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Health benefits of a COMmunity-based WALKing programme in Bahraini adults with type 2 diabetes

Submission date
14/06/2011

Recruitment status
No longer recruiting

Registration date
21/06/2011

Overall study status
Completed

Last Edited
22/05/2015

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 is a metabolic disease characterised by high blood sugar which over time may lead to complications which impair quality of life and reduce life expectancy. Despite its small size, the proportion of the population in Bahrain which is affected by type 2 diabetes is one of the highest in the world. The risk of developing this disease is increased if an individual is obese and/or physically inactive, and it is anticipated that cases of type 2 diabetes in Bahrain will continue to rise due to the high proportion of the population affected by these two conditions. High levels of physical activity such as walking are known to improve control of blood sugar and to reduce the risk of complications from types 2 diabetes. However, many diabetic patients are not active enough. Furthermore, there is still debate about the best approach to deliver or supervise walking programmes for these patients. The aim of this study is to test the procedures that will be used in a larger study to find out about the health benefits of a community-based walking programme for Bahraini adults with type 2 diabetes.

Who can participate?
Bahraini adults aged 24-60 with type 2 diabetes.

What does the study involve?
Participants will be randomly allocated to one of three treatments: standard diabetes treatment alone; standard diabetes treatment with physical activity education to promote walking; or standard treatment with physical activity education to promote walking and a step counter to record daily walking activity. Patients will have their blood glucose, physical activity level, fitness and body composition assessed at the start, middle (6 weeks) and end (12 weeks) of the study.

What are the possible benefits and risks of participating?
The investigators believe that the risks to the participants are minimal.

Where is the study run from?
Arabian Gulf University (Bahrain).

When is the study starting and how long is it expected to run for?
From January 2011 to February 2012.

Who is funding the study?
Arabian Gulf University and Ahlia University, Manama, Kingdom of Bahrain.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Efficacy of a COMmunity-based WALKing programme with or without a pedometer on markers of glucose control, cardio-respiratory fitness and lung inflammation in Bahraini adults with type 2 diabetes: a pilot randomised controlled trial

Acronym
COMWALK2

Study objectives
The aim of this pilot study is to test the robustness of the protocol and of the study methodologies prior to conducting the study on a larger group of patients. The main objectives of the pilot study are:
1. To test the integrity of the study protocol including inclusion/exclusion criteria, the randomisation process, storage and testing of equipment and materials, and training of staff in administration and assessment procedures.
2. To obtain initial data for the primary outcome measure haemoglobin A1c, in order to perform a sample size calculation for the main study.
3. To determine compliance with and acceptability of the exercise intervention by patients.
4. To test that the self-assessment questionnaires, information documents and consent forms are comprehensible and appropriate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Technical Support Team, Ministry of Health, Kingdom of Bahrain, 04/10/2010, ref: FA /SA/971/2010
2. Research & Ethics Committee, Arabian Gulf University, Kingdom of Bahrain, 16/02/2010

Primary study design
Interventional

Study design
Pilot randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Following baseline measurements, patients will be randomly assigned to one of three groups (n=15 each):
1. Standard diabetes treatment alone (i.e. control)
2. Standard treatment and two one-hour sessions of group-based physical activity education, each delivered at six week intervals, to promote walking
3. Standard treatment, a pedometer and two one-hour sessions of group-based physical activity education, each delivered at six week intervals, to promote steps-per-day goals.

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The numbers after the qualifications of each author refer to their home institution.
1= Arabian Gulf University
2= Ahlia University

Intervention Type
Behavioural

Primary outcome(s)
Change in haemoglobin A1c between baseline and the end of the 12-week programme

Key secondary outcome(s)
1. Pedometry (steps/day)
2. Physical activity level (International Physical Activity Questionnaire)
3. Fraction of nitric oxide in exhaled air (FeNO) to evalaute cardiorespiratory fitness
4. Body Mass Index
5. Percent body fat
6. Blood glucose
Assessed at baseline, 6 and 12 weeks

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Bahraini adults (aged 24-60 years) with type 2 diabetes (as defined by the American Diabetic Association, 1997) for more than 6 months
2. A baseline haemoglobin A1c of 6.6% to 9.9%.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Current insulin therapy
2. Participation in exercise two or more times per week for more than or equal to 20 minutes /session during the previous 6 months
3. Changes during the previous 2 months in oral hypoglycaemic, antihypertensive or lipid-lowering agents and body weight (more than or equal to 5%)
4. Serum creatinine level of 200 µmol/L or greater
5. Proteinuria greater than 1g/d
6. Blood pressure greater than 160/95 mm Hg
7. Restrictions in physical activity because of disease
8. Presence of other medical conditions that make participation inadvisable

Date of first enrolment
10/01/2011

Date of final enrolment

01/02/2012

Locations

Countries of recruitment
Bahrain

Study participating centre
Arabian Gulf University
Manama
Bahrain
22979

Sponsor information

Organisation
Arabian Gulf University (Bahrain)

Organisation
Ahlia University (Bahrain)

Organisation
Arabian Gulf University

ROR
https://ror.org/04gd4wn47

Funder(s)

Funder type
University/education

Funder Name
Arabian Gulf University (Bahrain) (research grant No. 72)

Funder Name

Ahlia University (Bahrain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration