

Improving walking via real-time visual feedback after stroke in treadmill training (RE-VISIT): a protocol for randomized controlled trial

Melhorando a caminhada por meio de feedback visual em tempo real após acidente vascular cerebral em treinamento em esteira (RE-VISIT): um protocolo para ensaio clínico randomizado

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ABSTRACT | BACKGROUND: After a stroke, most patients often suffer reduced walking ability and balance. Restoring walking ability and improving balance are major goals of stroke rehabilitation. Treadmills are often used in clinical setups to achieve these goals. Adding dimensions to the visual feedback in addition to the mirror for real-time frontal view is proven to enhance the gait. It is, therefore, important to design additional real-time visual feedback in treadmill training, in particular for the sagittal view involved side. **OBJECTIVE:** The objective of this study is to test if the real-time sagittal visual feedback during treadmill training is superior to the conventional mirror feedback treadmill training program of equivalent intensity in improving walking speed and balance after stroke. **METHODS/DESIGN:** The RE-VISIT trial (Real-time Visual feedback after Stroke in Treadmill training) is registered in the Clinical Trial Registry of India (CTRI/2023/10/058299). In this two-arm randomized control trial, which will be a single-blinded study, 42 eligible stroke survivors undergoing rehabilitation will be randomly allocated (1:1 ratio) to either real-time visual sagittal feedback along with front mirror (experimental) group or only front mirror treadmill training (control) group, all the participants will receive 15 sessions of treadmill training for up to 15 min at a safe self-selected speed over 5-6 weeks. The RE-VISIT (experimental) group will receive real-time, visual sagittal view feedback of the involved lower limb trajectory along with the routine front mirror view during treadmill training and will be asked to modify their gait pattern. The control group will receive treadmill walking training only with the routine front mirror view feedback. Clinical and gait assessments will be conducted at the baseline, immediately following the final session of training, and at the 9th week during follow-up. The outcome measures of interest are walking speed (primary) and balance (secondary), which will be measured prior to baseline, post 15 sessions of training, and at the 9th week following training. **DISCUSSION:** This REVISIT trial will provide insight and contribute to the existing innovation and modifications of incorporating real-time visual feedback during treadmill training in post-stroke gait rehabilitation. The findings will help the better designing of a gait rehabilitation program with a treadmill for post-stroke subjects to improve walking speed, and balance for those who have greater difficulties in community ambulation. We anticipate that those in the REVISIT training will demonstrate improved walking ability.

KEYWORDS: Stroke. Gait Training. Visual Feedback. Treadmill. Walking Speed. Balance.

RESUMO | CONTEXTO: Após o acidente vascular cerebral, a maioria dos pacientes frequentemente sofre redução da capacidade de caminhar e do equilíbrio. Restaurar a capacidade de caminhar e melhorar o equilíbrio são os principais objetivos da reabilitação do AVC. As esteiras são frequentemente usadas em ambientes clínicos para atingir esses objetivos. Está comprovado que adicionar dimensões ao feedback visual, além do espelho para visão frontal em tempo real, melhora a marcha. É, portanto, importante projetar feedbacks visuais adicionais em tempo real no treinamento em esteira, em particular para o lado envolvido na visão sagital. **OBJETIVO:** O objetivo deste estudo é testar se o feedback visual sagital em tempo real durante o treinamento em esteira é superior ao programa de treinamento em esteira com feedback de espelho convencional de intensidade equivalente na melhoria da velocidade de caminhada e equilíbrio após acidente vascular cerebral. **MÉTODOS/ DESENHO:** O ensaio RE-VISIT (feedback visual em tempo real após acidente vascular cerebral no treinamento em esteira) está registrado no Registro de Ensaios Clínicos da Índia (CTRI/2023/10/058299). Neste ensaio de controle randomizado de dois braços, que será um estudo cego, 42 sobreviventes de AVC elegíveis em reabilitação serão alocados aleatoriamente (proporção de 1:1) para feedback sagital visual em tempo real junto com grupo de espelho frontal (experimental) ou apenas Grupo de treinamento em esteira com espelho frontal (controle), todos os participantes receberão 15 sessões de treinamento em esteira por até 15 minutos em uma velocidade segura e autosselecionada durante 5-6 semanas. O grupo RE-VISIT (experimental) receberá feedback visual em tempo real da visão sagital da trajetória dos membros inferiores envolvidos, juntamente com a visão rotineira do espelho frontal durante o treinamento em esteira e será solicitado a modificar seu padrão de marcha. O grupo de controle receberá treinamento de caminhada em esteira apenas com o feedback rotineiro da visão do espelho frontal. Avaliações clínicas e de marcha serão realizadas no início do estudo, imediatamente após a sessão final de treinamento e na 9ª semana durante o acompanhamento. As medidas de resultados de interesse são a velocidade de caminhada (primária) e o equilíbrio (secundário), que serão medidos antes da linha de base, após a 15ª sessão de treinamento e na 9ª semana após o treinamento. **DISCUSSÃO:** este ensaio REVISIT fornecerá insights e contribuirá para a inovação e modificações existentes na incorporação de feedbacks visuais em tempo real durante o treinamento em esteira na reabilitação da marcha pós-AVC. As descobertas ajudarão no melhor desenho de um programa de reabilitação da marcha com esteira para indivíduos pós-AVC para melhorar a velocidade de caminhada e o equilíbrio para aqueles que têm maiores dificuldades na deambulação comunitária. Prevemos que aqueles no treinamento REVISIT demonstrarão melhor capacidade de caminhada.

PALAVRAS-CHAVE: Acidente vascular cerebral. Treinamento de marcha. Feedback visual. Esteira. Velocidade de caminhada. Equilíbrio.

1. Introduction

The prevalence of stroke in India is rising alarmingly, with as many as 18 lakh stroke cases being reported every year and countless unreported cases with it. According to reports, India's crude incidence and prevalence of stroke ranged from 108 to 172/100,000 people annually, one-month case fatality rates from 18% to 42%, and crude prevalence from 26 to 757/100,000 people annually. However, these figures are based on a small population denominator of 22.4 million people from a few clusters.^{1,2}

Stroke is a major catastrophic public health concern globally and in India, it is among the leading causes of mortality and morbidity. According to Global Burden of Disease 2019, the disability-adjusted life-years (DALYs) were 143 million due to stroke. More than 80% of stroke survivors suffer from walking impairment and poor balance, which impedes them from community ambulation and decreases the probability of returning to productivity.³ Further, stroke imposes a burden on the family and society. Hence, regaining walking ability and balance has long been the major rehabilitation goal in stroke management.

Slow walking speed and poor balance are strong predictors of limited ADL, physical inactivity, and community life restrictions.⁴ Stroke survivors develop apathy, leading to lost interest, and reduced motivation during the recovery phase, which is also a major barrier to effective physical rehabilitation. Therefore, it is mandated during the training sessions to encourage people to perform at their full capacity to get the maximum benefit from the session. There are various physical rehabilitation strategies reported and currently used to improve walking speed and balance. Treadmill with or without body weight support is one of the commonly practiced, useful, safe, and secured treatment options to improve walking parameters among post-stroke survivors.⁵⁻⁸

In recent times, the use of cues, both auditory and visual in treadmill interventions aimed to improve walking parameters has been proposed to be effective.⁹⁻¹¹ Treadmill walking in front of a mirror, virtual reality, and augmented reality are different means of visual cues proposed and reported in the literature. The proposed intent of these visual cues or feedback is to encourage self-motor adjustments and learning to attain a more symmetric gait pattern.

Preliminary research reported that visually-guided treadmill gait training among chronic stroke patients improved walking speed, balance, and level of physical activity.^{6,12-14} Stroke survivors involved in visually-guided treadmill training programs utilize the feedback from sensory systems to control or correct the ongoing movement and thus the potential to improve neuroplasticity is enhanced. This could be a contributing factor to their improvement in walking speed, balance, and physical activity. Most importantly, offering a variety of gait training and additional feedback, especially real-time cues may increase interest and self-motivation among stroke survivors.

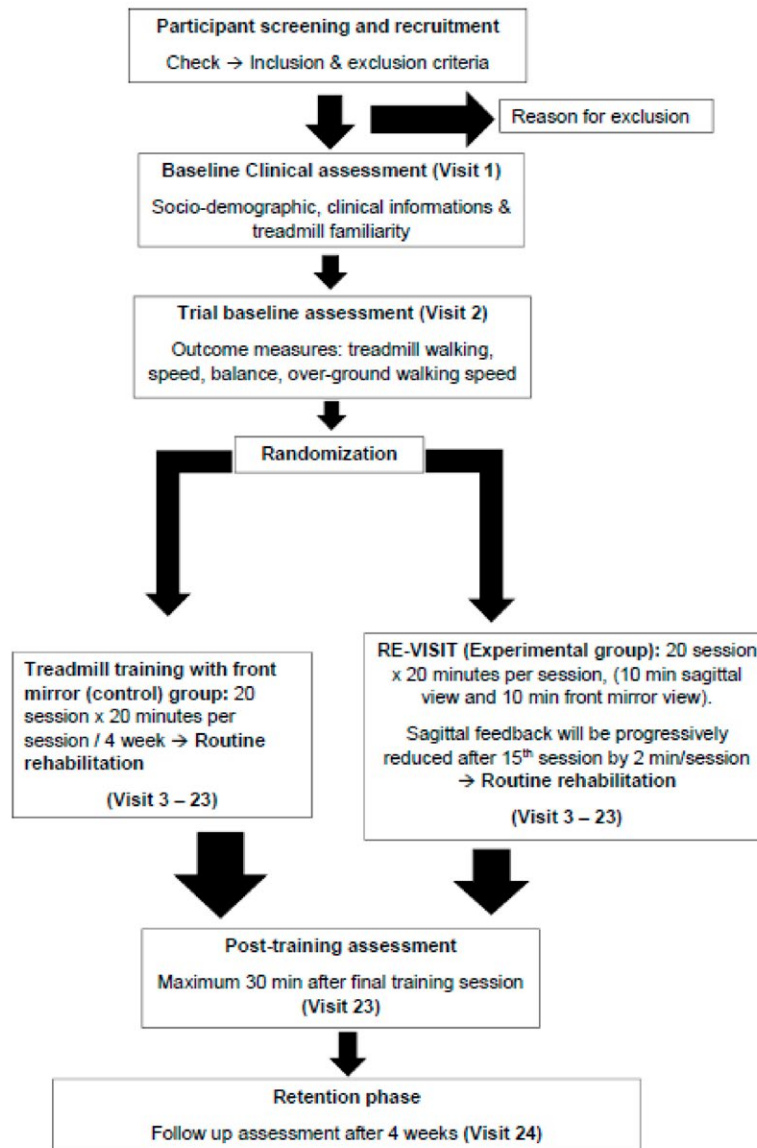
Given that treadmill walking training in front of the mirror offers only frontal plane real-time feedback to the patients which may not be enough to induce self and on-going movement corrections. Therefore, RE-VISIT trial aims to determine whether real-time visual feedback of the sagittal view of the involved side during treadmill gait training can significantly improve the walking speed and balance in people with stroke. We will test the efficacy of RE-VISIT program using a randomized controlled trial (RCT) design before and immediately after the training phase, further, we also intend to test the retention to conform to the relative permanence of the targeted behavior. The primary objective is to determine whether RE-VISIT will significantly increase the walking speed, and balance among adult chronic stroke survivors. Whether changes in the walking speed achieved treadmill, transfer to overground walking. It is hypothesized that compared to treadmill training with only front mirror feedback, training with real-time visual feedback of the sagittal view of the involved side will significantly improve walking speed and balance in adult people with chronic stroke. It is also hypothesized that the increase in walking speed demonstrated on a treadmill will transfer to over-ground walking. The secondary objective of this RCT is to assess the patient's level of satisfaction with the treadmill training to determine the understanding level of care provided and the pitfalls of the interventions provided in the trial.

2. Methods/Design

The RE-VISIT trial (Real-time Visual feedback after Stroke in Treadmill training) is a single-blinded, two-arm 1:1 randomized control trial designed to assess the effect of real-time sagittal view visual feedback on walking speed and balance following treadmill training. The RE-VISIT trial will conform to the CONSORT reporting guidelines.¹⁵ The study will be conducted at the Meenakshi Academy of Higher Education and Research (MAHER), Chennai, India. All the interventional and outcome measure assessments will be performed at the gait laboratory, Physiotherapy department, MAHER.

Ethical approval for the study protocol is obtained from Meenakshi Medical College Hospital and Research Institute, Chennai, India. The trial is prospectively registered in Clinical Trial Registry of India (CTRI/2023/10/058299) The study design flowchart is shown in Figure 1.

Figure 1. RE-VISIT trial study design flow chart



Source: the authors (2024).

2.1 Eligibility criteria of the participants

Participants aged 18–60 years, those who have sustained a single stroke (hemorrhagic and ischemic) at least 3 months duration, able to walk independently 50 meters with or without a single-sided mobility aid, able to walk at a minimum required speed of 0.8 meters per second, and capable of providing informed consent will be included. Stroke survivors using ankle-foot orthosis (AFO), patients with neurological, orthopedic, cardiac, respiratory, and other medical conditions in addition to stroke, and individuals contraindicated for treadmill walking, with a body weight of >150Kg (weight limit of body-weight support harness)¹⁶ and with visual impairment and/or moderate to severe visual-spatial neglect were excluded.

2.2 Sample size calculation

To determine the sample size for the between-group (mirror feedback with real-time visual feedback of involved side versus mirror feedback) comparisons, to detect the difference in walking speed a medium effect (Effect size = 0.41 m/s)¹⁷ was used from a study that exposed one group to virtual reality in treadmill training.

Hence, for between-group effects across the two time points (2 X 2 repeated measures design, baseline and after training), we set the alpha level as 0.05, power as 0.80, correlation of repeated measures as 0.7 and effect size as 0.41. Based on those input parameters, the estimated sample size was 42 participants. We used the G*Power 3.0 software to estimate the sample size, a general stand-alone power analysis product for statistical tests used commonly in social and behavioral research.¹⁸

2.3 Study settings and Participant recruitment

We aim to recruit 42 post-stroke adults living in and around the MAHER by pamphlet advertisements, and snowball sampling methods. Further, the post-stroke visiting the physiotherapy OPD at the MAHER, Chennai will be approached for consent to participate in this trial. The study setting is a teaching physiotherapy institution with an OPD facility and has 21 full-time physiotherapists and the gait laboratory of the Centre for Clinical Research in Physiotherapy (CCRP, MAHER) is equipped with body support harness treadmill facilities along with visual aid adjuncts. The consultations and physiotherapy services for neurological patients are free of cost.

2.4 Randomization

After the pre-training eligibility criteria test, participants will be randomly allocated to either the REVISIT treadmill training group or treadmill control group using a concealed allocation block randomization to attain similar group sizes and the random block will be sized as 7 blocks sized '6'. The sequence for allocation will be generated by a staff member who is neither involved in enrollment nor assigning participants to groups.

2.5 Blinding

Clinical physiotherapists and physiotherapy post-graduates (assessors) will be involved in the assessment but blinded to the group allocations and training programs. The assessors will carry out clinical evaluations, collect socio-demographic-related information, and measure walking speed and balance. The group assignment will be disclosed to the intervention therapists.

2.6 Intervention

All the selected participants, both (RE-VISIT) experimental and control groups, will walk on the treadmill with body support safety-harness and a postural mirror in front, following an identical schedule of training sessions. A self-selected or self-identified walking speed will be determined following a brief session of treadmill familiarization during the first visit. This self-selected walking speed will be recorded and the same walking speed will be followed for the training sessions. Each 20-minute session will be divided by a compulsory break time of 5 minutes and will be extended if the patient needs more time. The 20-minute single treadmill walking session will be divided into two bouts of 10 minutes each and a break or rest time of 5 minutes will be provided between these 2 bouts to avoid fatigue. To improve visible feedback and avoid distractions the participants from both the groups will be given treadmill walking training on a one-to-one basis (with no other patients inside the lab). The participants will wear the same type and brand of shoes of size fit provided at the training center, during the training and assessment of outcomes.

Participants in the control group will receive treadmill walking training with mirror feedback for frontal anterior view and the training dosage will be the same for both groups to ensure that the only manipulation is the additional sagittal feedback delivered to the REVISIT group. Participants randomized to the RE-VISIT (intervention group) will undergo gait training on the treadmill same as the control group for the first sub-session (10 min) and in the second sub-session the participants will be provided with a real-time visual display of the sagittal view of their involved side while walking on the treadmill displayed in the screen front of them.

The real-time visual feedback of the sagittal view of the involved side will be presented for the first 15 sessions, then progressively reduced (faded) across the rest of the 5 sessions. During fading, the feedback will be available for full 10 min until the beginning of sub-session 2 of session 16, 8 min of the beginning of sub-session 2 of session 17, 6 min of the beginning of sub-session 2 of session 18, 4 min of the beginning of sub-session 2 of session 19, and 2 min of the beginning of sub-session 2 of session 20 (final). The treadmill training walking speed of the participants of both groups will be set based on the over-ground walking speed using a 10-meter walk test, and we also anticipate the walking speed to change each week, and hence the treadmill walking speed will be increased accordingly through 5 weeks period of the REVISIT trial. The participants of both groups will be encouraged any adverse events during the outcome measures evaluation and intervention sessions.

Treatment adherence to treadmill walking will be reflected in the number of training sessions successfully completed and the trial team will monitor it.

3. Outcome measures

3.1 Assessments

3.1.1 Patient socio-demographic, clinical characteristics, and baseline measurements

Information like age, gender, type of stroke, duration of stroke, treadmill experiences questions, and visual feedback experience questions.

3.1.2 Study outcomes

The selection of the study dependent variable and tools is guided by 3 criteria:

1. Importance for the patient.
2. Pragmatic and ease of implementation in clinical set up.
3. Validity to detect the recovery of walking speed and balance.

3.1.3 Primary outcome measures

A straight corridor 10 meters walk test¹⁹ will be used to assess the participants' walking speed, and the same corridor will be used at all the timeline measurements (baseline, post-intervention, and follow-up). The outcomes of the 10-meter walk test demonstrate that comfortable walking speed is better than the 6-meter walk test. The Berg balance scale²⁰ will be used to assess the static balance of the participants at all three timelines.

3.1.4 Secondary outcome measure

To understand the participants' level of understanding of care, and experience of training, and gather feedback to allow improvement in the definite study of the REVISIT trial, the patient satisfaction questionnaire-18 (PSQ-18)²¹ will be used at baseline, post-intervention and follow-up timelines. The response of the PSQ-18 might help improve and identify areas to design this trial for patient-centered care.

Table 1. RE-VISIT trial outcomes

Outcomes	Assessment tool	Objectives
Walking speed	10 meters walk test	To estimate the effect of RE-VISIT on walking parameter.
Balance	Berg Balance Scale (BBS)	To estimate the effect of RE-VISIT on static balance
Perception of the intervention	Ad-hoc questionnaire (tailor-made)	To assess the participants' subjective perception of the intervention

Source: the authors (2024).

Baseline assessment (T0) will be taken prior to allocation, post-intervention assessment of the two groups at (T1), will serve to compare the effectiveness immediately after the treatment phase. The follow-up assessment at the 9th week (T2) will serve to detect the retention effects of the treatment. The Standard Protocol Items Recommended for Interventional Trials (SPIRIT) schedule²² is given in Table 2.

Table 2. Schedule of enrollment, intervention, and assessment, the SPIRIT guidelines

Study period	Screening	Baseline (T0)	Training sessions		Intervention period in W				Post-intervention assessment (T1)	Follow up T2
			S1 to S6	S17 to S20	1	2	3	4		
Time (weeks)	-8 to -1	0	S1 to S6	S17 to S20	1	2	3	4	5	9 W after discharge
Patient data	x									
Informed consent	x									
Demographic data	x									
Medical history	x									
Allocation (post T0)		X								
Treadmill training			X	x	X	X	x	x	X	
Control group			X	fade	X	X	x	x	X	
Intervention group			X	fade	X	X	x	x	X	
Walking speed		X							X	X
Balance (BBS)		X							X	X
PSQ-18									X	
Compliance and motivation (ad-hoc)									X	
Patient diary		X	X	x	X	x	x	x	X	
Routine PT	x	X	X	x	X	x	x	x	X	
Adverse effects		X	X	x	X	X	x	x	X	

Legend: Berg Balance Scale – BBS; Weeks – W; S – Session (Session 1 (S1) through Session 20 (S20)); Patient Satisfaction Questionnaire-18.
Source: the authors (2024).

The devices and instruments required are a motorized treadmill with a full postural mirror in front, a body weight support harness system, different-sized shoes of the same type and brand, and a stopwatch.

3.2 Statistical analysis

The Statistical Package for Social Science version 25 of IBM SPSS INC, Chicago IL, USA was used for statistical analysis. The mean, median, maximum, minimum, and standard deviation of walking speed for each walking condition, along with the characteristics of the participants, will be displayed using descriptive statistics. To compute the difference in walking speed and BBS between T0 and T1 and T2, we will utilize the baseline walking speed and BBS measurements.

The change will be computed by deducting the walking speed value from the baseline walking value. The repeated measures ANOVA will be used to ascertain statistically significant variations in the maximum walking speeds among the three performance conditions based on the variation in walking speed value. To clearly identify the variations between the performance conditions, we will perform a post hoc analysis (Tukey test). To determine whether the variation in walking speed is connected with the compliance and motivation (ad hoc) for every experimental condition, we will employ correlation analyses (i.e., Pearson/Spearman). The effects of the BBS score on walking speed will be examined using Analysis of Covariance (ANCOVA).

3.3 Safety and Confidentiality

The participants will be constantly supervised during assessment and intervention. Patients with fall risk and fear of falls will be identified and cared for accordingly. Vital parameters of the patients like heart rate, blood pressure, respiratory rate, temperature, and SpO2 will be frequently monitored. The participants will be allowed to use the handrails and their trunks will be harnessed to the body weight support system. At most care will be taken to avoid and treat potentials of fatigue, cramp, and muscle pain before, during, and after walking training.

The patient's information will be kept confidential and disclosure to third parties is prohibited.

4. Discussion

Attention is paid to the study's pragmatic design, to improve clinical applicability in the future, to enhance the generalizability, and useful findings. To evaluate the REVISIT trial protocol design, a rating grid proposed by the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) guideline is used and the domain, score and rationale of each item in the PRECIS-2 is presented in Table 3. Focus on sub-group with minimum pre-set walking ability, single center, urban study area may lead to representation errors; these are the points that tend to lower the scores.

Table 3. Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) scores of trial domains

	Domain	Score	Rationale
1.	Eligibility criteria	3	P: inclusion of patients with minimum walking ability E: focus on building upon the minimum ability to walk
2.	Recruitment path	3	P: Recruitment of participants from OPD units E: Checklist to assess eligibility, 8 weeks to recruit
3.	Setting	3	P: The catchment area is OPD in two areas E: Single training center trial (feasibility)
4.	Organization Intervention	5	P: Resource, expertise, and delivery of care in both arms are similar
5.	Flexibility of RE-VISIT delivery	5	P: Identical flexibility to routine care given
6.	Flexibility of RE-VISIT adherence	5	P: usual encouragement to adhere to routine PT
7.	Follow up	3	P: assessment of through routine care (4 weeks)
8.	Outcome	5	P: Outcomes are important predictors of community ambulation
9.	Analysis	5	P: intention-to-treat analysis will all available data

Score: 1 – Very explanatory; 2 – Rather explanatory; 3 – Equally pragmatic/explanatory; 4 – Rather pragmatic; 5 – Very pragmatic. P – Pragmatic; E – Explanatory.
Source: the authors (2024).

We believe that the study's findings will provide insight into the use and effect of real-time visual feedback of the involved side among stroke survivors while walking. Also, it will help in improving the strategies for gait rehabilitation in post-stroke subjects. Further, the add-on of a sagittal plane view of walking may attract future research in the area and will benefit in tailoring of new treadmill-assisted walking programs.

Acknowledgement

The authors would like to thank Alva's College of Physiotherapy and Research Centre, Moodubidire, DK, Karnataka for their constant support. The Authors also extend their thanks to Alva's Education Foundation, Moodubidire, DK, Karnataka and Meenakshi Academy of Higher Education and Research, (MAHER), Chennai, Tamilnadu, India for their guidance and facilities provided.

Authors' contributions

Ranganathan P and Janakiraman B conceived the concept of the study and revised the study protocol. They will write the statistical analysis plan and analyse the data. Ravichandran H, Janakiraman B, and Shetty KS will monitor the data collection. All authors designed the data collection tools and drafted the study protocol.

Conflicts of interest

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

Indexers

The Journal of Physiotherapy Research is indexed by [DOAJ](#), [EBSCO](#), [LILACS](#) and [Scopus](#).



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