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Title

Observational Study to Assess the Effectiveness of a Smartphone Application in Enhancing Adoption of the 2024 KDIGO CKD Guideline.

1. Background and Rationale

Chronic Kidney Disease (CKD) affects millions of individuals worldwide, and adherence to clinical guidelines is critical for managing the disease effectively. The 2024 KDIGO CKD Guidelines provide comprehensive recommendations for the diagnosis and management of CKD. However, implementation of these guidelines remains a challenge.
This study aims to evaluate the effectiveness of a smartphone application designed to assist doctors and patients in following the 2024 KDIGO CKD guidelines.

2. Objectives

Primary Objective

To assess the effectiveness of a smartphone application in enhancing the adherence to the 2024 KDIGO CKD guidelines over a 18-month period. This includes recommendations on lifestyle modification as well as optimal disease modifying medications to reduce the loss of kidney function and cardiovascular risk over time.

Secondary Objectives

- To evaluate changes in clinical parameters (e.g., blood pressure, eGFR, urinary protein excretion) over the study period.
- To assess patient satisfaction and engagement with the smartphone application.
- To determine the impact of the application on the quality of life of CKD patients.

3. Study Design

This is an observational, prospective cohort study. Participants will be assessed at baseline and at intervals over 18 months.

4. Study Population

Inclusion Criteria

- Adults aged ≥16 years.
- Diagnosed with CKD stages 1-5.
- Owns a smartphone and is capable of using mobile applications.
- Provides informed consent.

Exclusion Criteria

- Inability to provide informed consent due to cognitive impairment.

5. Study Procedures

Baseline Visit

1. Obtain informed consent.
2. Collect demographic and medical history.
3. Conduct baseline measurements:
- Blood pressure
- Serum creatinine
- Estimated Glomerular Filtration Rate (eGFR)
- Urine Albumin-to-Creatinine Ratio (ACR)
- Weight, height, BMI
4. Collect information on lifestyle factors:
- Diet
- Physical activity level
- Smoking status
- Alcohol consumption
5. Assist participant in downloading and setting up the smartphone application.

Follow-Up Visits

Participants will be assessed at 3, 6, 9, and 12 months. At each visit:

1. Collect follow-up measurements:
- Blood pressure
- Serum creatinine
- eGFR
- Urine ACR
- Weight, height, BMI

2. Review application usage data:
- Number of logins per week
- Frequency of viewing educational materials
- Frequency of logging health data
- Number of reminders received and responded to

3. Assess adherence to KDIGO guidelines: *Disease modifying medication*
prescription including ACE inhibitors and ARBs, SGLT2 inhibitors, GLP-1 analogues, Finerenone and endothelial antagonists.
- *Blood pressure control* versus targets recommended by the KDIGO Guidelines.
- Dietary recommendations
- Physical activity recommendations
- Attendance at medical appointments

4. Collect patient feedback on the application:
- Ease of use (scale 1-5)
- Usefulness of educational materials (scale 1-5)

- Effectiveness of reminders (scale 1-5)
- Overall satisfaction (scale 1-5)
- Suggestions for improvement

5. **Quality of life assessed in patients** using a validated questionnaire (e.g., POS-S-Renal).

6. Outcome Measures

Primary Outcome

- Adherence to the 2024 KDIGO CKD guidelines, measured by changes in adherence scores from baseline to 12 months in the variables specified above (recommended medications and lifestyle modifications).

Secondary Outcomes

- Changes in clinical parameters (blood pressure, serum creatinine, eGFR, urine ACR).
- Patient satisfaction and engagement with the application.
- Quality of life assessed in patients being managed as part of the conservative care pathway using a validated questionnaire (e.g., POS-S-Renal).

7. Data Management and Analysis

Data Collection

Data will be collected using electronic data capture systems. All data will be anonymized and stored securely.

Statistical Analysis

- Descriptive statistics for baseline characteristics and outcome measures.
- Paired t-tests or Wilcoxon signed-rank tests to compare baseline and follow-up measurements.

8. Ethical Considerations

Informed Consent

Written informed consent will be obtained from all participants through the smartphone application.

Confidentiality

Participant confidentiality will be maintained. Data will be anonymized and securely stored.

Ethical Approval

The study protocol has been approved by the hospital ethics committee.

9. Dissemination of Results

The results of the study will be published in peer-reviewed journals and presented at national and international conferences. A summary of the study results will be shared with participants through the smart phone application.

10. Timeline

- **Month 0**: Study initiation and baseline assessments.
- **Months 3, 6, 9**: Follow-up assessments.
- **Month 12**: Final follow-up assessments and data analysis.
- **Months 13-15**: Data analysis and manuscript preparation.
- **Month 16**: Dissemination of results.