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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**
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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
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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 |