

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 14/12/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 05/10/2018	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

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

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

All

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

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				

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