

# Characteristics of exercise and rehabilitation intervention clinical trials registered with Clinical Research Information Service: a review

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Exercise and rehabilitation interventions are essential for health restoration, yet reviews on related clinical trials remain limited despite increasing research interest. This study analyzed the characteristics, designs, sample sizes, and outcome variables of clinical trials registered with the Clinical Research Information Service in South Korea, focusing on exercise and rehabilitation interventions. A systematic search using "exercise" and "rehabilitation" identified 1,089 trials registered up to June 9, 2024, with 470 meeting the inclusion criteria. Most studies (79.79%) were retrospectively registered, and 45.11% were open-label trials. Behavioral interventions (26.60%) and medical devices (22.34%)

were most common, targeting circulatory (27.45%) and musculoskeletal (19.79%) conditions. Frequently assessed outcomes included 'balance,' 'pain,' and 'walking.' A notable increase in trials was observed since 2017. However, the high proportion of retrospective registrations and open-label designs highlights the need for more prospective and blinded trials to enhance research quality.

**Keywords:** Exercise, Rehabilitation, Intervention, Clinical trial, Clinical research

## INTRODUCTION

Exercise refers to physical activities performed regularly for the purpose of improving or maintaining health, such as enhancing muscle strength, improving cardiopulmonary function, and increasing flexibility. It can be performed by a wide range of individuals, from healthy people to athletes seeking to improve performance, those requiring prevention and management of chronic diseases, and the elderly (American College of Sports Medicine et al., 2009; Baskerville et al., 2024; Garber et al., 2011; Kanaley et al., 2022). Rehabilitation, on the other hand, is a broad concept that encompasses various therapeutic interventions aimed at restoring and maintaining bodily functions impaired by illness or injury (Negrini et al., 2022). It is targeted at individuals with physical impairments or disabilities due to accidents or diseases,

patients recovering from surgery, and people experiencing chronic pain (Kwakkel et al., 2023; Mathews and Davin, 2014; Spruit et al., 2013; Tao et al., 2023). The combined concept of exercise and rehabilitation, known as 'exercise rehabilitation,' is synonymous with or closely related to 'exercise therapy.' It involves systematic physical activities and therapeutic interventions to improve various health conditions, such as musculoskeletal, cardiovascular, and neurological disorders, while enhancing activities of daily living. Exercise rehabilitation aims to achieve two goals simultaneously: promoting physical health through exercise and restoring impaired functions through rehabilitation. It seeks to improve overall functional recovery and quality of life through an integrated, multidisciplinary approach. Ensuring the transparency and ethicality of clinical trials is crucial in verifying the effectiveness and safety of exercise rehabilitation.

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The Clinical Research Information Service (CRIS) is a platform that systematically registers and manages clinical trials conducted in South Korea, supporting researchers in conducting and registering clinical studies on various diseases and intervention methods (CRIS, 2024a). The clinical trial data registered with CRIS provide valuable information for understanding the overall status of clinical research conducted in South Korea and for analyzing research trends. Studies reviewing CRIS data across various fields have been reported, with results analyzing specific characteristics in medicine, traditional Korean medicine, and pharmacy. In medicine, a review of CRIS registered studies proposed that CRIS registration should be legally mandated (Choi et al., 2016). In traditional Korean medicine, randomized controlled trial (RCT) studies on Korean medicine interventions, such as acupuncture, herbal medicine, moxibustion, or cupping, investigated the minimum dropout rates (Jeon et al., 2021). In pharmacy, while pediatric clinical trials aimed at establishing the safety and efficacy of drugs in children have been increasing, concerns remain regarding studies conducted without approval from the Ministry of Food and Drug Safety. It has been reported that such issues could be resolved by implementing standardized databases and guidelines (Choi et al., 2017; Huh et al., 2021).

While most previous studies have focused on specific fields when reviewing CRIS data, there is a lack of systematic reviews on clinical trials involving exercise and rehabilitation interventions. Therefore, the purpose of this study was to analyze the key characteristics, study designs, sample sizes, and outcome measurement methods of clinical trials on exercise and rehabilitation interventions registered with CRIS, as well as to identify trends and issues in these studies to suggest future research directions in the field of exercise rehabilitation. Through this, we aimed to provide a comprehensive understanding of the current status of exercise and rehabilitation intervention studies conducted in South Korea and contribute to improving the quality and clinical applicability of future research.

## MATERIALS AND METHODS

### Search strategy for the CRIS database

In this review, clinical trials related to exercise and rehabilitation were systematically searched in the CRIS (cris.nih.go.kr). The search keywords used were “exercise” and “rehabilitation” in both Korean and English, with each keyword searched separately by language. The search results were downloaded as an Excel file for integrated management. The search period was set from the earliest available

date to June 9, 2024. One researcher led the search process.

### Inclusion and exclusion criteria

The inclusion criteria for this review were clinical studies related to exercise and rehabilitation registered in CRIS, specifically focusing on interventional studies. The exclusion criteria were interventional studies where the content was observational in nature or studies where the intervention involved surgery, medication, acupuncture, or dietary therapy instead of exercise and rehabilitation. The selection of studies was conducted independently by two researchers, and any discrepancies were resolved through consultation with a third researcher.

### Data collection

Data were collected for each study, including key information such as bibliographic details, study design, type of intervention, research objectives, target disease group, and outcome variables. The data collection process involved managing structured data using Excel, with consistent criteria applied to organize the information for each item. Data collection was conducted independently by two researchers, and any discrepancies were resolved through consultation with a third researcher.

### Data analysis

The data collected in this review were analyzed to identify the characteristics of the studies through frequencies and proportions. Trends in research by year and the frequency of outcome variables were visualized. Specifically, the frequency of outcome variables was presented using a word cloud generated with the Wordcloud2 package in the R program. During the text preprocessing phase, morphological analysis, noun extraction, and stopword removal were performed to enhance data accuracy. To unify similar words with slight variations in spelling or meaning, a normalization process was conducted after review by the researchers.

## RESULTS

### Study selection process

A total of 1,089 clinical trials were identified by searching CRIS with the keywords “exercise” and “rehabilitation.” Of these, 481 trials were identified as duplicates and subsequently removed, leaving 608 clinical trials. After excluding 67 observational studies and 71 studies unrelated to exercise and rehabilitation, a total of 470 clinical trials were included in this review (Fig. 1).

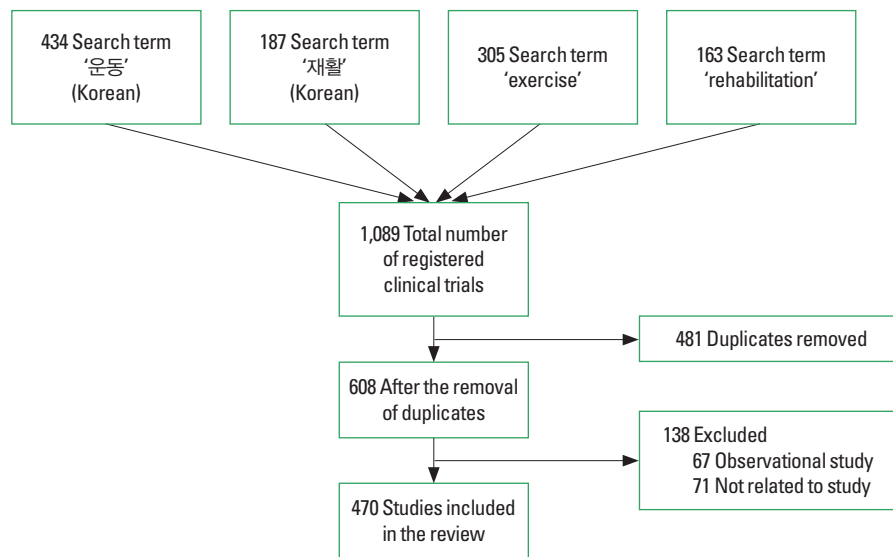


Fig. 1. Flowchart of Clinical Research Information Service search results.

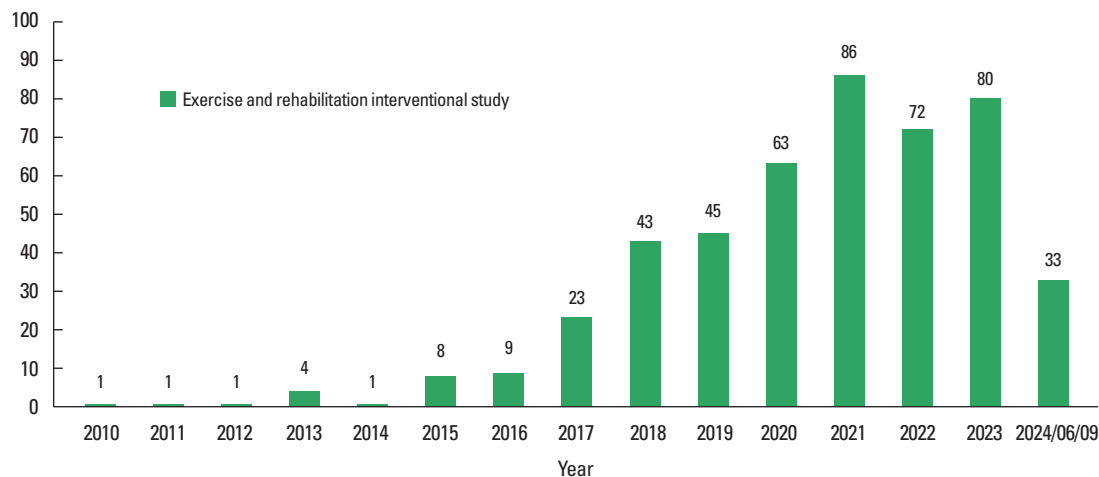


Fig. 2. Annual registration trends.

### Annual trends in clinical trial registrations

The annual registration trends for the 470 studies included in the final review range from 2010 to June 2024 (Fig. 2). From 2010 to 2016, the number of registered studies was low each year, but a sharp increase in registrations was observed after 2017. Notably, the highest number of studies was registered in 2021, followed by 72 and 80 studies registered in 2022 and 2023, respectively. In 2024, a total of 33 studies had been registered by June.

### Characteristics and design of the studies

This review analyzed the characteristics of clinical trials involving exercise and rehabilitation interventions registered in CRIS

(Table 1). The majority of studies were conducted at universities and medical institutions, with only a small proportion conducted at other types of institutions. Most studies were registered as retrospective, with a smaller number registered as prospective studies. Regarding study purposes, treatment-focused studies were the most common, followed by supportive care, prevention, and other purposes. An analysis of disease categories showed that the most frequently studied conditions included diseases of the circulatory system, musculoskeletal system, connective tissue, nervous system, mental and behavioral disorders, and neoplasms. Behavioral interventions were the most commonly used, followed by medical devices, procedures or surgery, and other types of interventions.

Variable	No. (%)
Organization type	
University	254 (54.04)
Medical institute	207 (44.04)
Others	9 (1.92)
Registration	
Retrospective	375 (79.79)
Prospective	95 (20.21)
Study purpose	
Treatment	264 (56.17)
Supportive care	91 (19.36)
Prevention	46 (9.79)
Others	69 (14.68)
Disease category	
Diseases of the circulatory system	129 (27.45)
Diseases of the musculoskeletal system and connective tissue	93 (19.79)
Not applicable	54 (11.49)
Diseases of the nervous system	42 (8.94)
Mental and behavioral disorders	27 (5.74)
Neoplasms	26 (5.53)
Others	99 (21.06)
Intervention type	
Behavioral	125 (26.60)
Medical device	105 (22.34)
Procedure/Surgery	21 (4.47)
Others	219 (46.59)

In terms of intervention models, parallel designs were the most frequently used, followed by single-group designs, factorial designs, and crossover designs (Table 2). Open-label studies were the most common among blinding methods, followed by single-blind and double-blind studies. RCT were the predominant allocation method, while some studies were nonrandomized or did not use randomization. The majority of studies involved two groups, with fewer studies using single-group or three-group designs. Sample sizes varied widely, ranging from 1 to 1,040 participants, with a median of 40 and an average of 56.14 (95% confidence interval, 50.34–61.94).

In the selected studies, the most frequently used outcome variable keyword was 'balance,' appearing 61 times, followed by 'pain' (36 times), 'walking' (31 times), 'muscle strength' (30 times),

Variable	No. (%)
Phase	
Not applicable	433 (92.13)
Phase 3	12 (2.55)
Phase 4	2 (0.43)
Phase 2 or less	23 (4.89)
Intervention model	
Parallel	303 (64.47)
Single group	72 (15.32)
Factorial	55 (11.70)
Crossover	28 (5.96)
Others	12 (2.55)
Blinding	
Open	212 (45.11)
Single	207 (44.04)
Double	51 (10.85)
Allocation	
RCT	384 (81.70)
Not applicable	60 (12.77)
Non-RCT	26 (5.53)
Groups	
1	73 (15.53)
2	326 (69.36)
3	58 (12.34)
Others	13 (2.77)
Target sample size	
Minimum sample size	1
Maximum sample size	1,040
Median sample size	40
Mean sample size (95% CI)	56.14 (50.34–61.94)

'cardiorespiratory' (29 times), 'blood variables' (27 times), 'ROM' (27 times), 'physical condition' (25 times), 'body composition'

(24 times), and 'Fugl-Meyer assessment' (23 times), making up the top 10 keywords (Fig. 3).

## DISCUSSION

This review analyzed the key characteristics and research trends of clinical trials involving exercise and rehabilitation interventions registered in CRIS, confirming a sharp increase in related studies in recent years. The results showed that the majority of clinical trials were registered as retrospective, with a high proportion of open-label studies. This raises potential concerns about the transparency and reliability of the studies. Additionally, the interventions varied, including behavioral interventions and medical devices, and were primarily focused on circulatory and musculoskeletal diseases. In terms of study design, parallel designs were the most commonly used, and many of the studies were small-scale.

In recent years, the sharp increase in the number of registered clinical trials involving exercise and rehabilitation interventions reflects growing research interest in this field. This increase in clinical trial registrations is similar to trends observed in other medical fields (Choi et al., 2016; Choi et al., 2017; Huh et al., 2021; Jeon et al., 2021). The registration of clinical trials offers advantages, such as facilitating the sharing of clinical research information and ensuring ethical standards and transparency (Sim et al., 2006). The International Committee of Medical Journal Editors has also required member journals to mandate clinical trial registration as a condition for considering publication (De Angelis et al., 2004). Therefore, clinical trial registration is necessary from both researchers' and journals' perspectives, and the number of registered clinical trials is expected to continue rising. However, the fact that most studies in this review were registered retrospectively may limit the transparency and reliability of the trials. Retrospective registration, which occurs during or after data collection rather than before, can make the research process easier but may lead to selective reporting of certain data by researchers. Previous studies reviewing clinical trial registrations in various medical fields have also reported that retrospective registration is more common than prospective registration (Birajdar et al., 2019; Haslberger et al., 2023; Showell et al., 2023; Trinquart et al., 2018). To address this issue, the International Society of Physiotherapy Journal Editors has recommended prospective registration for rehabilitation studies, particularly in the field of physical therapy (Babu et al., 2014; Costa et al., 2012). Moving forward, prospective registration should be more widely adopted for exercise and rehabilitation clinical trials in Korea.

The finding that open-label studies constitute a high proportion in this review raises important concerns about the design of exercise and rehabilitation intervention studies. Open-label studies allow both researchers and participants to be aware of the interventions, which can increase the potential for bias and reduce the reliability of the results (Schulz and Grimes, 2002). However, it has been reported that blinding is often not feasible in exercise and rehabilitation intervention studies, and that considering blinding during quality assessments in rehabilitation research is inappropriate (Malmivaara et al., 2020). Another previous study reported that, although no statistically significant difference was found in effect size comparisons and relationship analyses based on the presence or absence of blinding, blinding should still be maintained as a methodological safeguard in trials (Armijo-Olivo et al., 2017; Moustgaard et al., 2020). Even when blinding is difficult or impossible in rehabilitation studies, the risks posed by a lack of blinding are real (Kamper, 2018). Therefore, researchers should make efforts to report attempts at blinding, even if blinding is challenging or impossible, allowing readers to assess and consider the blinding information.

In this review, the majority of exercise and rehabilitation intervention studies selected behavioral interventions and medical device interventions. This is likely due to the wide range of studies conducted across fields such as rehabilitation medicine, physical therapy, and sports science, targeting both healthy individuals and patients, and encompassing various interventions from bodyweight exercises without tools to medical devices or robotic equipment. Nevertheless, a significant number of studies in this review selected "other" as the intervention type, despite their content largely involving exercise-related interventions. This may be due to insufficient explanations provided for behavioral and medical device interventions (CRIS, 2024b). To ensure more accurate data in future studies on exercise and rehabilitation interventions in Korea, detailed descriptions in the "input item guide" will be necessary.

The analysis of outcome variable usage trends in this review revealed that variables such as 'balance,' 'pain,' 'walking,' and 'muscle strength' were frequently used, indicating that exercise and rehabilitation interventions primarily focus on physical function recovery and pain management. In particular, 'balance' is an important indicator used to assess fall prevention and improve functional independence, and it is commonly studied in populations ranging from the elderly to stroke patients. 'Pain' is a crucial variable for individuals with musculoskeletal issues. According to previous studies, United States physical therapists often use pain scales as Patient-Reported Outcome Measures (PROM) and balance assess-



ments as Performance-Based Outcome Measures (PBOM) when evaluating patients after knee and hip arthroplasty (Imada et al., 2017). Similarly, UK physical therapists frequently use pain scales as PROM and range of motion, sensation, and muscle strength assessments as PBOM (Eldin Alreni et al., 2021). Korean physical therapists also tend to use PROM more frequently than PBOM (Lim et al., 2023). Therefore, variables such as 'balance,' 'pain,' 'walking,' and 'muscle strength' are commonly used to evaluate the effectiveness of exercise and rehabilitation interventions. However, an overemphasis on specific variables may lead to the neglect of other important outcomes. Future research should systematically consider a broader range of outcome variables.

This review has several limitations. First, it focused solely on clinical trials registered in CRIS, excluding data from other clinical trial registration platforms (such as ClinicalTrials.gov) and non-registered clinical trials. As this study is based on trials registered within Korea, it may not reflect research trends from other countries or international contexts. Second, the specific academic fields of the included clinical trials were not considered. In Korea, exercise and rehabilitation are researched in various disciplines, such as rehabilitation medicine, physical therapy, and sports science, but this review did not analyze the trials by academic discipline.

This study analyzed the key characteristics and research trends of clinical trials involving exercise and rehabilitation interventions registered in CRIS, highlighting a sharp increase in related studies since 2017 and the use of various intervention methods. However, the high proportion of retrospective registrations and the prevalence of open-label studies indicate limitations in improving the quality of the research. Therefore, expanding prospective studies and increasing the use of single or double-blind designs is necessary. This will strengthen the scientific evidence for exercise and rehabilitation interventions and enhance their clinical applicability.

## CONFLICT OF INTEREST

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

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