

# The 5 A's model in behavioural therapy versus brief advice on smoking cessation delivered by dentists in a dental setting

<b>Submission date</b> 15/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Everyone knows smoking kills. Tobacco smoke contains more than 7,000 chemicals of which around 70 can cause cancer. Research has proven that patients think that dentists should routinely offer services to help them quit smoking (smoking cessation services). It is also known that smoking cessation advice by dentists does not alienate patients who smoke. As smokers are more likely to have dental health issues than non-smokers, the dental profession can be seen as the "front liners" in helping people stop smoking, as they are often the health professionals that recognise when a patient is smoking first. They are able to help improve both the oral and general health of their patients by influencing their tobacco use. There are Ministry of Health facilities throughout Malaysia that provide smoking cessation services. These include counselling and pharmacotherapy (drug treatment) for quitting smoking. Medical doctors, nurses or medical assistants run these quit smoking clinics. Dentists and dental specialist have referred dental patients who want to quit smoking to these clinics. However, there has been no clear record as to whether these patients have gone to these clinics, have been seen by these health personnel or successfully quit. Interestingly, the Malaysia's National Oral Health Plan for 2011-2020, included, for the first time, provision for dentists to provide care and advice to their patients against tobacco use. It was part of the strategies to prevent people from smoking and promote early detection of oral health issues, particularly oral cancer. One barrier in this being successful, however, is a lack of training, lack of educational materials, lack of knowledge and lack of available resources for helping people to stop smoking. There have not yet been any studies looking at how successful smoking cessation services suitable for delivery via dentists in Malaysia are at helping people to stop smoking. The aim of this study is to investigate the effectiveness of a smoking cessation model called the 5A's model of advice compared to brief advice delivered by dentists in dental clinics.

### Who can participate?

Smokers aged between 15-70 years old attending a Ministry of Health Dental Clinics in Selango.

### What does the study involve?

Dental Public Health (DPH) specialists are randomly allocated to one of two groups. Those in

group 1 are trained to deliver the 5A's smoking cessation intervention. Those in group 2 are trained to deliver the brief advice intervention. Patients that the eligible to take part are given the intervention that their DPH specialist has been trained to deliver. All patients are followed up via a telephone call one month after being given the intervention and again at 3 months. All participants are assessed to see whether they have stopped smoking and how long for.

What are the possible benefits and risks of participating?

Benefits for patients include them being helped to stop smoking at the same time as any oral health issues being dealt with. Risks not provided at time of registration.

Where is the study run from?

Six dental clinics located in Selangor state (Malaysia)

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

February 2014 to August 2015

Who is funding the study?

University of Malaya

Who is the main contact?

Dr Nurul Askikin Yahya

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## Contact information

**Type(s)**

Public

**Contact name**

Dr Nurul Asyikin Yahya

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

The 5 A's model in behavioural therapy versus brief advice on smoking cessation delivered by dentists in a dental setting: a randomized controlled trial

### Study objectives

The 5A's smoking cessation intervention achieves a more positive outcome than brief advice [BA] given by dentists in a dental setting.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Faculty of Dentistry University of Malaya Research Ethics Committee, ref: DF CO1301/003(P)
2. Ministry of Health Malaysia, Medical Research Ethics Committee (MREC), ref: KKM/NIHSEC/P13-551)

### Study design

Two-arm single-blinded randomized controlled trial (parallel design)

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Smoking

### Interventions

A two-arm single-blinded randomized controlled trial (parallel design) will be conducted to compare the effectiveness of the 5A's smoking cessation intervention (5A's) versus a brief advice (BA) delivered by dentists in a dental setting. This trial involves the preventive oral health program within the oral health services provided by the ministry of Health Malaysia.

The 5A's (Ask, Advice, Assess, Assist and Arrange) are the evidence-based framework for structuring smoking cessation in health care settings originally developed as part of the United

States Department of Health's Clinical Practice Guideline. It advises on ways to increase motivation to quit smoking (5 R's), relating the reasons why to each individual and to re-assess their motivation and readiness to quit during their next visit for patients whom are at the precontemplation and contemplation stage of change. Patients in the preparation or action stage will be advised on the behavioural strategies to cope with withdrawal symptoms and relapse prevention. Later, patients in this intervention will receive self-help pamphlets and are encouraged to have a quit date within 2 weeks after this first visit.

The brief advice consists of verbal instructions to stop smoking with or without added information about the harmful effects of smoking. Patients will be given a brief message that includes the following:

1. The choice not to smoke has many benefits, including better oral health and more nice-looking teeth
2. I will give you a brochure that contains helpful information about quit smoking
3. Refraining from smoking can be hard, but it is important for your health

During the patients' dental visit, a receptionist at the registration counter of each dental clinic will invite patients who fit the inclusion criteria of this trial to participate. Once agreed, an explanation of the study will be given (patient information sheet) by a dental surgery assistant (DSA) and a consent form signed with a witness present. Patients will then be seen by a Dental Public Health (DPH) specialist involved with the smoking cessation intervention. The treatment period will be 6 months in total. Patients will be contacted by telephone for follow-ups at 1-month, 3-months and 6-months after their initial visit for quit smoking. A token of appreciation will be given to each patient after the visit.

Six DPH specialists posted at 6 different dental clinics located in Selangor state will be recruited as the health care providers for delivering the smoking cessation interventions in this study. A one-day Smoking Cessation Intervention Delivered by Dentists (SCIDD) workshop will be held for training and standardization of each intervention at the Faculty of Dentistry, Universiti Kebangsaan Malaysia on two separate dates. There will be interactive learning methods involving planned readings, lectures, group discussion and role-plays in a whole day session. All DPH specialists involved will also be briefed on the clinical trial protocols. Technique on using the carbon monoxide monitor will also be trained during this course. Continuing professional development (CPD) points upon completion of the training will be awarded to them.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. 30-days prolonged abstinence, self-reported
2. Abstinence at 6 months, measured with a carbon monoxide monitor

## **Secondary outcome measures**

Behaviour change of smokers at any level of stage of change based on the Contemplation Ladder questionnaire at 1-month and 3-months follow-up.

The stages of change were defined as follows:

1. Precontemplation: not thinking of quitting within the next 6 months
2. Contemplation: considering quitting in the next 6 months, but has no plans

3. Preparation: considering quitting in the next 30 days and has taken some behavioural steps in this direction

4. Action: quit in the last 6 months

**Overall study start date**

10/02/2014

**Completion date**

10/08/2015

## **Eligibility**

**Key inclusion criteria**

1. Smokers attending Ministry of Health Dental Clinics in Selango
2. A Malaysian citizen
3. Aged between 15-70 years
4. Smoke at least for the past 30 days
5. Are contactable by telephone
6. Is not currently under smoking cessation treatment with other health clinic

**Participant type(s)**

Other

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

500

**Key exclusion criteria**

1. Not a smoker
2. Not a Malaysian citizen
3. Not contactable by telephone

**Date of first enrolment**

10/03/2014

**Date of final enrolment**

10/06/2015

## **Locations**

**Countries of recruitment**

Malaysia

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Shah Alam Seksyen 7**

2, Persiaran Kayangan

Shah Alam

Malaysia

40000

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Shah Alam Seksyen 19**

Shah Alam

Malaysia

40000

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Kuala Kubu Bahru**

Kuala Kubu Bahru

Malaysia

44000

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Bandar Baru Bangi**

Bandar Baru Bangi

Malaysia

43650

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Kelana Jaya**

Kelana Jaya

Malaysia

47301

**Study participating centre**

**Dental Clinic (Klinik Pergigian) Salak**

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**Sponsor information**

**Organisation**

University of Malaya

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**Sponsor type**

University/education

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**ROR**

<https://ror.org/00rzspn62>

**Funder(s)****Funder type**

University/education

**Funder Name**

Universiti Malaya

**Alternative Name(s)**

University of Malaya, University Malaya, Malayan University, UM

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Malaysia

**Results and Publications**

Publication and dissemination plan

**Intention to publish date**

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

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2018	29/01/2019	Yes	No