

The non-concealed placebo: a randomized trial on smoking cessation

Submission date 24/02/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/03/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/09/2017	Condition category Mental and Behavioural Disorders	<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

This study would like to find out if a non-deceptive non-concealed placebo patch (that is a patch that contains no active ingredients) will help people reduce the number of cigarettes that they smoke. A placebo is something that looks like a real medical treatment, but isn't. It could be a pill for example, or another type of "fake" treatment. Placebos do not contain any active substances that have been developed to improve health. Researchers often use placebos to help them understand the effects of a new treatment (by comparing the effects on participants taking the new drug with those taking the placebo). However, some people do respond to a placebo. This is referred to the placebo effect and there are some cases where it happens even when a person knows that they are taking a placebo. It is seen as a possible explanation for why some patients have a greater chance of a good outcome when given a dummy pill rather than being given nothing at all. It is also a possible explanation of why some patients still believe in treatments that are known not to work or are not clinically proven. This could be due to belief or the powers of suggestion, which might be a very important aspect of a treatment. This study looks at whether given a patch known to be a placebo to smokers helps them to reduce the number of cigarettes that they smoke.

Who can participate?

Adults that have smoked for at least 2 years and want to stop smoking.

What does the study involve?

All participants are told before starting the study that the best way to stop smoking (and therefore reduce their dependence on nicotine) is to reduce the number of cigarettes that they smoke over time. Participants are randomly allocated to one of two groups. Those in group 1 (the placebo patch group) are given a 56 day supply of placebo smoking cessation patches. They are all told that the patches are placebos and are monitored for 56 days to see whether they reduce the number of cigarettes that they smoke. Those in group 2 (control group) are not given any patches but are also monitored for 56 days to see whether they reduce the number of cigarettes that they smoke.

What are the possible benefits and risks of participating?

It is possible that participating in this study will help in reducing the number of cigarettes that a person smokes. The main risk to participating is nicotine withdrawal symptoms.

Where is the study run from?

University of Santo Tomas (Philippines)

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

January 2015 to October 2015

Who is funding the study?

Investigator initiated and funded (Philippines)

Who is the main contact?

Mr Kevyn Yu

Contact information

Type(s)

Public

Contact name

Mr Kevyn Yu

Contact details

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Philippines

1008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

An open-label randomized interventional study to assess the effect of placebo smoking cessation patches versus no treatment on nicotine dependence scores of adult Filipino smokers

Study objectives

Ho: There would be no significant difference in the delta FTND (Fagerstrom test for Nicotine Dependence) scores between placebo treatments as compared to no treatment

Hi: There would be a significant difference in the delta FTND scores between a placebo patch treatment as compared to no treatment

This study asks the question: How significant is the difference in FTND score delta when a placebo is suggested as a Smoking cessation agent versus no treatment at all?

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Santo Tomas Faculty of Pharmacy Ethics Review Committee, 07/07/2015

Study design

Open-label randomized interventional

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Other

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 addiction

Interventions

There were two arms in the study, the placebo patch group and the control group.

1. Both groups:

- 1.1. Gave informed consent
- 1.2. Were within the inclusion and exclusion criteria of the study
- 1.3. Were told that the safe way to decrease nicotine dependence, was to incrementally reduce cigarette smoking with time
- 1.4. Data gathering by a blinded assessor

2. Placebo patch group:

- 2.1. Were given 56 day supply of placebo smoking cessation patches
- 2.2. Were told to apply the patches daily for 56 days
- 2.3. Were explicitly told that the patches given were placebos and had no active ingredient but

were for reducing nicotine dependence

2.4. Were monitored for a 56 day period, with data gathering for nicotine dependence on days 0, 28 and 56

3. Control group were monitored for a 56 day period, with data gathering for nicotine dependence on days 0, 28 and 56

Intervention Type

Other

Primary outcome measure

Nicotine dependence, measured using the Fagerstrom test for Nicotine Dependence (FTND) at 0, 28 and 56 days after provision of patches

Secondary outcome measures

Cigarettes per day, measured at 0, 28 and 56 days after provision of patches

Overall study start date

15/01/2015

Completion date

29/10/2015

Eligibility

Key inclusion criteria

1. 18 years or older
2. Male or female
3. Current smoker for 2 years
4. Very willing to quit smoking when assessed with 5 point commitment scale
5. Willing to use the placebo patch for a period of 2 months
6. Ethnically Filipino and currently residing in Sampaloc, Manila
7. Has signed the informed consent form and is aware of the purpose of the study

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Taking other smoking cessation treatment/ treatments (e.g. nicotine patches or gum)
2. Is under or have underwent smoking cessation counseling

Date of first enrolment

10/07/2015

Date of final enrolment

29/07/2015

Locations

Countries of recruitment

Philippines

Study participating centre**University of Santo Tomas**

España, Quezon Dr

Sampaloc, Manila

Philippines

1008

Sponsor information

Organisation

University of Santo Tomas

Sponsor details

Faculty of Pharmacy (ethics review committee)

España, Quezon Dr

Sampaloc, Manila

Philippines

1008

Sponsor type

University/education

ROR

<https://ror.org/00d25af97>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Plos One

Intention to publish date

29/02/2016

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

Not expected to be made available