ISRCTN66987085 https://doi.org/10.1186/ISRCTN66987085

Mechanisms of prevention of type 2 diabetes by lifestyle intervention in subjects with pre-diabetes or at high risk for progression

Submission date
20/03/2014

Recruitment status
No longer recruiting

Registration date
06/05/2014

Overall study status
Completed

Last Edited
11/04/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Despite scientific advances in the understanding of type 2 diabetes (T2DM), it remains a challenge to effectively identify and manage individuals in the general population who are at high risk of developing diabetes or those who already have undiagnosed diabetes. DEXLIFE (Diet, Exercise and Lifestyle) is an EU project that aims to identify biomarkers that better predict the development of type 2 diabetes.

Who can participate?
We propose to recruit 450 subjects at high risk of developing diabetes over the next 3 years and expect that 400 will complete the intervention.

What does the study involve?
Participants will be randomly allocated to the 3-month intervention or to a control group. The exercise intervention will involve 4 exercise sessions each week in Dublin City University (DCU) Sport. We will measure oral glucose tolerance, fitness, body fat, metabolic rate, and vascular health from each participant before and after the 3-month study. In addition, we will take a muscle biopsy and blood samples to identify biomarkers. Samples will be kept for a maximum of 15 years, and as new testing techniques and new relevant biomarkers are identified, they will also be tested for.

What are the possible benefits and risks of participating?
Possible benefits: Participants will undertake a lifestyle intervention or will get dietary and exercise advice (control group), which are associated with health benefits. It is expected that participation in the intervention group will lead to an increase in insulin sensitivity and an improvement in fitness. While the control group may not get this benefit during the 12-week study, we will offer them the same exercise programme and access to DCU Sport following the study.
Possible risks include:
Blood Draw: We will be taking blood samples for the determination of glucose tolerance and to identify biomarkers. The insertion and placement of the cannula should be minimally painful, a

slight ache may be felt and a bruise may appear on the arm. There is also a small risk of infection, but by using the appropriate techniques, this risk is minimal. Action: Only research personnel trained to take blood and insert cannulae will be allowed take the blood samples. In the event of a large hematoma or risk of infection, the study physician will see the participant as soon as possible.
VO2 peak test: The assessment of peak aerobic capacity (VO2max) is a key outcome determinant of the lifestyle intervention. A high aerobic capacity is associated with lower risk of diabetes and mortality but as a test of maximal effort, there are some risks. As subjects approach a maximal effort, they may experience episodes of transient light-headedness, chest discomfort, leg cramps, occasional irregular heartbeats, and abnormal blood pressure responses. The risk of a coronary event, although minor (approximately one occurrence per 15,000 tests), does exist. Action: We will be monitoring cardiac rhythm according to exercise testing guidelines and will have physician supervision of the exercise test. In the event of an incident, the study physician will stop the test and initiate appropriate medical management.
Exercise training: This may lead to muscle tightness, soreness, fatigue, and rarely a pulled muscle. Action: If a subject does develop an injury as a result of their participation in the exercise intervention they will be treated by the study physician who is also a sports medicine specialist. An on campus clinic (ExWell Medical) operated by the study physician has physiotherapists that will treat any injury. The exercise intervention will be modified according to recommendations.
Muscle biopsy: There will be some discomfort during the muscle biopsy procedure. Local anaesthesia will be administered to temporary numb the skin near the biopsy site. There is a risk of local bleeding and infection (< 1:200). By using appropriate techniques during these procedures the risks outlined above are minimised. We have conducted hundreds of biopsies in the last number of years and have a standard operating procedure to monitor the participants during and after this procedure. Action: Any adverse event will be monitored by the study physician and appropriately referred if required.
DEXA analysis: Dual Energy X-Ray Absorptiometry (DEXA) is a technique used to measure body fat. The body is scanned with a low dose of radiation. The radiation exposure from a whole body DEXA is approximately 1.0-3.6 µSv, in comparison to a standard chest X-ray of approximately 100 µSV. On an annual basis we are exposed to approximately 2400 µSv. Therefore, the DEXA is equivalent to no more than 1-3 days of background exposure. Action: The DEXA scans are 3-months apart, and while the radiation dose is very low we will exclude individuals who are pregnant or have any condition that might be affected by unnecessary radiation exposure.

Where is the study run from?
Dublin City University (Ireland)

When is the study starting and how long is it expected to run for?
September 2013 to June 2015

Who is funding the study?
European Union

Who is the main contact?
Dr Donal O'Gorman

Study website
http://Dexlife.eu

Contact information

Type(s)
Scientific

Contact name
Dr Donal O'Gorman

Contact details
Centre for Preventive Medicine
School of Health and Human Performance
Dublin City University
Glasnevin
Dublin
Ireland
9

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Grant agreement no: 279228

Study information

Scientific Title
Mechanisms of prevention of type 2 diabetes by lifestyle intervention in subjects with pre-diabetes or at high risk for progression: a two-armed randomized controlled trial

Acronym
DEXLIFE (Diet, Exercise and Lifestyle)

Study objectives
A 12-week partially supervised exercise training programme accompanied with individualised dietary advice will improve insulin sensitivity and assist with body fat reduction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dublin City University Research Ethics Committee, 08/06/2012, ref: DCUREC/2012/080

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Prediabetes

Interventions
Participants will be randomized into the following two groups (ratio 3:1):
1. Intervention arm: 12-week partially supervised exercise training programme accompanied with dietary advice
2. Control arm: lifestyle advice to increase daily physical activity and improve their diet

Intervention Type
Behavioural

Primary outcome measure
1. Transcriptomic, epigenetic, lipidomic and metabolic function by applying appropriate omics techniques in muscle and serum samples (at baseline, 3 months after baseline, and 9 months after baseline)
2. Insulin sensitivity by analysis of blood samples following intake of af glucose solution (plasma glucose and insulin from a 6-point oral glucose tolerance test) (at baseline and 3 months after baseline)
3. Fitness using the Vo2 Peak Test (at baseline and 3 months after baseline)
4. Adiposity (body composition by DEXA scanning and bio-impedance analysis, waist circumference, hip circumference, BMI) (at baseline and 3 months after baseline)

Secondary outcome measures
1. Fat distribution by assessment of subcutaneous and visceral fat through Ultrasonography (at baseline and 3 months after baseline)
2. Heart rate variability using the VAGUS apparatus (at baseline and 3 months after baseline)
3. Objectively measured physical activity by 7-day accelerometer assessment using ActiGraph (at baseline, 3 months after baseline, and 9 months after baseline)
4. Physical and mental health by questionnaires (SF-36, Benefits and Barriers Questionnaire, self-efficacy questionnaire) (at baseline, 3 months after baseline, and 9 months after baseline)
5. Dietary assessment (3-day semi-quantitative food diary) (at baseline and 3 months after baseline)
6. Pulse wave velocity using the SphygmoCor XCEL System (at baseline and 3 months after baseline) (in a subsample)

Overall study start date

21/09/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Male and female adults
2. Aged 18-65 years
3. Impaired fasting glucose (6.1-7.0 mmol/l) or impaired glucose tolerance (7.0-11.1 mmol/l after a 2-hr oral glucose tolerance test) OR normal glucose tolerance but a score >12 on the FINDRISC questionnaire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
400 (300 intervention, 100 control)

Total final enrolment
373

Key exclusion criteria
1. Individuals with diabetes, uncontrolled hypertension, cardiovascular disease, chronic lung disease, renal disease, active cancer, HIV infection, a seizure disorder or epilepsy, previous thyroid surgery or hyperthyroidism, chronic diarrhoea, being treated for obesity, chronic disabling conditions such as rheumatoid arthritis or Crohn's disease, or have had recent major surgery
2. Individuals who are pregnant or who are planning to become pregnant
3. Individuals with a peak aerobic capacity greater than 50 ml/kg/min
4. Individuals who have changed body weight >5% in the past month
5. Individuals who are found to have clinically significant abnormalities on routine lab testing
6. Individuals who have a positive response to the exercise stress test
7. Individuals who are unable to stay in the same geographic location for the duration of the study

Date of first enrolment

21/09/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin City University
Dublin
Ireland
9

Sponsor information

Organisation
Dublin City University (Ireland)

Sponsor details
Glasnevin
Dublin
Ireland
9

Sponsor type
University/education

ROR
https://ror.org/04a1a1e81

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)

EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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?
Other publications	study methods	01/11/2014		Yes	No
Protocol article	protocol	18/11/2015		Yes	No
Results article		08/04/2024	11/04/2024	Yes	No