Brief exercise for weight loss

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/03/2018		Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/04/2018	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
24/04/2019	Nutritional Metabolic Endocrine			

Plain English summary of protocol

Background and study aims

Over 70% of US population are overweight, and almost 40% are categorically obese based on body mass index (BMI). There are numerous programs, diets, and exercise regimes, but these are inadequate because obesity continues to rise. The purpose of this study is to determine if a unique 2-minute Energy-surge exercise routine (performed five times/day) is effective in reduced subjects' weight and girth sizes.

Who can participate?

Healthy adults aged 18-65 years who are obese (have a BMI of 30 or more).

What does the study involve?

Healthy obese subjects were randomly assigned to the Experimental or Control groups. Experimental group participants were taught how to make many movements such as riding a stationary bicycle or lifting dumbbells into an 'Aerobic-surge' exercise at or above 75% of calculated maximum heart rate. They were taught to perform these exercises for 2 minutes 5 times per day. Control subjects were simply told to exercise more. No dietary changes were made for either group.

What are the possible benefits and risks of participating?

The potential risks included joint injuries from exercise or falling and worsening of undiagnosed heart problems. The potential benefits included decreased weight and body size, improved appearance and self esteem, decreased hypertension and disease, and increased ability to perform activities of daily living.

Where is the study run from?

Participants were screened, trained and measured in Galveston, TX. They did the exercises at home.

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

Who is funding the study?

There is no external funding for the study.

Who is the main contact?

Dr FB Willis, DocWillis@yahoo.com

After being briefed on the study, Subjects: Fifty four adults were recruited for this study in Austin, Abilene, and Galveston Texas, USA. All subjects understood and completed written informed consent as required by the IRBs.

Subjects were then screened for exclusion criteria such as cardiovascular diseases and four subjects were withdrawn from the study. The remaining were were randomly categorized as Experimental (N=25 receiving treatment) or Control (N=25).

After being weighed, measurements of ten body circumferences were measured (neck, chest, waist hip, etc,). Experimental subjects were taught how to perform an "Aerobic-surge" exercise at 75% of their calculated maximum heart rate with different exercises (climbing stairs, stationary bicycle riding, etc.). They were instructed to perform this Aerobic-surge five times/day in this 60-day study.

Joint injuries from exercise or falling
Exacerbation of undiagnosed cardiac anomalies
4.2 Potential Benefits
Decreased weight and body mass
Increased appearance and self esteem
Decreased hypertension and disease
Increased activities of daily living

Contact information

Type(s)

Public

Contact name

Dr Dr FB WIllis, MBBS, PhD, FACSM

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Brief, aerobic-surge exercise for weight loss: a preliminary randomized, controlled trial

Study objectives

The purpose of this current study was to determine if a frequent, high intensity, 2-minute aerobic-surge exercise routine (5/day) was effective in reducing subjects' weight and girth sizes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

McMurry University IRB and Galveston Research IRB, 10/1/2016.

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Obesity

Interventions

The participants were randomly categorized as Experimental (N=25 receiving treatment) or Control (N=25). After being weighed, measurements of ten body circumferences were taken. Experimental subjects were taught how to perform an "Aerobic-surge" exercise at 75% of their calculated maximum heart rate with different exercises (including supine scissor kicks, running in place, stationary bicycling, jumping jacks, biceps curls, triceps extensions, medicine ball swings, climbing stairs, etc). They were instructed to perform this Aerobic-surge for 2 minutes five times /day in this 60-day study. (The goal for Energy-surge was 5/day but 4/day completion was expected.)

Intervention Type

Behavioural

Primary outcome measure

Changes in weight and body circumferences (neck, shoulders, chest, upper arm, lower arm, wrist, waist, hips, upper thigh, above knee, calf, ankle). The weight and body circumferences were measured at enrollment and after 60 days (+/-5 days) by the same research assistant under the supervision of the principal investigator.

Secondary outcome measures

Compliance assessed by weekly communication with participants and measured as the proportion who completed the exercises at least 4 times per day.

Overall study start date

01/08/2015

Completion date

01/05/2017

Eligibility

Key inclusion criteria

- 1. BMI >30 kg/m2
- 2. Aged 18-65 years

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

- 1. Cerebrovascular accident or traumatic brain injury
- 2. Cardiovascular pathologies, including uncontrollable hypertension, atrial fibrillation and history of myocardial infarction
- 3. Rheumatoid arthritis
- 4. Pregnancy
- 5. Hypothyroid secretion
- 6. Hypogonadal syndrome
- 7. Diabetes mellitus (type 1 or 2)
- 8. Other weight loss protocols, diets, or medication

Date of first enrolment 15/01/2016

Date of final enrolment 15/06/2016

Locations

Countries of recruitment United States of America

Study participating centre Galveston Clinical Research 6341 Stewart RD #115 Galveston United States of America 77551

Sponsor information

Organisation

None

Sponsor details

NA NA United States of America NA

Sponsor type

Not defined

Funder(s)

Funder type

Not defined

Funder Name

NONE

Results and Publications

Publication and dissemination plan

Preparing for submission to "BMC Sports Science, Medicine and Rehabilitation"

Intention to publish date

20/06/2018

Individual participant data (IPD) sharing plan

As of 09/04/2018)

Patient files were lost in the Hurricane Harvey floods but data sets may be acquired by contacting Dr Willis directly for the next 7 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No
Participant information sheet		09/04/2018	17/04/2018	No	Yes