The Physical and Psychological Effects of Telerehabilitation-based Exercise for Patients with Non-specific Low Back Pain: A Prospective Randomized Controlled Trial

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Submitted to: JMIR mHealth and uHealth
on: January 22, 2024

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Abstract

Background: Physical therapy has demonstrated efficacy in managing non-specific low back pain (NLBP) among patients. Nevertheless, the prevalence of NLBP poses a challenge, as the existing medical infrastructure may be insufficient to care for the large patient population, particularly in geographically remote regions. Telerehabilitation emerges as a promising method to address this concern by offering a method to deliver superior medical care to a greater number of NLBP patients.

Objective: The purpose of this study is to demonstrate the effectiveness of a telerehabilitation program in patients with NLBP.

Methods: Following the inclusion and exclusion criteria, individuals with NLBP for a duration exceeding 3 months were enrolled in this study. Subsequently, a random allocation process assigned participants to either the telerehabilitation-based exercise group (TBEG) or the Outpatient-based exercise group (OBEG). All subjects engaged in a 30-minute regimen of strength and stretching exercises every two days for 8 weeks. The Oswestry Disability Index (ODI) served as the primary outcome measure, assessing physical disability. Secondary outcomes include pain intensity, fear-avoidance tendencies, and quality of life, as shown by the Numeric Pain Rating Scale (NPRS), Fear-Avoidance Belief Questionnaire (FABQ), and 36-item Short-Form Health Survey (SF-36), respectively.

Results: 54 out of 128 eligible patients were enrolled and randomly assigned in the study. The findings indicate that the improvement observed in ODI scores within the TBEG group was comparable to that in the OBEG group at 2 weeks (mean difference -0.91, 95% Confidence Interval [CI] -5.96 to 4.14, P=0.718), 4 weeks (mean difference -3.80, 95% CI -9.86 to -2.25, P=0.213), and 8 weeks (mean difference -3.24, 95% CI -8.65 to 2.17, P=0.235). No statistically significant differences were observed between the two groups at the 8-week mark regarding the FABQ (mean difference 8.88, 95% CI -2.29 to 20.06, P=0.116), NPRS (mean difference -0.39, 95% CI -2.10 to 1.31, P=0.642), and SF-36 scores (P >0.05).

Conclusions: Telerehabilitation interventions demonstrate comparable therapeutic efficacy for individuals with NLBP when compared to conventional outpatient-based physical therapy, yielding comparable outcomes in pain reduction and improvement in functional limitations. Clinical Trial: Chinese Clinical Trial Registry: ChiCTR2300068984 ; (https://www.chictr.org.cn/showproj.html?proj=189852)

(JMIR Preprints 22/01/2024:56580)

DOI: https://doi.org/10.2196/preprints.56580

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Abstract

Background: Physical therapy has demonstrated efficacy in managing non-specific low back pain (NLBP) among patients. Nevertheless, the prevalence of NLBP poses a challenge, as the existing medical infrastructure may be insufficient to care for the large patient population, particularly in geographically remote regions. Telerehabilitation emerges as a promising method to address this concern by offering a method to deliver superior medical care to a greater number of NLBP patients.

Objective: The purpose of this study is to demonstrate the physical and psychological effectiveness of a user-centered telerehabilitation program, consisting of a smartphone application and integrated sensors, for patients with NLBP.

Methods: This is a single-center, prospective randomised controlled trial for individuals with NLBP for a duration exceeding 3 months. All participants are assigned randomly to either the telerehabilitation-based exercise group (TBEG) or the Outpatient-based exercise group (OBEG). All participants completed 30-minute regimen of strength and stretching exercises three times per week, with a total of 8 weeks and were required to complete assessment questionnaires at 0, 2, 4 and 8 weeks. TBEG completed home-based exercise and questionnaires using telerehabilitation program, while OBEG completed them in outpatient. The Oswestry Disability Index (ODI) served as the primary outcome measure, assessing physical disability. Secondary outcomes include the Numeric Pain Rating Scale (NPRS), Fear-Avoidance Belief Questionnaire (FABQ), and 36-item Short-Form Health Survey (SF-36), respectively.

Results:54 out of 129 eligible patients were enrolled and randomly assigned in the study.The completion of all the intervention and assessments in the TBEG and OBEG was 88.89% (24/27) and 81.49% (22/27). The findings indicate that no statistical significance was found in the difference of of ODI scores between the TBEG group and the OBEG group at 2 weeks (mean difference -0.91, 95% Confidence Interval [CI] -5.96 to 4.14, *P*=.718), 4 weeks (mean difference -3.80, 95% CI -9.86 to -2.25, *P*=.213), and 8 weeks (mean difference -3.24, 95% CI -8.65 to 2.17, *P*=.235), between outpatient rehabilitation therapy and telerehabilitation therapy. The improvement of ODI in the TBEG (mean -16.42, standard deviation [SD] 7.30) and OBEG (mean -13.18 , SD 8.48) was higher than 10 after 8-week intervention No statistically significant differences were observed between the two groups at the 8-week mark regarding the FABQ (mean difference 8.88, 95% CI -2.29 to 20.06, *P*=.116)and NPRS (mean difference -0.39, 95% CI -2.10 to 1.31, *P*=.642). In the subgroup analysis, there was no statistically significant difference in outcomes between the two groups.

Conclusion:Telerehabilitation interventions demonstrate comparable therapeutic efficacy for individuals with NLBP when compared to conventional outpatient-based physical therapy, yielding comparable outcomes in pain reduction and improvement in functional limitations.

Trial Registration: Chinese Clinical Trial Registry: ChiCTR2300068984 ; (https://www.chictr.org.cn/showproj.html?proj=189852)

Keywords:
non-specific low back pain; telerehabilitation; physical therapy.

Introduction

Non-specific low back pain (NLBP) is a broad category of low back pain lacking identifiable etiology[[1]]. The Global Burden of Disease (GBD) study report indicates that by 2020, the global prevalence of low back pain (LBP) will exceed 619 million, representing a 60% increase since 1990, with projections reaching 843 million by 2050 [2]. Years lived with disability (YLDs) is an index measuring the average duration of life lived with disability due to a disease from onset to death [3]. The GBD study reveals that LBP ranks first among 291 diseases in terms of age-standardized YLDs [4]. By 2020, 69 million individuals will experience limited life expectancy due to disability caused by LBP [2].

It is estimated that the annual economic burden for physical therapy of LBP patients exceeded $2.41 billion dollars [5]. Non-specific chronic low back pain (NLBP) includes individuals experiencing pain exceeding three months, constituting 85% of the overall NLBP population [6]. Therefore, it is urgent and necessary to explore innovative treatment modalities for individuals with NLBP.

Numerous clinical guidelines recommend incorporating exercise routines into the treatment of individuals with NLBP. This recommendation is based on the substantial pain relief and improved physical function observed in NLBP patients through exercise interventions. These interventions also tend to have fewer adverse effects compared to pharmaceutical and surgical approaches [7].

Under traditional clinic-based exercise model, patients are required to participate consistently in structured exercise programs. These programs are supervised by qualified physical therapists over an extended period. However, traditional clinic-based exercise model faces challenges because a substantial proportion of NLBP patients face barriers on completing a structured exercise program due to time constraints, transportation limitations, geographical challenges; Also, a large proportion of individuals with NLBP, who live in remote areas, have no access to qualified exercise guidance, because the medical resource is undistributed, especially in developing countries [11-13].

As a result, the traditional clinic-based exercise model encounters difficulties in addressing the diverse needs of this patient population [14]. Given these circumstances, the telerehabilitation-based exercise model, incorporation of home-based exercises into a telerehabilitation program, emerges as a promising and effective strategy to address the previously mentioned challenges associated with managing NLBP. The telerehabilitation-based exercise model provides patients with a digitalized exercise plan, enabling NLBP patients to complete their home exercise regimen promptly. In this model, patients' exercise performance is recorded, and any issues encountered are promptly addressed by professional healthcare providers. Compared to traditional clinic-based exercise models, the telerehabilitation-based model saves time, money, and medical resources.

In recent years, numerous research teams have studied telerehabilitation strategies for individuals with NLBP [18]. In the United States, Shebib R et al. pioneered a comprehensive digital care program (DCP) encompassing education, sensor-guided physiotherapy, aerobic exercise, and cognitive behavioral therapy tailored for NLBP patients. Their investigation revealed superior therapeutic outcomes within the DCP group compared to the control group [19]. In Germany, Toelle TR et al. developed the Kaia application specifically designed for NLBP patients. Results indicated that individuals receiving exercise guidance through the Kaia application exhibited significant pain relief and improvements in physical function compared to the control group [19].

Similarly, in the United Kingdom, Fatoye F et al. integrated telerehabilitation with the McKenzie exercise approach. Remarkably, the telerehabilitation group achieved therapeutic outcomes equivalent to outpatient rehabilitation. It also demonstrated lower average medical cost per patient compared to the outpatient group [20]. In developing nations such as China, the widespread adoption of telerehabilitation is important because of the large patient population and the lack of physical therapy services.

Furthermore, it is worth noting that psychosocial risk factors have a more significant impact on predicting pain-related outcomes in cases of NLBP compared to biomedical factors [22]. One widely accepted conceptual framework for understanding how psychosocial factors influence pain-related outcomes is the Fear-Avoidance Model (FAM)[24]. According to the Fear-Avoidance Model (FAM), anxiety, depression, fear, and catastrophizing are risk factors that contribute to pain-related disability [25]. Marshall PWM et al. found that a significant number of patients with non-specific low back pain (NLBP) did not experience improvements in pain intensity or limb disability after receiving professional exercise guidance and participating in weekly exercises. These patients were more susceptible to anxiety and fear[28]. In the traditional clinic-based exercise model, healthcare professionals such as physical therapists assist patients in correctly understanding pain and addressing their concerns to prevent the occurrence of anxiety and fear [28]. However, it remains unclear whether a telerehabilitation-based exercise model can reduce pain-related fear and anxiety in NLBP patients.

Objective

The research team used the Healbone Intelligent Rehabilitation System (HIRS), comprised of a smartphone application and integrated sensors. The primary objective is to evaluate the efficacy of this intervention. The program guides and monitors NLBP patients as they engage in a structured home-based exercise regimen. This study measures the program's impact on both the physical and psychological dimensions of NLBP management.

Methods

Trial Design

This study was a single-center, 2-arm, parallel-group RCT (participant-blinded) with 1:1 randomised controlled trial, conducted in Peking Union Medical College Hospital, Beijing, China. And this study has also been approved by the Ethics Committees of the Peking Union Medical College Hospital and registered in Clinical Trials.gov: ChiCTR2300068984. All patients were assessed on pain, function, quality of life, and fear-belief avoidance. Assessments occur at 0, 2, 4, and 8 weeks.

Inclusion and Exclusion Criteria

In this study, all subjects were recruited from Peking Union Medical College Hospital. Two physicians selected patients with NLBP who met the inclusion and exclusion criteria and referred them to rehabilitation therapists. These patients were thoroughly informed about the purpose, procedures, and potential risks of the trial. Additionally, patients did not participate in any other medical interventions for low back pain other than the exercise intervention of this trial until the study's completion. Upon obtaining informed consent, patients were included in the study.
Written informed consents were obtained from all patients. The inclusion and exclusion criteria are shown in Table 1.

Table1. Inclusion and exclusion criteria for the study.
Inclusion criteria:
- Aged between 18 and 60 years;
- Numeric Pain Rating Scale (NPRS) equal to or greater than 3 points;
- Oswestry Disability Index (ODI) equal to or greater than 15 points;
- Ongoing pain for at least 3 months;
- Able to use smartphone and complete the exercise protocol independently;
- Those who could sign the informed consent independently;

Exclusion criteria:
- Patients with Spinal deformity, spinal structure slip, spinal fracture history, spinal tumor;
- Diagnosed rheumatoid arthritis and ankylosing spondylitis;
- Patients with herniated disc;

- Pregnancy;
- Patients who receive other treatments before the experiments, including non-steroid anti-inflammatory drugs or plasters, physical agents therapy, and acupuncture.

Sample size calculation

The sample size was calculated using PASS 11. Based on the principle of non-inferiority randomized controlled trials[29] and previous clinical studies[20], the mean difference in ODI between the TBEG and the OBEG was 5, the standard deviation was estimated to be 6 for both groups, and the non-inferiority margin for ODI was 10. A sample size of 38 was required based on a bilateral alpha 0.05 and beta=0.2, and 54 for a 30% dropout rate.

Blinding and Randomization

54 Subjects were assigned in a randomized manner, with equal distribution, to either the TBEG or the OBEG through an online platform (https://www.random.org/). Subsequently, based on the results derived from the online platform (e.g., C, T, C, T, T, C, ...), slips of paper labeled with the letters "T" and "C" were placed into sealed, opaque, and identically sized envelopes. After completing the baseline measurements for all subjects, the envelopes were sequentially opened to reveal the group assignments.

The allocation sequence was prepared by two researchers with no involvement in the study using a blocked randomization model.

Intervention

The exercise plan for patients with NLBP in both TBEG and OBEG was identical. Both consist of muscle strengthening and stretching exercises to increase lumbar stability, coordination, and posture keeping. The detailed exercise plan is shown in Multimedia Appendix 1. Before the initiation of this trial, two physical therapists (PT) were trained in three 40-minute sessions.

TBEG

The HIRS was designed based on an user-centered theory, to provide patients with a platform for self-management interventions. Additionally, the HIRS system is made available at no cost to all participants in this study. Figure 1 illustrates the three distinct components of HIRS: the physician portal, the user portal, and the transmission portal.

Prior to the commencement of the experiment, professional medical personnel created specific videos for each training exercise in the rehabilitation program and uploaded them to the HIRS system along with detailed instructions. At the onset of the experiment, an application was installed on the smartphones of the TBEG patients, through which they registered personal accounts. Subsequently, during the initial session, rehabilitation therapists sent digital exercise training protocols to the patients' personal accounts and educated them on the correct usage of the application and sensors for home-based exercises.

Each time the patients engaged in the exercises, they were required to access the application via their personal accounts, and to calibrate the sensors to accurately performing each exercise within the regimen. Upon initiation of the exercise, the patients were to follow the instructions provided in the video to complete each action in the regimen. If a patient failed to exercise, the system would automatically send a reminder and notify the rehabilitation therapist, who would then contact the patient to ascertain the reason for non-participation. Concurrently, if an individual in the TBEG cohort sought advice from the rehabilitation therapist regarding concerns or inquiries related to back pain, the therapist would provide patient and detailed responses to prevent the individual from experiencing fear or anxiety.

Over an 8-week period, all TBEG patients were mandated to complete exercise sessions every other day, three times a week, with each session lasting 30 minutes. The HIRS transmission portal collected the results of the patients' assessments and automatically recorded their exercise performance, including the duration of each session and the frequency of weekly exercises.

Lastly, patients were required to complete digital assessment questionnaires via the application at weeks 0, 2, 4, and 8. The validity of HIRS had been verified by 25 patients before the trial.

OBEG

In the rehabilitation training group, patients underwent a consistent 30-minute exercise regimen every two days under the supervision of a physical therapist, with sessions scheduled thrice weekly. Concurrently, during each hospital visit for exercise guidance, the physical therapist provides face-to-face consultations to address any questions or concerns the patients may have. Furthermore, assessment questionnaires are administered in the outpatient clinic at baseline (Week 0), Week 2, Week 4, and Week 8.

Figure 1 illustrates the three different parts of the HIRS. The doctor's portal could be used to create and modify exercises, to monitor training progress, and to view patient data. The patients could use the user's portal to complete the prescribed exercises, view educational materials, and to provide feedbacks to the PTs. Finally, the transmitter portal encrypts and transmits the data collected, ensuring the overall system's integrity.

Outcomes Measures

The ODI, as the primary outcome measure, has been verified for reliability and validity [31]. It is commonly used to evaluate physical function. The Minimal Clinically Important Difference (MCID) refers to the smallest change in score that patients perceive as beneficial, irrespective of side effects and costs. Bombardier et al. determined that the MCID for the Oswestry Disability Index (ODI) score in patients with non-specific low back pain (NLBP) is 5 [32]. This indicates that an improvement in the ODI score by at least 5 points post-intervention is considered clinically meaningful for the patient.

In addition, a set of secondary outcome measures was also used. These measures include the NPRS for pain evaluation, the SF-36 for quality of life assessment, and the FABQ to gauge fear-avoidance beliefs related to work and physical activity[33]. Previous studies have determined that the Minimal Clinically Important Difference (MCID) for the Fear-Avoidance Beliefs Questionnaire (FABQ) in patients with non-specific low back pain (NLBP) is 11 Error: Reference source not found, and for the Numerical Pain Rating Scale (NPRS), it is 2 [36]. However, Grönkvist R established that the MCID for the eight dimensions of the Short Form Health Survey (SF-36) varies among NLBP patients [37].

The reliability and validity of the Chinese version of the SF-36 and the FABQ have been confirmed[33].

The collection of the primary and secondary outcome measures occurred at weeks 0,2,4, and 8. Patients in the TBEG completed all assessments through the HIRS, while patients in the OBEG completed these assessments in the outpatient clinic, guided by PTs.

Statistical Analysis

The outcomes were analyzed following the intent-to-treat approach, and all participants were analyzed according to the original group assignment. Missing data were handled using multiple imputations by chained equations (MICE) [38]. Besides, subgroup analysis was conducted following per protocal analyses in this study.

All the data in this study was analyzed using IBM SPSS 23.0. Demographic data are presented as means (standard deviation) and numbers (percentage). Descriptive statistics, independent sample t-tests, and Chi-squared tests were used to analyze participant characteristics. The normality of distribution for all data was tested by an independent sample t-test. The results of this study are presented as mean, standard deviation (SD), and 95% confidence interval (CI). The statistical analysis was conducted by a researcher who was blinded and not involved in this study.

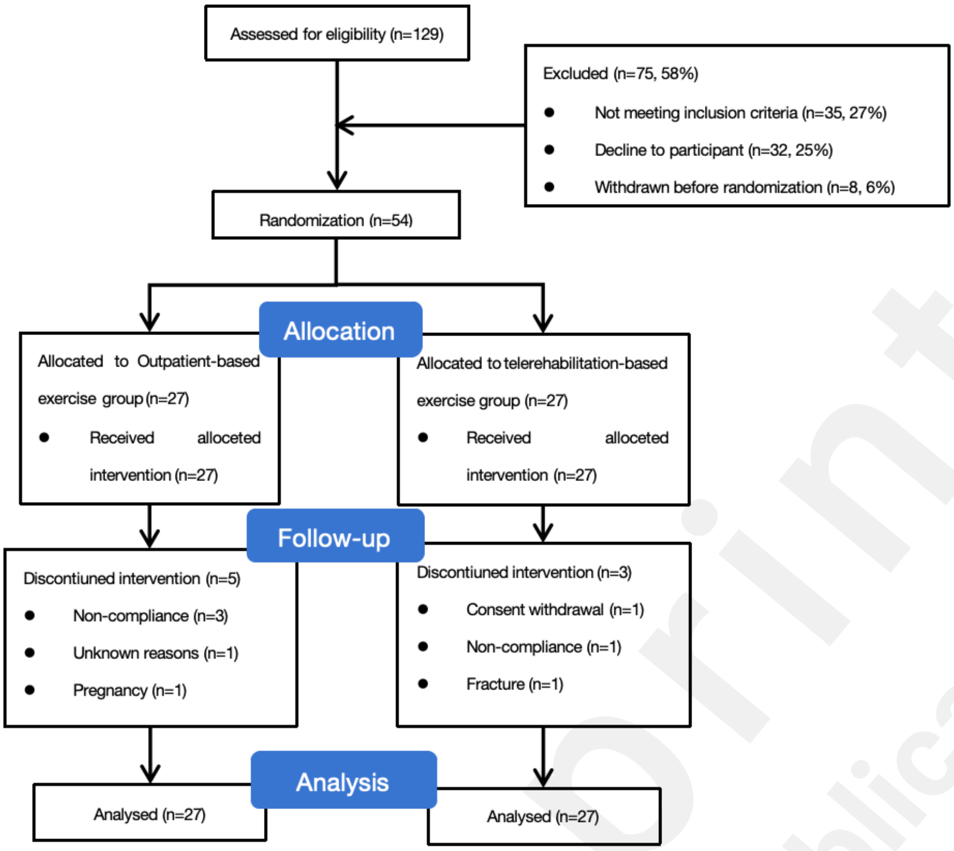
Results

Study population and Follow-up

Between March 9th, 2023 and November 1st, 2023, 129 patients were considered for eligibility. During the initial screening process, 35 patients did not meet the inclusion criteria or met the exclusion criteria. Among the remaining 94 eligible patients, 32 did not consent, and 8 patients withdrew prior to group randomization. Therefore, a total of 54 patients left for the final study. The population was randomly allocated into two groups: TBEG (n = 27) and OBEG (n = 27), as illustrated in Figure 2.

All patients completed the baseline assessment at week 0 and were asked to complete assessments at weeks 2, 4, and 8. All participants underwent baseline assessments. During the study, 3 patients in the TBEG group and 5 patients in the OBEG group withdrew due to pregnancy or other reasons. Ultimately, 24 patients in the TBEG group and 22 patients in the OBEG group completed all treatments and the 8-week follow-up.The completion rates for treatment and assessments in the OBEG group were as follows: 96.30% (26/27) at 2 weeks, 92.59% (25/27) at 4 weeks, and 81.48% (22/27) at 8 weeks. In comparison, the completion rates in the TBEG group were 100% (27/27) at 2 weeks, 96.30% (26/27) at 4 weeks, and 88.89% (24/27) at 8 weeks, as illustrated in Figure 2.

Figure 2. Participant flowchart



Between the two groups, patients showed similar clinical and demographic characteristics (see Table 1).

Table 2. Demographics and baseline characteristics of all participants.

Characteristics		OBEG[a] (n=27) Mean (SD)	TBEG[b] (n=27) Mean (SD)	*P* value
Age (years), mean (SD)		38.23 (11.55)	39.11 (10.45)	.772
Height (m), mean (SD)		1.69 (1.07)	1.65 (0.08)	.083
Weight (kg), mean (SD)		63.96 (9.89)	61.85 (10.50)	.461
Body Mass Index (kg/m²), mean (SD)		22.39 (3.19)	22.57 (2.98)	0.832
Sex,n (%)				.406
	Male	12 (57)	9 (43)	
	Female	14 (44)	18 (56)	
Sedentary time per day		6.69 (2.35)	7.08 (2.73)	.588
Pain duration (mouths), mean (SD)		10.23 (3.57)	10.11 (3.56)	.903
ODI[c]		18.80(6.57)	20.86 (11.40)	.214

NPRS[d]		5.02 (1.74)	5.42 (3.82)	.269
FABQ[e]		46.47 (14.36	41.32 (10.60	.232
SF-36[f]				
	Physical Functioning	61.85 (12.57)	60.96□2.54)	.868
	Role-Physical	45.37 (6.71)	46.15 (7.88)	.939
	Bodily-Pain	58.52 (17.26)	55.00 (20.45)	.501
	General Health	49.63 (16.35)	46.92 (13.12)	.510
	Vitality	73.70 (12.76)	72.50 (15.44)	.758
	Social Functioning	80.96 (16.20)	78.08 (18.45)	.549
	Role-Emotional	69.33 (2.25)	56.81 (2.83)	.278
	Mental health	66.30 (15.54)	72.73(15.87)	.142

[a]OBEG: Outpatient-based exercise Group
[b]TBEG: Telerehabilitation-based exercise Group
[c]ODI: Oswestry Disability Index
[d]NPRS: Numerical Pain Rating Scale
[e]FABQ: Fear-avoidance belief questionnaire
[f]SF-36: 36-item Short-Form Health Survey

Primary Outcomes

The baseline ODI scores showed comparable values between the TBEG and the OBEG . The mean ODI improvement for the OBEG was –4.70 (SD 9.20) at week 2, –8.40 (SD 10.13) at week 4, and –13.15 (SD 8.48) at week 8. The mean ODI improvement for the TBEG was –5.61 (SD 7.30) at week 2, –11.43 (SD 8.83) at week 4, and –13.70 (SD 7.30) at week 8. After 8 weeks of intervention, both the OBEG and TBEG groups demonstrated an improvement in ODI scores exceeding 10 points, indicating clinical significance.

At the 2nd week, the difference in ODI score changes between the TBEG and OBEG groups was 0.41 (95% CI -0.58 to 1.39); at the 4th week, the difference was -3.80 (95% CI -9.86 to 2.25); and at the 8th week, the difference was -3.24 (95% CI -8.65 to 2.17). Statistical analysis revealed no significant differences between the TBEG and OBEG groups at weeks 0, 2, 4, and 8 (see Figure 3). Following the 8-week intervention, the improvement in ODI scores in the TBEG group was non-inferior to that in the OBEG group.

Secondary Outcomes

The baseline NPRS scores showed comparable values between the TBEG and the OBEG. Statistical analysis found no significant differences between values for the TBEG and the OBEG at weeks 0, 2, 4, and 8(see table 2). At week 8, the NPRS improvement from baseline was -4.65 (SD 2.01) in OBEG and -4.65 (SD 2.01) in TBEG (see Figure 3).

The baseline FABQ scores showed comparable values between the TBEG and the OBEG. Statistical analysis found no significant differences between the values for the TBEG and the OBEG at weeks

0, 2, 4, and 8 (see table 2). At week 8, the improvement in FABQ scores from baseline was -40.15 (SD 13.38) in OBEG and -32.48 (SD 15.07) in TBEG(see Figure 3).

No statistically significant differences were found in the mean change of the SF-36 scores at weeks 0, 2, 4, and 8 (see table 2).

After an 8-week intervention, the NPRS, FABQ, and SF-36scores in both the Traditional Brace Exercise Group (TBEG) and the Optimized Brace Exercise Group (OBEG) showed significant improvement compared to baseline values. Furthermore, the extent of improvement in NPRS, FABQ, and SF-36 scores in the TBEG was found to be non-inferior to that observed in the OBEG.

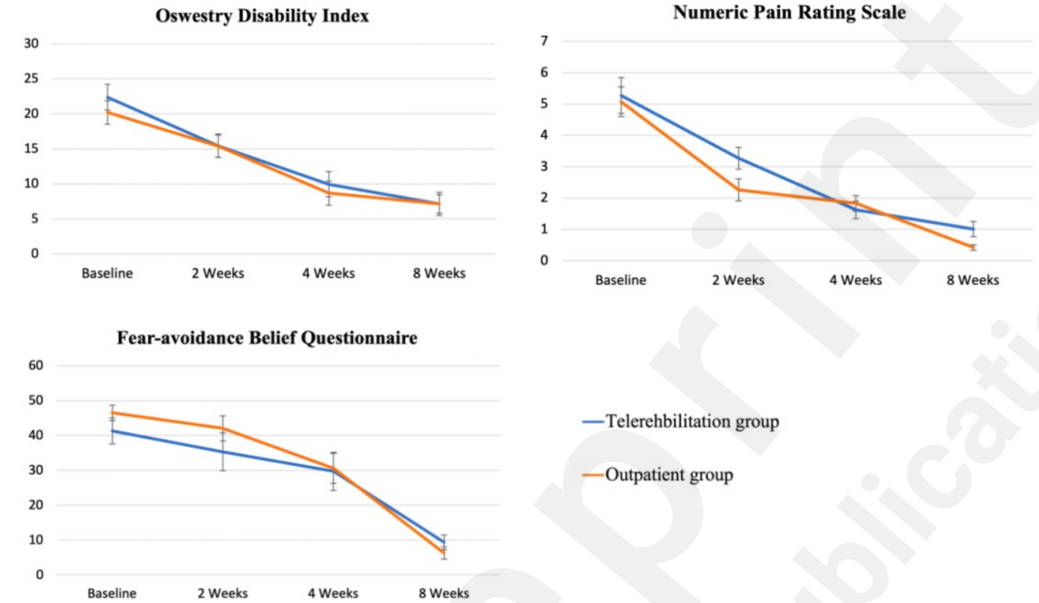


Figure 3. The primary and secondary outcomes ODI, NPRS, and FABQ at baseline and 2, 4, and 8 weeks; Error bars represent 95% confidence intervals.

Table 3. Primary and secondary outcomes for the OBEG and the TBEG.

	Two weeks			Four weeks			Eight weeks		
	OBEG[a] Mean (SD) (n=27)	TBEG[b] Mean (SD) (n=27)	Difference of Change between two groups Mean (95%CI)	OBEG[a] Mean (SD) (n=27)	TBEG[b] Mean (SD) (n=27)	Difference of Change between two groups Mean (95%CI)	OBEG[a] Mean (SD) (n=27)	TBEG[b] Mean (SD) (n=27)	Difference of Change between two groups Mean (95%CI)
Primary Outcome									
ODI[c]	-4.70 (9.20)	-5.61 (7.30)	-0.91 (-5.96 to 4.14) P=.718	-9.93 (10.13)	-13.73 (8.83)	-3.80 (-9.86 to -2.25) P=.213	-13.18 (8.48)	-16.42 (7.30)	-3.24 (-8.65 to 2.17) P=.235
Secondary Outcomes									
NPRS[d]	-2.41 (1.95)	-2.00 (1.60)	0.41 (-0.58 to 1.39) P=.410	-3.44 (2.38)	-3.65 (3.77)	-0.21 (-1.94 to 1.52) P=.809	-4.26 (3.90)	-4.65 (2.01)	-0.39 (-2.10 to 1.31) P=.642
FABQ[e]	-4.42 (17.51)	-6.00 (16.21)	-1.58 (-11.03 to 7.88) P=.739	-15.91 (17.87)	-11.60 (16.98)	4.31 (-7.60 to 16.22) P=.470	-40.15 (13.38)	-31.92 (15.07)	8.88 (-2.29 to 20.06) P=.116
SF-36[f]									
Physical Functioning	10.50 (16.75)	13.64 (23.31)	3.14 (-9.51 to	13.26 (15.99)	12.20 (24.72)	-1.06 (-13.05 to	16.35 (16.62)	15.38 (27.81)	-0.96 (-13.60 to

			15.78) *P*=.619			10.92) *P*=.590			11.67) *P*=.879
Role-Physical	5.00 (32.87)	13.86 (41.89)	8.86 (-14.52 to 32.25) *P*=.448	19.06 (34.12)	13.64 (40.21)	-6.62 (-28.57 to 15.34) *P*=.547	19.69 (38.96)	17.27 (47.50)	-0.96 (-25.30 to 23.38) *P*=.937
Bodily-Pain	14.71 (21.47)	12.27 (20.45)	-1.73 (-14.61 to 11.15) *P*=.788	16.30 (21.54)	19.00 (26.03)	2.70 (-12.01 to 17.40) *P*=.714	25.00 (15.48)	20.77 (26.84)	-4.23 (-16.84 to 8.38) *P*=.504
General Health	9.50 (11.95)	9.32 (14.33)	-0.18 (-8.24 to 7.88) *P*=.964	13.26 (16.04)	12.80 (14.77)	-0.46 (-9.22 to 8.30) *P*=.916	12.88 (17.06)	12.50 (11.62)	-0.38 (-8.69 to 7.92) *P*=.926
Vitality	7.40 (15.50)	4.32 (15.83)	-3.08 (-12.81 to 6.64) *P*=.526	11.30 (14.71)	6.00 (15.88)	-5.30 (-15.70 to 5.10) *P*=.310	13.75 (11.23)	10.00 (12.97)	-1.54 (-9.26 to 6.18) *P*=.691
Social Functioning	3.94 (22.00)	9.59 (19.30)	5.66 (-7.11 to 18.42) *P*=.376	9.39 (22.21)	10.80 (16.06)	1.41 (-10.04 to 12.85) *P*=.805	14.09 (17.60)	9.39 (21.81)	-4.70 (-15.37 to 5.98) *P*=.381
Role-Emotional	10.35 (14.28)	17.67 (24.08)	7.32 (-17.38 to 32.02) *P*=.553	32.92 (38.33)	26.47 (18.23)	6.44 (-20.68 to 33.56) *P*=.644	22.92 (15.53)	30.38 (29.76)	7.46 (-17.67 to 32.59) *P*=.554
Mental health	7.15 (16.09)	0.95 (15.03)	-6.20 (-16.41 to 4.02) *P*=.227	23.35 (14.41)	6.44 (23.88)	-6.91 (-19.94 to 3.01) *P*=.012	14.46 (17.28)	6.50 (15.77)	-7.96 (-17.53 to 1.06) *P*=.101

[a]OBEG: Outpatient-based exercise Group
[b]TBEG: Telerehabilitation-based exercise Group
[c]ODI: Oswestry Disability Index
[d]NPRS: Numerical Pain Rating Scale
[e]FABQ: Fear-avoidance belief questionnaire
[f]SF-36: 36-item Short-Form Health Survey

Subgroup Analysis

After an 8-week intervention, both the OBEG group and the TBEG group demonstrated clinically significant improvements in ODI, with a reduction exceeding 10 points, and no statistical differences was found in the changes of ODI between two groups, demonstrating non-inferiority. (see Table 4).

Table 4 Subgroup analysis of primary and secondary outcomes for the OBEG and the TBEG.

	Two weeks			Four weeks			Eight weeks		
	OBEG[a] Mean (SD) (n=26)	TBEG[b] Mean (SD) (n=27)	Difference of Change between two groups Mean (95%CI)	OBEG[a] Mean (SD) (n=25)	TBEG[b] Mean (SD) (n=26)	Difference of Change between two groups Mean (95%CI)	OBEG[a] Mean (SD) (n=22)	TBEG[b] Mean (SD) (n=24)	Difference of Change between two groups Mean (95%CI)
Primary Outcome									
ODI[c]	-5.11 (9.26)	-5.61 (7.30)	-0.50 (-5.63 to 4.63) *P*=.844	-9.76 (8.54)	-14.16 (12.14)	-4.40 (-10.37 to -2.25) *P*=.145	-12.77 (7.)	-17.48 (11.55)	-4.71 (-10.49 to 1.08) *P*=.108
Secondary Outcomes									
NPRS[d]	-2.42 (1.98)	-2.00 (1.60)	0.42 (-0.58 to 1.43) *P*=.401	-3.40 (2.31)	-3.72 (3.84)	-0.32 (-2.12 to 1.52) *P*=.722	-4.27 (1.78)	-4.87 (4.09)	-0.60 (-2.51 to 1.32) *P*=.533

FABQ[e]	-4.72 (17.81)	-6.00 (16.21)	-1.28 (-10.91 to 8.35) *P*=.790	-15.38 (19.94)	-12.54 (20.64)	2.84 (-9.40 to 15.08) *P*=.642	-41.90 (24.10)	-30.91 (15.27)	10.99 (-1.17 to 23.16) *P*=.075
SF-36[f]									
Physical Functioning	11.05 (16.63)	13.64 (23.31)	2.58 (-10.36 to 15.53) *P*=.689	11.90 (14.87)	11.88 (24.93)	-0.03 (-12.60 to 12.54) *P*=.996	14.05 (13.29)	16.09 (29.62)	2.04 (-12.16 to 16.24) *P*=0.773
Role-Physical	5.79 (32.50)	13.86 (41.89)	8.07 (-15.90 to 32.05) *P*=0.500	23.57 (35.25)	18.13 (41.49)	-5.45 (-28.78 to 17.88) *P*=0.640	22.14 (38.03)	23.70 (49.78)	1.55 (-25.60 to 28.70) *P*=.909
Bodily-Pain	13.68 (21.33)	12.27 (20.45)	-1.41 (-14.63 to 11.81) *P*=0.830	15.48 (21.54)	20.21 (27.84)	4.73 (-10.40 to 19.87) *P*=0.532	23.81 (16.58)	20.87 (29.53)	-2.94 (-17.70 to 11.82) *P*=0.690
General Health	10.00 (11.18)	9.32 (14.33)	-0.68 (-8.90 to 7.53) *P*=.868	12.62 (14.97)	13.75 (5.13)	1.13 (-7.94 to 10.20) *P*=.803	12.38 (17.57)	12.83 (12.31)	0.45 (-8.87 to 9.76) *P*=.921
Vitality	8.31 (15.50)	4.32 (15.83)	-4.00 (-13.82 to 5.83) *P*=.416	11.19 (15.48)	5.00 (19.78)	-6.19 (-16.98 to 4.60) *P*=.254	12.86 (12.41)	13.70 (15.54)	0.84 (-7.77 to 9.45) *P*=.845
Social Functioning	4.15 (22.)	9.59 (19.30)	5.45 (-7.66 to 18.56) *P*=.406	6.57 (17.97)	11.25 (19.51)	4.67 (-6.60 to 15.94) *P*=.410	11.42 (15.15)	9.16 (23.16)	-2.26 (-14.30 to 9.77) *P*=.706
Role-Emotional	10.89 (14.69)	17.67 (24.08)	6.77 (-18.58 to 32.13) *P*=.592	24.24 (43.56)	31.50 (50.69)	7.26 (-21.36 to 35.89) *P*=.612	22.00 (36.98)	30.00 (55.03)	8.00 (-20.81 to 36.81) *P*=.578
Mental health	7.32 (18.19)	0.95 (15.03)	-6.36 (-16.85 to 4.13) *P*=.231	23.67 (17.28)	15.79 (17.38)	-7.88 (-18.32 to 2.57) *P*=.136	15.81 (14.18)	8.77 (18.96)	-7.04 (-17.39 to 3.31) *P*=.177

[a]OBEG: Outpatient-based exercise Group
[b]TBEG: Telerehabilitation-based exercise Group
[c]ODI: Oswestry Disability Index
[d]NPRS: Numerical Pain Rating Scale
[e]FABQ: Fear-avoidance belief questionnaire
[f]SF-36: 36-item Short-Form Health Survey

Discussion

Principal Findings

This study is designed to determine the efficacy of the treatment between the TBEG and the OBEG. After 8-week intervention, the completion rate was 88.89% in the TBEG and 81.48% in the OBEG. The completion rate of exercise was higher in the Tele-rehabilitation-Based Exercise Group (TBEG) compared to the Outpatient-Based Exercise Group (OBEG). In the primary outcomes, there was no statistically significant difference between the TBEG and OBEG groups in improving pain-related physical dysfunction, demonstrating non-inferiority of the telerehabilitation. However, both groups demonstrated an improvement in the Oswestry Disability Index (ODI) score exceeding 10 points, indicating that both tele-rehabilitation exercises and outpatient exercises have clinical significance in improving ODI for patients with non-specific low back pain (NLBP). Regarding secondary outcomes, there were no statistically significant differences in the Short Form-36 (SF-36), Numeric

Pain Rating Scale (NPRS), and Fear-Avoidance Beliefs Questionnaire (FABQ) between the groups, the improvements in SF-36, NPRS, and FABQ surpassed the Minimal Clinically Important Difference (MCID). This suggests that both TBEG and OBEG interventions have clinical significance in pain relief, reduction in fear-avoidance beliefs, and enhancement of quality of life following an 8-week intervention with similar efficacy.

The Efficacy and Benefits of Telerehabilitation for NLBP Patients

As compared with previous studies [39-41], this study also demonstrates the efficacy of telerehabilitation for patients with NLBP in the improvement of pain intensity, physical disability and life of quality.

Additionally, we also found that exercise helped patients in both groups to reduce the impact of pain-related fear on work and daily activity after 8-week intervention. Figure 2, which visually presents the data, indicates significant improvements in both NPRS and ODI by week 4. Moreover, the FABQ demonstrates a noticeable reduction by week 8, suggesting a delayed improvement in patients' psychological fear.

Exercise is an important and widely accepted treatment for patients with NLBP [42] [[42],32]. To achieve the expected results, it is crucial for patients to consistently follow a prescribed exercise plan for an extended time. However, a study by Palazzo C et al. found that NLBP patients face challenges in adhering to home-based exercises [[12]2]. These challenges include factors such as remote locations, difficulties in the exercise program, the patient's attitude toward exercise, and the lack of supervision and follow-up outside of the hospital. Altogether, these factors reduce the effectiveness of the treatment [11,12].

Hence, we have introduced a telerehabilitation system using a smartphone application combined with sensors. This system is designed to offer better monitoring and follow-up beyond usual care. The exercise plan includes stretching and strength exercises, which have been shown to reduce pain and improve physical function [44-46]. The smartphone application uses visual and audio content to enhance patient experience.

Furthermore, the telerehabilitation system allows patients to receive prompt guidance from PTs. PTs can monitor the real-time physical functional status and exercise progression of patients. The exercise routines span over 8 weeks, with sessions occurring every 2 days, 3 times per week. In contrast to patients in the OBEG who need to schedule appointments with PTs in clinic, those in the TBEG can complete their exercises at home.

In contrast to OBEG, patients with non-specific low back pain (NLBP) in TBEG exhibited greater flexibility in their exercise scheduling. Within the scope of this study, they consistently adhered to their exercise regimens in a timely manner, which contributed to improved compliance with exercise plans and benefited NLBP patients. Moreover, the exercise model based on remote rehabilitation can help individuals save more time and expenses related to hospital visits, offering greater convenience compared to outpatient-based exercise models. Simultaneously, the remote rehabilitation-based exercise model provides NLBP patients with the opportunity to receive qualified exercise guidance. Lastly, this remote rehabilitation-based exercise model alleviates the burden on healthcare institutions and reduces treatment costs.

Telerehabilitation system enables patients with NLBP adhere to their treatment plans and allows them to manage their health at home with remote supervision. In long-term follow-ups, Hou et al.

found that patients using telerehabilitation showed more improvement in functional limitations compared to those relying on traditional in clinic method [Error: Reference source not found]. This is especially promising in areas lacking medical accessibility.

Limitations

This study was conducted at one medical center to compare telerehabilitation with traditional onsite rehabilitation for patients with NLBP. A total of 54 patients participaited in the trial, with 27 in the TBEG and 27 in the OBEG. The exercise routines spans over 8 weeks, and assessments were scheduled at weeks 0, 2, 4, and 8.

This is a single-center randomized controlled trial with a relatively small sample size. To address this limitation, the research team plans to conduct subsequent multi-center randomized controlled trials in regions with limited medical resources where NLBP (Non-Specific Low Back Pain) patients have difficulty accessing professional exercise guidance. Additionally, due to the relatively short follow-up period, future studies will involve more participants to investigate the effects of remote rehabilitation-based exercise interventions on NLBP patients over six months, one year, or even longer durations [47], focusing on adherence, pain relief, and improvement in pain-related physical dysfunction.

This study demonstrates that remote rehabilitation-based exercise training has therapeutic effects on pain relief and improvement in pain-related physical dysfunction in NLBP patients. However, there is currently limited research analyzing the factors influencing the efficacy of remote rehabilitation in NLBP patients, and it remains unclear which types of NLBP patients are more suitable for remote rehabilitation treatment.

Furthermore, the research team plan to validate the effectiveness of the telerehabilitation program through a multi-center clinical trial. These future efforts are designed to study the benefits of telerehabilitation in managing NLBP, providing valuable insights to the medical community.

Conclusion

This study confirms that telerehabilitation and traditional outpatient rehabilitation method produce comparable outcomes for patients with NLBP. Additionally, telerehabilitation reduces time, cost and medical resources. It exhibits potential as an alternative for patients lacking access to high-quality rehabilitation services.

Author contributions

The inception of the study was facilitated through the collaborative efforts of Yanyan Bian, Lixia Chen and Wangshu Yuan. Ye Lin, Yuhang Zhang and Weihong Shi undertook the experimental procedures and were responsible for the composition of the manuscript. Substantial contributions to the analysis and preparation of the manuscript were made by Di Liu, Houqiang Zhang and Huiling Zhang. Qiyang Feng executed the data analyses, and Yuying Yang played a crucial role in the analytical process through constructive discussions.

Multimedia Appendix 1

The detailed plan of exercise program

Research Funding

National High-Level Hospital Clinical Research Funding (2022-PUMCH-B-053)

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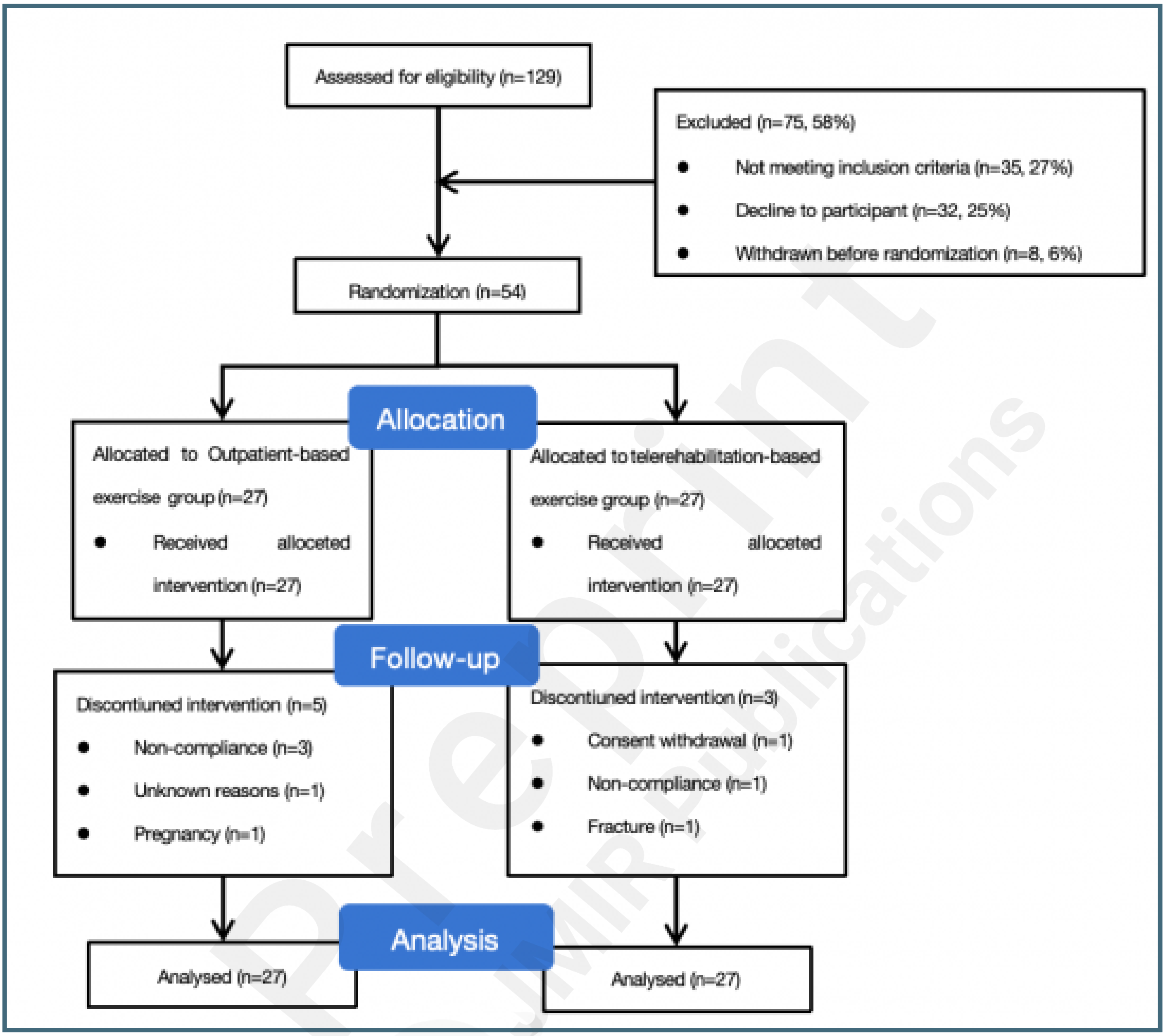
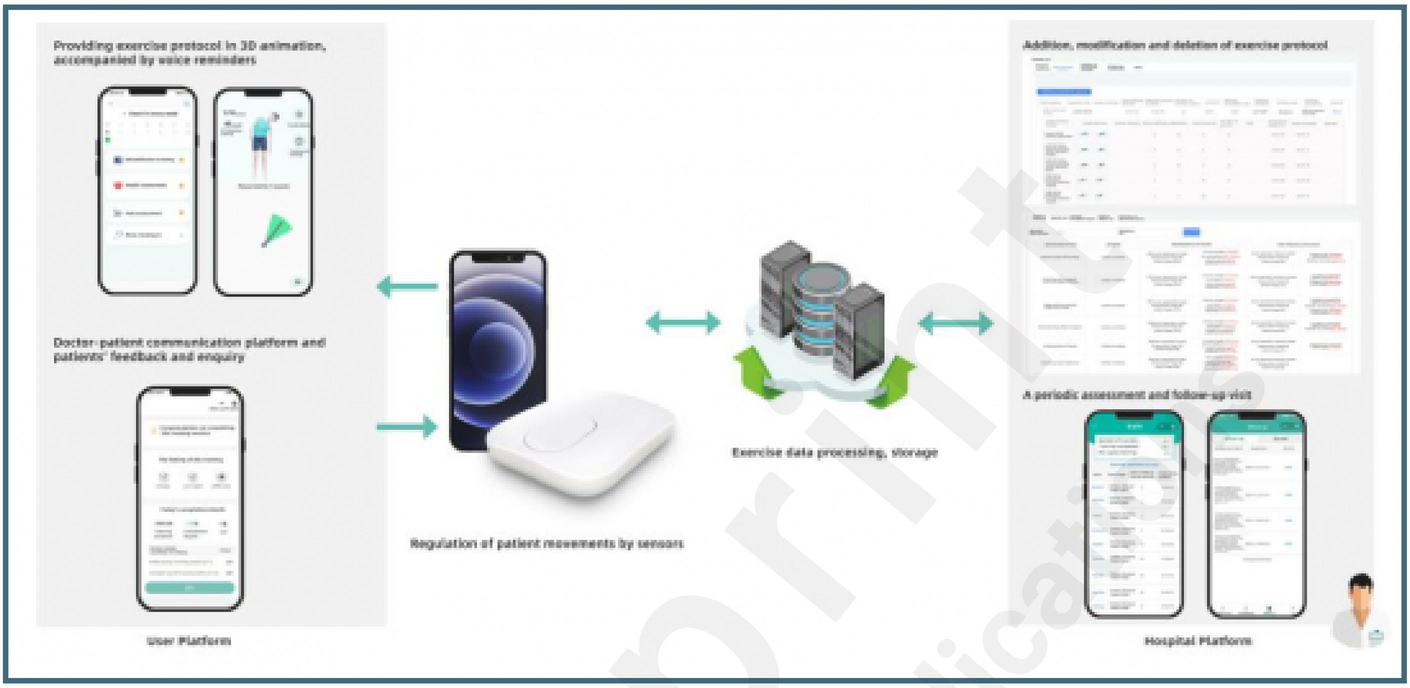
Supplementary Files

Untitled.

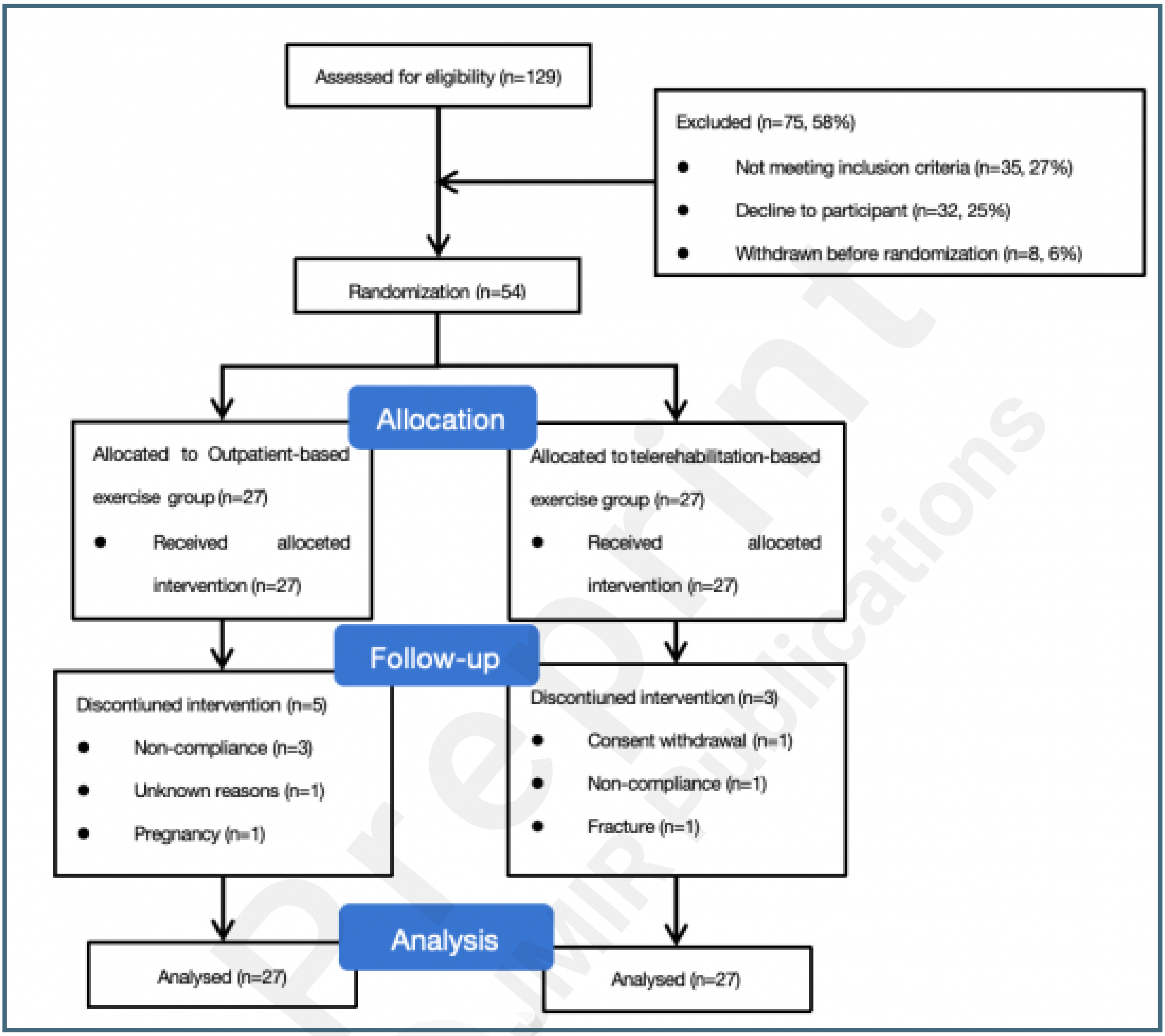

Assessed for eligibility (n=129)
Excluded (n=75, 58%)
Not meeting inclusion criteria (n=35, 27%)
Decline to participant (n=32, 25%)
Withdrawn before randomization (n=8, 6%)
Randomization (n=54)
Allocation
Allocated to Outpatient-based exercise group (n=27)
Received allocated intervention (n=27)
Allocated to telerehabilitation-based exercise group (n=27)
Received allocated intervention (n=27)
Follow-up
Discontiuned intervention (n=5)
Non-compliance (n=3)
Unknown reasons (n=1)
Pregnancy (n=1)
Discontiuned intervention (n=3)
Consent withdrawal (n=1)
Non-compliance (n=1)
Fracture (n=1)
Analysis
Analysed (n=27)
Analysed (n=27)

Figures

illustrates the three different parts of the HIRS. The doctor's portal could be used to create and modify exercises, to monitor training progress, and to view patient data. The patients could use the user's portal to complete the prescribed exercises, view educational materials, and to provide feedbacks to the PTs. Finally, the transmitter portal encrypts and transmits the data collected, ensuring the overall system's integrity.

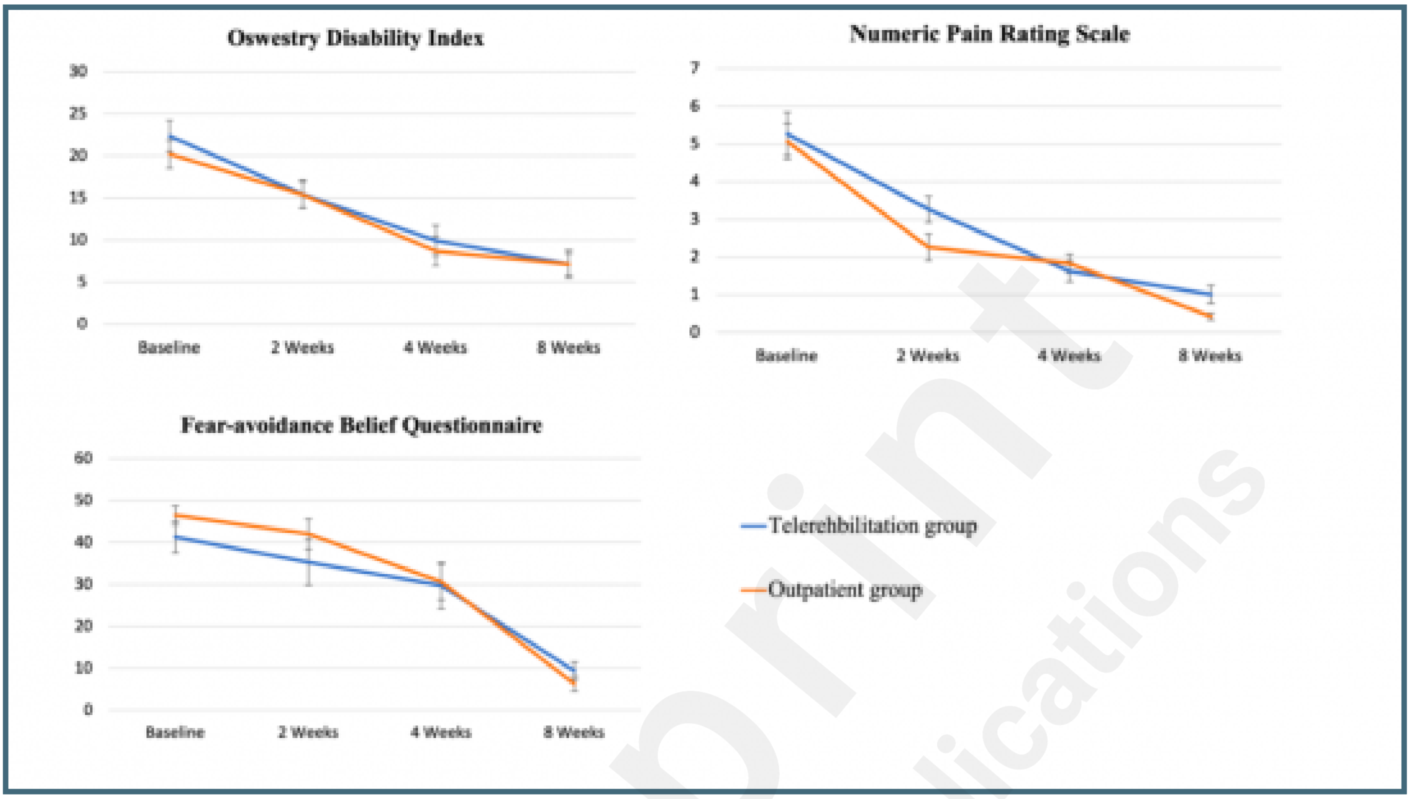


Untitled.



Assessed for eligibility (n=129)
Excluded (n=75, 58%)
Not meeting inclusion criteria (n=35, 27%)
Decline to participant (n=32, 25%)
Withdrawn before randomization (n=8, 6%)
Randomization (n=54)
Allocation
Allocated to Outpatient-based exercise group (n=27)
Received allocated intervention (n=27)
Allocated to telerehabilitation-based exercise group (n=27)
Received allocated intervention (n=27)
Follow-up
Discontiuned intervention (n=5)
Non-compliance (n=3)
Unknown reasons (n=1)
Pregnancy (n=1)
Discontiuned intervention (n=3)
Consent withdrawal (n=1)
Non-compliance (n=1)
Fracture (n=1)
Analysis
Analysed (n=27)
Analysed (n=27)

The primary and secondary outcomes ODI, NPRS, and FABQ at baseline and 2, 4, and 8 weeks; Error bars represent 95% confidence intervals.



Multimedia Appendixes

LBP Romote Home-Based Exercise Protocol.
URL: http://asset.jmir.pub/assets/d4560dfb990e19559569a073ee2bb9da.docx

CONSORT (or other) checklists

Untitled.
URL: http://asset.jmir.pub/assets/6ef489dd17f070076bf2c8ca1beaec4b.pdf

Untitled.
URL: http://asset.jmir.pub/assets/1fc92128bd7d4a5e65b1687e059ac467.pdf