

## Research Article



# Investigating the Effectiveness of Home-Based Exercise Therapy on Quality of Life and Depression in Orthotopic Liver Transplantation Recipients

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**ABSTRACT**

**Introduction:** Liver transplantation can change the quality of life, physical activity, mood, and psychological symptoms in patients. Considering that exercise capacity is correlated to the level of depression and quality of life among patients, this study investigates the effect of exercise therapy on the quality of life and depression in orthotopic liver transplantation recipients (LTRs).

**Materials and Methods:** This was a single-blinded study with randomized controlled trial parallel groups, and 30 LTRs were randomly assigned in a 1:1 ratio. The experimental group underwent a three-month home-based exercise therapy, while the control group received no exercise therapy. Assessments included short-form-36 and the Beck depression questionnaires, along with the 6-min walk test.

**Results:** There was no significant difference between groups in demographic characteristics. Before the intervention, the mean scores of depression in the intervention and control groups were  $27.87 \pm 8.68$  and  $25.77 \pm 6.77$ , respectively. After the intervention, t-test revealed a significant difference between the two groups ( $P=0.001$ ). The results of the t-test indicated that the average quality of life dimensions improved post-intervention compared to the control group, with significant differences in the scores of these dimensions. After the intervention, the t-test showed a significant difference between the two groups in terms of the 6-min walk test ( $P=0.001$ ).

**Conclusion:** Rehabilitation through prescribed exercise can improve quality of life and physical activity, and alleviate depression symptoms in LTRs. As a result, incorporating physiotherapy into the post-transplantation care of transplant recipients holds potential benefits.

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## Introduction

One of the most crucial treatments for people with end-stage liver disease is liver transplantation [1]. Both pediatric and adult populations need liver transplants for various reasons, including alcoholic or non-alcoholic fatty liver disease, cryptogenic disease, and viral illnesses leading to cirrhosis [2]. Between 2010 and 2014, liver disease and hepatocellular carcinoma associated with hepatitis C (HCV) were the predominant cause of liver transplantation [3]. The primary aim of liver transplantation is to reduce mortality rates and improve patient's quality of life and life expectancy [4]. Current articles focus on elevating the short-term survival rate after liver transplantation, which is currently greater than 80%. Patients' life expectancy also increases after liver transplantation [5]. Despite its efficacy in reducing disease and mortality, liver transplantation comes with substantial postoperative complications, including pulmonary issues, fluid imbalances, digestive challenges, and psychological disorders [6, 7]. Underlying diseases, individual factors, surgery-related factors, and the quality of post-operation care may contribute to the development of disease complications [6, 7].

Extended longevity due to orthotopic liver transplantation (OLT) has increased the incidence of numerous issues and illnesses including chronic fatigue, irritability, and social isolation [6], possibly leading to a gradual decline in health-related quality of life (HRQoL) [8]. One-year and five-year survival rates for patients with liver transplants are currently 90% and 70%, respectively, and even for specific conditions such as chronic obstructive liver diseases, the survival rate is higher [9]. The increase in graft survival in patients with liver transplants has shifted the focus of patient care and clinical effectiveness research to the quality of life of the patients and their caregivers [10].

Before OLT, patients typically experience a decline in physical function impacting their daily activities and social engagement [11]. The majority of mental and physical aspects of HRQoL improve during the first six months after a liver transplant, but this improvement is short-lived [12, 13]. One year after a liver transplant, the mental and emotional HRQoL begins to decline [14]. Significant tests measuring the quality of life and physical activity indicate that the score of patients who have received liver transplants is lower than average. Some patients who undergo liver transplantation may experience a complete improvement in their health, but physical and social issues may persist [15].

Examining the quality of life and psychological support of transplant patients reveals a significant increase in the patients' overall quality of life. About 34% of transplant recipients experience psychological symptoms, with anxiety and depression symptoms being the most prevalent in the first two years after transplantation and also persisting in the long term [16]. After transplantation, depression, difficulty returning to work, low income, and loss of abilities are among the most common issues that patients face [17]. A rehabilitation program based on exercise training and physical activity counseling is well tolerated and appears promising for reducing fatigue and improving fitness among LTRs. Rehabilitation involving supervised exercise training and daily physical activity counseling can improve daily functioning, participation, and HRQoL among LTRs [18, 19]. Accordingly, this study evaluates the efficacy of a home-based, exercise therapy program on the quality of life and depression in post-transplant recipients. This study is conducted due to the increasing survival rates of LTRs in Iran and the scarcity of trial studies demonstrating the efficacy of rehabilitation programs to improve patients' quality of life and depression.

## Materials and Methods

The design of this original study was a single-blinded, randomized controlled trial with parallel groups. This research aimed to determine the effect of physical rehabilitation on the quality of life of liver transplant recipients.

### Study participants

A total of 309 people underwent liver transplantation in this study. The inclusion criteria were being in the age range of 18 to 65 years and having a minimum of 6 months post-liver transplant. In addition, the exclusion criteria were having more than one organ transplant, having had serious comorbidities (e.g. cancer or recurrent cholangitis), having contraindications for exercise (e.g. severe cardiac disease prohibited from exercise), having required specialized care, and reluctance to participate due to concerns about transplant rejection and consequences.

### Study procedure

The research was carried out at the liver transplantation center of Tehran University of Medical Sciences located in Imam Khomeini Hospital Complex. This center is a known referral liver transplantation center in Iran. Relevant patients from various points of the country are referred to this center; hence, sampling at this center can

cover different types of patients considering culture, level of education, type of disease, etc. All participants were enrolled between May 2017 and February 2018 after receiving approval from the Institutional Review Board and Ethics Committee of Tehran University of Medical Sciences. All participants in the study were provided with sufficient information on how the project would be conducted, and their written consent was obtained. The study included comprehensive cardiac examinations for all participants to determine their capacity for moderate physical activity. At the beginning of the study, participants completed the 36-item short form survey (SF-36) form, the Beck depression questionnaire (BDI), and the 6-min walk test (6MWT). The participants were then allocated into two groups (intervention and control groups) using block balanced randomization method (block size = 4). The patients in the intervention group underwent a comprehensive musculoskeletal examination under the supervision of a physiotherapist (a PhD. candidate with three years of experience in the field of OLT), and in the case of any musculoskeletal disorders, they were evaluated accordingly. If the patient required specialized care, he was excluded from the study. Meanwhile, the remaining patients were enrolled in a three-month exercise program aimed at improving muscle strength and fitness. The participants were then evaluated for the second time after a three-month intervention.

### Study intervention

The protocol for the patients in the intervention group was to perform specific body exercises, first isometric and then progressive resistive exercises (PRE) (details and images are in the supplementary). The patients were instructed in such a way that the neck, back, hip, knee, and ankle exercises were initially isometric, and after two weeks they progressed to PRE and were gradually completed by the second month (Table 1). The patients then commenced aerobic exercise, starting with 20 min of walking three times per week and gradually increasing it to 45 min within a month. The patients were in-

structed that the intensity of the activity should be between 13 and 15 on the Borg scale, and they could speak clearly during the activity. In case of dyspnea or chest pain, exercise was ceased and further evaluation was performed. The control group received the usual care, with both groups completing the SF-36 form and BDI, and repeating the 6MWT following the program. All exercises were instructed to the patients by an expert physiotherapist in the field of musculoskeletal disorders and solid organ transplantations. Patients were asked to perform exercises at their home. The patients enrolled in the intervention group were asked to perform exercises for three months. They could be in contact with the physiotherapist if they needed for any reason.

### Outcome measures

In this study, three different outcome measurement instruments were utilized: The SF-36, BDI, and 6MWT. All assessments were carried out by another physiotherapist (with a master's degree and familiarity with the solid organ transplantation field) who was blinded to treatments and the randomization process. All evaluations were carried out before and after (three months) interventions.

### Short-form-36 (SF-36)

The SF-36 test is the most commonly used test to assess the quality of life among LTRs. This test consists of 36 questions that assess eight aspects of health, divided into two categories: Physical health and mental health. Physical performance, physical role (limitations due to physical health), body pain, and general health are used to evaluate physical health on this scale. On the other hand, vitality, social functioning, emotional role (limitations due to emotional problems), and mental health are used to evaluate mental health. The score of each component ranges from 0 to 100. One advantage of this test is that it can be compared to the average scores of a wide variety of cultures and diseases. In 1993, this test was

**Table 1.** Details of interventions

Weeks	Plans
First	20 min of exercise consisting of 5 min of warm-up, 10 min of brisk walking, and 5 min of cool down
Second	25 min of exercise consisting of 5 min of warm-up, 15 min of brisk walking, and 5 min of cool down
Third	Exercise consists of 35 min, including 10 min of warm-up, 15 min of brisk walking, and 10 min of cool down
Sixth	45 min of exercise, including 10 min of warm-up, 25 min of brisk walking, and 10 min of cool down

used to investigate the quality of life in LTRs for the first time [20]. All score calculations were performed by the principal investigator of the diagnostic value of the Iranian version of the SF-36 questionnaire [21].

### Beck depression index (BDI)

The BDI measures depressive symptoms in adolescents and adults through 21 items measuring irritation, cognition, guilt, fatigue, weight loss, and sexual desire. This questionnaire evaluates seven somatic symptoms, some of which are common in recipients of liver transplants. After scoring each item between 0 and 3, the total score is compared to the reference score. In some studies, LTRs diagnosed with depression on this test received low scores in 7 out of 8 domains of SF-36. Depression symptoms based on the BDI are accompanied by reports of an inability to perform daily or professional tasks [22].

### 6-Minute walk test (6MWT)

6MWT is a straightforward and practical physical performance evaluation tool used to assess submaximal physical capacity. It is considered a better evaluation tool for functional performance tests compared to sports tests, as it provides an objective measure of exercise intensity. During this test, patients are asked to walk as far as possible in 6 min using a 15-point scale to assess the patient's perception of physical activity (they must stop if experience fatigue). The test is conducted in a specific, smooth, and flat corridor, with no assistance or additional encouragement for patients. Heart rate and blood pressure are also measured before and after the test [23].

### Data analysis

This study used the Shapiro-Wilks test to confirm the normal distribution of all corrected data. The data were consistent with a normal distribution, so parametric tests were chosen for this study. Using an independent t-test, the difference in demographic information and intervention was compared. The covariance test was conducted to determine the difference between the pre-test and post-test scores of the two groups. Analyses were conducted utilizing the SPSS software version 21 for Windows, with a significance level set at  $P < 0.05$ . The sample size of this study was calculated based on the results of the initial pilot study with five samples per group. Considering type I error of 0.05, and 80% power, a sample size of 12 participants per group was calculated. After considering the risk of loss to follow-up, 15 patients per group was considered as the final sample size.

## Results

The general characteristics of the participants are presented in Table 2, demonstrating no statistically significant differences between the intervention and control groups. In the intervention group, the mean age was  $42.47 \pm 9.27$  years, 43.3% of participants were female, and the mean body mass index was  $23.62 \pm 2.51$  kg/m<sup>2</sup>. Furthermore, the control group had a mean age of  $41.60 \pm 7.18$  years and a mean body mass index of  $23.27 \pm 1.63$  kg/m<sup>2</sup>. Time since transplantation in the intervention and control groups were 1, 4 and 1, 47 days, respectively.

### The effect of physical rehabilitation on depressive symptoms

Before the intervention, the mean depression score in the intervention and control groups was  $27.87 \pm 8.68$  and  $25.77 \pm 6.77$ , respectively. After the intervention, a significant difference was observed between the two groups ( $P = 0.001$ ) (Table 3). Comparing data between the groups with baseline values as a covariable by covariance analysis revealed statistically significant differences in BDI-measured depression ( $P = 0.001$ ).

### The effect of physical rehabilitation on quality of life

Before the intervention, there was no significant difference between the quality-of-life dimensions ( $P > 0.05$ ). The results of the t-test showed that the average quality-of-life dimensions improved after the intervention compared to the control group, with a significant difference in the scores of the quality-of-life dimensions in the intervention group (Table 3). Comparing data between groups using baseline values as a covariable revealed significant differences in all quality-of-life variables except bodily pain and emotional role ( $P = 0.001$ ).

### The effect of physical rehabilitation on physical performance

The mean 6MWT score pre-intervention for the intervention and control groups was  $231.47 \pm 170.86$  and  $235.87 \pm 79.95$ , respectively. After the intervention, a significant difference was observed between the two groups ( $P = 0.001$ ) (Table 3). The average 6MWT scores after the intervention were  $522.73 \pm 265.95$  in the intervention group and  $284.54 \pm 109.14$  in the control group. Covariance analysis using baseline values showed statistically significant differences for the 6MWT ( $P = 0.001$ ).

**Table 2.** Demographics and clinical characteristics of participants

Characteristics		Mean±SD/ No.(%)		
		Total (n=30)	Physical Rehabilitation Group (n=15)	Control Group (n=15)
Age (y)		42.03±8.16	42.47±9.27	41.60±7.18
Sex	Male	17(56.7)	8(53.4)	9(60.0)
	Female	13(43.3)	7(46.6)	6(40.0)
Marital	Single	24(80.0)	11(73.4)	13(86.7)
	Married	6(20.0)	4(26.6)	2(13.3)
Height (cm)		173.63±9.53	172.87±10.52	174.40±8.74
Weight (kg)		70.93±9.97	70.80±10.85	71.07±9.40
BMI (kg/m <sup>2</sup> )		23.45±2.09	23.62±2.51	23.72±1.63
Time since transplant (y)		1.43±0.50	1.40±0.50	1.47±0.51
Diagnosis	Cryptogeni	11(36.7)	8(53.33)	3(20.0)
	HBV	4(13.30)	2(13.33)	2(13.33)
	Wilson's Disease	2(6.67)	1(6.67)	1(6.67)
	HCV	5(16.66)	0(0)	5(33.33)
	AIH	6(20.0)	4(26.67)	2(13.33)
	PBC	1(3.33)	0(0)	1(6.67)
	PCS	1(3.33)	0(0)	1(6.67)

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Abbreviations: HBV: Hepatitis B; SD: Standard deviation; BMI: Body mass index; HCV: Hepatitis C virus, AIH: Autoimmune hepatitis; PBC: Primary biliary cholangitis, PCS: Primary sclerosing cholangitis.

Notes: All of the participant's characteristics are statistically similar between groups based on t-test and chi-square test.

## Discussion

The findings of the present research highlight that implementing rehabilitation programs enhances the quality of life and alleviates depression symptoms in patients following liver transplantation. A study by Van Ginneken investigated the impact of a fatigue-reducing physical rehabilitation program on daily activity, HRQoL, anxiety, and depression in LTRs, in which improvements were observed in daily activity and quality of life after the treatment, but anxiety and depression remained unchanged. This trial included a 12-week rehabilitation program with supervised exercise training and daily physical activity counseling [19]. Similarly, Clarissa Bentes conducted a study one month after transplantation to determine the effect of rehabilitation on physical performance and quality of life in LTRs [24]. This study also discovered that rehabilitation improves the quality of life and physical performance of transplant recipients.

Physical activity increased the quality of life in LTRs, according to the findings of Valentina Totti's study [25]. This 12-month trial included physical and aerobic workouts performed under the supervision of a trainer. Tuba Yüksel Ergene's findings further supported that exercise therapy improved the physical performance of transplant recipients and that it can be employed in post-transplant physiotherapy [26].

Previous research found that general quality of life improved significantly after transplantation, compared to pre-transplantation health state [27-29]. In contrast, the vast majority of transplant patients have significant deficits in most dimensions of quality of life, compared to the general population. However, the findings of this study contradict the findings of other investigations, and we conclude that the notion of better quality of life following transplantation may be overestimated [27]. The main problem after liver transplantation is improving the

**Table 3.** Distribution of different outcomes according to two arms in addition to related effect sizes

Clinical Outcomes	Physical Rehabilitation Group (n=15)		Control Group (n=15)		P	MD
	Baseline	After	Baseline	After		
BDI	26.77±7.73	10.87±6.80	25.67±6.80	15.60±7.5	0.001	33.67 <sup>a</sup>
						291.26 <sup>b</sup>
6MWT	231.47±170.86	522.73±265.95	235.87±79.95	284.54±109.14	0.001	-10.06
						-21.73
PCS	31.87±9.92	87.27±5.67	31.87±9.92	50.80±18.22	0.001	23.73
						55.40
MCS	42.87±15.88	89.73±6.77	50.80±18.22	69.73±14.76	0.001	18.93
						46.86

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Abbreviations: MD: Mean difference; BDI: Beck depression index; 6MWT: 6-min walk test; PCS: Physical component score; MCS: Mental component score.

Notes: <sup>a</sup> shows the mean difference in the control group; <sup>b</sup> shows the mean difference in the intervention group.

quality of life. Several factors influence these people's quality of life including underlying disorders, surgical causes, gender, and transplant therapies. Patients' quality of life after transplantation can alter their outcomes and threaten their health [30]. The current study underscores the importance of physical rehabilitation in improving the quality of life in LTRs.

Furthermore, the study demonstrates that implementing rehabilitation programs improves depression symptoms in post-transplant patients. There have been few studies on the influence of rehabilitation on mood, psychological symptoms, and depressive symptoms. In contrast to Van Ginneken's study where anxiety and depression remained unaltered following the rehabilitation session, the current study suggests a more favorable outcome regarding depression symptoms [19]. Although various factors affect the level of quality of life and depression, different types of patients with various hepatic diseases, levels of quality of life, and depression were enrolled in the current study and assigned to both groups. Comparable research in heart transplant recipients has illustrated the potential of rehabilitation in alleviating depression and anxiety symptoms and psychological consequences, aligning with the current study's findings [31, 32].

Liver transplantation has an impact on patients' physical performance, and many patients may restrict their activity as a result of the transplant. The 6MWT, which determines how far a person can walk in six minutes,

is a measure used to assess patients' physical performance. According to review studies, the application of the 6MWT test is relatively simple and acceptable by the participants, and it provides a better reflection of the role of people's daily activities compared to other walking tests [33]. A significant difference in the 6MWT score was observed between the two groups, indicating that rehabilitation has a positive influence on the function and physical activity of transplant recipients. According to B Foronczewicz's research, rehabilitation improved the physical capacity, determined by 6MWT, of LTRs [23]. Adapted physical activity has also been shown to improve the physical performance of people awaiting liver transplants [34]. As a result, the issue of performance and physical capacity in LTRs is critical, and the current study has presented an effective solution to this problem.

## Conclusion

According to the findings of this study, rehabilitation programs can enhance the quality of life and physical activity, and mitigate depression symptoms in LTRs. The findings advocate for the incorporation of physiotherapy in post-liver transplant care. Nevertheless, the study's limited sample size warrants larger-scale research to further validate and generalize these outcomes.

## Study limitations

While the study presents noteworthy insights, it has some limitations including a small sample size and

patient reluctance to participate due to concerns about transplant rejection and consequences. Nevertheless, the study's limited sample size warrants larger-scale research to further validate and generalize these outcomes.

## Ethical Considerations

### Compliance with ethical guidelines

The study protocol was approved by the Institutional Review Board and Ethics Committee of [Tehran University of Medical Sciences](#) (Code: IR.TUMS.IKHC.REC.1396.4278) and Clinical Trial Registration (Code: IRCT20220214054022N1).

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### Authors' contributions

All authors contributed equally to the conception and design of the study, data collection and analysis, interpretation of the results, and manuscript drafting. Each author approved the submission of the final version of the manuscript.

### Conflict of interest

The authors declared no conflict of interest.

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