# The Happy Life Club™ study: a cluster randomised controlled trial of a type 2 diabetes health coach intervention

Submission date Recruitment status [X] Prospectively registered 03/11/2010 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 14/12/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category Nutritional, Metabolic, Endocrine 05/10/2018

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

The Happy Life Club™ study: a cluster randomised controlled trial of a telephone and face-to-face coaching intervention to improve glycaemic control and metabolic, physiological and psychological profiles of patients with type 2 diabetes

## Study objectives

## 1. Primary objective:

To determine the effectiveness of the Happy Life Club™ intervention in improving the glycaemic control of participants at 6, 12 and 18 months compared with usual care.

## 2. Secondary objective:

To determine the effectiveness of the Happy Life Club™ intervention in improving the metabolic, physiological and psychological profiles of participants at 6, 12 and 18 months compared with usual care.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The Monash University Human Research Ethics Committee, 03/06/2010

## Study design

Cluster randomised controlled trial

## Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Type 2 diabetes

## **Interventions**

Participants in the intervention group will receive a combination of both telephone and face to face health coaching over an 18 month period in addition to the same usual care received by participants in the control group. Health coaching will be performed by CHS doctors and nurses certified in coach assisted chronic disease management.

## Intervention Type

Other

#### Phase

Not Applicable

# Primary outcome(s)

Change in HbA1c between baseline and 18 month follow up

Outcome measures will be assessed at 6, 12 and 18 months.

#### Key secondary outcome(s))

- 1. Clinical Health Check
- 1.1. Anthropometric measurements
- 1.2. Blood pressure
- 1.3. Total cholesterol
- 1.4. Triglyceride
- 1.5. Low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol levels
- 1.6. 2 hour postprandial glucose
- 1.7. Homocysteine
- 2. Self-administered questionnaire
- 2.1. Quality of life
- 2.2. Diabetes management self-efficacy
- 2.3. Diabetes self care activities
- 2.4. Psychosocial distress
- 2.5. Lifestyle factors
- 2.6. Self-rated health

Outcome measures will be assessed at 6, 12 and 18 months.

## Completion date

01/06/2013

# Eligibility

## Key inclusion criteria

- 1. Community Health Stations:
- 1.1. All community health stations located in the Fengtai district of Beijing, China
- 2. Participants:
- 2.1. Previously diagnosed with type 2 diabetes
- 2.2. Aged 50 years and over
- 2.3. Reside in the Fengtai district of Beijing, China
- 2.4. Have an established health record and receiving care at one of the participating CHSs

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

#### Sex

Αll

#### Key exclusion criteria

- 1. Inability to understand and provide informed consent
- 2. Medical condition that precludes adherence to recommendations (e.g. end stage cancer, severe mental illness)

## Date of first enrolment

# Date of final enrolment 01/06/2013

# Locations

## Countries of recruitment

Australia

China

Study participating centre
Building 1
Notting Hill
Australia
3168

# Sponsor information

# Organisation

Chinese Centre for Disease Control and Prevention (China) - Fengtai District

#### **ROR**

https://ror.org/04wktzw65

# Funder(s)

## Funder type

Government

## **Funder Name**

Chinese Centre for Disease Control and Prevention (China) - Fengtai District

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

# Not provided at time of registration

# Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	04/03/2016	Yes	No
Results article	results	19/09/2018	Yes	No
Protocol article	protocol	09/02/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes