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Effective Smoking Cessation Augmented PackagE (ESCAPE): evidence-based new service package vs. routine package to stop smoking

Submission date	Recruitment status	[_] Prospectively registered
09/06/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/07/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Cardiovascular diseases (CVDs) are preventable, and a substantial number of CVD events and deaths can be prevented by giving up smoking. Thailand has a current smoking prevalence of 28-38% with severe health and economic impacts. Enhancing the implementation of community-based smoking cessation programs is an urgent necessity in Thailand. While smoking cessation programs (stop smoking programs) have been shown to be effective, the question of how to increase their effectiveness and practicality remains. In this study we will assess the effectiveness of a new evidence-based smoking cessation service package to be implemented at community-level hospitals in northern Thailand.
The primary objective of the study is to compare, after one year, the smoking cessation rate between the new evidence-based smoking cessation service package and the conventional smoking cessation service package. Other objectives are:
i. To compare the smoking cessation or quitting rate after six months.
ii. To compare the CVD risk by Framingham general cardiovascular risk score among intervention and control groups at the one-year follow-up
iii. To find out the characteristics of successful quitters and the determinants of behavioral change
iv. To find out the characteristics of relapse smokers after six months of cessation and the determinants of behavioral change
v. To compare the cardiovascular disease events among ex-smokers, reduced smokers and continuous smokers after one year
vi. To find out the cost effectiveness of the new smoking cessation service package

Who can participate?
The study participants are made up of current smokers, both male and female, aged over 35, who are at high risk of CVD by having either or both hypertension or diabetes, and who are attending the non-communicable disease clinic network in Maetha Hospital, Lampang, Thailand.

What does the study involve?
Study participants will be randomly allocated to one of the two smoking cessation programs:

receiving either the routine smoking-cessation service package or a new health service smoking cessation package.
The routine health service approach for smoking cessation as defined by the 5A's (ask, advise, assess, assist, and arrange follow-up), and the new service package, comprising evidence and experience-based approaches, will be compared. The routine health service approach for smoking cessation is as follows: (1) during the first meeting the hospital healthcare worker advises the patient on how to stop smoking; (2) the patient answers questions about their smoking habit to indicate their level of nicotine dependency; (3) the patient is reminded by the healthcare worker on subsequent visits to the hospital of how to stop smoking; (4) the patient is asked to let the healthcare worker know if and when they have successfully been able to give up smoking.
The new, augmented health service approach is as follows: (1) During the first meeting, a primary care unit (PCU) nurse motivates the patient to give up smoking by providing a clear explanation of how to do it. The same nurse will provide repeated advice each month over the next three months. (2) A device called a 'smokerlyzer' is used to show the level of the harmful gas carbon monoxide (CO) the patient breathes out, and the improvement of the patient's lung health over three successive months as the patient attempts to give up smoking. (3) A PCU nurse trains one member of the patient's family how to care for the patient until they have successfully given up smoking. (4) Patients who suffer from nicotine craving are given nicotine replacement chewing gum.
Smokers who refuse to attempt to give up smoking at the recruitment stage will be just followed up and monitored over a period of one year. All participants who agree to attempt to give up smoking will receive one of the two smoking cessation service packages in addition to the any health care provision for their current diseases, as provided under the universal health insurance system.

What are the possible benefits and risks of participating?
The major benefit of the study is that participants will receive assistance and support in their attempt to give up smoking. Furthermore, no new drugs will be tested and there will be no invasive collection of specimens. Thus, the current study will not introduce any harmful risks to the participants. Moreover, participants will receive useful measured health information from the study, such as the CO level in their exhaled air, the percentage of CO occupying their haemoglobin, the measurement of their waist and hip circumference, and their cardiovascular risk score. Participants will also receive nicotine replacement chewing gum, if necessary. The study will not introduce any new drugs; however, smoking cessation can cause the following nicotine withdrawal symptoms in patients to varying degrees: headache, nausea, constipation, diarrhoea, falling heart rate and blood pressure, fatigue, drowsiness, insomnia, irritability, difficulty in concentrating, anxiety, depression, increased hunger and food intake, increased desire for sweet food, and tobacco cravings.

Where is the study run from?
The study will take place in seven primary care units of Maetha Hospital, Lampang, Thailand. Maetha Hospital is the lead center in this trial.

When is the study starting and how long is it expected to run for?
The study will start in June 2013 and will run for one year. Participants will be recruited up until December 2013.

Who is funding the study?
The Ministry of Education, Culture, Sports, Science and Technology, Japan and the Department of Public Health, Juntendo University, School of Medicine, Tokyo, Japan

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
U1111-1145-6916; 3/2013

Study information

Scientific Title
Evidence-based new service package vs. routine service package for smoking cessation to prevent high risk patients from cardiovascular diseases (CVD): a randomized controlled trial

Acronym
ESCAPE

Study objectives

A smoking cessation service comprising continuous motivation by a single nurse, application of smokerlyzer, continuous family support, and nicotine replacement therapy based on individual need will lead to more successful behavior change than the routine smoking cessation service approach among cardiovascular risk patients.

On 12/11/2013 the overall trial end date was changed from 21/06/2014 to 21/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Juntendo University Ethical Committee, Japan, Permission number 2012194
2. Institutional review board at Boromarajonani College of Nursing, Lampang, Thailand, approval number E2556/005

Study design
Randomized controlled trial with an additional non-randomized arm

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Smoking, Cardiovascular Disease (CVD) prevention

Interventions
Once the participants have agreed and consented to participate in the trial, he/she will be asked whether they are willing to attempt quitting smoking. If the participant agrees to quit smoking, he/she will be randomized into an evidence-based new service package arm or a routine smoking cessation service package arm. If the participant denied quitting smoking, he/she will be automatically allocated to the non-randomized arm. Participants in this arm will not receive any active intervention for smoking cessation apart from the routine medical service for their existing disease such as diabetes and hypertension, under the universal coverage system.

The new, augmented health service will include the following interventions in a package:
1. During the first meeting, a primary care unit (PCU) nurse motivates the patient to give up smoking by providing a clear explanation and the same nurse will provide repeated advice each month over the next three months.
2. piCO+ smokerlyzer is used to show the level of carbon monoxide (CO) the patient breathes

out, and the improvement of the patient's lung health over three successive months as the patient attempts to give up smoking
3. A PCU nurse trains one member of the patient's family how to care for the patient until they have successfully given up smoking
4. Patients who suffer from nicotine craving are given nicotine replacement chewing gum.

The routine health service for smoking cessation package will include the following:
1. During the first meeting the hospital healthcare worker advises the patient on how to stop smoking
2. The patient answers questions about their smoking habit to indicate their level of nicotine dependency
3. The patient is reminded by the healthcare worker on subsequent visits to the hospital of how to stop smoking
4. The patient is asked to let the healthcare worker know if and when they have successfully been able to give up smoking.

Duration of intervention in the evidence-based smoking cessation service package:
1. Persistent motivating and coaching by the same PCU nurse for three months
2. Monthly application of piCO+ smokerlyzer to sustain motivation and positive feedback to the quitting smoker's attempt for three months
3. Assistance by trained family member for twelve months. (In case of smokers living alone, a health volunteer will be assigned to take care of quitting smoker.)

Duration of intervention in the routine arm:
1. Counseling by a health care worker only on the first time when a smoker patient was met at the hospital.
2. Reminding the smoker to stop smoking ad libitum on successive visits for 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Smoking cessation rate at one-year follow-up proven by measurement of CO in parts per million (ppmCO). Smoking cessation is defined as continuous quitting smoking for at least six months, confirmed by smokerlyzer.

Secondary outcome measures
1. Smoking cessation rate at six months follow up proven by measurement of CO in parts per million (ppmCO)
2. CVD risk by Framingham general cardiovascular risk score at 12 months follow-up
3. Blood pressure and heart rate at six months and 12 months follow-up
4. CVD events and death at 12 months of follow-up
5. Cost-effectiveness of the health service packages at base line and twelve months of follow-up

Overall study start date
22/06/2013

Completion date

21/12/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/08/2013:
1. Current smoker diabetes patient
2. Current smoker hypertensive patients
3. Current smoker with both diabetes and hypertension
4. Those who has never succeeded to stop smoking
5. Either sex
6. Age ranged from 35-80 years

Previous inclusion criteria:
1. Current smoker diabetes patient
2. Current smoker hypertensive patients
3. Current smoker with both diabetes and hypertension
4. Those who has never succeeded to stop smoking
5. Either sex
6. Age ranged from 35-70 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
440

Key exclusion criteria
1. Any female patients who are pregnant or planning to become pregnant
2. Patients aged younger than 35 years
3. Patients with documented type I diabetes
4. Patients with cancer
5. Patients with severe chronic pulmonary diseases using home oxygen therapy
6. Known diagnosis of previous cardiovascular disease (CVD) event

Date of first enrolment
22/06/2013

Date of final enrolment
21/12/2013

Locations

Countries of recruitment

Japan

Thailand

Study participating centre
Juntendo University
Tokyo
Japan
113-8421

Sponsor information

Organisation
Ministry of Education, Culture, Sports, Science and Technology (Japan)

Sponsor details
Kasumigaseki 3-2-2
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100-8959

Sponsor type
Government

Website
http://www.mext.go.jp/english/

ROR
https://ror.org/048rj2z13

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Culture, Sports,Science and Technology (Japan)

Alternative Name(s)
Monbu-kagaku-shō, , MEXT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Japan

Funder Name
Department of Public Health, Juntendo University, School of Medicine (Japan)

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?
Protocol article	protocol	05/12/2013		Yes	No
Results article	results	22/02/2019	25/02/2019	Yes	No