial is HbA1c at up to 40 month follow up as a measure of glycaemic control between groups, with the same secondary end points as in the main prevention trial. This small observational trial is not powered to detect differences in transition rates to T2DM, but is an observational study of effect size in this

understudied group, with 50 randomised to standard control group and 150 to standard intervention.

Intervention Type
Behavioural

Primary outcome measure
Project 2 (prediabetes study):
Progression to type 2 diabetes (T2DM), determined by fasting plasma glucose analysis and/or HbA1c analysis, at baseline, 4 months, 6 months, 12 months, 24 months, 36 months 40 months, 46 months (EXIT).

Project 4 (diabetes study):
Difference in mean HbA1c at timepoints and Quality and Outcomes Framework (QOF) scores for diabetes based on the diabetes QoF dataset. QOF – target is based on 7.5% (58mmol/mol and 10% (86mmol/mol) HbA1 thresholds – we describe % above and below these thresholds by arm.

Secondary outcome measures
The secondary outcome measures are measured at baseline, 4 months, 6 months, 12 months, 24 months, 36 months 40 months and 46 months:

Project 2 (prediabetes study):
1. Change from baseline in HOMA estimate of insulin sensitivity
2. Change from baseline in HOMA estimate of B-cell function
3. Change from baseline in physical activity (objectively measured by accelerometer)
4. Change from baseline in physical activity (self-reported short form IPAQ questionnaire)
5. Change from baseline in resistance activity (self reported study specific questionnaire)
6. Change from baseline in dietary behaviour (self-reported by DBQ study specific designed questionnaire) change from baseline in weight
7. Change from baseline in BMI
8. Change from baseline in waist circumference
9. Change from baseline in body fat %
10. Change from baseline in body fat (kg)
11. Change from baseline in visceral fat
12. Change from baseline in WBQ12
13. Change from baseline in ADDQoL
14. Composite score of changes in weight, BMI, waist circumference and exercise levels

Project 4 (diabetes study):
1. Change from baseline in HOMA estimate of insulin sensitivity
2. Change from baseline in HOMA estimate of B-cell function
3. Change from baseline in physical activity (objectively measured by accelerometer)
4. Change from baseline in physical activity (self-reported short form IPAQ questionnaire)
5. Change from baseline in resistance activity (self reported study specific questionnaire)
6. Change from baseline in dietary behaviour (self-reported by DBQ study specific designed questionnaire)
7. Change from baseline in weight
8. Change from baseline in BMI
9. Change from baseline in waist circumference,
10. Change from baseline in body fat %
11. Change from baseline in body fat (kg)

12. Change from baseline in visceral fat
13. Change from baseline in WBQ12
14. Change from baseline in ADDQoL
15. Change from baseline in EQ-5D
16. Change from baseline in DMSES
17. Change from baseline in DTSQs
18. Composite score of changes in weight, BMI, waist circumference and exercise levels

Overall study start date
01/04/2011

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Fasting plasma glucose 5.6 - 6.0 mmol/l AND HbA1c 42 - 47 inclusive on two occasions, OR fasting plasma glucose 6.1 - 6.9 inclusive on two occasions, both categories for the diabetes prevention project
2. Fasting plasma glucose > or = to 7.0 mmol/l on two occasions, OR HbA1c > or = to 48 mmol /mol on two occasions for the screen-detected Type 2 diabetes project
3. These criteria are gender independent, but main search criteria for subjects through primary care databases is 40 - 80 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000 in diabetes prevention project; 330 in screen detected Type 2 diabetes project

Total final enrolment
1330

Key exclusion criteria
1. Not able to provide GP details i.e. not registered with a GP or unwilling for their GP to be contacted
2. Unable to give informed consent due to lack of capacity through severe mental health, learning difficulties or significant cognitive impairment
3. Self-reported conditions which could adversely affect the trial results or patient clinical well being such as:
3.1. Terminal illness
3.2. Antipsychotic medication, which may affect glucose tolerance
3.3. High dose oral steroids (> 4 weeks or > 7.5 mg)

3.4. Active treatment for malignancy
3.5. Stage IV renal impairment or ongoing renal dialysis
3.6. Pregnant or lactating
3.7. Stage IV NYHA cardiac failure
4. Taking part in any research study which involves a dietary or lifestyle change intervention (exceptions are participants in observational research studies and EPIC*). Participation in other research studies will be assessed on an individual basis
5. Inability to attend or comply with the interventions or follow-up scheduling
6. Living with or related to someone in the programme team
7. GP advice on health grounds that the participant should not take part or be contacted

Date of first enrolment
01/04/2011

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital NHS Trust and University of East Anglia
Colney Lane
Norwich
United Kingdom
NR9 4HN

Study participating centre
Thetford Community Healthy Living Centre
Croxton Rd
Thetford
United Kingdom
IP24 1JD

Study participating centre
James Paget University Hospital
Lowestoft Rd
Gorleston-on-Sea, Great Yarmouth, Norfolk
United Kingdom
NR31 6LA

Study participating centre
Ipswich Hospital
Heath Rd
Ipswich, Suffolk
United Kingdom
IP4 5PD

Study participating centre
St James' Clinic Norfolk Community Healthcare Trust
Extons Road
King's Lynn, Norfolk
United Kingdom
PE30 5NU

Study participating centre
Rosedale Surgery
Ashburnham Way
Lowestoft
United Kingdom
NR33 8LG

Study participating centre
Colchester Medical Practice
52 Wimpole Road
Colchester, Essex
United Kingdom
CO1 2DL

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust (UK)

Sponsor details
Colney Lane
Norwich
England
United Kingdom

NR4 7UY
+44 (0)1603 286286
lisa.chalkley@nnuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
www.nnuh.nhs.uk/

ROR
https://ror.org/01wspv808

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
To be confirmed at a later date

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/01/2017		Yes	No
Results article	results	19/04/2018	17/04/2019	Yes	No
Results article	results	27/05/2019	03/02/2020	Yes	No
Results article	results	01/11/2019	03/02/2020	Yes	No
Results article	results	01/02/2021	03/11/2020	Yes	No
Results article		19/08/2021	19/05/2023	Yes	No
Statistical Analysis Plan		19/08/2021	19/05/2023	No	No