

# Tailored intervention compared to usual care on smoking type 2 diabetic patients to promote smoking cessation and improved glycaemic control

<b>Submission date</b> 05/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/12/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Growing evidence suggests that smoking has a substantial impact on patients with diabetes, but smoking cessation (quitting smoking) is largely ignored in routine diabetic care. The aim of this study is to test the effectiveness of a tailored smoking cessation intervention to improve the quit rate and the control of blood sugar levels of smoking type 2 diabetic patients.

### Who can participate?

Smoking type 2 diabetic patients aged 18 or over.

### What does the study involve?

Participants complete a lifestyle questionnaire and their exhaled carbon monoxide level is measured (this indicates how much they smoke). They are then randomly allocated to either the intervention group or the control group. The intervention group receive education materials about smoking cessation and a 30-minute face-to-face counselling session. The control group receive leaflets about diabetes management and a self-help smoking cessation guide.

Counselors contact both groups 1 week and 1 month later. Participants are also contacted regularly after 3, 6 and 12 months. At the 12-month follow-up, saliva samples and exhaled carbon monoxide are collected from participants who successfully quit smoking or reduce their cigarette consumption by at least 50%.

### What are the possible benefits and risks of participating?

This study is completely safe and will not cause any discomfort. All information gathered is confidential. Individuals' names will not be used during data analysis nor identified when the results are reported.

### Where is the study run from?

This study is conducted by the School of Nursing and Department of Community Medicine, School of Public Health, of the University of Hong Kong with the Hospital Authority of the Hong

Kong government. About 10 diabetes specialty outpatient clinics under the Hong Kong Hospital Authority will be participating in this study. Six confirmed clinics are listed below:

Caritas Medical Centre, Diabetes Care Centre

Tung Wah Eastern Hospital, DM Centre

Queen Mary Hospital, DM Centre

Pok Oi Hospital, DM Centre

United Christian Hospital, Diabetes Ambulatory Care Centre

Ruttonjee Hospital, Diabetes Centre

When is the study starting and how long is it expected to run for?

January 2011 to June 2013.

Who is funding the study?

Hong Kong Health and Health Services Research Fund

Who is the main contact?

Prof. Sophia Chan

nssophia@hku.hk

## Contact information

### Type(s)

Scientific

### Contact name

Prof Sophia SC Chan

### Contact details

The Univeristy of Hong Kong

Li Ka Shing Faculty of Medicine

4/F William MW William Block,

21 Sassoon Road

Pokfulam

Hong Kong

-

-

nssophia@hku.hk

## Additional identifiers

### Protocol serial number

08091061

## Study information

### Scientific Title

A randomized controlled trial of a tailored intervention compared to usual care on smoking type 2 diabetic patients to promote smoking cessation and improved glycaemic control

### Study objectives

To test the effectiveness of a tailored smoking cessation intervention targeting type 2 diabetic patients who smoke in achieving:

1. Smoking cessation and/or improvement in smoking behaviours
2. A better control of HbA1c level
3. Predictive factors for the success of the two primary outcomes and
4. Cost-effectiveness of the intervention compared to the control

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster, 22/4/2008, ref: UW 08-142

### **Study design**

Multicentre single-blinded randomized controlled trial

### **Primary study design**

Interventional

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

Quality of life

### **Health condition(s) or problem(s) studied**

Type II diabetes

### **Interventions**

The intervention group will receive education materials about smoking cessation, and a 30-minute face-to-face smoking cessation counselling conducted by a trained nurse smoking cessation counsellor at baseline. A 20-minute follow up phone counselling will be provided at 1-week and 1-month after recruitment.

The control group will receive leaflets on diabetes management and self-help smoking cessation guide.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Self-reported 7-day tobacco abstinence rate at 12 months

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

1. The change in glycated haemoglobin (HbA1c) levels
2. Biochemical validated quitting and changes in smoking behaviors (reduction in cigarette consumption and progression to a higher stage of readiness to quit)
3. Clinical outcomes [body mass index (BMI), sodium, potassium chloride, blood glucose, blood pressure and renal function] and
4. Lifestyle risk factors (drinking, fruit and vegetable intake)

Measured at 12 months

**Completion date**

30/06/2013

## Eligibility

**Key inclusion criteria**

1. Smokes at least 2 cigarettes daily in the past 30 days
2. Diagnosed with type 2 diabetes for at least 6 months such that their diabetic conditions and treatments should be stable
3. Age 18 or above
4. Can communicate in Cantonese

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Too sick to receive intervention
2. Poor cognitive state
3. Mental illness
4. Undergoing other smoking cessation program
5. With unstable diabetic or other medical conditions deemed to be not suitable by the doctor in charge

**Date of first enrolment**

01/02/2012

**Date of final enrolment**

01/03/2013

## Locations

**Countries of recruitment**

Hong Kong

**Study participating centre**  
**The Univeristy of Hong Kong**  
Pokfulam  
Hong Kong

-

## **Sponsor information**

### **Organisation**

Hong Kong Health and Health Services Research Fund (Hong Kong)

### **ROR**

<https://ror.org/03qh32912>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Hong Kong Health and Health Services Research Fund (Hong Kong) (Ref: 08091061)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration