

# arm

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### Aims and Scope

*Annals of Rehabilitation Medicine (ARM)* is the official journal of the Korean Academy of Rehabilitation Medicine. It is an international, peer-reviewed open access journal, which aims to be a global leader in sharing up-to-date knowledge dedicated to the advancement of care and enhancing the function and quality of life of persons with various disabilities and chronic illnesses. As the official journal of one of the largest societies of rehabilitation medicine in Asia and Oceania, nearly 8,000 physiatrists receive this journal every two months as a member benefit. This journal is endorsed by the International Society of Physical and Rehabilitation Medicine (ISPRM) and the Asia-Oceanian Society of Physical and Rehabilitation Medicine (AOSPRM). International members comprise approximately half the editorial board and conduct peer-review of submitted manuscripts.

The journal encompasses all aspects of physical medicine and rehabilitation, including clinical practice, experimental and applied research, and education. Research areas covered by this journal include rehabilitation of brain disorders and spinal cord injury; electrodiagnosis; musculoskeletal disorders and pain; pediatric, geriatric, cardiopulmonary, sports, cancer, cognitive, and robotic rehabilitation; neuromodulation; neuroimaging; orthotics and prosthetics; physical modalities; clinical trials; quality of life issues; and basic research, as well as other emerging fields in rehabilitation medicine.

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## Letter to the Editor

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# Letter to the Editor: Eccentric Versus Concentric Exercises in Patients With Rheumatoid Arthritis and Rotator Cuff Tendinopathy: A Randomized Comparative Study

Vanshika Agarwal, BPT, MPT, Jeyanthi. S, BPT, MPT, PhD, Adarsh Sharma, BPT, MPT, PhD

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Dear Editor,

We read the article entitled “Eccentric versus concentric exercises in patients with rheumatoid arthritis and rotator cuff tendinopathy: a randomized comparative study” by Wahba MM, Selim M, Hegazy MM, Elgohary R, Abdelsalam MS with interest. However, we would like to provide some comments regarding its content and methodology reported [1].

Firstly, we would like to draw attention to the title which should be written according to PICO guidelines, it could be reframed as, “To compare the effectiveness of eccentric versus concentric exercises in patients with rheumatoid arthritis and rotator cuff tendinopathy: a randomized clinical trial” [2].

Secondly, we would like to appraise the information provided in the introduction part regarding rotator cuff tendinopathy and its relation to rheumatoid arthritis. Our understanding is expanded by the prevalence, hazard ratio, and a brief discussion of murine models. However, the stated inclusion and exclusion criteria need to be modified. The age bar at which research participants were included and the amount of time since the disease's inception was absent from the inclusion criteria. The presence of deformities like ulnar deviation, boutonniere deformity, swan neck deformity, Z-deformity of thumb, contractures, and limited range of motion, are common in rheumatoid arthritis patients and would make it difficult for them to perform the desired exercises as part of the study intervention, and thus, it is suggested to be added to the exclusion criteria [3]. Nonetheless, we appreciate the authors' reference to the grades of tendinopathy, which clarifies the situation and advances our understanding. The study hypothesis has not been acknowledged by the authors. However, we believe that this should be a two-tailed hypothesis: there might be a significant difference in the efficacy of eccentric and concentric exercises to improve shoulder function, pain, and tendon characteristics in patients with rotator cuff tendinopathy and rheumatoid arthritis, and the null hypothesis could have been there might not be any significant difference in the efficacy of eccentric and concentric exercises to improve shoulder function, pain, and tendon characteristics in patients with rotator cuff tendinopathy and rheumatoid arthritis. Further, the sample size used in the study did not match the calculations made using G\*Power parameters, and the text also lacked a study setting.

Third, it would have been preferable if the number of therapy sessions per week—for exam-

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ple, daily or alternately had been specified.

The data analysis was difficult to comprehend because it was unclear, for which outcome measures parametric or non-parametric tests were used [4]. However, the discussion and results are consistent with other recent evidence that supports the notion that eccentric exercises are superior to concentric exercises in reducing shoulder pain and improving shoulder function in individuals suffering from rotator cuff tendinopathy associated with rheumatoid arthritis.

We are curious about the author's thoughts on these remarks.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## Response: Eccentric Versus Concentric Exercises in Patients With Rheumatoid Arthritis and Rotator Cuff Tendinopathy: A Randomized Comparative Study (*Ann Rehabil Med* 2023;47:26-35)

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Dear Editor,

At the beginning, we would like to thank Professor Agarwal et al. for their comments on the article “Eccentric versus concentric exercises in patients with rheumatoid arthritis and rotator cuff tendinopathy: a randomized comparative study” [1]. Regarding the title, though it is better to include PICO in the title, the CONSORT Statement states that the title should identify the article as a randomized trial, and there is no recommendation regarding the PICO [2]. Regardless, the population is clearly explained in the title “Patients with rheumatoid arthritis and rotator cuff tendinopathy.” In addition, control and intervention are stated clearly in the title “Eccentric versus concentric exercises.” Comparing the recommended title to the actual title, no change found other than language editing. It is also important to highlight that the word effectiveness does not add additional meaning to the title as it did not mention which kind of effectiveness. Thus, “effectiveness” cannot be considered as an outcome.

Regarding inclusion and exclusion criteria, the protocol was registered at the National institute of health (clinicalTrials.gov) with the number NCT05054920 where more details regarding the inclusion and exclusion criteria can be found. Mean age and disease duration were stated clearly in the results section. In addition, statistical analysis showed that our data were homogeneous.

Since the authors excluded any patients “scheduled for rotator cuff surgery, had a rotator cuff full-thickness tear, or had a shoulder fracture, dislocation, or surgery history,” none of the patients included had limited shoulder internal, external rotation or shoulder scaption range less than 90. Thus, the patients were able to perform the exercises. Though rheumatoid arthritis (RA) is known to affect mainly small joints, large joints, including shoulders, are also affected. Large joints are more frequently affected in elderly onset RA [3]. This could explain the reason for our mean age to be 45.20, 43.65 in group 1 and group 2 and why we did not face any patients

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with hand deformity preventing them from using the elastic resistance.

We would like to confirm that the sample size was calculated as mentioned in the article using G\*Power 3.1, where assuming  $\alpha$  (two-sided)=0.05 and  $1-\beta=0.80$  based on a similar study assessing the shoulder function at week 3 (primary outcome of the study). It seems that the letter's authors calculated it based on a different parameter or measurement week. It is important to mention that the sample size was clearly mentioned in the registered protocol at the National Institute of Health (clinical-Trials.gov).

The number of sessions and the duration of treatment were mentioned clearly in the article in the procedure section: "Patients received 12 sessions at a pace of three sessions per week with day after day rate."

We also found that the letter's authors referred to the unit defining each outcome in the tables to identify continuous and ordinal data. All our continuous data were homogenous; thus, all continuous data were parametric. We only used non-parametric tests for ordinal data, which were sex and tendinopathy stages.

As mentioned in the discussion, our data support the idea that eccentric was more effective than concentric in improving shoulder pain and function. However, within the study's time frame, we could not detect any change regarding the tendon characteristics between the two groups. What was interesting was that we found the concentric exercise was beneficial in improving subscapularis tendon characteristics. At the same time, eccentric exercise improved supraspinatus tendon characteristics.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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# Effectiveness of Community-Based Rehabilitation (CBR) Centers for Improving Physical Fitness for Community-Dwelling Older Adults: A Systematic Review and Meta-Analysis

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To synthesise the best available evidence for the effectiveness of interventions delivered in community-based rehabilitation (CBR) centers on physical fitness, for community-dwelling older adults living in Asian countries. This study is a systematic review and meta-analysis. Seven English and two Chinese electronic databases were searched for randomised controlled trials (RCTs) and quasi-experimental studies that were conducted by centers providing CBR. Independent reviewers screened, quality-appraised and extracted data. The primary outcome was physical fitness measured by validated assessment tools, including the Timed Up and Go Test (TUG), gait speed, hand grip strength, Functional Reach Test (FRT), and one-leg standing test. Assessments of activity of daily living and quality of life using tools including the Barthel Index, Short Form (SF)-12, and SF-36 were secondary outcomes. After screening 5,272 studies, 29 studies were included (16 RCTs, 13 quasi-experimental studies) from four countries. Meta-analyses found that CBR programs significantly decreased TUG time (mean difference [MD], -1.89 seconds; 95% confidence interval [95% CI], -2.84 to -0.94;  $I^2=0\%$ ;  $Z=3.90$ ,  $p<0.0001$ ), improved gait speed (MD, 0.10 m/s; 95% CI, 0.01–0.18;  $I^2=0\%$ ;  $Z=2.26$ ,  $p=0.02$ ), and increased one-leg standing time (MD, 2.81 seconds; 95% CI, 0.41–5.22;  $I^2=0\%$ ;  $Z=2.29$ ,  $p=0.02$ ). Handgrip strength and FRT showed no statistically significant improvement in the meta-analyses. CBR may improve aspects of physical fitness for older adults in Asian countries. However, variability in intervention components and measurement tools reduced the ability to pool individual studies. Further trials are required with robust designs including standardised measures of physical fitness.

**Keywords:** Rehabilitation, Physical fitness, Elderly, Community

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## INTRODUCTION

The global population is ageing, with the proportion of older adults (aged 60 years or over) increasing in nearly every country [1]. Managing this change has been identified as a major public health issue in many countries, especially in Asian countries [2]. The United Nations Economic and Social Commission for Asia and the Pacific estimates that the proportion of older adults in Asian countries will increase from 12.4% in 2018 to 25% (1.3 billion) in 2050 [3]. This social phenomenon in Asian countries creates significant challenges for health, economic and social services [4,5].

Taking modifiable (smoking, dietary, and exercise behaviors) and non-modifiable (ageing processes) risk factors together, the prevalence of chronic diseases increases with age [6]. The increasing incidence of chronic diseases, including cardiovascular, neurodegenerative, and metabolic diseases, is associated with a decline in functional ability of older adults [7-9]. Functional ability is defined as “having the capabilities that enable all people to be and do what they have reason to value” and includes basic activities of daily living (ADLs) such as dressing, toileting, and ambulating [10]. Physical fitness is considered an essential component of functional ability and refers to all movement including during leisure or work time [11]. Impaired physical fitness is associated with loss of independence, reduced ability to perform ADL, reduced quality of life and increased mortality [12,13]. Therefore, older adults should be encouraged to maintain and improve their physical fitness to avoid associated loss of functional ability and independence [14]. Rehabilitation interventions, including exercises, occupational therapy, education, and group training, effectively improve physical fitness and performance of ADL of community-dwelling older adults [15,16]. Concurrently, there is established level one evidence that exercise reduces fall rates, improves endurance, range of motion, muscle strength, balance, mental health, functional ability, and health-related quality of life (HRQoL) in older adult populations [17-23]. Hence, effective interventions implemented by health systems that maintaining the physical fitness, functional ability, and reduce rising pressure on health care costs of older adults are important in the context of the ageing population [4,24,25].

Rehabilitation is provided by general or rehabilitation hospitals throughout China for individuals with new or chronic disabilities. However, only approximately 1% of older adults have access to timely, comprehensive rehabilitation services in their

community [26]. To adequately meet the need for rehabilitation services including services for older adults, World Health Organization (WHO) guidelines recommend community-based rehabilitation (CBR) [27,28]. This focus on CBR aims to improve HRQoL for individuals living with disabilities and prevent new disability. CBR utilizes local community resources to deliver a broad range of rehabilitation programs, which are provided by healthcare professionals [29,30]. Previous research has demonstrated that CBR has a positive impact on health and social outcomes in developed Asian countries [31]. However, limitations and barriers to implementing CBR in developing Asian countries have also been described, such as lack of guidelines, insufficient local medical resources, shortages of health care professionals and limited programs being delivered by multidisciplinary teams [32,33].

A systematic review reported that CBR can help to improve both mental and physical function for individuals living with disabilities and improve their HRQoL, however, this review did not use aged-based inclusion criteria [29]. The quality of randomised controlled trial (RCT) that have evaluated providing CBR for ageing populations are relatively low due to small sample sizes, and limited reporting on intervention duration [34-36]. A preliminary search of both the literature and PROSPERO identified no systematic reviews that have evaluated the effectiveness of CBR for improving physical fitness or ADL for community-dwelling older adults, or specifically for older adults in Asian countries [37]. Different countries and regions have different cultures and histories, which may influence the effectiveness of CBR in older adult populations and implementation of CBR may differ in developed regions compared to developing regions of the world. Therefore, the objective of this systematic review was to synthesize the best available evidence for the effectiveness of interventions performed in CBR centers on physical fitness, ADL and HRQoL for older adults living in Asian countries. Findings aimed to inform the ongoing development of CBR in Asia counties and may be useful for other developing countries.

## METHODS

This review was undertaken according to a published protocol [38] and reported following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Supplementary Table S1) [39]. The review was prospectively registered on PROSPERO (CRD42021292088).

### Search strategy

Advice on the search and data sources was provided by a senior health sciences librarian. A three-step search strategy was used that included electronic and manual searches to ensure all published and unpublished literature in English and Chinese was located for the reviews [40]. Preliminary web searches through PubMed, CINAHL and Google Scholar using MeSH terminology [41] aimed to identify similar systematic reviews and relevant keywords. Then, a full text search with identified keywords using seven English electronic databases (CINAHL, MEDLINE, Scopus, ProQuest, Embase and Cochrane Library, and Web of Science), two Chinese electronic databases (China National Knowledge Internet and Wanfang Database) and grey literature (OpenGrey) from inception dates to 1st January 2022 was completed. Searches were re-run on 1st March 2023 to identify any new articles that were eligible for inclusion in the review. Finally, a manual search of the reference lists of all identified publications, including any systematic reviews, was undertaken to identify any additional studies. An example of a search strategy performed on MEDLINE can be found in [Supplementary Table S2](#).

### Inclusion and exclusion criteria

Two independent reviewers (WX and JU for English studies, WX and DX for Chinese studies) screened the titles and abstracts of all identified studies. Studies were included if: participants were community-dwelling adults aged 60 years or over living in 48 Asian countries (including Central, Northern, South-Eastern, Western, and Far East) (<https://www.ncbi.nlm.nih.gov/mesh/68001208>); interventions were programs conducted by centers providing CBR (including physiotherapy, exercise training, exercise, occupational therapy, Chinese traditional therapy, education, and medical services). Studies that evaluated palliative care, rehabilitation in the home or interventions delivered by hospitals, individual community medical practitioners or home visiting nurses were excluded; comparators could be usual or standard care or another intervention such as providing the control group with educational material. Study designs included were RCT and quasi-experimental trials. Case control studies, observational cohort studies, protocols, conference abstracts, qualitative studies, and reviews were excluded. Quasi-experimental studies were included as a source of further evidence [42]. Healthcare interventions may often be evaluated using quasi-experimental studies and preliminary searches had indicated that there were limited numbers of RCT

published that addressed the topic within the geographical region of interest. The Cochrane handbook suggests that, if including non-randomized studies, attention is paid to the study design and addressing risk of bias (ROB) [42]. Quasi-experimental studies were only included if the design included the use of a control group and the ROB of any included quasi-experimental studies was subsequently addressed by using an appraisal tool specific to quasi-experimental studies [43].

### Data extraction and analysis

The primary outcome was physical fitness including Timed Up and Go Test (TUG) [44], gait speed [45], handgrip strength [46], Functional Reach Test (FRT) [47], and one-leg standing test [48]. The TUG measures an individual's ability to balance, sit to stand and walk [44]. Gait speed (the speed at which an individual walks) can be influenced by a number of factors, both voluntary and involuntary, and marks a functional skill that underpins a majority of the tasks that are essential to a person's ability to function on a daily basis [45]. Grip strength is a measure of muscular strength or the maximum force/tension generated by one's forearm muscles which is a screening tool for the measurement of upper body strength and overall strength [46]. FRT aims to measure dynamic balance using one simple task of reaching forward in a standing position [47]. The one-leg standing test is used to assess static postural and balance control [48].

The secondary outcomes were performance of ADL and HRQoL [49,50]. Studies were only included if they measured physical fitness outcomes using validated assessment tools, that included the Barthel Index (BI) [51] and the Short Form (SF)-12 [52] and SF-36 [53].

Joanna Briggs Institute (JBI) critical appraisal tools for RCT and quasi-experimental trials [40] were utilized for assessing the methodological quality of all included studies by two independent reviewers (DX and WX for Chinese articles and AMH and WX for English articles). Any disagreement between the two reviewers was resolved through discussion by all three researchers to reach a consensus.

The standardized data extraction tool from the JBI reviewer's manual was utilized for quantitative data extraction, including publication date, country, participants' baseline characteristics, study setting, methods, type, intensity, and duration of the CBR intervention and data measuring outcomes relevant to physical fitness, ADL and HRQoL [40]. Data extraction was conducted by two independent reviewers (WX and JU) to ensure the accu-

racy of all the extracted data.

### Statistical analysis and data synthesis

All data were subjected to double data entry. The mean and standard deviation of post-intervention quantitative outcome data of the included studies was used for performing meta-analyses [42]. However, studies with baseline differences between the control group and intervention group were omitted from these analyses. Data were entered into Review Manager 5 statistical software and described graphically using forest plots [54]. Study data reported in non-parametric format (median, range or inter-quartile range) or as standard errors were converted to means and standard deviations [55].  $I^2$ -statistics and visual inspection of forest plots were used to assess heterogeneity which was rated as low (25%), moderate (50%) or high (75%) [56]. Sensitivity analyses were performed when high heterogeneity ( $>75\%$ ) occurred. Random effects models were used to calculate effect sizes if there was substantial heterogeneity ( $I^2>50\%$ ); otherwise, a fixed-effects model was used [56]. Treatment effect results were presented as mean difference (MD) with 95% confidence interval (95% CI). Studies unable to be pooled into meta-analysis were reported narratively using tables [57].

We used the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system, recommended by Cochrane, to determine the certainty of evidence for the primary outcome of physical fitness, and presented results in a summary of findings table. The GRADE system categorizes the certainty of the evidence as very low, low, moderate, or high by rating the evidence through consideration of five domains: ROB, inconsistency of results, indirectness, imprecision, and publication bias [58]. The within-study ROB was downgraded by one level if 25% or more of the participants in the comparisons were from included studies with high ROB. The inconsistency of results was assessed by considering heterogeneity of point estimates, 95% CIs, and statistical measures, and was downgraded by one level if there was a wide variation of effect estimates or the  $I^2$  statistic was greater than 50%. In terms of indirectness, the quality of evidence was downgraded by one level if more than 50% of participants differed to the target population. We downgraded the quality of evidence by one level for imprecision if the sample size was less than 400 participants and downgraded two levels if the sample size was less than 200 participants. Due to the small sample sizes and limited numbers of studies we downgraded one level for suspicion of publication bias.

## RESULTS

### Literature search and study selection

The screening and selection of studies included in the review is presented in [Supplementary Fig. S1](#). A total of 5,272 studies were identified through database searches and after final screening, 29 studies met the inclusion criteria. Studies excluded after full text review are summarized in [Supplementary Table S3](#) with reasons for exclusion. Eight English studies [31,59-65] were included in meta-analyses. Twenty-one studies (14 English studies [62,66-78] and seven Chinese studies [34-36,79-82]) were narratively synthesized due to unique outcomes evaluated, or active interventions being delivered to the control groups. The seven Chinese studies [34-36,79-82] included in the narrative synthesis were of very low quality and the outcomes data were unable to be extracted due to absence of information about the mode, frequency and intensity of interventions that were evaluated.

### Study characteristics

The characteristics of the included studies are presented in [Table 1](#). One study was conducted in Israel [67], four in Korea [60,62,70,78], four in Japan [31,61,66,69], and 20 in China [34-36,59,63-65,68,72,73,75-77,79-81,83-86]. There were 16 RCTs [34-36,62,67-70,74,76-81,86], and 13 quasi-experimental studies [31,59-61,63-66,72,73,75,82,83]. The mean sample size of all included studies was  $n=198$  and the mean age of all participants was  $71.65\pm6.34$  years. Nine studies [34-36,67,68,70,73,81,82] recruited older adults with stroke, three studies [65,79,80] recruited older adults with pulmonary dysfunction, four studies [62,63,66,71] older adults with knee pain, and 13 studies [31,59-61,64,69,72,74,75-78,83] included participants with other health conditions, including frailty, functional disability, and heart disease. Of the CBR interventions provided, all 29 studies delivered exercises, 13 studies provided education [34-36,63,65,67,68,77,79-81,83,85], and four studies provided counselling [34,63,68,84]. Eighteen studies [31,34-36,59-61,63,67-69,71,72,75,78-80,85] compared CBR with usual care, five studies [62,66,73,74,83] compared a new CBR intervention with standard CBR medical care or placebo intervention, five studies [64,65,70,76,86] compared CBR with home-based rehabilitation, and two studies [77,81] compared CBR with health education.

### Methodological quality appraisal

The methodological quality rating of the included studies (both



**Table 1.** Characteristics of included studies

| Reference/country             | Design    | Participants   | Primary/secondary outcomes (how measured)   | Intervention group   | Control group                |
|-------------------------------|-----------|--|---|--|------------------------------|
| Cao [81]/China                | Quasi-exp | Stroke survivors (n=70, CBR=35, control=35)  | Physical fitness (FMA)  | Education<br>Exercise <sup>a)</sup>  | Usual care                   |
| Cui and Zhang [80]/China      | RCT       | COPD patients (n=150, CBR=75, control=75)  | Physical fitness (6MWT)   | Education<br>Standardized drug therapy<br>Lung rehabilitation training<br>Exercise <sup>a)</sup>   | Usual care                   |
| Dai [34]/China                | RCT       | Stroke survivors (n=76, CBR=38, control=38)  | Physical fitness (FMA)/ADL (BI)   | Education<br>Exercise<br>Counselling <sup>a)</sup>   | Usual care                   |
| Dun et al. [76]/China         | RCT       | Adults ≥65 pre-frailty (n=43, CBR=21, control=22)  | Physical fitness (2.4-meter Up and Go, 6 min walk distance)                                     | Exercise: 15 min/3×/wk, once every other day/3 mo (stretching exercise and strength exercise)  | Exercise without supervision |
| Gong et al. [68]/China        | RCT       | Hypertensive patients (n=450, CBR=232, control=218)  | Physical fitness (self report physical activity)  | Education, counselling, group exercise: 2×wk/45–60 m/6 mo  | Usual care                   |
| Harel-Katz et al. [67]/Israel | RCT       | Stroke survivors (n=39, CBR=20, control=19)  | Physical fitness (FIM)  | Occupational therapy-based group intervention: 2.5 h/once weekly/12 wk   | Usual care                   |
| Hasegawa et al. [66]/Japan    | Quasi-exp | High risk elderly individuals with motor function decline (n=193, CBR=68, control=125)         | Physical fitness (WOMAC and VAS)  | Exercise: 2 h/per week/12 wk (relaxation of general joints and muscles, strength training, and stretching)   | Only observation             |
| Inokuchi et al. [31]/Japan    | Quasi-exp | ≥5 or more risk factors for fall (n=238, CBR=144, control=124)                                 | Physical fitness (TUG, 9FRT), 5MWT, leg standing test (LST)                                     | Exercise: 2 h/per week/17 wk (stretching and strengthening the hip flexors, hip extensors, hip abductors and quadriceps muscles, balance retraining and cool-down)   | Usual care                   |
| Ji [36]/China                 | RCT       | Stroke survivors (n=74, CBR=35, control=35)  | Physical fitness (FMA)/ADL (BI)   | Education<br>Exercise <sup>a)</sup>  | Usual care                   |
| Kamada et al. [69]/Japan      | RCT       | Adults 40 to 79 years old, (n=3,337, CBR=2,518, control=819)                                   | Physical fitness (regular physical activity)  | Exercise: for 3 yr   |                              |
| Kao et al. [63]/China         | Quasi-exp | Older people who suffered from knee pain, (n=205, CBR=114, control=91)                         | Physical fitness (WOMAC)  | Exercise: 20 m/4 per week (stretching and strengthening)<br>Education: 20 m/4 per week<br>Discussion: 40 m/4 per week  | Usual care                   |
| Kwok and Tong [64]/China      | Quasi-exp | Participants with moderate or severe level of impairment (n=50, CBR=2518, HBR=819)             | Physical fitness (Elderly Mobility Scale [EMS], Berg Balance Scale [BBS]/quality of life SF-12) | Exercise: 60 m 1–2 sessions/w/6 mo (including flexibility, strength, balance, and aerobic exercise with pain management)   | Home-based rehabilitation    |
| Lee et al. [62]/Korea         | RCT       | Older people with osteoarthritis of the knee, (n=44, CBR=29, control=15)                       | Physical fitness (WOMAC/6MWT)/HRQoL (SF-36)   | Exercise: 1 h, 2×/per week/8 wk (Tai Chi Qigong)   | Waiting list control         |
| Lee et al. [78]/Korea         | RCT       | Adults ≥60, (n=80, CBR=40, control=40)   | Physical fitness (angle of ROM)   | Resistance program: 2 h, 3×/per week/12 wk (resistance program using an elastic band)  | Usual care                   |
| Li et al. [74]/China          | RCT       | Older people reside within 15 walking distance from the hospital (n=269, CBR=129, control=140) | Physical fitness (fried frailty criteria [FFC]/ADL [BI])  | 6-month medication adjustment, exercise instruction <sup>a)</sup> , nutritional support, physical rehabilitation, social worker consultation and specialty referrals | Screening evaluation         |

(Continued to the next page)

**Table 1.** Continued

| Reference/country       | Design               | Participants  | Primary/secondary outcomes (how measured)  | Intervention group  | Control group  |
|-------------------------|----------------------|---|--|---|--|
| Liang et al. [77]/China | RCT                  | Currently receiving Taiwan National Health Insurance services (n=733, CBR=382, control=351)                       | Physical fitness (frailty score, handgrip strength, gait speed and physical activity)  | Exercise: 45 m/12 mo (strength, balance, and flexibility)<br>Education: 15 m/12 mo  | Health education lessons   |
| Ota et al. [61]/Japan   | RCT                  | Certified for long term care need at the levels of requiring support (n=46, CBR=24, control=22)                   | Physical fitness (hand grip strength, lower limb strength, one legged standing, functional reach, TUG, timed 10MWT)                  | Exercise: 2×wk/12 wk <sup>a)</sup> (machine training with light resistance)   | Usual care   |
| Ru et al. [73]/China    | Quasi-exp            | Stroke survivors, (n=1,008, CBR=520, control=488)   | Physical fitness (FMA)/social functional activities (BI)   | Group training: 2×wk/1 h/2 yr (technique treatment)   | Usual care   |
| Song et al. [83]/China  | RCT                  | (DEMMI score 39–67) and had gait speed of ≤1 m/s (n=28, CBR=16, control=12)                                       | Mobility (DEMMI), ADL (BI), physical function (SPPB)   | Physical training: 2.5 h group for 10 wk (balance, stretching, pelvic floor exercises, aerobic exercises)<br>Education: 2.5 h for 10 wk   | Placebo treatments   |
| Song and Boo [60]/Korea | Quasi-exp            | Adults ≥65, pre-frail, candidates for home visiting nursing services (n=126, CBR=62, control=64)                  | Physical fitness (TUG, measure of frailty, hand grip strength)   | Exercise, cognitive training, and education for nutrition and disease management<br>Exercise: two 40 m/1×wk/12 wk (stretching, resistance exercises with elastic TheraBands, and aerobic movements) | Usual care   |
| Sun et al. [72]/China   | Quasi-exp            | Adults 65 years and over (n=122, CBR=62, control=60)  | Physical fitness (total fitness score), frailty (Kihon checklist)  | Exercise and music: 1×wk/120 m/12 wk (warm-up, followed by a main body movement, and ended with a relaxation exercise, with a 10-min break between each part)                                       | Usual care   |
| Tong et al. [79]/China  | RCT                  | COPD patients (n=252, CBR=127, control=125)   | Physical fitness (6 min walk distance)   | Education<br>Standardized drug therapy<br>Exercise training (4×wk/30 m/12 wk)   | Standardized drug therapy  |
| Tsang et al. [65]/China | Retro-spective study | Pneumoconiosis patients (n=181, community-based rehabilitation program=155, home-based rehabilitation program=26) | Physical fitness (6 min walk distance)/quality of life SF-12   | Exercise <sup>a)</sup><br>Health education, teaching energy conservation techniques and panic control skills  | Home-based rehabilitation  |
| Wang et al. [71]/China  | RCT                  | KOA (n=189, CBR=103, control=86)  | Physical fitness (five time sit to stand test/WOMAC and TUG)   | Exercise: 30–40 min/3 days/per week/2 wk  | Exercise program guidance without any exercise adherence interventions |
| Yang et al. [59]/China  | Quasi-exp            | Adults ≥65 living in the community (n=90, CBR=45, control=45)   | Physical fitness (SPPB, one leg stance, forward reach, TUG, 10MWT)   | Exercise: 90 min/2×/wk/3 mo (a stick [length 100–110 cm] or trekking pole for substitution, TheraBand, sandbag and a small ball led by a physical therapist)  | Usual care   |
| Yoo and Yoo [70]/Korea  | Quasi-exp            | Stroke survivors (n=28, CBR=14, control=14)   | Physical fitness (Wolf Motor Function Test (Korean version), Motor Activity Log (Korean version)/quality of life (stroke short form) | Supervised exercise: 3 day×per week/70 m/24 wk (walking, stretching, muscular relaxation exercises, functional tasks)   | Self-monitored exercise  |

(Continued to the next page)

**Table 1.** Continued

| Reference/country       | Design    | Participants  | Primary/secondary outcomes (how measured)                 | Intervention group  | Control group |
|-------------------------|-----------|---|---|---|---------------|
| Yu [82]/China           | Quasi-exp | Stroke survivors (n=76, CBR=38, control=38)   | Functional ability (FMA)/ quality of life SF-36, ADL (BI) | Education<br>Physical exercise <sup>a)</sup>                                  | Usual care    |
| Zhang et al. [75]/China | RCT       | Patients with a recent coronary event defined as acuter myocardial infarction (MI), (n=126, CBR=57, control=69) | Functional ability (6MWT)/ quality of life (SF-12)        | Exercise: 6 day per week/ 20–40 m/6 mo (warm-up, aerobic training, cool down) | Usual care    |
| Zhu [35]/China          | RCT       | Stroke survivors (n=130, CBR=65, control=65)  | Functional ability (FMA)/ ADL (BI)                        | Education<br>Exercise <sup>a)</sup>   | Usual care    |

FMA, Fugl-Meyer Assessment; RCT, Randomised Controlled Trial; COPD, chronic obstructive pulmonary disease; 6MWT, 6-Minute Walk Test; CBR, Community-based Rehabilitation; ADL, Activity of Daily Living; BI, Barthel Index; FIM, Functional Independence Measure; WOMAC, Western Ontario and McMaster; VAS, visual analogue scale; TUG, Timed Up and Go Test; FRT, Functional Reach Test; SF, Short Form; HRQoL, health-related quality of life; ROM, range of movement; DEMMI, de Morton Mobility Index; SPPB, Short Physical Performance Battery; KOA, Knee Osseous Archrophlogosis.

<sup>a)</sup>No detailed information provided in the study.

RCT and quasi-experimental studies) is presented in [Supplementary Tables S4, S5](#) and summarized in [Supplementary Figs. S2-S5](#). Overall, the ROB for items including random sequence generation and reporting bias was considered low for the included RCT. The ROB due to participants not being blinded to the intervention was rated as high for 14 studies. Six quasi-experimental studies were judged to be of low quality due to inappropriate statistical analyses. The certainty of evidence for the primary outcome of physical fitness measured by GRADE system is presented in [Table 2](#).

### Effectiveness of interventions

#### Primary outcome – physical fitness

Physical fitness was measured by 31 different assessment tools. Seventeen assessments tools were used by more than two studies, and five of these assessment tools: TUG [31,59-61,66,76], gait speed [31,59,61,62], handgrip strength [31,60,61,87], FRT [31,59,61], and one-leg standing time [31,59,61] were pooled in meta-analysis. Findings from five studies that assessed motor function of older adults with stroke, using the Fugl-Meyer motor function assessment [34-36,81,82] were presented as an unpooled forest plot. Findings from the remaining studies were narratively synthesized in [Supplementary Table S6](#).

#### TUG

Six studies [31,59-61,66,76] evaluated the effectiveness of a CBR program (exercise, including both strength and balance training) on physical fitness using the TUG. Four studies were included in the meta-analysis (493 participants) [31,59-61]. Results demon-

strated that older adults receiving CBR exercise programs made significant improvement in the TUG compared to usual care (MD, -1.89 seconds; 95% CI, -2.84 to -0.94;  $I^2=0\%$ ;  $Z=3.90$ ,  $p<0.0001$ ), with no statistical heterogeneity found ([Fig. 1](#)).

#### Gait speed

Six studies [31,59,61,62,66,77] evaluated the effectiveness of a CBR program (exercise) on gait speed and four studies [31,59,61,62] were pooled in meta-analysis ( $n=397$  participants), and no statistical heterogeneity was found. A statistically significant difference was found between the two groups (MD, 0.10 m/s; 95% CI, 0.01–0.18;  $I^2=0\%$ ;  $Z=2.26$ ,  $p=0.02$ ; [Fig. 2](#)).

#### Handgrip strength

Five studies measured handgrip strength [31,60,61,66,77] and three of these studies [31,60,61] were pooled in meta-analysis. In 2007, Inokuchi et al. [31] investigated the effect of CBR (exercise) on handgrip strength on both participants' left and right sides but only the right side was pooled in meta-analysis. The heterogeneity was moderate and there was no statistically significant difference between the two groups (MD, 1.39 kg; 95% CI, -0.89 to 3.66;  $I^2=73\%$ ;  $Z=1.20$ ,  $p=0.23$ ; [Fig. 3](#)).

#### One-leg standing time

Four studies [31,59,61,76] evaluated the effect of a CBR program (exercise) on one-leg standing time; three studies ( $n=353$  participants) [31,59,61] were pooled in meta-analysis. The results were homogenous and a significant difference in one-leg standing time was found between the groups (MD, 2.81 sec-

**Table 2.** Summary of findings of GRADE: the effectiveness of CBR on physical fitness

| CBR compared with control (e.g., usual care)  |  |  |   |                               |                                      |  |
|---|--|--|---|-------------------------------|--------------------------------------|--|
| Participants or population: older population aged over 60                               |  |  |   |                               |                                      |  |
| Setting: community-based health service center or community-based rehabilitation center |  |  |   |                               |                                      |  |
| Intervention: community-based rehabilitation  |  |  |   |                               |                                      |  |
| Comparison: non-provision control <sup>a)</sup>   |  |  |   |                               |                                      |  |
| Outcome: physical fitness <sup>b)</sup>   |  |  |   |                               |                                      |  |
| Outcomes of physical fitness  | Anticipated absolute effects <sup>c)</sup> (95% CI)                    |  | Absolute relative effect <sup>c)</sup> (95% CI) | No. of participants (studies) | Certainty of the evidence (GRADE)    | Comments   |
|   | Assumed risk Control   | Corresponding risk Intervention                      |   |                               |                                      |  |
| Functional ability-TUG (lower score=faster)<br>Follow-up: range 12 to 17 wk             | The mean TUG time (sec) in the control group was 13.32                 | MD, 11.7 sec faster (8.29 sec faster to 17.9 slower) | MD, -1.89 (-2.84, -0.94)                        | 493 (4 RCTs)                  | ⊕⊖⊖⊖<br>Very low <sup>d),e),f)</sup> | Long term exercise intervention and strengthening training in all studies may increase TUG and the 95% CI shows all faster in TUG                                |
| Physical fitness-gait speed (m/s)<br>Follow-up: range 8 to 17 wk                        | The mean gait speed (m/s) in the control group was 0.82                | MD, 0.91 faster (0.6 slower to 1.12 faster)          | MD, 0.10 (95% CI, 0.01–0.18)                    | 397 (4 RCTs)                  | ⊕⊖⊖⊖<br>Very low <sup>d),e),f)</sup> | Long term exercise intervention and resistance training in all studies may increase gait speed and the 95% CI shows all increase in gait speed                   |
| Handgrip strength<br>Follow-up: range 12 to 17 wk                                       | The mean handgrip strength (kg) in the control group was 19.3          | MD, 22.3 higher (19.9 lower to 25.5 higher)          | MD, 0.30 (95% CI, 0.10–0.51)                    | 360 (3 RCTs)                  | ⊕⊖⊖⊖<br>Very low <sup>d),e),f)</sup> | Long term exercise intervention and strengthening training in all studies may increase gait speed and the 95% CI shows all increase in handgrip strength         |
| Balance-one-leg standing test<br>Follow-up: range 12 to 17 wk                           | The mean one-leg standing test (seconds) in the control group was 9.05 | MD, 11.81 higher (9.23 lower to 13.7 higher)         | MD, 2.81 (95% CI, 0.41–5.22)                    | 353 (3 RCTs)                  | ⊕⊖⊖⊖<br>Very low <sup>d),e),f)</sup> | Long term exercise intervention and strengthening training in all studies may increase gait speed and the 95% CI shows all increase in one leg standing test     |
| Balance - FRT<br>Follow-up: range 12 to 17 wk   | The mean FRT (cm) in the control group was 19.33                       | MD, 22.3 further (19.9 shorter to 25.5 further)      | MD, 0.42 (95% CI, 0.00–0.83)                    | 360 (3 RCTs)                  | ⊕⊖⊖⊖<br>Very low <sup>d),e),f)</sup> | Long term exercise intervention and strengthening training in all studies may increase gait speed, however, the 95% CI shows both no improve and increase in FRT |

GRADE Working Group grades of evidence.

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

GRADE, Grading of Recommendations, Assessment, Development, and Evaluations; CBR, community-based rehabilitation; 95% CI, 95% confidence interval; TUG, Timed Up and Go Test; MD, mean difference; RCT, randomised controlled trial; FRT, Functional Reach Test.

<sup>a)</sup>A non-provision control is defined as no intervention, usual care, sham exercise (the exercise was intended to be a control or appeared to be of insufficient intensity and progression to have beneficial effects on mobility) or a social visit.

<sup>b)</sup>Physical fitness, measuring the ability of a person to move. Scales may measure a number of aspects of mobility (e.g., TUG, gait speed, and balance).

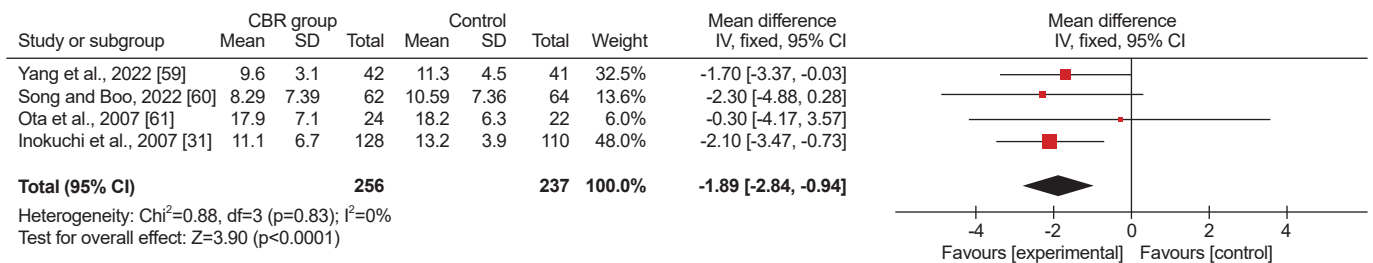
<sup>c)</sup>The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). The absolute relative effect (and its 95% CI) is based on the relative effect between the intervention and control.

<sup>d)</sup>Downgraded one level for risk of bias (non-RCT).

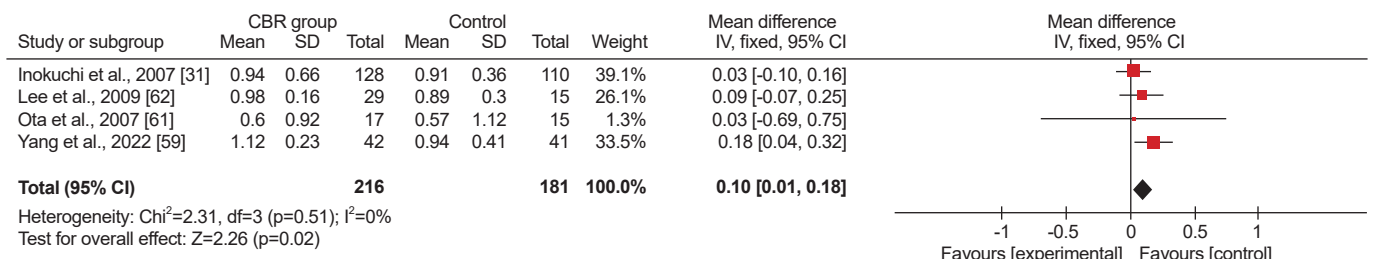
<sup>e)</sup>One level for indirection (different duration of intervention), and one level for imprecision (sample size<400).

<sup>f)</sup>One level for imprecision (sample size<400).

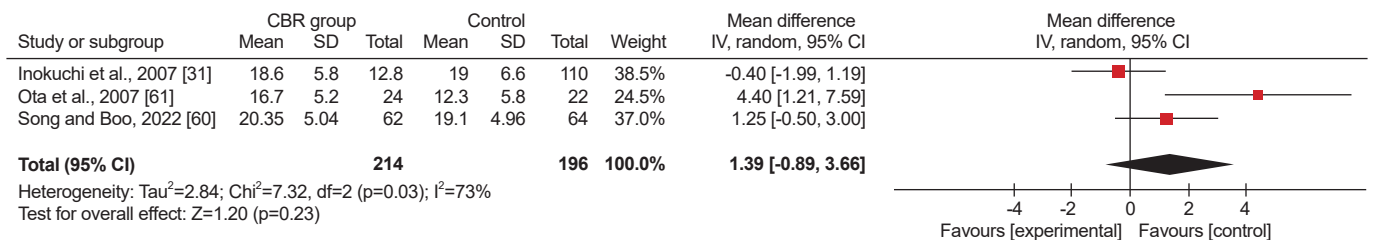




**Fig. 1.** Effects of CBR program on TUG. Values are in second. CBR, community-based rehabilitation; TUG, Timed Up and Go Test; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 2.** Forest plot of the effects of CBR on gait speed. Values are in meter per second (m/s). CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 3.** Forest plot of the effects of CBR on handgrip strength. Values are in kilogram. CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.

onds; 95% CI, 0.41–5.22;  $I^2=0\%$ ;  $Z=2.29$ ,  $p=0.02$ ; Fig. 4).

### FRT

Three studies [31,59,61] (360 participants) evaluated physical fitness using the FRT and were pooled in meta-analysis. Pooled results (moderate heterogeneity) showed no significant changes in FRT distance between the CBR (exercise) groups and usual care groups (standard MD, 0.42 cm; 95% CI, 0.00–0.83;  $I^2=64\%$ ;  $Z=1.96$ ,  $p=0.05$ ) after the intervention (Fig. 5).

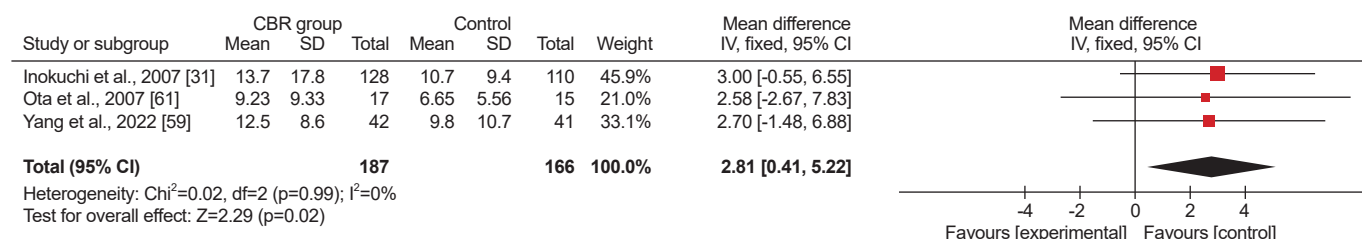
### Fugl-Meyer Assessment

Changes in motor function in older adults who received CBR (stroke exercise and health-related education) after stroke (mea-

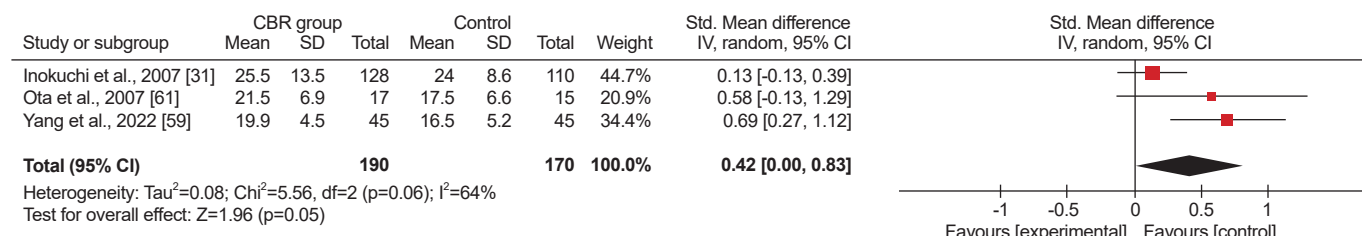
sured using the Fugl-Meyer Assessment, FMA) compared to a control group who received usual care alone were evaluated in five studies [36,80–82,88]. All five studies reported a significant improvement in the FMA in the CBR group compared to the control group after the intervention [34–36,81,82]. Results were presented using an un-pooled forest plot, because the intervention durations were not reported in these studies and the quality of the evidence for findings for physical fitness outcomes was rated as very low (Fig. 6).

### Secondary outcomes-performance of ADLs

Six studies evaluated the effectiveness of CBR (exercise and health education) on older adults' performance of ADL (using



**Fig. 4.** Forest plot of the effects of CBR on one-leg standing time. Values are in second. CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 5.** Forest plot of the effects of CBR on Functional Reach Test. Values are given centimeter. CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.

the BI) compared to usual care alone. Results were presented using an un-pooled forest plot (Fig. 7). Studies could not be pooled due to methodological problems, including that some studies did not provide information about the intervention duration, the method of randomization or whether data were examined for normality [89].

#### Secondary outcomes-HRQoL

Six studies evaluated the effectiveness of CBR on HRQoL [62-65,70,81]. Three assessment tools were used for evaluating HRQoL, and two of these tools (SF-36 and SF-12) were used by more than two studies.

Two studies evaluated the effectiveness of CBR (exercise) on HRQoL (using the SF-36) [62,63] for older adults with knee osteoarthritis and the pooled analysis of these two studies found homogenous effects (non-significant) favoring the CBR intervention group (MD, 8.74; 95% CI, -2.71 to 20.18;  $I^2=0\%$ ;  $Z=1.50$ ,  $p=0.13$ ; Fig. 8).

Two studies [64,65] evaluated the effect of CBR (exercise, education, and occupational therapy) on HRQoL (measured using SF-12) between two groups compared to a group receiving home-based rehabilitation. Pooled results demonstrated no significant differences between the groups (MD, 2.32; 95% CI, -1.99 to 6.64;  $I^2=66\%$ ;  $Z=1.06$ ,  $p=0.29$ ; Fig. 9).

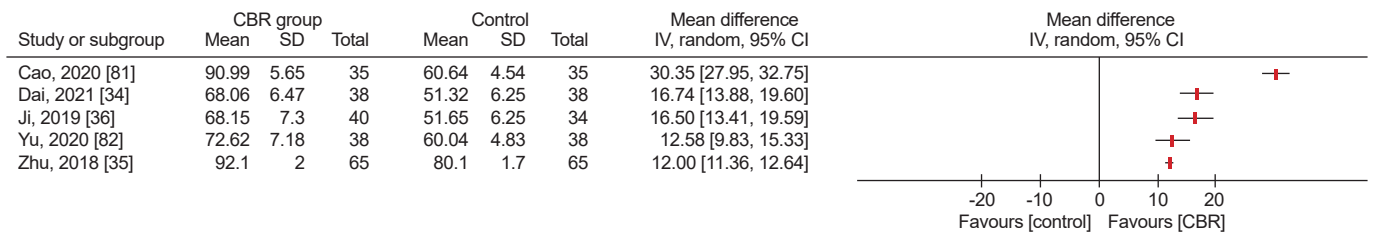
#### Other outcomes-narrative synthesis

Findings from 17 studies reporting physical fitness assessments [31,61,64-70,72-77,83,86] and four studies [67,70,73,75] reporting secondary outcomes of HRQoL and ADL were not able to be pooled in meta-analysis. These studies were synthesized narratively (Supplementary Table S6).

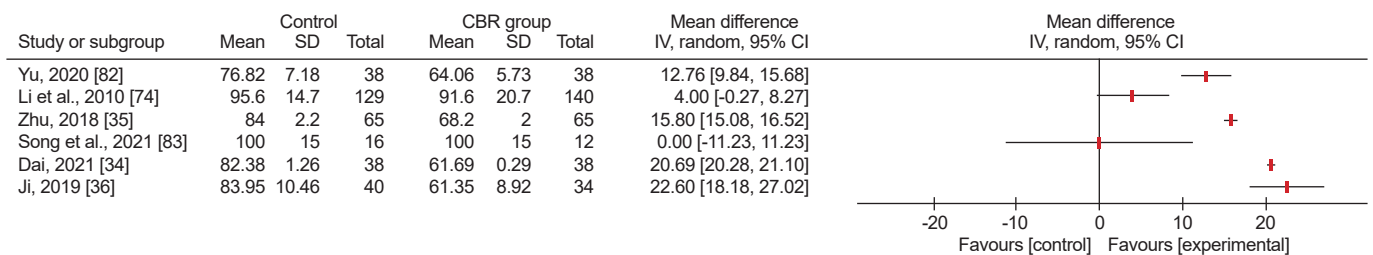
## DISCUSSION

This systematic review synthesized the best available evidence for the effectiveness of CBR for improving physical fitness in community-dwelling older adults living in Asian countries. Results indicated that CBR significantly improves aspects of older adults' physical fitness, including functional ability (TUG), gait speed, and balance function (one-leg standing test) but there was no significant improvement in strength (handgrip strength).

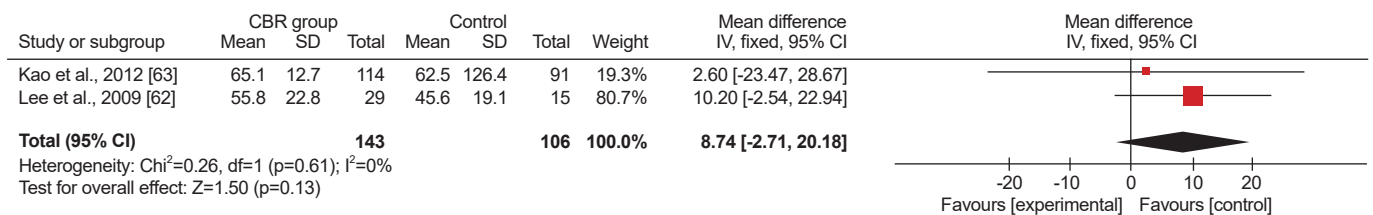
The pooled results showed that compared with usual care, CBR (multi-component exercise programs) can significantly improve the functional ability (TUG time) of community-dwelling older adults. The improvement in the TUG outcome (-1.89 seconds) reached clinical significance (the minimal clinically important difference [MCID] reported for the TUG is 1.2 seconds) [90]. This positive result is possibly due to the pooled studies were all being conducted in Eastern Asia (Japan,



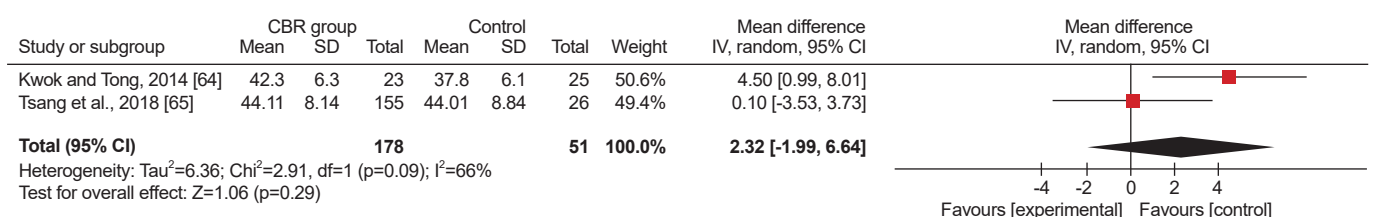
**Fig. 6.** Forest plot (un-pooled) of the effects of CBR on physical fitness Fugl-Meyer Assessment on older adults with stroke. Values are given point. CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 7.** Forest plot (un-pooled) of the effects of CBR measured using the Barthel Index. Values are given point. CBR, community-based rehabilitation; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 8.** Forest plot of the effects of CBR on health-related quality of life (SF-36) on older adults. Values are given point. CBR, community-based rehabilitation; SF, Short Form; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.



**Fig. 9.** Forest plot of the effects of CBR on health-related quality of life (SF-12) on older adults. Values are given point. CBR, community-based rehabilitation; SF, Short Form; SD, standard deviation; IV, inverse variance; 95% CI, 95% confidence interval; df, degrees of freedom.

Korea, and China), and having intervention duration of (12–17 weeks) [31,59–61]. These studies delivered similar intervention components, including strength training as part of the super-

vised-group exercise intervention. These findings concur with Dun et al. (2022) [76], which utilized 2.4-meter Up and Go test and showed a CBR program (supervised exercise) significantly

improved 2.4 m TUG compared with un-supervised exercise ( $p<0.05$ ). Another un-pooled study, Hasegawa et al. (2013) [66], compared TUG time between genders only in the CBR (strength and balance exercise) group. Findings demonstrated significantly improved TUG time in female participants ( $p=0.01$ ), but not in males ( $p=0.82$ ). These differing results may be due to the unequal and small sample size of each between genders ( $n=60$  in female,  $n=8$  in male). Moreover, Hasegawa et al. (2013) [66] failed to compare the TUG time between the CBR intervention group and the un-supervised exercise group.

Walking is an important activity for maintaining and improving physical fitness and an essential component of older adults' functional ability [91]. Normative age-related values for gait speed indicate an older adult have effective functional ability to engage in their community and slow gait speed is predictive of negative health outcomes like incident health events, increased length of stay when hospitalized, postoperative morbidity, and death [91,92]. The pooled MD for gait speed was 0.10 m/s which was a clinically significant improvement (MCID for gait speed is 0.10–0.17 m/s) [91]. This pooled result was supported by Liang et al. (2021) [77] who found participants in the “normal cohort” who received the CBR intervention (multidomain intervention including physical and cognitive training, nutritional advice, and health education) showed significant improvement compared with health education only.

Handgrip strength is also an important indicator of frailty and functional decline, and is associated with overall strength in ageing adults. [93,94] Previous systematic reviews reported the MCID of handgrip strength as ranging from 5.0 to 6.5 kg and 2.44 to 2.6 kg. [92,95] However, these two systematic reviews did not provide information specifically for older adults. Our pooled results demonstrated that undertaking CBR programs resulted in no statistically or clinically significant improvement in handgrip strength. This negative finding possibly due to the small number of studies included. Two un-pooled study reported significant improvement on handgrip strength. Hasegawa et al. (2013) [66] found a CBR program significantly improves handgrip strength in female participants. Liang et al. (2021) [77] reported that physical and cognitively declined older adults who completed a CBR program showed significant improvement in handgrip strength compared to the control group after the intervention. However, due to the low quality of study designs and different inclusion criteria these two studies were not able to be pooled in meta-analysis.

Impaired balance is a strong predictor of falls in older adults

[96]. Pooled results for assessment of balance using one-leg standing time found statistically and clinically significant improvement in the CBR (exercise) group compared to the usual care group (MCID for one leg standing time is 2.0 seconds) [97]. Although the meta-analysis did not demonstrate a significant difference in balance between the CBR group and the control group (as measured by FRT) the pooled result showed that after the intervention, the FRT result in the CBR group was improved compared to baseline measurements. Balance improvements were also reported by two Chinese studies that compared CBR (exercise) with home-based rehabilitation (exercise) [64,83]. These two studies found significant improvements in balance in the CBR group (measured using the Berg Balance Scale and the Short Physical Performance Battery) [64,83]. However, these two studies could be pooled in meta-analysis due to the different outcome measurements and use of interventions in the control group.

Overall, the modest clinically significant improvement observed in pooled analyses of physical fitness may indicate that the CBR programs provided were not sufficiently intensive for older adults. Healthcare professionals who deliver CBR should design and deliver programs for older adults that are informed by relevant guidelines, such as the WHO guidelines for physical activity for older adults [27]. Some interventions with comprehensive programs included weekly group exercise classes, containing integrated strength and balance exercises, and supervised by professional healthcare staff [31,61,66,77]. Previous systematic reviews have found that community-based group exercise programs provided by healthcare professionals have better adherence compared with individual physical activities, since group exercise programs provide regular, structured, and supervised exercise opportunities which can improve exercise motivation, and provide peer support [98,99].

Un-pooled analysis of studies evaluating ADL showed improvements in the BI of between 4 and 22 points. The MCID of the BI in older patients with femur fracture has been estimated to be 9.8 points [100], therefore this was a clinically important improvement in some studies [34–36,82,83]. This evidence was of low quality as some studies could not be pooled due to insufficient data regarding intervention duration and randomization methods, which ultimately increases the uncertainty of the results.

Appraisal of the certainty of evidence according to GRADE indicated very low-quality results for each outcome and should be interpreted cautiously. There was moderate ROB found in six studies, and indirectness, imprecision and inconsistency were rated as serious for all outcomes because the pooled stud-



ies used different intervention durations, had small sample sizes and participants had mixed diagnoses. CBR could adopt older adults' exercise guidelines and standardized delivery and assessment tools could be utilized by researchers, to facilitate robust evaluation of the effectiveness of CBR for improving older adults' physical fitness. Interventions should also be designed using evidence-based guidelines that are relevant for older adults' physical fitness, including physical activity, fall prevention and frailty guidelines [101,102], to be sure they are of sufficiently intensity.

### Limitations of the review

Firstly, the relatively small number of studies included in the review suggest that there is a gap in the published evidence for the effectiveness of CBR programs for older adults in Asian countries. Only four countries, including China, Japan, Korea, and Israel, were represented in the review. Findings may not be generalizable for all developing countries in Asia, because differing government policies, available CBR services and cultural context may influence the effectiveness of CBR programs.

Secondly, since GRADE approach was used to rate the certainty of the evidence, this identified that study heterogeneity caused by differing designs reduced the certainty of the findings and limited recommendations that could be made.

Therefore, future studies should use larger sample sizes and robust designs to evaluate the efficacy of CBR programs for improving physical fitness, as well as ADL and HRQoL. Further research comparing the effectiveness of CBR with inpatient rehabilitation or home-based programs on physical fitness would also assist to determine how to effectively increase delivery of evidence-based physical fitness programs for older adults in Asian countries.

## CONCLUSION

Chronic diseases in the increasing ageing populations in Asia are associated with a decline in functional ability that results in loss of independence and increasing use of health care services. Programs for older adults that focus on maintaining or improving physical fitness and functional ability and are accessible to older adults in their local community are required to be scaled up. Older community-dwelling adults who completed CBR programs made improvements in some aspects of physical fitness, including functional ability. However, few CBR programs comprehensively addressed physical fitness, such as including elements of strength,

balance, and aerobic activity of sufficient intensity, alongside ADL training where required and relevant behavior change support. Research recommendations include using rigorous study designs that include larger sample sizes, validated assessment tools for older adults, interventions of sufficient intensity and describing the intervention components clearly. Further research to design and evaluate CBR programs for community-dwelling older adults in Asian countries is required.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Xin W. Methodology: Hill AM, Xu D, Xin W, Dou Z. Formal analysis: Xin W, Jacques A, Umbella J. Funding acquisition: Hill AM, Xin W, Dou Z. Project administration: Hill AM, Xu D, Xin W, Dou Z. Visualization: Hill AM, Xu D, Xin W, Dou Z. Writing – original draft: Xin W. Writing – review and editing: Hill AM, Xu D, Dou Z. Approval of final manuscript: all authors.

## AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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## SUPPLEMENTARY MATERIALS

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# The Korean Version of the Oxford Cognitive Screen (K-OCS) Normative Study

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**Objective:** To generate a Korean version of the Oxford Cognitive Screen (K-OCS) and obtain cutoff scores that determine the impairment of each subdomain. Post-stroke cognitive impairment (PSCI) negatively impacts the rehabilitation process and independence in daily life. Its obscure manifestations require effective screening for appropriate rehabilitation. However, in most rehabilitation clinics, psychological evaluation tools for Alzheimer's dementia have been used without such considerations. The OCS is a screening assessment tool for PSCI and vascular dementia that can evaluate the cognitive domains most often affected by stroke, including language, attention, memory, praxis, and numerical cognition. It comprises 10 subtasks and enables quick and effective cognitive evaluation.

**Methods:** The K-OCS, which considers Korea's unique cultural and linguistic characteristics, was developed with the approval and cooperation of the original author. Enrollment of participants without disabilities was announced at Duksung Women's University, Yongin Sevrance Hospital, CHA Bundang Medical Center. The study was conducted between September 2020 and March 2022 on 97 male and female participants aged ≥30 years.

**Results:** All the 97 participants completed the task. In this study, the 5th percentile score was presumed to be the cutoff value for each score, and the values are provided here. The cutoff score for each OCS subtask was similar to that of the original British version.

**Conclusion:** We suggest the usability of the K-OCS as a screening tool for PSCI by providing the cutoff value of each subtask.

**Keywords:** Oxford Cognitive Screen, Cognition, Domain, Stroke, Neuropsychological assessment

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## INTRODUCTION

In Korea, one in forty adults is reported to have a history of stroke; in addition, 232 subjects per 100,000 have a stroke every year [1]. Stroke is the leading cause of disability worldwide, and patients manifest various neurological symptoms according to

their brain lesions. Although paralysis and severe aphasia are relatively common, post-stroke cognitive impairment (PSCI) remains highly prevalent and disabling [2]. Previous reports on cognitive deficits after stroke show inconsistent results, reporting prevalence in approximately 10%–91.5% of all the patients with a history of stroke [3–6]. This wide range in the preva-

lence of PSCI is attributable to various evaluation times and differences in the demographic characteristics of participants between the studies. However, the lack of a global standard evaluation tool for PSCI has been identified as the main cause of discordant outcomes [7].

According to the World Health Organization's 2018 Wilson-Jungner criteria guidelines, all stroke survivors should undergo cognitive and emotion screening [8]. However, there has been little consensus on assessment tools to evaluate PSCI [9]. To date, the most frequently used cognitive evaluation tools for PSCI are the Mini-Mental State Examination [10] and Montreal Cognitive Assessment (MoCA) [11], which were primarily developed to assess Alzheimer's disease [12,13]. Consequently, the specificity and sensitivity of these tools cannot be used to determine the cognitive status of stroke survivors [14]. Conventional screening tools for dementia not only fail to evaluate typical PSCI but may also present deviated reports affected by frequent impairments in stroke, including language and visual perception. Therefore, a specialized screening tool is urgently required to identify PSCI.

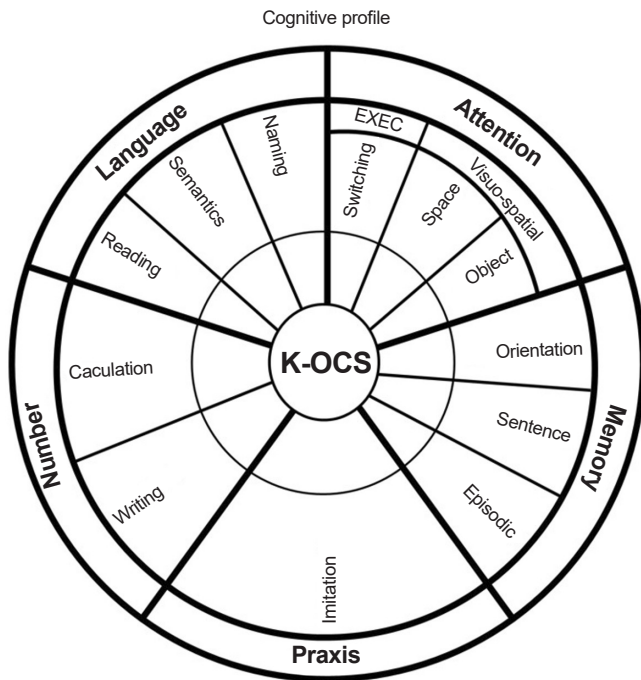
The Oxford Cognitive Screen (OCS) was developed in the United Kingdom (UK) to detect PSCI and vascular dementia.

It evaluates five cognitive domains, namely, attention, language, number, praxis, and memory, and is composed of 10 tasks [15,16]. The tasks are described in detail in Table 1. The OCS has several strengths that make it more suitable for post-stroke patients than other options: (a) it can be administered briefly and is available at bedside; (b) the material provides multiple-choice questions, allowing patients with speech impairment to answer by pointing; and (c) a stimulus is simultaneously linked to several tasks, which maximizes time efficiency [17]. Another advantage of this tool is the resultant "visual snapshot" (Fig. 1) of the cognitive profiles of a patient, which enables an understanding of overall cognitive characteristics and communication within a multidisciplinary team. In addition, it can facilitate figuring out the cognitive status of a patient for the family. The OCS was validated in the British population with high specificity [15]. Subsequently, its validation studies have been conducted in Italy, Hong Kong, Russia, Denmark, Portugal, Belgium, and Australia [18-24].

The primary aim of this study was to develop a Korean version of the OCS (K-OCS) that considers the cultural and linguistic features of Korea. We also aimed to provide a cutoff score for each task by obtaining percentile data to screen for

**Table 1.** Description of tasks of each domain in Korean version of the Oxford Screening (K-OCS)

| Domain                | Task                         | Description  |
|-----------------------|------------------------------|--|
| Language (expressive) | Picture naming               | The patient is presented with 4 pictures of objects separately and asked to name each object   |
| Language (receptive)  | Semantics                    | The patient is presented with 4 pictures of objects at the same time and asked to point one that belongs to the "semantics" task the examiner had asked  |
| Language (expressive) | Sentence reading             | The patient is presented with a sentence with 14 syllables arranged in 4 rows on the center of the page and asked to read out loud the sentence. If the patient is unable to read due to speech impairments, the examiner read the sentence with pointing each word that are read simultaneously to help the patient remember the sentence                               |
| Memory                | Orientation                  | The patient is asked to respond to questions about time and place either by uttering free response or pointing one from the multiple-choice options in the booklet   |
| Memory                | Recall & recognition         | The patient is asked to recall the sentence he read or the examiner read to him earlier. If he failed to recall all of the target words, he is presented with multiple options to make him recognize them  |
| Numerical cognition   | Number writing & calculation | In "number writing" task, the patient is given a paper and pencil and asked to write down the numbers in figures that the examiner said. In "calculation" task, the patient is asked to mentally calculate and give answers by either uttering free response or choosing one from the multiple options in the booklet  |
| Attention             | Hearts cancelation           | The patient is asked to find and cross out the hearts without any gaps among all the hearts with a gap either in right or left side and without gap scattered on the worksheet   |
| Executive function    | Executive task (mixed)       | There are two subtasks: (1) in "simple task," the patient is asked to connect either circles or triangles scattered randomly on the worksheet in the order that the figures get smaller successively; (2) in "complex task," the patient is asked to connect circles and triangles altogether by alternating between the two shapes from the largest to the smallest one |
| Praxis                | Imitation                    | The patient is asked to copy the examiners' meaningless gestures using his dominant hand   |
| Visual perception     | Visual field                 | The examiner raises both hands upper fields and wave either left or right hand gently. The same procedure is followed for the lower fields. At the time, the patient is asked to fix their gaze at the examiner's nose and asking to wiggle the fingers of the left or right hand  |



**Fig. 1.** Visual snapshot Korean version of the Oxford Cognitive Screen (K-OCS) cognitive profile. EXEC, executive.

cognitive impairment in the domain [25]. Additionally, the criteria were compared with those of previous large-scale validation studies to verify the validity of the K-OCS.

## METHODS

### Characteristics of the OCS scoring system

The OCS was comprehensively designed for aphasia and neglect symptoms. This was achieved by adopting short high-frequency words, forced-choice testing procedures, vertical layouts, and multimodal presentations. It uses some tasks intended to assess more than one domain. For example, the “reading” task is used not only for memory but also for neglect symptoms. This feature was attributed to the short administration time of the OCS (within 15 minutes) to complete. It can also be administered from the acute phase of stroke, three days after onset. The original author, Nele Demeyere, specified minimum target number of subjects as 60 for statistically valid standards in the translation and linguistic validation process [26].

As for the criteria to determine impairment, the OCS uses 5th-percentile cutoffs. Mostly, the scores of  $\leq 5$ th percentile represent impairment. However, according to the task, the scores of  $\geq 95$ th percentile in the following three tasks also indicate

impairment: (1) “space asymmetry,” (2) “object asymmetry,” and (3) “executive function total” scores. In the “space and object asymmetry” tasks, which detect neglect, high positive and negative scores represent left and right spatial neglect, respectively. Thus, both the 5th percentile and 95th percentile could be used as criteria for the norm in these tasks.

In “executive function” tasks, which have four sorts of scores, stimuli are composed of seven circles and triangles each, which might distract examinees. One point is assigned to each correct connection. The next point is given if the subject correctly completes the connection on the next try, even for existing errors at some points in the previous line connection drawing. Therefore, the maximum number of points was six each for circle and triangle connections. Moreover, the alternative circle and triangle connecting task, the “executive (mixed)” task (maximum of 13 points) is to be followed. Then, the “executive function total” score can be obtained by subtracting the “executive (mixed)” score from the sum of scores in the “executive (circles)” and “executive (triangles)” tasks. The higher the score of the task, the greater the loss of executive function; thus, the score of the 95th percentile is the cutoff score.

### Development of the K-OCS test

Two licensed clinical psychologists in their psychology PhD program, who were proficient in English, translated the original OCS [15], and another clinical psychology specialist who received a PhD in the United States conducted a reverse translation without reading the original version. The original writer, Nele Demeyere at Oxford University, assisted with the entire translation process and provided the final approval.

The basic structure of the test and the scoring rules of the original version were applied to the K-OCS without any changes. However, as this study aimed to adapt the OCS to Korean culture and language characteristics, some objects and words were replaced. A pilot study was conducted with 15 adult participants without disabilities, and a few nationality-adapted modifications were made. The first modification was required for the “picture naming” task in the language domain. The objects provided for the naming test should be challenging enough for patients with cognitive impairments but, simultaneously, familiar enough to be recognized. Some of the objects in the original version, such as “pear” and “filing cabinet,” were reported to be unfamiliar to most of the participants, especially to people older than 40 years who were expected to be the main subjects of this test. To select valid figure objects as options, we performed a

validation study on the major candidate age population. Correct answer rates for the five candidate objects in the pilot test, “hippopotamus,” “watermelon,” “axe,” “pomegranate,” and “fire extinguisher” were 87.5%, 100%, 100%, 72.4%, and 87.5%, respectively (n=15). As the test is supposed to measure one’s naming function in usual daily living, rather than knowledge level, the word with accuracy under 80%, that is, “pomegranate” was excluded. The final selected number of the items was four—“hippopotamus,” “watermelon,” “axe,” and “fire extinguisher”—similar to the original version.

The second modification was made for the “reading” task of the language domain and the “recall and recognition” task in the memory domain, both of which used the same sentence. The principles of the sentence construction proposed by the original author were as follows: (a) placing the high neighborhood words (i.e., words that can change meaning by changing or deleting one letter, such as “cat” and “pat” in English) leftmost in four lines of the sentence; (b) the sentence consisting of 14 words including particles, and 4 of those should be infrequent words; and (c) phonically irregular words, such as “islands,” “quay,” “colonel,” and “yacht” should be included. To generate a new Korean sentence based on these principles, several adjustments and agreements with the original author were required to address the phonetic and syntactic differences between Korean and English. First, as there are few phonetically irregular words in Korean, infrequently used words were adopted instead of irregular words based on the frequency of modern Korean word usage [27]. The second adjustment was to make sentences in Korean similar to the original sentence in speech duration rather than word count itself, owing to mismatches in the syntax between the two languages. To match the speech duration, we added one more syllable for the pilot trial. Thus, 15 syllabi were included in the sentence, while the standard number of syllables in the original English sentence was 14. In a preliminary study (n=15), when the number of words in a sentence was 14, the mean value of the “sentence reading” performance was 13.97. When the number of included words was 15, its mean value was 14.65, indicating that an increase in the number of words in a sentence exerted no significant effect on the results of the “recall and recognition” tasks. Accordingly, a 15-syllable sentence is created.

Both the OCS and K-OCS include the following materials for testing: (1) a test booklet for multiple-choice items and examples, (2) a patient pack of paper-and-pencil task worksheets, (3) an easy scoring template, and (4) a user manual. The patient pack contains a visual snapshot report (Fig. 1), where impaired

domains are marked by coloring in the blank spaces of the task for abnormal scores. Furthermore, detailed information about the patient can be shared by leaving comments adjacent to the figure, such as comments about the patient’s mood, physical state, or attitude that deserve consideration. The normative data and additional materials of the K-OCS can be downloaded from <https://process.innovation.ox.ac.uk/clinical/p/ocs/questionnaire/1>.

### Participants and evaluations

The study protocol was approved by the Institutional Review Board of Duksung Women’s University (no. 2020-007-015-A) in Seoul and Yongin Sevrance Hospital, and the CHA Bundang Medical Center (no. 2020-07-0202) in Gyeonggi Province. Written informed consent was obtained from all participants in the study. Participants without known disabilities were recruited from September 2020 to March 2022 via notice board announcements at Duksung Women’s University, Yongin Sevrance Hospital, and CHA Bundang Medical. A total of 97 volunteers who were more than 30 years old, and lived in Seoul or Gyeonggi Province, participated in this study. All participants were personally interviewed and screened using the Christensen Health Screening criteria [28], Korean version of MoCA (K-MoCA) [29], and the Beck Depression Inventory the 2nd version (BDI-II) [30]. Patients with neurological diseases, brain damage, visual and speech impairments, or psychiatric history were excluded. The K-OCS was administered to those who were finally enrolled after screening for eligibility. When the K-MoCA and K-OCS were conducted on the same day, the time interval was set to at least 30 minutes.

### Data and statistical analysis

For data analyses, IBM SPSS Statistic 21, R4.1.3 version (IBM Corp.) was used. Descriptive statistics were used to demonstrate the demographic features of the study population, as well as the mean, median, standard deviation, and range of each K-OCS task score. To verify the goodness of fit, Kolmogorov–Smirnov and Shapiro–Wilk normality tests were conducted. Correlations between K-OCS scores and demographic variables, such as gender, age, and education level, were analyzed using Spearman’s correlation (one-sided test) due to the distribution of K-OCS values that deviated from normality. Finally, we computed the percentile values of each task to obtain the cutoff scores by performing a frequency analysis [25]. In addition, we performed logistic regression analysis to verify whether the participants’

age and education level could predict the results of each task.

## RESULTS

### Subject characteristics

Among 135 voluntary participants, 8 scored below the normal cutoff value of the K-MoCA according to age [29], and 15 participants were determined to have depression with BDI-II > 18 points (i.e., the cutoff score) and were excluded from the final analyses. Therefore, the data from 97 participants (33 male [34.0%] and 64 female [66.0%]) were included in the final analysis. Among them, 15 were enrolled in both the pilot and main studies. The age ranged from 35 to 74 with a mean age and standard deviation of  $54.3 \pm 9.7$ . Their education level ranged from 5 to 18 years, and the mean education level and standard deviation were  $13.8 \pm 2.7$  years. Demographic characteristics and the results of MoCA and BDI-II by age group are shown in Table 2. Significant differences were observed in the MoCA

scores between the <50- and >59-year age groups ( $p=0.001$ ), whereas no differences were found in education level or BDI-II scores.

### Normative data of the K-OCS

According to interim analysis after assessing 30 cases, the score of the “reading” task was found to be lower than that of the original English version [15] and other reports [18,21]. Thus, we edited the sentence, which was the main stimulus of the task, to increase its score level in the middle of the study. Consequently, the data from 30 participants, who were examined before the sentence amendment were excluded, and those from the other 67 participants were included for analyses of “reading” and verbal memory “recall and recognition” tasks where the same revised sentence was used. The mean scores for each age and years of education group for the K-OCS task are presented in Table 3. Kolmogorov–Smirnov and Shapiro–Wilk normality tests showed that the tasks, except for “semantics” and “executive

**Table 2.** Characteristics of the participating subjects

| Group    | Age range (yr) | n (%)     | Age (yr)       | % of males | Years of education (yr) | Score of K-MoCA  | Score of BDI-II |
|----------|----------------|-----------|----------------|------------|-------------------------|------------------|-----------------|
| <50 yr   | 35–49          | 37 (38.2) | $44.7 \pm 4.0$ | 29.7       | $15.0 \pm 1.9$          | $27.1 \pm 1.7$   | $6.9 \pm 4.9$   |
| 50–59 yr | 50–59          | 30 (30.9) | $54.5 \pm 3.0$ | 36.7       | $13.4 \pm 2.6$          | $26.3 \pm 2.1$   | $7.6 \pm 4.4$   |
| >59 yr   | 60–74          | 30 (30.9) | $65.8 \pm 5.0$ | 36.7       | $12.7 \pm 3.3$          | $24.7 \pm 2.8^a$ | $8.8 \pm 4.7$   |

Values are presented as mean  $\pm$  standard deviation.

K-MoCA, Korean version of Montreal Cognitive Assessment; BDI-II, Beck Depression Inventory the 2nd version.

<sup>a</sup>) Significant difference with  $p < 0.05$  compared to <50 years.

**Table 3.** Mean scores (points) of age and years of education in each Korean version of the Oxford Cognitive Screen (K-OCS) task

| Task                       | Maximum score | Age (yr)   |              |            | Years of education (yr) |             |            |
|----------------------------|---------------|------------|--------------|------------|-------------------------|-------------|------------|
|                            |               | <50 (n=37) | 50–59 (n=30) | >59 (n=30) | $\leq 6$ (n=4)          | 7–12 (n=38) | >12 (n=55) |
| Picture naming             | 4             | 3.92       | 4            | 3.77       | 3.5                     | 3.89        | 3.94       |
| Semantics                  | 3             | 3          | 3            | 3          | 3                       | 3           | 3          |
| Orientation                | 4             | 4          | 3.97         | 3.9        | 4                       | 3.89        | 4          |
| Visual field               | 4             | 4          | 4            | 3.97       | 4                       | 4           | 3.98       |
| Sentence reading           | 15            | 14.58      | 14.72        | 14.47      | 14                      | 14.77       | 14.54      |
| Number writing             | 3             | 3          | 2.97         | 3          | 2.75                    | 3           | 3          |
| Calculation                | 4             | 3.76       | 3.80         | 3.63       | 3.5                     | 3.58        | 0.84       |
| Hearts cancellation        | 50            | 47.35      | 47.47        | 47.13      | 46                      | 47.24       | 47.57      |
| Space asymmetry            | 4             | -0.08      | -0.16        | -0.30      | -1.25                   | 0.052       | -0.23      |
| Object asymmetry           | 3             | 0          | 0            | 0          | 0.25                    | 0.026       | 0          |
| Imitation                  | 12            | 11.83      | 11.93        | 11.4       |                         | 11.57       | 11.86      |
| Recall                     | 4             | 2.41       | 2.22         | 1.38       | 0.67                    | 1.62        | 2.73       |
| Recognition                | 4             | 3.79       | 3.55         | 3.43       | 3.34                    | 3.34        | 3.81       |
| Episodic memory            | 4             | 3.89       | 3.76         | 3.83       | 3.5                     | 3.79        | 3.88       |
| Executive task (circles)   | 6             | 6          | 6            | 6          | 6                       | 6           | 6          |
| Executive task (triangles) | 6             | 6          | 5.97         | 6          | 6                       | 5.97        | 6          |
| Executive task (mixed)     | 13            | 12.92      | 12.57        | 12.53      | 12                      | 12.61       | 12.8       |
| Executive function total   | 2             | -0.92      | -0.47        | -0.53      | 0.25                    | -0.55       | -0.80      |



task (triangles)” did not meet the normality criteria ( $p<0.001$ ). Finally, the score distribution and cutoff value with criteria of the 5th or 95th percentile for each task were obtained (Table 4).

### Comparison of cutoff values in other countries

The cutoff scores of previous studies conducted in Denmark,

the UK, and Italy are presented in Table 5. Most task scores in the current study were comparable to those of large-scale studies conducted in other countries. Tasks that showed different cutoff scores with  $\geq 1$  point from all of the other countries were “sentence reading” and “imitation.”

**Table 4.** Score distribution of each task on Oxford Cognitive Screen (OCS) based on the whole sample (5th percentile and 95th percentile)

| Task                       | N  | Minimum | Maximum | Mean  | Median | Standard deviation | 5th Percentile score (cutoff value) | 95th Percentile score |
|----------------------------|----|---------|---------|-------|--------|--------------------|-------------------------------------|-----------------------|
| Picture naming             | 97 | 2       | 4       | 3.9   | 4      | 0.37               | 3                                   |                       |
| Semantics                  | 97 | 2       | 3       | 2.99  | 3      | 0.10               | 3                                   |                       |
| Orientation                | 97 | 1       | 4       | 3.96  | 4      | 0.32               | 4                                   |                       |
| Visual field               | 97 | 3       | 4       | 3.99  | 4      | 0.10               | 4                                   |                       |
| Sentence reading           | 67 | 11      | 15      | 14.64 | 15     | 0.72               | 13                                  |                       |
| Number writing             | 97 | 2       | 3       | 2.99  | 3      | 0.10               | 3                                   |                       |
| Number calculation         | 97 | 1       | 4       | 3.73  | 4      | 0.53               | 3                                   |                       |
| Hearts cancellation        | 97 | 34      | 50      | 41.80 | 48     | 2.99               | 41.80                               |                       |
| Space asymmetry            | 97 | -3      | 4       | -0.18 | 0      | 1.27               | -2                                  | 3                     |
| Object asymmetry           | 97 | 0       | 1       | 0.03  | 0      | 0.14               | 0                                   | 0 <sup>a)</sup>       |
| Imitation                  | 97 | 10      | 12      | 11.73 | 12.00  | 0.53               | 10.90                               |                       |
| Recall                     | 67 | 0       | 4       | 2.03  | 2.00   | 1.10               | 0                                   |                       |
| Recognition                | 67 | 1       | 4       | 3.60  | 4.00   | 0.68               | 2                                   |                       |
| Episodic memory            | 97 | 3       | 4       | 3.83  | 3.84   | 0.37               | 3                                   |                       |
| Executive task (circles)   | 97 | 6       | 6       | 6     | 6      | 0                  | 6                                   |                       |
| Executive task (triangles) | 97 | 5       | 6       | 6     | 5.99   | 0.10               | 6                                   |                       |
| Executive task (mixed)     | 97 | 10      | 13      | 13    | 12.69  | 0.68               | 11                                  |                       |
| Executive function total   | 97 | -5      | 2       | -0.70 | -1     | 0.89               |                                     | 1                     |

<sup>a)</sup>For a more consistent approach: it is recommended to use the absolute cutoff value.

**Table 5.** Cutoffs compared across studies: 5th percentile (95th percentile)

|                          | Korea (N=67-97)      | Denmark (N=89-91)    | United Kingdom (N=140) | Italy (N=489)        |
|--------------------------|----------------------|----------------------|------------------------|----------------------|
| Age range (yr)           | 35-74                | 36-89                | 25-96                  | 18-89                |
| Picture naming           | 3                    | 3                    | 3                      | 2.9-3.7              |
| Semantics                | 3                    | 3                    | 3                      | 3                    |
| Orientation              | 4                    | 4                    | 4                      | 3.9-4.0              |
| Visual field             | 4                    | 4                    | 4                      | 4                    |
| Sentence reading         | 13                   | 15                   | 14                     | 14.1-15.0            |
| Number writing           | 3                    | 3                    | 3                      | 2.8-3.0              |
| Number calculation       | 3                    | 3                    | 3                      | 3.3-3.8              |
| Hearts cancellation      | 41.80                | 39.5                 | 42                     | 43.4-47.4            |
| Space asymmetry          | -2 (3) <sup>a)</sup> | -2 (2) <sup>a)</sup> | -2 (3) <sup>a)</sup>   | -3 (3) <sup>a)</sup> |
| Object asymmetry         | 0                    | 0                    | 0                      | -2 (2) <sup>a)</sup> |
| Imitation                | 10.9                 | 8                    | 8                      | 9                    |
| Recall                   | 0                    | 1                    | 0                      | - <sup>b)</sup>      |
| Recognition              | 2                    | 3                    | 3                      | 2.4-3.4              |
| Episodic memory          | 3                    | 3.5                  | 3                      | 3.4-3.8              |
| Executive task (mixed)   | 11                   | 11                   | 7                      | 10.5-11.0            |
| Executive function total | (1) <sup>a)</sup>    | (1) <sup>a)</sup>    | (4) <sup>a)</sup>      | (3) <sup>a)</sup>    |

<sup>a)</sup>95th Percentile scores are used to determine impairment (Danish, Robotham et al., 2020 [21]; Demeyere et al., 2015 [15]; Mancuso et al., 2016 [18]).

<sup>b)</sup>In the Italian study, the recall cutoff was not obtained and was integrated into the recognition performance. Italian cutoff were adjusted according to age and/or education year for sub-tests in which these variables influenced scores. For these sub-tests ranges of cutoffs are provided.

### Prediction of the K-OCS score according to age and years of education

We conducted a logistic regression analysis to verify whether years of education could predict the K-OCS scores. Cutoff scores of “semantics” and “executive task (circles)” had the maximum values, and the cutoff score of “recall” had the minimum value, of the score ranges; thus, these were excluded from the analysis. According to the regression model, all the tasks, except for the “imitation” task (odds ratio > upper confidence interval,  $p=0.05$ ), did not predict task scores regarding education level and age.

## DISCUSSION

In stroke clinics, PSCI, including attention, spatial recognition, memory, and executive function, may be obscure and easily neglected [7,8]. By applying effective screening assessments, patients with PSCI may receive timely interventions and early screening may help to understand longer term cognitive impairments [31]. This study aimed to set the measurement standards of the K-OCS by screening healthy normal participants for PSCI as the first essential step. The K-OCS was adapted to be applied to Koreans based on their unique language and cultural characteristics while maintaining the essentials of the OCS.

The resultant percentile scores of the Korean participants were compared with those provided in the Danish [21], Italian [18], and British [15] validation studies that enrolled larger samples (Table 5). The resultant cutoff scores of the K-OCS were similar to those in large-scale studies in other countries, indicating that this Korean version was adapted well enough to maintain its significant validity when applied to South Koreans. Only two tasks, “sentence reading” and “imitation” were found to show little difference in the cutoff scores. First, the cutoff scores of “sentence reading” were 15, 14, and 14.1–15 points in Denmark, the UK, and Italy, respectively. In the present study, it was 13 points, a relatively lower cutoff score than in the compared countries. The sentence in this task was not simply translated from the original OCS questionnaire but was newly constructed based on the basic principles of the original version. After a thorough analysis of the errors in the sample population, we found a relatively low cutoff score.

The cutoff score of “imitation” was higher than the previous studies. The “imitation” task requires mirroring the set of meaningless movements and detecting the signs of apraxia with a score ranging from 0 to 12. It may be possible to apply looser criteria depending on the position and the angle of the arm or

hand, which are not precisely described, including degrees or if the gestures are easier for Koreans. Moreover, the possibility of deviation from interpretation seems low, as the verbal component is not significantly involved in this task. Thus, more practice could help understand the score of the “imitation” task.

While the cutoff values of the other tasks were not different from all of the previous reports, the value of “recognition” might be regarded to have a lower score compared with those in Denmark and the UK. The “recognition” task is evaluated as remembering the “sentence reading” stimulus performed beforehand, the cutoff score of which was also lower as previously mentioned. The relatively low “sentence reading” performance might have affected the subsequent “recognition” score.

The cutoff score for “object asymmetry” was similar to that in studies with a small number of participants, such as those in the UK and Denmark [15,21]. However, the value was different in large-scale studies such as in Italy [18], which necessitates further validation studies with larger populations to investigate the effect of sample size. In the MoCA test—a cognitive function screening test—there is a language fluency task in which participants are given a single letter and asked to tell as many as possible words starting with the letter. Due to differences between languages, eleven words as the cutoff number in North America correspond to six words in Korean [29]. Similarly, the cutoff scores for Korean language impairment may differ. However, the relatively low “recognition” scores did not lead to the floor effect; thus, it is not regarded to have affected as a limitation in applying this tool.

The cutoff score for “executive function total” in the K-OCS was identical to that in Denmark but was different to those of the UK and Italy. In this study, we examined whether the outlier values affected the cutoff score calculation and found that the cutoff score was still identical, even when the extreme values were included in the calculation.

This study has a few limitations. First, 97 normal participants enrolled in this study. Although this study met the minimal criteria to demonstrate equivalence with the original test, a larger Korean normative study is required to achieve an even more representative normative sample. Second, the super-aged group is not included. The subjects of the elderly over 75 years of age had difficulty participating in the study due to the impact of coronavirus disease 2019, which needs to be supplemented in follow-up research. Third, although age did not correlate with results other than performance score, some tasks showed correlations between education level and performance score in

previous studies. In this study, the cutoff scores according to age and education level could not be calculated because of the relatively small number of cases. Future studies should focus on enrolling a larger number of participants to analyze the correlation between demographic factors and the K-OCS task performance, cutoff scores, and prediction results.

In conclusion, this study is significant in that it has developed and validated a K-OCS through a normative study, which has real-world applications for improving clinical practice.

Considering the current limitations in assessing PSCI, the development of the K-OCS will contribute to detecting PSCI and may facilitate appropriate interventions.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Cho E. Methodology: Cho E. Formal analysis: Cho E. Funding acquisition: Kim MY. Project administration: Cho E, Kim MY, Choi S. Visualization: Cho E. Writing – original draft: Cho E, Kim MY, Hwang SSS. Writing – review and editing: Cho E, Kim MY, Demeyere N, Choi S. Approval of final manuscript: all authors.

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# The Effectiveness of Goal-Oriented Dual Task Proprioceptive Training in Subacute Stroke: A Retrospective Observational Study

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**Objective:** To show the effectiveness of goal-oriented proprioceptive training in subacute stroke for balance, autonomy, and fall risk.

**Methods:** Out of a total of 35 patients, consistent in age ( $75.31 \pm 8.65$  years), type of stroke (ischemic, 3 to 11 weeks before), and motor impairment, 18 patients underwent solely proprioceptive rehabilitation, the other 17 dual task exercises. The study assessed autonomy using Barthel Index, fall risk with Timed Up and Go Test (TUG), balance through Berg Balance Scale (BBS) and Tinetti test.

**Results:** After two months, significant improvements were recorded in Barthel Index, BBS ( $p < 0.0001$ ), Tinetti test ( $p < 0.0001$  in dual task group,  $p = 0.0029$  in single task group), and TUG ( $p = 0.0052$  in dual task group,  $p = 0.0020$  in single task group) in both groups. Comparing the two groups, dual task group showed a significant difference in Tinetti balance assessment ( $p = 0.0052$ ), between the total score of Tinetti test and TUG in single ( $p = 0.0271$ ), and dual task ( $p = 0.0235$ ). Likewise, Tinetti gait test was significantly related to TUG in single ( $p = 0.0536$ ), and dual task ( $p = 0.0466$ ), while Tinetti balance test to Barthel Index ( $p = 0.0394$ ), BBS ( $p < 0.0001$ ), and TUG in single ( $p = 0.0219$ ), and dual task ( $p = 0.0196$ ). Lastly, there is a positive correlation of the use of aids with BBS ( $p = 0.0074$ ), and total score of Tinetti test ( $p = 0.0160$ ).

**Conclusion:** In subacute stroke, goal-oriented proprioceptive training improved balance, but only partially autonomy. Furthermore, the use of aids after dual-task exercises improved recovery of balance, but did not reduced falls.

**Keywords:** Stroke, Rehabilitation, Proprioception, Falls, Task performance

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## INTRODUCTION

Stroke is one of the main causes of disability, with serious economic and social consequences [1].

In stroke patients, balance and proprioceptive impairment are important causes of functional limitations [2], and they are present in 48.1% [3] and 34%–64% [4] respectively.

Sherrington's definition of proprioception encompasses the perception of joint positioning and bodily motion within space [5]. This description underlines the contemporary interpretation of the concept. Proprioception involves coordinated responses from various mechanoreceptors, including proprioceptors found in tendons, muscles, ligaments, and joint capsules [6]. These proprioceptors, such as the Golgi tendon organ, muscle spindle, and Pacini corpuscle, relay joint position and motion information to the central nervous system (CNS) [7]. The CNS processes this sensory information, integrates it with other inputs, and sends responsive commands to target tissues. Proprioceptive feedback is crucial for regulating body movement, protecting against joint overstretching and controlling posture and balance, allowing awareness of joint and body movements [8,9]. A decline in proprioception can change the joint biomechanics and the neuromuscular control of the limbs, resulting in impaired balance and a higher possibility of falls [7,10].

A negative significant correlation is suggested between the severity of proprioception impairment and both motor and functional abilities [11], and risk of falling [12]. Likewise, an impaired reactive balance (the ability to execute appropriate and effective reactions to keeping balance despite perturbations) makes hard walking and producing functional movements, resulting in a loss of autonomy in everyday life [13], and an increase of risk of falling [14].

The multiple sensory impairments, i.e. tactile sensations disorder, present in 7%–53%, and loss of stereognosis, present in 31%–89% of patients [4], contribute also to a high prevalence of falls [2,14].

Finally, daily activities in human life require the concomitant completion of motor tasks and cognitive functions, particularly difficult for stroke people [15], making them frail and disabled [16]. Furthermore, the difficulties in dual task activities increase the risk of falling among stroke subjects [17].

As well as the proprioceptive and reactive balance impairment, the severity of somatosensory impairments, and the degree of mobility-interference during dual task activities can help to predict the risk of falling and guide the therapeutic strategies

to maximize long-term participation, minimize disability and reduce the risk of falls [12,18,19]. To obtain these goals, the rehabilitation must focus not only on autonomy, but also on balance, and task performance, and on falls prevention [20,21].

The aim of the study is to show the effectiveness of goal-oriented proprioceptive training in subacute stroke for the recovery of balance, autonomy in activities of daily living (ADLs), and for the prevention of falling. Secondary aims are to compare the effectiveness of goal-oriented proprioceptive training with dual task training or single task exercises. Lastly, sharing the rehabilitation program could guide physicians and therapists in their clinical practise, because, until now, recommendations about specific exercises in subacute stroke are not standardized.

## METHODS

All procedures performed in this study involving human participants were in accordance with the 2013 Helsinki declaration and its later amendments or comparable ethical standards. The article was a retrospective study, so the approval of the ethical committee was not necessarily required. Informed consent was obtained from all participants included in the study.

### Participant selection and characteristics in rehabilitation

The data of 35 subacute stroke patients, hospitalized in an intensive rehabilitation facility from September 2021 to March 2022, were retrospectively collected (Table 1). They were homogeneous in terms of type of stroke having experienced ischemic events between 3 to 11 weeks prior to the study. Their average age was  $75.31 \pm 8.65$  years. In terms of severity, their symptoms ranged from mild to moderate, manifesting primarily as spastic hemiparesis, weakness, balance issues, disability in daily activities. The distribution of the patients' specific brain lesions was as follows: 22 patients had lesions in the territory of the middle cerebral artery 6 in the posterior limb of the internal capsule (2 underwent single task proprioceptive training, 4 dual task proprioceptive training), and 7 exhibited lacunar strokes in the capsular region (4 underwent single task proprioceptive training, 3 dual task proprioceptive training). At the onset of the study, both groups demonstrated homogeneity across all submitted scales, and this homogeneity extended to the subgroups stratified based on the location of stroke (Table 1).

Importantly, they exhibited no cognitive impairments, with normal vigilance, cooperation, orientation, memory, attention, decision-making, and general cognitive processing capabilities

**Table 1.** Characteristics of participants

| Clinical characteristic | Dual        |             | Single      |             | Single vs. Dual | Single    | Dual      | Single vs. Dual |
|-------------------------|-------------|-------------|-------------|-------------|-----------------|-----------|-----------|-----------------|
| No. of patients         | 17          |             | 18          |             |                 |           |           |                 |
| Sex, female/male        | 9/8         |             | 11/7        |             |                 |           |           |                 |
| Age (yr)                | 74.58±10.69 |             | 76.72±6.41  |             |                 |           |           |                 |
| Autonomy with aids      | T0          | T1          | T0          | T1          |                 |           |           |                 |
| Wheelchair              | 3           | 0           | 2           | 0           |                 |           |           |                 |
| Walker                  | 3           | 7           | 2           | 6           |                 |           |           |                 |
| Cane                    | 3           | 2           | 5           | 3           |                 |           |           |                 |
| Without                 | 8           | 8           | 9           | 9           |                 |           |           |                 |
| Scales                  | T0          | T1          | T0          | T1          | T0              | T0 vs. T1 | T0 vs. T1 | T1              |
| Barthel Index           | 22.82±10.00 | 55.82±18.33 | 28.88±10.50 | 79.44±16.25 | p=0.0903        | p<0.0001  | p<0.0001  | p=0.5193        |
| NRS                     | 3.00±3.31   | 0.35±1.45   | 2.38±1.57   | 1.27±1.52   | p=0.4973        | p=0.0092  | p=0.0026  | p=0.0759        |
| BBS                     | 14.41±15.03 | 39.59±10.45 | 13.38±10.24 | 21.27±14.47 | p=0.8145        | p=0.0001  | p<0.0001  | p=0.200         |
| Tinetti balance test    | 5.06±5.52   | 12.29±3.58  | 6.66±2.00   | 8.94±3.01   | p=0.2705        | p=0.0029  | p<0.0001  | p=0.0052        |
| Tinetti gait test       | 5.23±4.60   | 8.59±4.06   | 6.94±2.75   | 9.44±3.71   | p=0.1972        | p=0.0093  | p=0.0023  | p=0.193         |
| Tinetti total score     | 10.29±9.11  | 20.88±7.31  | 9.22±4.75   | 18.38±6.48  | p=0.6416        | p<0.0001  | p<0.0001  | p=0.2929        |
| TUG in single task      | 48.54±26.60 | 33.12±14.95 | 37.11±18.13 | 31.77±17.75 | p=0.1393        | p=0.1393  | p=0.0035  | p=0.9907        |
| TUG in dual task        | 47.14±23.18 | 33.79±14.94 | 37.21±11.18 | 35.41±10.43 | p=0.1234        | p=0.0020  | p=0.0052  | p=0.7102        |

Values are presented as number only or mean±standard deviation.

Dual, dual task proprioceptive training group; Single, single task proprioceptive training group; T0, at admission; T1, at discharge (after two months of rehabilitation); NRS, Numerical Rating Scale; BBS, Berg Balance Scale; TUG, Timed Up and Go Test.

(ability to understand, process, and respond to information effectively), as a dedicated psychologist reported. No patients necessitated psychological support during their hospitalization. Moreover, there were no visual deficits, ensuring intact depth perception, reading abilities, facial recognition, and effective navigation of their surroundings without any visual field cuts or double vision. The participants were consistent also in terms of similar prior health conditions, being sufficiently autonomous in ADLs before the acute event. Furthermore, they were awake, alert, and cooperative at admission. Dual task group had 3 patients each using wheelchairs, walkers, and canes, with 8 requiring no aids. The single task group had varied distributions with 2 using wheelchairs, 2 with walkers, 5 with canes, and 9 without aids.

During the study period, the focus was on capturing a representative sample of patients undergoing rehabilitation post-stroke. It was noteworthy to clarify that the inclusion of only infarction stroke patients was not due to an intentional exclusion criterion set against haemorrhagic stroke cases. Rather, the patient demographics available for inclusion during the study timeline naturally led to this composition.

A total of 2 patients were excluded for incomplete data present in their medical record, instable clinical conditions during the hospitalization, and comorbidities that interfered with the intensive rehabilitative program.

### Clinical evaluation tests and assessment tools

To gain a comprehensive understanding of the participants' health and functional capabilities, several clinically validated assessment scales were employed. The clinical assessments included the following scales: Numerical Rating Scale (NRS) for pain [22], Barthel Index to assess the functional autonomy [23], Tinetti test [24] and Berg Balance Scale (BBS) for balance [25], Timed Up and Go Test (TUG) in single and dual tasks for the risk of falling [26]. The cognitive dual tasks, executed during TUG, included counting backward while walking; the motor dual task included carrying a half full glass while walking.

NRS was utilized to evaluate the subjective experience of pain among participants. Patients were asked to rate their pain on a scale from 0 (no pain) to 10 (worst possible pain). Barthel Index measured performance in ADLs, and assessed participants' functional autonomy, covering aspects from mobility to self-care. Tinetti Test gauged both balance and gait capabilities. By examining participants as they performed specific physical tasks, the test provided insights into their stability and coordination. These scales were administered at admission and at discharge, after a mean of 59.82±2.72 days of hospitalization in rehabilitation facility.

The evaluations were consistently conducted by the same physician who was a specialist in Physical Medicine and Rehabilitation, with over 3 years of experience specifically working

with stroke patients, with a focus on balance disorders and postural instability. This consistency in the evaluator ensured uniformity and reliability in the assessment process throughout the study.

**Proprioceptive training: procedure and dual task implementation**

The rehabilitation consisted of 3 hours a day of goal-oriented proprioceptive training for 7 days a week, organized in two sessions of 1.5 hours a day. All participants performed a consistent traditional rehabilitation program. The distinction between the two groups was based on different proprioceptive training approaches. The single task group underwent proprioceptive exercises, while the dual task group integrated both motor and cognitive exercises in their training regimen. The specific exercises for each group are detailed in [Table 2](#).

Within these sessions, specific exercises were performed at varying intensities, tailored to the individual needs and progression of each patient. The intensity was regularly adjusted based on patient feedback, performance, and therapist observation to

ensure both safety and challenge.

The difficulty of tasks was progressively increased. For instance, patients initially started with simpler tasks, like walking while naming fruits. As their proficiency improved, they would progress to tasks that demanded more cognitive load, such as walking while performing serial subtractions. Continuous feedback was provided to the participants about their performance. If a participant struggled, the complexity was adjusted to ensure safety while still providing adequate challenge.

For the integration into daily activities, as participants became more comfortable, the dual tasks were integrated into more complex ADLs, like navigating a crowded area while carrying a conversation or holding objects.

Thanks to the homogeneity of the sample, this implementation remained consistent across all participants, ensuring uniformity in the training experience for every individual.

In the motor dual task, participants simultaneously engaged in two motor activities. Examples included walking while holding a tray laden with cups of water or dribbling a ball while walking. Conversely, the cognitive task combined motor and

**Table 2.** Rehabilitation program of approximately 2 months, consisting of 3 hours a day of training for 7 days a week, organized into two sessions of 1.5 hours each

| Traditional exercises<br>45 minutes twice a day for both groups  | Goal-oriented proprioceptive training<br>45 minutes twice a day for single task group   |
|--|---|
|  | Single task exercises   |
| Passive exercises for the recovery of the range of motion in the joints of the involvement segments  | Exercises for balance on irregular, soft or unstable surfaces;<br>Star Excursion Balance exercise   |
| Exercises of postural control during slow standing balance movements   | Exercises for feedback and feedforward control with external perturbation, mild pushes or visual, tactile and auditive cues   |
| Stretching of anterior and posterior kinetic chain   | Ability to adopt and maintain different postures to keep balance  |
| Recovery of ADLs and IADLs with occupational therapy   | Postural control during fast pointing movements<br>Changing direction or speed during fast pointing movements<br>Keeping balance with rotation of trunk and during semi-squat on a soft pad   |
| Techniques to improve muscle force:<br>Core exercises,<br>Isometric exercises for arms and legs,<br>Isometric for antigravity muscles,<br>Concentric and eccentric training of the lower limbs,<br>Closed and open kinetic chain exercises | Proprioceptive balance pads:<br>In sitting position,<br>In standing with support and assistance,<br>Changing direction of movement (lateral or antero- to posterior) or free inclination in balance pad   |
|  | Dual task exercises for dual task group   |
| Mobility and balance training:<br>Exercises to support the body mass by lower limbs,<br>Body weight shift and propulsion of the body in the intended direction,<br>Basic locomotor rhythm,<br>Gait training,<br>Stepping                   | Enhance cognitive and motor multitasking abilities under additional motor challenges:<br>Cognitive dual tasks: talking about planning or organizing a trip, talking about food or weather, praying, telling a story,<br>Motor dual tasks: carrying a glass half full, moving an object from one hand to the other;<br>Improve adaptability to changing environments:<br>Train adaptability and flexibility in real-time scenarios,<br>Introduce “obstacles” along the pathway. These were soft mats, small hurdles, irregular surfaces (like a cushion or a gravel patch) |

ADLs, activities of daily living; IADLs, instrumental activities of daily living.

cognitive elements. While participants performed a motor activity, such as walking, they also undertook a cognitive challenge. This could involve counting backwards, verbally solving arithmetic problems, or naming items from a specific category, all while continuing their motor task. The primary aim was to assess the participant's ability to coordinate and execute two distinct motor functions simultaneously, reflecting many real-world scenarios where multitasking is required.

### Statistical analysis and methodology

The R statistical software (igraph package) was used for data analysis. Quantitative data were expressed as mean and standard deviation and were compared using t-test. The paired t-test was used to assess outcomes within each group before and after training. The unpaired t-test was utilized for comparing the two groups at baseline (T0) to evaluate sample homogeneity. At the follow-up assessment (T1), the unpaired t-test was applied to analyze the comparative effectiveness of the two different treatments.

The correlation between the scales was estimated using the Pearson and Spearman's coefficient. For Spearman correlation, the data of mobility aids were ranked in 1 indicating their unnecessary use, 2 for the use of canes, 3 for walkers, and 4 for wheelchairs.  $p < 0.05$  was considered with statistical significance.

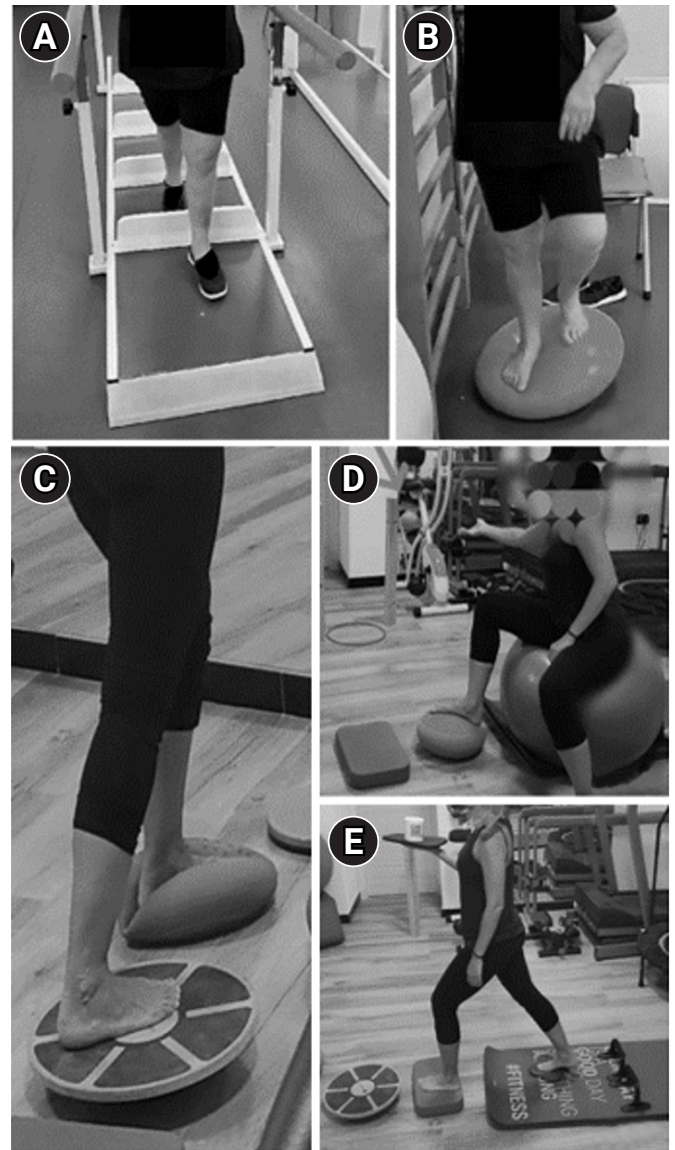
## RESULTS

During a mean of  $59.82 \pm 2.72$  days hospitalization in a rehabilitation facility, 35 subacute stroke patients conducted (1) a traditional rehabilitation program with (a) postural and core exercises, (b) mobility training, (c) occupational therapy, and (2) a goal-oriented proprioceptive training that consisted in proprioceptive and reactive balance training (Fig. 1). A total of 18 out of 35 patients performed a goal-oriented single task proprioceptive rehabilitation, while 17 patients performed dual task training with goal-oriented motor and cognitive exercises (Table 2).

There were no statistically significant differences between the two groups at the initial assessment (T0) across all the scales used.

At discharge, statistically significant differences were recorded in both groups for (1) Barthel Index ( $p < 0.0001$ ), with the recovery of the autonomy in ADLs; (2) Tinetti test (total score  $p < 0.0001$ , balance assessment  $p < 0.0001$  in dual task group,  $p = 0.0029$  in single task group, gait assessment  $p = 0.0023$  in dual task group,  $p = 0.0093$  in single task group); (3) BBS ( $p < 0.0001$ ),

with an improvement of balance; (4) TUG with dual task exercises ( $p = 0.0052$  in dual task group,  $p = 0.0020$  in single task group); and (5) TUG with single task exercises only for dual



**Fig. 1.** Illustrative representations of rehabilitation exercises. (A) Traditional rehabilitation exercise emphasizing balance restoration and gait training. (B) Single-task proprioceptive exercise, focusing on maintaining balance on a proprioceptive cushion. (C) Single task proprioceptive exercise, focusing on maintaining balance with the right foot on a Friedman pad and the left foot on a proprioceptive cushion. (D) Dual-task proprioceptive exercise: maintaining balance on a proprioceptive cushion, while sitting as skilfully centring the ball within the circle. (E) Dual-task proprioceptive exercise: maintaining balance on a proprioceptive pad while walking as simultaneously carrying a tray.



task group ( $p=0.0035$ ) with a reduction of the risk of falling (Table 1). Comparing the two groups, balance, as assessed with Tinetti balance assessment, showed a significant difference in dual task proprioceptive training group than single task group ( $p=0.052$ ). Thus, the study showed that goal-oriented both single and dual task proprioceptive rehabilitation significantly improved autonomy (Barthel Index in single and dual task groups  $p<0.0001$ ), balance (BBS in single  $p=0.0001$  and dual task groups  $p<0.0001$ ; Tinetti balance test in single  $p=0.0029$  and dual task groups  $p<0.0001$ ), and gait (Tinetti gait test in single  $p=0.0093$  and dual task groups  $p<0.0023$ ; Tinetti total score in single and dual task groups  $p<0.0001$ ) and reduced the risk of falling (TUG during dual task conditions in single task group  $p=0.0020$  and dual task groups  $p=0.0052$ ).

Considering the three subgroups, the first, related to strokes in the territory of the middle cerebral artery, the most numerically significant, showed similar results in terms of significance after both single and dual-task proprioceptive training and in the comparison between single and dual task training. Indeed, an improvement in Barthel Index (after single and dual task training  $p<0.0001$ ), BBS (after single  $p=0.0172$ , dual task training  $p=0.0013$ ), Tinetti balance test (after single and  $p=0.0340$ , dual task training  $p=0.0108$ ), Tinetti gait test (after single and  $p=0.0340$ , dual task training  $p=0.0108$ ), TUG during single task activities (dual task training  $p=0.0453$ ), TUG during dual task activities (after single  $p=0.0262$ , dual task training  $p=0.0263$ ) were recorded.

The other subgroups, with locations in the posterior limb of the internal capsule and lacunar strokes, differed from the results of the first subgroup. Indeed, the second subgroup showed no significant results in the scales related to balance, gait and risk of falls after either single or dual task training ( $p>0.05$ ). The only noteworthy improvement observed was in autonomy (after single task training  $p=0.0219$ , dual task training  $p=0.0270$ ).

The third group showed no results after single task training ( $p>0.05$ ), but improvements in balance after dual task training, assessed by BBS ( $p=0.0261$ ) and Tinetti balance ( $p=0.0481$ ).

The comparison between single and dual task training revealed a significant improvement in BBS and Tinetti balance in the first two groups and in TUG in single task in the third subgroup. Particularly, in patients with stroke affecting the territory of the cerebral middle cerebral artery, there was a significant enhancement of autonomy (Barthel Index  $p<0.0001$ ), and balance (BBS= $0.0056$ , Tinetti balance test  $p=0.0908$ ) after dual task training compared with single task training. After stroke in

the internal capsule, dual task training resulted in an improved BBS ( $p=0.048$ ) and Tinetti balance scale ( $p=0.0245$ ) compared to single task training. In lacunar strokes of the capsular region, dual task training led to a significant improvement in TUG during single task activity ( $p=0.0154$ ).

Given that subgroups with fewer patients exhibited only partial results, consolidating them into a single group could enhance the overall statistical robustness and consistency of the findings.

After rehabilitation, in dual task proprioceptive training group, the values of TUG in single and in dual task were associated and changed correspondingly ( $r=0.9867$ ,  $p<0.0001$ ). Moreover, a significant relationship was present between the total score of Tinetti test and (1) BBS ( $r=0.8382$ ,  $p<0.0001$ ), (2) TUG in single task ( $r=-0.5343$ ,  $p=0.0271$ ), (3) TUG in dual task ( $r=-0.5455$ ,  $p=0.0235$ ). Likewise, Tinetti gait test was significantly related to (1) BBS ( $r=0.7640$ ,  $p=0.0004$ ), (2) TUG in dual task ( $r=-0.4885$ ,  $p=0.0466$ ). Furthermore, Tinetti balance test was significantly related to (1) Barthel Index ( $r=-0.5033$ ,  $p=0.0394$ ), (2) BBS ( $r=0.8443$ ,  $p<0.0001$ ), (3) TUG in single task ( $r=-0.5510$ ,  $p=0.0219$ ), (4) TUG in dual task ( $r=-0.5594$ ,  $p=0.0196$ ). Conversely, no correlation was recorded between Barthel Index and (1) Tinetti gait test ( $r=-0.2629$ ,  $p=0.3081$ ), (2) total score of Tinetti test ( $r=-0.3927$ ,  $p=0.1189$ ), (3) BBS ( $r=-0.3631$ ,  $p=0.1520$ ), (4) TUG in single task ( $r=0.3934$ ,  $p=0.1182$ ), and (5) TUG in dual task ( $r=0.3563$ ,  $p=0.1603$ ). Likewise, no significant relationship was showed between BBS and (1) TUG in single task ( $r=-0.3762$ ,  $p=0.1367$ ), (2) TUG in dual task ( $r=-0.4012$ ,  $p=0.1105$ ), and (3) total score of Tinetti ( $r=-0.4758$ ,  $p=0.0536$ ). Thus, after rehabilitation, the improvement of balance was related to the reduction of the risk of falling, (showed by the positive relationship between Tinetti test and TUG in single task and in dual tasks), but only partially to the recovery of autonomy (positive relationship between Barthel Index and Tinetti balance test, but no significant between Barthel and BBS; Table 3).

A significant relationship was found between the use of mobility aids and (1) BBS ( $r=-0.625$ ,  $p=0.0074$ ), (2) Tinetti gait test ( $r=-0.602$ ,  $p=0.0105$ ), and (3) total score of Tinetti test ( $r=-0.574$ ,  $p=0.0160$ ). Conversely, no significant relationship was found between the use of aids and (1) Barthel Index ( $r=-0.0374$ ,  $p=0.8865$ ), (2) Tinetti balance test ( $r=-0.453$ ,  $p=0.0682$ ), (3) TUG in single task ( $r=0.375$ ,  $p=0.1385$ ), and (4) TUG in dual task ( $r=0.400$ ,  $p=0.1113$ ). Therefore, these data highlighted a positive correlation between the use of aids and the recovery of balance (positive relationship of aids with BBS and total score



of Tinetti test). Nevertheless, the use of aids did not improve autonomy (no significant relationship between aids and Barthel Index), nor reduce the risk of falling (no significant relationship between aids and TUG in single task and dual task; Table 3).

## DISCUSSION

The novelty of this study lies in its integrative approach to post-stroke rehabilitation. Instead of relying on just one type of therapeutic intervention, we incorporate three distinct types of rehabilitation: (1) goal-oriented training, (2) proprioceptive training, and (3) dual task training. By weaving these three methodologies together, our objective is to foster a more comprehensive and synergistic rehabilitative experience. We suggest that the union of these specific training types has the potential to yield superior outcomes, capitalizing on the strengths of each individual method. The confluence of goal setting, enhancing body spatial awareness, and promoting multitasking abilities forms the foundation of our holistic rehabilitation strategy, set-

ting the stage for optimized patient recovery.

Proprioceptive training is a specialized rehabilitative approach that underscores the body's ability to discern its position in space, an essential component for ensuring coordinated and smooth movements [8]. In addressing such deficits, goal-oriented training gets patients to concentrate on specific movement or position-based objectives, by making them focus on achieving specific action or position-based goals. It seems to increase the intensity of practice in stroke rehabilitation [27].

This specificity can aid in rejuvenating neural pathways connected to proprioception, despite there is no solid evidence about the underlying long-term neuroplastic changes associated proprioceptive training [28]. Moreover, in single-task exercises, patients are primarily engaged in one specific activity at a time. On the other hand, dual task proprioceptive training requires patients to multitask, effectively managing two activities simultaneously. This simultaneous engagement in dual task training inherently exerts a greater cognitive and motor demand as compared to single task exercises. While the single task approach can

**Table 3.** Statistical results of the study

| Assessment scale                             | Statistical correlation                 |   |
|--|---|---|
|  | Dual task proprioceptive training group | Single task proprioceptive training group |
| Barthel Index-BBS                            | r=-0.3631, p=0.1520                     | r=0.04943, p=0.8456                       |
| Barthel Index-Tinetti balance test           | r=-0.5033, p=0.0394                     | r=-0.08455, p=0.7387                      |
| Barthel Index-Tinetti gait test              | r=-0.2629, p=0.3081                     | r=0.1066, p=0.6737                        |
| Barthel Index-Total score of Tinetti         | r=-0.3927, p=0.1189                     | r=0.02170, p=0.9319                       |
| Barthel Index-TUG in single task             | r=0.3934, p=0.1182                      | r=0.1837, p=0.4657                        |
| Barthel Index-TUG in dual task               | r=0.3563, p=0.1603                      | r=0.01795, p=0.9437                       |
| TUG in single task-TUG in dual task          | r=0.9867, p<0.0001                      | r=-0.2182, p=0.3844                       |
| TUG in single task-BBS                       | r=-0.3762, p=0.1367                     | r=0.1224, p=0.6284                        |
| TUG in dual task-BBS                         | r=-0.4012, p=0.1105                     | r=0.07866, p=0.7564                       |
| Tinetti balance test-BBS                     | r=0.8443, p<0.0001                      | r=0.04883, p=0.8474                       |
| Tinetti balance test-TUG in single task      | r=-0.5510, p=0.0219                     | r=-0.09165, p=0.7176                      |
| Tinetti balance test-TUG in dual task        | r=-0.5594, p=0.0196                     | r=-0.07530, p=0.7665                      |
| Tinetti gait test-BBS                        | r=0.7640, p=0.0004                      | r=-0.01666, p=0.9477                      |
| Tinetti gait test-TUG in single task         | r=-0.4758, p=0.0536                     | r=-0.2010, p=0.4238                       |
| Tinetti gait test-TUG in dual task           | r=-0.4885, p=0.0466                     | r=0.05122, p=0.8401                       |
| Total score of Tinetti-BBS                   | r=0.8382, p<0.0001                      | r=0.01320, p=0.9585                       |
| Total score of Tinetti-TUG in single task    | r=-0.5343, p=0.0271                     | r=-0.1579, p=0.5316                       |
| Total score of Tinetti test-TUG in dual task | r=-0.5455, p=0.0235                     | r=-0.005729, p=0.9820                     |
| Barthel Index-use of aids                    | r=-0.0374, p=0.8865                     | r=-0.261, p=0.2950                        |
| BBS-use of aids                              | r=-0.625, p=0.0074                      | r=0.000, p=1.0000                         |
| Tinetti balance test-use of aids             | r=-0.453, p=0.0682                      | r=-0.103, p=0.6846                        |
| Tinetti gait test-use of aids                | r=-0.602, p=0.0105                      | r=-0.0696, p=0.7837                       |
| Total score of Tinetti test-use of aids      | r=-0.574, p=0.0160                      | r=-0.0683, p=0.7877                       |
| TUG in single task-use of aids               | r=0.375, p=0.1385                       | r=-0.102, p=0.6862                        |
| TUG in dual task-use of aids                 | r=0.400, p=0.1113                       | r=0.102, p=0.6865                         |

BBS, Berg Balance Scale; TUG, Timed Up and Go Test.

be pivotal during the initial phases of rehabilitation, dual task training, with its augmented cognitive load, mirrors the multifaceted demands often encountered in real-world situations [29].

According to the results of the study, in subacute stroke patients, the goal-oriented proprioceptive training, both with single and dual task exercises, improved balance and autonomy in ADLs, and reduced the risk of falling, during dual task activities too. Thus, the pivotal element to reach these results is the goal-oriented proprioceptive training. Whether applied through single or dual-task exercises, the distinction between them appears superimposable. Furthermore, the comparison between the scales at discharge showed what rehabilitation goals were achieved. In particular, after goal-oriented dual task proprioceptive training, the positive relationship between Tinetti test and TUG was related to a reduced risk of falling secondary to an improvement of balance. Nevertheless, the lack of correlation of Barthel Index with BBS and with Tinetti test (gait assessment tool and total score of Tinetti test) could explain why the recovery of balance only partially was related to autonomy (positive relationship between Barthel Index and Tinetti balance test), despite the reduction of the risk of falling. Lastly, the use of mobility aids resulted closely related to the recovery of balance (positive relationship between the aids and the score of BBS and Tinetti gait test and total score), but it did not improve autonomy (no significant relationship between aids and Barthel Index), nor reduced the risk of falling (no significant relationship between aids and TUG in single task and dual task). This demonstrated that the use of aids was not sufficient to make mobility and gait safe and to acquire autonomy, but only helped to improve balance. Indeed, mobility aids can enhance proprioceptive feedback and provide stability, aiding in balance recovery. However, autonomy involves more than just balance; it encompasses daily functional activities, which might not be directly improved by the mere presence of an aid. Furthermore, while aids help in improving balance, patients might become overly dependent on them, potentially limiting their autonomy in daily tasks without the aid.

Among the foremost objectives of rehabilitation for stroke patients there are enhancing activity levels, reducing fatigue, and minimizing the risk of falls [30]. The choice of the rehabilitation program, with goal-oriented therapy, proprioceptive exercises, and dual task training was based upon the goals to be achieved, the recovery of autonomy, balance and the reduce of the risk of falling.

The contribution of this research is mainly represented by its

comprehensive approach to post-stroke rehabilitation. While much of the existing literature tends to focus on proprioceptive, dual-task, or goal-oriented training separately, this study melds all three therapeutic interventions, goal-oriented rehabilitation, proprioceptive training, and dual-task exercises.

Actually, literature agrees that proprioceptive training has positive effects on balance performance, gait speed, trunk control, and basic functional mobility among people with stroke [31,32]. Furthermore, current literature has shown a growing interest in the effects of dual-activity training across various conditions, including older adults [33], dementia [34], Parkinson's disease [35], and multiple sclerosis [36], with stroke being a prominent focus. Indeed, in stroke patients, despite the high heterogeneity of proposed exercises, all integrated cognitive and motor tasks with proprioceptive exercises proved effective, independently from the rehabilitation session's organization and timing [37,38,39]. In particular, dual task training shows an improvement in step length, cadence [18], balance, and a reduction of the risk of falling [40].

Furthermore, a task specific training, with an "oriented" dual task exercise, with a specific purpose and functional activity, is deemed to have positive effects on proprioceptive, balance, gait speed and spasticity in stroke survivors [41,42]. Several studies highlighted the significance of incorporating goal-oriented and motivational components into rehabilitation. A study utilized aquatic games [43], and another introduced tango lessons [44]. Such innovative approaches not only enhanced the patients' enjoyment of their rehabilitation program but also fostered greater treatment adherence and improved final outcomes. Moreover, combining specific task-oriented training with manual therapy appeared to improve balance and mobility in patients after stroke [45]. Furthermore, exergaming [39] and virtual reality-based dual task training [46] not only aids in walking and balance control [39,46], but also has discernible cognitive benefits in stroke survivors [39].

According to the results of the study, the integration of the following rehabilitation techniques (goal-oriented therapy, proprioceptive exercises, and dual task training) with traditional treatment (postural and core exercises, and gait training) allowed patients to recover independence and balance, and reduce the risk of falls, which is very important also for families and caregivers.

## Limitations

Despite the limitations related to the retrospective methods of

data collection and the small number of patients, we considered valuable to present our experience because of the absence of guidelines and consensus on this topic. While our study offered significant insights into the functional outcomes of goal-oriented proprioceptive training, especially in the context of balance and mobility, it did not include direct assessments of proprioception, such as joint position sense or specific proprioceptive tests, nor a comprehensive evaluation of muscle strength, nor a detailed evaluation of upper extremity function.

The retrospective nature of the research and the absence of standardized psychological scales were notable constraints. Indeed, patients were included based on the psychologist's qualitative evaluation, considering factors such as vigilance, cooperation, orientation in time and space, ability in maintaining their memory, attention, decision-making, and general cognitive processing capabilities (ability to understand, process, and respond to information effectively), as well as willingness and adherence to the rehabilitation program. Even if this approach lacked specific objective evaluation indicators, it allowed to include patients with favourable psychological attributes to active participation in rehabilitation.

This retrospective study did not include a direct assessment of muscle strength using dynamometers. The level of strength could be indirectly inferred based on the aids used by patients at admission and discharge.

## Conclusions

This study uniquely combines three key post-stroke rehabilitation strategies: goal-oriented, proprioceptive, and dual task training, offering a comprehensive therapeutic approach.

In the subacute phase of stroke, the goal-oriented proprioceptive training, both with single and dual task exercises, improved balance, abilities in ADLs, and reduced the risk of falls. Comparing the two rehabilitative strategies, dual task training demonstrated a significant improvement of balance, as assessed by Tinetti balance assessment, compared to single task exercises. Certainly, the consequent improvement of balance reduced the risk of falling, but only partially improved autonomy. Moreover, after goal-oriented dual task proprioceptive training, the use of mobility aids was strictly connected to the recovery of balance, supported by significant relationships with BBS and the Tinetti test's total score, particularly the gait component. However, these aids did not show a corresponding improvement in autonomy, as evidenced by the lack of a significant relationship with the Barthel Index. Additionally, mobility aids

did not significantly reduce the risk of falls, with no significant associations found in both single-task and dual-task versions of the TUG. Moreover, the use of mobility aids did not show a significant reduction in fall risk, as evidenced by the absence of significative associations in TUG performed both in single-task and dual-task and TUG.

However, more research is needed about this topic, to compare different rehabilitation strategies and find the best protocol to reduce the disability related to stroke.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Chiaramonte R, Bonfiglio M, Pirrone S, D'Amico S, Caramma S, Ronsisvalle MG, Grasso G. Methodology: Chiaramonte R, Bonfiglio M, Pirrone S. Formal analysis: Chiaramonte R, Pirrone S, Ronsisvalle MG. Project administration: D'Amico S, Caramma S. Supervision: D'Amico S, Caramma S. Writing – original draft: Chiaramonte R, Bonfiglio M. Writing – review and editing: Caramma S, Pirrone S, D'Amico S. Approval of final manuscript: all authors.

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# Insole Pressure Sensors to Assess Post-Stroke Gait

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**Objective:** To confirm that the simplified insole does not affect the gait speed and to identify objective sensor-based gait parameters that correlate strongly with existing clinical gait assessment scales.

**Methods:** Ten participants with gait impairment due to hemiplegic stroke were enrolled in this study. Pairs of insoles with four pressure sensors on each side were manufactured and placed in each shoe. Data were extracted during the 10-Meter Walk Test. Several sensor-derived parameters (for example stance time, heel\_on-to-toe\_peak time, and toe\_peak pressure) were calculated and correlated with gait speed and lower extremity Fugl-Meyer (F-M) score.

**Results:** The insole pressure sensor did not affect gait, as indicated by a strong correlation ( $\rho=0.988$ ) and high agreement ( $\text{ICC}=0.924$ ) between the gait speeds with and without the insole. The parameters that correlated most strongly with highest  $\beta$  coefficients against the clinical measures were stance time of the non-hemiplegic leg ( $\beta=-0.87$  with F-M and  $\beta=-0.95$  with gait speed) and heel\_on-to-toe\_peak time of the non-hemiplegic leg ( $\beta=-0.86$  with F-M and  $-0.94$  with gait speed).

**Conclusion:** Stance time of the non-hemiparetic leg correlates most strongly with clinical measures and can be assessed using a non-obtrusive insole pressure sensor that does not affect gait function. These results suggest that an insole pressure sensor, which is applicable in a home environment, may be useful as a clinical endpoint in post-stroke gait therapy trials.

**Keywords:** Stroke, Gait analysis, Insole pressure sensor, Outcome measure

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## INTRODUCTION

Gait impairment is a common consequence of stroke. In the United States alone, an estimated 795,000 people suffer from stroke every year, and more than 80% of survivors experience gait impairment after stroke [1,2]. In order to test new rehabilitation therapies that may improve gait, it is important to have an objective measure of a patient's gait. The gold standard for

gait assessment is camera-based motion analysis in gait laboratories [3]. However, the relative complexity of the setup and the sparsity of gait laboratories in outpatient clinics makes gait analysis in a dedicated gait laboratory impractical for large-scale clinical trials. Another limitation of testing gait in a laboratory is the artificial environment used. As an alternative to formal gait testing in gait laboratories, trials have opted to use clinic-based assessments, such as the 10-Meter Walk Test (10MWT), as their

study endpoint [4]. While these tests are more practical than those obtained in gait laboratories, they are more limited in scope because they produce only a single dimension temporal score, they still require a trained observer, and they are obtained in a clinical setting that may not reflect the patient's gait during everyday life [5].

Assessing gait using sensors that can be worn during everyday life could prove more clinically relevant by providing multidimensional objective and quantitative outcome data without the complexities and time involved with laboratory or clinic-based testing. Recent studies have investigated the use of accelerometers, gyro sensors, and pressure sensors to assess dynamic balance during standing and walking and to assess the walking strategies of persons with stroke [6-11]. The parameters analyzed in such studies provide quantitative data such as asymmetry, kinematic characteristics, and gait performance. However, the clinical relevance of these parameters has not been verified.

To address these limitations, we designed, fabricated, and tested an insole pressure sensor to assess gait. The goal of this study was to confirm that the simplified insole does not affect the gait speed and to identify objective insole sensor-based gait parameters that correlate strongly with existing clinical gait assessment scales.

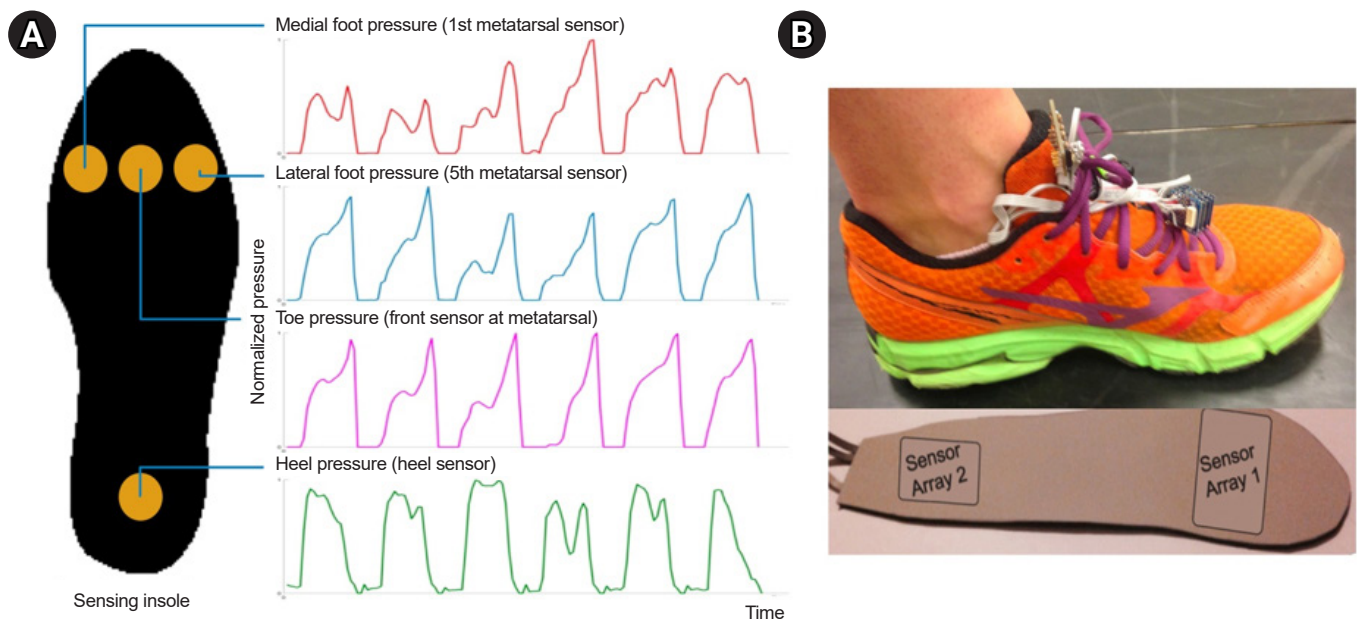
## METHODS

### Insole pressure sensor system

Pairs of insoles with four pressure sensors were manufactured. The sensors were positioned at the plantar aspect of the 1st metatarsal head (medial pressure), 3rd metatarsal head (toe pressure), 5th metatarsal head (lateral pressure), and the calcaneal tuberosity (heel pressure, Fig. 1A). The pressure sensor data were acquired every 60 ms (approximately 16.7 Hz) with a timestamp and normalized to a 0 to 1 scale. The beginning and end of the data acquisition were controlled using a button switch. Sensor data from the four sensors on each insole were time-synchronized, but the data were not time-synchronized between insoles. Thin insoles and simple pressure sensor arrays were selected to simplify the device and minimize its effect on gait. Multiple insoles were created to ensure proper fit and placement of the sensors across a range of foot sizes for both male and female. Fig. 1B shows a person wearing a shoe with the insole pressure sensor system.

### Protocol

This study was approved by the Institutional Review Board of Stanford University (IRB No. 32540), and informed consent was obtained from all participants. Stroke patients were screened



**Fig. 1.** (A) Schematic image of the 4 insole sensors and their example data. (B) A photo of a person wearing the shoe with the insole pressure sensor system is shown.

for this study in the Ambulatory Stroke Clinic of the Neurology Department of Stanford University. Participants were eligible for the study if they were determined to have gait impairment secondary to stroke by the attending neurology clinician, but were able to ambulate without the assistance of a person. The use of a cane, walker, and/or ankle-foot orthosis was permitted. At baseline, demographic data including age, sex, height and weight, hemiplegic side, and the National Institutes of Health Stroke Scale (NIHSS) and lower extremity Fugl-Meyer (F-M) scores were obtained. The F-M assessment was performed by a physical therapist for the lower extremities using the standard protocol at the time of enrollment to the study [12]. The participants performed the 10MWT for three trials with and three trials without instrumented insoles [13]. Participants were instructed to walk at their normal comfortable speed and were informed that they could stop or rest at any time. To mitigate the effects of fatigue on determining whether the device itself affected gait, the order of performing the 10MWT with or without the device was first randomized. Gait speed was measured manually in all trials, following the standard scoring procedures of the 10MWT.

### Sensor-derived parameters

Based on the pressure data from the four sensors, more than 10 consecutive effective steps were extracted (average of approximately 12 steps), and the timestamps of heel\_on, heel\_peak, toe\_peak, and toe\_off were determined. From these timestamps, six gait parameters were calculated for both the non-hemiplegic and hemiplegic lower extremities: (1) stance time, (2)

heel\_on-to-heel\_peak time, (3) heel\_on-to-toe\_peak time, (4) heel\_peak-to-toe\_peak time, (5) toe\_peak pressure before normalization, and (6) stance ratio, calculated as non-hemiplegic stance time divided by hemiplegic stance time (Fig. 2A).

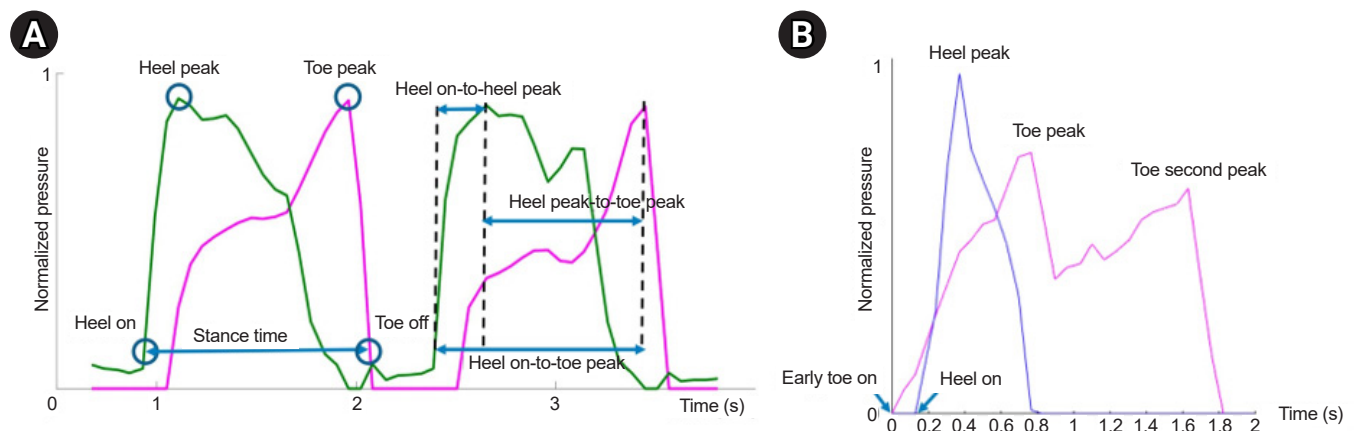
### Statistical analysis

A Spearman's rank correlation analysis, linear regression, and inter-rater correlation coefficient (ICC) calculation were performed between gait speed without the device and gait speed with the device to assess the impact of the device on gait. Spearman's rank correlation coefficients were calculated between the sensor-derived parameters and two clinical measures (lower extremity F-M score and gait speed). Based on the correlation analysis, univariate linear regression analyses were performed for each variable. IBM SPSS 25.0 (IBM Corp.) was used for all statistical analyses. p-value was set at  $p < 0.05$ .

## RESULTS

### Participants

Ten participants with stroke were enrolled in this study. In two participants, the right sensor malfunctioned and did not collect sufficient data for analysis, leaving eight participants for the analyses. These subjects consisted of 4 participants with left hemiplegia and 4 with right hemiplegia. The mean age was  $61 \pm 15$  years, and there were 6 male and 2 female. Assistive devices such as a cane, walker, and ankle-foot orthosis were used by four participants during gait testing. The demographic data of the participants are presented in Table 1. Disability levels



**Fig. 2.** (A) Definitions of main parameters in this study are visually shown based on toe and heel pressure sensor data. (B) An example of toe and heel pressure sensor data pattern in a participant with severe ankle spasticity.

**Table 1.** Demographic data of the study subjects

| Variable                              | Value (n=8) |
|---------------------------------------|-------------|
| Age (yr)                              | 61±15       |
| Sex (male/female)                     | 6/2         |
| Height (m)                            | 1.72±0.13   |
| Weight (kg)                           | 74.4±20.4   |
| Hemiplegic side (left/right)          | 4/4         |
| Duration since stroke onset (yr)      | 2.95±2.39   |
| NIHSS score                           | 4.5±2.3     |
| Lower extremity F-M score             | 25.6±5.45   |
| No. of subjects with assistive device |             |
| Cane                                  | 2           |
| Ankle-foot-orthosis                   | 1           |
| Walker                                | 1           |
| None                                  | 4           |

Values are presented as mean±standard deviation or number only.  
NIHSS, National Institutes of Health Stroke Scale; F-M, Fugl-Meyer.

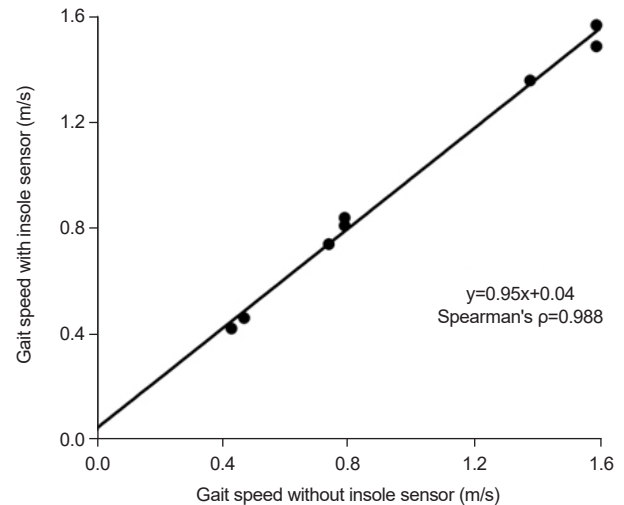
among the participants ranged from moderate to no significant disability, with NIHSS scores ranging from 1 to 7 and lower extremity F-M scores ranging from 20 to 34.

### Feasibility data (gait speed with vs. without insole pressure sensor)

Gait speed while wearing shoes with the insole pressure sensors inside the shoes and gait speed without the insole pressure sensors showed a strong linear relationship ( $\rho=0.988$ ,  $p<0.001$ ) with a slope near 1 ( $\beta=0.95$ ) and near-zero y-intercept (0.04), with an ICC of 0.924 ( $p=0.002$ ), showing high agreement of the independently measured speeds. This suggests minimal influence of the insole pressure sensor on gait speed and that it is appropriate to use for gait measurements (Fig. 3).

### Correlation analysis and univariate linear regression of sensor data and clinical measures

The Spearman's correlation coefficients and  $\beta$  coefficients of univariate linear regression model between sensor-based parameters and clinical measures (lower extremity F-M score and gait speed) are listed in Table 2. The sensor-based data that correlated most strongly with highest  $\beta$  coefficient with the lower extremity F-M score were stance time of the non-hemiplegic leg ( $\rho=-0.99$ ,  $\beta=-0.87$ ), followed by heel\_on-to-toe\_peak time of the non-hemiplegic leg ( $\rho=-0.75$ ,  $\beta=-0.86$ ) and heel\_on-to-heel\_peak time of the non-hemiplegic leg ( $\rho=-0.78$ ,  $\beta=-0.78$ ). The same three parameters also showed highest  $\beta$  coefficient with gait speed ( $\beta=-0.95$  for non-hemiplegic stance time;  $\beta=-0.94$  for non-hemiplegic heel\_on-to-toe\_peak time;  $\beta=-0.84$



**Fig. 3.** Gait speed without insole sensor vs. gait speed with insole sensor are plotted for all 8 study subjects, which show strong linear relationship ( $\rho=0.988$ ,  $p<0.001$ ) with an inter-rater correlation coefficient of 0.924 ( $p=0.002$ ).

for non-hemiplegic heel\_on-to-heel\_peak time). Among the toe\_peak pressure parameters, hemiplegic toe\_peak pressure showed significant correlation with gait speed ( $\rho=-0.79$ ,  $\beta=0.71$ ). Stance ratio did not show significant correlation with the clinical measures. Univariate linear regression results with highest  $\beta$  coefficients are shown in Fig. 4. Sensor-based parameters with high  $\beta$  coefficients were chosen because higher absolute value of  $\beta$  suggests higher prediction.

## DISCUSSION

This study demonstrated that insoles with pressure sensors can be used to evaluate gait function in patients with stroke. The insole pressure sensor did not alter the subjects' natural walking speeds (Fig. 3). Several of the sensor-based measures correlated strongly with gait speed and lower extremity sensorimotor impairment; stance time of the non-hemiplegic foot was the sensor-based measure that correlated most strongly with these clinical outcome measures. In addition to the stance time of the non-hemiplegic limb, the heel\_on-to-toe\_peak time of the non-hemiplegic foot also demonstrated good correlations with lower extremity F-M and gait speed. This is intuitive because the heel\_on-to-toe\_peak time is closely related to the stance time; heel\_on-to-toe\_peak time equals the stance time minus the short period from toe\_peak-to-toe\_off (Fig. 2A).

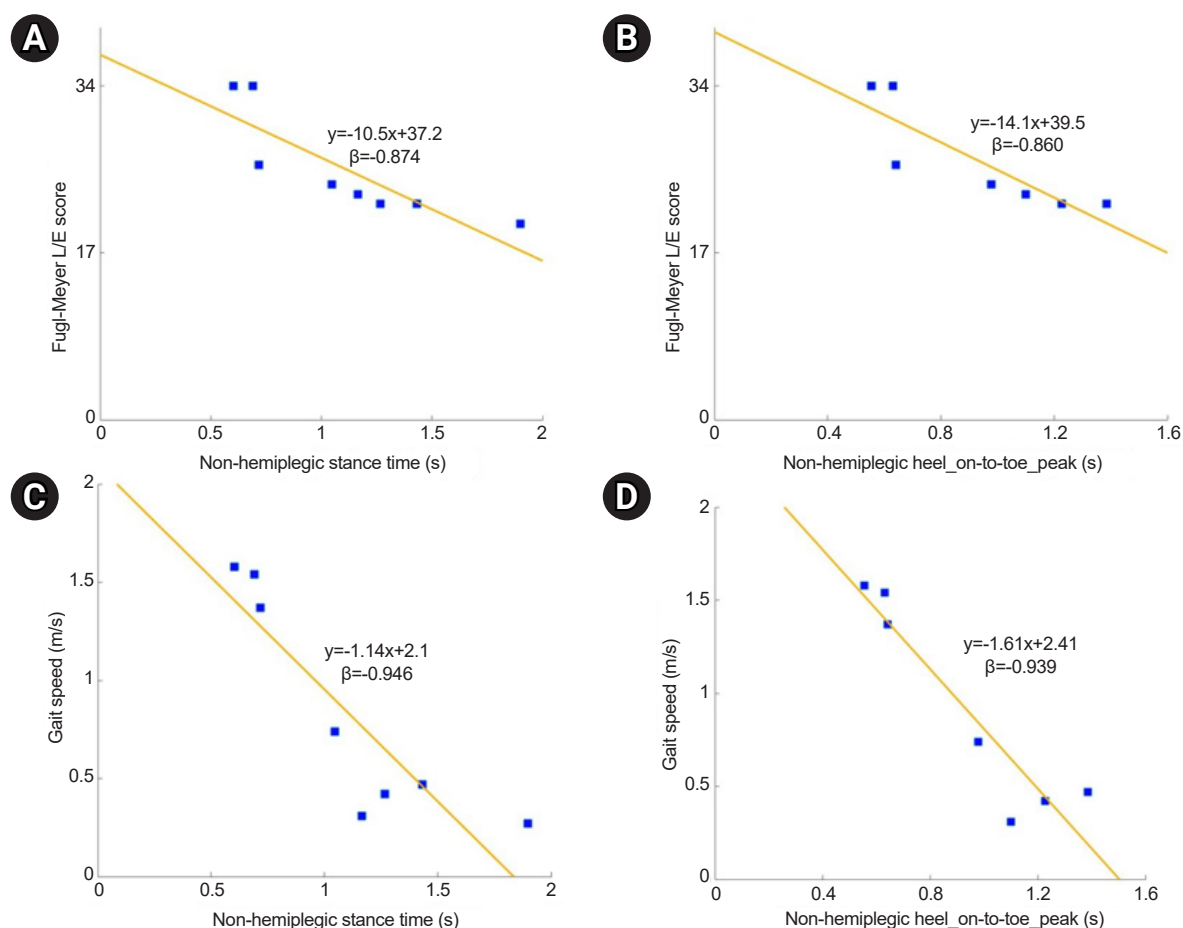
**Table 2.** Mean values of the sensor-based parameters and their relationship between lower extremity F-M score and gait speed

| Gait parameter                      | Mean±SD (s)               | Lower extremity F-M score |                           | Gait speed (m/s)         |                           |
|-------------------------------------|---------------------------|---------------------------|---------------------------|--------------------------|---------------------------|
|                                     |                           | $\rho$ (p) <sup>a)</sup>  | $\beta$ (p) <sup>b)</sup> | $\rho$ (p) <sup>a)</sup> | $\beta$ (p) <sup>b)</sup> |
| Hemi_stance time                    | 0.97±0.36                 | -0.99 (<0.01*)            | -0.74 (0.03*)             | -0.91 (<0.01*)           | -0.76 (0.03*)             |
| Hemi_heel_on-to-heel_peak time      | 0.24±0.20                 | -0.57 (0.14)              | -0.66 (0.08)              | -0.69 (0.06)             | -0.71 (0.05*)             |
| Hemi_heel_on-to-toe_peak time       | 0.73±0.28                 | -0.84 (0.01*)             | -0.72 (0.04*)             | -0.76 (0.03*)            | -0.70 (0.06)              |
| Hemi_heel_peak-to-toe_peak time     | 0.49±0.36                 | -0.59 (0.12)              | -0.23 (0.59)              | -0.38 (0.35)             | -0.18 (0.68)              |
| Hemi_toe_peak pressure              | 309.8±138.1 <sup>d)</sup> | 0.66 (0.07)               | 0.50 (0.21)               | 0.79 (0.02*)             | 0.71 (0.05*)              |
| Non-hemi_stance time                | 1.09±0.40                 | -0.99 (<0.01*)            | -0.87 (<0.01*)            | -0.91 (<0.01*)           | -0.95 (<0.01*)            |
| Non-hemi_heel_on-to-heel_peak time  | 0.29±0.27                 | -0.78 (0.02*)             | -0.78 (0.02*)             | -0.79 (0.02*)            | -0.84 (<0.01*)            |
| Non-hemi_heel_on-to-toe_peak time   | 0.95±0.31                 | -0.75 (0.03*)             | -0.86 (0.01*)             | -0.67 (0.07)             | -0.94 (<0.01*)            |
| Non-hemi_heel_peak-to-toe_peak time | 0.67±0.22                 | -0.24 (0.57)              | -0.72 (0.07)              | -0.17 (0.69)             | -0.80 (0.03*)             |
| Non-hemi_toe_peak pressure          | 424.6±120.4 <sup>d)</sup> | -0.24 (0.61)              | -0.15 (0.75)              | 0.11 (0.82)              | 0.02 (0.96)               |
| Stance ratio <sup>c)</sup>          | 1.12±0.12                 | -0.37 (0.36)              | -0.50 (0.20)              | -0.38 (0.35)             | -0.59 (0.13)              |

SD, standard deviation; F-M, Fugl-Meyer.

<sup>a)</sup>Spearman's correlation analysis ( $\rho$  indicates coefficient of Spearman's correlation).<sup>b)</sup>Univariate linear regression analysis ( $\beta$  indicates beta coefficient of linear regression model).<sup>c)</sup>Stance ratio=non-hemi\_stance time/hemi\_stance time (no dimension).<sup>d)</sup>Presented in sensor value recorded from the insole pressure sensor.

\*p&lt;0.05 were considered statistically significant.

**Fig. 4.** Univariate linear regression analyses with non-hemiplegic stance time and non-hemiplegic heel\_on-to-toe\_peak time as independent variables, and lower extremity Fugl-Meyer score (A, B) and gait speed (C, D) as dependent variables are shown. All results indicate significant negative linear relationships. L/E, lower extremity.



Several systems have been developed for the gait evaluation of various neurological and musculoskeletal diseases [14]. Camera-based gait analysis systems provide detailed, multifaceted, and accurate information but require abundant space, sufficient manpower, time, and costs. These limitations are particularly burdensome when repeated measurements are required, such as is often the case in a longitudinal follow-up study of gait function after stroke. Inertial measurement unit (IMU)-based sensor systems that can measure step time or stride time exist; however, these systems may not be accurate in patients with stroke who often have abnormal gait patterns. We aimed to address these limitations by developing a pressure-based sensor system that can automatically detect and analyze discrete and easily identifiable events such as heel strike and toe push-off [15,16]. The pressure sensor insole system developed and tested in this study consists of a simple pair of insoles that are highly portable and can be used in laboratory, clinic, or home settings.

In this study, we used two clinical measures as a reference for each subject's functional status: lower extremity F-M score and gait speed. The F-M score is the most widely used and verified functional evaluation tool in stroke rehabilitation [12]. Gait speed is known to best describe general physical performance, including walking performance, and is a patient-centered outcome measure, as it affects patients' quality of life [14]. Among the different sensor-based measures, this study found that the stance time of the non-hemiplegic limb had the highest correlation and predictivity with both clinical measures: lower-extremity F-M score and gait speed (Table 2). The non-hemiplegic stance time demonstrated highest  $\beta$  coefficient (-0.87) in linear regression model with the clinical measures (Fig. 4), in which the absolute value is near 1. This supports the potential use of the parameter in a clinical setting because a certain extent of change in the non-hemiplegic stance time may predict meaningful change in the F-M score or gait speed as well. This finding is consistent with previous studies that reported that a longer stance time of the unaffected limb correlates with worse functional outcomes assessed with the Berg Balance Scale and gait speed [17,18]. Our findings are also consistent with the common clinical knowledge that hemiplegic gait exhibits a relatively short stance time of the hemiplegic limb and a long stance time of the non-hemiplegic limb as a result of a prolonged swing phase of the hemiplegic side [15].

Parameters indicative of gait asymmetry have been investigated in previous studies, and it has been suggested that the stance ratio between the non-hemiplegic and hemiplegic sides may be

a useful clinical outcome parameter [11,19-22]. In our study, this parameter did not show a significant correlation with clinical measures (Table 2). Also, the ratio of peak pressure of each sensor did not show significant correlation with clinical measures (data not shown). While same-side sensors were time synchronized for this study, they were not synchronized between sides, which may have influenced the symmetry measures. Pressure asymmetry has also been suggested to be a clinically meaningful parameter [21]. We confirmed this in our study as we showed that decreased toe\_peak pressure of the hemiplegic side was correlated with slower gait speed ( $\rho=0.79$ , Table 2). This is explained by weight shifting to the non-hemiplegic side and impaired push-off function in the forefoot area of the impaired limb during walking in patients with a hemiplegic gait [15,23].

In most of the cases when the ankle spasticity is not too severe, the pressure data followed similar patterns as shown in Fig. 2A. However, in the cases with severe ankle spasticity and equinovarus deformity, it showed relatively early toe onset, short duration of heel pressure, and significant double peak of toe pressure: first on initial contact due to insufficient heel strike, and second on push off phase (Fig. 2B). In some steps the first peak was higher than the second peak. This pattern supports the study results that the heel\_on-to-heel\_peak time average is similar in both sides, but the heel\_on-to-toe\_peak time is apparently shorter in the hemiplegic side.

This study has some limitations. First, the number of participants was too small to generalize the results to the entire stroke population, and larger follow-up studies are necessary to validate our results. However, some of the sensor-based gait parameters correlated strongly with the clinical outcome measures, and the results were significant despite the small number of participants. Second, the timestamps of the left and right insole pressure sensors were not synchronized. Further investigations focusing on the pressure relationship between the two limbs may provide additional clinically relevant information. Third, the sensor did not provide accurate pressure data especially in abnormal gait patterns. There are similar issues when using IMU sensors for stroke gait analysis, especially when the system is intended to be unobtrusive and simple; usually accuracy and practical clinical feasibility is in a trade-off relationship [24]. Therefore, we aimed to extract a simple sensor-based parameter highly correlating with clinical measures.

In conclusion, the stance time and heel\_on-to-toe\_peak time of the non-hemiplegic foot were the most indicative of gait

function in stroke subjects. Insole pressure sensors may be useful by providing clinicians and researchers with simple objective outcome measures, which correlates with clinical measures, that could be assessed in an unobtrusive way during short gait testing in clinics or in the patient's home environment during routine activities.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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None.

## AUTHOR CONTRIBUTION

Conceptualization: Lansberg MG. Methodology: Clancy C, Lansberg MG. Formal analysis: Nam HS, Smuck M, Lansberg MG. Visualization: Nam HS, Lansberg MG. Writing – original draft: Nam HS, Smuck M, Lansberg MG. Writing – review and editing: Nam HS, Clancy C, Smuck M, Lansberg MG. Approval of final manuscript: all authors.

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# Efficacy and Safety of High Density LED Irradiation Therapy for Patients With Hand Osteoarthritis: A Single-Center Clinical Study

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**Objective:** To assess the safety and effectiveness of high-density light-emitting diode (LED) irradiation therapy in patients with hand osteoarthritis (OA) and compare the pre- and post-intervention symptoms.

**Methods:** Twenty-three patients with hand OA underwent eight sessions of high-density LED irradiation therapy directed at the five most painful areas in the finger joints. Each session lasted for 18 minutes; and the sessions were conducted twice a week, for 4 weeks. We evaluated the degree of pain using the visual analogue scale, ring size, and passive range of motion (flexion+extension) for two most painful joints from the baseline to post-therapy (weeks 4 and 6).

**Results:** High-density LED irradiation therapy significantly reduced the pain posttreatment compared with that observed at the baseline ( $p<0.001$ ). Although improvements were observed in ring size and joint range of motion at 4 and 6 weeks, they were not statistically significant ( $p>0.05$ ). No adverse events were observed.

**Conclusion:** We examined the safety and effectiveness of high-density LED irradiation therapy in reducing pain and hand swelling and improving joint mobility in patients with hand OA. These results suggest that high-density LED irradiation therapy has the potential to be an important strategy for managing hand OA.

**Keywords:** Hand, Osteoarthritis, Pain, Phototherapy

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## INTRODUCTION

Osteoarthritis (OA) is a musculoskeletal disease whose prevalence is rapidly increasing with the aging population and obesity trends [1,2]. OA is the fourth leading cause of nonfatal disability

worldwide, with a large impact on medical and indirect costs due to work losses and premature retirement [3]. Patients with OA often experience significant limitations in their daily lives due to the severity of their illness. Unfortunately, damaged cartilage cannot regenerate, and reduced activity due to pain results

in a decrease in synovial fluid volume, causing the affected joint to become stiff [4]. In the early stages, the pain tends to worsen when the joint is moved; however, as the disease progresses, it persists regardless of movement. Chronic pain is a hallmark of advanced arthritis and can significantly affect the quality of life [5]. As arthritis progresses, several characteristic symptoms appear, including decreased range of motion (ROM) of the joint, swelling, and tenderness around the affected joint [6]. The combined effects of these symptoms can lead to functional impairment and reduced mobility in patients with arthritis [7].

Hand OA can involve multiple joints, such as the distal and proximal interphalangeal joints, and presents with various patterns [8]. Patients with hand OA have weak grip strength, poor accuracy, and poor fine motor skills, which not only cause loss of work capacity but also pose many obstacles to their daily lives. Despite its high prevalence and complications, previous studies have focused only on arthritis of large joints such as the hips and knees, and research on arthritis of small joints such as those of the hands is lacking [9,10].

The primary goal of hand OA treatment is to alleviate the associated symptoms. Treatment modalities for hand OA include non-pharmacological approaches such as ROM training, muscle strengthening exercises, utilization of supportive devices, and the application of splints [11]. Pharmaceutical interventions involve the use of acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) orally or topically. The European League Against Rheumatism has proposed an integrated approach that combines both non pharmacological and pharmacological treatments to effectively manage hand OA [12]. However, among the representative pharmacological therapies, therapy using NSAIDs may adversely affect the digestive system and blood coagulation mechanism [13]. In addition, the opioids used for pain relief may induce sedation, mood fluctuations, depression, and increased anxiety, combined with drug dependence [14].

In some cases, medical professionals administer intra-articular injections of corticosteroids or hyaluronic acid into the affected joints to reduce symptoms and improve mobility. However, these effects are temporary and may promote articular cartilage degeneration and infection, potentially impeding disease progression [15]. Consequently, the long-term effectiveness of intra-articular therapies in the management of hand OA is limited [16]. Moreover, the 2012 American College of Rheumatology (ACR) guidelines do not recommend this approach [17].

Surgical procedures such as arthroscopic debridement, synovectomy of the trapeziometacarpal joint, and early tendon

arthroplasty are typically considered the last option for the treatment of hand OA and are pursued only when less invasive treatments have proven ineffective [18]. Because surgical interventions are highly invasive, complications such as pain, infection, instability, nerve dysfunction, tendon-pulling sensation, and chronic regional pain syndrome are common. Furthermore, the patients need to undergo postoperative rehabilitation [19].

Photobiomodulation therapies such as low-power laser therapy and light-emitting diode (LED) therapy have been proposed as novel treatments for skin cancer and pain relief [20,21]. They have the advantage of being safe, non-addictive, and non-invasive without side effects [21]. LEDs influence cellular metabolism by initiating intracellular photobiochemical reactions. The notable outcomes include increased adenosine triphosphate production, modulation of reactive oxygen species, reduction of pro-inflammatory cytokines like interleukin (IL)-1 $\beta$ , IL-6, and tumor necrosis factor- $\alpha$ , activation of transcription factors, changes in collagen synthesis and angiogenesis, and improvements in blood circulation [22]. Prior research has demonstrated the efficacy of LEDs in reducing inflammation, pain, and edema through these mechanisms [20,23]. Owing to their relatively low cost and safety compared with that of lasers, LEDs are used worldwide in various fields. Despite these advantages, research on the effects of LEDs on musculoskeletal problems is insufficient.

In this study, we aimed to determine the safety and efficacy of high-density LED irradiation therapy in patients with hand OA and compare the patients' symptoms before and after the intervention.

## METHODS

### Participants and study design

This single-group study was performed between July and August 2023 at a single clinical center. Individuals aged between 40 and 80 years, diagnosed with arthritis according to the ACR guidelines, exhibiting hand OA in anteroposterior radiographs, and with a visual analogue scale (VAS) score of 40 mm or greater at the screening visit were included.

Patients who had undergone hand-joint surgery, experienced pain in areas other than the hand joint, or had ligament instability of >5 mm were excluded. Individuals who had taken NSAIDs within 48 hours before screening, immunosuppressive medications within 6 weeks, psychotropic or narcotic analgesics within 8 weeks, or intra-articular injections within 6 months



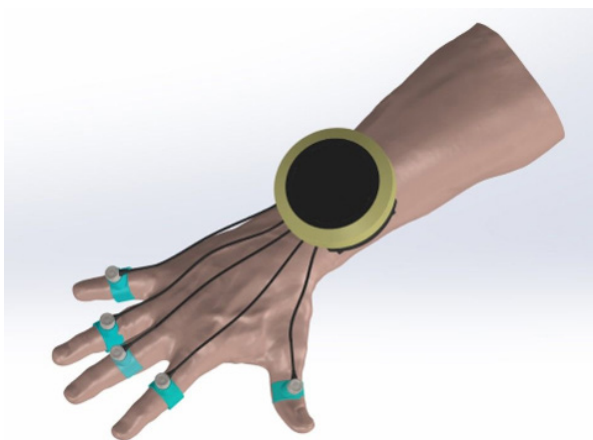
were excluded.

A total of 23 patients participated in the study. We evaluated the degree of pain in the hand at rest using a 100-mm VAS and circumference and passive ROM of the two most painful joints at the baseline, based on the design of the single previous study on irradiation therapy for hand OA, in which an average of  $2.50 \pm 1.54$  joints per patient were examined [9]. The VAS score was assessed after 10 minutes of rest in the sitting position. According to the neutral-zero method, the zero position of a joint is defined as the normal anatomical position [24]. The ROM was determined by adding the flexion and extension angles. The measurements were obtained by an expert in the field of Physical Medicine and Rehabilitation. After eight treatment sessions lasting 4 weeks, the three outcome measures were re-evaluated for all patients.

The study protocol was approved by the Institutional Review Board of Yonsei University Wonju Severance Christian Hospital (No. CR222026). All the participants provided written informed consent. The investigators explained the purpose, methods, and potential risks of the study to all the participants.

### High-density LED irradiation therapy

A high-density LED irradiation therapy device (PT-100/iPHOTON; MI.One) was used to treat the five most painful interphalangeal joints (Fig. 1). The device was equipped with infrared LEDs having wavelengths of 850 and 940 nm. High-density



**Fig. 1.** High-density light-emitting diode (LED) irradiation therapy device (PT-100/iPHOTON; MI.One) used to hand osteoarthritis. A probe equipped with infrared LEDs of 850 and 940 nm wavelengths and can be applied to total of five joints at once.

light irradiation was applied for 18 minutes per session, twice a week, for a total of eight times over 4 weeks.

### Safety assessment

Adverse events were evaluated for each treatment session up to 30 minutes after the end of the application. Vital signs (systolic/diastolic blood pressure, pulse rate, and body temperature) were recorded. The patients were asked to spontaneously report information on adverse events such as pain, erythema and blistering and other discomfort they felt, as needed. Patient diaries were prepared, and interviews with the patients were conducted throughout the study period.

### Statistical analysis

To analyze the results of this study, the SAS software version 9.4 (SAS Institute Inc.) and R Studio software version 4.1.3 were used. Descriptive statistics (including mean, standard deviation, median, and minimum and maximum values) were used to examine the changes in patient outcome measurements. This assessment was conducted using a paired t-test with the baseline hand pain value considered as a covariate.

We used the repeated measures ANOVA technique and performed Bonferroni analysis for multiple comparisons. Differences among groups in terms of continuous variables were evaluated using one-way ANOVA, and post hoc comparisons were adjusted using the Bonferroni method. For dichotomous variables,  $\chi^2$  tests were performed. The relationships between continuous variables were analyzed using Pearson's correlation coefficients. For all tests, statistical significance was set at a p-value of less than 0.05.

## RESULTS

A total of 23 patients of 6 males and 17 females were enrolled in the study, and a significant difference was observed between the sexes

**Table 1.** Clinical characteristics of patients

| Variable                              | Value (n=23)       |
|---------------------------------------|--------------------|
| Age (yr)                              | 66.87 $\pm$ 4.35   |
| Sex: male/female                      | 6 (26.1)/17 (73.9) |
| VAS (mm): baseline (week 0)           | 72.78 $\pm$ 13.14  |
| Circumference (mm): baseline (week 0) | 57.41 $\pm$ 7.96   |
| ROM ( $^{\circ}$ ): baseline (week 0) | 75.22 $\pm$ 17.19  |

Values are presented as mean $\pm$ standard deviation or number (%).

VAS, visual analogue scale (0 mm=no pain, 100 mm=most severe pain); ROM, range of motion (flexion+extension).

( $p=0.0218$ ). The mean age of the patients was  $66.87 \pm 4.35$  years, and the baseline VAS was  $72.78 \pm 13.14$  mm. The baseline circumference of 46 joints (two joints in 23 patients) was  $57.41 \pm 7.96$  mm and the degree of ROM was  $75.22^\circ \pm 17.19^\circ$  (Table 1).

The post hoc analysis using Bonferroni for multiple comparisons among the three time points revealed a significant difference between the VAS scores at the baseline and the 4 weeks posttreatment, as well as between the scores at the baseline and 6 weeks posttreatment ( $p<0.0001$ ). However, no statistically significant difference was observed between the scores obtained at 4 and 6 weeks posttreatment ( $p=0.59$ ). Although the ring sizes and joint ROMs improved at 4 and 6 weeks from the baseline, these changes were not statistically significant ( $p>0.05$ ; Table 2, Figs. 2-4).

No adverse reactions were observed after the treatment and during the follow-up period.

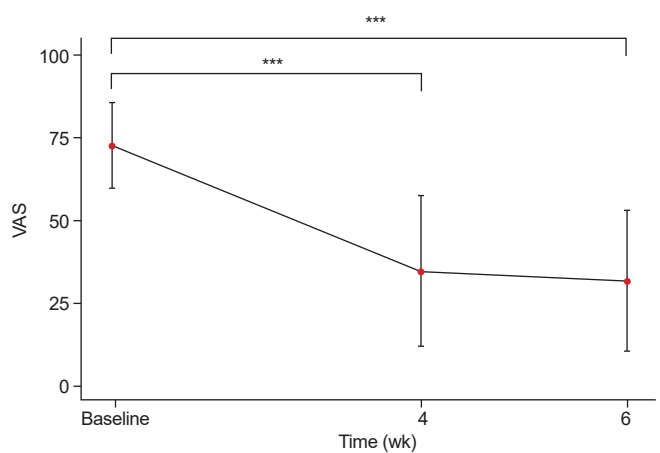
## DISCUSSION

This is the first study in which the efficacy and safety of high-density LED irradiation therapy for pain relief, hand edema, and improved joint ROM was evaluated in patients with hand OA.

A statistically significant improvement in pain was observed at 4 and 6 weeks from the baseline ( $p<0.0001$ ); however, no significant difference was observed between the symptoms at these two intervals ( $p=0.59$ ). The treatment resulted in significant pain reduction after 4 weeks, and the delayed effect lasted for two weeks. Clinical improvements in ring size and joint ROM were observed from the baseline to weeks 4 and 6; however, these changes were not statistically significant ( $p>0.05$ ). It is possible that the participants exhibited high initial VAS scores

but relatively mild edema and limited ROM. Moreover, there was a significant enhancement in the VAS scores was evident after the LED irradiation therapy. Consequently, we observed improvement of circumference or passive ROM plausibly indicative of clinical progress without any statistically significant outcomes. Therefore, further studies focusing on cases with severe edema and limited ROM are warranted.

Previous studies on LED irradiation therapy have shown that prolonged irradiation can cause treatment-site pain, erythema, hyperpigmentation, and blistering. However, most patients recover without permanent injuries [25,26]. The safety evaluation



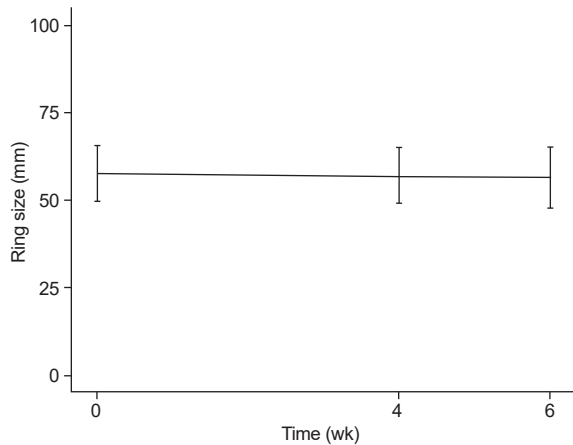
**Fig. 2.** Changes in mean visual analogue scale (VAS; 0 mm=no pain, 100 mm=most severe pain) scores at baseline (week 0), after week 4 and 6 over time error bars indicate standard deviations, p-values were calculated by one-way within subjects ANOVA's and Bonferroni corrected post hoc comparisons. \*\*\* $p<0.0001$

**Table 2.** Clinical efficacy evaluation

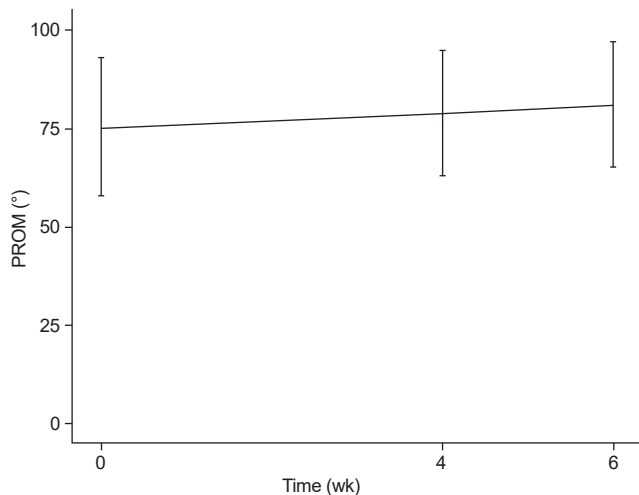
|               | ANOVA       |            | Post-hoc comparison (Bonferroni) |                 |            |
|---------------|-------------|------------|----------------------------------|-----------------|------------|
|               | F-statistic | p-value    | Comparison                       | Mean difference | p-value    |
| VAS           | 31.69       | <0.0001*** | Baseline vs. Week 4              | 38.174          | <0.0001*** |
|               |             |            | Week 4 vs. Week 6                | 3.043           | 0.5997     |
|               |             |            | Week 6 vs. Baseline              | -41.217         | <0.0001*** |
| Circumference | 0.23        | 0.7958     | Baseline vs. Week 4              | 0.652           | 0.7032     |
|               |             |            | Week 4 vs. Week 6                | 0.500           | 0.7702     |
|               |             |            | Week 6 vs. Baseline              | -1.152          | 0.5011     |
| ROM           | 1.42        | 0.2458     | Baseline vs. Week 4              | -3.587          | 0.2928     |
|               |             |            | Week 4 vs. Week 6                | -2.065          | 0.5442     |
|               |             |            | Week 6 vs. Baseline              | 5.652           | 0.0984     |

VAS, visual analogue scale (0 mm=no pain, 100 mm=most severe pain); ROM, range of motion (flexion+extension).

\* $p<0.05$  is significant at  $\alpha=0.05$ , \*\*\* $p<0.0001$ .



**Fig. 3.** Changes in ring size at baseline (week 0), after week 4 and 6 over time error bars indicate standard deviations.



**Fig. 4.** Changes in joint passive range of motion (PROM, flexion+extension) baseline (week 0), after week 4 and 6 over time error bars indicate standard deviations.

revealed the absence of any adverse events after the application of high-density LED irradiation therapy, and the risk associated with high-density LED irradiation therapy devices was considered low. In several other studies conducted using LEDs for skin lesions, the side effects were either mild or not reported [21,23].

The depth of tissue penetration depends on the tissue type. In general, penetration depths are as follows: less than 1 mm at 400–470 nm, 0.5–2 mm at 570–590 nm, 2–3 mm at 630–700 nm, and 5–10 mm at 800–1,200 nm [21]. The longer the wavelength, the higher is the penetration. Several studies have high-

lighted that combining LED wavelengths is more effective than using a single wavelength to treat skin lesions [22,23,27]. Hence, we opted for infrared wavelengths to reach the joint effectively and chose a combination of LED wavelengths.

Various treatments, including medications, physical therapy, and surgery, have been used to treat OA, but their use has been limited due to several disadvantages such as multiple organ damages from NSAIDs [13], the risk of opioid abuse [14], and infectious arthritis and cartilage damage from intra-articular injections [15]. Therefore, noninvasive light therapies such as lasers and LEDs have recently emerged as treatments for musculoskeletal problems. Although studies have been conducted on the improvement of pain, inflammation, and edema using low-level lasers, research on LED therapy is lacking [28–32]. In addition, LED light therapy is not only safer than laser therapy, which is associated with side effects (eye and skin irritations), but also has numerous advantages: convenience of utility at home, application to a wider range of target tissue areas, wearable feature, and the considerably lower cost than laser therapy [33].

### Limitations

Our study had several limitations. Firstly, because it was not a randomized controlled trial, we could only compare the symptoms of the patients pre- and post-therapy and could not examine untreated versus treated patients. Additionally, we cannot completely rule out the possible influence of placebo effects. Secondly, the study had a limited sample size and a significant sex imbalance, with a higher proportion of female than that of male. Thirdly, we examined a relatively short-term effect for approximately 6 weeks; and thus, the long-term effect could not be verified. Finally, since the LED therapy was applied only to patients with OA of the hand, verification of the therapy's effectiveness is difficult in patients with OA affecting other parts of the body.

### Conclusions

LED irradiation therapy showed to have effect on pain relief based on the reported results among our study participants. This study suggests that high-density LED irradiation therapy is a safe and effective approach and a novel treatment strategy for hand OA.

### CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

## FUNDING INFORMATION

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## AUTHOR CONTRIBUTION

Conceptualization: Kim K, Kim SH, Hong J. Methodology: Kim K, Choi WW, Hong J, Kang DR, Hong S. Formal analysis: Kim K, Kim JH, Hong J. Funding acquisition: Kim SH. Project administration: Kim K, Kim SH, Hong J. Visualization: Kim K, Yong SY, Kim SJ, Hong J. Writing – original draft: Kim K, Hong J. Writing – review and editing: Kim K, Kim SH, Kim HD, Oh KJ, Hong J. Approval of final manuscript: all authors.

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# Health-Related Quality of Life Is Associated With Pain, Kinesiophobia, and Physical Activity in Individuals Who Underwent Cervical Spine Surgery

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**Objective:** To determine the association between health-related quality of life (HRQOL) and neck pain, kinesiophobia, and modalities of physical activity in individuals with postoperative degenerative cervical myelopathy and radiculopathy (DCM/R) because postoperative pain after cervical spine surgery is likely to persist, causing kinesiophobia and avoidance of physical activity.

**Methods:** A questionnaire was distributed to 280 individuals with DCM/R. The questionnaire comprised the following four items: HRQOL (EuroQol 5-dimensions 5-level), neck pain (numerical rating scale [NRS]), kinesiophobia (11-item Tampa Scale for Kinesiophobia [TSK-11]), and physical activity (paid work, light exercise, walking, strength training, and gardening). Hierarchical multiple regression analysis was performed using the NRS, TSK-11, and physical activity as independent variables.

**Results:** In total, 126 individuals provided analyzable responses (45.0%). After including the NRS score as an independent variable to the multiple regression equation for participants' background, the independent rate of the regression equation significantly improved by only 4.1% ( $R^2=0.153$ ). The addition of the TSK-11 score significantly improved this effect by 11.1% ( $R^2=0.264$ ). Finally, the addition of physical activity also significantly improved the explanatory rate by 9.9% ( $R^2=0.363$ ).

**Conclusion:** Neck pain, kinesiophobia, and physical activity (specifically paid work and walking) were independently associated with HRQOL in individuals with postoperative DCM/R.

**Keywords:** Quality of life, Neck pain, Kinesiophobia, Exercise, Motor activity

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## INTRODUCTION

The annual prevalence of neck pain, which exceeds 30% [1], has a substantial socioeconomic impact. Degenerative cervical myelopathy and radiculopathy (DCM/R) is one of the diseases with neck pain as a major symptom, and it includes cervical

spondylosis, ossification of the posterior longitudinal ligament, and disc herniation [2].

Neck pain is a factor that negatively affects health-related quality of life (HRQOL) [3], which is one of the treatment outcomes [4]. Similarly, a negative association between pain and HRQOL has been found in other pain-induced diseases [5-8].

Eliminating pain is the first measure for improving HRQOL; however, if pain cannot be eliminated, other approaches should be developed. Although cervical surgery is indicated for moderate-to-severe DCM/R, neck pain also persists even postoperatively [9], requiring an approach with a target other than pain.

The fear-avoidance model (FAM) is a framework for improving HRQOL in DCM/R from perspectives other than pain. It conceptualizes a vicious cycle where pain generates fear of movement or kinesiophobia and consequently induces the avoidance of physical activity, resulting in disability [10]. While pain relief remains crucial, the reduction of kinesiophobia and improvement of physical activity may also possibly play substantial roles in enhancing HRQOL, as suggested by the FAM framework. Several reports, although not in the context of DCM/R, have indicated that kinesiophobia [11,12] and physical activity [13,14] are associated with HRQOL. However, whether kinesiophobia and physical activity are independently associated with HRQOL has not yet been addressed. Therefore, bridging this research gap is critical to devising strategies to optimize HRQOL in postoperative patients with DCM/R, considering both kinesiophobia and physical activity.

This study aimed to determine whether neck pain intensity, kinesiophobia, and modalities of physical activity are independently associated with HRQOL in individuals with postoperative DCM/R and evaluate their strength if an association exists. We hypothesized that the intensity of neck pain, kinesiophobia, and modalities of physical activity would be independently related to HRQOL in individuals with postoperative DCM/R. Therefore, this study will provide a valuable resource for treatment strategies to improve HRQOL in individuals with postoperative DCM/R since kinesiophobia and physical activity are modifiable factors [15].

## METHODS

### Study design and ethical considerations

This study was part of a mailed survey of individuals with postoperative DCM/R (Sapporo Maruyama Study), and a secondary analysis was conducted with objectives different from those previously reported [16]. The sample size required for the multiple regression analysis of this study, according to G\*Power 3.1 (Heinrich-Heine-Universität Düsseldorf), was 127 patients with medium effect size ( $f^2=0.15$ ), a significance level of 0.05, power of 0.80, and 12 independent variables described.

The study was conducted following the principles of the Decla-

ration of Helsinki. Approval was obtained from the Ethical Review Committee of Sapporo Maruyama Orthopedic Hospital before conducting the study (approval number: 35). The study's explanation and a research participation consent form were enclosed with the questionnaire, and the participants were informed to sign the consent form if they were willing to participate.

### Participants

This study's inclusion criteria were as follows: (1) individuals aged at least 20 years (since 20 years was the minimum age to provide independent informed consent for participation in studies in Japan at that time); (2) those diagnosed with DCM/R by a spine surgeon based on clinical and radiological findings and who had undergone surgery for DCM/R between December 2017 and June 2021 at Sapporo Maruyama Orthopedic Hospital; and (3) those who did not receive personal care because of cognitive decline. The diagnosis of DCM/R was made by specialists in spine surgery based on clinical and radiological findings. Surgery was indicated for patients whose symptoms did not improve with conservative treatment, or whose motor dysfunction or pain greatly interfered with their daily life. Decompression with fixation was chosen when radiological findings showed dynamic instability of the cervical spine or severe compression of the cervical spinal cord and/or nerve roots, while decompression (laminoplasty) was chosen in other cases. Thus, decompression with fixation was preferred when the disease was severe. Individuals with cervical spine fractures and dislocations, spinal cord tumors, previous cervical spine surgery, and a diagnosis of psychiatric or neurological disease (e.g., multiple sclerosis and cerebrovascular disease) were excluded.

In total, 293 individuals who met the inclusion criteria and did not meet the exclusion criteria were selected from the Sapporo Maruyama Study Database. The questionnaire was mailed to all participants in July 2022, i.e., at least 1 year postoperatively. However, 13 participants (4.4%) had unknown addresses; therefore, we finally mailed the questionnaire to 280 individuals.

### Assessment items

#### *Physical function*

Physical function was assessed using the Japanese version of the neck disability index (NDI), which shows high internal consistency [17]. The NDI is a 10-item questionnaire, where each item scored from 0 to 5 points. Therefore, the possible scores range from 0 to 50, where higher scores indicate lower physical function.

### HRQOL

EuroQol 5-dimensions 5-level (EQ5D) is recommended for measuring HRQOL in individuals after spinal surgery [18]. A utility value (EQ5D index value) ranging from 0 “a state as bad as being dead” to 1 “full health” is calculated as an overall measure of HRQOL [19].

### Neck pain

An 11-point numerical rating scale (NRS) was used to assess the neck pain intensity, with 0 and 10 points defined as “no pain at all” and “unbearable pain,” respectively. The NRS is a reliable scale for rating pain intensity at various sites, including the neck [20]. Respondents were asked to indicate the average intensity of their pain over 1 week.

### Kinesiophobia

We used the 11-item Tampa Scale for Kinesiophobia (TSK-11), an abbreviated version of the Tampa Scale for Kinesiophobia, which is the mostly used instrument with confirmed internal consistency in individuals with degenerative diseases of the spine [21]. The scores range from 11 to 44, with higher scores indicating stronger kinesiophobia.

### Modalities of physical activity

Respondents were asked how frequently they performed each of the five modalities of physical activity (paid work, light exercise, walking, strength training, and gardening) investigated by Higuchi et al. [22] in developing their model of HRQOL and physical activity in patients after lumbar spine surgery during the past month. We used a 5-point scale as follows: one point, “not at all;” two points, “irregularly;” three points, “once or twice a week;” four points, “three or four times a week;” and five points, “five or more times a week.”

### Statistical analysis

Imputing missing values is recommended because listwise deletion of missing values in the analysis reduces the reliability of the estimates [23]. Therefore, missing values were completed using the hot-deck method after excluding respondents who did not answer most of the questions or those who reported having pain on the EQ5D pain domain but did not report a score of  $\geq 1$  on the NRS and vice versa. The hot-deck imputation method is a technique where non-respondents (recipients) are matched with similar respondents (donors) and replaced by the observed values of the donors [24]. Hot-deck imputation method is used

in various surveys, including the United States Census Bureau [25].

We performed hierarchical multiple regression analysis, which is a multiple regression analysis in which independent variables are entered in several steps and is used to assess the extent to which the additional independent variables contribute to the improvement of the model [26], using the EQ5D index as the dependent variable. In step one, sex (0, male; 1, female), age, surgical technique (0, decompression; 1, decompression and fixation) duration of postoperative days, and NDI were used as the independent variables. In step two, the NRS score was added as an independent variable 2; the TSK-11 score was added in step three; and in step four, paid work, light exercise, walking, strength training, and gardening were added. Each time an independent variable was added, we assessed whether the model improved and subsequently determined the final model. The referred statistics are the changes in F ( $\Delta F$ ) and  $R^2$  ( $\Delta R^2$ ) values; if the F-value is significantly larger, the model is judged to have been improved by the additional independent variables. Finally, the regression coefficients for the final model were obtained.

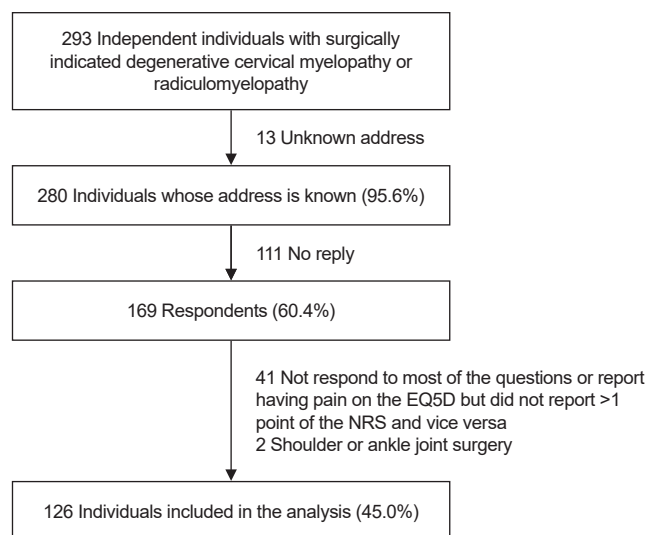
Statistical analysis was performed using R version 4.2 (R Foundation), with a significance level of  $p=0.05$ .

## RESULTS

A questionnaire was mailed to 280 individuals who underwent surgery for DCM/R more than a year earlier, and 169 (60.4%) responded. Among these, 43 individuals (41 individuals who did not respond to most of the questions or reported having pain on the EQ5D but did not report  $>1$  point on the NRS and vice versa, and 2 who underwent shoulder or ankle joint surgery) were excluded, leaving 126 (45.0%) in the analysis (Fig. 1). The mean age of the eligible individuals was  $65.0 \pm 12.2$  years, and 84 and 42 were males and females, respectively (Table 1).

We collected 22 item responses (EQ5D, five items; NRS, one item; TSK-11, 11 items; and physical activity, five items) from each study participant. Therefore, 2,772 items were collected from 126 participants in the analysis. Of these, 21 items (0.8%) were missing data. These 21 missing values were obtained by using the hot-deck method. Table 2 summarizes the basic statistics of the assessed items after the completion of missing values.

The step-two model, with the addition of the NRS score, showed  $\Delta F$  of 5.690 ( $p=0.019$ ) and  $\Delta R^2$  of 0.041, indicating that the NRS score significantly improved the explanatory rate of the model by 4.1% compared with the step-one model. Similarly,



**Fig. 1.** Flow chart of the study participants. EQ5D, EuroQol 5-dimensions 5-level; NRS, numerical rating scale.

the TSK-11 score significantly improved the explanatory rate by 11.1% in the step-three model compared with the step-two model ( $\Delta F=17.874$ ,  $p<0.001$ ). Finally, physical activity significantly improved the rate of explanation by 9.9% in the step-four model compared with the step-three model ( $\Delta F=3.497$ ,  $p=0.006$ ; Table 3).

Table 4 presents the partial regression coefficients of the multiple regression equations obtained in step four of the hierarchical multiple regression analysis. The partial regression coefficients (t-values) for the NRS score, TSK-11 score, paid work, light exercise, and walking were -0.206 (-2.401), -0.275 (-3.494), 0.273 (2.870), -0.179 (-1.986), and 0.233 (2.513), respectively.

## DISCUSSION

### Main finding

Here, we examined whether neck pain intensity, kinesiophobia, and physical activity are independently associated with HRQOL in individuals with postoperative DCM/R based on the FAM and evaluated their strength if an association exists. This study's results showed that neck pain, kinesiophobia, and physical activity, such as paid work and walking, were independently associated with HRQOL to the same extent in individuals with postoperative DCM/R, which confirms our hypothesis.

### Characteristics of the study participants

In this study, the mean NRS score for neck pain and EQ5D in-

**Table 1.** Characteristics of the analyzed individuals

| Characteristic                                      | Value (n=126)                         |
|---|---------------------------------------|
| Age (yr)  | 65.0±12.2 (29–91) <sup>a)</sup>       |
| Sex   |                                       |
| Male  | 84 (66.7)                             |
| Female  | 42 (33.3)                             |
| Diagnosis   |                                       |
| Spondylotic myelopathy                              | 63 (50.0)                             |
| Spondylotic radiculopathy                           | 38 (30.2)                             |
| Ossification of the posterior longitudinal ligament | 17 (13.5)                             |
| Disc herniation                                     | 8 (6.3)                               |
| Surgical technique                                  |                                       |
| Decompression                                       | 64 (50.8)                             |
| Decompression with fixation                         | 62 (49.2)                             |
| Duration (day after surgery)                        | 776.6±263.1 (388–1,326) <sup>a)</sup> |
| Neck disability (point)                             | 12.0±9.9 (0–50) <sup>b)</sup>         |

Values are presented as number (%), <sup>a)</sup>mean±standard deviation (minimum–maximum), or <sup>b)</sup>median±quartile deviation (minimum–maximum).

**Table 2.** Basic statistics of the assessed items (n=126)

| Item (range)                 | Median | Quartile deviation | Minimum | Maximum |
|------------------------------|--------|--------------------|---------|---------|
| EQ5D index (0–1 point)       | 0.74   | 0.081              | 0.164   | 1.000   |
| NRS (0–10 points)            | 2      | 2.0                | 0       | 10      |
| TSK-11 (11–44 points)        | 25     | 3.0                | 11      | 43      |
| Paid work (1–5 points)       | 2.5    | 2.0                | 1       | 5       |
| Light exercise (1–5 points)  | 2      | 1.4                | 1       | 5       |
| Walking (1–5 points)         | 2      | 1.0                | 1       | 5       |
| Muscle training (1–5 points) | 1      | 0.5                | 1       | 5       |
| Gardening (1–5 points)       | 1      | 0.5                | 1       | 5       |

EQ5D, EuroQol 5-dimensions 5-level; NRS, numerical rating scale; TSK-11, 11-item Tampa Scale for Kinesiophobia.

dex of the participants were 3.0 and 0.738 points, respectively. A study that followed the postoperative course of patients who underwent cervical spine surgery showed that the NRS score for neck pain and EQ5D index were approximately 3 and 0.5 points, respectively, at 2 years postoperatively, with stable values at 1 and 2 years [26]. HRQOL was better among our study participants, although the neck pain intensity was similar between our study participants and those of Revesz et al.'s [27] study. HRQOL was also better in our study participants than in those

in other reports 1 year after cervical spine surgery [28]. However, the HRQOL of our study participants was lower than that of the general population, as the general population's mean EQ5D index was 0.83 points, even for individuals aged >75 years [29]. The factors contributing to better postoperative HRQOL of the

participants in our study are unknown, and one factor for this may be our inclusion of individuals with DCM/R for >1 year; therefore, we included those with DCM/R for up to 3 years.

### Relationships between HRQOL and neck pain, kinesiophobia, and physical activity

We demonstrated that neck pain intensity, kinesiophobia, and physical activity were independently associated with HRQOL in patients with postoperative DCM/R. This finding supports the use of the FAM to better understand the relationship between HRQOL and neck pain in patients with postoperative DCM/R.

A report on contemporaneous improvements in neck pain and HRQOL postoperatively [4] suggested an association between neck pain and HRQOL. We hypothesized that pain interacts with various issues, such as sleep disruption, emotional disturbance, and reduced labor productivity (presenteeism), which directly or indirectly reduce HRQOL. Therefore, the HRQOL model that focuses on kinesiophobia and physical activity was developed in this study; however, there is room to improve and expand the model.

Kinesiophobia and physical activity were independently associated with HRQOL and neck pain in this study. A systematic review indicated that kinesiophobia is a psychosocial factor involved in the HRQOL of patients with chronic low back pain [30]. Kinesiophobia has also been reported as a risk factor for poor HRQOL in patients after undergoing hip surgeries [31]. Therefore, generalizing that kinesiophobia caused by pain re-

**Table 3.** Results of the model evaluation from steps 1 to 4 in the hierarchical multiple regression analysis (n=126)

| Step | Independent variable   | R <sup>2</sup> | ΔR <sup>2</sup> | ΔF     | p-value   |
|------|--|----------------|-----------------|--------|-----------|
| 1    | (Intercept)<br>Sex<br>Age<br>Surgical technique<br>Duration<br>NDI                 | 0.112          | 0.112           | 3.026  | 0.013*    |
| 2    | Step 1 +<br>NRS  | 0.153          | 0.041           | 5.690  | 0.019*    |
| 3    | Step 2 +<br>TSK-11   | 0.264          | 0.111           | 17.874 | <0.001*** |
| 4    | Step 3 +<br>Paid work<br>Light exercise<br>Walking<br>Muscle training<br>Gardening | 0.363          | 0.099           | 3.497  | 0.006**   |

Dependent variable: EuroQol 5-dimensions 5-level.

NDI, neck disability index; NRS, numerical rating scale; TSK-11, 11-item Tampa Scale for Kinesiophobia.

\*p<0.05, \*\*p<0.01, and \*\*\*p<0.001.

**Table 4.** Partial regression coefficients and t-values in the model for step 4 in the hierarchical multiple regression analysis (n=126)

| Independent variable | Partial regression coefficient | Standardized partial regression coefficient | t-value | p-value   |
|----------------------|--------------------------------|---|---------|-----------|
| (Intercept)          | 0.973                          | -   | 6.850   | <0.001*** |
| Sex                  | 0.018                          | 0.056                                       | 0.696   | 0.488     |
| Age                  | 0.000                          | -0.001                                      | -0.014  | 0.989     |
| Surgical technique   | 0.052                          | -0.173                                      | 1.995   | 0.048*    |
| Duration             | 0.000                          | 0.010                                       | 0.128   | 0.898     |
| NDI                  | -0.001                         | -0.066                                      | -0.792  | 0.430     |
| NRS                  | -0.009                         | -0.206                                      | -2.401  | 0.018*    |
| TSK-11               | -0.007                         | -0.275                                      | -3.494  | 0.001**   |
| Walking              | 0.025                          | 0.233                                       | 2.513   | 0.013*    |
| Light exercise       | -0.018                         | -0.179                                      | -1.986  | 0.049*    |
| Muscle training      | -0.019                         | -0.139                                      | -1.565  | 0.120     |
| Gardening            | 0.004                          | 0.032                                       | 0.397   | 0.692     |
| Paid work            | 0.022                          | 0.273                                       | 2.870   | 0.005**   |

Dependent variable: EuroQol 5-dimensions 5-level.

NDI, neck disability index; NRS, numerical rating scale; TSK-11, 11-item Tampa Scale for Kinesiophobia.

\*p<0.05, \*\*p<0.01, and \*\*\*p<0.001.



sulting from bone and joint diseases, regardless of the disease, may have a negative impact on HRQOL. However, the relationship between pain intensity and kinesiophobia, a psychosocial variable, is not necessarily unidirectional.

Kinesiophobia is the largest factor associated with HRQOL, followed by paid work, walking, neck pain intensity, and light exercise. Paid work is a measure to improve physical activity because performing one's job duties or commuting to work involves physical activity, i.e., work-related physical activity. However, work-related physical activity was reported to differ between white- and blue-collar workers [32]; therefore, as in this study, the frequency of performing paid work alone could not accurately represent the amount of physical activity. Even if eliminating neck pain is difficult, interventions to reduce kinesiophobia and promote physical activity, such as paid work and walking, can be modified, indicating that these factors may be effective in improving HRQOL. This study did not measure the amount of physical activity using a tri-axial accelerometer or an international standard questionnaire but only asked about the modalities and the frequencies of physical activity they usually perform; therefore, whether paid work and walking are related to HRQOL dose-dependently remains unclear. Assessing the quantitative and qualitative impact of physical activity on HRQOL will contribute to further understanding and effective support of HRQOL in individuals with DCM/R who underwent surgery. Finally, contrary to the hypothesis, the conduct of light exercise was found to be negatively associated with HRQOL. The etiology of this cannot be addressed in this study. However, it was hypothesized that those individuals who had neck complaints tried to move their necks more than those who did not have any complaint.

### Strengths and limitations of this study

This is the first study to examine factors associated with postoperative HRQOL in individuals with DCM/R based on the FAM framework. The knowledge obtained through this study to better understand the relationship between postoperative HRQOL and neck pain can contribute to developing postoperative rehabilitation strategies.

However, this study had some limitations. First, the rate of questionnaire collection was low. Consequently, a low response rate can lead to sampling bias, raising concerns regarding the robustness of the results. Second, as previously mentioned, the physical activity levels were not quantified. Therefore, reporting past performance does not rule out recall or social desirability

biases, and the quantitative relationship between physical activity and HRQOL cannot be determined. Because of these methodological limitations, this study's results should be interpreted with caution, and our research should be developed to clarify the quantitative and qualitative relationship between physical activity and HRQOL. Third, this was a cross-sectional study. Although this study hypothesized a causal relationship based on the FAM, determining the causal relationship between HRQOL and its associated factors was difficult. Therefore, future interventional studies on kinesiophobia and physical activity should be designed to establish a causal relationship. Finally, HRQOL was assessed as a unidimensional construct. We used the EQ5D index value that operationally defines scores of 0 as "a state as bad as being dead" and 1 as "full health." The 36-item Short Form Survey uses a two-factor model of physical and mental health [33]. Therefore, further analysis using HRQOL substructures may provide additional information that requires validation.

In conclusion, this study reveals that the reduction of neck pain, reduction of kinesiophobia, and promotion of physical activity, such as paid work and walking, may be effective intervention strategies to improve HRQOL in individuals with postoperative DCM/R.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Higuchi D, Kondo Y. Methodology: Kondo Y. Formal analysis: Higuchi D. Funding acquisition: Higuchi D. Project administration: Higuchi D. Visualization: Higuchi D. Writing – original draft: Higuchi D. Writing – review and editing: Watanabe Y, Miki T. Approval of final manuscript: all authors.

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# Predicting Age of Independent Walking in Preterm Infants: A Longitudinal Study Using Neonatal Characteristics and Motor Development Variables

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**Objective:** To formulate an equation estimating months to independent walking in moderate to late preterm infants based on neonatal characteristics and gross motor development from 7 months to independent walking.

**Methods:** Sixty infants born between 32 to 36 weeks were assessed using Alberta Infant Motor Scale (AIMS) for gross motor development. Neonatal characteristics were recorded at 7 months, and caregiver-reported independent walking onset. Pearson correlation analyzed age, AIMS scores, and neonatal factors. Multiple regression developed the prediction equation.

**Results:** The equation for independent walking onset, which included gestational age (GA) at birth, total AIMS score at 10 months of age (10th AIMS), and birth head circumference (BHC), exhibited a strong correlation ( $r=0.707$ ) and had a predictive power of 50.0%. The equation is as follows: age onset of independent walking (months)=33.157, -0.296 (GA), -0.132 (10th AIMS), -0.196 (BHC), with an estimation error of 0.631 months.

**Conclusion:** Neonatal characteristics, such as GA, 10th AIMS, and BHC, are key determinants in estimating the onset of independent walking in moderate to late preterm infants.

**Keywords:** Preterm infants, Walking, Gestational age, Alberta, Prognosis

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## INTRODUCTION

The attainment of independent walking stands as a crucial milestone in the motor development of infants, holding considerable sway over their fine motor skills and linguistic capabilities [1]. Typically, infants acquire the ability to walk independently between the ages of 8.2 and 17.6 months, as indicated by a multinational study conducted by the World Health Organization [2].

However, preterm infants often face challenges, including delayed and incomplete standing capabilities, primarily attributed to delays in their vertical developmental trajectory and antigravity movements [3].

Although some preterm infants may attain developmental milestones similar to their full-term peers in prone and supine positions by eight months, disparities emerge when it comes to sitting and standing positions, which necessitate robust muscu-

lar engagement against the force of gravity. This developmental gap persists even when observed up to 12 months of age, with preterm infants frequently achieving lower scores on gross motor assessments [4]. These disparities may arise from variations in the rate and sequence of neurological development, which unfold along a continuous continuum, commencing with the formation of tissues in both the central and peripheral nervous systems and culminating in the initiation of coordinated motor movements [5].

Preterm infants often experience walking delays, as indicated by a systematic review of 24 studies using the Alberta Infant Motor Scale (AIMS). At 3 months, moderate preterm infants exhibited a 12% abnormal motor development rate, signaling delays in standing at 4 and 6 months [6]. Subsequent research with 403 preterm and 1,038 full-term infants further emphasized distinctions, especially in the standing sub-scale, at 1.5 and 18.5 months [7,8]. The significance of independent walking, vital for preterm infants' motor milestones and language skills, is influenced by complex factors [1]. Understanding neonatal characteristics, including congenital diseases, birth weight (BW), birth head circumference (BHC), and gestational age (GA) at birth, is crucial for identifying developmental risks. A study revealed a positive correlation between GA and gross motor development in the first year [9]. Low BW, frequently associated with prematurity, increases the risk of delayed gross motor development [10]. BHC influences gross motor and cognitive domains, while a low Apgar score at birth signals clinical complications and an increased risk of poor gross motor development [11].

Evaluating motor development as a predictor for cerebral palsy (CP) is crucial, particularly in high-risk children, as emphasized in insights from CP. A systematic review and meta-analysis in 2018 highlighted the importance of achieving independent sitting by age two for potential ambulation in children with CP, revealing a strong association (relative risks, 4.82; 95% confidence interval [95% CI], 3.20–7.24) [12]. This consistent finding underscores the essential role of early assessments in guiding clinical decisions, where the AIMS stands out for its simplicity and minimal equipment requirements.

Monitoring and promoting gross motor development in healthy preterm infants is crucial to reduce developmental delays. The Thai version of AIMS is a reliable tool for assessing gross motor development, starting as early as 15 days and continuing up to 18 months [13]. Only a previous cross-sectional study examined the impact of biological and environmental fac-

tors on the acquisition of gross motor skills in Thai. This study identified the key factors as internal systems, the environment, task complexity, and movement experiences. Caution is advised regarding the use of baby walkers in typically developing infants during their first year of life due to potential negative impacts [14]. Therefore, predicting the age of independent walking in preterm infants remains a challenging and understudied area, likely due to the complex influence of neonatal characteristics and individual variations in motor proficiency.

Limited research exists on the long-term assessment of how neonatal characteristics contribute to the essential gross motor development required to achieve walking milestones in moderate to late preterm infants raised at home. The aim of this study was to yield a significant contribution to the current academic literature by demonstrating that AIMS scores serve as a feasible predictor of independent walking in moderate to late preterm infants. In clinical and research aspects, the formulated predictive model utilizing AIMS and neonatal characteristics can serve as a straightforward and practical tool for assessing gross motor development in moderate to late preterm infants. Through establishing an association among independent walking, gross motor development, and neonatal characteristics, this academic investigation holds promise for fostering a new methodological approach. Should this research yield theoretical outcomes, it could potentially enable healthcare professionals to assess both independent walking and gross motor development. This pivotal outcome could facilitate targeted rehabilitation programs, spanning from 7 months to independent walking for moderate to late preterm infants. It would enable meticulous monitoring and the strategic design of interventions for addressing gross motor assessment in this population.

## METHODS

### Participants

This research employed a prospective longitudinal assessment with a correlational study design to develop a prediction equation. A cohort of 60 moderate to late preterm infants were selectively recruited through outreach efforts involving district health-promoting hospitals and community healthcare volunteers. The selection of parents or guardians with infant dyads was made based on every second order from the provided name list. After applying inclusion/exclusion criteria, 88 preterm infants initially met the specified criteria, with 28 subjects subsequently excluded for various reasons. Among those excluded,



17 declined participation, 7 experienced acute illness within the last 7 days before assessment, and 4 families moving their houses. Therefore, the study involved the participation of 60 preterm infants, with a mean admission age of  $6.74 \pm 0.38$  months, residing in Muang District, Phayao Province, Thailand, out of the initial 60 subjects available for analysis.

For calculating the required sample size, we employed the Correlation: bivariate normal model G\*Power analysis program, with a low correlation ( $r$ ) value of 0.30,  $\alpha=0.05$ , and  $\text{power}=0.95$ . Participants who met the inclusion criteria, which included being healthy preterm males and females with controllable symptoms, such as glucose-6-phosphate dehydrogenase deficiency, and able to walk independently with an average age of  $12.0 \pm 0.9$  months were included in the study and are listed in Table 1. Infants were excluded if they had a documented history of seizures, visual or hearing impairments, congenital abnormalities, significant brain damage, periventricular leukomalacia beyond grade I [15], intraventricular hemorrhage exceeding grade II [16], or a neonatal intensive care unit stay lasting more than 17 days. Approval for this study was obtained from the Human Research Ethics Committee at the University of Phayao (No.1.3/056/64 and 1.3/013/66).

### Research protocol

The parents or guardians of the infants in this study were provided with comprehensive information regarding the research's purpose and the data collection procedures. Before participating in the study, they were required to complete a consent form. Data related to parents or guardians and infants were collected from parents or guardians. Neonatal characteristics and vaccination data of preterm infants were recorded from the personal

health booklet. Infant demographic information was documented in the structured questionnaire.

Subsequently, scheduled sessions were organized to evaluate the progress of gross motor development. On the appointed date, a direct observation was conducted for each infant to assess their gross motor development. This assessment took place in a quiet area of the infant's home, a place they were familiar with, with a parent or guardian in close proximity. Infants were unclothed except for wearing a diaper, allowing clear observation of their gross motor movements. They were given the freedom to move without restraint and received minimal physical contact during the evaluation, although the option to use a toy to encourage their movements was available. The infants remained awake and alert throughout the assessment. In cases where some infants were unprepared for the evaluation, their gross motor development was reevaluated within five days following the initial assessment.

The assessments were consistently conducted each month, within a window of plus or minus 5 days, starting from the corrected age of 7 months until the infants accomplished independent walking. Parents or guardians were requested to document the date of independent walking attainment in the logbook recording (parents/guardians note) and promptly inform the researcher. To confirm independent walking, as per the operational definition described below, the researcher assessed the infant's independent walking within 5 days of receiving notification from the parents or guardians. The assessment procedure and approach followed the description below:

#### *The AIMS test of gross motor movement*

The AIMS is a standardized assessment tool designed for the

**Table 1.** Neonatal characteristic of all infants (n= 60)

| Demographics data  | Mean $\pm$ SD       | Range       |
|--|---------------------|-------------|
| Birth weight (g)   | 2,306.2 $\pm$ 383.8 | 1,610–2,955 |
| Birth length (cm)  | 47.5 $\pm$ 2.1      | 43–52       |
| Birth head circumference (cm)                              | 30.4 $\pm$ 1.5      | 29–33       |
| The Apgar score at 5 min (point)                           | 9.4 $\pm$ 0.5       | 8–10        |
| Gestational age (wk)                                       | 34.5 $\pm$ 1.3      | 32–36       |
| The age at walking independent (months of corrected age)   | 12.0 $\pm$ 0.9      | 10.3–13.3   |
| Thai version of total AIMS score (months of corrected age) |                     |             |
| At 7   | 27.6 $\pm$ 1.8      | 24–33       |
| At 8   | 29.9 $\pm$ 1.8      | 26–36       |
| At 9   | 31.2 $\pm$ 2.0      | 27–36       |
| At 10  | 37.7 $\pm$ 1.8      | 35–42       |

SD, standard deviation; AIMS, Alberta Infant Motor Scale.

evaluation of gross motor development in infants aged 0 to 18 months [17]. It comprises 21 items for assessing prone position, 9 for supine, 12 for sitting, and 16 for standing, with the option to incorporate toys for stimulation. The assessment process emphasizes minimal physical contact to observe infants' spontaneous movements, with the assessor offering assistance for transitions into sitting or standing positions as necessary. Each item is categorized as either "observed" or "not observed."

The range of motor development is determined by identifying the lowest and highest observed items within each position, known as a "window." Items preceding this window are referred to as "previous items." Subscale scores are computed based on observed items within the window and the previous items, ultimately contributing to the calculation of total scores, which entail summing all subscale scores (Fig. 1) The typical duration of the assessment for each infant is approximately 15 minutes. In this specific study, the AIMS Thai version was utilized. This version has demonstrated robust inter-rater reliability (intraclass correlation coefficient [ICC], 0.988; 95% CI, 0.976–0.994) and intra-rater reliability (ICC, 0.995; 95% CI, 0.989–0.998) [13].

#### *The age of independent walking (months)*

The operational definition of independent walking in the current study is defined as the ability of infants to walk without any external support while maintaining a stable trunk in a vertical position with a straight back [18]. To determine when independent walking begins, parents or guardians were asked to notify us when their infant could take five consecutive steps without any assistance or falling. This date was recorded in a logbook and reported to the researcher by phone. To confirm that the infant's capacity for independent walking aligned with the operational definition, a test was conducted within five days of

receiving the notification from parents or guardians.

#### *The structured questionnaire*

Parents or guardians participated in face-to-face interviews during which they completed a structured questionnaire regarding neonatal characteristics, including BW, birth length (BL), BHC, Apgar score at 5 minutes, gestational age (GA), age at admission, sex, and health status in the 7 days prior to the assessment.

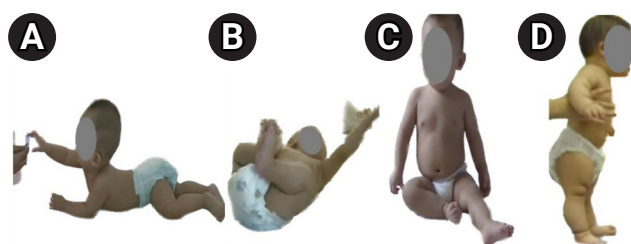
#### **Statistical analyses**

The Kolmogorov–Smirnov test was used to evaluate the data distribution, indicating a normal distribution among the variables. Descriptive statistics were employed to provide a characterization of the subjects, while the Pearson product moment correlation coefficient was utilized to establish the correlation coefficient between the age onset of independent walking (months), neonatal characteristics, and the total AIMS score from corrected age at 7 to 10 months. The study employed the Stepwise Multiple Linear Regression Analysis technique to create a prediction equation for the age onset of independent walking (months) through a multiple regression analysis. The equation incorporated several variables, including the age of independent walking onset (measured in months), neonatal characteristics, and the total AIMS score. The selection was made based on identifying the most optimal model, determined by the highest adjusted  $r^2$  value and the lowest degree of variance inflation. To identify the most significant independent variable coefficients for each prediction model, an in-depth analysis was conducted to ascertain their significance. All statistical analyses were performed using IBM SPSS Statistics 21 (IBM Corp.), adhering to a consistent significance level of 0.05 for all statistical tests.

## **RESULTS**

The study enrolled a sample of 60 preterm infants, consisting of 37 males and 23 females, with an average age  $6.74 \pm 0.38$  months corrected age. The infants' average BW was  $2,306.2 \pm 383.8$  g, average BL was  $47.5 \pm 2.1$  cm, average BHC was  $30.4 \pm 1.5$  cm, average Apgar score at 5 minutes was  $9.4 \pm 0.5$ , and average GA was  $34.4 \pm 1.3$  weeks. The age onset of independent walking was found to be  $12.0 \pm 0.9$  months corrected age, while the average total AIMS score was  $37.7 \pm 1.8$  as shown in Table 1.

The study investigated the association between neonatal characteristics, such as BW, BL, BHC, Apgar score, GA, total AIMS score from the corrected age of 7 to 10 months and their



**Fig. 1.** The components of the Alberta Infant Motor Scale, including (A) prone, (B) supine, (C) sitting, and (D) standing positions. This figure is approved and allowed to be legally published by the guardian of the infant.

age onset of independent walking. The results revealed negative moderate levels of correlation ranging from  $r=-0.568$  to  $-0.311$ , all statistically significant at  $p<0.01$ . The age onset of independent walking exhibits a modest negative association with BHC ( $r=-0.439$ ,  $p<0.001$ ). Furthermore, the study identified a low negative correlation ( $r=-0.354$ ,  $-0.311$ ,  $-0.328$ , respectively,  $p<0.005$ ) between age onset of independent walking and the Total AIMS score at 7, 8, 9 months. While a moderate negative correlation ( $r=-0.501$ ,  $p<0.001$ ) was observed between age onset of independent walking and total AIMS score at 10 months of age (10th AIMS). [Table 2](#) presents the detailed correlation results.

Based on the results of a multiple regression analysis of the age onset of independent walking, all 3 models of factors were identified and are presented in [Table 3](#). Model 1 showed that only the GA factor had a significant effect on the age onset of independent walking. Meanwhile, models 2, and 3 included GA factor and 10th AIMS, respectively. Among all 3 models, model 3 was significant strongly correlation ( $r=0.707$ ,  $p<0.01$ ) and had the highest coefficient of determination ( $r^2=0.500$ ), indicating that the combined effect of the GA, 10th AIMS, and BHC accounted for 50.0% of the variance in the age onset of independent walking. The standard error of estimation was approximately 0.631 month.

As a result, the equation for the age onset (month) of independent walking's predictive accuracy was  $33.157$ ,  $-0.296$  (GA),  $-0.132$  (10th AIMS),  $-0.196$  (BHC)  $\pm 0.631$ , where GA (month), BHC (cm), and 10th AIMS variable.

## DISCUSSION

The aims of the current study were to: (1) investigated the re-

lationship between the age of walking independent correlation gross motor development of moderate to late preterm Thai infants via AIMS score from 7 to 10 months corrected age and variables obtained from neonatal characteristics and (2) to examine an equation to calculate the age of walking independent. Additionally, the study focused at other neonatal characteristic factors that may affect the ability to walking independent, such as GA, BW, BL, BHC, and the Apgar score at 5 minutes. The study revealed that a prediction equation could be developed to calculate the age of walking independent of moderate to late preterm infant based on the gross motor development measured via the Thai version of total AIMS score and variables obtained from neonatal characteristics. It is a well-established relationship between GA, 10th AIMS, and BHC.

**Table 2.** Correlation between age onset of independent walking and demographic information of the participant, and total AIMS score at 7, 8, 9, and 10 months

| Dependent variable            | The age onset of independent walking (p-value) |
|-------------------------------|--|
| Birth weight (g)              | -0.346* (0.007)                                |
| Birth length (cm)             | -0.122 (0.353)                                 |
| Birth head circumference (cm) | -0.439** (<0.001)                              |
| Apgar score (point)           | 0.168 (0.199)                                  |
| Gestational aged (wk)         | -0.568** (<0.001)                              |
| Total AIMS score (point)      |  |
| At 7 mo                       | -0.354* (0.006)                                |
| At 8 mo                       | -0.311* (0.016)                                |
| At 9 mo                       | -0.328* (0.010)                                |
| At 10 mo                      | -0.501** (<0.001)                              |

AIMS, Alberta Infant Motor Scale.

\*Correlation is significant at  $p<0.05$ .

\*\*Correlation is significant at  $p<0.001$ .

**Table 3.** Model of regression analysis for walking independent age with different predictive variables

| Model | Included variable | $\beta$ | p-value  | r     | Adjusted $r^2$ | SEE   |
|-------|-------------------|---------|----------|-------|----------------|-------|
| 1     | Constant          | 24.931  | <0.001** | 0.568 | 0.323          | 0.722 |
|       | GA                | -0.376  | <0.001** |       |                |       |
| 2     | Constant          | 29.307  | <0.001** | 0.669 | 0.447          | 0.658 |
|       | GA                | -0.306  | <0.001** |       |                |       |
|       | 10th AIMS         | -0.180  | 0.001*   |       |                |       |
| 3     | Constant          | 33.157  | <0.001** | 0.707 | 0.500          | 0.631 |
|       | GA                | -0.296  | <0.001** |       |                |       |
|       | 10th AIMS         | -0.132  | 0.014**  |       |                |       |
|       | BHC               | -0.196  | 0.018*   |       |                |       |

SEE, standard error of estimation; GA, gestational aged (mo); 10th AIMS, total Alberta Infant Motor Scale score at 10 months of age; BHC, birth head circumference (cm).

\*Correlation is significant at  $p<0.01$ .

\*\*Correlation is significant at  $p<0.001$ .

Certainly, while the independent walking age for moderate to late preterm infants may align closely with that of full-term children utilizing the AIMS remains valuable. The strength of the calculation formula found in this study lies in its multifaceted nature [19], considering variables such as GA, 10th AIMS, and BHC. If any of these variables show less typical progression than expected [20,21], employing AIMS together with these factors allows for heightened sensitivity to detect deviations more promptly. Even if the overall walking age aligns with norms [22], AIMS offers a comprehensive evaluation beyond just predicting walking age. It provides a detailed assessment of diverse motor domains, enabling the detection of potential developmental delays or disparities in specific motor skills. This sensitivity allows for early intervention strategies tailored to an infant's unique motor development profile, facilitating timely support despite the general alignment of walking ages between preterm and full-term infants. Therefore, utilizing AIMS enhances our understanding by offering a more nuanced assessment of motor development beyond the mere prediction.

Strong interactions among GA, 10th AIMS, and BHC play a crucial role in predicting challenges during walking. Specifically, it was found that for every 1 unit decrease in the GA (week), and 10th AIMS (point), and BHC (cm) there was an associated later at the age onset of independent walking (month) by 0.296, 0.132, and 0.196 month, respectively.

Additionally, it was found that lower gross motor scores coincident with small BHC (cm) had a significant impact on later walking independent. This aligns with previous research, indicating that preterm infants born between 32 and 36 weeks, though typically free from life-threatening complications at birth, show increased fragility and susceptibility to medical issues in childhood. Infants born between 34 and 36 weeks exhibit lower gross motor abilities, particularly in standing and walking independently [23], during their first year, compared to full-term infants [24].

In previous studies [18,25] were noted that infants, aged from 6 months to their first year, acquire new skills related to upright postures, including crawling, sitting up, pulling to stand, cruising, and eventually walking independently. During this stage, infants learn to coordinate lower body and pelvis movements, which improve their upper trunk and chest motor skills, especially when they're on prone position [26]. Approximately 9 to 10 months, infants typically transition to an upright posture, preparing them for standing and walking [2]. In our recent study, even though participants were born prematurely, they

demonstrated the ability to achieve independent walking within this age range. We found a moderate correlation between 10th AIMS and walking milestones, indicating that, while preterm infants had not achieved independent walking, their overall low gross motor development in prone, supine, sitting, and standing positions, as demonstrated by 10th AIMS, was interconnected. This suggests the potential for developing an equation to predict future walking ability based on 10th AIMS.

These findings are consistent with a previous study, where they continuously monitored infants of various ages to track the development of gross motor skills using different positions. The assessment of supine position at 6 months provided valuable insights. As infants progressed to 8, 12, and 18 months, evaluating motor skills in a vertical position offered consistent surveillance benefits [27]. Specifically, assessing the total AIMS score with sitting and standing subscales importance to the ongoing monitoring of gross motor development, especially in comparing extremely preterm infants to those born full-term [3]. The study also emphasized the importance of observing developmental aspects related to balance against gravity in the vertical position, reinforcing the value of continuous surveillance [3,27].

The importance of low GA in monitoring preterm infants' walking skills is evident. Our study found a moderate negative correlation ( $-0.568$ ,  $p < 0.001$ ) between GA and the age of independent walking, underlining the relevance of considering GA when evaluating later standing proficiency during independent walking assessments. Previous study investigates the impact of intrauterine environments on children's motor development at 3 and 6 months. It included 346 mother/newborn pairs from public hospitals, grouped by maternal conditions: diabetes, newborns with intrauterine growth restriction (IUGR), maternal smoking during pregnancy, and a control group. IUGR infants showed lower 6 month gross motor scores, with anthropometrics and sociodemographic negatively affecting motor development. This highlights the significance of monitoring preterm infants' walking skills, especially those with low GA [28].

Additional support for this observation is provided by a study in 2011, where it was reported that moderate to late preterm infants exhibited lower gross motor skills in the standing subscale at 4 months when compared to full-term infants ( $p = 0.014$ ) [7]. At 6 months, these preterm infants also scored notably lower in standing proficiency than their full-term counterparts, suggesting potential challenges in muscle tone regulation for upright support and balance [29]. Furthermore, a study conducted in 2017 illustrated consistent lower developmental scores in premature in-

infants, encompassing extremely, very, moderate, and late preterm cases, from 1 to 12 months of age when compared to their full-term counterparts. These differences were statistically significant across all age groups, with extremely premature infants exhibiting the lowest standing abilities, significantly lower than infants with higher GA at all assessment periods ( $p < 0.0001$ ) [23].

In the context of preterm infants, the upright position's importance cannot be overstated, it impacts coordination, language skills, fine motor abilities, and cognitive functions [1]. This association between lower GA at birth and an increased risk of delayed gross motor development is particularly significant for infants born after 32 weeks, including those with low-risk preterm births [30]. Our study has revealed a noteworthy positive linear relationship between GA and both gross motor developmental scores. Prior research has identified key factors contributing to sitting development delays in moderate to late preterm infants aged 4 to 9 months, specifically those born between 33 to 36 weeks of gestation. These delays primarily result from deficits in flexor and extensor muscle activation, impacting trunk postural muscles. Consequently, low GA at birth may lead to balance instability, elevating the risk of delayed gross motor development in preterm infants' upright position [31].

The evaluation of gross motor development in infants involves analyzing the variability of percentile values via the AIMS. The AIMS is the gold standard for precision, considering tool like weight-bearing, posture, and antigravity compositions in four subscale positions. The commonly used method assesses long-term developmental percentile variations, using cutoff values to gauge the risk of developmental delays at different ages. In Thailand, though, there are no specific cutoff values; instead, they rely on continuous long-term developmental monitoring to detect variations, indicating typical development. When infants experience delayed gross motor development, their percentiles tend to remain consistently low throughout the monitoring period. These methods help identify developmental delays or consistent changes in raw scores. However, each approach has its advantages and limitations. Therefore, it's essential to consider the pros and cons of each testing method when evaluating development. Our study provides valuable insights for predicting independent walking development in preterm infants. We utilize raw scores from standardized tools, such as 10th AIMS, in associate with neonatal characteristic factors. Low cost and time consuming with basic neonatal characteristic data were applied in the current study.

Trunk postural control is a vital developmental milestone for infants, enabling them to achieve an upright posture and

perform various tasks [32,33]. However, extremely and very preterm infants typically attain independent walking at around 14 months, later than full-term infants who achieve this milestone at around 12 months [6,8]. In very high risk infants, walking independence may be further delayed, occurring at approximately 16 months [8]. Our study highlights that moderate to late preterm infants exhibit a lower rate of independent walking ability, with only 42 out of 60 infants achieving independent walking by 12 months corrected age. This discrepancy is likely attributed to inadequate trunk control in premature infants, impacting their capacity to perform complex gross motor skills, particularly walking.

BHC serves as a valuable predictor of independent walking age in preterm infants, as evidenced by a significant negative association in our study (Table 2). Regression analysis identified GA, 10th AIMS, and BHC as predictive factors for the age of independent walking. These findings align with previous studies, indicating that head circumference is linked to extending beyond the average age for walking attainment and persists into the infant's first year. Several studies have emphasized the association between smaller head circumference and delayed gross motor development. Recent research has established a positive connection between having a larger head circumference at one month of age and the enhanced gross motor development of preterm infants, as evaluated by the AIMS motor scale [34].

Conversely, infants with smaller BHC, regardless of intrauterine factors, exhibit a higher risk of early motor development delays within their first 6 months of life [6,35]. The assessment of BHC is a standardized, non-invasive medical procedure that measures the circumference over the occiput and just above the eyebrows [2], with the standard measurement for Thai infants set at an average of 31.6 centimeters at 34 weeks GA [21]. Our study found that infants had head circumferences below the average for 34 weeks GA. We relied on birth history data recorded in the personal health booklet (Pink Book) as secondary data. Notably, a one-unit change in BHC could lead to an alteration in the age at which independent walking occurs, with an approximate difference of 36 days. Hence, when caring for preterm infants, healthcare providers and families should take into account the infant's BHC and evaluate their motor development, specifically their capacity for independent walking, to address their developmental requirements.

This study aimed to establish a prediction equation that proves valuable in estimating the age at which preterm infants will achieve independent walking. This equation leverages



gross motor development scores obtained from the Thai version of AIMS, considered a gold standard in developmental assessments, and neonatal characteristics for forecasting the age onset of independent walking. The equation of age onset of independent walking (months) =  $33.157 - 0.296 (GA) - 0.132 (10th\ AIMS) - 0.196 (BHC) \pm 0.631$ , where GA is denoted in weeks, 10th AIMS for AIMS total score at 10 months, BHC. The prediction equation was found to have moderate predictive ability, yielding a prediction accuracy of roughly 50.0%, with a corresponding measurement error of approximately 0.631 month. The utilization of a prediction equation in this research study resulted in the significant method holds practical applicability in clinical settings and is easily implemented. The benefit of using the prediction equation lies in early precision and efficiency in diagnosing and stimulating gross motor development at the 10-month, especially in preterm infants with lower GA and smaller BHC. Timely interventions can prevent delays in achieving independent walking by addressing gross motor development stimulations.

One potential clinical implication is the utilization of estimated age of independent walking as an objective measure to gross motor abilities in preterm infants with four main postures: supine, prone, sitting, and standing. By incorporating this estimation into clinical assessments, healthcare professionals can gain valuable insights into infants gross motor development and overall neonatal characteristics. This information can guide early intervention planning, goal setting, and monitoring of progress over time. Furthermore, the study's results can inform the development or modification of strategies aimed at stimulating walking and gross motor developments during early development. Using the estimated age of walking ability as a baseline measure, healthcare providers can customize rehabilitation or stimulation programs to address specific delays in gross motor ability or challenges in maintaining an upright balance in infants. This customization allows for the implementation of various postures or exploration of alternative stimulation techniques to enhance walking development. While this study has presented a predictive equation for estimating the age of independent walking onset, future research should prioritize its validation. By comparing predicted age values for independent walking from the equation with observed values in independent samples, researchers can assess its performance and reliability. These insights may lead to refinements that enhance its predictive accuracy in assessing infant motor development.

Although this study provides valuable insights, it has limita-

tions, notably regarding the assessment of gross motor development in preterm infants using the Thai version of the AIMS. Although this assessment is considered a gold standard and can provide percentile values for long-term variability comparisons, it is important to note that Thai infants have not yet established cutoff values indicating developmental risk across various age points from birth to 18 months.

Consequently, for the sake of efficiency, raw scores were employed for the analysis, as converting the scores to percentiles would necessitate a substantial amount of time and extended longitudinal data collection. This approach, unlike the Canadian version, which uses percentile values at specific cutoff points, may lack the level of detail provided by percentile comparisons [34]. Nonetheless, raw AIMS scores remain widely utilized for assessing developmental values and exploring relationships with factors influencing motor development [28] and upright posture in premature infants [31], ensuring an accurate assessment of various contributing factors.

Furthermore, the research exclusively involved participants from a specific geographic region, which raises questions about the applicability of the findings to diverse populations or other geographic areas. This study did not stratify the population by GA, resulting in uneven subject distribution. Additionally, data on the history of using devices that affect movement and upright positioning in daily activities were not collected. It is imperative to acknowledge this limitation when interpreting and extrapolating the results to broader contexts, as it holds significant importance and warrants attention. One limitation in this study is the assumption that moderately to late preterm infants are prone to milder developmental delays without congenital diseases or medical complications. However, it is crucial to recognize that these assessments rely solely on parental reports of independent walking ability, potentially leading to issues like misclassification or underreporting.

Building upon the Thai version of AIMS, this study analyzed motor development and its impact on neonatal characteristics in healthy preterm infants with the goal of early detection of walking development delays and timely intervention. However, limitations, such as excluding preterm infants with medical conditions, should be acknowledged. Future research should enhance these aspects for a more comprehensive exploration of motor development in preterm infants. To address these limitations, future research should investigate the relationship between postural efficiency during standing and the onset of independent walking in preterm infants. Considering these

factors, it is vital to account for these limitations when interpreting factor analysis results. Environmental elements, such as the infant's engagement in other activities, use of assistive tools, and safety measures limiting movement exploration, can affect gross motor development and independent walking attainment. Additionally, there might be additional variables influencing independent walking in premature infants that were not included in our study. Future investigations could indeed benefit from considering a broader spectrum of factors to provide a more comprehensive understanding of this developmental milestone. Factors like nutritional status and medical conditions require careful consideration. This investigation should consider serious medical conditions, environmental factors, and caregiving practices that influence gross motor development assessed by the Thai version of AIMS. These limitations may impact the generalizability and external validity of the findings to a broader population, constraining their applicability. Future research should consider these factors to enhance our comprehension of this field, offering valuable insights and a deeper understanding of the determinants of independent walking ability in healthy preterm infants.

In conclusion, the present study identified several factors that have a significant impact on the walking independently, including GA, 10th AIMS, and BHC. Based on our findings, we were able to develop a predictive equation to estimate the age of walking independently which provides a useful tool for clinicians and researchers to estimate the gross motor development as well as to assess the effectiveness of interventions aimed at improving this important aspect of gross motor development.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Sangkarit N, Tapanya W. Methodology:

Sangkarit N, Tapanya W. Formal analysis: Sangkarit N, Tapanya W. Funding acquisition: Sangkarit N, Amput P. Project administration: Sangkarit N. Visualization: Tapanya W. Writing – original draft: Sangkarit N, Tapanya W, Srithawong A. Writing – review and editing: Sangkarit N, Tapanya W, Amput P, Suwannakul B. Approval of final manuscript: all authors.

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# Feasibility of Mobile Health App-Based Home Aerobic Exercise for Physical Performance in Healthy Young Adults

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**Objective:** To investigate the feasibility and effects of a mobile app-based home cycling exercise program compared to home cycling exercise without additional monitoring system. Compared with fitness facilities or outdoor exercise, home-based exercise programs effectively improve physical performance in an indwelling community. However, a flexible, informal environment may decrease motivation and impair adherence to physical exercise. Mobile devices for aerobic exercise and mobile applications provide real-time monitoring, immediate feedback, and encouragement to increase motivation and promote physical performance. We investigated the feasibility and effects of a mobile app-based home exercise program on body composition, muscular strength, and cardiopulmonary function.

**Methods:** Between February and May 2023, 20 participants were randomly allocated to the intervention (mobile application with a tablet) and control groups, and they performed aerobic exercise using a stationary bicycle for  $\geq 150$  minutes per week for 6 weeks ( $\leq 30$ -minute exercise session, with 3-minute warm-up and 3-minute cool-down). Karvonen formula-based heart rate defined the weekly increase in exercise intensity. Outcome measures included body-composition parameters, isokinetic knee flexor and extensor strength tests, cardiopulmonary exercise test results, and rate of target heart rate (HR) achievement. Participants were assessed at baseline and after the intervention.

**Results:** Unrelated personal events led two participants to drop out. The intervention and control groups had similar baseline characteristics. Compared with the control group, in the post-intervention isokinetic strength test, bilateral knee flexor and extensor power, and time to target HR achievement significantly increased each week in the intervention group.

**Conclusion:** Home-based exercise to achieve long-term cardiovascular fitness with portable electronic/mobile devices facilitates individualized exercise using real-time feedback to improve motivation and adherence.

**Keywords:** Physical activity, Mobile applications, Physical performance, Self-management, Bicycling

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## INTRODUCTION

Physical activity (PA) has several health benefits. A single bout of moderate to vigorous PA not only improves sleep and anxiety and reduces blood pressure but also provides benefits including prevention of chronic diseases, such as cardiovascular disease, stroke, and diabetes; decreased risk of weight gain, depression, and falls; and improvement in bone health [1]. Regular PA has been associated with decreased incidence, symptoms, and mortality of viral infection through immunomodulation [2,3]. Several studies on the benefits of exercise using bioelectrical impedance analysis (BIA), have shown that PA prevents an increase in fat mass [4] and is inversely related to body mass index (BMI) and body fat percentage [5]. Regular exercise with moderate-to-vigorous intensity led to higher phase angle A values, indicating its potential benefits for cellular health and muscle quality [6]. A recent systematic review showed a curvilinear dose–response relationship between PA and health status, wherein significant health benefits, such as reduced risks for chronic disease and mortality, can occur with a small change in PA; this emphasizes the importance of being physically active [7].

In Korea, interest in aerobic exercise is gradually increasing in line with the era of pursuing a healthy lifestyle, although PA is not being performed appropriately. This failure to perform PA correctly is possibly due to reasons such as not being familiar with or not knowing the PA guidelines. According to data from the Korea National Health and Nutritional Examination Survey, the adherence rate to aerobic PA guidelines was less than 50% and had decreased by more than 10% in 5 years [8]. In 2020, less than 20% of adults in Korea satisfied the criteria for both aerobic and muscle strengthening PA guidelines [9].

Compliance with both muscle strengthening and aerobic PA guidelines is important due to its correlation with a substantial decrease in all-cause mortality risk compared to following either guideline alone [10]. However, it is difficult for the Korean population to meet these PA guidelines. A considerable amount of working time and continuously increasing sedentary lifestyles, characterized by sitting in a chair for more than 8 hours per day, could be a contributing factor [8,11]. The prevalence of insufficient PA was more than 50% among Korean adults in 2020, surpassing the global physical inactivity level [9,12].

Long working hours are associated with a higher risk of physical inactivity, and the accumulation of physical inactivity may gradually induce health problems [13]. In addition, during the coronavirus disease 2019 (COVID-19) pandemic, the social

distancing and quarantine policies of the Korean Disease Control and Prevention Agency led to worsened inactivity. In one questionnaire study in Korea, daily step counts decreased by more than 10% after the COVID-19 pandemic compared to before [3]. During the pandemic, a decrease in PA and an increase in sedentary time were observed, which were negatively and positively related to changes in BMI, respectively [14]. Lee et al. [15] showed that the prevalence of obesity in Korean adults revealed a significant increase of 2.5% in 2020 compared with that in 2019, which may be associated with low PA and unhealthy eating habits.

Considering these circumstances associated with restricted mobility, the interest in and demand for non-contact health care and home-based exercise (HBE) has increased [16]. Not only have the sales of fitness equipment for home exercise increased by 59%, compared to before the COVID-19 pandemic, but also the use of fitness-related applications has increased significantly [17].

In particular, HBE with healthcare devices can provide exercise monitoring and feedback and is a safe and appropriate method for alleviating physical inactivity and maintaining or improving cardiovascular health [18]. In addition, individuals can exercise at home at any time without restrictions. Individualized home exercise programs among adults have already been shown to be effective in improving physical activities or activities of daily living [19,20]. However, the treatment adherence was relatively poor in the HBE group. Additionally, it may be challenging for individuals to regularly conduct structured exercise programs at home without supervision or exercise prescriptions. Digital health interventions (DHIs) can help alleviate these barriers and encourage exercise. HBE delivered by DHIs was effective in enhancing physical function and quality of life related to health among older individuals [21].

Among the DHIs, mobile health can be used to make the exercise environment more appealing and entertaining through gaming [22]. The combination of PA with gaming through mobile health could be a great strategy for increasing PA and encouraging consistent participation in exercise.

The primary aim of this study was to evaluate the feasibility of HBEs using mobile applications and devices. We used a stationary bicycle, DETS Bike (UNIVR), as an exercise tool because the equipment is safe and helpful for aerobic and strengthening exercises and has fewer space restrictions at home. The second aim was to determine effectiveness by comparing the outcomes of physical performance in young adults between groups with exercise using a mobile application and those with conventional



exercise after 6 weeks.

## METHODS

### Study design

This single-center randomized controlled trial of healthy adults was conducted in accordance with CONSORT (Consolidated Standards of Reporting Trial) guidelines and the principles of the Declaration of Helsinki. The study protocol was approved by the Institutional Review Board and Ethics Committee of Chungnam National University Hospital (no. 2021-11-076).

All procedures were performed with adequate understanding and written informed consent was obtained from all participants. This study is registered with [cris.nih.go.kr](https://cris.nih.go.kr) (registration number: KCT0008876).

### Study participants

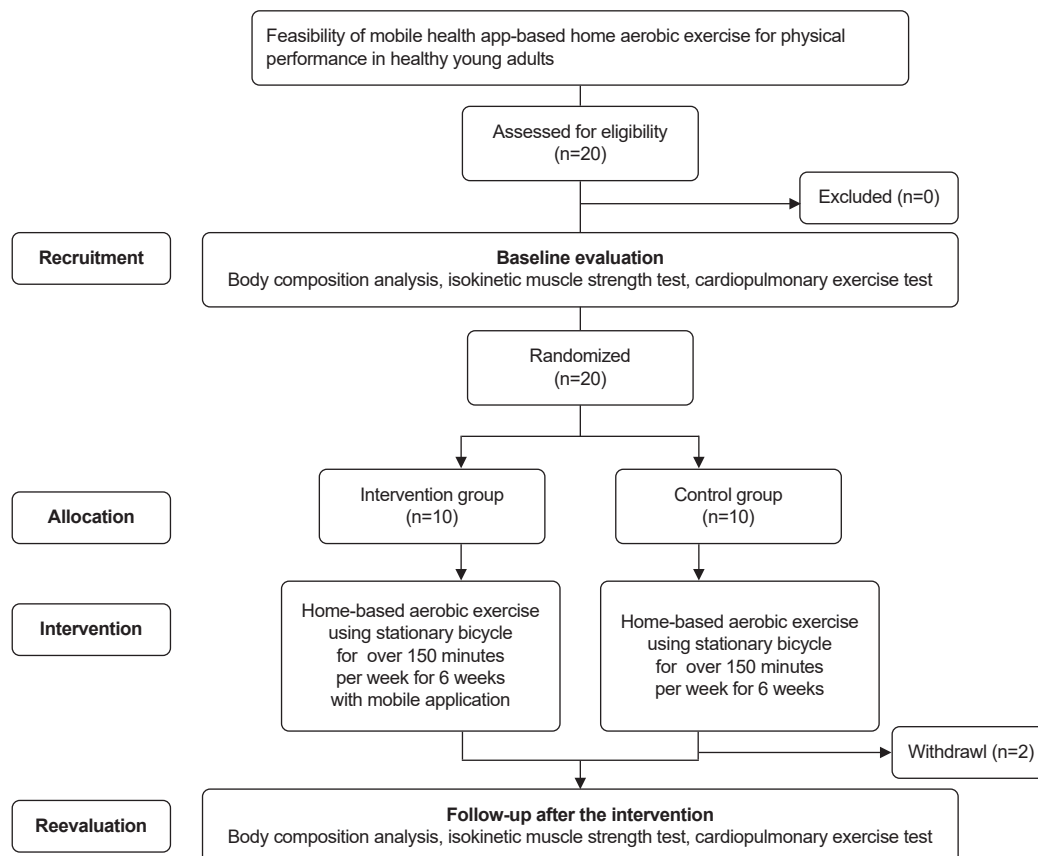
Participants were recruited through paper-based and online advertisements in the Department of Rehabilitation Medicine of a

tertiary hospital. The enrollment was conducted between February and May 2023. In total, 20 individuals were enrolled and randomly allocated to each arm (the intervention and control groups) in a 1:1 ratio (Fig. 1).

Participants who met the following inclusion criteria were recruited to participate in the study: (1) aged 18 years or older; (2) agreed to participate in the study voluntarily; (3) not diagnosed with cardiovascular disease; (4) able to use mobile devices, including installing and using mobile applications; and (5) able to understand and perform the exercise protocol at home and provide feedback without difficulty. The exclusion criteria included: (1) medical problems or physical disabilities that would prevent participation in exercise; and (2) inability to read and understand the exercise manual.

### Exercise protocol

Before each exercise session, both intervention and control group participants wore a heart rate (HR) sensor (exa-i; Shenzhen Chleaf Electronics) on either their right (Rt) or left (Lt)



**Fig. 1.** Flow chart of the participants selection.

forearm to monitor their HR. They were instructed to exercise using a stationary bicycle for a minimum of 150 minutes per week based on the WHO PA guidelines [11]. Participants were required to perform each exercise session for a minimum of 30 minutes, including 3-minute warm-up and cool-down phases.

The entire exercise program was performed for 6 weeks. Exercise intensity was increased weekly using the calculated HR based on the Karvonen formula [23]. Participants began the program by exercising at an intensity of resting HR+50% of HR reserve (HRR) in the first week and gradually increased to an intensity level as follows: second week, resting HR+60% of HRR; third week, resting HR+65% of HRR; fourth week, resting HR+70% of HRR; fifth week, resting HR+75% of HRR. Finally, in the sixth week, exercise was performed at an intensity of resting HR+80% of HRR. The HR, measured in real-time, was displayed on a screen.

### Intervention with mobile application

In the intervention group, participants were instructed to install the mobile app, Clinic C (UNIVR) on a tablet and were educated on how to use the application before starting the exercise. When the participants run the application, a message regarding the link between the HR sensor and the bicycle appears. When the connection between the application and bicycle is confirmed, the HR sensor moves on to a screen to record simple personal information, current exercise weeks, and target exercise time. Subsequently, the virtual reality game screen appears, and the exercise begins.

The target HR of the session is automatically calculated based on the resting HR measured using an HR sensor (Fig. 2A) and presented on the screen during the game. The virtual reality

game consists of a warm-up, the main exercise, and a cool-down. There is a game character in the middle of the screen. When the participants begin cycling, the wireless sensor embedded in the bicycle monitors their speed and reflects it by adjusting the speed of the character. At the top of the screen, the target HR is displayed as a yellow line in the middle, and the current HR is displayed in red. The relative amount of time elapsed since the start of the exercise is shown as a bar graph on the left-hand side of the screen (Fig. 2B). When the participant's HR is lower than the target HR, comics are displayed on the screen to encourage the participant to exert more effort (Fig. 2C). After each session, the achievement rate of the target HR, total exercise time, and actual exercise time are displayed on the screen (Fig. 2D). In contrast, the control group underwent the same exercise protocol without using the mobile application.

### Measures

All participants were assessed at baseline and 6 weeks post-intervention. Measurements included body composition analysis, isokinetic muscle strength test, and cardiopulmonary exercise test (CPET). All measurements were performed by the same experienced physiotherapist who was blinded to the study.

#### Body composition measurement

Using an automatic height- and weight-measuring device, BSM370 (Biospace), the participants' height (cm) and weight (kg) were measured to the first decimal place in an upright position without shoes. Body composition was determined by BIA using InBody S10 (InBody). Participants stood barefoot on two-foot electrodes and gently held two hand electrodes placed in the palm of their hand with their fingers wrapped around the



**Fig. 2.** Home-based exercise program using tablet and wireless heart rate tracker. (A) Setting for the intervention with a heart rate sensor placed on the participant's right forearm. (B) Screenshot of the game screen delivered to the participants that is displayed while exercising on a bike. Box a: (above) Range of the target HR (yellow line) and current HR (asterisk). Box b: (left) Bar graph showing the relative amount of time elapsed in the game. (C) Screenshot of the game screen showing the lyrics displayed as encouragement when the participants did not reach the target HR range. (D) Summary of training sessions showing the achievement rate of the target HR and the total and actual exercise time on the screen. HR, heart rate.

hand electrode so that the palms, fingers, and soles could be in contact with the electrodes during the test. The skeletal muscle mass (SMM), percentage body fat (PBF), visceral fat area (VFA), segmental lean analysis (SLA), and phase angle of both legs were measured using BIA.

#### *Isokinetic strength test*

To measure lower extremity muscle strength, bilateral isokinetic knee flexor (KF) and extensor strength tests were performed. Before the test, each participant was required to cross their arms over the chest, and Velcro straps were used to fix the trunk, pelvis, and thighs in place to minimize body compensation. At an angular velocity of 60°/s, using an isokinetic dynamometer (Medical Systems 4; BIODEX), the participants were required to perform five maximal repetitions of flexion and extension in both legs after submaximal trials for adaptation. The peak torque generated over five repetitions was recorded, and the peak torque per body weight was calculated.

#### *Cardiopulmonary exercise test*

To determine the exercise capacity of the participants, experienced physiotherapists performed the incremental CPET with 12-lead electrocardiographic monitoring on a treadmill (Marquette T2000; GE HealthCare). The participants underwent symptom-limited exercise testing using a Korea Institute of Sports Science protocol developed for the evaluation of national athletes. A breath-by-breath expired gas analyzer (Quark CPET; COSMED), blood pressure monitor, and pulse monitor were used during testing. Termination of the CPET was done by following the guidelines set by the American Heart Association [24].

An oxygen consumption ( $\text{VO}_2$ ) peak was determined as the highest recorded  $\text{VO}_2$  value during a given 15-second interval within the last 90 seconds of exercise [25]. Anaerobic threshold (AT) refers to  $\text{VO}_2$  at the onset of blood lactate accumulation and is the point at which minute ventilation increases disproportionately relative to  $\text{VO}_2$ ; the AT is generally observed at 60%–70% of  $\text{VO}_2$  max [26,27].  $\text{VO}_2$  peak, predictive percentage, and  $\text{VO}_2$  values over the AT were used for the study.

#### **Achieved target HR percentage**

For each exercise session, the exercise time and HR were automatically recorded on a mobile platform. These data were used to calculate the total exercise time for each week and the percentage of time spent within the target HR range (target  $\text{HR} \pm 10$  beats per minute). These parameters were used to assess the

intergroup difference in the rate of reaching the target HR and thereby evaluate the effectiveness and feasibility of the mobile application as an adjunctive tool for promoting PA during HBE.

#### **Statistical analysis**

Demographic and clinical characteristics are presented as means and standard deviations. Baseline characteristics were compared using the Mann–Whitney U-test for continuous variables and the chi-square test for dichotomous variables. Statistical analyses included the Mann–Whitney U-test for intergroup comparisons and Wilcoxon signed-rank tests for within-group comparisons. All statistical analyses were performed using IBM SPSS Statistics 29.0 (IBM Corp.). The level of statistical significance was 0.05.

## **RESULTS**

#### **Baseline variables**

Among the 20 participants recruited, 18 completed the study, and two in the control group were excluded from the study due to aggravation of back pain and orthopedic surgery due to trauma, respectively. The participant's back pain was originally caused by long-standing sedentary lifestyles and has recently been worse due to prolonged sitting from recent increase in workload regardless of exercise intervention. The baseline demographic and clinical characteristics of both the groups are listed in Table 1. The average ages of the participants were  $29.50 \pm 4.45$  and  $27.75 \pm 4.62$  years in the intervention and control groups, respectively. The sex ratios (male:female) in the intervention and control groups were 5:5 and 3:5, respectively.

There was no significant intergroup difference in age ( $p=0.408$ ), sex ( $p=0.680$ ), or height ( $p=0.762$ ), or in baseline differences in parameters of body composition (SMM,  $p=0.897$ ; PBF,  $p=0.633$ ; BMI,  $p=0.897$ ; VFA,  $p=0.897$ ; SLA Rt.leg,  $p=0.897$ ; SLA Lt.leg,  $p=0.897$ ; phase angle Rt.leg,  $p=0.237$ ; phase angle Lt.leg,  $p=0.101$ ), isokinetic strength test (Rt.knee extensor [Rt.KE],  $p=0.573$ ; Rt.KF,  $p=0.696$ ; Lt.KE,  $p=0.460$ ; Lt.KF,  $p=0.829$ ), CPET ( $\text{VO}_2$  peak,  $p=0.408$ ;  $\text{VO}_2$  % [pred],  $p=0.360$ ).

#### **Outcome variables after the 6-week intervention**

Table 2 presents the descriptive results of the outcomes during the study period for both the intervention and control groups. Intergroup analysis showed no statistically significant mean differences in body composition parameters. In the isokinetic strength test, significant differences were found between the

**Table 1.** Demographic characteristics of the participants

|                                  | Intervention group (n=10) | Control group (n=8) | p-value |
|----------------------------------|---------------------------|---------------------|---------|
| Age (yr)                         | 29.50±4.45                | 27.75±4.62          | 0.408   |
| Sex                              |                           |                     | 0.680   |
| Male                             | 5                         | 3                   |         |
| Female                           | 5                         | 5                   |         |
| Height (cm)                      | 167.25±7.93               | 165.21±7.86         | 0.762   |
| Body composition                 |                           |                     |         |
| SMM (kg)                         | 27.66±5.90                | 27.29±7.25          | 0.897   |
| PBF (%)                          | 26.69±4.66                | 28.46±8.03          | 0.633   |
| BMI (kg/m <sup>2</sup> )         | 24.04±2.54                | 25.20±6.21          | 0.897   |
| VFA (cm <sup>2</sup> )           | 75.13±16.35               | 84.99±54.97         | 0.897   |
| SLA Rt.leg (kg)                  | 7.65±1.57                 | 7.57±1.74           | 0.897   |
| SLA Lt.leg (kg)                  | 7.68±1.52                 | 7.56±1.82           | 0.897   |
| Phase angle Rt.leg (°)           | 6.11±1.13                 | 6.58±0.65           | 0.237   |
| Phase angle Lt.leg (°)           | 5.99±1.08                 | 6.65±0.69           | 0.101   |
| Isokinetic strength test (%)     |                           |                     |         |
| Rt.KE                            | 217.92±34.39              | 211.83±22.22        | 0.573   |
| Rt.KF                            | 112.85±28.82              | 115.04±15.69        | 0.696   |
| Lt.KE                            | 220.28±38.47              | 207.54±20.43        | 0.460   |
| Lt.KF                            | 107.06±29.91              | 112.01±11.16        | 0.829   |
| CPET                             |                           |                     |         |
| VO <sub>2</sub> peak (mL/min/kg) | 33.08±5.39                | 30.60±4.01          | 0.408   |
| VO <sub>2</sub> % (pred)         | 83.50±13.60               | 76.50±13.23         | 0.360   |

Values are presented as mean±standard deviation or number only.

SMM, skeletal muscle mass; PBF, percentage body fat; BMI, body mass index; VFA, visceral fat area; SLA, segmental lean analysis; Rt, right; Lt, left; KE, knee extensor; CPET, cardiopulmonary exercise test; VO<sub>2</sub>, oxygen consumption.

**Table 2.** Outcome measures of participants from before to after the intervention

| Outcome measures                 | Intervention group |              |             |                                    | Control group |              |             |                                    | Intergroup difference, p-value |
|----------------------------------|--------------------|--------------|-------------|------------------------------------|---------------|--------------|-------------|------------------------------------|--------------------------------|
|                                  | Pre-test           | Post-test    | Change      | Between pre- and post-test p-value | Pre-test      | Post-test    | Change      | Between pre- and post-test p-value |                                |
| Body composition                 |                    |              |             |                                    |               |              |             |                                    |                                |
| SMM (kg)                         | 27.66±5.90         | 27.76±5.71   | 0.10±0.56   | 0.512                              | 27.29±7.25    | 27.31±6.86   | 0.02±0.60   | 0.944                              | 0.633                          |
| PBF (%)                          | 26.69±4.66         | 26.39±5.52   | -0.30±1.85  | 0.342                              | 28.46±8.03    | 28.73±8.24   | 0.26±1.25   | 0.484                              | 0.274                          |
| BMI (kg/m <sup>2</sup> )         | 24.04±2.54         | 24.10±2.60   | 0.06±0.27   | 0.394                              | 25.20±6.21    | 24.11±3.28   | -1.09±3.82  | 0.500                              | 0.965                          |
| VFA (cm <sup>2</sup> )           | 75.13±16.35        | 74.42±20.88  | -0.06±0.51  | 0.475                              | 84.99±54.97   | 86.36±58.53  | 1.38±6.31   | 0.499                              | 0.360                          |
| SLA Rt.leg (kg)                  | 7.65±1.57          | 7.59±1.59    | -0.10±0.60  | 0.646                              | 7.57±1.74     | 7.57±1.61    | 0.00±0.18   | 0.779                              | 0.965                          |
| SLA Lt.leg (kg)                  | 7.68±1.52          | 7.57±1.55    | -0.71±9.90  | 0.799                              | 7.57±1.82     | 7.53±1.60    | -0.03±0.26  | 0.779                              | 0.573                          |
| Phase angle Rt.leg (°)           | 6.11±1.13          | 6.10±1.02    | -0.01±0.29  | 0.812                              | 6.58±0.65     | 6.73±0.66    | 0.15±0.28   | 0.181                              | 0.237                          |
| Phase angle Lt.leg (°)           | 5.99±1.08          | 6.03±0.85    | 0.04±0.42   | 0.797                              | 6.65±0.69     | 6.81±0.69    | 0.16±0.25   | 0.105                              | 0.515                          |
| Isokinetic strength test (%)     |                    |              |             |                                    |               |              |             |                                    |                                |
| Rt.KE                            | 217.92±34.39       | 248.59±41.04 | 30.67±18.30 | 0.007*                             | 211.83±22.22  | 204.55±31.42 | -7.27±26.05 | 0.401                              | 0.004*                         |
| Rt.KF                            | 112.85±28.82       | 126.46±34.25 | 13.61±10.16 | 0.005*                             | 115.04±15.69  | 110.23±12.44 | -4.81±13.08 | 0.208                              | 0.004*                         |
| Lt.KE                            | 220.28±38.47       | 244.20±47.92 | 23.92±18.44 | 0.007*                             | 207.54±20.43  | 198.90±27.12 | -8.64±20.80 | 0.401                              | 0.004*                         |
| Lt.KF                            | 107.06±29.91       | 115.91±29.04 | 8.85±7.86   | 0.007*                             | 112.01±11.16  | 109.24±10.63 | -2.77±9.22  | 0.327                              | 0.021*                         |
| CPET                             |                    |              |             |                                    |               |              |             |                                    |                                |
| VO <sub>2</sub> peak (mL/min/kg) | 33.08±5.39         | 36.26±6.41   | 3.18±6.31   | 0.241                              | 30.60±4.01    | 28.59±2.88   | -2.00±3.76  | 0.241                              | 0.083                          |
| VO <sub>2</sub> % (pred)         | 83.50±13.60        | 88.50±14.03  | 5.00±14.17  | 0.507                              | 76.50±13.23   | 72.00±10.62  | -4.50±9.15  | 0.507                              | 0.122                          |

Values are presented as mean±standard deviation.

SMM, skeletal muscle mass; PBF, percentage body fat; BMI, body mass index; VFA, visceral fat area; SLA, segmental lean analysis; Rt, right; Lt, left; KE, knee extensor; CPET, cardiopulmonary exercise test; VO<sub>2</sub>, oxygen consumption.

\*p<0.05.

baseline and post-intervention assessments in the intervention group (Rt.KE,  $p=0.007$ ; Rt.KF,  $p=0.005$ ; Lt.KE,  $p=0.007$ ; Lt.KF,  $p=0.007$ ), whereas no significant difference was found in the control group (mean changes in Rt.KE,  $p=0.401$ ; Rt.KF,  $p=0.208$ ; Lt.KE,  $p=0.401$ ; Lt.KF,  $p=0.327$ ).

In the CPET, the  $\text{VO}_2$  peak and  $\text{VO}_2$  % (pred) values were increased in intervention group after the intervention but without statistical significance.

Table 3 demonstrates the average total exercise time and target HR achievement rate in each group. During the 6-week intervention period, both the average total exercise time and the achieved target HR rate were significantly higher in the experimental group compared to that in the control group ( $p=0.043$ ,  $p<0.001$ , respectively). Specifically, the difference in average target HR attainment rate was larger than that of average total exercise time between the two groups ( $53.02\pm25.72\%$  vs.  $5.50\pm9.63\%$ ).

Fig. 3 comprises box plots showing the degree of target HR achievement in each group. Compared with the control group, the

intervention group showed a significantly higher target HR achievement rate every week (week 1,  $p=0.012$ ; week 2,  $p<0.001$ ; week 3,  $p=0.001$ ; week 4,  $p=0.001$ ; week 5,  $p<0.001$ ; week 6,  $p<0.001$ ).

## DISCUSSION

The main result of our study was that HBE combined with a mobile application for 6 weeks improved lower extremity muscle strength and target HR achievements. However, its effects on body composition and cardiopulmonary function remain unclear.

### Body composition before and after the intervention

There are no clear statements regarding how long or intense exercise should be to produce changes in body composition or cardiorespiratory function. This might be due to the different exercise volumes, intensities, programs, and participant characteristics among the studies, which makes it difficult to generalize the results. Several studies have investigated the relationship among exercise type, intensity, and changes in body composition. A systematic review on the effectiveness of various types of exercise on body composition showed that combined resistance and aerobic training had the greatest effect on reducing BMI, PBF, and inflammatory cytokine levels [28]. Grediagin et al. [29] demonstrated that a 12-week exercise program showed no significant difference in changes in body weight, PBF, fat-free mass, and fat mass between high- and low-intensity exercise groups in overweight women, and this emphasized the importance of energy expenditure rather than exercise intensity. In

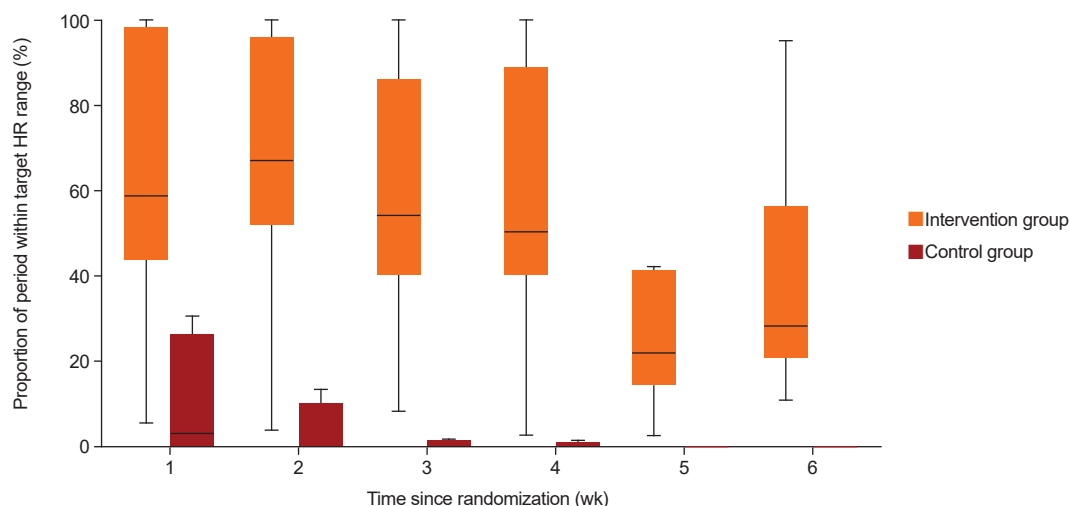
**Table 3.** Average total exercise time and target HR achievement rate of the participants

|  | Intervention group | Control group | p-value  |
|--|--------------------|---------------|----------|
| Average total exercise time (min)      | 115.24±9.43        | 98.95±20.66   | 0.043*   |
| Average target HR achievement rate (%) | 53.02±25.72        | 5.50±9.63     | <0.001** |

Values are presented as mean±standard deviation.

HR, heart rate.

\* $p<0.05$  and \*\* $p<0.001$ .



**Fig. 3.** Achieved target heart rate percentage stratified by each study group for 6 weeks. HR, heart rate.



another 12-week high-intensity functional training study, both low- and moderate-resistance load groups with similar total volume load experienced comparable increase in lean body mass. Additionally, during the 6 weeks of the study, both groups demonstrated a decrease in fat mass [30]. Similarly, another study of how walking speed affects body fat in postmenopausal healthy women showed comparable body fat reduction in both the slow- and fast-walking groups after a 30-week walking regimen, suggesting that the degree of energy expenditure is important [31].

Therefore, rather than determining the duration of exercise, it seems reasonable to prescribe exercise types and the total amount of exercise to reflect energy expenditure, considering that these are important factors in changes in body composition. Although the stationary cycling used in this study was an appropriate form of exercise combined with aerobic and resistance training [32], the exercise volume, including the total duration of exercise (weeks) and the intensity of exercise, may not be sufficient to produce significant changes in body composition.

### **Change in isokinetic strength test results from before to after the intervention**

We demonstrated that the intervention group showed a marked improvement in lower-extremity strength measured by peak torque/body weight compared with that in the control group. During the early phases (first 6–8 weeks) of resistance training, neural adaptations are the primary mechanisms for increased muscular strength [33]. As the 6 weeks of exercise conducted in this study constitutes too short a duration to provoke muscle fiber hypertrophy and conversion to the fast fiber type, which contributes to strength gains in the later phase (12–26 weeks) [33], it seems reasonable that substantial muscular strength gains in participants of the intervention groups were attributed to adaptation.

### **CPET before and after the intervention**

A systematic review showed a graded dose–response relationship between total weekly PA volume and cardiorespiratory fitness, and a more distinct relationship was observed between the intensity of PA and  $\text{VO}_2$  max [34]. A recent meta-analysis on the effects of training intensity on  $\text{VO}_2$  max in young healthy adults demonstrated that training at any intensity at or greater than 60% of  $\text{VO}_2$  max seems to show an improvement in  $\text{VO}_2$  max, without additional gain with an increase in the intensity above 60%. In addition, high-intensity training can

efficiently generate similar enhancement in  $\text{VO}_2$  max through shorter training sessions and reduced training volumes [35]. In contrast, a randomized controlled study by Helgerud et al. [36] showed that 8 weeks of higher aerobic endurance training is more effective than other training at lower intensities in improving  $\text{VO}_2$  max.

Considering these studies, prescribing exercise at an intensity greater than 60% of  $\text{VO}_2$  max for sufficient total volume is likely to improve  $\text{VO}_2$  max. If the exercise duration is short, exercise at a higher intensity would be more appropriate.

In this study, although the intervention group showed some improvement in cardiopulmonary function after the intervention compared with the control group, a statistically significant difference was not found. The total volume of exercise may not be sufficient to improve cardiovascular fitness in terms of exercise duration and intensity. However, compared to the control group, the intervention group showed a significantly higher target HR achievement rate each week. As exercise intensity was determined by the target HR, a greater exercise volume in the intervention group could have improved  $\text{VO}_2$  max.

### **Achieving the target HR percentage in the intervention group**

Various factors can influence adherence to HBE. A study on patients with chronic illness demonstrated that factors linked to patients, such as motivation and perceived behavior control, along with socioeconomic factors like education, as well as factors pertaining to their conditions, including comorbidities, play a significant role in adherence to HBE [37]. A previous systematic review of the predictors of adherence to HBE suggested that greater self-efficacy, motivation, social support, intentions, and previous adherence to physical therapy predicted higher adherence to HBE [38]. Our research demonstrated that the intervention group showed significantly higher average total exercise time and rate of target HR achievement compared to the control group throughout the intervention period. It is believed that the use of mobile applications influenced motivation and significantly increased adherence to exercise.

This could suggest that employing strategies such as exercise with mobile applications using electronic devices, as in this study, could serve as a suitable additional method for enhancing participant motivation and intentions to maximize exercise outcome, especially considering the non-adherence rate of HBE reaches as high as 70% [38].

## Limitations

This study has several limitations. First, only 18 participants were eligible because of the study's short recruitment period. Our study may be underpowered as a result of the relatively small number of participants. The young, healthy participants of this study may not reflect the state of young adults in the overall population. Second, there were limitations in controlling for various factors, including participation in other exercises and degree of nutrient supplementation. In addition, there were practical difficulties in checking whether the participants performed the exercises with full attention. Accordingly, the degree of participation among the participants may have varied even within the group. Third, the relatively short-term exercise intervention and follow-up time were insufficient to demonstrate the effects of exercise. Future studies should be conducted with larger sample sizes, longer intervention durations, and longer follow-up periods to determine the sustained effects of the intervention.

## Conclusions

Mobile app-based 6-week HBE using portable electronic devices induced significant improvements in lower-extremity muscle strength and differences in target HR achievement, but not in body composition or aerobic exercise capacity. However, by demonstrating a significant increase in exercise participation time and the rate of target HR achievement, the intervention has confirmed feasibility and could potentially have a positive effect on cardiopulmonary function with longer-duration application.

## CONFLICTS OF INTEREST

The authors declare potential conflicts of interest related to this research. Taejin Kwak is a CEO of UNIVR company and the authors utilized products from the company in this study. Such conflicts of interest could potentially influence the impartiality of the research.

To mitigate these conflicts, We collaborated with other authors to ensure independence in the design and data collection process of this study, and other researchers participated in the outcome measurement and data analysis process. Through this, the authors aim to minimize the influence of conflicts of interest and maintain the accuracy and credibility of the research.

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## AUTHOR CONTRIBUTION

Conceptualization: Jung IY, Kwak T, Moon CW. Data curation: Nam JS, Kim HA. Methodology: Jung IY, Moon CW. Formal analysis: Kim HA. Investigation: Kim HA. Funding acquisition: Jung IY, Kwak T, Moon CW. Project administration: Kwak T. Visualization: Nam JS, Moon CW. Writing – original draft: Nam JS. Writing – review and editing: Cho KH, Moon CW. Approval of final manuscript: all authors.

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# Epidemiology of Traumatic Spinal Cord Injury in the Himalayan Range and Sub-Himalayan Region: A Retrospective Hospital Data-Based Study

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**Objective:** To compile epidemiological characteristics of traumatic spinal cord injury (TSCI) in the Northern Indian Himalayan regions and Sub-Himalayan planes.

**Methods:** The present study is a retrospective, cross-sectional descriptive analysis based on hospital data conducted at the Department of Physical Medicine and Rehabilitation and Spine Unit of Trauma Centre in a tertiary care hospital in Uttarakhand, India. People hospitalized at the tertiary care center between August 2018 and November 2021 are included in the study sample. A prestructured proforma was employed for the evaluation, including demographic and epidemiological characteristics.

**Results:** TSCI was found in 167 out of 3,120 trauma patients. The mean age of people with TSCI was 33.5±13.3, with a male-to-female ratio of 2.4:1. Eighty-three participants (49.7%) were from the plains, while the hilly region accounts for 50.3%. People from the plains had a 2.9:1 rural-to-urban ratio, whereas the hilly region had a 6:1 ratio. The overall most prevalent cause was Falls (59.3%), followed by road traffic accidents (RTAs) (35.9%). RTAs (57.2%) were the most common cause of TSCI in the plains' urban regions, while Falls (58.1%) were more common in rural plains. In both urban (66.6%) and rural (65.3%) parts of the hilly region, falls were the most common cause.

**Conclusion:** TSCI is more common in young males, especially in rural hilly areas. Falls rather than RTAs are the major cause.

**Keywords:** Spinal cord injuries, Trauma, Demography, Epidemiology

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## INTRODUCTION

Traumatic spinal cord injury (TSCI) is one of the most common causes of disability. Depending on the nature of the injury, damage to the skeletal, disco-ligament, spinal cord, and nerve roots

can result in varying degrees of disability, including complete paralysis, pain, sensory loss, and bladder-bowel involvement. TSCI has a substantial psychological and economic impact on individuals' lives, families, and society [1]. Although timely and proper surgical decompression can improve the odds of neuro-



logical recovery, rehabilitation is still the most crucial factor in improving these individuals' quality of life [2].

According to a systematic review by Kumar et al. [3], the global incidence of TSCI is 10.5 cases per 100,000 people. According to the World Health Organization, the incidence of TSCI ranged from 3.4 per 100,000 in Europe to 13.7 per 100,000 in Southeast Asia and 54 cases per million in the United States of America. The most common mechanisms for TSCI worldwide were road traffic accidents (RTAs) followed by falls [3,4].

Regional and cultural factors and infrastructural disparities influence significant demographic and epidemiological data differences among countries. Most European research points to transportation-related accidents as the leading cause of TSCI, followed by falls and sports-related injuries. In contrast, the United States sees violence, specifically firearm injuries, as a major contributor after transportation and sports [4-7]. In Asia, patterns vary: China reports falls as the predominant cause, followed by motor vehicle collisions and striking injuries, while Iran emphasizes motor vehicle accidents and falls, including severe drops and related violence. In Nepal and Northern India, falls from significant heights, such as ladders, trees, and cliffs, are particularly prevalent, with RTAs also being a major concern [8-11].

Narrow valleys, steep cliffs and slopes overload India's Himalayan and Sub-Himalayan regions, and this territory also experiences heavy rains during the monsoon season. The transport infrastructure is not in very good condition. The parapets on the roof of houses and side walls of stairs are either of low height or completely lacking, making them a source of injury. People residing in these areas depend on nearby forest areas for their livelihood.

These geographical factors play a crucial role in the incidence, prevalence, mortality, and morbidity of TSCI patients in this part of the country. Moreover, this part has limited access to tertiary-level healthcare facilities. Even though India is the world's second-most populous country, demographic and epidemiological data are scarce for TSCI. The present study aimed to assemble demographic and epidemiological characteristics of TSCI in the Himalayan and Sub-Himalayan regions.

## METHODS

The current study is a cross-sectional descriptive analysis of people with TSCI based on hospital data. It was carried out with prior approval from the Institute Ethics Committee, All India

Institute of Medical Sciences, Rishikesh (approval number: AIIMS/IEC/21/12) in the Department of Physical Medicine and Rehabilitation and the Spine Unit of the Trauma Centre of a tertiary care hospital in Uttarakhand, India. The requirement of informed consent in this study was waived because the study was a retrospective study. All personal details of the participants were kept confidential throughout the study. The study sample comprises individuals with TSCI admitted to the tertiary care center between August 2018 and November 2021. A prestructured proforma was used for evaluation, including demographic parameters such as age, sex, marital status, address, educational status, and occupation. The epidemiological variables included mode of injury, time of arrival in the Institute after injury, mode of transport used during transfer, body position during transfer, any previous hospitalisation, type of care provided during initial admission at another healthcare facility, vertebral level of injury, neurological level of injury (NLI), the severity of injury based on American Spinal Injury Association Impairment Scale (AIS) [12], and associated injuries. People who died before arriving at the hospital were excluded from the study.

## Operational definition

TSCI results from a sudden, traumatic impact on the spine that fractures or dislocates vertebrae, where displaced bone fragments, disc materials, or ligaments bruise or tear into the spinal cord tissue [13].

**Himalayan region:** The Indian Himalayan region in Northern India is denoted as the hilly region in the study, further divided into hilly-urban and hilly-rural areas.

**Sub-Himalayan region:** The plains after the foothills of the Himalayas in Northern India are denoted as the plains in the study, which are further divided into plains-urban (PU) and plains-rural (PR) areas.

## Statistical analysis

IBM SPSS 27.0 (IBM Corp.) and Microsoft Excel 2016 Professional Plus (Microsoft Corp.) software were used for data management and analysis. In the statistical analysis, categorical variables were presented in number (%), and continuous variables were presented as mean±standard deviation. For multigroup comparisons of categorical variables like sex and marital status, a chi-square test was used. A one-factor ANOVA test for independent measures was used for continuous variables like age. The p-value was significant at <0.05.

## RESULTS

A total of 3,120 trauma patients were admitted during the study period, with 167 having TSCI. The mean age of the people with TSCI was  $33.5 \pm 13.3$ , ranging from 4 to 72 years. The age difference was not statistically significant between rural and urban areas of hills and plains. Males were significantly affected in this study, with a male-to-female ratio of 2.4:1. Most participants, 108 (64.7%), were married at the time of the injury, although the difference is insignificant. Roughly 74 (44.3%) individuals had a high school education or less, while 23 (13.7%) were uneducated (without formal education in any institute). In this study, the majority of patients were from the state of Uttarakhand 112 (67.1%), followed by Western Uttar Pradesh districts 52 (31.1), and a few from neighbouring Himachal Pradesh 3 (1.8%). A total of 83 participants (49.7%) are from the plains, while 84 (50.3%) are from the hilly region. Individuals from the plains had a rural-to-urban ratio of 2.9:1, compared to 6:1 in the hilly region. The study included a wide range of occupations, but homemakers 30 (17.9%), students 44 (26.4%), farmers 27 (16.2%), and labourers 21 (12.6%) were the most common (Table 1).

In this study, the most common cause of TSCI was Falls 99 (59.3%), followed by RTAs 60 (35.9%), other causes were 8 (4.8%), which involved assault 2 (1.2%), bullet injury 2 (1.2%), a heavy object falls on back 3 (1.8%), Ankylosing spondylitis 1 (0.6%). Falls were the most common cause in urban 8 (66.6%) and rural 47 (65.3%) areas of the hilly region. RTAs were the most common 12 (57.2%) in the PU areas, while Falls were more common in the PR area 36 (58.1%). Falls were more common in both males and females than RTAs, but females had a much higher proportion of Falls 41 (82.0%) than males 58 (49.6%).

The time taken to get to the health center after an injury varies greatly. A total of 35 (20.9%) participants were reached within 24 hours of injury, and 45 (26.9%) were brought between 24 and 48 hours. After an injury, the most common transfer mode was an ambulance 128 (76.1%), but cars 38 (22.8%), and bikes 1 (0.6%) were also used. Most cases were transferred supine during the transfer 165 (98.8%). A total of 143 (85.6%) participants were previously hospitalized at a nearby primary health care facility and referred to the tertiary center; only 24 (14.4%) participants reported directly. A total of 55 (32.9%) participants

**Table 1.** Demographic profile of the patients

| Variable            | Total           | Hilly-urban    | Hilly-rural     | Plains-urban    | Plains-rural    | p-value |
|---------------------|-----------------|----------------|-----------------|-----------------|-----------------|---------|
| Participant         | 167 (100)       | 12 (7.2)       | 72 (43.1)       | 21 (12.6)       | 62 (37.2)       |         |
| Age (yr)            | 33.5 $\pm$ 13.3 | 32.3 $\pm$ 9.5 | 34.1 $\pm$ 15.2 | 36.8 $\pm$ 12.2 | 31.9 $\pm$ 11.8 | 0.53    |
| Sex                 |                 |                |                 |                 |                 | 0.005   |
| Male                | 117 (70.0)      | 6 (5.2)        | 43 (36.7)       | 19 (16.3)       | 49 (41.8)       |         |
| Female              | 50 (29.9)       | 6 (12.0)       | 29 (58.0)       | 2 (4.0)         | 13 (26.0)       |         |
| Marital status      |                 |                |                 |                 |                 | 0.17    |
| Married             | 108 (64.7)      | 10 (9.3)       | 41 (37.9)       | 16 (14.8)       | 41 (37.9)       |         |
| Unmarried           | 59 (35.3)       | 2 (3.4)        | 31 (52.5)       | 5 (8.5)         | 21 (35.5)       |         |
| Education           |                 |                |                 |                 |                 |         |
| Uneducated          | 23 (13.7)       | 0 (0)          | 14 (60.8)       | 3 (13.1)        | 6 (26.1)        |         |
| Up to high school   | 74 (44.3)       | 8 (10.8)       | 33 (44.6)       | 6 (8.1)         | 27 (36.5)       |         |
| Up to intermediate  | 41 (24.5)       | 0 (0)          | 16 (39.1)       | 7 (17.1)        | 18 (43.9)       |         |
| Graduate            | 29 (17.4)       | 4 (13.8)       | 9 (31.1)        | 5 (17.3)        | 11 (37.9)       |         |
| Occupation          |                 |                |                 |                 |                 |         |
| Housewife           | 30 (17.9)       | 5 (16.6)       | 19 (63.3)       | 1 (3.3)         | 5 (16.6)        |         |
| Student             | 44 (26.4)       | 4 (9.1)        | 20 (45.5)       | 6 (13.6)        | 14 (31.8)       |         |
| Farmer              | 27 (16.2)       | 1 (3.7)        | 7 (25.9)        | 5 (18.5)        | 14 (51.8)       |         |
| Labourer            | 21 (12.6)       | 0 (0)          | 9 (42.8)        | 3 (14.3)        | 9 (42.8)        |         |
| Unemployed          | 5 (2.9)         | 0 (0)          | 3 (60.0)        | 1 (20.0)        | 1 (20.0)        |         |
| Government employee | 3 (1.8)         | 0 (0)          | 1 (33.3)        | 0 (0)           | 2 (66.6)        |         |
| Shop keeper         | 8 (4.8)         | 0 (0)          | 4 (50.0)        | 1 (12.5)        | 3 (37.5)        |         |
| Private job         | 14 (8.4)        | 2 (14.3)       | 4 (28.5)        | 4 (28.5)        | 4 (28.5)        |         |
| Others              | 15 (8.9)        | 0 (0)          | 5 (33.3)        | 0 (0)           | 10 (66.6)       |         |

Values are presented as number (%) or mean $\pm$ standard deviation.

were managed conservatively, while 112 (67.1%) were managed surgically. Out of 112 participants, 83 were operated on inside the Institute, while 29 were outside.

A total of 38 of the participants (22.7%) suffered various associated injuries. In total, musculoskeletal injuries (single/multiple bone fractures or dislocations at different sites) are more common (9.0%), followed by chest injuries (6.5%) (rib fracture, pneumothorax, and haemothorax). A total of 19 participants (11.4%) had multiple vertebrae fractures, while the rest (89.2%) had single vertebrae fractures. Cervical (C1–C7), thoracic (T1–T10), thoracolumbar (T11–L1), and lumbar (below L1) regions accounted for 28.2%, 24.5%, 32.3%, and 3.5% of vertebral injuries, respectively, in single vertebrae. Thoracic vertebrae (41.3%) were the most commonly affected in this study, followed by cervical vertebrae (30.5%).

In this study, NLI distribution was like upper cervical (C1–C4) (10.8%), lower cervical (C5–C7) (21.0%), upper thoracic (T1–T6) (11.3%), lower thoracic (T7–T12) (40.1%) and lumbar (L1–L5) (19.1%). Complete paralysis (AIS-A) was found in 85 individuals (50.9%), incomplete sensory (AIS-B) in 22 individuals (13.2%), and incomplete motor (AIS-C) in 36 (21.5%). The average length of stay in the hospital was  $14.6 \pm 14.6$  days, with stays ranging from 1 day to 125 days. In the first week of admission, 47 individuals (28.1%) were discharged, while 67 people (40.1%) were discharged in the second week. Length of stay was more for higher levels (above T6 level) ( $16.2 \pm 18.6$  days) in comparison to the lower level (below T6 level) ( $13.3 \pm 9.7$  days). A total of 6 people with TSCI (3.5%) reported death, all belonging above the T6 level (Table 2).

## DISCUSSION

TSCI is one of the most debilitating disabilities that affect people with TSCI and their families and is a social and economic burden on society. Families in developing countries must face hospitalisation costs and continued treatment due to a lack of socialized medicine and structured medical insurance policies. As a result, determining modifiable factors using precise epidemiological features will undoubtedly aid in formulating prevention initiatives.

In our study, the average age of the afflicted was  $33.5 \pm 13.3$  years, aligning with the mean age observed in various South Asian and Middle Eastern countries: India (34.4 years), Pakistan (33.3 years), Nepal (21–30 years), Saudi Arabia (29.5 years), and Iran (29.1 years) [9,14–16]. In contrast, Western studies show a

trend of increasing age over time. For instance, the United State saw the average age at injury rise from 29 years in the 1970s to 43 years post-2015. Similarly, New Zealand's median age of injury increased from 43 to 48 years, and Denmark's shifted from 29.0 to 47.5 years. Notably, Italy and Iceland present average ages of 59.2 and 39 years, respectively [5–7,17,18].

The male-to-female ratio in this study was 2.4:1, which was quite similar to the distribution in other countries like Spain and Austria [19,20] but lower than the worldwide (3.8:1) [21] and other Indian studies [11,22]. This finding suggests that young males are more prone to TSCI than females. A possible explanation is that in most families, males are the primary earning members of the family and hence get exposed to greater risk for falls and RTAs. On the other hand, women were primarily involved in low-risk home jobs and outdoor areas [23].

Most participants in our study were married at the time of injury, compared to individuals in studies from the United States (30.6%) [24]. This could be because Indians marry at a younger age. Most of the participants in this study fall into the category of low education and working as manual labour in farming and other dangerous vocations, making them more vulnerable to TSCI. Those with a higher level of education were less likely to be involved in TSCI accidents.

In Hilly-rural areas, housewives, students, and unemployed people are more frequently involved in TSCI. It is possible because they mostly engage in domestic work like fetching household goods and water, collecting wood from forests, and climbing trees, and hilly geography makes them prone to incidents like falling from height.

Our study's overall rural versus urban background ratio was approximately 4:1 against the proportion of 3:1 for the Indian population [25]. It might be due to the hospital's location in the foothills of the Himalayas in Northern India. The center primarily serves the rural population as it is the only specialized referral center in this region. This tertiary center caters to a large population, including people from Uttarakhand, Western Uttar Pradesh districts, and neighbouring Himachal Pradesh. In the present study, 31.1% of participants were employed at the time of injury compared to the Indian population (48.24%) [26]. It is possible that folks with a lower socioeconomic position would have travelled long distances to get treatment at our Institute.

Falls were a more common cause of TSCI than RTAs in this study. In contrast to affluent countries where RTAs were the most common cause, Falls were the most common mode of

**Table 2.** Epidemiological variables

| Mode of injury   | Overall, falls: 99 (59.3%), RTAs: 60 (35.9%), Others: 8 (4.8%) |                                    |                                  |                                    |
|--|--|------------------------------------|----------------------------------|------------------------------------|
|  | Plains-urban (n=21)  | Plains-rural (n=62)                | Hilly-urban (n=12)               | Hilly-rural (n=72)                 |
|  | RTAs: 12<br>Falls: 8<br>Others: 1                              | RTAs: 23<br>Falls: 36<br>Others: 3 | RTAs: 4<br>Falls: 8<br>Others: 0 | RTAs: 21<br>Falls: 47<br>Others: 4 |
| Post-injury duration of arrival at the Institute (day) | ≤1   |                                    |                                  | 35 (20.9)                          |
|  | 1–2  |                                    |                                  | 45 (26.9)                          |
|  | 3–7  |                                    |                                  | 31 (18.6)                          |
|  | 8–30   |                                    |                                  | 19 (11.4)                          |
|  | >30  |                                    |                                  | 37 (22.2)                          |
| Mode of transport                                      | Ambulance  |                                    |                                  | 128 (76.6)                         |
|  | Car  |                                    |                                  | 38 (22.8)                          |
|  | Bike   |                                    |                                  | 1 (0.6)                            |
| Position of the patient during the transfer            | Supine   |                                    |                                  | 165 (98.8)                         |
|  | Sitting  |                                    |                                  | 2 (1.2)                            |
| Previous hospitalization                               | Yes  |                                    |                                  | 143 (85.6)                         |
|  | No   |                                    |                                  | 24 (14.4)                          |
| Initial management                                     | Conservative   |                                    |                                  | 55 (32.9)                          |
|  | Surgical   |                                    |                                  | 112 (67.1)                         |
| Associated injury                                      | No associated injury   |                                    |                                  | 129 (77.2)                         |
|  | Head trauma  |                                    |                                  | 4 (2.4)                            |
|  | Short bone fracture  |                                    |                                  | 7 (4.2)                            |
|  | Long bone fracture   |                                    |                                  | 4 (2.4)                            |
|  | Multiple bone fracture   |                                    |                                  | 4 (2.4)                            |
|  | Multiple rib fracture  |                                    |                                  | 4 (2.4)                            |
|  | Pneumothorax   |                                    |                                  | 4 (2.4)                            |
|  | Haemothorax  |                                    |                                  | 3 (1.8)                            |
|  | Abdominal injury   |                                    |                                  | 1 (0.6)                            |
|  | Multiple injuries  |                                    |                                  | 7 (4.2)                            |
| Vertebral levels                                       | Cervical   |                                    |                                  | 47 (28.2)                          |
|  | Thoracic   |                                    |                                  | 71 (42.5)                          |
|  | Lumbar   |                                    |                                  | 30 (17.9)                          |
|  | Multiple vertebrae   |                                    |                                  | 19 (11.4)                          |
| Neurological level of injury                           | C4   |                                    |                                  | 18 (10.7)                          |
|  | C5   |                                    |                                  | 9 (5.4)                            |
|  | C6   |                                    |                                  | 12 (7.2)                           |
|  | C7   |                                    |                                  | 14 (8.4)                           |
|  | T3   |                                    |                                  | 7 (4.2)                            |
|  | T4   |                                    |                                  | 1 (0.6)                            |
|  | T5   |                                    |                                  | 11 (6.6)                           |
|  | T6   |                                    |                                  | 6 (3.6)                            |
|  | T7   |                                    |                                  | 7 (4.2)                            |
|  | T8   |                                    |                                  | 2 (1.2)                            |
|  | T10  |                                    |                                  | 14 (8.4)                           |
|  | T11  |                                    |                                  | 12 (7.2)                           |
|  | T12  |                                    |                                  | 22 (13.1)                          |
|  | L1   |                                    |                                  | 23 (13.7)                          |
|  | L2   |                                    |                                  | 6 (3.6)                            |
|  | L3   |                                    |                                  | 2 (1.2)                            |
|  | L4   |                                    |                                  | 1 (0.6)                            |

(Continued to the next page)

**Table 2.** Continued

|                               |                           |           |
|-------------------------------|---------------------------|-----------|
| ASIA Impairment Scale (AIS)   | A                         | 85 (50.9) |
|                               | B                         | 22 (13.2) |
|                               | C                         | 36 (21.5) |
|                               | D                         | 24 (14.4) |
| Length of hospital stay (day) | Overall 14.6±14.6 (1–125) |           |
|                               | ≤7                        | 47 (28.2) |
|                               | 8–14                      | 67 (40.1) |
|                               | 15–30                     | 43 (25.7) |
|                               | >30                       | 10 (5.9)  |

Values are presented as number (%) or mean±standard deviation (range). RTAs, road traffic accidents; ASIA, American Spinal Injury Association.

injury in most Indians [22,27,28] and southern Asian research [29,30]. More specifically, Falls were widespread in urban and rural parts of the hilly region. This finding correlates with a study in the hilly areas of the North-East part of India and Nepal [10,31]. Urban areas have more RTAs in the plains, while falls are common in rural areas. It suggests that because of better road conditions and highways, metropolitan areas are more involved in RTAs. Poor road infrastructure and poor driving conditions in rural areas, on the other hand, limit the RTAs.

Post-injury duration of arrival at a tertiary care facility is crucial. Clinical evidence favours a 24-hour threshold in defining early surgical decompression. A significantly greater proportion of patients who underwent early surgery (19.8%) demonstrated a 2-or-more grade improvement in AIS at six months compared with those who underwent late surgical intervention (8.8%) [32]. About 52% of participants in our study were admitted after 48 hours of injury. Most of them were initially managed at the primary care center and then referred to a higher center. The reason could be a lack of transport logistics from the field, access to a tertiary care center, or polytrauma.

Most of the individuals were transported in the supine position after the injury. For suspected TSCI cases, immobilisation during hospital transit is a significant concern. To minimise subsequent neurological injuries during transportation, supine placement, a board, a collar, and head immobilisation with towels or foam wedges have been proposed [23,33,34]. Primary healthcare providers in hilly locations should be trained in the initial management of SCI and the early and safe transfer of affected persons to a specialized center.

The thoracic spine is injured in most of the participants in the present study, while combined T12 and L1 have the highest proportion. In a systematic review by Golestani et al. [35], out of 37 studies, in 22 studies, most injuries occurred at the cer-

vical level, while in 12 studies, the thoracic level was the most prevalent level of injury, and only in 3 studies, the lumbosacral level had the highest injury frequency. Because of anatomical considerations, the thoracolumbar junction is the most usual location. The rib cage, the most movable part of the spine, makes the dorsal spine less mobile than the lumbar spine. The thoracolumbar area is vulnerable to injury as it transitions from a fixed to a mobile component [27].

Prevention is the key to reducing the burden of TSCI. Some preventive strategies are building adequate height bannisters on the roof, railing with hand support near stairs, preventing unnecessary tree climbing, utilising rough tiles for bathroom floors, building good road infrastructure with proper barricading, enforcing speed limits on city roads, and raising awareness of traffic rules. Integrating specialized rehabilitation services for people with TSCI can aid their recovery, improve their quality of life, and increase their contribution to society.

There are some limitations in the generalizability of the findings to the broader Indian TSCI population because our sampling method was only based on one hospital record from Northern India. Also, excluding 6 individuals who passed away before reaching the hospital might lead to underestimating the severity in some instances.

In conclusion, to summarise, the demographic and epidemiological data of TSCI in India differ from those in developed countries, with Falls rather than RTAs being the leading cause. Most people belong to younger age groups and have a complete injury, with the thoracolumbar spine being the most affected. In terms of future research, a multicentric longitudinal study with a larger number of TSCI patients is required to evaluate the long-term impact of the injury on functional status, community integration, and quality of life indicators. Other information, such as the financial impact of the injury and caregiver



stress, may also be provided. With the number of TSCI patients expected to rise in the years ahead, establishing a national database would be beneficial for developing preventive and rehabilitative measures.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Neyaz O. Methodology: Neyaz O. Formal analysis: Neyaz O, Kanaujia V, Yadav RK. Project administration: Azam MQ, Kandwal P. Visualization: Neyaz O, Kanaujia V, Writing – original draft: Neyaz O, Kanaujia V, Sarkar B. Writing – review and editing: Neyaz O, Kanaujia V, Yadav RK. Approval of final manuscript: all authors.

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# Impact of COVID-19 Pandemic on People With Locomotor Disability in North India: A Cross-Sectional Analysis

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**Objective:** To assess, analyse, and infer the impact of the coronavirus disease 2019 (COVID-19) pandemic on people living with locomotor disability in North India.

**Methods:** Patients with locomotor disabilities who met the inclusion criteria received a questionnaire that had already undergone testing and validation. It covered topics highlighting the effect of the pandemic on general health, financial burden, psychological and mental health, social life and behaviour, disability and comorbidity management, transportation, and healthcare accessibility during the pandemic. In order to gauge the pandemic's effects on the population of people with locomotor disabilities, the answers to the questions were collected and analyzed.

**Results:** The COVID-19 pandemic has adversely affected people living with locomotor disability, ranging from loss of wages and financial crisis to anxiety, depression and lack of sleep. People with disabilities had limited reach to health and community services that were vital for them, including basic life and functional needs, besides risks of mistreatment and other psychological consequences.

**Conclusion:** This analysis suggests that the root cause of pandemic disparities is the lack of disability-inclusive planning and, more significantly, the pre-existing socioeconomic disparities and challenges that disabled people have been experiencing for a long time. We suggest that unambiguous public health and policy responses should be incorporated, and health, social participation, and socioeconomic disparity causes for disabled people should be addressed in tandem.

**Keywords:** COVID-19, Disabled persons, Rehabilitation, Quality of life

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## INTRODUCTION

In March 2020, the World Health Organization (WHO) declared the outbreak of a novel coronavirus disease, coronavirus disease 2019 (COVID-19), to be a pandemic. More than 200 countries

across the world have been affected in due course. According to the WHO, the definition of “disability” is quoted as, “Disability is an umbrella term, covering impairments, activity limitations, and participation restrictions. An impairment is a problem in body function or structure; an activity limitation is a difficulty

encountered by an individual in executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations” [1]. As per WHO, around 16% of the total population, that is, 1.3 billion people, are currently living with a disability [2]. Specifically, around 80% of these can be traced to middle to low-income countries [3]. While the pandemic has affected people globally, disrupting routine healthcare services, it has disproportionately affected specific populations, like patients who have terminal illnesses, victims of trauma, emergency medical and surgical care services and those with disabilities [4]. Persons with disability (PWD), in particular, those living in developing nations like India, were more at risk of the deleterious impact of the COVID-19 pandemic as these countries have limited resources to counteract the effect of the pandemic [5]. According to a WHO survey, more than half of PWDs are not able to meet the expense of health services as compared to those without disability [6]. This gap further widened during the COVID-19 pandemic as the world tried newer models of patient treatments, such as using a digital platform and telemedicine as alternatives to conventional models.

The promoted methods to contain the spread of COVID-19, like social distancing, self-isolation, repeated washing of hands, and sanitization practices, were not effortless for PWDs. Besides, it has been seen that PWDs are more likely to be living with comorbidities like cardiac and diabetes, making them vulnerable to coronavirus [7]. They also suffer from the fear of economic instability, social insecurity, and social isolation, which could worsen the physical and psychological well-being of PWDs.

In this paper, we have collected and analyzed data through in-depth telephonic interviews and self-administered questionnaires related to the effect of the pandemic on different aspects of life in PWD during the pandemic. The study also demonstrates some of the coping mechanisms used by PWDs during the pandemic, highlighting both issue and intervention opportunities for those participating in the pandemic response. The present study aimed to assess, analyse and infer the impact of the COVID-19 pandemic on PWDs.

## METHODS

The present study was a prospective cross-sectional observational design. This multicentric study was conducted at two Level III COVID-19 health care centres in North India from

January 2021 to July 2022. Patients who satisfied the inclusion criteria and agreed to participate in the study after giving verbal consent were included. Due clearance was obtained from the Ethical committees of the SGPGI Ethic Cell and VMMC Ethic Cell (IEC code: 2021-72-IP-EXP-36 and IEC-6/2020). Patients were contacted on their telephone and explained about the study and took consent. Later, they were sent the questions in Google form on WhatsApp (Meta Platforms, Inc.), and their responses were noted. Those who were unable to fill out the Google form were interviewed telephonically. The responses were analyzed to measure the impact of the pandemic on all the above-given parameters, including socioeconomic and demographic parameters.

### Study population

PWDs already enrolled and under treatment at the two study centres were contacted for participation in the study. Those aged between 18 and 65 years and with any type of locomotor disability, including long-term neurological conditions, multiple disabilities, and leprosy, were included in the study. PWDs with low intellect, inability to read or hear, unwillingness to participate in the study, and inability to comprehend Hindi and English were excluded.

### Questionnaire designing

Together with a team of four physiatrists, a psychiatrist and a statistician, a questionnaire was created that addressed several topics, including how the pandemic affected people's general health, financial burden, psychological and mental health, social life and behaviour, managing their disability and comorbidities, and accessibility to transportation and medical care. These experts were asked to grade the overall questionnaires on a 5-point scale of relevance, clarity, simplicity and free of ambiguity. The obtained responses were entered into Microsoft Excel (Microsoft Corp.), and the statistical measures for the external validation of the questionnaire were calculated. From the obtained responses (scores between 1 to 5, where a higher score indicates the goodness of the questionnaires), it was seen that relevance was 93.3%, clarity was 96.7%, and simplicity was 90%, whereas free of ambiguity was 86.7%. The overall agreement among the experts was 91.7%. The questionnaire is added as a [Supplementary Material](#) in the end.

Further, the same questionnaires were used for pilot testing on 20 patients at one of the two study centres. The collected data were entered in Microsoft Excel and analyzed. Based on

the pilot data, Cronbach's alpha, a measure of internal consistency, also called a measure of scale reliability, was calculated. Cronbach alpha was 82.5%, which showed good reliability or internal consistency among the scales.

### Sample size estimation

This was an exploratory study, and the prevalence of the disabled population affected by the COVID-19 pandemic was unknown. To get the maximum sample size, we assumed that the pandemic impacted at least 50% of people with disabilities. At a minimum, with a two-sided 95% confidence interval and 15% as a relative error in the assumed prevalence, the sample size was calculated to be 178. The sample size was estimated using PASS 16 (NCSS).

### Statistical analysis

Questionnaire responses related to impacts were converted into ordinal scales. Categorical variables were expressed as percentages. Continuous variables were expressed as mean±standard deviation. The association of the impact of COVID-19 on domestic violence was evaluated before and during the COVID-19 pandemic using the McNemar test. Data was analyzed using IBM SPSS Statistics 23 (IBM Corp.).

## RESULTS

A total of 450 PWDs under follow-up at 2 study centres were contacted telephonically during the study period. All were delivered validated electronic questionnaires in Google forms through social messaging platforms. Initially, 186 PWDs submitted complete and required details. Another 14 willing PWDs were interviewed telephonically. Therefore, we had 200 PWDs, all with locomotor disabilities, with equal numbers from both the study centres. Most of the patients were young males and belonged to the age group 17–30 years (42.5%). Around 84% of the study population was literate (Table 1). It was alarming to note that approximately 65.5% of the study population was unemployed and entirely financially dependent on others, whereas 8% of the PWDs claimed to be partially dependent on others to meet their financial needs.

Furthermore, this highlights the fact that despite being literate, a significant portion of the population of people with disabilities was unemployed. The mean duration of disability was  $8.64 \pm 10.21$  years. The mean disability percentage calculated according to the Government of India gazette was  $58.13 \pm 14.53$ .

### COVID appropriate behaviour

All patients said they were aware of the current pandemic and could access the information regarding prevention and precautions advised to prevent COVID-19 infection through digital and print media. Around 36.0% faced difficulty wearing a mask, 12.0% faced difficulty in regular hand washing, and 34.0% faced difficulty accessing a hand sanitiser (Table 2). Maintaining social distancing took much work for 44.0% of respondents.

### Financial stress during pandemic

Forty percent of the patients agreed that the pandemic had increased their dependency on others. Around 73% of employed respondents said they faced decreased wages during the pandemic. Consequently, around 37% of the patients struggled to get a balanced and nutritious diet during the same period. However, 27.5% of the disabled population reported an increase

**Table 1.** Socio-demographic profile of the study subjects

|                        | Value (n=200) |
|------------------------|---------------|
| Age (yr)               |               |
| 17–30                  | 85 (42.5)     |
| 31–40                  | 33 (16.5)     |
| 41–50                  | 46 (23.0)     |
| 51–60                  | 27 (13.5)     |
| 61–70                  | 9 (4.5)       |
| Sex                    |               |
| Female                 | 64 (32.0)     |
| Male                   | 136 (68.0)    |
| Literacy status        |               |
| Illiterate             | 32 (16.0)     |
| High school            | 87 (43.5)     |
| Senior secondary       | 46 (23.0)     |
| Graduate               | 23 (11.5)     |
| Post-graduate or above | 12 (6.0)      |
| Occupation             |               |
| Unemployed             | 131 (65.5)    |
| Self-earning           | 17 (8.5)      |
| Housewife              | 3 (1.5)       |
| Job                    | 49 (24.5)     |

Values are presented as number (%).

**Table 2.** Distribution of study subjects according to their ability to practice appropriate behaviour related to COVID-19 (n=200)

| COVID appropriate behaviour follow | Yes        | No        |
|------------------------------------|------------|-----------|
| Wear a mask                        | 128 (64.0) | 72 (36.0) |
| Wash hands                         | 176 (88.0) | 24 (12.0) |
| Use sanitiser                      | 132 (66.0) | 68 (34.0) |
| Social distancing                  | 112 (56.0) | 88 (44.0) |

Values are presented as number (%).

COVID-19, coronavirus disease 2019.



in weight during this period, and 18% had a decrease in weight. 28% of the population felt a worsening in the general health conditions during the pandemic compared to before.

### Psychological and social issues during pandemic

During the period, 43% of the PWD felt anxious, while before the pandemic, only 21% had any form of anxiety in their daily life. Approximately 59.5% of the PWD felt more isolated as compared to before. Around 55% of the study group felt depressed, and 40% faced difficulty in sleeping during the pandemic. Nearly 44% of respondents said they had decreased interest in leisure activities. Around 27.5% of the respondents had faced domestic violence in some form during the pandemic, whereas before it was faced by 11.5% of the respondents (Table 3).

### Public transport, health care service and telemedicine accessibility

A total of 58% of the respondents had difficulty accessing public transport. Nearly 32% felt that the pandemic had worsened their comorbidities, 22% felt it was more costly to get treatment, and 39% found it challenging to manage their comorbidities. Overall, 28% felt worsening general health conditions compared to pre-COVID levels. Although many hospitals, including centres of the study, had started facilities for telemedicine, including tele-rehabilitation, during the pandemic, only 24.5% were aware of it. Of those who availed of the facility, 95.9% were satisfied with the system, 81.6% preferred tele-rehabilitation over conventional treatment, and felt it was cheap. Two percent of patients faced difficulty accessing tele-rehabilitation (Table 4).

## DISCUSSION

The 2011 Census shows 26.8 million PWD live in India [7]. They comprise one of the largest marginalised groups in India. India's population of PWD has marginally increased over the past ten years, going from 21.9 million in 2001 to 26.8 million [8].

Through the establishment of secure lockdown and social segregation measures, some of which are still in effect today, the

epidemic altered the social landscape around the world. People with disabilities were at a higher risk of suffering from the pandemic due to both direct health effects and consequences of the pandemic response [9]. Factors associated with disability, like older age, underlying comorbidities, poverty and rural living, made this group more vulnerable to adverse health outcomes [10]. Furthermore, the pandemic hurt people with disabilities who needed personal care assistance with daily activities or routine medical treatment, especially for diseases and needs that approaches could not successfully treat like telemedicine [11,12].

Data from 200 PWD, primarily young males, revealed that 65.5% were unemployed, and 73% were financially dependent on their caregivers. Therefore, if earning family members lost their jobs or could not go to work, it adversely affected the dependent members of the family. This made them more vulnerable to the financial crisis during the pandemic time. Around 40% of respondents felt that the pandemic had increased their dependency on others.

The results from a previous work suggest that working-age PWDs were particularly affected financially by the lockdown

**Table 4.** Tele-rehabilitation responses from the study population

|  | Yes       | No         |
|--|-----------|------------|
| Awareness of tele-rehabilitation services (n=200)                            | 49 (24.5) | 151 (75.5) |
| Satisfaction with the management offered (n=49)                              | 47 (95.9) | 2 (4.1)    |
| Value (n=49)   |           |            |
| Preference for tele-rehabilitation or conventional rehabilitation            |           |            |
| Tele-rehabilitation is more convenient                                       | 40 (81.6) |            |
| Conventional rehabilitation is more convenient                               | 9 (18.4)  |            |
| Difficulties encountered while accessing tele-rehabilitation services        |           |            |
| No issues  | 47 (96.0) |            |
| Lack of device   | 1 (2.0)   |            |
| Unable to understand   | 1 (2.0)   |            |
| Cost preference for tele-rehabilitation services over conventional treatment |           |            |
| Yes  | 45 (91.8) |            |
| No   | 2 (4.1)   |            |
| Both are same  | 2 (4.1)   |            |

Values are presented as number (%).

**Table 3.** Frequency of domestic violence during and before the pandemic (n=200)

| Frequency    | Domestic violence during the pandemic | Domestic violence before the pandemic | p-value |
|--------------|---------------------------------------|---------------------------------------|---------|
| Never        | 145 (72.5)                            | 177 (88.5)                            | <0.001  |
| Sometimes    | 28 (14.0)                             | 17 (8.5)                              | 0.082   |
| Fairly often | 27 (13.5)                             | 6 (3.0)                               | <0.001  |

Values are presented as number (%).

Mcneemar test: p<0.0001.

[13]. According to another study, people with disabilities were disproportionately impacted by lockdown-related efforts to contain the COVID-19 pandemic in terms of their socioeconomic status, health, educational opportunities, social support, and engagement in society [14]. Disabled people often have a small social circle, became more socially isolated due to the pandemic, and found it challenging to access crucial communications during emergencies, such as those relating to transport and public health [14]. Our study also inferred similar results concerning social isolation and means of transportation.

According to results from an additional study, the pandemic made it difficult for PWDs to get transport and other essential goods and services [15]. Fifty-eight percent of the respondents said that using public transport during the pandemic was difficult due to social distancing behaviour. As a result, it became challenging to obtain healthcare services. According to one study, individuals with disabilities face more difficulties and concerns during the COVID-19 pandemic, increasing their risk of experiencing stress and trauma from the disease itself as well as the pandemic's social repercussions [7]. Due to the pandemic, many persons with impairments lost their occupations, which left them in financial hardships. Since small businesses and non-profit organisations were mainly closed during the lockdown, their employees with disabilities lost their jobs [16]. People with disabilities in lower-middle-income countries frequently labour in the informal sector, particularly women, and suffer food insecurity as well as the lack of sick leave and unemployment benefits [17]. In developing countries like ours, a large proportion of people with disabilities live in single-income households; therefore, COVID-related unemployment provides economic hardship. In our study, around 73% of employed respondents said they faced decreased wages during the pandemic. It was primarily due to job loss, job change, decreased work and demand for their service. This added to their financial burden. Consequently, around 37% of the patients struggled to get a balanced and nutritious diet during the same period.

Anxiety, melancholy, malnutrition, dementia, and cognitive decline are all established risk factors for health-related effects and have been linked to social isolation and loneliness in older persons [18,19]. Disruptions to routines, activities, and support networks and loss of financial support can have various psychological effects on people with disabilities, making them particularly vulnerable to these effects. In addition, there is perpetual stress and worry due to the worry of contracting COVID-19 infection or from a general ignorance about the pandemic

and its restrictions. The pandemic led to social isolation and a depressed environment. People lost their loved ones and saw sickness all around. Forty-three percent felt anxious during this period, and 59.5% felt more isolated than before. Nearly 44% said they had decreased interest in doing leisure activities, 55% of the study population felt depressed, and around 40% faced difficulty sleeping. A study demonstrated how increases in anxiety, stress, and despair are associated with financial hardship brought on by COVID-19 and increased social isolation as a result of observing protective measures, highlighting mental health struggles among people with disabilities and chronic health conditions [20]. Studies have shown that isolation can cause disabled people to become anxious, angry, stressed, and agitated [21], and consequent increased risk for suicidal behaviours [22]. During the pandemic, it was also found that there was an increase in stress and burden of care for family members and caregivers. We also found a 16% increase in the incidence of domestic violence against PWD during the pandemic. A survey-based study found that 86.3% of respondents had reservations about the COVID-19 pandemic's impact on their lives and that 44% of participants claimed the COVID-19 pandemic had presented them with new health concerns [12].

Additionally, in another online survey on how the pandemic was affecting the lives of people with disabilities, three-quarters of respondents said that the pandemic had negatively impacted their health in some way, with problems like limited access to healthcare facilities and secondary deterioration in comorbidities [23]. In addition to obstructing access to treatment for acute and chronic medical conditions, it was found in a study that the pandemic also disrupted the approach to preventative health care and screenings, such as cancer screenings, theoretically leading to later cancer diagnosis and increased mortality [24]. Additionally, disabled people also earned lower wages and had to face financial crises during the pandemic. In India, those without proper documentation, including refugees and migrants with disabilities, have more difficulty gaining healthcare owing to lockdown restrictions [25]. Our study found that 28% of the respondents complained of a worse general health condition than before.

Unfortunately, it was often seen that many people with disabilities had certain primary or secondary health conditions, such as cardiovascular disease and pulmonary disease. In our study, around 39% found it challenging to manage comorbidities during this period, and 32% felt it was more costly to get treated for their existing comorbidities. They experienced

chronic stress and moderated access to resources during the pandemic. For example, for people with lower socioeconomic standing, meal delivery services were not easily accessible or affordable, and the congested living circumstances that are a fact of life in many low-income housing complexes made social isolation even more challenging [26].

During the pandemic, many essential healthcare services for individuals with disabilities, such as outpatient care, daycare, and some in-patient services, were either shut down or maintained at a reduced capacity as a result of the lockdown. Due to a lack of transportation during lockdowns, people with disabilities had limited access to in-person healthcare treatments [27,28]. This reduction in physical inactivity leads to deconditioning and new disability risks and exacerbates existing ones [16,29]. In our study, 27.5% had found an increase in weight due to less physical activity. Besides, 18.5% had an overall reduction in weight, which could be attributed to financial stress and lack of nutritious diet by 15% of the study group.

Disabled people are frequently excluded from discussions concerning social policy, especially issues regarding disability [30]. This becomes more important during difficult times like a pandemic when the marginalised and vulnerable populations are, more often than not, disregarded and given less priority. Therefore, it is not surprising that the disabled community has experienced intense worries and concerns as a result of this pandemic.

To the best of our knowledge, this is the first study conducted in India that uses a validated questionnaire created by subject-matter experts to highlight the impact of a pandemic on people with disabilities. The study includes a sizable sample size from two distinct northern Indian regions. The study's findings will aid in improving plans for PWD in the event of a pandemic of this size in the future. The study draws attention to some PWD-related issues that were previously overlooked, such as financial strain during pandemics, domestic abuse, and accessibility to healthcare services. However, our sample population does not represent the country as a whole. We could not evaluate issues unique to PWDs from rural backgrounds since we could not include them. Furthermore, persons with disabilities other than locomotor disabilities have not been included. Future reviews must take into account and evaluate the impacts faced by individuals with other forms of disabilities, too, given that they are a population that is particularly susceptible to adverse consequences amidst this crisis.

In conclusion, the study examined a wide variety of inter-

connected socioeconomic and health inequities that affected people with disabilities for three years during the COVID-19 pandemic in India. People with disabilities had limited access to health and community services that were necessary for them, including addressing basic functional and life needs in addition to the dangers of maltreatment and psychological effects. Their families and caregivers also experienced an inconsistent burden and stress. According to this analysis, all of these pandemic disparities result from a lack of disability-inclusive preparedness and responses and, more importantly, from long-standing socioeconomic disparities that affect persons with disabilities. We propose that precise public health and policy interventions are required to prevent or minimise them. These must simultaneously address socioeconomic inequality, social involvement, and health.

## CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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## AUTHOR CONTRIBUTION

Conceptualization: Rai S, Uppal H, Gunjiganvi M. Methodology: Rai S, Uppal H, Gunjiganvi M. Formal analysis: Rai S, Uppal H, Mishra P. Project administration: Rai S, Uppal H, Gunjiganvi M, Joshi N. Writing – original draft: Uppal H, Mishra P, Joshi N. Writing – review and editing: Rai S, Uppal H, Gunjiganvi M. Approval of final manuscript: all authors.

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## SUPPLEMENTARY MATERIALS

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# Instructions for authors

Enacted in May, 2011  
Revised on January 31, 2013  
Revised on August 1, 2018  
Revised on March 11, 2019

Revised on March 16, 2020  
Revised on June 9, 2023  
Revised on January 19, 2024

## 1. AIMS & SCOPE

*Annals of Rehabilitation Medicine* (ARM) is the official journal of the Korean Academy of Rehabilitation Medicine. It is an international, peer-reviewed open access journal, which aims to be a global leader in sharing up-to-date knowledge dedicated to the advancement of care and enhancing the function and quality of life of persons with various disabilities and chronic illnesses. As the official journal of one of the largest societies of rehabilitation medicine in Asia and Oceania, nearly 8,000 physiatrists receive this journal every two months as a member benefit. This journal is endorsed by the International Society of Physical and Rehabilitation Medicine (ISPRM) and the Asia-Oceanian Society of Physical and Rehabilitation Medicine (AOSPRM). International members comprise approximately half the editorial board and conduct peer-review of submitted manuscripts.

The journal encompasses all aspects of physical medicine and rehabilitation, including clinical practice, experimental and applied research, and education. Research areas covered by this journal include rehabilitation of brain disorders and spinal cord injury; electrodiagnosis; musculoskeletal disorders and pain; pediatric, geriatric, cardiopulmonary, sports, cancer, cognitive, and robotic rehabilitation; neuromodulation; neuroimaging; orthotics and prosthetics; physical modalities; clinical trials; quality of life issues; and basic research, as well as other emerging fields in rehabilitation medicine.

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## 3. GENERAL GUIDELINES

The manuscript guidelines for ARM are based on the “Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals” published by the International Committee of Medical Journal Editors (<http://www.icmje.org>), and instructions which are not mentioned in the present guidelines are referred to the guidelines stated in the Recommendations. There are no fees payable to submit in this journal.

### 1) ARTICLE TYPES

Manuscripts include original articles, review articles, brief reports, case reports, images in this issue, and letters to the editor.

#### (1) Original articles

This form of publication represents original research articles reporting the results of basic and clinical investigations that are sufficiently well documented to be acceptable to critical readers.

#### (2) Review articles

The Editorial Board welcomes state-of-the-art review articles. The ARM strongly prefers systematic reviews of the literature. Invited review articles provide a comprehensive review of a subject of importance to clinicians and researchers and are commissioned by the editorial board to an invited expert in the field.

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These manuscripts are short but important reports to provide preliminary communications with less complete data sets than would be appropriate for original contributions that present novel and impactful clinical and basic research of a more preliminary nature.

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#### **(6) Letters to the editor**

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## **2) LANGUAGE OF MANUSCRIPT**

All manuscripts must be written in clearly understandable English. Authors whose first language is not English are requested to have their manuscripts checked for grammatical and linguistic correctness before submission. Correct medical terminology should be used, and jargon should be avoided. Use of abbreviations should be minimized and restricted to those that are generally recognized. When using an abbreviated word, it should be spelled out in full on first usage in the manuscript followed by the abbreviation in parentheses. Numbers should be written in Arabic numerals, but must be spelled out when placed in the beginning of a sentence. Measurements should be reported using the metric system, and hematologic and biochemical markers should be reported in International System (SI) of Units. All units must be preceded by one space except percentage (%), temperature (°C), and degree (°).

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All manuscripts should be written with strict adherence to the research and publication ethics guidelines recommended by Council of Science Editors (<http://www.councilscienceeditors.org/>), International Committee of Medical Journal Editors (ICMJE, <http://www.icmje.org/>), World Association of Medical Editors (WAME, <http://www.wame.org/>), and the Korean Association of Medical

Journal Editors (KAMJE, [https://www.kamje.or.kr/en/main\\_en](https://www.kamje.or.kr/en/main_en)). For all studies involving human subjects, the principles embodied in the Declaration of Helsinki (<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>) should be upheld, informed consent must be obtained from all participants, and must be approved by a recognized Institutional Review Board (IRB) or research ethics committee. The editor may request submission of copies of informed consents from human subjects in clinical studies or IRB approval documents. Experiments involving animals should comply with the NIH guidelines for the use of laboratory animals ([https://www.nlm.nih.gov/services/research\\_report\\_guide.html](https://www.nlm.nih.gov/services/research_report_guide.html)) and/or be reviewed by an appropriate committee (e.g., Institutional Animal Care and Use Committee, IACUC) to ensure the ethical treatment of animals in research. Also, studies with pathogens requiring a high degree of biosafety should pass review of a relevant committee (e.g., Institutional Biosafety Committee, IBC). *ARM* will follow the guidelines by the Committee on Publication Ethics (COPE, <http://publicationethics.org/>) for settlement of any misconduct.

## **1) REDUNDANT PUBLICATION AND PLAGIARISM**

All submitted manuscripts should be original and should not be considered by other scientific journals for publication at the same time. No part of the accepted manuscript should be duplicated in any other scientific journal without the permission of the editorial board. If plagiarism or duplicate publication related to the papers of this journal is detected, the manuscripts may be rejected, the authors will be announced in the journal, and their institutes will be informed. There will also be penalties for the authors.

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*ARM* follows the recommendations by International Committee of Medical Journal Editors (ICMJE, <http://www.icmje.org/>) and the Korean Association of Medical Journal Editors (KAMJE, [https://www.kamje.or.kr/en/main\\_en](https://www.kamje.or.kr/en/main_en)). Authorship is credited to those who have direct involvement in the study and have made significant contributions to (a) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (b) drafting the work or revising it critically for important intellectual content; AND (c) final approval of the version to be published; AND (d) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved as recommended by ICMJE. The primary investigator is designated the first author of the study, unless contested by the other authors. The correspond-

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### 3) CONFLICT OF INTEREST

The corresponding author of an article is asked to inform the editor of the authors’ potential conflicts of interest possibly influencing their interpretation of data. A potential conflict of interest must be disclosed during the online submission process on the appropriate web page. Such conflicts may be financial support or private connections to pharmaceutical companies, political pressure from interest groups, or academic problems based on the “ICMJE Uniform Disclosure Form for Potential Conflicts of Interest” ([http://www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf)). The editor will decide whether the information on the conflict should be included in the published paper. Before publishing such information, the editor will consult with the corresponding author. In particular, all sources of funding for a study should be explicitly stated.

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Clinical trial defined as “any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome” is recommended to be registered to the primary registry to be prior publication. *ARM* recommend, as a condition of consideration for publication, registration in a public trials registry. *ARM* accepts the registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (<http://www.who.int/ictrp/en/>), NIH ClinicalTrials.gov (<http://www.clinicaltrials.gov/>), ISRCTN Resister ([www.isrctn.org](http://www.isrctn.org)), ANZCTR (<https://www.anzctr.org.au/>), EudraCT Database (<https://eudract.ema.europa.eu/>), Clinical Trials Information System (<https://euclinicaltrials.eu/>), University Hospital Medical Information Network ([www.umin.ac.jp/ctr/index/htm](http://www.umin.ac.jp/ctr/index/htm)), EU Clinical Trials Register (<https://www.clinicaltrial-sregister.eu/>) or The Clinical Research Information Service (<http://cris.nih.go.kr/>). The clinical trial registration number will be published at the end of the abstract.

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When the journal faces suspected cases of research and publication misconduct such as redundant (duplicate) publication, plagiarism, fraudulent or fabricated data, changes in authorship, an undisclosed conflict of interest, ethical problems with a submitted manuscript, a reviewer who has appropriated an author’s idea or data, complaints against editors, and so on, the resolution process will follow the flowchart provided by the Committee on Publication Ethics (COPE, <https://publicationethics.org/guidance/Flowcharts>). The discussion and decision on the suspected cases are carried out by the Editorial Board.

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A structured abstract with the headings of Objective, Methods, Results, and Conclusion must succinctly describe the paper in 250 words or less. Use complete sentences and do not number the results. At the end of the abstract, list up to 5 relevant keywords which are in accordance to the Medical Subject Headings (MeSH) in the Index Medicus (<http://www.nlm.nih.gov/mesh>).

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Clearly present the objective of the study and its relationship to earlier work in the field. A brief background to inform the readers of the relevance of the study may be necessary. However, avoid extensive review of the literature.

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Describe the participants or research materials of the study, and explain in detail the inclusion and exclusion criteria for both the experimental and control groups. Describe the experimental methods in a logical and systematic manner so that they can be reproducible by another investigator. Experimental drugs should be stated in the generic name. When proprietary brands are used, include the brand name and the name of the manufacturer in parentheses after the first mention of the generic name. When using experimental devices or other products, state the brand name then follow with the name of the manufacturer, in parentheses, e.g., Flow Cytometer (Coulter Electronic Inc.). To ensure anonymity during the peer review process, the authors' affiliations or institutional setting of the study should not be revealed. Statistical analysis and criteria for determining significance should be described in enough detail to allow the knowledgeable reader with access to the original data to verify the reported results. An ethics statement should be placed here when the studies are performed using clinical samples or data, and animals.

Ensure correct use of the terms sex (when reporting biological factors) and gender (identity, psychosocial or cultural factors), and, unless inappropriate, report the sex and/or gender of study participants, the sex of animals or cells, and describe the methods used to determine sex and gender. If the study was done involving an exclusive population, for example in only one sex, authors should justify why, except in obvious cases (e.g., prostate cancer).

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Summarize and describe logically the significant findings and trends observed in the results using text, figures and tables. Avoid extensive repetition of contents of the tables and figures in the text.

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Interpret the results in respect to the objective of the study, and describe differences with previous studies and significant findings which lead to the deduction of the conclusion. Refrain from excessive review of historic studies, textbook facts, or irrelevant references. Accentuate newly obtained observations from the study, and include significant limitations of the study.

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### (7) Funding information

All sources of funding applicable to the study should be stated here explicitly. All original articles, editorials, reviews, and new technology articles must state funding sources for the study.

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The individual contributions of the authors to the manuscript should be specified in this section.

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Persons who have made contributions to the study, but who are not eligible for authorship can be named in this section. Their contribution must be specified, such as data collection, financial support, statistical analysis, or experimentation. The corresponding author must inform the named contributor of the acknowledgment, and acquire consent before manuscript submission.

### (10) References

- Cite only references which are quoted in the text. Limit the number of references 40.



- When quoting a reference in the text, refrain from stating the author's name, and identify references with Arabic numerals in brackets such as [1], [2-4], and [5,7,9].
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- For more on references, refer to the NLM Style Guide for Authors, Editors, and Publishers (<http://www.nlm.nih.gov/citingmedicine>).

#### *Journals*

1. Jeon JH, Jung YJ, Lee JY, Choi JS, Mun JH, Park WY, et al. The effect of extracorporeal shock wave therapy on myofascial pain syndrome. *Ann Rehabil Med* 2012;36:665-74.
2. Geraud G, Spierings EL, Keywood C. Tolerability and safety of frovatriptan with short- and long-term use for treatment of migraine and in comparison with sumatriptan. *Headache* 2002;42 Suppl:S93-9.

#### *Book & Chapter of book*

3. Frontera W, Silver JK, Rizzo TD. Essentials of physical medicine and rehabilitation. 2nd ed. Saunders; 2008. p. 579-82.
4. Esquenazi A. Upper limb amputee rehabilitation and prosthetic restoration. In: Braddon RL, editor. Physical medicine and rehabilitation. 2nd ed. Saunders; 2000. p. 263-78.

#### *Proceedings of academic conference*

5. Harnden P, Joffe JK, Jones WG. Germ cell tumours V. Proceedings of the 5th Germ Cell Tumour Conference; 2001 Sep 13-15; Leeds, UK. New York: Springer; 2002.

#### *Thesis (Dissertation)*

6. Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant, MI: Central Michigan University; 2002.

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# Checklist for Authors

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- ☐ All elements of the manuscript are printed in English and double-spaced with 1-inch margins at top, bottom, and sides. Right margins are unjustified.
- ☐ All pages are numbered in the following order: title page, structured or standard abstract, body of the text, conflict of interests, Funding information, Author contribution, Acknowledgments (when applicable), references, legends, and tables.
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- ☐ A structured abstract with the headings of Objective, Methods, Results, and Conclusion (A nonstructured abstract for case reports) must succinctly describe the paper.
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