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Movie watching during dialysis sessions reduces depression and anxiety and improves quality of life: A randomized clinical trial

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ABSTRACT

Objective: Evaluate the effect of watching comedy movies as a complementary practice during dialysis on levels of anxiety, depression, quality of life, stress, laboratory findings and intra-dialysis complications.Methods: A randomized clinical trial was conducted involving the practice of presenting comedy movies during dialysis. The primary outcome was depression. The secondary outcomes were anxiety, quality of life, stress, laboratory findings and intra-dialysis complications.ResultsTwenty-six patients were in the control group and 35 were in the experimental group. Significant intra-group differences [6.0 to 3.0 ($p < 0.001$) and 8.0 to 4.0 ($p < 0.001$), respectively] and inter-group differences [5.0 vs. 3.0 ($p = 0.016$) and 7.0 vs. 4.0 ($p = 0.017$), respectively] were found regarding anxiety and depression scores, with improvements in the experimental group. The experimental group was also less likely to have intra-dialysis complications, such as hypertension ($p = 0.003$) and headache ($p = 0.020$), and reported significant improvements in different domains of quality of life [symptoms/problems ($p = 0.003$); effects of the disease ($p = 0.008$); pain ($p = 0.027$); general health state ($p = 0.004$); and social function ($p = 0.036$)]. No significant differences were found in salivary cortisol or the results of the biochemical exams, with the exception of a reduction in hematocrit in the control group.ConclusionsThe proposed complementary practice was associated with reductions in anxiety and depression scores and intra-dialysis complications (hypertension and headache) as well as improvements in quality of life in patients with chronic kidney disease.

1. Introduction

Chronic kidney disease (CKD) is characterized by the slow, progressive, irreversible loss of kidney function.[1] Despite advances in treatment with dialysis, the prevalence and mortality rates are high.[2] Moreover, CKD exerts a negative impact on emotional wellbeing and quality of life.[1]

Changes in lifestyle imposed by substitutive renal therapy as well as the clinical and psychosocial repercussions of CKD cause high levels of stress, anxiety and depression.[3,4] When not diagnosed and treated adequately, these psychological problems contribute to an increase in morbidity, hospitalization and mortality rates as well as low adherence to treatment.[4,5,3]

The quality of life of patients undergoing dialysis is significantly lower than that of the general population and tends to decline with the progression of the disease.[6] Complications or adverse reactions occur in more than one-third of dialysis sessions, compromising the effectiveness of treatment due to the association with electrolytic imbalances and clinical alterations.[7] Hematological manifestations are also frequent, such as anemia, hydroelectrolytic disorders and bone metabolism disorders.[8]

Some investigations have described the benefits of using non-pharmacological complementary practices during dialysis,[9,10,11] which are interventions that generate health benefits, make the environment more pleasant and can have a positive impact on patient wellbeing. The most widely used complementary therapies are biological products, such as herbs and supplements,[12,13] intra-dialytic exercises[14] and mind-body practices (yoga, tai chi, deep breathing, meditation and simulated laughter).[15,16] Such practices have led to reductions in levels of anxiety, depression[11,15] and stress,[9] improvements in mood, satisfaction,[15]

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quality of life and physical function[14] as well as reductions in undesirable symptoms and adverse outcomes.[9]

The beneficial effects of complementary therapies have motivated the investigation of leisure practices that can improve patient wellbeing during dialysis and reduce the discomfort inherent to the procedure. Although watching television without inducing a specific program is considered a passive act (much like sleeping) compared to other complementary practices (games, conversation, reading and doing puzzles),[17] we believe that exhibiting a specific form of entertainment, such as comedy movies, could generate effects similar to those achieved with other complementary practices, with the advantage of less difficulty implanting the therapy in healthcare services. The use of movies as a therapeutic intervention has not yet been tested on patients in dialysis, but has been reported for procedures such as colonoscopy, leading to a significant reduction in pain and anxiety.[18] Therefore, the aim of the present study was to analyze the effect of watching comedy movies as a complementary practice during dialysis on levels of stress, anxiety, depression, quality of life, intra-dialysis complications and laboratory findings in patients with CKD.

2. Methods

2.1. Study design

A randomized, controlled, parallel, two-arm, clinical trial was conducted. The flowchart for the randomization procedure is shown in Fig. 1, following the Consolidated Standards of Reporting Trials (CONSORT statement). This study received approval from the Human Research Ethics Committee of *Universidade Regional do Noroeste do Estado do Rio Grande do Sul* (protocol number: 2.761.602; certificate number: 89153218.9.0000.5350), was registered with the Brazilian Clinical Trials Register (RBR-9PJKGW) and was conducted in accordance with ethical research principles.

2.2. Inclusion and exclusion criteria

We recruited patients undergoing treatment at the Renal Unit of Santo Ângelo Hospital in the city of Rio Grande do Sul, Brazil between June 2018 and January 2019. Adults receiving regular dialysis three times per week for at least three months were included. Individuals with acute kidney failure, those with difficulty understanding the protocol of the study and those who were not clinically stable were excluded.

2.3. Randomization and intervention

Cluster randomization was performed. Following a simple lottery procedure, patients undergoing dialysis on Mondays, Wednesdays and Fridays were allocated to the intervention group and those undergoing dialysis on Tuesdays, Thursdays and Saturdays were allocated to the control group. Due to the nature of the intervention, the participants could not be blinded to the allocation. The experimental group received a complementary leisure activity combined with the standard routine of the service. The control group only followed the standard routine of the service.

The intervention occurred twice per week for six weeks. Each session lasted approximately two hours. The evaluation protocols were applied at the beginning of the activity on the first day of the

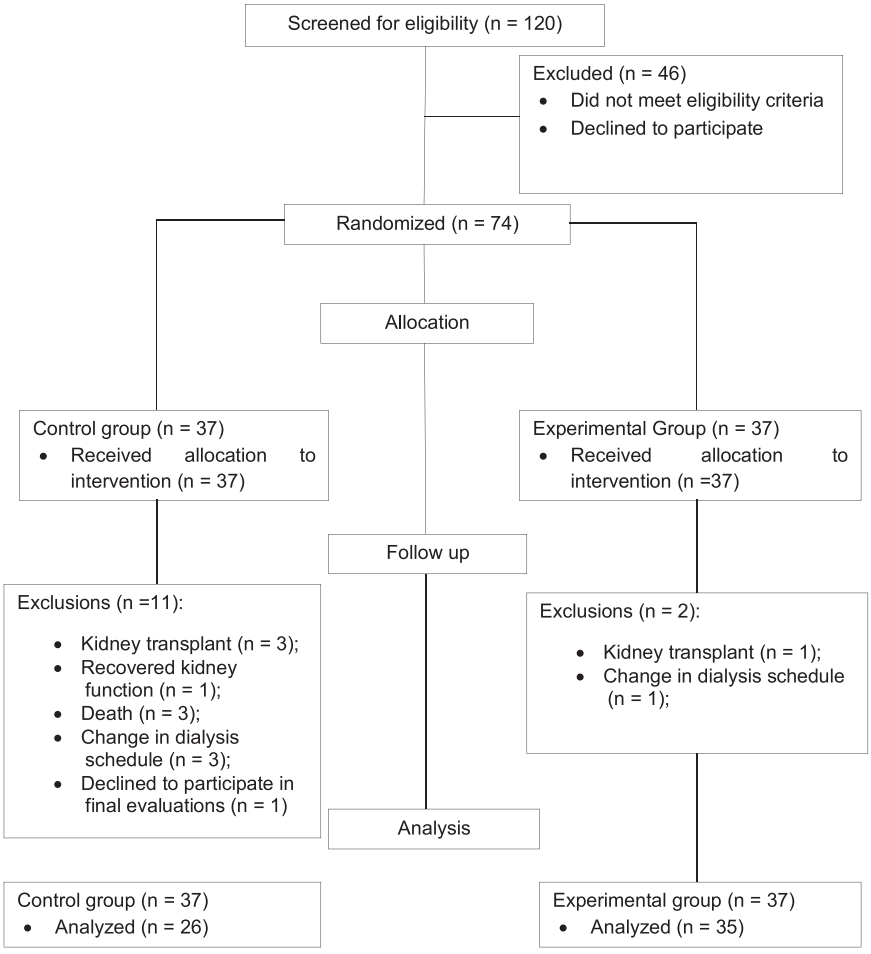

Fig. 1. Flowchart of study in accordance with CONSORT statement.

Table 1
Baseline clinical characteristics, biochemical findings and scores on evaluation scales among patients undergoing dialysis.

Characteristics	Total (n = 61)	Control Group (n = 26)	Experimental Group (n = 35)	p
Age, years	61.7 ± 13.9	61.7 ± 13.2	61.7 ± 14.6	0.992
Body mass, kg	75.9 ± 18.4	74.7 ± 15.5	76.7 ± 20.4	0.665
Time on dialysis, months	24.0 (7.0–58.0)	16.5 (9.25–36.0)	42.0 (6.0–72.0)	0.150
Male sex, n (%)	43 (70.5)	17 (65.4)	26 (74.3)	0.451
Etiology of CKD, n (%)				0.032*
Arterial hypertension	15 (24.6)	2 (7.7)	13 (37.1)	
Diabetes	24 (39.3)	16 (61.5)	8 (22.9)	
Obstructive uropathy	5 (8.2)	2 (7.7)	3 (8.6)	
Cancer	2 (3.3)	1 (3.8)	1 (2.9)	
Sclerosis	1 (1.6)	1 (3.8)	–	
Polycystic kidneys	4 (6.6)	2 (7.7)	2 (5.7)	
Not specified	8 (13.1)	2 (7.7)	6 (17.1)	
Kidney atrophy	1 (1.6)	–	1 (2.9)	
Systemic lupus erythematosus	1 (1.6)	–	1 (2.9)	
Dialysis time, n (%)				0.844
7 to 10:30 am	20 (32.8)	8 (30.8)	12 (34.3)	
11 am to 2:30 pm	29 (47.5)	12 (46.2)	17 (48.6)	
3 to 6:30 pm	12 (19.7)	6 (23.1)	6 (17.1)	
Leisure activity, n (%)	51 (83.6)	19 (73.1)	32 (91.4)	0.113
Hemoglobin, g/dl	10.5 ± 1.9	10.7 ± 1.6	10.4 ± 2.1	0.546
Hematocrit, %	33.1 ± 5.8	33.6 ± 4.9	32.7 ± 6.4	0.529
Calcium, mg/dl	9.1 ± 1.4	9.1 ± 0.8	9.1 ± 1.7	0.938
Phosphorus, mg/dl	5.1 ± 1.5	4.7 ± 1.0	5.4 ± 1.7	0.071
Potassium, mmol/l	5.3 ± 1.0	5.4 ± 0.7	5.2 ± 1.2	0.501
Salivary cortisol, ug/dl	0.16 (0.10 – 0.25)	0.14 (0.11 – 0.22)	0.16 (0.09 – 0.26)	0.705
Hamilton Anxiety Scale	6.0 (3.0–10.0)	5.5 (3.0–8.5)	6.0 (3.0–11.0)	0.583
Beck Depression Inventory	8.0 (4.5–13.5)	7.5 (3.75–14.0)	8.0 (5.0–13.0)	0.651
General Health Score – KDQOL	65.1 ± 19.5	63.5 ± 14.9	66.3 ± 22.4	0.579

CKD: chronic kidney disease; KDQOL: Kidney Disease Quality of Life; data expressed as mean ± standard deviation or median (interquartile range), as appropriate; * $p < 0.05$ indicative of significant difference between groups; Student's *t*-test or Mann-Whitney, as appropriate; Pearson's chi-square test for categorical variables.

intervention and after the intervention period in both groups. The complementary leisure activity consisted of the presentation of comedy movies shown on audiovisual equipment to the patients in the experimental group during dialysis. A projector and sound system were placed in each dialysis room and patients sat in their armchairs with an inclination of 45 degrees so that they could watch the films. A total of 12 movies were shown. All had previously been selected by the research group, were presented in Portuguese. The films were selected based on criteria such as appropriate humorous content, good reviews and the possibility of generating laughter and a good mood.

2.4. Outcomes

The main outcome of the study was depression. The secondary outcomes were anxiety, quality of life, stress, intra-dialysis complications and laboratory findings. The baseline data were collected using a specific questionnaire administered at the onset of the intervention. The outcome evaluations were performed before and after the intervention period and the instruments were administered by the researcher.

Depression was assessed using the Beck Depression Inventory (BDI).[5,19] Anxiety was assessed using the Hamilton Anxiety Scale.[20] Quality of life was measured using the Kidney Disease Quality of Life - Short Form (KDQOL-SF™).[21] Stress was measured quantitatively through the determination of the concentration of salivary cortisol before and after the intervention. Saliva was collected at the same time of day on both occasions. Intra-dialysis complications were recorded based on observations and an analysis of the patient charts after each dialysis session. The laboratory findings (hematocrit, hemoglobin, serum calcium, phosphorus and potassium) were also extracted from the patient charts.

2.5. Calculation of sample size

The sample size was calculated at the Epidemiology and Statistics Lab (http://www.lee.dante.br/pesquisa.html). Based on data from previous studies,[22] assuming a mean difference in the BDI of 6.5 with a standard deviation of 10.9, a 90 % test power and 5% significance level, a minimum of 30 patients was needed for each group. Considering possible dropouts throughout the study, the sample was increased to 37 patients in each group.

2.6. Statistical analysis

All analyses were conducted using the Statistical Package for the Social Sciences version 23.0 (SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to determine the normality of the data. Continuous data were expressed as either mean and standard deviation (SD) or median and interquatile range, as appropriate. Categorical data were expressed as absolute and relative frequencies. Differences between groups were determined using either the Student's *t*-test or the Mann-Whitney test, as appropriate. Intra-group differences were determined using either the paired t or Wilcoxon test, as appropriate. Inter-group differences for categorical variables were determined using Pearson's chi-square test. The level of significance was set to 5% ($p < 0.05$).

3. Results

A total of 120 patients with CKD were screened, 46 of whom did not meet the eligibility criteria or declined to participate in the study. Thus, 37 patients were allocated to each group. Fig. 1 shows the flowchart of the study in accordance with the CONSORT statement.

After the occurrence of dropouts, the final sample was composed of 26 patients in the control group and 35 in the experimental group. The overall sample was composed of 43 men (70.5 %) and 18 women (29.5 %). No significant differences were found between the experimental and control groups with regards to clinical characteristics, biochemical findings or scores on the assessment measures, with the exception of the etiology of CKD (Table 1).

The main findings of the study after the six weeks of intervention are displayed in Table 2. The patients in the experimental group had significantly lower anxiety and depression scores compared to the control group ($p = 0.016$ and $p = 0.017$, respectively). The most frequent intra-dialysis complications were arterial hypotension, nausea, headache, hypertension and cramps. The patients in the experimental group were significantly less likely to experience hypertension ($p = 0.003$) and headache ($p = 0.020$) during the dialysis session. The other outcomes were also better in the experimental group, but the differences did not achieve statistical significance.

Table 3 displays the intra-group differences in the outcomes before and after the intervention. No significant differences occurred in the biochemical exams, with the exception of hematocrit, which was significantly reduced in the control group ($p = 0.027$). Salivary cortisol increased in the control group and decreased in the experimental group, but the differences were not statistically significant. Depression and anxiety scores diminished in both groups, but the reduction was only significant in the experimental group ($p < 0.001$). High scores on the anxiety and depression scales were not common.

Table 2
Outcomes evaluated after six weeks of intervention with comedy movies during dialysis.

Characteristics	Total (n = 61)	Control Group (n = 26)	Experimental Group (n = 35)	p
Primary outcome				
Beck Depression Inventory	5.0 (2.5–8.5)	7.0 (3.7–12.2)	4.0 (2.0–7.0)	0.017*
Secondary outcomes				
Hamilton Anxiety Scale	4.0 (2.0–6.0)	5.0 (3.0–9.0)	3.0 (2.0–5.0)	0.016*
General Health Score – KDQOL	65.4 ± 20.4	61.9 ± 21.2	68.0 ± 19.8	0.255
Nº of complications per patient during dialysis *	1.0 (0.0–2.5)	2.0 (0.0–3.0)	1.0 (0.0–2.0)	0.166
Complications recorded, n (%)				
Hypotension	29 (47.5)	14 (53.8)	15 (42.9)	0.445
Hypertension	9 (14.8)	8 (30.8)	1 (2.9)	0.003*
Queasiness	22 (36.1)	11 (42.3)	11 (31.4)	0.428
Headache	12 (19.7)	9 (34.6)	3 (8.6)	0.020*
Cramps	8 (13.1)	3 (11.5)	5 (14.3)	1.0
Nausea and/or vomiting	3 (4.9)	2 (7.7)	1 (2.9)	0.390
Pain at puncture site	1 (1.6)	0 (0.0)	1 (2.9)	1.0
Problem with catheter	1 (1.6)	0 (0.0)	1 (2.9)	1.0
Hypoglycemia	1 (1.6)	1 (3.8)	0 (0.0)	1.0
Abdominal pain	1 (1.6)	0 (0.0)	1 (2.9)	1.0
Salivary cortisol, ug/dl	0.13 (0.09 – 0.24)	0.17 (0.10 – 0.24)	0.12 (0.09 – 0.24)	0.516
Hemoglobin, g/dl	10.5 ± 1.8	10.4 ± 1.6	10.5 ± 1.9	0.854
Hematocrit, %	32.6 ± 5.4	32.3 ± 4.9	32.9 ± 5.7	0.680
Calcium, mg/dl	8.9 ± 1.1	8.8 ± 1.1	9.1 ± 1.0	0.236
Phosphorus, mg/dl	5.0 ± 1.4	4.6 ± 0.9	5.2 ± 1.6	0.082
Potassium, mmol/l	5.4 ± 1.1	5.4 ± 0.9	5.4 ± 1.3	0.938

KDQOL: Kidney Disease Quality of Life; * number of complications per patient recorded in dialysis sessions during six weeks of intervention with comedy movies; data expressed as mean ± standard deviation or median (interquartile range), as appropriate; * $p < 0.05$ indicative of significant difference between groups; Student's *t*-test or Mann-Whitney, as appropriate; Pearson's chi-square test for categorical variables.

Intra-group differences in the means of the KDQOL-SF questionnaire after the intervention are displayed in Table 4. The lowest quality of life scores were found for the work status and sexual function domains in both groups. The patients in the experimental group had significant improvements in five KDQOL domains after the intervention period: symptoms/problems ($p = 0.003$), effects of the disease ($p = 0.008$), pain ($p = 0.027$), general health state ($p = 0.004$) and social function ($p = 0.036$). The patients in the control group only had a significant improvement in the cognitive function domain ($p = 0.007$).

During each session, approximately one-third of the patients did not watch the movie during dialysis. The mean number of movies seen fully and partially during the 12 dialysis sessions was 6.0 (2.0–9.0) and 2.0 (1.0–3.0), respectively.

4. Discussion

The present clinical trial was conducted to investigate the influence of a complementary practice of watching comedy movies on patients during dialysis sessions. The experimental group presented significant reductions in depression and anxiety scores as well as improvements in five quality of life domains. The experimental group was also less likely to experience the intra-dialysis complications of hypertension and headache. A reduction (albeit non-significant) was also found in salivary cortisol.

Table 3
Intra-group differences in outcomes evaluated after six weeks of intervention with comedy movies during dialysis.

Characteristics	Control group (n = 26)			Experimental group (n = 35)		
	Pre	Post	p	Pre	Post	p
Primary outcome						
Depression – Beck Inventory	7.5 (3.75–14.0)	7.0 (3.7–12.2)	0.192	8.0 (5.0–13.0)	4.0 (2.0–7.0)	< 0.001*
Beck Depression Inventory classification, n (%)						
Absence of symptoms (0 − 13)	19 (73.1)	21 (80.8)		27 (77.1)	34 (97.1)	
Mild depression (14 − 19)	5 (19.2)	4 (15.4)		3 (8.6)	0 (0.0)	
Moderate depression (20 − 28)	1 (3.8)	0 (0.0)		4 (11.4)	1 (2.9)	
Severe depression (29 − 63)	1 (3.8)	1 (3.8)		1 (2.9)	0 (0.0)	
Secondary outcomes						
Hamilton Anxiety Scale	5.5 (3.0–8.5)	5.0 (3.0–9.0)	0.311	6.0 (3.0–11.0)	3.0 (2.0–5.0)	< 0.001*
Hamilton scale classification, n (%)						
Normal - (0 − 17)	26 (100.0)	26 (100.0)		33 (94.3)	34 (97.1)	
Mild (18 − 24)	0 (0.0)	0 (0.0)		1 (2.9)	1 (2.9)	
Moderate (25 − 29)	0 (0.0)	0 (0.0)		1 (2.9)	0 (0.0)	
Severe (≥ 30)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Salivary cortisol, ug/dl	0.14 (0.11 – 0.22)	0.17 (0.10 – 0.24)	0.703	0.16 (0.09 – 0.26)	0.12 (0.09 – 0.24)	0.318
Hemoglobin, g/dl	10.7 ± 1.6	10.4 ± 1.6	0.149	10.4 ± 2.1	10.5 ± 1.9	0.560
Hematocrit, %	33.6 ± 4.9	32.3 ± 4.9	0.027*	32.7 ± 6.4	32.9 ± 5.7	0.750
Calcium, mg/dl	9.1 ± 0.8	8.8 ± 1.1	0.104	9.1 ± 1.7	9.1 ± 1.0	0.979
Phosphorus, mg/dl	4.7 ± 1.0	4.6 ± 0.9	0.808	5.4 ± 1.7	5.2 ± 1.6	0.436
Potassium, mmol/l	5.4 ± 0.7	5.4 ± 0.9	0.859	5.2 ± 1.2	5.4 ± 1.3	0.175

Data expressed as mean ± standard deviation or median (interquartile range), as appropriate; * $p < 0.05$ indicative of significant difference; paired *t*-test or Wilcoxon test, as appropriate; Pearson's chi-square test for categorical variables.

Table 4
Intra-group differences in means on KDQOL-SF questionnaire after six weeks of intervention with comedy films.

KDQOL-SF domains	Control group (n = 26)			Experimental group (n = 35)		
	Pre	Post	Pre	Post	Pre	Post
Symptoms/problems	82.3 ± 10.7	83.6 ± 9.9	0.216	78.2 ± 15.9	85.2 ± 9.3	0.003*
Effects of disease	82.6 ± 15.5	85.5 ± 12.6	0.061	82.0 ± 17.2	88.6 ± 12.9	0.008*
Disease burden	45.7 ± 24.3	45.7 ± 24.2	1.000	49.3 ± 27.1	53.0 ± 24.7	0.398
Work status	0.0 (0.0–50.0)	0.0 (0.0–50.0)	1.000	0.0 (0.0–50.0)	0.0 (0.0–50.0)	0.317
Cognitive function	91.6 ± 10.1	94.9 ± 7.4	0.007*	92.8 ± 13.5	91.8 ± 17.4	0.810
Social interaction	84.6 ± 14.8	84.9 ± 12.9	0.901	87.1 ± 14.9	90.9 ± 12.9	0.180
Sexual function	0.0 (0.0–75.0)	0.0 (0.0–65.6)	0.083	0.0 (0.0–56.2)	0.0 (0.0–75.0)	0.755
Sleep	72.2 ± 14.7	75.6 ± 17.9	0.110	75.9 ± 17.6	77.4 ± 17.3	0.598
Social support	94.4 ± 12.4	89.7 ± 17.7	0.230	91.9 ± 19.5	87.1 ± 20.6	0.223
Encouragement from health team	94.7 ± 12.3	92.3 ± 15.4	0.422	95.0 ± 9.7	93.6 ± 12.6	0.473
Health in general	63.5 ± 14.9	61.9 ± 21.2	0.609	66.3 ± 22.4	68.0 ± 19.8	0.560
Patient satisfaction	77.6 ± 16.3	76.9 ± 15.0	0.713	69.0 ± 18.6	70.0 ± 17.5	0.762
Physical function	45.0 (20.0–71.2)	52.5 (18.7–65.0)	0.633	55.0 (30.0–75.0)	55.0 (35.0–75.0)	0.303
Physical role limitation	12.5 (0.0–75.0)	12.5 (0.0–75.0)	0.442	25.0 (0.0–75.0)	50.0 (0.0–75.0)	0.108
Pain	80.4 ± 20.2	78.9 ± 21.1	0.637	66.9 ± 26.2	77.1 ± 26.1	0.027*
General health state	39.0 ± 18.6	41.1 ± 16.9	0.371	40.7 ± 20.4	49.6 ± 15.3	0.004*
Emotional wellbeing	71.2 ± 21.0	72.6 ± 21.3	0.564	76.2 ± 19.8	78.6 ± 21.0	0.185
Emotional role limitation	85.9 ± 32.9	84.6 ± 36.8	0.769	89.5 ± 26.5	92.4 ± 25.7	0.646
Social function	70.7 ± 26.2	73.1 ± 27.1	0.579	67.9 ± 27.2	76.1 ± 21.9	0.036*
Energy/fatigue	59.6 ± 19.3	62.7 ± 18.6	0.168	63.1 ± 22.3	66.7 ± 21.5	0.192
Physical composition	34.3 ± 8.5	33.9 ± 8.2	0.605	33.2 ± 9.6	35.6 ± 9.3	0.104
Mental composition	52.9 ± 9.3	53.9 ± 10.5	0.451	54.3 ± 9.7	55.7 ± 9.0	0.264

KDQOL-SF: Kidney Disease Quality of Life - Short Form; Data expressed as mean ± standard deviation or median (interquartile range), as appropriate; * $p < 0.05$ indicative of significant difference between groups; paired *t*-test or Wilcoxon test, as appropriate.

The practice of watching comedies during dialysis sessions was effective at reducing depression and anxiety scores in the present study. The literature describes other non-pharmacological techniques that assist in reducing these outcomes in patients undergoing dialysis, such as physical exercises,[23] relaxation exercises,[24] acupressure,[25] music therapy[11,26] and herbal therapy.[12] In contrast, techniques such as mediation[27] and yoga combined with simulated laughter[14] did not achieve significant results, despite reports of subjective benefits on the part of the patients. These are non-pharmacological techniques that demonstrate benefits for mild cases of depression and anxiety and, unlike pharmacological interventions, do not cause interactions or the accumulation of toxic metabolites in the organisms, which are often not adequately removed during the dialysis procedure.[23]

In the present sample, high depression and anxiety scores were uncommon, which differs from studies conducted at other dialysis centers.[4,6] In our study, the overall depression score was reduced in the intervention group. Moreover, seven of the eight patients classified with mild, moderate or severe depression prior to the intervention were classified as not having depression after the intervention. Likewise, the mean overall anxiety decreased after the intervention, although the scale classification was normal. It is important to note that this study was randomized and one-third of the patients did not fully watch all the films. However, different patients did not watch the films in different sessions and therefore none of these patients were excluded from the study. This finding may be explained by the interest and willingness of patients to watch a film that was not of their choosing. Problems of adherence to proposed activities were also reported in a study involving yoga as a complementary practice.[10] The reasons for not participating included sleep, the occurrence of complications or not finding the film entertaining. However, there was a still a decrease in overall depression and anxiety in the intervention group, which reinforces the promising results of this study. Improved outcomes were also found in the patients who did not receive the intervention, but the results were non-significant. External factors of everyday life can exert a positive or negative influence that may affect mean scores of depression and anxiety, which underscores the importance of randomizing the study.

The choice of comedy films rather than films chosen freely from an available list was to provide humor and relaxation as well as to generate the physiological effects described with the use of simulated laughter interventions.[16] This type of intervention differs from the simple act of turning the television to any channel with no specific programming, as occurs in the waiting room of many health services, enabling the possibility of programs that can have a negative effect.

The most common intra-dialysis complications were arterial hypotension, nausea, headache, hypertension and cramps, which are similar to findings described in previous studies.[7,9] The complementary practice of watching comedies led to a significantly lower occurrence of intra-dialysis hypertension and headache. Intra-dialysis complications compromise the effectiveness of treatment and are related to electrolytic imbalances and clinical alterations, exerting a negative impact on quality of life.[7] Headache is the most common neurological symptom in patients on dialysis and may be caused by several factors, such as changes in blood pressure and uremia, the elimination of sodium and other factors.[28] There are reports of a reduction in this symptom with the use of aroma therapy as a complementary practice.[29] Intra-dialysis hypertension occurs in approximately 10 % of patients and is associated with negative outcomes, such as an increase in hospitalization as well as greater cardiovascular morbidity and mortality. The main causes of this complication are excessive extracellular volume, endothelial dysfunction and the release of anti-hypertensive medications during dialysis.[30]

Quality of life is an important indicator of health and wellbeing and its assessment enables monitoring the effectiveness of treatments and interventions.[1] Moreover, specific protocols for patients with CKD demonstrate the extent to which the disease affects activities of daily living. In the present study, the lowest quality of life scores were found for the work status and sexual function domains. This is in agreement with data described in previous studies, which also report reductions in patient satisfaction, physical function, general health state and emotional function.[1,31]

Therefore, options for improving the quality of life of patients undergoing dialysis are important. With the use of the complementary practice of watching comedies, improvements were found in five quality of life domains after the intervention: symptoms/problems, effects of the disease, pain, general health state and social function. This demonstrates that non-pharmacological complementary practices, such

as the one employed here, can improve the quality of life of kidney patients, as described in previous studies involving tai chi,[32] intradialytic activities,[17] leisure activities,[14] music therapy[26] and simulated laughter.[16]

Another variable analyzed was salivary cortisol, for which a non-significant reduction was found after the intervention. Cortisol assist cells in producing energy and its concentration is increased in situations of fear and physical and mental discomfort, in which the body prepares to combat a stressful event.[33] The level of cortisol demonstrates the activation of the hypothalamus-pituitary-adrenal axis and can increase up to nine times in episodic situations of stress.[34] Cortisol is also used as a marker of psychological problems.[9,33] The collection only at the beginning and end of the intervention period may explain the lack of a significant reduction, as stressful situations external to the activity may have interfered in the results. In previous studies, the practice of music therapy demonstrated beneficial effects on the reduction in cortisol,[9] whereas the use of simulated laughter had no significant effect.[16]

The complementary practice of watching comedies had no effect on the results of the biochemical exams. The significant reduction in hematocrit levels in the control group may have occurred due to iron deficiency or a reduction in the hormone erythropoietin and may have been caused by a iron-poor diet or the loss of blood during the procedure.[35] However, hematocrit levels are more influenced by changes in blood volume and the concentration of hemoglobin is more reliable for the diagnosis of anemia in kidney patients.[36]

This was a pioneering study demonstrating the use of movies as a therapeutic intervention during dialysis. However, some limitations should be considered. 1) The full attention of patients during the entire exhibition of a comedy film may be diverted by the routine procedures of the service and intra-dialytic complications that may occur with any patient, affecting the group's attention. 2) Moreover, as it was a group intervention, it was not possible to enable individual choices in the selection of the film, which may affect full adherence to the proposed sessions. 3) Moreover, the high cost of laboratory evaluations impeded an additional collection of salivary cortisol during the intervention, which could have revealed a significant change.

5. Conclusions

The present findings demonstrate that the complementary practice of watching comedy movies during dialysis sessions reduced levels of depression, anxiety and intra-dialysis complications as well as improved the quality of life of the patients. The proposed intervention generated benefits similar to those reported for other practices with the additional advantage of being easy to execute and not requiring specific training. This method could therefore be employed at other dialysis centers.

Summary at a glance

This randomized clinical trial evaluates the effect of watching comedy movies during dialysis. The experimental group experienced reductions in depression and anxiety, improvements in quality of life and a fewer number of intra-dialysis complications.

CRediT authorship contribution statement

Edinara Moraes Morais: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Paulo Ricardo Moreira:** Conceptualization, Funding acquisition, Methodology, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. **Eliane Roseli Winkelmann:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing.

Declaration of Competing Interest

None of the authors have any conflicts of interest to disclose.

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