

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The effect of backpack carriage in different weights and gradients on kinetics and kinematics of schoolchildren's gait

#### Protocol summary

##### Study aim

Evaluating the effects of backpack carriage in different weights (10 and 15% of BW) and gradients (+15% and -15%) on the kinetics and kinematics of schoolchildren's gait compared to the control level walking

##### Design

Within group comparison of eleven times randomized (repeated) measuring for each participant with applying independent variables, Single blind

##### Settings and conduct

Location:Tehran city, sport science laboratory of payame-noor university, Tehran branch. Method: Each participant in one day, walks on Gaitway treadmill, while carrying backpack in tow different weights. The surface of treadmill will randomly change to get to the target slopes. At the end of each trial, then, the data recording will be done. All randomized measurements (11 trials) will save with a code then later calculations and analysis will be done. After calculations and at the time of data entering into the SPSS, trials will be arranged according to the primary list. Thus researcher and measurer don't know how the measurements arrangement are, and each file of data is related to which trial, till the end of process.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. male gender (boys living in Tehran), 2. ages between 10-12 years, 3. informed consent, 4.right dominant hand and foot; Exclusion criteria: 1. current pain, disease and taking drug, 2. any history of injuries for recent 6 month, 3. any history of surgery, 4. obvious postural abnormality, 5. flat foot, 6. vision and hearing impairment

##### Intervention groups

Intervention groups: Backpack in two weights, gradient in four levels Control group: Level surface

##### Main outcome variables

Vertical ground reaction force parameters including the peaks and loading rate, push off rate, time to peak, etc.; kinematical parameters of gait including stride length,

step width, double support time, cadence, swing phase time, etc.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180614040101N1**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **retrospective**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

##### Registration date

2018-10-31, 1397/08/09

##### Registrant information

##### Name

Fateme Ahmadi Godini

##### Name of organization / entity

Kharazmi

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8001

##### Email address

std\_ahmadi.ths@khu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-08, 1397/05/17

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of backpack carriage in different weights and gradients on kinetics and kinematics of schoolchildren's gait

**Public title**  
Evaluating the effect of backpack carriage on schoolchildren's gait in different gradients

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
male gender (boys living in Tehran) ages between 10-12 years informed consent right dominant hand and foot  
**Exclusion criteria:**  
current pain, disease and taking drug any history of injuries for recent 6 month any history of surgery obvious postural abnormality, flat foot vision and hearing impairment

**Age**  
From **10 years** old to **12 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **19**  
More than 1 sample in each individual  
Number of samples in each individual: **11**  
1. no load, no slope 2. 10% load, no slope 3. 15% load, no slope 4. 10% load, +10% slope 5. 10% load, -10% slope 6.10% load, +15% slope 7.10% load, -15% slope 8. 15% load, +10% slope 9.15% load, -10% slope 10.15% load, +15% slope 11. 15% load, -15% slope

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Each participant is given a code, and all repetitions of measurement are run randomly, but the number is issued by the technician of the device, respectively. Therefore, the researcher and evaluator until the end of the analysis process in SPSS is unaware from the nature of the data and their relationship to the repetition.

**Placebo**  
Not used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

•Ethics committee of Tarbiat Modares University of Medical Sciences

##### Street address

Jalal AleAhmad, Nasr, Tarbiat Modares University

##### City

Tehran

##### Province

Tehran

##### Postal code

14115-111

#### Approval date

2018-07-21, 1397/04/30

#### Ethics committee reference number

IR.MODARES.REC.1397.045

## Health conditions studied

### 1

#### Description of health condition studied

Backpack, gait, kinetics, kinematics, slope, schoolchildren

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Vertical ground reaction force

#### Timepoint

one time, while applying independent variable

#### Method of measurement

H/P/Cosmos Gaitway

### 2

#### Description

Spatiotemporal parameters of gait

#### Timepoint

one time, while applying independent variable

#### Method of measurement

H/P/Cosmos Gaitway

## Secondary outcomes

empty

## Intervention groups

## 1

### **Description**

Control group1: walking no load on level surface

### **Category**

Prevention

## 2

### **Description**

Control group2: walking while carrying a backpack with 10% of body weight load on the level surface.

### **Category**

Prevention

## 3

### **Description**

Control group3: walking while carrying a backpack with 15% of body weight load on the level surface.

### **Category**

Prevention

## 4

### **Description**

Intervention group1: walking while carrying a backpack with 10% of body weight load on 10% sloped surface.

### **Category**

Prevention

## 5

### **Description**

Intervention group2: walking while carrying a backpack with 15% of body weight load on 10% sloped surface.

### **Category**

Prevention

## 6

### **Description**

Intervention group3: walking while carrying a backpack with 10% of body weight load on 10% negative sloped surface.

### **Category**

Prevention

## 7

### **Description**

Intervention group4: walking while carrying a backpack with 15% of body weight load on 10% negative sloped surface.

### **Category**

Prevention

## 8

### **Description**

Intervention group5: walking while carrying a backpack with 10% of body weight load on 15% sloped surface.

### **Category**

Prevention

## 9

### **Description**

Intervention group6: walking while carrying a backpack with 15% of body weight load on 15% sloped surface

### **Category**

Prevention

## 10

### **Description**

Intervention group7: walking while carrying a backpack with 10% of body weight load on 15% negative sloped surface.

### **Category**

Prevention

## 11

### **Description**

Intervention group8: walking while carrying a backpack with 15% of body weight load on 15% negative sloped surface.

### **Category**

Prevention

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Payam-e noor university

##### **Full name of responsible person**

Sport science lab technician

##### **Street address**

Nejatollahi

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1598686613

##### **Phone**

+98 21 8891 0055

##### **Email**

mahdieh.koosha2014@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kharazmi university

##### **Full name of responsible person**

Ali Abbasi

##### **Street address**

Mirdamad, Hesari

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##### **Province**

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4398-15875  
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abbasi@khu.ac.ir  
**Web page address**  
https://pess.khu.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Kharazmi university  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**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**  
Kharazmi university  
**Full name of responsible person**  
Fateme Ahmadi Godini  
**Position**  
MSc student  
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Bachelor  
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Sport biomechanics  
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## Person responsible for scientific inquiries

**Contact**  
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Mehdi Khaleghi Tazeji  
**Position**

Assistant professor  
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## Person responsible for updating data

**Contact**  
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**Latest degree**  
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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**  
There is no need to publish IPD in this study.  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable

**Title and more details about the data/document**

The mean and standard deviation of demographic information, and all data will publish as thesis and original article. There is no need to publish more than these.

**When the data will become available and for how long**

After defense of the thesis and publishing its article; December may be.

**To whom data/document is available**

It will be free after publishing the thesis and article.

**Under which criteria data/document could be used**

After publish, it will be free with referencing.

**From where data/document is obtainable**

Kharazmi university to achieve and reading full text of the thesis, and after publishing the article, by searching in related scientific databases.

**What processes are involved for a request to access data/document**

There is no other kind of request to achieve more information.

**Comments**