Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

To compare the effects of exergame and exercises with exercises only on functional activities in newly fitted patients with unilateral trans tibial amputation

Protocol summary

Study aim
The aim of this study is to clarify the effects of adding exergame to conventional exercise program on functional activities in newly-fitted patients with unilateral trans-tibial amputation.

Design
22 patients were divided into two parallel groups using simple randomization (11 in each group). C represent the control group and EG represent the Exergame group. 22 cards with numbers were collected inside a plastic container. Number one represent the exergame group and number two represent the control group. The Assessor was blinded to the type of the group.

Settings and conduct
The patients were recruited after they received their prostheses and finished their primary fitting. The assessor applied the outcome measures before the intervention and then the patients were randomly divided into group EG or C as follows: group EG) Exergame and exercise, group C) only exercise.

Participants/Inclusion and exclusion criteria
Inclusion criteria Newly fitted patients with unilateral Trans-tibial amputation; Age ranging from 30 to 65 years; Be cognitively able to engage in the program; Participants should not have any medical conditions (e.g., Congestive heart failure, Neurological disorder) that limit exercise participation; Participants should not have any prosthetic fit issues (e. g, pain, and discomfort) as indicated by scores <6 on the Prosthetic Socket Fit Comfort Scale. Exclusion criteria: Unable to give informed consent; Previous experience using the XBOX Kinect™; Major cardiopulmonary problems.

Intervention groups
The patients were randomly divided into two groups: Exergame group: which received exercises and exergame, 3 sessions per week for four weeks. Control group: which received only exercises, 3 sessions per week for four weeks.

Main outcome variables
Distance of walking. Speed of movement. Functional activities. Energy expenditure.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220715055472N1**
Registration date: **2022-07-18, 1401/04/27**
Registration timing: **retrospective**

Last update: **2022-07-18, 1401/04/27**
Update count: **0**

Registration date
2022-07-18, 1401/04/27

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-01, 1400/07/09

Expected recruitment end date
2022-05-30, 1401/03/09

Actual recruitment start date

2021-10-01, 1400/07/09

Actual recruitment end date

2022-05-30, 1401/03/09

Trial completion date

2022-05-30, 1401/03/09

Scientific title

To compare the effects of exergame and exercises with exercises only on functional activities in newly fitted patients with unilateral trans tibial amputation

Public title

To compare the effects of exergame and exercises with exercises only on functional activities in newly fitted patients with unilateral trans tibial amputation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newly fitted patients with unilateral Trans-tibial amputation Age ranged from 30 to 65 years Be cognitively able to engage in the program (receive a score on the Arabic version of the Modified Mini-Mental Status Exam score of >23) Participants should not have any medical conditions (e.g., Congestive heart failure, Neurological disorder) that limit exercise participation.

Exclusion criteria:

Unable to give informed consent Previous experience of using the XBOX Kinect™ Major cardiopulmonary problems.

Age

From **30 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **22**

Actual sample size reached: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization in which 22 cards collected inside a plastic container. card with number one represent experimental group and card number two represent control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor was blinded to the type of group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran University of Medical Sciences

Street address

Central building, Ghods street, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

13

Approval date

2021-09-26, 1400/07/04

Ethics committee reference number

IR.TUMS.FNM.REC.1400.120

Health conditions studied

1

Description of health condition studied

Exergame and exercises for patients with trans tibial amputation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Distance of walking: 2MWT was administered to check the distance of walking in the meter before and after the intervention. The test was implemented on a walking path that is free from obstacles (including other people) and 50 feet in length as available. The measuring wheel was used to measure the exact distance be covered by the patient during the test. The physiotherapist holds the walking wheel and walk behind the patient to calculate the distance. The patient walked for 2 minutes and the distance was calculated automatically by measuring the wheel. The assistive device could be used and was documented from test to test. The time starts upon “Go” and stop timing at 2 minutes. The patient will be instructed as follows “Cover as much ground as possible over 2 minutes. Walk continuously if possible, but do not be concerned if you need to slow down or stop to rest. The goal is to feel at the end of the test that more ground could not have been covered in the 2 minutes.” There are different pathways that can be used in the 2MWT. in this study, “Out and Back” pathway was chosen.

Timepoint

At baseline, after two weeks and after four weeks of the intervention

Method of measurement

2 Minutes Walking test (2MWT)

2

Description

The speed of walking: The TUG test was used to assess the speed of walking before and after the intervention. Measuring tape, chair with armrest, tape to mark the ground, and stopwatch was used in this test. A 3-meter (or 9 ft, 10 in) walkway was measured by the measuring tape. On one end, a chair was placed facing down the walkway with the front legs as the start point of the 3-meter distance. On the other end, a piece of tape (or cone) was placed to serve as a marker. The patient sat on a chair with their back against the back rest preparing for the test. The patient was instructed as following; "When I say 'go', stand up and walk to the marker in front of you. Turn around once you get to the marker and return to your chair and sit. Make sure that you walk quickly, but safely." the time that was required by the patient to complete the test, was measured. The stopwatch starts by saying, "Go" and stopped once the patient's bottom contacts the chair. Usage of an assistive device was allowed and was documented consistently at each additional assessment. The patient was allowed one practice trial prior to the timed performance. The Clinical Metrics and Instructions Sheet includes updated tables with values for tested populations was printed and laminated and was used as a reference during the test..

Timepoint

At baseline, after two weeks and after four weeks of the intervention

Method of measurement

Time up and Go test (TUG)

3

Description

Functional activities: The functional activities of the patient were measured using the Amputee Mobility Predictor with Prosthesis Test (AMPPRO) as described by Gailey . The test consists of 42 scores. The test was designed to assess the functional ambulation in patients with lower limb amputation. The AMP can be administered with a prosthesis (AMPPRO) or without a prosthesis (AMPPRE). In this study, the participants used their prosthesis for the test. The AMPPRO takes approximately 15 minutes to apply. AMP Scores have been correlated with the functional Medicare classification system of 0 - 4 . Mean AMP scores for each K level are: K1 0-1 (25), K2 2 (34.6), K3 3 (40.5), K4 4 (44.7). The AMPPRO is reliable and valid for patients with transtibial amputations with excellent interrater and interrater reliability and with intraclass coefficient (ICC) scores ranging from 0.96 to 0.99.

Timepoint

At baseline, after two weeks and after four weeks of the intervention

Method of measurement

Amputee Mobility Predictor with Prosthesis test (AMPPro)

4

Description

Energy expenditure: The physiological Cost Index (PCI) was used to measure the energy expenditure. PCI is a reliable test to track the changes of metabolic energy expenditure. The test was administered during the 2MWT as follows: 1.The patient sits quietly for 2 minutes until the heart rate reaches a steady state.2. The walking speed was measured in meters per minute. The participants walked on a level surface at their preferred pace. 3.The working heart rate was measured using Polar H7 for measuring heart rate. 4.After finishing the 2MWT, the heart rate was subtracted and divided by walking speed to obtain the PCI in beat/meter (see the equation below). 5.The participants was instructed to avoid taking any tobacco, coffee/tea or a big meal at least 2 h before the PCI-test.

Timepoint

At baseline, after two weeks and after four weeks of the intervention

Method of measurement

Physiological Cost Index test (PCI)

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: The patients did home strengthening exercise and gait training exercises to improve their strength, balance, gait pattern, and coordination under the supervision of the first author. After that, the patients played the six games using XBOX Kinect, 3 times per week for 4 weeks.

Category

Rehabilitation

2

Description

Control group: The patients in the control group received home strengthening exercise for the global muscles (quadriceps, hamstring, hip and core muscles) and gait training exercises only under the supervision of the first author. The protocol was 3 sessions per week for four weeks in total.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sader Al Qanat Physical Rehabilitation Center and Baghdad Physical Rejabilitation Center

Full name of responsible person

Mohammed Abdul Hussein Jabbar Al Sawaedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tehran University of Medical Sciences
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD, IPD collected for the primary outcome measure only
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
For academic and clinician physiotherapist and those who are working in the field of rehabilitation.
Under which criteria data/document could be used
no specific criteria
From where data/document is obtainable
first author and the journal
What processes are involved for a request to access data/document
email the author, or the journal
Comments
no comments