

Document Type:
Study Protocol with Statistical Analysis Plan (SAP)

Official Title of Study:
**Effects of Personalized Actionable Connected Extensible (PACE) Interventions
Among Patients With Chronic Kidney Disease**

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Main Protocol – Taiwan Implementation Site

Sponsor:
National Cheng Kung University Hospital

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- Study Objectives: To examine the effectiveness Personalized Actionable Connected Extensible (PACE) Interventions for frailty among patients with CKD.
- Study Design: A randomized controlled trial with a single-blinded experimental design.
- Eligibility Criteria:
 1. The eligibility criteria included: (1) age 20 years or older; (2) diagnosis of CKD stage 1 to 5 for at least 6 months; (3) identified as frail; (4) the ability to communicate in Mandarin Chinese or Taiwanese; and (5) willingness to participate in the study.
 2. The exclusion criteria were: (1) receiving renal replacement therapy, (2) a history of mental illness, and (3) having reached TTM stage 5.
- Intervention/Comparator Descriptions:
 1. The PACE intervention involves using Line (technological devices) to establish a collaborative group with patients. The researchers will regularly provide reminders to chronic kidney disease patients regarding the importance of nutrition and exercise. They will also provide information on how to adhere to nutritional and exercise regimens, offering praise for consistent performance.
 2. Nurses provide routine education and consultation.
- Outcome Measures:
 1. Primary Outcome Measure: Tilburg Frailty Indicator (TFI)
 2. Secondary Outcome Measures: International Physical Activity Questionnaires (IPAQ, Taiwan Version); Health-promoting Lifestyle Behaviors (HPLP-II, Taiwan Version); Mini Nutritional Assessment Short-Form (MNA-SF, Taiwan Version)
- Statistical Analysis Plan:
 1. Descriptive Statistics: Mean \pm SD for continuous variables, Frequency (%) for categorical variables
 2. Comparative Analysis: Generalized estimating equations (GEE) are used to account for the non-independence of repeated measures over time within individuals and to control for potential confounding factors. The GEE models included main effects for group (intervention vs. control), time, and group-by-time interaction terms to examine whether there were statistically significant differences in outcome trajectories between the two groups over time. Covariates controlled in the models included age and gender. A significance level of 0.05 was used for hypothesis testing. All analyses were conducted using SPSS 25 version software.