Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Single-Task and Dual-Task Training on Gait and Quality of Life in People with Unilateral Transtibial Amputation: A Randomized Control Trial; RCT

Protocol summary

Study aim
To compare the effect of single and dual task exercises on the kinetic and kinematic characteristics of walking, postural control and quality of life in people with unilateral transtibial amputation

Design
A clinical trial with a control group and two experimental groups, designed as a randomized parallel-group study, conducted on 45 individuals with unilateral transtibial amputation.

Settings and conduct
Participants with unilateral transtibial amputation who will refer to the Red Crescent Orthotics and Prosthetics Clinic in Tehran, after eligibility confirmation and informed consent, will be randomly assigned to three groups: single-task, dual-task, and control. The 8-week intervention will be conducted in the training hall and biomechanics lab of the Faculty of Sport Sciences, Shahid Beheshti University.

Participants/Inclusion and exclusion criteria
Inclusion: Unilateral below-knee amputation, age between 18 to 50 years, body mass index between 22 to 29 kilograms per square meter, continuous use of prosthesis for at least one year, ability to walk at least ten meters without assistance, Montreal Cognitive Assessment (MoCA) score greater than twenty-one, functional level K2 Exclusion: Any medical or orthopedic condition affecting gait, neurological or cognitive disorders, recurrent pain or ulcer in the stump area

Intervention groups
The intervention will be conducted for 8 weeks,3 sessions per week(each 60 minutes). Single-task group: Strengthening exercises for the hip and thigh muscles,balance,walking and stretching exercises will be performed. Dual-task group:The same exercises along with simple cognitive tasks such as mental calculation and answering questions will be performed. Control group:No intervention will be provided.

Main outcome variables
gait speed,stride length,Hip range of motion,Knee joint range of motion,postural control,quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240703062314N1**
Registration date: **2025-10-11, 1404/07/19**
Registration timing: **prospective**

Last update: **2025-10-11, 1404/07/19**
Update count: **0**

Registration date
2025-10-11, 1404/07/19

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Single-Task and Dual-Task Training on Gait and Quality of Life in People with Unilateral Transtibial Amputation: A Randomized Control Trial; RCT

Public title
Comparison of two types of exercise on walking, balance, and quality of life in people with below-knee amputation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral transtibial amputation Age between 18 and 50 years Body mass index between 22 and 29 kilograms per square meter Continuous use of prosthesis for at least one year Ability to walk at least ten meters without assistance Montreal Cognitive Assessment score greater than twenty-one K-level 2 functional level
Exclusion criteria:
Presence of any medical or orthopedic condition affecting gait Presence of neurological or cognitive disorders Recurrent pain or ulcer at the stump area
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be performed using SPSS software. The steps are planned as follows: 1- First, a random variable will be created using the Transform > Compute Variable tool. This variable will be defined with the formula TRUNC(RV.UNIFORM(0,1) * 3) + 1, which randomly assigns individuals to one of three groups (1, 2, or 3). 2- The data will be sorted based on this variable using the Data > Sort Cases tool. 3- Finally, participants will be randomly divided into three groups: the control group (number 1) and two experimental groups (numbers 2 and 3). This method represents a simple and transparent randomization process that will be applied in the future for the execution of the study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University
Street address
Shahid Shahriari Sq., Evin District, Tehran
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Tehran
Province
Tehran
Postal code
1983969411
Approval date
2023-12-23, 1402/10/02
Ethics committee reference number
IR.SBU.REC.1402.172

Health conditions studied

1

Description of health condition studied
Unilateral Transtibial Amputation
ICD-10 code
S88
ICD-10 code description
Traumatic amputation of lower leg

Primary outcomes

1

Description
gait speed
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.
Method of measurement
Motion Analysis (Vicon), VERO v2.2 model, made in England

2

Description
stride length
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.

Method of measurement
Motion Analysis (Vicon), VERO v2.2 model, made in England

3

Description
Hip range of motion
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.
Method of measurement
Motion Analysis (Vicon), VERO v2.2 model, made in England

4

Description
Knee joint range of motion
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.
Method of measurement
Motion Analysis (Vicon), VERO v2.2 model, made in England

5

Description
postural control
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.
Method of measurement
Force plate (Kistler) model 9260AA made in Switzerland

6

Description
quality of life
Timepoint
Outcome measurement was performed at two time points: once one week before the intervention and once one week after completion of the eight-week intervention period.
Method of measurement
World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Single-task Exercises, Participants in the first intervention group followed a single-task exercise program. These exercises included balance movements, lower-limb resistance exercises (such as half squats, modified lunges, and leg raises), and stretching exercises, all performed without any accompanying cognitive task. The program was carried out over 8 weeks, three sessions per week, with each session lasting 60 minutes (10 minutes warm-up, 40 minutes main exercises, and 10 minutes cool-down). The exercises were conducted in the rehabilitation hall using simple equipment such as exercise mats, resistance bands, and chairs, under the supervision of the researcher.
Category
Rehabilitation

2

Description
Intervention Group 2: Dual-task Exercises, Participants in this group, in addition to performing the same motor exercises as Group 1 (balance, resistance, and stretching exercises), simultaneously carried out a simple cognitive task such as backward counting or reciting predetermined words. The aim was to examine the combined effect of physical and cognitive exercises on balance and gait. The program lasted 8 weeks, with three sessions per week, and each session was 60 minutes long (10 minutes warm-up, 40 minutes main exercises integrating motor and cognitive tasks, and 10 minutes cool-down). The exercises were performed in the rehabilitation hall using simple equipment such as exercise mats, resistance bands, and chairs, under the supervision of the researcher.
Category
Rehabilitation

3

Description
Control group: The control group did not receive any intervention (in this study, it means cognitive and motor exercises).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Red Crescent Comprehensive Rehabilitation Center
Full name of responsible person
Masoumeh Madahi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Shahid Beheshti
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available