

Effectiveness of short-term health coaching according to willingness of participants in coaching groups: a diabetes coaching pilot study

Submission date 26/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/05/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/11/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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 and it is the fifth leading cause of death in Taiwan. Since the size of the aging population is growing, the prevalence of diabetes continues to rise, so the disease is likely to continue to cause medical and economic burdens within Taiwan. In recent decades, health and wellness coaching has become a new technique used in the care and management of chronic diseases around the world. So far, health behavior counseling become more and more important in chronic diseases management. But until now, there are almost no behavior consultant service within hospitals in Taiwan. The aim of this study is to find out whether a health coaching intervention could improve type 2 diabetes patients' HbA1c control, self-management efficacy and health behaviors.

Who can participate?

Patients aged 20 to 75 who have had type 2 diabetes for at least one year and an HbA1c of 7.0% or higher in the last 6 months

What does the study involve?

Participants selected the group they wished to join: either a health coaching intervention every two weeks or a health coaching intervention only when they returned for a check-up every 3 months. The coach helps them to set their own HbA1c and behaviour goal. Once they set their 6-month goal, they have to set their action plan and the coach tracks their work in the following six sessions. The coach has International Coach Federation ACC credentials. Both groups have general diabetes education. HbA1c (a measure of how well a person's diabetes is being controlled) is measured by blood test at the start of the study, 3 months, 6 months and 1 year.

What are the possible benefits and risks of participating?

There will be no assured direct benefits to those taking part since it depends on the degree of effort that participants put in. There are no risks of health coaching since both groups have diabetes health education before the intervention. Also, participants can call two certified diabetes educators at any time.

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

When is the study starting and how long is it expected to run for?
June 2017 to October 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Ching-Ling Lin
work5halfday@cgh.org.tw
2. Associate Professor Ruey-Yu Chen
rueyyu@tmu.edu.tw

Contact information

Type(s)
Scientific

Contact name
Dr Ching-Ling Lin

ORCID ID
<https://orcid.org/0000-0002-9548-6300>

Contact details
Department of Endocrinology & Metabolism
Cathay General Hospital
280 Renai Rd. Sec.4
Taipei
Taiwan
106
+886 (0)2 27082121 # 3165
work5halfday@cgh.org.tw

Type(s)
Scientific

Contact name
Prof Ruey-Yu Chen

Contact details
School of Public Health
Taipei Medical University
No.250, Wu-Hsing Street
Taipei
Taiwan
110
+886 (0)2 27361661 #6521
rueyyu@tmu.edu.tw

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

An innovative approach for increasing adherence to medical regimen and glycaemic control among type II diabetes patients: a randomized controlled trial of hospital-based health coaching

Study objectives

Health coaching intervention could improve type 2 diabetes patients' HbA1c control, self-management efficacy and health behaviors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cathay General Hospital, 05/06/2017, ref: CGH-OP106001

Study design

Single-centre two-arm non-blinded interventional quasi-experimental design

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Participants were recruited from Cathay General Hospital in Taipei, Taiwan. Two physicians who specialize in endocrine and metabolic disorders screened potential patients with type 2 diabetes mellitus. If a patient met the inclusion criteria, one of the doctors explained the study and assessed his or her willing to participate. Once they agree to join and sign informed consent, participants selected the group they wished to join: (1) coaching intervention every two weeks or (2) coaching intervention only when they returned for a check-up every three months. The study design was not blinded. The health coaching intervention includes one face-to-face coaching session at start and six sessions telephone coaching within six months. Coachees have to set their HbA1c goal and their behavior change goal, then follow up by coach. The coach has International Coach Federation ACC credentials. Both groups have general diabetes education. Data collection to evaluate outcomes difference between baseline and upon completion of the every 3 months within study period.

Intervention Type

Behavioural

Primary outcome(s)

HbA1c (%), measured by biochemical test at baseline, 3 months, 6 months and 1 year

Key secondary outcome(s)

Measured at baseline, 3 months, 6 months and 1 year:

1. Self-management efficacy, measured using Perceived Diabetes Self-Management Scale
2. Physical activity, measured using Godin leisure-time physical activity scale
3. Self-blood glucose monitoring, measured using self-report

Completion date

31/10/2018

Eligibility**Key inclusion criteria**

1. Diagnosed with type 2 diabetes for at least one year
2. 20 to 75 years old
3. HbA1c of 7.0% or greater in the last six months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

116

Key exclusion criteria

1. Type 1 diabetes mellitus
2. Pregnant or trying to become pregnant
3. Participated in another similar program in the last 6 months
4. Clinically significant depression or cognitive dysfunction
5. Failed to sign informed consent

Date of first enrolment

05/06/2017

Date of final enrolment

31/10/2017

Locations

Countries of recruitment

Taiwan

Study participating centre

Cathay General Hospital

280 Renai Rd. Sec.4

Taipei

Taiwan

106

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, who can provide clean SPSS data (.sav). This data will become available once the paper has been published. This data will be completely anonymous, meets the IRB approval requirement, and all variables' definitions will be marked in the .sav data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/10/2019	19/11/2019	Yes	No

