

# Effectiveness of diabetes mellitus self management programme

<b>Submission date</b> 23/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/01/2012	<b>Condition category</b> 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

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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, assessed at baseline, week 8, week 16 and week 28
4. Exercise level, assessed at baseline, week 8, week 16 and week 28

5. Body mass index (BMI), assessed at baseline, week 8, week 16 and week 28

6. Waist-hip ratio, assessed at baseline, week 8, week 16 and week 28

### **Key secondary outcome(s)**

1. Improvement in urine albumin creatinine ratio between baselines and week 28

2. Improvement in blood pressure between baselines and week 28

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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)

### 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

### 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?
<a href="#">Results article</a>	results	01/10/2011		Yes	No