Trial Review

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Trial registered on ANZCTR

Trial ID	ACTRN12617000421336
Ethics application status	Approved
Date submitted	20/02/2017
Date registered	11/04/2017
Date last updated	11/04/2017
Type of registration	Retrospectively registered

Titles & IDs

Public title	Aerobic versus resisted exercise training on glycated hemoglobin and blood glucose levels in prediabetic individuals
Scientific title	A comparison between aerobic versus resisted exercise training on glycated hemoglobin and blood glucose levels in prediabetic individuals
Secondary ID [1]	Nil known
Universal Trial Number (UTN)	U1111-1193-2658
Trial acronym	
Linked study record	

Health condition

Health condition(s) or problem(s) studied:

pre-diabetic individuals

Condition category	Condition code
Physical Medicine / Rehabilitation	Physiotherapy
Metabolic and Endocrine	Diabetes
Physical Medicine / Rehabilitation	Other physical medicine / rehabilitation

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	Subjects will be randomly assigned into three equal numbers (n=20) into one of the three groups: Aerobic exercise, Resistance training, Control group. The exercise programme will be determined in accordance with the ACSM guidelines (ACSM,2006). Parameters All the subjects in 3 groups will be recommended to follow a low caloric diets. Furthermore, subjects of the control group will be instructed to maintain their present lifestyle until the end of the project. Baseline biochemical tests will include glycated hemoglobin (HbA1c), fasting and post-prandial blood glucose (FBG)will be performed both before and after the intervention. • These tests will also be repeated by their physicians at 3-monthly visits. All of the subjects will repeatedly monitor their blood sugar tests using a glucometer. Their heart rate and blood pressure will be measured. Exercise training protocol The exercise sessions will be regularly held two or three times a week with the close supervision of the project staff and trainers. Moreover, the probability of hypoglycaemic episodes during the sessions will be monitored and blood pressure fluctuations will be assessed regularly. The subjects will be asked to

	have sweet eatable or drinkable things and not to use their lunches or medications just before the beginning of training. However, they could supply the water required by their bodies in the middle of the sessions. All types of exercise training were done according to the ACSM guidelines. All sessions will include 10-15 minutes of stretching and flexibility movements to warm up as well as 10-15 minutes of relaxation activities to cool down. Group A: Aerobic exercise programme Participants in group A will be submitted to a 40 min aerobic session on a treadmill. The initial 5-min warm-up phase will be performed on the treadmill at a low load. Each training session will last 30 min and end with a 5-min recovery and relaxation phase either walking or running, based on heart rate, until the target heart rate according to the American College of Sport Medicine guidelines will be reached. Participants will progress from 20 minutes per session at 60% of the maximum heart rate to 30 minutes per session at 75% of their maximum heart rate based on established protocols (Bweir et al.,2009). The programme will begin with 10 min of stretching exercises for the major muscles of the upper and lower limbs and will be conducted using the maximal heart rate index (HRmax) estimated by: 220-age. First 2 weeks =60–70% of HRmax, 3rd to 12th weeks= 70–80% of HRmax .(Abd El-Kader, 2011). Group B: Resistance training programme Patients in group B were submitted to a 40 min session of resistance training. The programme will begin with 10 min of stretching for the major muscles of the upper and lower limbs and then exercises on seven resistance machines will be conducted. The manual resistance machines that will be used are; shoulder press,bench press,seated bicep curl, triceps push down, lateral pull down, abdominals crunch, and leg extension. The protocol will start on 2 days of the week during the first month and will increase to 3 non-consecutive days per week. Training will start during weeks 1 and 2 with intensity 60% one-repetition maximum (1RM) and will progress to intensity 75% 1RM.The number of sets will be 1-2 during the first month. Participants will perform 3 sets of 8-10 repetitions (with a 90- 120 s rest between sets) for 40 minutes.(yavari et al.,2012).
Intervention code [1]	Prevention
Intervention code [2]	Rehabilitation
Comparator / control treatment	Control group C did not performed any type of exercises.
Control group	Placebo

Outcomes

Primary outcome [1]	Baseline biochemical tests including glycated hemoglobin, using Cobas Integra Tina-quant Hemoglobin A1c Gen.2 kit (Roche Diagnostics, GmbH, Sandhofer Strasse 116, D/68305 Mannheim, Germany.
Timepoint [1]	At baseline and after intervention
Secondary outcome [1]	Fasting and post-prandial glucose levels
Timepoint [1]	at baseline before and after the intervention

Eligibility

Key inclusion criteria	1- prediabetics 2- overweight, 3- an inactive previous lifestyle, A1c level < 6.4%.
Minimum age	25 Years
Maximum age	45 Years
Gender	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	BMI>40,Diabetes, recent blood loss, hemolytic anemia, or genetic differences in the hemoglobin molecule (hemoglobinopathy) such as sickle-cell disease and other conditions, as well as those that have donated blood recently, pregnant women, severe retinopathy, nephropathy and neuropathy, history of serious cerebrovascular or cardiovascular diseases, and severe musculoskeletal problems restricting physical activity.

Study design

Purpose of the study	Prevention
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	sealed opaque envelopes
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	Permuted block randomisation
Masking / blinding	Blinded (masking used)
Who is / are masked / blinded?	The people administering the treatment/s

	The people assessing the outcomes The people analysing the results/data
Intervention assignment	Parallel
Other design features	
Phase	Not Applicable
Type of endpoint(s)	Safety/efficacy
Statistical methods / analysis	Statistical analysis will be conducted using SPSS for windows, version 18 (SPSS, Inc., Chicago, IL). 3×2 mixed design MANOVA will be used to compare the tested variables of interest at different tested groups and measuring periods. With the initial alpha level set at 0.05. Prior to final analysis, data will be screened for normality assumption, homogeneity of variance, and presence of extreme scores. Descriptive analysis using histograms with the normal distribution curve will be used to ensure that the data will be normally distributed and not violates the parametric assumption for each of the measured dependent variables. Additionally, testing for the homogeneity of covariance will be implemented. The box and whiskers plots of each of the tested variables after removal of the outliers will be done. All these will allow the researchers to conduct parametric analysis. Power analysis will be performed from pervious reported data, based on an estimated 45% decrease in glucose levels after exercise exposure, with a power of 95%, type 1 error was set at 0.05, mean of 6.9 and 4 with a standard deviation of 2.7. The sample of each group was 20 subjects.

Recruitment

Recruitment status	Not yet recruiting

Date of first participant enrolment			
Anticipated	20/03/2017	**Actual**	

Date of last participant enrolment			
Anticipated	30/06/2017	**Actual**	

Date of last data collection			
Anticipated	30/06/2017	**Actual**	

Sample size			
Anticipated	60	**Actual**	

Recruitment outside Australia	
Country [1]	Egypt
State/province [1]	Cairo

Funding & Sponsors

Funding source category [1]	Self funded/Unfunded
Name [1]	Mary Kamal Nassif Takla
Address [1]	School of Physical therapy, Cairo university 7 Ahmed Elzaiat St. Ben Elsaryat - El Dokki-Giza - Egypt. 11432
Country [1]	Egypt
Primary sponsor type	University
Name	Cairo University
Address	School of Physical therapy, Cairo university 7 Ahmed Elzaiat St. Ben Elsaryat - El Dokki-Giza - Egypt. 11432
Country	Egypt
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	The Board Council of Higher Education of the School of Physical Therapy, Cairo university
Ethics committee address [1]	El-Tahrir st. - in front of Ben El- Sarayat Traffic - Dokki - Giza, Giza, 11432
Ethics committee country [1]	Egypt

Date submitted for ethics approval [1]	07/01/2017
Approval date [1]	14/01/2017
Ethics approval number [1]	
Ethics committee name [2]	Institutional Review Board of Higher Education and Research of Cairo University
Ethics committee address [2]	1 Cairo University Rd, Giza, Giza Governorate. 12613
Ethics committee country [2]	Egypt
Date submitted for ethics approval [2]	21/01/2017
Approval date [2]	28/01/2017
Ethics approval number [2]	

Summary

Brief summary	Background: Prediabetic individuals have higher blood glucose levels than normal people, but not yet high enough to be diagnosed as diabetes. Prior to the development to type 2 diabetes, they almost always have prediabetes. Purpose: The purpose of this study is to investigate and compare between aerobic and resisted exercises on glycated hemoglobin (HbA1c) and fasting and post-prandial blood glucose (FBG) in prediabetics. Subjects: Sixty subjects with HbA1C (5.7-6.4) , will be recruited from the local community via flyers and advertisements. Their age will range from 25-45years. Participants will be divided into 3 equal groups; Aerobic group (A), Resisted group (B) and Control group (C). Procedure: Group A will receive aerobic exercise with intensity 60-75% of maximum heart rate (MHR), for 30 -40 min. Group B will receive resisted exercise with moderate intensity 60-75% of 1 maximum repetition (1RM). Control group C will not receive any type of exercises. The exercises given to groups A,B will performed for 3 months, 3 times per week, day after day. Participants in all groups will be instructed to follow a low caloric diet during the duration of the study. HbA1c and FBG will be measured before and after 3 months of the treatment.
Trial website	
Trial related presentations / publications	
Public notes	

Contacts

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< BACK