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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