ISRCTN05172176 https://doi.org/10.1186/ISRCTN05172176

Smoking reduction intervention for smokers not willing to quit smoking: a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
08/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2019	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HHSRF 01030611

Study information

Scientific Title
Smoking reduction intervention for smokers not willing to quit smoking: a randomised controlled trial

Acronym
Smoking Reduction (SR) Project

Study objectives
1. The quit rate and the reduction rate are higher in the intervention groups than the control group
2. In the intervention groups, (a) the adherence rate to replacement therapy (NRT) and (b) the quit rate and the reduction 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)
Institutional Review Board of the University of Hong Kong/ Hospital Authority, Hong Kong West Cluster. Date of approval: 29/05/2003 (ref: UW 03-103 T/103)

Study design
Single-centre, randomised, single-blind, placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Smokers who have no intention to quit in the near future

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 NRT 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 NRT 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. Reduction rate at 6 month follow-up
3. Adherence rate to NRT use at 4 weeks after the first use of NRT

Secondary outcome measures
1. Validated quit rates at 6 months
2. Quit rate at 1 month without validation
3. Self-reported use of NRT continuously for at least 4 weeks or 8 weeks
4. Number of quitting attempts made by the subject. Duration of follow-up: 6 months after the baseline visit

Overall study start date
25/10/2004

Completion date
30/07/2006

Eligibility

Key inclusion criteria
1. Both males and females, age 18 or above
2. Ethnic Chinese
3. Smokes at least 2 cigarettes per day
4. Have no intention to quit in the near future
5. Intends to reduce smoking in the next 7 days
6. Has no contraindication to NRT

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3,826

Total final enrolment
1154

Key exclusion criteria
1. Subjects who are psychologically or physically unable to communicate
2. Children and teenagers (age below 18)
3. Pregnant or intention to become pregnant within the next 6 months
4. 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
25/10/2004

Date of final enrolment
30/07/2006

Locations

Countries of recruitment
China

Study participating centre
University of Hong Kong
Hong Kong
China
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Sponsor information

Organisation
Food and Health Bureau (China)

Sponsor details
Government of the Hong Kong Special Administrative Region
Secretary for Food and Health
19/F, Murray Building
Garden Road
Hong Kong
China

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+852 21892748
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Sponsor type
Government

Website
http://www.fhb.gov.hk/en

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
Health and Health Services Research Fund, Food and Health Bureau, Government of Hong Kong Special Administrative Region (China) (grant ref: No. 01030611)

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	01/06/2011	11/06/2019	Yes	No