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

Submission date
05/12/2011

Recruitment status
No longer recruiting

Registration date
05/03/2012

Overall study status
Completed

Last Edited
08/12/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

Secondary outcome measures
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

Overall study start date
01/01/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
379 patients will be required in each group to achieve a significant outcome. Hence the total sample size of the study will be 758 (DM and Control groups).

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
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Sponsor information

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

Sponsor details
Research Fund Secretariat
Research Office
Food and Health Bureau
18/F, Murray Building
Garden Road, Central
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Sponsor type
Government

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

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