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# 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

**Registration date**
10/05/2018

**Overall study status**
Completed

**Last Edited**
19/11/2019

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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2. Associate Professor Ruey-Yu Chen
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# Contact information

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
An innovative approach for increasing adherence to medical regiment 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

### Secondary study design
Quasi-experimental design

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

### Secondary outcome measures
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

### Overall study start date
05/06/2017

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
120

### 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
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## Sponsor information

### Organisation
Cathay General Hospital

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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 Diabetes Care

**Intention to publish date**
09/08/2018

**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 |