

***Effect Of Hand Reflexology Massage on Fatigue and Anxiety Levels Among Patients Receiving Maintenance Hemodialysis: A Randomized Control Trial***

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## **1. PROBLEM STATEMENT**

Patients receiving maintenance hemodialysis (MHD) suffer from highly prevalent fatigue (60-97%) and anxiety (up to 90%), which severely impact their quality of life and treatment adherence. In Iraq, resource-limited settings and the impracticality of foot reflexology (due to lower limb edema and vascular access issues) necessitate safe, non-pharmacological nursing interventions. Hand Reflexology Massage (HRM) is a viable, safe, and cost-effective option, yet its efficacy in simultaneously reducing both fatigue and anxiety in Iraqi MHD patients lacks randomized controlled trial (RCT) evidence.

## **2. RESEARCH QUESTION**

How effective is HRM in reducing fatigue and anxiety levels in patients receiving MHD compared to usual care after eight sessions?

## **3. HYPOTHESES**

There is a statistically significant difference in fatigue and anxiety levels between hemodialysis patients receiving HRM plus usual care and those receiving usual care alone.

## **4. OBJECTIVES**

- Assess baseline fatigue and anxiety levels prior to HRM.
- Evaluate the effect of the HRM program on fatigue and anxiety post-intervention.
- Compare post-intervention changes between the intervention and control groups.
- Examine associations between socio-demographic/clinical characteristics and HRM effectiveness.

## **5. DEFINITION OF TERMS (Operational)**

- Hand Reflexology Massage (HRM): A 21-minute organized protocol applied by nurses to specific reflex zones on both hands (solar plexus, diaphragm, adrenal gland, kidney, pituitary gland, and heart) during dialysis sessions.
- Fatigue: Measured using the Arabic FACIT-Fatigue Scale (13 items, scored 0-52). Higher scores indicate lower fatigue levels and better quality of life.

- Anxiety: Measured using the Arabic Beck Anxiety Inventory (Ar-BAI) (21 items, scored 0-63). Scores are classified into minimal (0-7), mild (8-15), moderate (16-25), and severe (26-63) anxiety.

## 6. METHODOLOGY

- **Study Design:** Two-group parallel Randomized Controlled Trial (RCT) with a 1:1 allocation ratio.
- **Setting:** Hemodialysis units in Iraq.
- **Sample Size:** 70 adult patients receiving MHD (35 in the intervention group, 35 in the control group).
- **Intervention Group:** Received eight 21-minute HRM sessions over four weeks (two sessions per week) during routine hemodialysis, in addition to usual care.
- **Control Group:** Received usual care only (routine dialysis nursing care) without HRM.
- **Data Collection Time Points:**
  - T0: Baseline (before the first session).
  - T1: Mid-intervention (after the 4th session).
  - T2: Post-intervention (after the 8th session).

## 7. STUDY INSTRUMENTS

1. Demographic and Clinical Characteristics Questionnaire (age, gender, education, income, duration of HD, etc.).
2. Arabic FACIT-Fatigue Scale (Version 4).
3. Arabic Beck Anxiety Inventory (Ar-BAI).

## 8. ETHICAL CONSIDERATIONS

- Ethical approval was obtained from the relevant institutional review board.
- Written informed consent was obtained from all participants prior to enrollment.

- Participation was voluntary, with the right to withdraw at any time without affecting their medical care.
- Confidentiality of participant data was strictly maintained (no names or identifiers are recorded in data collection tools).

## **9. STATISTICAL ANALYSIS PLAN**

- Normality Testing: Shapiro-Wilk test will be used to assess the normal distribution of continuous variables.
- Within-Group Comparisons: Parametric tests (e.g., Repeated Measures ANOVA) for normally distributed data, and non-parametric tests (e.g., Friedman test) for non-normal data across the three time points (T0, T1, T2).
- Between-Group Comparisons: Independent t-test or Mann-Whitney U test to compare post-intervention scores between the intervention and control groups.
- Multiple Comparisons: Bonferroni correction will be applied for post-hoc pairwise comparisons to control Type I error.
- Associations: Chi-square or Fisher's exact tests will be used to examine relationships between demographic/clinical characteristics and HRM effectiveness.
- Clinical Significance: Minimal Clinically Important Difference (MCID) will be calculated to determine the practical relevance of fatigue and anxiety score improvements. Analysis will be performed using SPSS.