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Effects of Virtual Reality (VR) Rehabilitation on Mental Health in SCI Patients: A Randomized Controlled Trial

Zahra Sedghazar [1], Maria Karaminasian [1], Somayeh Sadeghi [1], Jamal Alshorman [2] and Ruba Altahla [2,*]

[1] MBBS Tongji Medical Collage, Huazhong University of Science and Technology, Wuhan 430030, China; malikaazar2020@gmail.com (Z.S.); mariakara@163.com (M.K.); www.somijoon1380@gmail.com (S.S.)

[2] Orthopedic Department, Second Affiliated Hospital of Hainan Medical University, Haikou 570311, China; Jamalking61@yahoo.com (J.A.)

* Corresponding author. E-mail: rubamntahla91@gmail.com (R.A.)

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ABSTRACT: This randomized controlled trial investigates the effects of virtual reality (VR) rehabilitation on mental health in spinal cord injury (SCI) patients. Seventy-four participants were randomized to 12 weeks of VR-based or traditional rehabilitation, with mental health assessed via the Hospital Anxiety and Depression Scale (HADS) and World Health Organization Quality of Life-BREF (WHOQOL-BREF). The VR group showed significantly greater reductions in HADS scores at 6 weeks (mean change: −4.2 *vs.* −2.4, $p < 0.001$) and 12 weeks (mean change: −6.4 *vs.* −3.9, $p < 0.001$), with a large effect size (Cohen's $d = 1.21$). VR also improved WHOQOL-BREF psychological health scores (+13.5 *vs.* +6.4, $p < 0.001$), self-esteem (+7.2 *vs.* +3.2, $p < 0.001$), and sleep quality (−5.1 *vs.* −2.8, $p < 0.001$). Subgroup analysis indicated greater benefits for younger patients and those with incomplete SCI. VR rehabilitation outperforms traditional methods in enhancing mental health, supporting its integration into comprehensive SCI care.

Keywords: Spinal cord injury; Virtual reality; Rehabilitation; Mental health; Randomized controlled trial

1. Introduction

Spinal cord injury (SCI) is a severe neurological condition that not only causes profound physical disabilities [1,2], including paralysis, loss of sensation, and autonomic function impairments, but also significantly impacts patients' mental health [3,4]. Furthermore, the WHO's International Classification of Functioning, Disability and Health (ICF) for SCI provides a standardized framework to assess body functions, activity limitations, and participation restrictions, emphasizing environmental and personal factors influencing rehabilitation and quality of life (QoL) [3,4]. Abundant studies have reported high incidences of depression, anxiety, and post-traumatic stress disorder (PTSD) among SCI patients, which not only diminish their QoL, but also hinder physical rehabilitation and overall well–being [5,6]. Traditional rehabilitation methods for SCI predominantly focus on restoring physical functions through physical therapy, occupational therapy, and exercise training [7]. While crucial for motor function and daily living skill improvement, these approaches often neglect patients' mental health needs, and their monotonous nature can lead to fatigue and reduced compliance [8].

Emerging as a promising alternative or supplementary approach in rehabilitation medicine, virtual reality (VR) technology creates immersive, interactive, computer-generated environments that simulate real-life scenarios [9]. For SCI patients, VR-based rehabilitation holds several advantages: its immersive quality can boost patient motivation and compliance by offering engaging and challenging simulated environments. It allows customized rehabilitation programs targeting physical and mental functions like balance training and stress management [10,11]. Moreover, VR has demonstrated potential in treating psychological disorders; for instance, virtual reality exposure therapy effectively reduces anxiety by exposing patients to feared stimuli in a controlled virtual setting [12,13]. Similar benefits may apply to SCI patients, as VR could help them confront and overcome injury-related fears and anxieties through gradual exposure, and VR-based relaxation exercises could alleviate stress and enhance mood [14,15].

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Notwithstanding these potential benefits, the existing body of research lacks robust evidence from well-designed randomized controlled trials (RCTs). Most studies are small-scale pilot projects or lack appropriate control groups, rendering it challenging to determine the true efficacy of VR rehabilitation on the mental health of SCI patients [16,17]. Hence, this RCT is designed to rigorously evaluate the impact of VR-based rehabilitation on the mental health of SCI patients, with the primary objective of comparing its effectiveness against traditional rehabilitation. Secondary objectives include identifying the specific mental health aspects most influenced by VR-based rehabilitation, examining how patient-related factors affect the intervention's efficacy, and exploring the underlying mechanisms.

2. Materials and Methods

2.1. Study Design

This is a single-blinded, randomized controlled trial. Patients were randomly assigned to the VR-based rehabilitation group (experimental group) or the traditional rehabilitation group (control group). The assessors who evaluate the patients' mental health status are blinded to the group allocation of the patients.

2.2. Participants

Inclusion Criteria: 1. Patients with a confirmed diagnosis of SCI, regardless of the cause (traumatic or non-traumatic), level (cervical, thoracic, lumbar, or sacral), or completeness (complete or incomplete) of the injury. 2. Aged between 18 and 65 years old. 3. Able to understand and provide informed consent. 4. Efficient visual and auditory function to engage with the VR system (for the experimental group). As well as the exclusion criteria: 1. Presence of severe cognitive impairment (such as dementia or severe traumatic brain injury) that may prevent the patient from participating in the rehabilitation programs or completing the mental health assessments. 2. Unstable medical conditions, such as uncontrolled hypertension, heart failure, or active infections. 3. History of severe mental illness (such as schizophrenia or bipolar disorder) may confound the assessment of the effects of VR-based rehabilitation on mental health. 4. Allergy or intolerance to any of the materials used in the VR equipment or traditional rehabilitation aids.

2.3. Intervention

2.3.1. VR-Based Rehabilitation Group

The VR-based rehabilitation program was developed in collaboration with experts in rehabilitation medicine and virtual reality technology. The VR system consisted of a head-mounted display (HMD), motion sensors, and a control unit. The virtual scenarios were designed to target rehabilitation's physical and mental aspects.

For physical rehabilitation, scenarios included virtual environments for practicing walking, using a simulated exoskeleton or walker in the virtual world for patients with lower-limb impairments, upper-limb reaching and grasping tasks, and balance training on various terrains. Alongside these physical tasks, mental health-focused scenarios were also incorporated. For example, there were relaxation scenarios such as virtual nature walks, where patients practiced deep breathing and mindfulness techniques. Additionally, exposure-based scenarios gradually exposed patients to situations that might cause them anxiety in real life, such as using public transportation in a wheelchair or interacting with others in a social setting.

Patients in the VR-based rehabilitation group received 30 min of VR-based training thrice a week for 12 weeks. Each session started with a 5-min warm-up period, followed by 20 min of VR-based exercises, and ended with a 5-min cool-down and relaxation period.

2.3.2. Traditional Rehabilitation Group

Patients in the traditional rehabilitation group received standard physical and occupational therapy. Physical therapy included exercises to improve muscle strength, range of motion, and balance, such as stretching, resistance, and gait training. Occupational therapy focuses on enhancing activities of daily living skills, including dressing, grooming, and eating. The frequency and duration of traditional rehabilitation matched those of the VR-based rehabilitation group, consisting of 30 min of therapy three times a week for 12 weeks.

2.4. Outcome Measures

2.4.1. Primary Outcome Measure

The primary outcome measure was the change in the Hospital Anxiety and Depression Scale (HADS) score. The HADS is a widely used self-report scale that consists of two sub-scales: the anxiety sub-scale (HADS-A) and the depression sub-scale (HADS-D) [18]. Each sub-scale had a score range of 0–21, with higher scores indicating more severe symptoms of anxiety or depression, and the Cronbach alpha of the subscales was 0.753 and 0.764. The HADS was administered at baseline, 6 weeks, and 12 weeks of the intervention.

2.4.2. Secondary Outcome Measures

This measure contains three evaluation scales. 1. The World Health Organization Quality of Life-BREF (WHOQOL-BREF) scale was used to assess the overall quality of life of SCI patients. The Chinese version with Cronbach's alpha exceeded 0.7, and ICC exceeded 0.4 [19]. It included four domains: physical health, psychological health, social relationships, and environment. The WHOQOL-BREF was administered at the same time points as the HADS.

The Rosenberg Self-Esteem Scale was used to measure patients' self-esteem. It consisted of 10 items; higher scores indicated higher self-esteem, and the 90% CI was (0.043, 0.062) [20]. This scale was also administered at baseline, 6 weeks, and 12 weeks.

The Pittsburgh Sleep Quality Index (PSQI) was used to evaluate the sleep quality of SCI patients. A higher PSQI score indicated poorer sleep quality [21]. The PSQI was administered at the same time points as the other outcome measures.

2.5. Sample Size Calculation

The sample size calculation was based on the primary outcome measure, the change in HADS score. Assuming a medium-sized effect size of 0.5 (Cohen's d), a significance level (α) of 0.05, and a power of 0.80, we estimated that a sample size of 37 SCI patients in each group (total N = 74) was required using a two-sample *t*-test formula. This calculation considered a potential dropout rate of 20%, so we planned to recruit 37 patients in each group to ensure that at least 30 patients completed the study. Dropouts in the study were managed using intention-to-treat (ITT) principles, ensuring all randomized participants were included in their original groups regardless of completion status, which helps minimize bias. The initial sample size calculation accounted for a 20% dropout rate, recruiting 37 patients per group to ensure at least 30 completions. Additionally, the last observation carried forward (LOCF) method may have been employed to impute missing data, enhancing the statistical analysis's robustness and maintaining the findings' validity despite dropout occurrences.

2.6. Randomization and Blinding

Patients who met the inclusion criteria were randomly assigned to either the VR-based rehabilitation group or the traditional rehabilitation group using a computer-generated random number table. The randomization sequence was concealed in sealed, opaque envelopes until patient enrollment.

The assessors who administered the outcome measures were blinded to the patients' group allocation. They were not involved in delivering the interventions and only received the patients' identification numbers for assessment purposes. This blinding procedure helped minimize potential bias in assessing the outcomes.

2.7. Statistical Analysis

Data was analyzed using SPSS software (version 29). Demographic and baseline characteristics of the two groups were compared using independent samples *t*-tests for continuous variables and chi-square tests for categorical variables to ensure that the groups were comparable at baseline.

For the primary outcome measure, the change in HADS score from baseline to 12 weeks was compared between the two groups using an independent samples *t*-test. A repeated-measures analysis of variance (ANOVA) was used to analyze the changes in HADS scores over time (baseline, 6 weeks, 12 weeks) within each group and to test for group-by-time interactions.

Similar statistical methods were applied to the secondary outcome measures. Independent samples *t*-tests were used to compare the changes in WHOQOL—BREF, Rosenberg Self-Esteem Scale, and PSQI scores between the two groups at 12 weeks, and repeated-measures ANOVA was used to analyze the changes over time.

Effect sizes (Cohen's d) were calculated for all significant differences to determine the practical significance of the results. A *p*-value of less than 0.05 was considered statistically significant.

3. Results

3.1. Participant Characteristics

74 patients were enrolled (37 in each group), with 30 patients completing the study in each arm (dropout rate: 18.9%). Baseline demographics and clinical characteristics were comparable between groups ($p > 0.05$, Table 1), including age, gender distribution, SCI level/completeness, and time since injury.

Table 1. Demographic and Clinical Characteristics of Study Participants (N = 74).

Characteristics	VR Rehabilitation Group ($n = 30$)	Traditional Rehabilitation Group ($n = 30$)	*p*-Value
Age (years), mean (SD)	34.5 (10.2)	36.2 (9.8)	0.432
Gender (male/female)	25/12	23/14	0.689
SCI Level	-	-	0.571
Cervical	14	16	-
Thoracic	18	17	-
Lumbar/Sacral	5	4	-
SCI Completeness (AIS)	-	-	0.328
Complete (A/B)	20	18	-
Incomplete (C/D)	17	19	-
Time since Injury (months), mean (SD)	12.8 (6.5)	14.2 (7.1)	0.315
Comorbid Depression History	11 (29.7%)	9 (24.3%)	0.546

3.2. Primary Outcome: HADS Scores

The VR rehabilitation group demonstrated significantly greater reductions in HADS scores compared to the traditional group at both 6 weeks (mean change: −4.2 *vs.* −2.4, $p < 0.001$) and 12 weeks (mean change: −6.4 *vs.* −3.9, $p < 0.001$, Table 2). Repeated-measures ANOVA revealed a significant group-by-time interaction $F(2,116) = 28.7$, $p < 0.001$), with the VR group showing a steeper decline in anxiety and depression symptoms over time. The effect size at 12 weeks was large (Cohen's $d = 1.21$), indicating a substantial practical significance.

Table 2. Comparison of Primary Outcome: HADS Scores Change Between Groups.

Time Point	VR Group ($n = 30$)		Traditional Group ($n = 30$)		Group Difference (95% CI)	*p*-Value
	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline		
Baseline	14.7 (3.2)	-	15.1 (3.5)	-	−0.4 (−1.8, 1.0)	0.563
6 Weeks	10.5 (2.8)	−4.2 (−5.1, −3.3)	12.7 (3.1)	−2.4 (−3.2, −1.6)	−1.8 (−2.9, −0.7)	<0.001
12 Weeks	8.3 (2.5)	−6.4 (−7.2, −5.6)	11.2 (2.9)	−3.9 (−4.7, −3.1)	−2.5 (−3.7, −1.3)	<0.001
Effect Size (Cohen's *d*)	-	1.02	-	0.78	-	1.21

3.3. Secondary Outcomes

The VR group demonstrated significant improvements in various outcome measures compared to the traditional group. Specifically, psychological health scores increased by 13.5 points in the VR group, compared to a 6.4-point increase in the traditional group ($p < 0.001$). Similar enhancements were observed in physical health and social relationship domains ($p < 0.05$). Additionally, the VR group exhibited a 7.2-point increase in Rosenberg Self-Esteem Scale scores, surpassing the traditional group's 3.2-point increase ($p < 0.001$), indicating enhanced self-perception and confidence. Sleep quality also improved, with a 5.1-point reduction in PSQI scores for the VR group versus a 2.8-point reduction in the traditional group ($p < 0.001$), likely due to reduced anxiety and improved mood. Subgroup analysis revealed that patients with incomplete SCI (AIS C/D) in the VR group had a mean change of −7.1 in HADS scores, while those with complete SCI (AIS A/B) had a mean change of −5.8 ($p = 0.021$). Younger patients (<40 years) experienced greater reductions in anxiety symptoms ($p = 0.015$). Notably, three patients in the VR group reported mild dizziness during sessions, which resolved quickly, and no severe adverse events were recorded, indicating good safety and tolerability (Table 3).

Table 3. Secondary Outcomes: Changes in Mental Health Measures at 12 Weeks.

Outcome Measure	VR Group (n = 30)	Change from Basline	Traditional Group (n = 30)	Change from Basline	Group Difference (95% CI)	p-Value
WHOQOL-BREF Psychological Health						
Baseline	45.2 (6.1)	-	44.8 (5.8)	-	0.4 (−2.1, 2.9)	0.741
12 Weeks	58.7 (5.9)	+13.5	51.2 (6.3)	+6.4	+7.3 (4.2, 10.4)	<0.001
Rosenberg Self-Esteem Scale						
Baseline	22.3 (4.3)	-	21.9 (4.1)	-	0.4 (−1.5, 2.3)	0.678
12 Weeks	29.5 (3.8)	+7.2	25.1 (4.2)	+3.2	+4.4 (2.1, 6.7)	<0.001
Pittsburgh Sleep Quality Index (PSQI)						
Baseline	11.8 (3.5)	-	12.1 (3.2)	-	−0.3 (−1.7, 1.1)	0.719
12 Weeks	6.7 (2.4)	−5.1	9.3 (2.8)	−2.8	−2.4 (−3.6, −1.2)	<0.001

4. Discussion

The study presents a significant contribution to the understanding of rehabilitation approaches for SCI patients, particularly in the context of mental health. Traditional rehabilitation methods have historically focused on physical recovery, often neglecting the psychological aspects that are crucial for overall well-being. This manuscript highlights the potential of VR rehabilitation to address physical and mental health needs, which is a critical advancement in rehabilitation medicine. The scalability of VR rehabilitation programs for SCI patients depends on addressing several key factors: equipment cost, accessibility, and patient digital literacy. High initial costs of VR systems can limit their use in underfunded healthcare settings; thus, developing tiered, affordable solutions and seeking partnerships for funding are essential. Accessibility involves ensuring that VR setups can be used in various environments, including patients' homes, and that they integrate seamlessly into existing rehabilitation practices. Additionally, enhancing patient digital literacy through user-friendly interfaces and training programs is crucial for effective engagement. By tackling these challenges, VR rehabilitation can become a widely adopted and impactful approach in patient care.

4.1. Enhanced Mental Health Outcomes

The results demonstrate that VR rehabilitation significantly reduces anxiety and depression levels, as evidenced by marked improvements in HADS scores. This aligns with existing literature suggesting that immersive environments can effectively mitigate psychological distress by providing controlled exposure to anxiety-provoking situations [5,22].

4.2. Quality of Life Improvements

The study reports substantial increases in QoL as measured by the WHOQOL-BREF, indicating that VR rehabilitation addresses mental health and enhances overall life satisfaction. This finding underscores the importance of integrating mental health interventions within physical rehabilitation programs [22].

4.3. Self-Esteem and Sleep Quality

The significant improvements in self-esteem and sleep quality among VR group participants further highlight this approach's multifaceted benefits. Enhanced self-perception can lead to better engagement in rehabilitation efforts, vital for recovery. Improved sleep quality is particularly noteworthy, as sleep disturbances are common in SCI patients and can exacerbate mental health issues [23].

4.4. Subgroup Analyses

The subgroup analyses revealing greater benefits for patients with incomplete SCI and younger individuals provide valuable insights into tailoring rehabilitation strategies. This suggests that VR may be particularly effective for certain demographics, warranting further exploration into customized rehabilitation protocols. The greater improvements observed in patients with incomplete SCI and younger individuals can be attributed to enhanced neuroplasticity and differences in engagement [24]. Incomplete SCI patients retain some neural function, allowing for greater recovery potential through rehabilitation, while younger patients typically exhibit higher neuroplasticity, facilitating quicker improvements [25]. Additionally, younger individuals are generally more comfortable with technology, which

enhances their motivation and adherence to VR rehabilitation. This combination of factors likely contributes to these subgroups' significant mental health benefits following VR interventions.

4.5. Limitations and Future Directions

While the findings are promising, the study is not without limitations. The single-center design may limit the generalizability of the results, as the patient population may not represent the broader SCI community. Future research should aim for multicenter studies with diverse populations to validate these findings. Additionally, the reliance on self-reported measures may introduce bias. Incorporating objective assessments of mental health and functional outcomes could enhance the robustness of future studies. Finally, as VR technology evolves, exploring its integration into standard rehabilitation practices could lead to innovative, patient-centered care models. Further investigation into the long-term effects of VR rehabilitation on mental health and physical recovery is essential to understand its potential fully. The study does not explicitly address follow-up after the 12-week intervention, but exploring long-term effects of VR rehabilitation on mental health in SCI patients is crucial. Long-term follow-up could help assess the durability of improvements in anxiety, depression, quality of life, self-esteem, and sleep quality.

Future research should consider implementing follow-up assessments at multiple time points post-intervention, such as 3, 6, and 12 months, to evaluate the persistence of benefits. Additionally, incorporating objective measures alongside self-reports can provide a comprehensive understanding of the lasting impacts of VR rehabilitation. Investigating factors such as sustained engagement with VR systems and ongoing mental health support could also offer insights into maintaining improvements over time.

5. Conclusions

VR-based rehabilitation was more effective than traditional rehabilitation in improving mental health outcomes for SCI patients, with significant reductions in anxiety/depression, enhanced quality of life, self-esteem, and sleep quality. These findings support integrating VR technology into standard SCI rehabilitation programs to address physical and psychological needs. Future studies should explore long-term effects and cost-effectiveness across diverse patient populations.

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Author Contributions

Conceptualization, M.K. and Z.S.; methodology, M.K.; software, Z.S.; validation, S.S. and J.A.; formal analysis, M.K.; investigation, Z.S.; resources, M.K.; data curation, M.K.; writing—original draft preparation, Z.S.; writing—review and editing, R.A.; visualization, S.S.; project administration, M.K.; funding acquisition, Z.S. All authors have read and agreed to the published version of the manuscript.

Ethics Statement

This study adhered to the ethical guidelines set forth in the Declaration of Helsinki for the treatment of all human participants. The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Ethics Committee of Second Affiliated Hospital of Hainan Medical University (protocol code IRB20250314 and date of approval was 14 March 2025.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

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

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Declaration of Competing Interest

The authors declare no conflict of interest.

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