

An innovative approach for increasing adherence to improve healthy lifestyle, diabetes distress and glycemic control among type 2 diabetes patients

Submission date 12/07/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/08/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a serious chronic disease that affects people worldwide. According to a report by the World Health Organization (WHO), the global prevalence of diabetes doubled between 1980 and 2014 and is approximately 8.5% in the adult population in 2017. Globally, diabetes caused an estimated 1.5 million deaths in 2012. Diabetes is the fifth leading cause of death in Taiwan; with a prevalence of 11.8% in the adult population, but this figure has been rising and is expected to continue to increase. In 1997, Taiwan established the "Diabetes Shared Care Network," which integrated nationwide medical institutions and adjusted health insurance payments for diabetes care, however, lifestyle change counseling is seldom applied in diabetes prevention and treatment. In recent decades, health and wellness coaching has become a new technique used in the care and management of chronic diseases around the world. Health coaching is a patient-centered, patient-decided approach to disease management. The aim of this study is to find out whether a health coaching intervention can improve patients' blood sugar control and decrease diabetes distress.

Who can participate?

Patients aged 20 - 75 with type 2 diabetes

What does the study involve?

Participants are randomly allocated to either the intervention group or the control group. The intervention group receive usual care and a health coaching intervention for improving their medical adherence, diet and physical activity and diabetes distress syndrome. The coaching intervention involves monthly face-to-face or telephone or mixed coaching as chosen by the participant, and it lasts for 6 months. The length of the coaching intervention depends on the participant's need, but most of them finish in under 30 mins. The control group have usual care only.

What are the possible benefits and risks of participating?

The possible benefits to participants are improving their blood sugar control, decreasing diabetes distress, and better health behaviors.

Where is the study run from?

Cathay General Hospital, Taipei, Taiwan

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

May 2019 to July 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Yao-Tsung Chang

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Contact information

Type(s)

Scientific

Contact name

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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 healthy lifestyle, diabetes distress and glycemic control among type 2 diabetes patients, a randomized-control trial on health coaching efficacy

Study objectives

Health coaching intervention can improve patients' glycemic control and decrease diabetes distress.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/03/2019, Cathay General Hospital (280 Renai Rd. Sec.4, Taipei, Taiwan; Tel: +886 (0) 2 27082121; Email: irb@cgh.org.tw), Approval number: CGH-OP108002

Study design

Single-center randomized control study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Type 2 diabetes mellitus with low glycemic control

Interventions

Potential eligible patients are screened from their medical records beforehand and randomly assigned to either the intervention group or the control group:

The intervention group will have usual care and a health coaching intervention for improving their medical adherence, diet and physical activity and diabetes distress syndrome. The coaching intervention will involve monthly face-to-face or telephone or mixed coaching as chosen by the participant, and it will last for 6 months. The length of the coaching intervention depends on the participant's need, but most of them will finish in under 30 mins.

The control group have usual care only.

Intervention Type

Behavioural

Primary outcome measure

1. Diabetes distress measured using the Diabetes Distress Scale at baseline, 3 months, and 6 months
2. HbA1c collected from database at baseline, 3 months, and 6 months

Secondary outcome measures

1. Self-efficacy of diabetes management measured using self-designed items at baseline, 3 months, and 6 months
2. Physical activity measured using Goldin Leisure time activity scale at baseline, 3 months, and 6 months
3. Healthy diet measured using Alternate Healthy Eating Index for Taiwan (AHEI-T) at baseline, 3 months, and 6 months
4. Self-measured blood sugar behavior measured using one self-designed question at baseline, 3 months, and 6 months
5. Weight and BMI measured collected from database at baseline, 3 months, and 6 months

Overall study start date

22/05/2019

Completion date

31/07/2021

Eligibility

Key inclusion criteria

1. 20 - 75 years old
2. Be diagnosed with Type 2 diabetes for 1 year or above
3. HbA1c was higher than 7.0% in past 6 months
4. Creatinine lower than 1.9 mg/dL in recent test
5. Did not participate in other similar research projects at the time of recruitment

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

140 (both intervention and control group have 70 persons)

Total final enrolment

114

Key exclusion criteria

1. Type 1 diabetes patient
2. Having cancer
3. Pregnant, or planning to be pregnant during the trial

Date of first enrolment

01/09/2019

Date of final enrolment

30/06/2020

Locations

Countries of recruitment

Taiwan

Study participating centre**Cathay General Hospital**

No. 280, Sec. 4, Ren'ai Rd., Da'an Dist.

Taipei

Taiwan

10630

Sponsor information

Organisation

Cathay General Hospital

Sponsor details

c/o Dr Ching-Ling Lin

Endocrinology & Metabolism

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03c8c9n80>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal within 1 year after the end of the intervention.

Intention to publish date

31/07/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Yao-Tsung Chang (D508102002@tmu.edu.tw).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2021	01/06/2021	Yes	No
Results article		29/10/2021	18/08/2023	Yes	No