ISRCTN13070778 https://doi.org/10.1186/ISRCTN13070778

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

Submission date	Recruitment status	[_] Prospectively registered
15/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

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)

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

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