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

**Submission date**
03/11/2010

**Recruitment status**
No longer recruiting

**Registration date**
14/12/2010

**Overall study status**
Completed

**Last Edited**
05/10/2018

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Treatment

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

## 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 measure
Change in HbA1c between baseline and 18 month follow up

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

### Secondary outcome measures
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.

### Overall study start date
01/06/2011

### 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

### Age group
Senior

### Sex
Both

### Target number of participants
A total sample of 720 participants is required from 42 Community Health Stations (an average of 17 participants per CHS) (updated on 28/06/2011; 1320 participants at time of registration)

### 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
01/06/2011

### 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

### Sponsor details
3 Xi An Street
Fengtai District
Beijing
China
10007

### Sponsor type
Research organisation

### 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 09/02/2011 | | Yes | No |
| Results article | results | 04/03/2016 | | Yes | No |
| Results article | results | 19/09/2018 | | Yes | No |