Study Protocol

Digital Dyadic Empowerment Program on Lifestyle Modification for Chronic Kidney Disease Management

Official Title for Year 3 Feasibility Study:

A randomized controlled feasibility trial evaluating the Implementation of Digital Dyadic Empowerment Program (DDEP) on Lifestyle Modification for Chronic Kidney Disease Management

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A Randomized Controlled Feasibility Trial Evaluating the Implementation of Digital Dyadic Empowerment Program (DDEP) on Lifestyle Modification for Chronic Kidney Disease Management

Objective

This study aims to conduct a feasibility trial to explore the experiences and engagement of patient-significant other dyads in the implementation of the Digital Dyadic Empowerment Program (DDEP) for chronic kidney disease (CKD) management.

Design

A feasibility study will employ a randomized controlled trial (RCT) design, adhering to the Clinical Practice and Consolidated Standards of Reporting Trials (CONSORT) guidelines (Eldridge et al., 2016).

Participants

Participants will include CKD patients aged 20 years and older (stage 1–5 CKD, minimum six months) and their identified significant others. Inclusion criteria are:

1. Patients can identify a supportive significant other, and both are willing to participate.
2. Patients can communicate in Mandarin or Taiwanese.

Exclusion criteria:

1. Significant other is a healthcare provider.
2. Either participant has a known mental illness.
3. Patients are receiving renal replacement therapies.

Setting

The study will be conducted in nephrology outpatient clinics at a medical center in Southern Taiwan.

Sample Size

Sixty dyads will be recruited. This number, in line with feasibility study guidelines (Hertzog, 2008; Leon et al., 2011), will allow determination of feasibility and provide effect size estimates for a future definitive trial.

Measurements

Data will be collected using validated instruments, including:

- Demographics and Disease-Related Characteristics.
- Transtheoretical Model (TTM) Staging Inventory.
- Dyadic Adjustment Scale (DAS).
- Adherence to Health Behaviors Scale (AHBS).
- Helping Relationships with Significant Others (HRSO).
- Health Promotion Lifestyle Profile-II (Chinese version, short form).
- WHO Quality of Life Questionnaire (WHOQOL-BREF).

Procedure

Eligible patients will be referred by case managers during routine clinic visits. Dyads who provide informed consent will be randomly assigned (via a paper-ballot method) to the experimental group (DDEP) or control group (routine care). Baseline data will be collected, including relationship quality (DAS), quality of life (WHOQOL-BREF), and patient-specific measures (AHBS, HRSO, Health Promotion Lifestyle Profile-II). Data collection will occur in private rooms and require approximately 50 minutes.

The intervention group will receive the DDEP, while the control group will receive routine education and care. Baseline and post-intervention stages of change and outcomes will be evaluated. Participants will receive a small gift after each data collection period.

Data Analysis

Feasibility metrics will include recruitment rates, attrition, and acceptability of interventions. These will be reported using CONSORT guidelines. An intention-to-treat analysis will address attrition to ensure unbiased group comparisons. Baseline characteristics will be statistically analyzed for group differences, and descriptive results will be presented as summary statistics.

This feasibility study will provide valuable insights into the acceptability of trial design, interventions, and measurement tools, supporting the development of a definitive RCT in the future.

References

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., Lancaster, G. A., & PAFS consensus group (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ (Clinical Research Ed.)*, *355*, i5239. https://doi.org/10.1136/bmj.i5239

Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing & Health*, *31*(2), 180–191. https://doi.org/10.1002/nur.20247

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008