

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

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| Submission date 31/03/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 24/05/2011 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 20/12/2016 | Condition category Respiratory | <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

Protocol serial number
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

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Passive smoking in children

Interventions

At baseline: The smoking cessation counsellors (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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

Pokfulam

Hong Kong

852

Sponsor information

Organisation

Flight Attendant Medical Research Institute (USA)

Funder(s)

Funder type

Government

Funder Name

Flight Attendant Medical Research Institute, Miami Center, Suite 1310, 201 South Biscayne Boulevard, Miami, Florida 33131 (CIA 062496)

Funder Name

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

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 | 01/03/2017 | | Yes | No |