

# Evaluating the effects of humor therapy on fatigue levels of hemodialysis patients: A single-blind, randomized clinical trial study

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**Background:** This study investigated the effects of humor therapy on the fatigue levels of patients receiving hemodialysis (HD). **Materials and Methods:** A single-blind, randomized clinical trial of 66 HD patients for 3 weeks was conducted, in which two groups were randomly allocated – humor therapy and control. In the intervention group, humor therapy sessions were conducted twice a week for 3 weeks. As a pre- and postintervention assessment, the Fatigue Symptom Inventory (FSI) was completed. **Results:** According to the repeated-measures ANOVA test, FSI values exhibited a significant decline in the humor therapy group and an increase in the control group at the first, second, and third visits (humor therapy vs. control:  $30.38 \pm 8.75$  and  $61.80 \pm 13.92$ ,  $P < 0.001$ ;  $35.71 \pm 10.05$  and  $69.53 \pm 15.32$ ,  $P < 0.001$ ; and  $34.85 \pm 9.24$  and  $70.34 \pm 22.26$ ,  $P < 0.001$ , respectively) compared with baseline (humor therapy vs. control:  $49.26 \pm 5.19$  and  $52.09 \pm 11.69$ ,  $P = 0.204$ ). **Conclusion:** Findings suggest that humor therapy can effectively reduce fatigue levels in patients presenting with HD.

**Key words:** Fatigue, laughter therapy, renal dialysis

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## INTRODUCTION

Renal failure (RF) is a progressive and irreversible condition that is a significant public health issue and one of the 10 leading causes of death worldwide;<sup>[1]</sup> it affects patients' physical, psychological, and social well-being.<sup>[2,3]</sup> Patients with advanced chronic RF require alternative therapies to extend their life expectancy. Patients undergoing hemodialysis (HD) maintain a higher life expectancy than those without HD.<sup>[4]</sup> Long-term HD treatment may present some complications, including psychological and physical symptoms, depression, anxiety, and fatigue.<sup>[5]</sup>

Symptoms of HD include fatigue, weakness, diminished cognitive function, decreased physical function, and

a lack of energy that leads to decreased activities.<sup>[4,6]</sup> In most HD patients, fatigue symptoms result from accumulated waste products in the body. Over 80% of patients with HD experience fatigue within 5 h after HD.<sup>[7]</sup> Most of these patients rest or nap within 5 h of their HD. This state has been linked to decreased self-esteem, diminished daily functioning, and ultimately reduced life quality for HD patients.<sup>[2,8]</sup> Caregivers' and patients' perspectives on fatigue elimination are often viewed as equally critical as survival itself.<sup>[9]</sup> Approximately 60% of HD patients in Iran suffer from fatigue symptoms.<sup>[4]</sup> Since fatigue is a mental symptom that may be invisible to the care team, while the primary focus of their efforts is usually to treat kidney disease, the health-care team may overlook the fatigue disorder.<sup>[10]</sup> Fatigue symptoms

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are one of kidney disease's most irritating side effects. It has been demonstrated that reducing fatigue levels in HD patients could increase their desire to continue dialysis treatment by 94%.<sup>[4]</sup> In addition to pharmacological interventions associated with cost, complications, and dependence, nurses use several nonpharmacological nursing interventions to reduce fatigue levels in patients with chronic diseases. Humor therapy is one of the treatments described in many articles as complementary and sometimes alternative treatments. The literature confirms the method's effectiveness in reducing physical stress, increasing health and adaptability by discharging harmful mental energies, and maintaining mental balance.<sup>[11]</sup> Humor therapy involves telling jokes, watching comedy videos, or other methods that promote a sense of happiness, while laughing therapy, like laughing yoga or simulated laughter, requires a nurse to implement and can be challenging for some patients to laugh.

Laughter therapy has been shown to improve a patient's quality of life by strengthening the immune system, regulating blood pressure, and reducing stress and pain.<sup>[11]</sup> As already stated, the existing knowledge regarding the benefits of laughter therapy for medical centers is inadequate. Laughter therapy can alleviate a patient's pain, anxiety, and illness by reducing the symptoms of the illness rather than by adopting a therapeutic approach. Using humor techniques, like comedy movies, can increase well-being and decrease fatigue levels in HD patients. Moreover, further research is recommended regarding the effects of humor therapy on dialysis patients' psychological symptoms, like fatigue levels.<sup>[12]</sup> Despite the growing evidence of the benefits of laughter therapy in Western countries, enough research has not been conducted in Eastern cultural centers.<sup>[12]</sup>

Despite Bennett *et al.* showing that humor techniques, like comedy movies, improved well-being in HD patients and decreased fatigue levels; they recommend further research regarding the effects of humor on other psychological symptoms associated with HD, particularly fatigue levels.<sup>[12]</sup> Thus, the present study sought to evaluate the effects of humor therapy on fatigue symptoms in HD patients. In addition to its novelty and significance, this study's contribution to existing literature may provide insight into a better understanding of humor's effects on fatigue in HD patients.

## MATERIALS AND METHODS

This single-blind, randomized study utilizing a parallel design was conducted on 66 HD patients to assess the effects of humor therapy on fatigue levels among these patients between 2018 and 2019.

### Participants

Study participants included all outpatients referred to Mehr Clinic for dialysis treatment. The inclusion criteria were subjects between the ages of 18 and 65, who had undergone HD treatment for at least 6 months, had attended the care facility regularly (excluding guests or periodic dialysis patients), and had hemoglobin levels above 8 mg/dL. Some conditions, like anemia, were regarded as exclusion criteria to avoid confounding effects on fatigue. Exclusion criteria included reluctance to participate, not attending for more than one humor session, hemoglobin below 7 mg/dL, kidney transplantation or peritoneal dialysis, and death.

### Intervention

Eligible subjects were divided into two – intervention (humor therapy) and control groups. Participants in both groups completed a questionnaire on demographic characteristics (age, gender, marital status, educational attainment, occupational status, place of residence, and income level) as well as a Fatigue Symptom Inventory (FSI) after 1 h of preliminary explanations before commencing HD on the 1<sup>st</sup> day. A trained researcher treated the patients in the intervention group with humor therapy sessions twice a week for 60 min. A predetermined random assignment was used to assign patients between the two groups. This was conducted with their physician's permission and the nurse's cooperation at the care center. In prior research,<sup>[12]</sup> video therapy and narration of fun stories were recommended during dialysis sessions. As a result, the interventions were carried out in each session in three different ways: (a) playing images (happy song slides) and humorous videos (30 min), (b) participating in fun competitions with jokes (15 min), and (c) joking (15 min). Various humorous game clips were also included in each session, such as chair racing and painting teeth (Duchenne induction smile). Patients were encouraged to tell jokes or participate in some competitions while the facilitator maintained active interaction with them, the staff on duty, and the nurses. Patients of each course of HD received six sessions of humor therapy immediately before HD started. These sessions were held in the hospital waiting room for 3 weeks. All patients in both groups were provided with the researcher's telephone number to facilitate communication and answer questions. Continuous communication (three times a week) was maintained with the patients throughout the research study. Patients who could not attend more than one session due to illness, complications, or other reasons were removed from the study during the intervention process. During HD, patients were normally monitored for hemoglobin, urea, and creatinine levels. In the control group, participants received regular follow-up care by only listening to relaxing music. Each patient completed the FSI on the 1<sup>st</sup> day of the study to determine baseline data, and this was repeated three times per month at the

same time (2–10 pm) in the subsequent week. Researchers followed up with all participants, and if a participant could not complete the questionnaire, the researcher completed it on their behalf through telephone contact; if this was impossible, the period was subsequently extended to 12 h. As part of the FSI, information was collected weekly to assess fatigue levels during the previous week. To prevent information exchange, the following precautions were implemented: (i) patients were asked not to disclose the contents of the intervention to others; (ii) intervention materials were restricted from being released to control subjects; and (iii) intervention materials were promised to control subjects at the end of the follow-up period.

### Outcome assessment

The primary endpoint of this study was the evaluation of fatigue levels before and after implementing the intervention. Fatigue levels were assessed using the FSI tool. FSI is a multidimensional fatigue measurement tool designed by Hann *et al.*<sup>[13]</sup> This questionnaire consists of 14 questions that have four options each. It assesses the severity (4 Qs), the frequency (2 Qs), the interference with daily activities (7 Qs), and the pattern of fatigue (1 Q) per day during the last week. The content validity and reliability of the questionnaire were confirmed by Rad.<sup>[14]</sup> In the present study, Cronbach's alpha coefficient indicated a reliability of 0.81 for the questionnaire. In this questionnaire, the questions ranged from nonfatigue to maximum fatigue levels on a Likert scale. The fatigue levels were determined based on the average score of the first 13 quantitative FSI questions. A low FSI score indicates a lower level of fatigue, while a higher score indicates a higher level of fatigue. In total, the FSI score was divided into three fatigue levels: mild (0–44), moderate (45–88), and severe (89–134) fatigue. An analysis of fatigue patterns was conducted based on the last questionnaire question.

### Ethical considerations

The research was approved by the Ethics Committee of Sabzevar University of Medical Sciences with the code number IR.MEDSAB.REC.1397.063. In addition, the study was registered in the Iranian Registry of Clinical Trials under the code No: IRCT20131113015393N4. Data collection was conducted in a confidential and anonymous manner at all stages. Each participant's identity was assigned an ID number.

### Sample size determination

According to Heo *et al.*'s study in 2016, the sample size was estimated to be 70 individuals based on a type 1 error of 0.05, an effect size of 0.4, and a power of 90%. The final sample size was determined to be 35 individuals in each group considering a 10% attrition rate. Statistical significance was set at  $P < 0.05$ . The sample size was calculated using the G\*Power software version 3.0.10 developed by Heinrich-

Heine-Universität Düsseldorf in Düsseldorf, North Rhine-Westphalia, Germany.

### Blinding and random assignment

Eligible subjects were randomly assigned to the humor therapy or control groups using permuted block randomization with block sizes of 4 in a 1:1 ratio. The allocation concealment process was conducted using 70 sequentially numbered, opaque, sealed envelopes (SNOSE). Initially, the nurse researcher shuffled the envelopes and distributed them to the patients. On opening the envelopes, patients were assigned to one of the interventions. This study was single-blind in which patients were unaware of the study protocol.

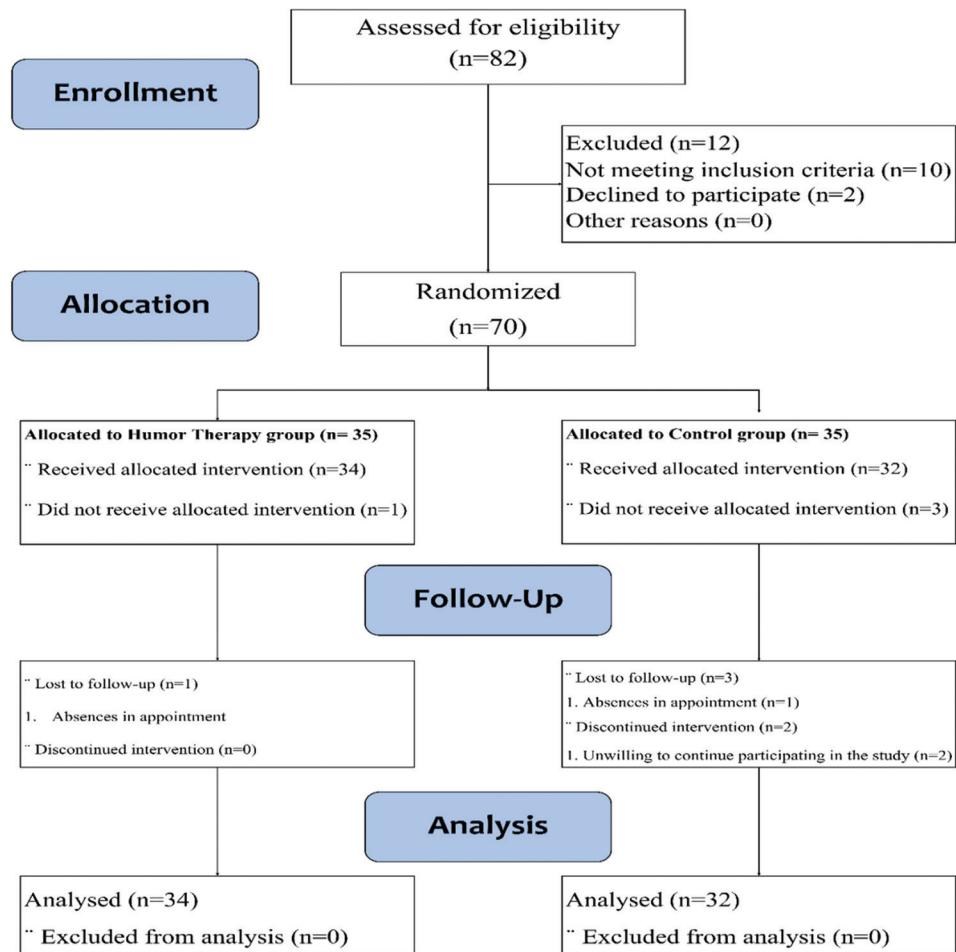
### Statistical analysis

Qualitative and quantitative parameters were expressed as mean, standard deviation, and number (%). Normality was checked using the Kolmogorov-Smirnov test. Independent *t*-test, Chi-squared, or nonparametric equivalent as appropriate was used to compare the baseline data. Analysis of covariance test was employed to compare the mean FSI levels between both groups at each visit, with baseline considered a covariate. Moreover, the repeated-measures ANOVA test was implemented to compare the means of FSI scores in the study groups over time (before treatment, during the first, second, and third visits). Mauchly's test of sphericity was used to test the assumption of sphericity. Patients were assessed in accordance with the intention-to-treat principle. All analyses were conducted using STATA (version 12, Stata Corp., College Station, Texas, USA), and  $P < 0.05$  was considered statistically significant.

## RESULTS

As indicated by the flow diagram provided in this study, one participant in the humor group and two participants in the control group were excluded due to absences from their appointments. Finally, 34 and 32 patients' data were analyzed in the humor and control groups, respectively [Figure 1]. The mean age of patients in the humor therapy and control groups was  $58.41 \pm 6.11$  and  $54.50 \pm 13.80$  years, respectively, with 17 (47%) and 19 (53%) being male in each group, respectively. Baseline demographic and clinical features are summarized in Table 1.

As shown in Table 2, based on ANCOVA results, the FSI scores were significantly decreased in the humor therapy group and increased in the control group at the first visit (humor therapy vs. control  $30.38 \pm 8.75$  and  $61.80 \pm 13.92$ ;  $P < 0.001$ ), second visit (humor therapy vs. control  $35.71 \pm 10.05$  and  $69.53 \pm 15.32$ ;  $P < 0.001$ ), and third visit (humor therapy vs. control  $34.85 \pm 9.24$  and



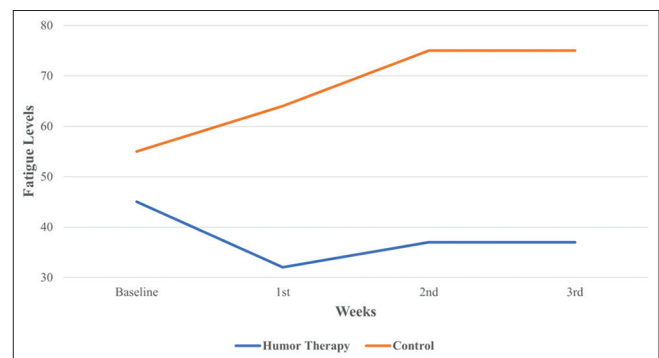
**Figure 1:** CONSORT flow diagram of the study

70.34  $\pm$  22.26;  $P < 0.001$ ) compared to baseline (humor therapy vs. control 49.26  $\pm$  5.19 and 52.09  $\pm$  11.69;  $P = 0.204$ ). Moreover, the result of the repeated-measures ANOVA test showed a significant reduction in the mean fatigue score from the baseline to the last week in the humor therapy group ( $P < 0.001$ ). This finding indicates that the mean levels of FSI in the control group are significantly higher than those in the humor therapy group over time.

The fatigue scores of the two groups varied over time, and the humor significantly reduced fatigue levels in the intervention group [Figure 2].

## DISCUSSION

This study aimed to evaluate the effects of humor therapy on the severity of fatigue levels in HD patients. The results of this study demonstrate that humor therapy reduces fatigue severity in patients in the intervention group compared to the control group during treatment with humor. According to the analysis of the intragroup effect, both groups experience different levels of fatigue before and after the intervention.



**Figure 2:** Comparison of fatigue level during 4 weeks before and after intervention between humor therapy and control groups

There is abundant evidence indicating that humor has positive physical and psychological health effects, but a limited number of studies have examined the symptoms of HD patients.<sup>[6,15]</sup> A study conducted by Heo *et al.*<sup>[16]</sup> examined the effects of laughter therapy on some psychological symptoms and quality of life in HD patients. Contrary to the present study's method, which relies on humor, they used simulated laughter during their intervention. They reported that laughter therapy proved to be an effective



treatment for the symptoms of depression over several weeks and 60 min/session. This is like the results of our study. The humor method was selected in our study due to its applicability in dialysis wards, ease of implementation, simplicity of training, and low cost. Brown *et al.*<sup>[17]</sup> reported satisfactory outcomes of the same intervention through weekly (once a week) laughter yoga sessions and assessed the well-being of 16 HD patients for 4 weeks. Rad *et al.*<sup>[18]</sup> examined the effect of laughter therapy in eight sessions over 4 weeks on fatigue severity in breast cancer patients. As a result of their intervention, patients reported a reduction in fatigue. Similar to this study, block randomization was used to allocate participants to two groups: intervention and control. In this study, relaxing music was used instead of routine care for the control group, while their study included routine care for the control group. In chronic patients receiving severe treatment like dialysis, there is a natural tendency for psychological symptoms to develop or worsen over time, including depression, fatigue, anxiety, and frustration levels.

There is also a significant difference between the two group's slopes of the fatigue scores, indicating that humor

therapy can reduce fatigue levels. After humor therapy and fatigue reduction at the end of the 3<sup>rd</sup> week, there is no fixed pattern of fatigue in the intervention group. In contrast, in the control group, fatigue levels were consistent 24 h a day. In general, fatigue symptoms were more prevalent in both groups in the evening, perhaps due to the cumulative effects of waste products. The meeting conductor in the present study had been trained. It is imperative to learn how to conduct humor sessions to ensure good communication with patients or to manage patients with different humor thresholds. However, it is readily teachable and does not require specific expertise. According to the World Health Organization, Iran is one of the saddest and most stressful countries.<sup>[19]</sup> Despite this, the rich Islamic Iranian culture provides Iranians with great happiness. There are some misconceptions about laughter that people learn from their childhood. There is an association between laughter and principles and customs, especially for women. As a result, Iranians cannot laugh easily in various situations. Another factor contributing to the loss of the art of laughing is the presence of numerous stresses. As a result, the culture of happiness and laughter in Iranian society should be considered by the public, especially those who suffer from diseases.

Further studies should be conducted on other psychological symptoms of patients undergoing HD. Moreover, studies need to be conducted on disseminating the proposed intervention around various chronic diseases, like diabetes. It is still unclear whether laughter has long-term effects, and further research is required. In addition, further research should be carried out to validate the FSI tool for HD patients. Finally, future studies should incorporate different methods as a control group, including exercise, hobbies, and art.

### Limitations and strengths

A major advantage of this study is that it is the first to examine the effects of humor therapy on HD patients' fatigue levels. Moreover, the group therapy interventions used in this study had a number of positive effects, including integrating nurses into patient meetings and improving relationships between nurses and patients. As a limitation, it is imperative to note that the sample size of participants may be considered relatively small, which may adversely affect statistical power and generalizability. A possible reason

**Table 1: Baseline demographic and clinical characteristics between the two groups; mean±standard deviation and n (%)**

Parameters	Groups		P*
	Humor therapy	Control	
Age (years)	58.41±6.11	54.50±13.80	0.137
Sex			
Male	17 (47)	19 (53)	0.445
Female	17 (57)	13 (43)	
Marital status			
Single	6 (17.5)	1 (2.9)	0.155
Married	31 (55)	25 (45)	
Widow	0	3 (100)	
Educational levels			
Illiterate	11 (61)	7 (39)	0.265
Diploma and below diploma	22 (51)	21 (49)	
Above diploma	1 (20)	4 (80)	
Duration of dialysis (months)	44.50±29.49	35.15±26.82	0.177
Hemoglobin (mg/dL)	9.08±1.49	9.22±2.06	0.753
Creatinine (mg/dL)	5.22±1.60	4.44±1.50	0.046
BUN (mg/dL)	26.17±8.67	29.65±7.70	0.090

\*Independent t-test and Chi-squared tests or nonparametric equivalent as appropriate. BUN=Blood urea nitrogen

**Table 2: Comparison of fatigue scores before and after intervention between the two groups**

Time	Groups (mean±SD)		P*	Greenhouse–Geisser test**		
	Humor therapy	Control		Group (between effects)	Time (within effects)	Group × time
Baseline	49.26±5.19	52.09±11.69	0.204	<0.001	<0.001	<0.001
1 <sup>st</sup> week	30.38±8.75	61.80±13.92	<0.001			
2 <sup>nd</sup> week	35.71±10.05	69.53±15.32	<0.001			
3 <sup>rd</sup> week	34.85±9.24	70.34±22.26	<0.001			

\*ANCOVA test with basal as a covariate, \*\*Repeated-measures ANOVA test. SD=Standard deviation

for this may arise from the calculation of the sample size through the formula and based on existing literature, as well as a few limitations like the low number of whole referred patients to the Mehr Clinic. As a second consideration, individuals differ in their humor thresholds and emotions. Due to the diverse ages of the patients in the study, the high energy of the young patients was transferred to the elderly patients. As a result, they were also able to benefit from humor therapy. Third, the study did not provide long follow-up period tests to demonstrate the long-term effects of humor therapy. Finally, the control group was entertained by relaxing music in addition to routine care during dialysis treatment. It may not have been the most appropriate comparison for humor therapy to choose relaxing music as the control group.

Nursing managers in HD departments should use the simple yet cost-effective method proposed in this study as a complementary treatment. There are, however, some potential risks and disadvantages associated with humor. Humor may not necessarily be regarded as an effective or useful solution for all patients due to differences in individual and cultural perspectives, and therefore, some may find it uncomfortable or unhelpful. As Sousa *et al.* state,<sup>[20]</sup> humor is a multifaceted phenomenon that must be applied appropriately to each situation.

## CONCLUSION

The findings suggest that humor therapy can effectively reduce fatigue levels in chronic kidney disease patients undergoing HD. This cost-effective, simple, and readily available intervention, with no reported side effects, is recommended as a complementary therapy. Its implementation not only creates a joyful therapeutic environment for both patients and nurses but also positively influences patients, leading to lower fatigue levels during their experience with HD.

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## Author's contribution

All authors have contributed significantly. MS contributed to the conception of the work, conducting the study, contributed to the analysis and interpretation of the data, approval of the final version of the manuscript, and agreed to all aspects of the work; MA contributed to the conception of the work, conducting the study, collecting

the data, revising the draft, approval of the final version of the manuscript, and agreed to all aspects of the work; FA contributed in the conception of the work, conducting the study, collecting the data, revising the draft, approval of the final version of the manuscript, and agreed to all aspects of the work; FB contributed in the conception of the work, conducting the study, collecting the data, revising the draft, approval of the final version of the manuscript, and agreed to all aspects of the work.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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