Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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Nejatollahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi university
Full name of responsible person
Ali Abbasi
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Mirdamad, Hesari
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Tehran

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Email
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
Latest degree
Bachelor
Other areas of specialty/work
Sport biomechanics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Mehdi Khaleghi Tazeji
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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
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 lore 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