Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of kinesio taping in addition to routine physical therapy on balance, gait and quality of life in patients with Parkinson's disease

Protocol summary

Study aim

Primary aim of this study is to evaluate kinesio taping (KT) in addition to routine physical therapy (RPT) on balance, gait and quality in Parkinson's disease (PD) patients. Secondary aim, evaluate effectiveness of KT on motor symptoms, freezing of gait and activities of daily livings in PD. This study also investigate the immediate effects of KT on balance and gait in PD patients.

Design

Parallel group, double blind, randomized controlled trial, enrolled between March 2019 and July 2019, and followed for 3 months

Settings and conduct

University Physical Therapy and Rehabilitation Clinic, University of Lahore. Participant, outcome assessor and data analyser blinded.

Participants/Inclusion and exclusion criteria

Patients are eligible if they had diagnosis of PD according to UK Brain Bank criteria, modified Hoehn & Yahr Stage 2.5-3, MDS-UPDRS III subscore for "gait" and "postural stability" is ≥ 1. Stable dose of levodopa for last 4 weeks. They are excluded if they score Mini Mental State Examination < 24/30. Patient had deep brain stimulation surgery. Fixed vertebral deformities. Have severe cardiovascular or pulmonary problems.

Intervention groups

In RPT, stretching, strengthening exercises, balance exercises; aerobic exercises, treadmill training were also given. In intervention group KT along with RPT given. KT was applied in a tailored manner for each patient, on two regions, back and leg. On back, 2 strips were applied along the dorsal lumbar spinal tract between the T1 and L5 vertebrae spinous processes, bilaterally. While adding 1 other vertical strip on the lumbar region (quadratus lumborum muscle) opposite to the flexed side. On both legs, KT was attached to the skin on the course of tibialis anterior muscle.

Main outcome variables

GAITRite Platinum system (GaitRite, CIR system Inc., USA, 2008). Parkinson's Disease Questionnaire 39 (PDQ-39) Berg Balance Scale MDS-UPDRS III

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191216045759N1**
Registration date: **2019-12-30, 1398/10/09**
Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**
Update count: **0**

Registration date

2019-12-30, 1398/10/09

Registrant information

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Name of organization / entity

The University of Lahore

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-10, 1397/12/19

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

2019-03-15, 1397/12/24

Actual recruitment end date

2019-08-15, 1398/05/24

Trial completion date

2019-12-16, 1398/09/25

Scientific title

Effectiveness of kinesio taping in addition to routine physical therapy on balance, gait and quality of life in patients with Parkinson's disease

Public title

Effect of kinesio taping in Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic Parkinson’s disease clinically diagnosed by neurologist (according to the UK PDS Brain Bank criteria). Both males and females; 50 - 80 years of age. Modified Hoehn and Yahr stage 2.5 to 3 Movement Disorder Society-Unified Parkinson’s Disease Rating Scale III subscore ‘gait’ or ‘postural stability’ ≥ 1 Receive a stable dopaminergic medication dose (both levo-dopa and/or a dopamine agonist are allowed) for one month before the study

Exclusion criteria:

A Mini Mental State Examination score < 24/30 Diagnosed with any other neurological disease other than PD Patient underwent surgery i.e. deep brain stimulation and lesioning surgery (thalamotomy, pallidotomy, subthalamotomy) Fixed vertebral deformities (ankylosing spondylitis, vertebral pathology such as fracture, spinal cord pathology such as syrinx, idiopathic or degenerative scoliosis). Have severe cardiovascular or pulmonary problems Have lower extremity disorders (e.g. deformities, fractures, rheumatologic disease and operations). Visual or acoustic limitations A major change in medicine existed during the training period Any skin or allergic reaction to kinesio tape

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was designed to be a parallel group randomized controlled trial. After baseline assessment, eligible patients were randomly assigned (in a 1:1 ratio) to either kinesio taping + routine physical therapy (kinesio taping intervention group) or routine physical therapy (control group). Computer generated randomization assignments were designed by an independent statistician and randomization was done by one of the research team member who was not involved in patient recruitment or assessment or data analysis. Randomization is without stratification, with the use of permuted-block randomization; the randomization assignments were kept in opaque, sealed envelopes and unsealed by a researcher after baseline testing.Outcome assessors were unaware of group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

After randomisation, study participants were only informed about the content of their allocated programme by their therapist, remaining unaware of the intervention in the other group. Patient brochure stated that the study purpose was to evaluate the effects of physical therapy interventions on Parkinson’s disease symptoms, without mentioning that one of the programmes was considered a control intervention. Information about the details of both programmes was not provided except for similarities across both groups (treadmill training, aerobic exercise three times per week). Both programmes were personalised to the patient’s abilities to ensure all eligible patients could complete the programme. Researchers who assessed outcomes or did data analyses were masked to group allocation. Patients were instructed not to talk about the content of their exercise programme during the post intervention visit and could contact their therapist in case of any problems during trial participation. Moreover, if two or more study participants were in the clinic/hospital at the same time, they were assigned to different treatment areas without any opportunity to observe each other or their treatment times were rearranged to prevent unintended crossover. During outcomes assessment patients were covered in such a way that kinesio tape could not be visible to assessor and it also did not impede patient’s abilities to perform activities.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of The University of Lahore

Street address

1-KM Defence Road, Off Bhobatian Chowk, Lahore

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Lahore

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54000

Approval date
2019-03-01, 1397/12/10
Ethics committee reference number
IRB-UOL-FAHS/440/2019

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance
Timepoint
Baseline assessment i.e. before intervention (t0), on the day of second session of treatment but before treatment of patient (t1), after end of treatment sessions (t2) and after 3 months of intervention (t3).
Method of measurement
Berg balance scale (BBS) and Timed Up and Go Test (TUG). BBS is a 14 item list with each item consisting of a five-point ordinal scale ranging from 0 to 4. 0 denotes inability to complete the item, and 4 the ability to accomplish the task independently (total score range, 0–56; higher = better performance). Scores of less than 45 out of 56 are accepted as indicative of balance disorders in the elderly, while scores of less than 43.5 out of 56 are accepted as indicative in Parkinson’s disease. The TUG test is aimed at assessing mobility, balance, walking ability, and fall risk in older adults. The patient is asked to get up from a standard chair, walk at a comfortable and safe speed to a line 3 m away, turn at the line and walk back to the chair to sit down. In patients with Parkinson’s disease, a score higher than 7.95 s may indicate a high risk of falling

2

Description
Gait
Timepoint
Baseline assessment i.e. before intervention (t0), on the day of second session of treatment but before treatment of patient (t1), after end of treatment sessions (t2) and after 3 months of intervention (t3).
Method of measurement
GAITRite Platinum and Functional gait assessment. Gait function was measured using GAITRite Platinum system (GaitRite, CIR system Inc., USA, 2008). As the subject walked along the walkway, the sensors captured each footfall as a function of time and transferred the gathered information to a personal computer for processing into footfall patterns. The parameters evaluated will be gait velocity, cadence, and step length, and the mean of three repetitions will be used.
Functional Gait Assessment: The FGA is a 10-item gait test. Each item is scored on a 4-pointordinal scale with scores of 0, 1, 2, and 3. The maximum total score is 30; higher scores represent better balance and gait ability

3

Description
Quality of Life
Timepoint
Baseline assessment i.e. before intervention (t0), after end of treatment sessions (t1) and after 3 months of intervention (t2).
Method of measurement
Parkinson’s disease questionnaire 39 (PDQ 39) is 39 item questionnaire offers a patient reported measure of health status and quality of life. Scores are then transformed to a common range of 0 to 100 (100 = maximum level of problems). Lower score reflect better quality of life

Secondary outcomes

1

Description
Motor Symptoms
Timepoint
Baseline assessment i.e. before intervention (t0), after end of treatment sessions (t1) and after 3 months of intervention (t2)
Method of measurement
Movement Disorder Society-Unified Parkinson's Disease Rating Scale Motor Examination Part (MDS-UPDRS III)

2

Description
Freezing of gait
Timepoint
Baseline assessment i.e. before intervention (t0), after end of treatment sessions (t1) and after 3 months of intervention (t2)
Method of measurement
Freezing of gait questionnaire (FOGQ)

3

Description
Activities of daily living
Timepoint
Baseline assessment i.e. before intervention (t0), after end of treatment sessions (t1) and after 3 months of intervention (t2)
Method of measurement
Barthel Index

Intervention groups

1

Description
Intervention group: Kinesio taping plus routine physical

therapy

Category
Rehabilitation

2

Description
Control group: Routine physical therapy

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
University Physical Therapy and Rehabilitation Clinic, The University of Lahore

Full name of responsible person
Prof. Dr. Ashfaq Ahmad

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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 Lahore

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
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Position
Lecturer

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Bachelor

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

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
IPD, study protocol, statistical analysis plan, informed consent form and clinical study report will be shared for primary and secondary outcome measure with interested research after considering the ethics and confidentiality.

When the data will become available and for how long
Data will be available after 6 months of publication for 3 consecutive years.

To whom data/document is available
Data will only be shared with individual researcher and academic researchers working in movement disorders. Data will not be shared for any commercial purposes/businesses for any reasons.

Under which criteria data/document could be used
Data can be used under confidentiality and ethics.

From where data/document is obtainable
Data can be obtained by emailing at haiderullah@live.com. Mobile number 0092 331 4127210

What processes are involved for a request to access data/document
Simple email can do this. But this can take up to 4 weeks depends on busy schedule of investigator.

Comments