ISRCTN38144270 https://doi.org/10.1186/ISRCTN38144270

Prevention of type 2 diabetes mellitus through educational intervention for adolescents at risk in high schools in Jordan

Submission date
06/07/2014

Recruitment status
No longer recruiting

Registration date
29/07/2014

Overall study status
Completed

Last Edited
30/07/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes (T2DM) happens when the body does not make enough insulin to work properly, or when the bodys cells dont react to the insulin properly (insulin resistance). It can cause serious long-term health problems such as blindness, kidney failure, leg amputations, heart disease and stroke. People are more likely to develop the disease if they are overweight or obese, do little exercise and eat an unhealthy diet. Eating healthily, losing weight (if overweight) and regular exercise can all help in controlling symptoms of T2DM and actually preventing the disease from developing. The purpose of this study was to measure the effect of a lifestyle education program designed to prevent T2DM on adolescents in Jordan in danger of developing the condition.

Who can participate?
Adolescents between 12-18 years of age that are visually overweight, not diagnosed with T2DM and have a normal fasting blood glucose level (a measure of how much sugar there is in the blood)

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group participate in a lifestyle education program. The program is designed to help participants make healthy diet choices and increase the amount of exercise that they do, supported by teaching them to believe that they are actively able to make these changes (though a technique called social cognitive theory self-efficacy). Parental and school staff support is provided. The program includes group education lessons and lifestyle advice. Information on the risks associated with T2DM and how to prevent the disease from developing are offered by each participants school. A 12 week individual guide on nutrition, physical exercise and healthy shopping is then provided together with information on social cognitive theory (self-efficacy). Each participant is then monitored and supported over the next three months though fortnightly meetings and by phone. Participants in the control group are offered education on diet and exercise, social

cognitive theory (self-efficacy) and provided with the written materials for a 12 week self-treatment course. At the end of the program, the weight of all participants and their fasting blood glucose levels are measured and compared to those before the trial.

What are the possible benefits and risks of participating?
Participation in the lifestyle program has the potential to alter peoples behaviors to prevent T2DM. There are no possible risks as the trial does not involve drugs or any invasive procedures.

Where is the study run from?
Al-Zaytoonah University of Jordan (Jordan)

When is the study starting and how long is it expected to run for?
October 2011 to October 2012

Who is funding the study?
Al-Zaytoonah University of Jordan (Jordan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of a 12-week early intervention for Jordanian adolescents at risk for Type 2 diabetes using lifestyle change and self efficacy: Randomized controlled trial

Study objectives
1. The reduction in weight in three months is significantly greater in the group receiving intervention.
2.The fasting blood glucose levels reduction is significantly greater in the intervention group in three months.
3. There will be significantly greater improvement in nutritional habits in the group receiving intervention in three months, considering the gender, genetic risk factors and parental educational level.
4. There will be significantly increased physical activity in the intervention group in three months, considering the gender, genetic risk factors and parental educational level.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Human Research Ethics Committees of the University of the Sunshine Coast, Aug. 2011 ref 3 /10/37101.
2. Jordanian Ministry of Education, Sept. 2011, ref. S/11/351 .

Study design
Single-blinded 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
Overweight or obese adolescents at high risk for type 2 diabetes mellitus

Interventions
Participants were randomly allocated into one of two groups.
1. Group A - intervention group
2. Group B - control group

The intervention was a program of lifestyle education to support participants to select a healthy diet and increase physical activity supported by social cognitive theory-self efficacy to reduce weight and fasting blood glucose with the aim of preventing type 2 diabetes mellitus (T2DM) in adolescents. This was achieved through self-care supported by parental supervision with school staff enabling the study. The key components were group information/education, lifestyle advice for improvement and strategies to achieve the desired outcome, provided at school meetings with Group A participants and their parents. Essential information was given at the participants schools on T2DM risks, outcomes andcomplications of developing T2DM and prevention using diet, exercise and self efficacy . Following this, an adapted 12-week individual guide on nutrition, physical activity and healthy shopping was provided together with an explanation of social cognitive theory (self-efficacy) to assist and support adherence with the program. The following three months included monitoring and assistance on demand for participants at fortnightly meetings or by phone. At the end of the intervention the weight and fasting blood glucose measures were repeated in the school environments for comparison. Following this, surveys were conducted to evaluate and analyse outcomes/changes.

Group B participants were told of the purpose of the intervention were offered education on diet and exercise, social cognitive theory (self-efficacy) to help in adherence, and provided with the written materials for a 12 weeks self-treatment guide

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Reducing the risk of developing T2DM by maintaining lifestyle changes is proposed to reduce youth T2DM development. Such a long-term result could not be measured in this time-limited study, but it provides a basis for future long-term intervention studies. The key question was: Will an educational intervention with follow-up support over 3 months reduce modifiable risk factors in lifestyle to prevent the development of T2DM in Jordanian adolescents? Factors considered and analysed included gender, diabetes mellitus family history and parental education levels.
Two primary outcome measures were identified and analyzed:
1. Weight
2. Fasting blood glucose (FBG)

Secondary outcome measures
1. Diet
2. Physical activity
All primary and secondary outcomes were measured at baseline and 12 weeks after (upon completion of the intervention).

Overall study start date
01/10/2011

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Consenting male and female adolescents 12-18 years
2. Visually overweight/obese
3. Not diagnosed with type 2 diabetes
4. Demonstrating normal fasting blood glucose (FBG) level of 60-125mg/dl

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
FBG that is more than 126 mg/dl or 6.99 mmol/l

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Jordan

Study participating centre
Al-Zaytoonah University of Jordan
Amman
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11733

Sponsor information

Organisation
Al -Zaytoonah University (Jordan)

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Sponsor type
University/education

ROR
https://ror.org/04a5b0p13

Funder(s)

Funder type
University/education

Funder Name
Al-Zaytoonah University of Jordan (Jordan)

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