

A randomised controlled trial on smoking cessation and adherence intervention on patients with erectile dysfunction

Submission date 15/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2011	Condition category 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

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

ED Project

Study objectives

1. The quit rate is higher in the intervention group than in the control group
2. In the intervention group, a) the adherence rate to nicotine replacement therapy (NRT) and b) the quit rate are greater in those who have received additional adherence intervention than those who have not

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee, Faculty of Medicine, University of Hong Kong. Date of approval: 19/02/2003 (ref: EC 1966-02)

Study design

Multicentre randomised single blind placebo controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Smokers with erectile dysfunction

Interventions

Intervention group 1: Face-to-face stage-matched smoking cessation counselling delivered by trained counsellors at initial contact, 1 week and 1 month with nicotine replacement therapy adherence intervention.

Intervention group 2: Face-to-face stage-matched smoking cessation counselling delivered by trained counsellors at initial contact, 1 week and 1 month without nicotine replacement therapy adherence intervention.

Control: A placebo healthy diet education material and usual care provided by the hospital.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Quit rate at 6-month follow-up
2. Adherence rate to NRT use at 4 weeks after the first use of NRT

Secondary outcome measures

1. Erectile function based on international index of erectile function (IIEF) at 6 months
2. Self-reported use of NRT continuously for at least 4 weeks or 8 weeks
3. Quit rate at 3 months without validation
4. Validated quit rates at 6 months
5. Reduction of daily smoking by at least 50% by the subjects at 6 months
6. Number of quitting attempts made by the subject at 6 months

Overall study start date

01/11/2003

Completion date

31/10/2005

Eligibility

Key inclusion criteria

1. Ethnicity: Chinese
2. Age 18 or above, male
3. Those with erectile dysfunction
4. Smokes at least 1 cigarette per day
5. Intends to quit smoking within the next 7 days of the first contact and would use NRT
6. Has no contradictions to NRT
7. Is not following other forms of smoking cessation interventions
8. Has signed an informed consent form, or have given verbal consent (for those contacted by telephone)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

1,210

Key exclusion criteria

1. Patients who are psychologically or physically unable to communicate
2. Children and teenagers (age below 18)
3. Those on regular psychotropic medications and in the presence of any serious health problems that may make them unsuitable for using NRT, such as recent stroke, palpitation, or other life threatening conditions

Date of first enrolment

01/11/2003

Date of final enrolment

31/10/2005

Locations

Countries of recruitment

China

Study participating centre

5/F, William MW Mong Block

Hong Kong

China

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Sponsor information

Organisation

The Hong Kong Research Grants Council (China)

Sponsor details

7/F, Shui On Centre

6-8 Harbour Road

Wanchai

Hong Kong

China

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ugc@ugc.edu.hk

Sponsor type

University/education

Website

<http://www.ugc.edu.hk/eng/rgc>

ROR

<https://ror.org/00djwmt25>

Funder(s)

Funder type

University/education

Funder Name

The Hong Kong Research Grants Council (RGC) (China)

Funder Name

The Hong Kong Council on Smoking and Health (China)

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?
Results article	results	01/09/2010		Yes	No