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Family intervention to reduce second hand smoke (SHS) exposure in children

Submission date 31/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/05/2011	**Overall study status** Completed	
Last Edited 20/12/2016	**Condition category** Respiratory	

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

Family Intervention by nurses and counselors to reduce second hand smoke (SHS) exposure in children in Maternal and Child Health Centers (MCHC) of the Department of Health in Hong Kong a randomized controlled trial

Study objectives
The study is a randomized controlled trial to evaluate the effectiveness of a multi-step family smoking cessation intervention delivered by nurses to non-smoking mothers to execute a household no smoking policy and persuade their smoking husbands to attend a smoking cessation intervention provided by trained smoking cessation counsellors (SCC).

The specific objectives of the study are to:
1. Examine the decline in household SHS exposure in infants
2. Evaluate the effectiveness of a multi-step family smoking cessation intervention to motivate the mothers to execute a household no smoking policy, move husband to a higher stage of readiness to quit, persuade them to participate in a smoking cessation intervention provided by SCC, and quit successfully.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) on 31/05/2007 (IRB reference number: UW 07-211)
2. Ethics Committee of the Department of Health, Hong Kong government on 18/02/2008 (Reference number: L/M 281/2007)

Study design
Randomised single-blind standard care-controlled multi-centered study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Passive smoking in children

Interventions
At baseline: The smoking cessation counelors (SCCs) (registered nurses) will:
1. Provide a health education intervention to the mother outlining the hazards of SHS exposure

among women and children
2. Encourage the mother to execute a household no-smoking policy at home, and
3. Invite the mother to participate in a smoking cessation group session with the father provided by trained SCCs. An information sheet about the details of the smoking cessation group will be provided to both the father and the mother
4. The SCC will proactively call the father within 2 days to provide motivational telephone counseling
5. Invite the father (and mother) to participate in a smoking cessation group activity (within a month) where free NRT (for 1 week) and discount coupons will be provided for subsequent purchase from outside pharmacists
6. Furthermore, stage-matched smoking cessation materials will be posted to the father
7. If for some reason the family did not attend the group session, NRT will be posted to the father as appropriate

At 1 week and 1 month:
1. SCCs will give telephone reminders to both mothers and fathers to assess the feasibility and any barriers to execute the no-smoking policy at home, to assess the fathers smoking status, further engage him in the behavioral change process, enhance self efficacy, encourage use of self-help materials, and identify subject-specific barriers and facilitators 2. Fathers adherence in using NRT and their possible side effects will also be monitored 3. Further health education self-help smoking cessation materials will be posted to the fathers if necessary

Control group:
Mothers will receive standard care routinely provided by the MCHCs, a set of health education materials on the hazards of SHS exposure among women and children and a self-help smoking cessation pamphlet for the smoking fathers

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Child: reduction of infants household SHS exposure measured:
1.1. Directly by a decrease in saliva nicotine level
1.2. Indirectly by improving of family smoking hygiene
1.3. Indirectly by reducing health care utilization in particular lower respiratory illnesses in infants at 12 months
2. Mother:
2.1. Reduction of mothers household SHS exposure
2.2. Mothers execution of the household no-smoking policy at 12 months.
3. Father:
3.1. The self-reported 12-month quit rates
3.2. The validated 12-month quit rates (7-day point prevalence) of the smoking fathers (defined as not smoking during the 7 days preceding the 12-month follow-up). The 7-day point prevalence is considered to be a reliable measure as most major trials have reported solely the point prevalence

Secondary outcome measures

1. Father:
1.1. 7 day point prevalence self report quit rate at 6-months
1.2. Continuous self-report quit rate at 6-months and 12-months (defined as continuously not smoking during the 12 months preceding the 12-months follow-up)
1.3. Fathers smoking reduction (by at least 50% compared to baseline) at 6-month and 12-month
1.4 Fathers progress in the stage of readiness to quit at 6-month and 12-month
1.5. Quit attempt
2. Cost-effectiveness:
2.1. Costs incurred includes cost of training the nurses
2.2. Cost of delivering the intervention
2.3. Cost of free and discounted nicotine replacement therapy
2.4. Cost of providing self help literature to the fathers
2.5. Cost per quitter and cost per one less hospitalization among infants will be calculated

Overall study start date
01/06/2008

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Non-smoking mother aged 18 or above taking her infant to the MCHC
2. Father aged 18 or above smokes one or more cigarettes daily in the past 30 days
3. Father, mother and infant are living together in the same household in the past 7 days
4. Father resides in Hong Kong for at least 5 days a week
5. Both father and mother can communicate in Cantonese

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
1152

Key exclusion criteria
Father is undergoing other smoking cessation programme

Date of first enrolment
01/06/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Hong Kong

Study participating centre
4/F William MW Mong Block
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Sponsor information

Organisation
Flight Attendant Medical Research Institute (USA)

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Sponsor type
Research organisation

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Funder(s)

Funder type
Government

Funder Name
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Funder Name
Health and Health Services Research Fund (HHSRF), Food and Health Bureau, Government Secretariat, Hong Kong Government (project number: 05060751)

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	01/03/2017		Yes	No