Effects of a self-management program on patients with early stage chronic kidney disease

Submission date	Recruitment status	Prospectively registered
12/06/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/06/2012	Completed	Results
Last Edited	Condition category	Individual participant data
26/06/2012	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Background and study aims

Without treatment, patients with chronic kidney disease (CKD) will experience deterioration in renal functions. Preventing the progression of CKD and avoiding early entry into the dialysis are urgent issues. The study attempted to develop a self-management education program based on the self-regulation theory and to assess whether and how it helped patients with early stage CKD to manage their condition.

Who can participate?

Patients with early stage CKD.

What does the study involve?

After informed consents were obtained, blood samples were taken and questionnaires were filled in. Participants received a five-week, group sessions self-management program based on self-regulation theory. Participants were pre-tested to establish a baseline (T0) and then there were three post-at 3 months (T1), 6 months (T2), and 12 months (T3) after the self-management program was delivered.

What are the possible benefits and risks of participating?

Participants who participate the intervention (i.e., self-management program) will learn how to self manage their CKD to prevent further deterioration.

There is no any known risk found in this study.

Where is the study run from?

Subjects were recruited from the following four hospitals in southern Taiwan:.

- 1. Kaohsiung Medical University Chung-Ho Memorial Hospital
- 2. Kaohsiung Municipal Hsiao-Kang Hospital
- 3. Chia-Yi Christian Hospital
- 4. Chi-Mei Medical Center

When is the study starting and how long is it expected to run for? The study ran from September 2008 to December 2009, lasting 16 months.

Who is funding the study?

This study was supported by funds from the National Science Council, Taiwan (NSC95-2314-B-037-052-MY3).

Who is the main contact? Chiu-Chu Lin chiuchu@kmu.edu.tw

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effects of a self-management program on patients with early stage chronic kidney disease: a repeated measures longitudinal study

Study objectives

Without intervention, patients with chronic kidney disease (CKD) will experience deterioration in renal functions. Preventing the progression of CKD and avoiding early entry into the dialysis are urgent issues.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Kaohsiung Medical University Institutional Review Board, December 29, 2005, ref: KMUH-IRB-940359

Study design

One-group pretest-posttest repeated measures longitudinal study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Early stage chronic kidney disease

Interventions

The CKD self-management program designed by the research team was based on the self-regulation theory. Each study subject was scheduled for a five-week self-management program which included face-to-face sessions involving groups of 6 to 8 participants, and group sessions of 90-minute per week. After subjects watched the CKD self-management video, the lead investigator led subjects to discuss and learn about the self-regulation processes. Self-regulation activities were developed and used as models by study participants. By watching the examples demonstrated in the video, participants could learn new self-management strategies. At the end of each session, participants were given assignments to monitor and record their daily activities, using the self-monitoring workbook, from which they could find the possible causes or circumstances producing the problems.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

- 1. CKD self-efficacy
- 2. CKD self-management behavior

Measured at 3 months (T1), 6 months (T2), and 12months (T3) after the intervention of a self-management program.

Key secondary outcome(s))

- 1. Serum creatinine (SCr)
- 2. Glomerular filtration rate (GFR)

Measured at 3 months (T1), 6 months (T2), and 12months (T3) after the intervention of a self-management program.

Completion date

30/12/2009

Eligibility

Key inclusion criteria

- 1. Was diagnosed with CKD 1-3a stage six months or more prior to the study
- 2. Aged 18 years or older
- 3. Without visual or aural impairment

- 4. Spoke Taiwanese or Mandarin
- 5. Consented to fill out questionnaires and to blood tests in order to test the CKD progression

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Diagnosed with CKD 3b-5 stage

Date of first enrolment

01/09/2008

Date of final enrolment

30/12/2009

Locations

Countries of recruitment

Taiwan

Study participating centre 100 Shih-Chuan

Kaohsiung Taiwan 807

Sponsor information

Organisation

National Science Council (Taiwan)

ROR

https://ror.org/02kv4zf79

Funder(s)

Funder type

Government

Funder Name

National Science Council (Taiwan) (NSC95-2314-B-037-052-MY3)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Participant information sheetParticipant information sheet11/11/202511/11/2025NoYes