The Effect of Non-Pharmacological (Home-Based Exercise) Intervention on Psychological Distress of Patients Undergoing Hemodialysis at Al Suwaiq Renal Dialysis Center

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Study Objectives

Primary Objective: To evaluate the effect of home-based exercise on reducing psychological distress (depression and anxiety) in patients undergoing hemodialysis.

Secondary Objective: To describe the baseline prevalence and severity of depression and anxiety among hemodialysis patients.

Study Design

Phase I: Cross-sectional assessment of depression and anxiety levels using the University of Michigan Depression Center's tools.

Phase II: Randomized controlled trial (RCT) with intervention and control groups.

Phase III: Post-intervention reassessment after 6 months.

Study Population

Sample size: Initially 132 screened → 54 enrolled → 26 participants per group in final analysis.

Inclusion/Exclusion Criteria: As defined in the study protocol.

Variables

Primary Outcomes: Depression Score (0–27) using PHQ-9 scoring; Anxiety Score (0–21) using GAD-7 scoring.

Independent Variable: Intervention group assignment (Home-based exercise vs. Control).

Covariates: Age, gender, duration of dialysis, comorbidities.

Data Collection Method

Face-to-face interviews for questionnaire administration. Baseline data from Al Shifa system (demographics, clinical history).

Statistical Analysis

-        Data Management: Data entry and cleaning in SPSS v22. Descriptive statistics for demographics and baseline variables: Continuous variables: Mean ± SD (or median and IQR if non-normal). Categorical variables: Frequencies and percentages.

-        Baseline Comparisons: Independent t-test, Chi-square, or Fisher's exact test for categorical variables.

Main Analysis: Paired t-test for within-group changes; Independent t-test for betweengroup differences in change scores.

-Significance Level: p-value < 0.05 considered significant; two-tailed tests.

-       Handling Missing Data: Intention-to-treat principle; Last Observation Carried Forward method for missing values.

Presentation of Results

Tables for baseline demographics, pre- and post-intervention scores. Paired t-test results with mean difference, 95% CI, and p-value. Graphical representation of score changes.

Ethical Considerations

Analysis will be performed on anonymized datasets. Results will be reported in aggregate without identifying participants.