

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

Submission date 27/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/01/2022	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

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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

29/12/2021

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

Age group

Adult

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Patients with type 1 diabetes
2. Patients 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**

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Sponsor information

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Taipei Medical University

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<https://ror.org/05031qk94>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

If the results are positive, the researchers will consider submitting the manuscript to Diabetes Care and other endocrinology journals, or continuing a series of past studies and submitting the manuscript to Frontiers in Public Health.

Intention to publish date

31/07/2025

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