Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of administrated placebo on physical fitness in adolescents with normal weight.

Protocol summary

Study aim

1- To determine the efficacy of administered placebo in enhancing the physical fitness in adolescents. 2- To check the relationship between administered placebo and motivation level in adolescents.

Design

RCT

Settings and conduct

Schools of Islamabad/ Rawalpindi.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Healthy Adolescents of Rawalpindi/Islamabad. Age: 10-19 (According to WHO) both genders, after taking written consent of participants from their parents/ guardians. Exclusion Criteria Diagnosed cases of acute or chronic diseases Adolescent with any deformity or Psychological illness Family history of sudden cardiac death, comorbidities (Asthma and Diabetes) History of exercise associated with dizziness, pre-syncope or collapse Refusal of giving informed consent

Intervention groups

1- Control group 2- Experimental group Control group: Control group adolescents will be pre-tested on four fitness tests (sit & reach test, reduced cooper test, broad jump and 20 meter running) and motivation level using Physical activity and leisure motivation scale PALMS by the first investigator. Then there would be a break of 30 minutes in which they will only receive water. After that, all the participants will be Post- tested on the basis of same fitness tests and motivation scale as mentioned above. Experimental group: In this group adolescents will be pre-tested on the same fitness tests and motivation as mentioned above. Then in the break these adolescents will be given placebo drink (included water + red food color) along with leaflet (statement written reinforcing the effect of placebo drink), and will be post tested by using same tests as mentioned in control group.

Main outcome variables

Distance Time Exertion Motivation Pulse rate

General information

Reason for update

Acronym

PPA(Placebo on Physical fitness in Adolescents)

IRCT registration information

IRCT registration number: **IRCT20210524051380N1**
Registration date: **2021-07-03, 1400/04/12**
Registration timing: **retrospective**

Last update: **2021-07-03, 1400/04/12**
Update count: **0**

Registration date

2021-07-03, 1400/04/12

Registrant information

Name

Naima Farooq

Name of organization / entity

Shifa Tameer-e- Millat University

Country

Pakistan

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Email address

naima_dpt.ahs@stmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-15, 1400/01/26

Expected recruitment end date

2021-05-15, 1400/02/25

Actual recruitment start date

2021-04-15, 1400/01/26

Actual recruitment end date

2021-05-15, 1400/02/25

Trial completion date

2021-05-15, 1400/02/25

Scientific title

Effects of administrated placebo on physical fitness in adolescents with normal weight.

Public title

Effects of administrated placebo on physical fitness in adolescents with normal weight.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

 Healthy Adolescents of Rawalpindi/Islamabad. Age: 10-19 (According to WHO) both genders, after taking written consent of participants from their parents/ guardians.

Exclusion criteria:

 Diagnosed cases of acute or chronic diseases Adolescent with any deformity or Psychological illness Family history of sudden cardiac death, comorbidities (Asthma and Diabetes) History of exercise associated with dizziness, pre-syncope or collapse Refusal of giving informed consent

Age

From **10 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **111**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method was used, the participants were assigned in control and experimental group through sealed enveloped method. Procedure of Randomization: No: of Participants=60 Material used: - 60 Envelops - 60 Sheets of properly cut Aluminum paper double the size of the paper. - 60 Sheets of Carbon paper, cut in to appropriate size according to the paper used. Procedure: Step I - A standard sized square paper was taken in which group "A" was marked. In this way 30 papers were prepared marked with "A" and 30 squared shaped paper marked with "B". Step II The sheet of paper on which either A or B was marked were folded to fit the envelop. Step III A sheet of Carbon paper was placed on the top of the folded paper (marked either A or B) facing the envelop. Step IV Then the sheet of Aluminum foil was wrapped on the carbon paper (with folded paper inside). Step V All the above prepared were placed in the envelop (which was completely opaque), the enveloped was then sealed. Step VI In this way 30 envelops of "A" and 30 envelops of "B" were prepared. with a total number of 60 envelops. Step VII - These 60 envelops were then thoroughly shuffled like deck of cards. - The envelopes were then marked with number 1-60. Each participants picked the envelop in order from 1-60 and was given placebo (water or drink) accordingly.

Blinding (investigator's opinion)

Double blinded

Blinding description

The second investigator was blinded to avoid biasness and water was given to control group and placebo to the experimental group by first investigator.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board & Research Committee (IRB&EC) Shifa International Hospital and Shifa Tam

Street address

Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University

City

Islamabad

Postal code

44000

Approval date

2021-04-09, 1400/01/20

Ethics committee reference number

IRB # 066-21

2

Ethics committee

Name of ethics committee

Institutional Review Board & Research Committee (IRB&EC) Shifa International Hospital and Shifa Tam

Street address

Department of Rehabilitation Sciences, Dar ul Shifa Campus, Shifa Tameer e Millat University

City

ISLAMABAD

Postal code

44000

Approval date

2021-04-09, 1400/01/20

Ethics committee reference number

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Health conditions studied

1

Description of health condition studied
Physical Fittness and Motivation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
To determine pre and post heart rate and level of exertion of placebo in normal weight adolescents between and within the groups
Timepoint
30 minute interval between pre and post measurements
Method of measurement
Rate of Perceived Exertion Scale (RPE), Digital Pulse oximetry

2

Description
To determine pre and post physical fitness between and within the groups
Timepoint
30 minute interval between pre and post measurements
Method of measurement
Physical activity questionnaire for adolescents and children (PAQ-A & PAQ-C), Standing broad Jump test, Sit and reach test, Running 20m, Reduced cooper test

3

Description
To compare pre and post motivation of normal weight adolescents.
Timepoint
30 minute interval between pre and post measurements
Method of measurement
Physical Activity and Leisure Motivation Scale (PALMS)

Secondary outcomes

1

Description
To determine the physical activity of normal weight adolescents.
Timepoint
no interval
Method of measurement
Physical Activity Questionnaire for Adolescent (PAQ-A), Physical Activity Questionnaire for Children (PAQ-C)

Intervention groups

1

Description
Intervention group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Decent Public School
Full name of responsible person
Muhammad Azam
Street address
Azam Plaza , Street #9, Gulzar e Madina Road, H-13, Islamabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Naima Farooq
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Nil
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shifa Tameer-e-Millat Univeraity, Islamabad, Pakistan

Full name of responsible person
Naima Farooq

Position
Senior Lecturer

Latest degree
Master

Other areas of specialty/work
Rehabilitation management

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to ethical considerations

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available