ISRCTN71490154 https://doi.org/10.1186/ISRCTN71490154

Testing a health coaching intervention for early-stage chronic kidney diseases

Submission date	Recruitment status	[X] Prospectively registered
27/01/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/01/2022	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic kidney disease is a long-term condition where the kidneys don't work as well as they should. It can be caused by type 2 diabetes. Dialysis treatment to replicate some of the kidney's functions may be necessary for advanced chronic kidney disease. The dialysis rate in Taiwan has been the highest in the world for many years, and the cost of dialysis is high. Therefore it is important to help patients with diabetic chronic kidney disease to follow the doctor's advice to change their lifestyle habits and delay the deterioration of kidney disease. Health coaching is a way to improve patient health behaviors and self-efficacy by asking open-ended questions under a framework of positive psychology. The aims of this study are to improve patients' self-management in diabetic chronic kidney disease care, including medical compliance and health behavior, and to improve the indicators of diabetes and kidney disease.

Who can participate?
Patients aged 20-80 years with type 2 diabetes and chronic kidney disease

What does the study involve?
Each participant in the intervention group will receive 2 years of health coaching and will be followed up until the end of the study.

What are the possible benefits and risks of participating?
The result of this study will help with the development of health and wellness coaching in the hospital.

Where is the study run from?
Cathay General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2021 to December 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
An innovative approach for increasing adherence to improve the disease control of early-stage diabetic chronic kidney disease, self-efficacy and glycemic control among diabetes patients: a randomized controlled trial on health coaching efficacy

Study objectives
1. The health coaching intervention can assist the patient to effectively maintain the renal function, so that the eGFR and other.
2. The health coaching intervention can significantly improve the exercise habits, eating habits and self-efficacy of patients in the intervention group.
3. There is a significant difference in the slope of renal function index change between the intervention group and the control group, and the intervention group's disease condition is significantly better than that of the control group.
4. The degree of changes in healthy living behaviors can significantly predict the differences in renal function indicators between groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 29/12/2021, Institutional Review Board of the Cathay General Hospital (Cathay General Hospital, 280 Renai Rd. Sec.4, Taipei; +886 (0)2 27082121 #6984; cgh411332@cgh.org.tw), ref: CGH-OP110004

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
One physician will screen and select prospective patients with type 2 diabetes mellitus from the hospital's database, followed by an independent researcher randomly assigning them to the intervention group and the control group by using computer-generated random numbers. Two physicians recruit them individually during their regular outpatient visits. Patients in the intervention group are informed of the coaching program by a health coach, whereas the patients in the control group are informed of a pre-posted questionnaire survey.

Coaching is provided on a one-on-one basis by a professional health coach. In the first session, the coach asks each participant to set eGFR and HbA1c goal and an initial target for behavioral change, in addition to focusing on healthy diet, and other behaviors related to diabetes self-management such as physical activity, medical adherence, and regular self-monitoring blood glucose (SMBG) can also be set. Then, the coach discusses with patients implementation schedules for action plans and checks progress via a monthly call while reinforcing participants' values and responsibilities of self-management. In other words, the health coach empowers patients to actively change their behaviors through guiding and applying what they have learned in health education to bring about specific and feasible changes in diabetes self-management and thereby effectively promote blood sugar management.

Each participant in the intervention group will receive 2 years of health coaching and will be followed up until the end of the study.

Intervention Type
Behavioural

Primary outcome(s)
1. eGFR obtained from the blood test records of the participants during their regular hospital visits at baseline, 3, 6, 9, 12, 18, 24 months
2. HbA1c obtained from the blood test records of the participants during their regular hospital visits at baseline, 3, 6, 9, 12, 18, 24 months

Key secondary outcome(s)
Measured at baseline, 3, 6, 9, 12, 18, 24 months:
1. Eating habits measured using an eating journal

2. Diabetes distress measured using the Taiwan diabetes distress scale
3. CKD self-efficacy measured using the Taiwan CKD self-efficacy scale

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 20-80 years old
2. Diagnosed with type 2 diabetes for at least 1 year
3. In the past year, there have been at least two return visits to confirm the diagnosis of chronic kidney disease in the first to third stage
4. Currently not participating in other diabetes-related research intervention projects

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with type 1 diabetes
2. Patents with cancer, are pregnant or plan to become pregnant within the next year
3. Cognitive, behavioral or mental disorders
4. Severe hearing loss
5. Cannot understand Mandarin or Taiwanese
6. No phone or other communication tool to contact the person at home
7. The patient's primary caregiver opposes
8. Refuse to participate in the trial or refuse to sign the subject consent form

Date of first enrolment
15/02/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Taiwan

Study participating centre
Cathay General Hospital
280 Renai Rd. Sec.4
Taipei
Taiwan
106438

Sponsor information

Organisation
Taipei Medical University

ROR
https://ror.org/05031qk94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
According to Taiwan’s regulations, it is not possible to actively disclose files, but if there is an application by letter, information can be provided under appropriate circumstances.

IPD sharing plan summary
Available on request