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Effectiveness of diabetes mellitus self management programme

Submission date	Recruitment status
23/07/2010	No longer recruiting
Registration date	**Overall study status**
25/08/2010	Completed
Last Edited	**Condition category**
10/01/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] 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

Contact name
Prof Albert Lee

Contact details
School of Public Health and Primary Care
The Chinese University of Hong Kong
4th Floor, School of Public Health
Shatin
Hong Kong
N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled study of the effectiveness of diabetes mellitus (DM) self-management service in DM patients

Study objectives
Self management programme with focus on improvement of self efficacy and addressing the psycho-social needs of patients with diabetes mellitus would lead to improved health outcomes including clinical parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint Chinese University of Hong Kong and New Territory East Cluster Clinical Research Ethics Committee approved on the 31st May 2007 (ref: CREC-2007-136-T)

Study design
Randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Both intervention and control groups received their usual medical follow-ups in their GOPCs. The intervention group underwent the six sessions of weekly course of DM self-management service with emphasis on self efficacy and participatory approach addressing the critical gap between the psycho-social and self management support for diabetes patients.

If a subject fulfilled entrance criteria after being assessed by the investigator, s/he was invited to attend a DM care seminar. The objective and the procedures of the study of DM self-management service, and their rights were explained at the end of the seminar. Those interested received further explanation and a written consent was obtained. The subjects were randomised to study group or control group by simple randomisation. The intervention group attended the six sessions of DM Self-management Service in six weeks (one session per week), each session lasted for 2.5 hours.

The total duration of follow up for both groups was 28 weeks. The intervention group received six sessions of training over six weeks period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. HbA1c level, assessed during baseline, week 8 and week 28
2. DM self efficacy scale, assessed during baseline, week 8 and week 28
3. Dietary behaviours, assesed at baseline, week 8, week 16 and week 28
4. Exercise level, assesed at baseline, week 8, week 16 and week 28
5. Body mass index (BMI), assesed at baseline, week 8, week 16 and week 28
6. Waist-hip ratio, assesed at baseline, week 8, week 16 and week 28

Secondary outcome measures
1. Improvement in urine albumin creatinine ratio between baselines and week 28
2. Improvement in blood pressure between baselines and week 28

Overall study start date
01/04/2007

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Patients attending general outpatient clinics (GOPC) in Hospital Authority New Territory East Cluster
2. For patients with unstable DM control: HbA1C reaches 8.5 or greater
3. Capable of filling in study diary
4. Capable of giving informed written consent
5. Aged over 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2007

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Hong Kong

Study participating centre
School of Public Health and Primary Care
Shatin
Hong Kong
N/A

Sponsor information

Organisation
Centre for Health Education and Health Promotion (Hong Kong)

Sponsor details
Chinese University of Hong Kong
4th Floor
Lek Yuen Health Centre
Shatin
Hong Kong
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Sponsor type
Research organisation

Website
http://www.cuhk.edu.hk/med/prof_lee/main.html

ROR
https://ror.org/00t33hh48

Funder(s)

Funder type
University/education

Funder Name
Chinese University of Hong Kong (Hong Kong) - Centre for Health Education and Health Promotion

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?
Results article	results	01/10/2011		Yes	No