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Comparing different approaches to reduce injuries in the home among children in Malaysia

Submission date
01/12/2017

Recruitment status
No longer recruiting

Registration date
23/01/2018

Overall study status
Completed

Last Edited
18/01/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Educational interventions may be effective in reducing injury risk to children . This study looks at two different educational programmes. The first is an interactive tutorial programme, that is more time- and effort- intensive, involving a 30 minute tutorial by a trained field assistant. The second programme providing a pamphlet with information on risk factors for child injuries and how to mitigate them. There is previous evidence suggesting that a more active training session is effective, but it is also expensive in terms of time and labor and could be seen as more intrusive as well. This study attempts to understand if a more passive method of education using a pamphlet, might also reduce the risk factors for child injuries, and if so how efficacious it might be. This study aims to address injuries among children within the home environment

Who can participate?
Households with children between 12-59 months of age. Participants are the parents/primary caregivers of the child.

What does the study involve?
Households are assigned to one of two groups. Those in the first group receive an in-home safety tutorial. Those in the second group receive an educational pamphlet. The participants (parents/primary caregivers) taking part in the study answer survey questions at baseline and follow up visits. They also allow a trained field staff to do a walk-through of their house to complete a checklist based assessment to identify any hazards that may increase the risk of injury to the child. The participants are assigned to the tutorial arm or the pamphlet arm, and receive information about hazards around the home, and how to mitigate them.

What are the possible benefits and risks of participating?
The direct benefits to those taking part in the study is the receipt of information that will allow them to rectify any identified hazards that potentially put their child(ren) at risk for injuries. The indirect benefit is for enhancing our understanding of what works and what doesn't work in terms of disseminating information on making the home a safer place for children. The risks are minimal –potential distress when reporting injuries that may have occurred.

Where is the study run from?
1. Johns Hopkins International Injury Research Unit (USA)
2. Universiti Putra Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
July 2012 to December 2015

Who is funding the study?
Johns Hopkins International Injury Research Unit (USA)

Who is the main contact?
Dr Abdulgafoor Bachani

Contact information

Type(s)
Scientific

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21205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRB#4912

Study information

Scientific Title
Assessing the effectiveness of intervention strategies to address home injuries among children in Malaysia: a community-based cluster randomized trial

Acronym
Child Injury Prevention in Malaysia

Study objectives
Null Hypothesis:
There is no difference in the risk of injury at home across the two arms - home improvement, pamphlet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Boards at Johns Hopkins Bloomberg School of Public Health, 07/16/2013, ref: 4912
2. Universiti Putra Malaysia Ethics Board, Malaysia, 11/10/2012

Study design
Interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Child injuries in or near the home environment

Interventions
The household is the unit of intervention. Two parallel study arms are examined with 1:1 allocation:

1. An active intervention: in-home safety tutorial
2. A passive intervention: educational pamphlet

The trial enrolls a cohort of households and administer a baseline and two follow-up home assessments at 2 and 4 months after the initial visit (Figure 1). The intervention (an in-home safety tutorial or an educational pamphlet) is delivered during the baseline visit, with the two follow-up assessments designed to evaluate the effectiveness of the intervention on reducing home safety hazards, which is the primary outcome.

Intervention Type
Behavioural

Primary outcome measure
Hazards for child injuries within the home environment are measured using the a home assessment checklist which is completed by direct observation at the participant's home.

Secondary outcome measures
Unintentional child injury is measured using a structured questionnaire implemented by the trained field staff. The questions ask about injuries in the 3 months preceding the initial visit, and between each of the following visits

Overall study start date
01/07/2012

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. The study participants are parents/guardians of the child(ren), who have the authority to modify the home environment to improve its safety.
2. Households with children between 12-59 months of age. Participants are the parents/primary caregivers of the child

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
We would require 20 clusters with a total of 500 households per arm of the study. Assuming a 20% loss to follow-up based on previous studies [13] a minimum of 1200 households (600 households per arm and 30 households per cluster) will be enrolled

Key exclusion criteria
The study excludes households that do not have any parent/guardian who can read Bahasa Malay (the local language) or English, or those who plan to move from the area within 2 months of the baseline interview.

Date of first enrolment
01/06/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Malaysia

United States of America

Study participating centre
Johns Hopkins International Injury Research Unit
Health Systems Program, Department of International Health
Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street
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21205

Study participating centre
Universiti Putra Malaysia
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43400

Sponsor information

Organisation
Johns Hopkins International Injury Research Unit

Sponsor details
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21205

Sponsor type
Research organisation

Website

https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-international-injury-research-unit/

ROR
https://ror.org/00za53h95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Johns Hopkins International Injury Research Unit

Results and Publications

Publication and dissemination plan
We plan to publish our study protocol report, our baseline survey findings, and our follow up survey findings once we finish our data collection and analysis. We also plan additional analyses looking for predictors of interest or subgroups with trends of significance within our data.

Intention to publish date
01/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the consent process which informed participants that their data will not be shared with others.

IPD sharing plan summary
Not expected to be made available