

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of coordinative locomotor training on pain, balance and gait in chemotherapy induced peripheral neuropathy patients

Protocol summary

Study aim

To determine the effect of coordinative locomotor training on pain, balance and gait in chemotherapy induced peripheral neuropathy patients

Design

A randomized controlled trial with two parallel groups, a single blinded study of 3rd phase with 19 patients in each group which in total is 38

Settings and conduct

Allied Hospital Faisalabad, Madina teaching hospital Faisalabad. patients will be kept unaware which group they are allocated to.

Participants/Inclusion and exclusion criteria

- Age 35 to 60 years
- Both genders male and female
- Willing to participate in research
- Cancer patients of stage I-III
- Receiving neurotoxic drugs (platinum based, taxanes based or both in combination)
- Have received at least 4 cycles of chemotherapy treatment
- Having numbness and tingling in distal areas
- Pain in distal areas
- At medium (19-24) to high (<19) risk of fall according to POMA
- Able to communicate in Punjabi/Urdu/English
- Cognitive dysfunction (Mini-Mental State exam score < 24)
- Any recent major surgery
- Unhealed lower extremity fracture
- Having diabetic neuropathy before getting chemotherapy drugs
- Other neurological problems including brain cancer
- Cardiovascular diseases
- Bone metastasis
- Lower limb lymphedema
- Musculoskeletal problems
- Amputated limb
- with abnormal visual or auditory senses
- uncooperative patients

Intervention groups

Group A: coordinative locomotor training group. Group B: Conventional therapy group

Main outcome variables

1.pain 2.balance 3.gait

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240311061260N1**
Registration date: **2024-05-03, 1403/02/14**
Registration timing: **prospective**

Last update: **2024-05-03, 1403/02/14**

Update count: **0**

Registration date

2024-05-03, 1403/02/14

Registrant information

Name

Aqsa Liaqat

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 323 6002906

Email address

2022-ms-pt-047@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-06, 1403/02/17

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of coordinative locomotor training on pain, balance and gait in chemotherapy induced peripheral

neuropathy patients

Public title

Effectiveness of coordinative locomotor training on pain, balance and gait in chemotherapy induced peripheral neuropathy patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 35 to 60 years Both genders male and female
Willing to participate in research Cancer patients of stage I-III Receiving neurotoxic drugs (platinum based, taxanes based or both in combination) Have received at least 4 cycles of chemotherapy treatment Having numbness and tingling in distal areas Pain in distal areas At medium (19-24) to high (<19) risk of fall according to POMA Able to communicate in Punjabi/Urdu/English

Exclusion criteria:

Cognitive dysfunction (Mini-Mental State exam score < 24)
Any recent major surgery Having diabetic neuropathy before getting chemotherapy drugs Unhealed lower extremity fracture Other neurological problems including brain cancer Cardiovascular diseases Bone metastasis Lower limb lymphedema Musculoskeletal problems Amputated limb With abnormal visual or auditory senses Uncooperative patients

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants selected through purposive sampling will be randomly allocated through lottery method to either interventional group or active control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant in this study will be blinded as they will be randomly allocated through lottery method

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics/Technical Committee for the University of Faisalabad

Street address

University Avenue, Faisal Town Canal Road

City

Faisalabad

Postal code

38000

Approval date

2024-02-17, 1402/11/28

Ethics committee reference number

TUF/DR/SA/MSPP/2024/408

Health conditions studied

1

Description of health condition studied

Chemotherapy induced peripheral neuropathy

ICD-10 code

G64

ICD-10 code description

Other disorders of peripheral nervous system

Primary outcomes

1

Description

Pain

Timepoint

Before treatment and at the end of 4 weeks of intervention

Method of measurement

Numerical pain rating scale(NPRS) was used

2

Description

Balance

Timepoint

Before the treatment and at the end of 4 weeks of intervention

Method of measurement

Performance oriented mobility assessment (POMA)

3

Description

Gait

Timepoint

Before the treatment and at the end of 4 weeks of intervention

Method of measurement

Timed up and go test(TUG), F8WT(figure of 8 walk test)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Coordinative Locomotor Training group

Category

Treatment - Other

2

Description

Control group: conventional training (Reaching out with hands crossed in sitting position, Sitting and getting up from chairs of various heights, Stepping forward, backward and sideways, Toe standing, Standing balanced and straight, Standing up from chair walk a certain distance and return to sit down, Climbing stairs)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Anbreena Rasool

Street address

Dr. Tusi Raod

City

Faisalabad

Postal code

38000

Phone

+92 345 7936825

Email

assistant.professor.rehab.419@tuf.edu.pk

Web page address

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2

Recruitment center

Name of recruitment center

Madinah Teaching Hospital

Full name of responsible person

Anbreena Rasool

Street address

Sargodha road university town

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Anbreena Rasool

Street address

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Web page address

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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 Faisalabad

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

The University of Faisalabad

Full name of responsible person

Aqsa Liaqat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Province

Punjab

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not 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

Effectiveness of Coordinative locomotor training on pain, balance and gait in chemotherapy induced peripheral neuropathy patients

When the data will become available and for how long

Starting 6 months after publication and it will remain available for everyone

To whom data/document is available

This will be available for everyone

Under which criteria data/document could be used

assistant.professor.rehab.419@tuf.edu.pk (mobile no. +92 345 7936825)

From where data/document is obtainable

aqsa786liaqat@gmail.com (mobile no. +92 335 7813723)

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

Any applicant just need to contact through email at aqsa786liaqat@gmail.com (mobile no. +92 335 7813723)

Comments