

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

Submission date 12/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/06/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

One-group pretest-posttest repeated measures longitudinal study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please contact Chiu-Chu Lin, PhD RN, chiuchu@kmu.edu.tw to request a patient information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/09/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Of the 44 subjects recruited, 37 people consented to participate in this study. Finally, 33 subjects completed this study.

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

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Sponsor information

Organisation

National Science Council (Taiwan)

Sponsor details

106, Sec. 2

Heping E. Rd

Taipei

Taiwan

10622

Sponsor type

Government

Website

<http://web1.nsc.gov.tw/mp.aspx?mp=7>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration