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Determining the effects of football with a diet regimen on patients with type 1 diabetes

Submission date
07/01/2019

Recruitment status
No longer recruiting

Registration date
15/01/2019

Overall study status
Completed

Last Edited
14/09/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Previous studies have shown that physical activity does not improve the glycemic (blood sugar) control of type 1 diabetes mellitus (T1DM) patients in 12 weeks. The aim of this study is to identify the effects of football (soccer) combined with a diet regimen on the glycemic control, health-related fitness, and health-related quality of life of boys with T1DM.

Who can participate?
Patients aged 13-18 who have had diabetes for more than a year, who do not have a disease that will hinder their participation in the study, and who can come to the study location

What does the study involve?
Participants are randomly allocated into four groups: football with diet, football only, diet only, and the control group. The football groups participate in 1 hour 30 minutes of football practice, twice a week for 12 weeks. The diet groups are provided with diet recommendations. The control group receive no interventions (usual care only). Body mass index (BMI), cardiorespiratory fitness, muscular fitness, resting heart rate, blood pressure, blood lipids, fasting blood glucose, glycated hemoglobin (HbA1c), and health-related quality of life are measured at the start of the study and after the program.

What are the possible benefits and risks of participating?
Benefits include an improvement in glycemic control after 12 weeks, blood lipids, blood pressure, health-related fitness, and health-related quality of life. The risk involved is that the participants in the football groups may experience low blood sugar levels while sleeping.

Where is the study run from?
The football program will take place at King Fahd University of Petroleum & Minerals. The patients in the diet group follow their regimen from their homes.

When is the study starting and how long is it expected to run for?
July 2016 to April 2019

Who is funding the study?
King Fahd University of Petroleum & Minerals (Saudi Arabia)

Who is the main contact?
Dr Mohammed Hamdan Hashem Mohammed

Contact information

Type(s)
Scientific

Contact name
Dr Mohammed Hamdan Hashem Mohammed

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31261

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IN171042

Study information

Scientific Title
Effects of 12 weeks football with a diet regimen on glycemic control, selected health-related fitness parameters, and health-related quality of life of patients with type 1 diabetes: a randomized controlled trial

Study objectives
Football combined with a diet regimen is the most suitable method for good glycemic control after 12 weeks for patients with type 1 diabetes when compared to football or diet alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics committee: Deanship of Scientific Research, King Fahd University of Petroleum & Minerals, PO Box 5083, Dhahran - 31261, Tel: +966138603200, Email: src@kfupm.edu.sa, 15/04 /2018, ref: IN171042

Study design
Single-centre interventional randomised statistician-masked trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus

Interventions
Allocation: Simple randomization. The lab technicians and statistician will be blinded to group assignment.

Group 1: Football and diet regimen
Group 2: Football only
Group 3: Diet regimen only
Group 4: Regular care

Each football session will last 1 hour 30 minutes twice times a week for 12 weeks.

Expert dietitians will be consulted to provide a diet regimen for the intervention groups. The regimen will provide the necessary calories to reach and maintain the ideal body weight of the patients. The regimen will consider the cultural setting, food preferences, the weight of the patients, and their exercise and insulin dosage. The patients will be instructed to eat a fixed amount of calories daily for 12 weeks. A nutritionist specialized for patients with diabetes will provide information and training to the patients and their parents on how they should consume the amount of calories they need and how they record what they have eaten. The patients will submit weekly what they have consumed to the dietitians in order to check if they followed their recommendations.

The control group will receive no intervention (usual care only).

Body mass, body mass index (BMI), cardiorespiratory fitness, muscular fitness, resting heart rate, blood pressure, blood lipids, fasting blood glucose, HbA1c, and HRQoL will be measured at baseline and after the program. The HRQoL will be determined using The Pediatric Quality of Life Inventory (PedsQL™) with Diabetes Module 3.0. The primary outcome will be assessing glycemic control through changes in HbA1c after 12 weeks.

Intervention Type
Behavioural

Primary outcome measure
Glycemic control assessed through changes in glycated hemoglobin (HbA1c) at baseline and 12 weeks

Secondary outcome measures
Measured at baseline and 12 weeks:
1. Blood lipids and blood glucose measured by a lab test
2. Body mass index: mass and height measured with a mass scale and stadiometer, respectively
3. Cardiovascular fitness measured using the FitKids Treadmill Test
4. Muscular strength measured using standing long jump
5. Health-related quality of life measured using Arabic version of the PedsQL™ with the Diabetes Module 3.0

Overall study start date
01/07/2016

Completion date
15/04/2019

Eligibility

Key inclusion criteria
1. 12-18 years
2. Male
3. Diagnosed for diabetes for more than one year.
4. Should not have any medical condition that will hinder their participation in the study

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex

Male

Target number of participants
40

Key exclusion criteria
1. Has any medical condition that will hinder their participation in the study
2. Was diagnosed with diabetes less than a year ago
3. Those who cannot come to the study location

Date of first enrolment
16/01/2019

Date of final enrolment
17/01/2019

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Fahd University of Petroleum & Minerals
Dhahran
Saudi Arabia
31261

Sponsor information

Organisation
King Fahd University of Petroleum & Minerals

Sponsor details
Deanship of Scientific Research
Dhahran
Saudi Arabia
31261

Sponsor type
University/education

Website
http://www.kfupm.edu.sa/deanships/dsr/en/Pages/default.aspx

ROR

https://ror.org/03yez3163

Funder(s)

Funder type
University/education

Funder Name
King Fahd University of Petroleum and Minerals

Alternative Name(s)
, King Fahd University of Petroleum & Minerals, KFUPM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan, other) will be available upon request. Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
01/05/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mohammed Hamdan Hashem Mohammed. The data will be available after the first paper is published. The names of the participants shall be removed in order to hide their identities.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/03/2021	14/09/2023	Yes	No