

Delivering the Diabetes Prevention Programme in a UK community setting: UEA-IFG Study

Submission date 24/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/02/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4832

Study information

Scientific Title

Delivering the Diabetes Prevention Programme in a UK community setting: UEA-IFG Study

Acronym

DRN135 (Diabetes Prevention Programme: UEA-IFG Study)

Study objectives

This two year feasibility programme will screen for participants at risk of diabetes (impaired fasting glucose). For those participants at risk of diabetes, the second stage of the programme will be to investigate whether a structured diet and lifestyle programme (called UEA-IFG) can be developed and whether the programme reduces the risk of Type 2 Diabetes Mellitus. The end stage would be to develop a full RCT to test the intervention programme fully.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 08/H0301/102)

Study design

Single centre randomised interventional prevention and screening trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2, Not Assigned; Disease: All Diseases, Prevention/screening

Interventions

Diabetes Prevention Programme: Lifestyle programme based on the U.S. Diabetes Prevention Programme. Participant targets will be to:

1. Lose 7% of body weight
2. Build up to 2.5 hours of brisk physical activity each week
3. Build up to walking at least 10,000 steps a day
4. Eat more healthily by eating less fat

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Transition to type 2 diabetes mellitus (fasting plasma glucose of 7.0 mmol/l or greater) after 17 months

Secondary outcome measures

Not provided at time of registration

Overall study start date

08/12/2008

Completion date

14/01/2010

Eligibility

Key inclusion criteria

1. Male or female
2. Aged 45 - 70 years
3. One of the following:
 - 3.1. First degree relative with type 2 diabetes
 - 3.2. Body mass index (BMI) greater than 25 kg/m²
 - 3.3. Waist circumference greater than 94 cm (male) or greater than 80 cm (female)
 - 3.4. History of gestational diabetes
 - 3.5. History of coronary heart disease

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 870; UK sample size: 870

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

08/12/2008

Date of final enrolment

14/01/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Colney Lane

Norwich

United Kingdom

NR4 7UY

Sponsor information**Organisation**

Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

Sponsor details

Colney Lane

Colney

Norwich

England

United Kingdom

NR4 7UY

Sponsor type

Hospital/treatment centre

Website

<http://www.nnuh.nhs.uk/>

ROR

<https://ror.org/01wspv808>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

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 article	results	01/05/2012	30/01/2020	Yes	No