

Clinical Trial Nursing Experience with a Knee Rehabilitation Device for Elderly Patients

Cao Lei¹ Sun Bohan¹ Sun Rongjin¹ Zhou Yan²

¹Jiangsu Vocational College of Food and Drug Technology

²Huai'an Fifth People's Hospital

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Abstract: *Objective: To explore the clinical application effect of a new rehabilitation training device for elderly knee joints, and to provide a basis for its promotion and the optimization of elderly knee joint rehabilitation nursing. Methods: Eighty elderly patients with knee joint diseases were selected to conduct a 4-week clinical trial of the new rehabilitation training device, and targeted nursing interventions were implemented. The knee joint function score (HSS) and visual analog scale (VAS) were used to evaluate the patients' knee joint function and pain degree, and the treatment compliance, satisfaction and incidence of adverse events were counted. Results: After the trial, the patients' HSS score (78.5 ± 7.2) was significantly higher than that before the trial (62.3 ± 8.5), and the VAS score (2.3 ± 1.1) was significantly lower than that before the trial (6.8 ± 1.5). The differences were statistically significant ($P < 0.05$). The patients' treatment compliance was 95%, the total satisfaction with the device and nursing work was 97.5%, and the incidence of adverse events was only 2.5% (2 cases of mild knee joint soreness and discomfort, which were relieved after intervention). Conclusion: The new rehabilitation training device for elderly knee joints combined with targeted nursing intervention can effectively improve the patients' knee joint function, relieve pain, and has high safety and patient recognition, which is worthy of clinical promotion.*

Keywords: elderly patients, knee joint diseases, rehabilitation training device, clinical trial, knee joint function, pain relief, nursing intervention

INTRODUCTION

With the acceleration of population aging, the incidence of knee joint diseases among the elderly has been rising year by year. The prevalence of knee osteoarthritis exceeds 50% in individuals over 60 years old and soars to over 70% in those aged 80 and above. Such conditions not only cause symptoms like pain, swelling, and limited mobility, severely impacting patients' daily functioning and quality of life, but also impose a heavy burden on families and society.

Rehabilitation training is a key method for improving knee function in the elderly, and rehabilitation training devices are essential tools for facilitating successful rehabilitation. However, many commercially available devices currently suffer from issues such as complex operation, inadequate safety, and insufficient comfort, making them difficult to adapt to the actual needs of elderly patients. Based on this, our team has developed a novel knee rehabilitation training device for the elderly and conducted clinical trials. During these trials, nursing care played a crucial role.

Therefore, this study aims to summarize and analyze nursing practices during the clinical trial of the new device, clarifying key nursing priorities, methods, and value. On one hand, this provides a reference for the subsequent promotion and application of the device, as well as for optimizing geriatric knee rehabilitation nursing practices. It ensures the smooth implementation of rehabilitation training, enhances patient compliance and rehabilitation outcomes, and reduces adverse events. On the other hand, it offers new practical experience for the field of geriatric rehabilitation nursing, promoting the development of nursing work toward greater professionalism and precision, and further improving the quality of rehabilitation care for elderly patients.

I. Clinical Data and Methods

1. Clinical Data

A total of 80 elderly patients undergoing knee rehabilitation treatment at the Rehabilitation

Medicine Department of Huai'an Fifth People's Hospital from January to June 2025 were enrolled. The cohort comprised 38 males and 42 females; Ages ranged from 60 to 85 years, with a mean age of (72.3 ± 5.6) years. Disease types included 52 cases of knee osteoarthritis and 28 cases of postoperative knee rehabilitation. All patients exhibited varying degrees of knee pain and limited mobility, with knee function scores (HSS) < 80 points.

Inclusion Criteria: (1) Age ≥ 60 years; (2) Diagnosed knee joint disease requiring rehabilitation training; (3) Clear consciousness with ability to cooperate in trial use and care activities; (4) Informed consent obtained from both patient and family members via signed consent form.

Exclusion Criteria: (1) Severe cardiac, hepatic, renal, or other organ dysfunction; (2) Acute knee joint infection, fracture, tumor, or similar conditions; (3) Cognitive impairment or psychiatric disorders preventing cooperation; (4) Allergy to device materials.

METHODS

Rehabilitation Device Description

The geriatric knee rehabilitation device used in this clinical trial comprises a training unit, control system, safety protection system, and comfort support system. The training body enables multidimensional exercises including knee flexion/extension and rotation, with an adjustable angle range of 0° – 120° . Training speed is infinitely adjustable from $0.5^{\circ}/s$ to $3^{\circ}/s$ based on patient condition.

The control system features a high-definition touchscreen for intuitive operation, displaying real-time training parameters (angle, duration, intensity) and automatically recording exercise data. The safety protection system incorporates emergency stop buttons, overload protection, and angle limiters. Training can be immediately halted when patients experience discomfort or device malfunctions, ensuring patient safety. The comfort support system utilizes breathable, soft medical-grade foam material that conforms to the body contours of elderly patients, minimizing discomfort during training.

Nursing Intervention Methods

Pre-use Nursing:

(1) Patient Assessment: Prior to device trial, nursing staff must conduct a comprehensive evaluation of the patient's physical condition, knee joint function, pain level, cognitive abilities, and psychological state. The HSS scoring system is used to assess knee joint function, the Visual Analogue Scale (VAS) to evaluate pain intensity, and communication is employed to understand the patient's cognitive level and awareness of rehabilitation training. Concurrently, attention is paid to the presence of negative emotions such as anxiety or fear.

(2) Health Education: Based on assessment results, nursing staff thoroughly explain the operating principles, structural components, usage methods, training protocols, expected outcomes, and precautions of the novel knee rehabilitation device to patients and their families. Through video demonstrations, live presentations, and informational brochures, patients and families gain a clear understanding of the device's operation, with particular emphasis on its safety and efficacy to alleviate concerns. Simultaneously, the importance of knee rehabilitation training is explained to enhance patient treatment adherence.

(3) Psychological Care: Elderly patients, facing declining physical function and disease burdens, are prone to negative emotions such as anxiety, depression, and low self-esteem, potentially leading to apprehension toward the new rehabilitation device. Nursing staff must proactively engage in communication, patiently listen to patient concerns, and provide psychological support and emotional reassurance. By sharing successful rehabilitation cases, boost patients' confidence in recovery and help them adopt a positive mindset toward trying the rehabilitation device.

(4) Device Preparation: Before patient trials, nursing staff must conduct a comprehensive inspection of the rehabilitation device. This includes checking the device's appearance for integrity, ensuring all components are securely connected, verifying the control system functions normally, confirming the safety protection system is responsive, and ensuring the comfort support system is clean. Simultaneously, adjust the device's seat height, armrest position, and support pad placement according to the patient's body dimensions to ensure the device meets their usage requirements.

During Trial Use

(1) Assisting Patient Positioning: Nursing staff help the patient slowly sit on the device seat, adjust their body posture to align the knee joint with the device's training axis, and ensure even force distribution on the knee joint during training. Secure the patient with the safety belt and adjust the

comfort support system to ensure the patient is in a comfortable and stable position.

(2) Training parameter setup: Based on the patient's assessment results and the physician's orders, the nursing staff collaborates with the rehabilitation therapist to set appropriate training parameters for the patient. These include training angle, training speed, training duration, and training intensity. During initial training, set lower intensity and smaller angles to allow gradual adaptation to the device's training mode. Subsequently, adjust parameters progressively based on the patient's adaptation and rehabilitation progress.

(3) Real-time Monitoring and Guidance: Throughout rehabilitation training, nursing staff must remain present to closely observe vital signs, facial expressions, and limb responses. Inquire about the patient's sensations to assess for pain or discomfort. Simultaneously, guide patients to properly engage with the training, such as maintaining correct breathing techniques and relaxing muscles, to ensure standardized and effective movements. If patients experience worsening pain, dizziness, palpitations, or other adverse symptoms during training, nursing staff must immediately press the emergency stop button to halt the session and promptly notify the physician for intervention.

(4) Documentation and Feedback: Nursing staff shall meticulously record each patient's training duration, angle, speed, intensity, and response, including any discomfort symptoms, their manifestations, and management measures. Following each session, promptly relay this information to the rehabilitation therapist to enable treatment plan adjustments based on the patient's progress.

Post-Training Care

(1) Condition Monitoring: After training, nursing staff assist the patient in slowly disengaging from the device. The patient rests for 15-30 minutes while nursing staff closely observe for knee swelling, increased pain, and stable vital signs. Apply cold compresses if knee swelling occurs. Notify the physician promptly for pain management if pain intensifies.

(2) Rehabilitation Guidance: Based on the patient's training progress, nursing staff develop a personalized home rehabilitation plan. They instruct the patient on simple knee functional exercises, such as straight leg raises and quadriceps contraction training, while explaining precautions for home training, including exercise intensity, duration, and proper form. Additionally, remind the patient to keep the knee warm, avoid overexertion and strenuous activities, and prevent knee injuries.

(3) Dietary and Lifestyle Care: Nursing staff provide dietary guidance, recommending foods rich in protein, calcium, vitamins, and other nutrients—such as milk, eggs, soy products, fresh vegetables, and fruits—to enhance physical condition and promote knee joint recovery. They also instruct patients to maintain healthy habits, ensure adequate sleep, and avoid staying up late to create favorable physical conditions for knee rehabilitation.

(4) Follow-up and Communication: Establish patient follow-up records and conduct regular telephone or outpatient follow-ups to monitor home rehabilitation progress, knee function recovery, and any discomfort. Adjust care plans and home exercise regimens based on follow-up findings to provide ongoing support.

RESULTS

Improvement in Knee Joint Function

Following a 4-week clinical trial and nursing intervention, all 80 patients demonstrated varying degrees of improvement in knee joint function. Prior to the trial, the average HSS score was (62.3 ± 8.5) points; After the trial, the average HSS score was (78.5 ± 7.2) points, showing a significant improvement compared to pre-trial levels with statistically significant differences ($P < 0.05$). Results are presented in Table 1.

Pain Relief in Patients

Before the trial, the average VAS score was (6.8 ± 1.5) points; After the trial, the average VAS score was (2.3 ± 1.1) points, showing a significant decrease compared to before the trial, with a statistically significant difference ($P < 0.05$). Results are shown in Table 1.

Table 1 Comparison of HSS and VAS Scores Before and After Trial in 80 Patients ($\pm$ s, points)

Evaluation Indicators	Before Trial (n=80)	After Trial (n=80)	Difference (After Trial - Before Trial)	t-value	P-value
Knee Joint Function (HSS)	62.3 ± 8.5	78.5 ± 7.2	16.2 ± 5.8	22.15	< 0.05
Pain intensity (VAS)	6.8 ± 1.5	2.3 ± 1.1	-4.5 ± 1.3	30.28	< 0.05

Note: Data in the table were analyzed using paired t-tests. $P < 0.05$ indicates statistically significant differences.

Patient Compliance and Satisfaction

Throughout the clinical trial, 76 out of 80 patients strictly followed nursing staff guidance to complete rehabilitation training, achieving a compliance rate of 95%. Patient satisfaction with the rehabilitation training device and nursing care was assessed via questionnaire. Among these, 58 patients reported being very satisfied, 20 were satisfied, and 2 were dissatisfied, yielding an overall patient satisfaction rate of 97.5%. Results are presented in Table 2.

Table 2 Distribution of Treatment Compliance and Satisfaction Among 80 Patients

Evaluation Dimension	Specific Categories	Number of Examples (n=80)	Percentage (%)
Treatment adherence	Compliance (Following instructions)	76	95.0
	Non-compliance (Unauthorized adjustments / Interruptions)	4	5.0
Overall Satisfaction	Very satisfied	58	72.5
	Satisfied	20	25.0
	Average	0	0.0
	Dissatisfied	2	2.5
	Very dissatisfied	0	0.0
	Overall satisfaction (Very satisfied + Satisfied)	78	97.5

1.4 Incidence of Adverse Events

During the trial period, only 2 patients experienced mild knee discomfort characterized by soreness and swelling. Symptoms resolved after nursing staff adjusted training parameters and patients took appropriate rest. No other serious adverse events occurred, with an overall adverse event incidence rate of 2.5%. Results are presented in Table 3.

Table 3 Incidence of Adverse Events During Trial Period in 80 Patients

Type of Adverse Event	Number of Cases (n=80)	Incidence Rate (%)	Management Approach	The End
Knee joint soreness and discomfort	2	2.5	Adjust the training angle (lower by 5°-10°), shorten the duration of each training session (reduce from 30 minutes to 20 minutes), and rest for 15 minutes.	Symptom relief
Other serious adverse events (such as fractures, infections, etc.)	0	0.0	-	-

Results indicate:

From a therapeutic efficacy perspective: Data in Table 1 show that patients' HSS scores significantly improved and VAS scores significantly decreased after trial use (both $P < 0.05$). This demonstrates that the novel geriatric knee rehabilitation training device, combined with nursing interventions, effectively improves knee function and alleviates pain in patients, meeting core requirements for geriatric knee rehabilitation.

From the perspective of compliance and satisfaction: Table 2 indicates that 95% of patients adhered to training guidelines, and 97.5% expressed satisfaction with the device and nursing care. This demonstrates patient recognition of the device's ease of operation, safety, and the quality of nursing services, laying a foundation for future implementation.

From the perspective of safety: Table 3 shows that the adverse event rate was only 2.5%, and symptoms resolved after simple intervention, proving the device's good safety. Real-time monitoring and parameter adjustments in nursing interventions can effectively reduce risks.

Nursing Insights

Comprehensive Assessment: Foundation for Successful Trial Implementation

During the clinical trial of the geriatric knee rehabilitation device, pre-trial comprehensive assessment proved critical. Given the complex and varied physical conditions of elderly patients, along with individual differences, only thorough evaluation could accurately determine patients' physical function, knee joint pathology severity, cognitive level, and psychological state. This provided essential basis for subsequent health education, psychological care, training parameter settings, and nursing plan development. For instance, nursing staff must employ simpler, more intuitive methods for health education with patients exhibiting poor cognitive abilities. For patients experiencing significant pain, initial training intensity should be set lower to avoid exacerbating pain symptoms. In this study, comprehensive assessments enabled the development of personalized care plans for each patient, effectively enhancing compliance and reducing adverse events.

High-Quality Psychological Care is Key to Improving Patient Compliance

Elderly patients often experience anxiety and fear due to insufficient disease awareness and unfamiliarity with new devices. These negative emotions can impair treatment adherence and consequently affect rehabilitation outcomes. During this trial, nursing staff prioritized psychological care. By establishing positive nurse-patient relationships, patiently listening to concerns, and providing emotional support and encouragement, they helped alleviate negative emotions and bolstered patients' confidence in recovery. Additionally, sharing success stories allowed patients to visualize recovery prospects, further enhancing their treatment motivation and adherence.

Real-time Monitoring and Precise Guidance: Core Elements for Safe and Effective Training

Given the frail physical condition of elderly patients, discomfort symptoms may easily arise during rehabilitation training. Consequently, real-time monitoring and precise guidance by nursing staff are particularly crucial. Throughout this trial, nursing staff remained constantly present beside patients, closely observing vital signs, facial expressions, and limb responses. They promptly identified any signs of discomfort and implemented effective interventions, ensuring patient safety during training. Simultaneously, caregivers provided precise movement guidance based on each patient's training progress, helping them master correct techniques to maximize rehabilitation outcomes. For instance, during knee flexion/extension exercises, caregivers instructed patients to maintain proper seated posture while controlling exercise speed and intensity, preventing knee injuries from improper form.

Multidimensional Nursing Interventions: A Critical Foundation for Patient Recovery

Knee rehabilitation in elderly patients is a systematic process requiring nursing interventions across physiological, psychological, and lifestyle dimensions. During this trial, nursing staff not only focused on restoring knee function but also prioritized pain management, psychological adjustment, and improvements in dietary and lifestyle habits. Through multidimensional nursing interventions, a conducive rehabilitation environment was created, promoting patients' overall recovery^{8,9}. For instance, nursing staff developed personalized home rehabilitation exercise plans, enabling patients to continue training after discharge and ensuring continuity of rehabilitation. Concurrently, dietary guidance helped patients replenish nutrients and enhance physical condition, providing a material foundation for knee rehabilitation.

IV. Existing Issues and Improvement Measures

1.1 Existing Issues

Some elderly patients exhibit limited cognitive abilities and comprehension, leading to incomplete understanding of the rehabilitation device's usage methods and precautions. This necessitates repeated explanations and demonstrations by nursing staff, increasing their workload.

A minority of patients demonstrate impatience during training, disregarding nursing staff guidance and arbitrarily adjusting training parameters, thereby elevating the risk of adverse events. Although the device's comfort support system uses soft materials, some patients with unique body types (e.g., obese or emaciated individuals) still experience discomfort during use, which affects training effectiveness.

Improvement Measures

For patients with limited cognitive abilities and comprehension, caregivers can create illustrated, easy-to-understand training instruction cards to distribute to patients and their families for convenient reference. Additionally, one-on-one instruction should be provided, offering repeated hands-on training until patients master the device's operation.

Enhance health education for patients, emphasizing the importance of progressive rehabilitation training and informing them of the risks associated with unauthorized parameter adjustments to

improve self-protection awareness. Simultaneously, caregivers may implement password locks on the device to restrict patient access to training parameter settings, preventing unauthorized modifications.

Communicate with the R&D team to recommend optimizing the device's comfort support system. Enhance the adjustability of support pads by offering options with varying thicknesses and shapes to accommodate patients of different body types. Additionally, incorporate ventilation holes on the support pad surfaces to improve airflow, thereby reducing discomfort during training sessions.

The results of this clinical trial demonstrate that the novel knee rehabilitation training device for the elderly exhibits favorable safety and efficacy. It effectively improves knee function and alleviates pain symptoms in elderly patients with knee joint disorders. During the trial period, multidimensional nursing interventions—including comprehensive assessments, health education, psychological care, real-time monitoring, precise guidance, and home rehabilitation support—effectively enhanced patient compliance and satisfaction while reducing adverse events. These measures provided robust nursing support for the device's clinical application. Concurrently, this nursing practice established a set of clinical trial-specific nursing protocols for the elderly knee rehabilitation device, providing a reference framework for future geriatric knee rehabilitation nursing.

As the number of elderly patients with knee joint disorders continues to rise, demand for rehabilitation devices and nursing services will expand accordingly. Moving forward, we will further refine our nursing intervention protocols. By integrating information technology—such as developing a rehabilitation training app—we aim to enable remote monitoring and guidance for patients' home-based rehabilitation, thereby enhancing the efficiency and quality of nursing care. Concurrently, we will strengthen collaboration with the R&D team to continuously improve and refine the rehabilitation training device based on issues identified in clinical practice, ensuring it better meets the needs of elderly patients. Furthermore, we will conduct large-scale, multi-center clinical studies to validate the safety and efficacy of this novel knee rehabilitation device for the elderly. This will provide robust evidence for its widespread clinical adoption, ultimately benefiting more patients with knee joint disorders.

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Author Profile: Cao Lei (2004–), male, currently enrolled in a specialized program, research focus: clinical nursing research.

Corresponding Author: Sun Rongjin (1981–), female, doctoral candidate, Associate Professor, research focus: nursing education. E-mail:402661291@qq.com.

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