

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

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

D508102002@tmu.edu.tw

## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Yao-Tsung Chang

**ORCID ID**

<https://orcid.org/0000-0003-1028-8450>

**Contact details**

Wuxing St., Xinyi Dist.,

Taipei

Taiwan

110

+886-911839631

D508102002@tmu.edu.tw

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

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

## **Study type(s)**

Other

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

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

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Results article</a>		14/05/2021	01/06/2021	Yes	No
<a href="#">Results article</a>		29/10/2021	18/08/2023	Yes	No