

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Phone

+92 51 8441751

##### 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 envelops 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**  
IRB # 066-21

**Health conditions studied**

## 1

### Description of health condition studied

Physical Fitness 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

##### City

Islamabad

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##### Phone

+92 51 8841752

##### Email

naima\_dpt.ahs@stmu.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shifa Tameer e Millat University

##### Full name of responsible person

Naima Farooq

##### Street address

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

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##### Phone

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hanfar144@gmail.com

#### 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 University, 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 scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shifa Tameer e Millat University

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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