

A cluster randomised controlled trial on effectiveness of health education-based intervention to improve parental practice in preventing unintentional childhood injury among parents attending health clinics: A study protocol

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ABSTRACT

Introduction: Unintentional childhood injuries is one of the public health challenges among developing countries. The injuries often cause mortality and have significant burden of morbidity in Malaysia, and this can be prevented. Parents play important role in practicing preventive measures to reduce likelihood of unintentional injuries among their children. The objective of the study is to develop, implement, and evaluate the effects of health education intervention on parental practices to reduce unintentional childhood injuries among parents of young children.

Materials and Methods: Health education module focusing on preventing childhood unintentional injuries was developed based on information–motivation–behavioural skills (IMB) theory. This intervention was implemented among parents of children under seven years attending government health clinics in Putrajaya. The effectiveness of the intervention was assessed using single-blinded, randomised controlled trial. Parents were excluded if their children have any chronic disease or disabilities or are currently participating in any other community trials. All four health clinics in Putrajaya with eight personalised care zones/groups were included in the study and randomly assigned to either intervention or control groups after the recruitment of eligible parents is completed. The intervention was delivered by the researcher, and data consisting of validated self-administered parental questionnaires were collected at the baseline, one-month post-intervention and three-month post-intervention to assess the effects of the intervention. Data were analysed using Generalised Linear Mixed Model (GLMM) adjusting for covariates.

Results: The study is anticipated to be able to discover factors associated with injury preventive practice among the parents of children attending selected government child health clinics in Putrajaya and determine the effect of the health education intervention on the parental injury preventive practice.

Conclusion: The implementation of the intervention to the parents is expected to improve the parents' knowledge, motivation and practice to prevent unintentional childhood injuries. The health education module developed in this

study can be taught to the health staff to standardize their knowledge and transfer of information to the parents during visit. The intervention module can be used to complement existing health education activities in the government health clinics.

KEYWORDS:

information-motivation-behavioural skills model, theory-based health education, child injury prevention, parental injury preventive practice

INTRODUCTION

Childhood injury is now a growing global public health concern as it carries a significant burden with wide range of personal, social, and economic implications. Injury-related causes are one of the major causes of death among children under 14 years worldwide and also the leading cause of death and long-term morbidity among children under five years in the last decade.¹ From all injury-related deaths, unintentional injuries accounted for more than 90% of these deaths, and this is alarming as unintentional injuries are preventable when all the appropriate safety measures are taken. Young children are exceptionally vulnerable to unintentional injuries because of their nature of curiosity to explore the environment; yet they are not capable of protecting themselves or understand the consequences and danger of their behaviour.

The WHO Global Burden of Disease reported that the global reduction in disease burden from infectious and nutritional causes were accompanied by significant increase in the injuries and non-communicable disease burden.² The ranking of injuries as the cause of death among children has increased over the years consistently with age and increasing sociodemographic index. Road traffic injuries were at the top, followed closely by drowning. The burden of childhood injury is the heaviest among the children in poor countries with poor incomes, and within these countries, the burden is greatest among the family with low-socioeconomic status.³ In Malaysia, a nationwide population survey reported the prevalence of injury among 116,600 children under seven years in Malaysia in 2011 was 8.3% (95% CI: 6.4–10.4).⁴ The latest population survey in 2016 only captured the prevalence of unintentional injury among 76,920 children

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aged one to four years, which is 3.8% (95% CI: 2.8–5.2), and it is difficult to comment on the trend, but it remains prevalent in the community.⁵ Not only the child can be severely disabled, but injuries also impacted the caregivers and the family members in term of economic costs of treatment and medical care, psychological wellbeing as well as their productivities in general. The overall economic cost of childhood injuries was estimated to be between USD0.5 million and USD9.5 million per year.⁶

Sustainable Development Goals (SDGs) call for concentrated effort to ensure better health of the children by ending preventable deaths for children under five years and reducing the number of deaths from traffic injuries for older children (5–18 years old) under the health targets.⁷ Therefore, countries are now looking at reducing the burden of childhood injury as the main agenda to improve child health as the burden has shifted away from the communicable diseases that are caused by sanitation and hygiene factors. Prevention and control of unintentional injuries in childhood age often use a combination of passive and active strategies where the passive strategies are referring to the environmental and products' change, and active strategies are directed towards behavioural changes.⁸ Parents and caregivers play a vital role in adopting appropriate injury preventive behaviour to help prevent the unintentional injuries among the children and subsequently reducing the risk of any injuries.

Parental factors are one of the important protective factors in reducing the overall risk of injury in children. Injury risk can be defined as any factors or in combinations of individual, familial, social, economic, and physical environment that can contribute to the occurrence of injury event.⁹ There is no universal definition on injury preventive practice or a standard checklist of what constitutes good practice. Each type of injuries has its own practice based on different circumstances and background. However, parental injury preventive practices can be broadly grouped under three strategies: teaching own children safety measures,¹⁰ safety proofing behaviour,^{11,12} and parental supervision.^{13–17} These three measures were used in combination for this study as they cover all parental practices on preventing unintentional childhood injuries.

Factors associated with childhood injury preventive practice tend to be multifactorial, which include parental and child factors and socioeconomic and environmental factors. The modifiable factors were largely the parental factors such as knowledge,^{18–20} motivation,^{21–24} and behavioural skills.^{25,26} These modifiable factors are amenable to health intervention if designed properly, thus improving the parental preventive practice and ultimately reducing the risk of childhood injury. These factors are consistent with the construct of information–motivation–behavioural skills (IMB) theory where it illustrates the significance of information (knowledge) and motivation, as well as self-efficacy to ensure successful behaviour change. Although the combination and synergistic effect of all the contributing factors to childhood injuries are very complex and difficult to pinpoint the exact occurrence of injury, evidence however has shown that modification of any determinants is sufficient to reduce the overall risk of injury.²⁷

At present, there are initiatives to address injury prevention among children in Malaysia, but they are still lacking compared to other developed countries. Current injury prevention programs scatter across ministries and non-governmental organisations throughout the country. National child health program delivered through primary health clinics in Malaysia uses the child health record book as a tool to educate parents regarding child safety and basic injury prevention measures, but the content and the effectiveness of the intervention have never been evaluated. Furthermore, other injury prevention approaches, such as enforcement and adherence to law, remain difficult if the behaviour is not changed. Evidence suggests that health education alone can achieve the most modest gain but legislation alone without education component will result in non-compliance and objective will not be met.²⁸ This emphasises on the importance of health education as main strategy in preventing childhood injuries. Literature on risk factors and predictors of childhood injury is quite prevalent and able to provide rich body of knowledge to the policymakers and healthcare providers; however, the evidence on the effectiveness of intervention is still scarce. A review of study designs in published literature related to the prevention of unintentional childhood injury between 2013 and 2016 found that majority of the studies are descriptive or observational with only 3% of the studies being randomised controlled trials.²⁹ This highlights the gap of knowledge in knowing which intervention is effective to improve the childhood injury preventive practice and reduce the risk of childhood injury.

The objective of the study is to develop, implement, and evaluate the effects of IMB-based health education intervention on parental practices to reduce unintentional childhood injuries among parents of young children.

MATERIALS AND METHODS

Study location

The study was conducted in four government primary health clinics in Putrajaya, Malaysia. Putrajaya represents the urban state in Malaysia as the urbanisation level is 100% as reported by the Department of Statistics Malaysia. This justifies the location chosen for the study as the National Health Morbidity Survey 2011 and 2016 reported that the prevalence of childhood injury is significantly higher among the urban population. The services provided in the primary health clinics include well-child clinic where it caters for all children aged below seven years who come regularly for immunisation, growth and developmental assessment, and monitoring of physical or any learning disorder. Each clinic has personalised care zones where the families were grouped based on their residential address and being taken care of by the same team of health personnel throughout any visit at the clinic. The groups were given different appointment dates according to the schedule in each clinic. There are a total of eight personalised care zones within four health clinics in Putrajaya.

Study design

This study is a cluster, randomised, single blinded, controlled trial with two parallel arms of intervention and wait-list control groups. The protocol for this study has been reported

according to the Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT) 2013 Guidelines.³⁰

Study duration

This study took about 24 months to complete – from the proposal of the study, the development and validation of the questionnaire, development, validation, and testing of the implementation of the health education intervention program, and lastly the implementation and evaluation of the intervention programme. The activities of the intervention program commenced in April 2021. Figure 1 shows the flowchart of the study based on CONSORT extension for cluster trial 2012.³¹

RESULTS

Study population and study setting

The study population for this study was one of the parents of children under seven years (0 to 6 years old) who are registered at the primary health clinics in Putrajaya and attending the follow-up. Inclusion criteria are parents aged 18 years and those who are literate and able to communicate in Malay or English language. Exclusion criteria are parents with index child having chronic diseases or disabilities or currently participating in other community trials. Parents who score extremely low in the baseline survey were also excluded from the study to allow for immediate intervention with regards to child safety. The baseline survey is the same set of questionnaires, which was used throughout the study.

Sample size

The sample size for this study was calculated using formula for mean differences within the intervention groups at baseline and three months post-intervention. The sample size was inflated by the design effect for fixed size cluster study design,³² with 95% level of significance, 80% power, and 20% attrition rate. Based on the previous study on the effectiveness of injury prevention intervention,³³ their intra-cluster correlation coefficient of 0.05 was used; thus, the total number of participants required in this study was 178 with equal number in each control and intervention groups.

Recruitment

Participants were recruited directly from the health clinics. Standing banner and poster were placed strategically within the clinic waiting area two months before the commencement of the study. Health clinic staff helped to identify suitable participants and distribute study flyers directly. The benefits of the study include improving knowledge and skills on how to prevent unintentional childhood injuries, and this information was conveyed in the flyers and banners to convince parents to participate in the study and adhere to the study protocol. All parents who agreed to participate scanned the QR code that will register their details and consent, as well as screening questions to assess their eligibility to participate.

Randomisation, allocation concealment, and blinding

The randomisation was conducted at the cluster level, where the randomisation units were the personalised care zones. Respondents in each personalised care zone were allocated to either control or intervention group based on the cluster randomisation results. By confining the intervention and

control to specific personalised care zones, contamination issues can be avoided since they are segregated by residential address, health personnel team, and appointment date, thus increasing the validity of the study. The randomisation was made through a computerised sequence generation created by computer software from the website, www.random.org.³⁴ Block randomisation was used in this study to preserve the balance between the number of intervention and control groups. Randomisation process was conducted by an independent person who is not involved in this study. The person generated the random allocation sequence, enrolled the clusters, and assigned the clusters to either intervention or control group in strictest confidential manner. Single blinding technique was used where participating respondents were not aware of the status of the group participation. The researcher allocated the group to interventions based on the randomisation result provided by the independent person.

Intervention

Intervention development and validation

The intervention module is named 'Keeping Kids Safe', which aims to improve parental injury preventive practice, subsequently reducing the risk of unintentional childhood injuries. The intervention module was newly developed by the researcher based on extensive literature review including peer-reviewed journal articles and established guidelines for childhood injury prevention. The components of IMB theory were used to design the intervention program. It consists of three constructs: information, motivation, and behavioural skill. The details of the intervention module content and delivery are summarised in Table I. The module has been reviewed for their contents by Family Medicine Physicians who work in primary care clinics, Public Health Physicians from the health ministry and state health department, senior health educator officer, and academician. The module was then piloted to a small group of respondents where the presentation and readability of the contents were being appraised. Discussion and feedbacks were considered to make adjustment and modification to further improve and finalise the module.

Intervention format and delivery

The module was developed into a series of health education videos and infographics. There are a total four animation, non-narrated videos of three to five minutes duration each. The first two videos were designed to deliver mainly information regarding risk of injury and child development stages. The third video contained real case scenarios from local news and explanation on the myths and facts related to childhood unintentional injury. This video aimed to increase parents' motivation and self-efficacy in injury prevention. The last video summarised important injury preventive practices. Participants received one video per day for four consecutive days. At two months of interval post-intervention, participants were sent with infographics that summarise the content of video they receive during the intervention week as reminder. All the content of the intervention module was delivered online via individual WhatsApp to each participant in the intervention group.

Control group

The control group continued their usual care and received existing health education from the clinic delivered by their

Table I: Summary of intervention program content and delivery

Intervention program	IMB constructs*	Content	Format and delivery	Week
Baseline survey	-	Questionnaire	Google form link	0
Module 1	I	Introduction to injury Statistics of injury in Malaysia Types and risk of injuries	Video	4
Module 2	I	Child development stages and risk of injury	Video	4
Module 3	M, B	Real cases scenarios from local news Myths and facts	Video	4
Module 4	I, B	Injury preventive practice Self-efficacy	Video	4
Post-intervention survey 1	-	Questionnaire	Google form link	8
Reminder 1	I, B	Childhood injury	Infographic	12
Reminder 2	M	Consolidate appropriate beliefs and attitudes for preventive practice	Infographic	12
Reminder 3	M, B	Self-efficacy	Infographic	12
Reminder 4	I	Injury preventive practice	Infographic	12
Post-intervention survey 2	-	Questionnaire	Google form link	16

* I= Information, M= Motivation, B= Behavioural skill

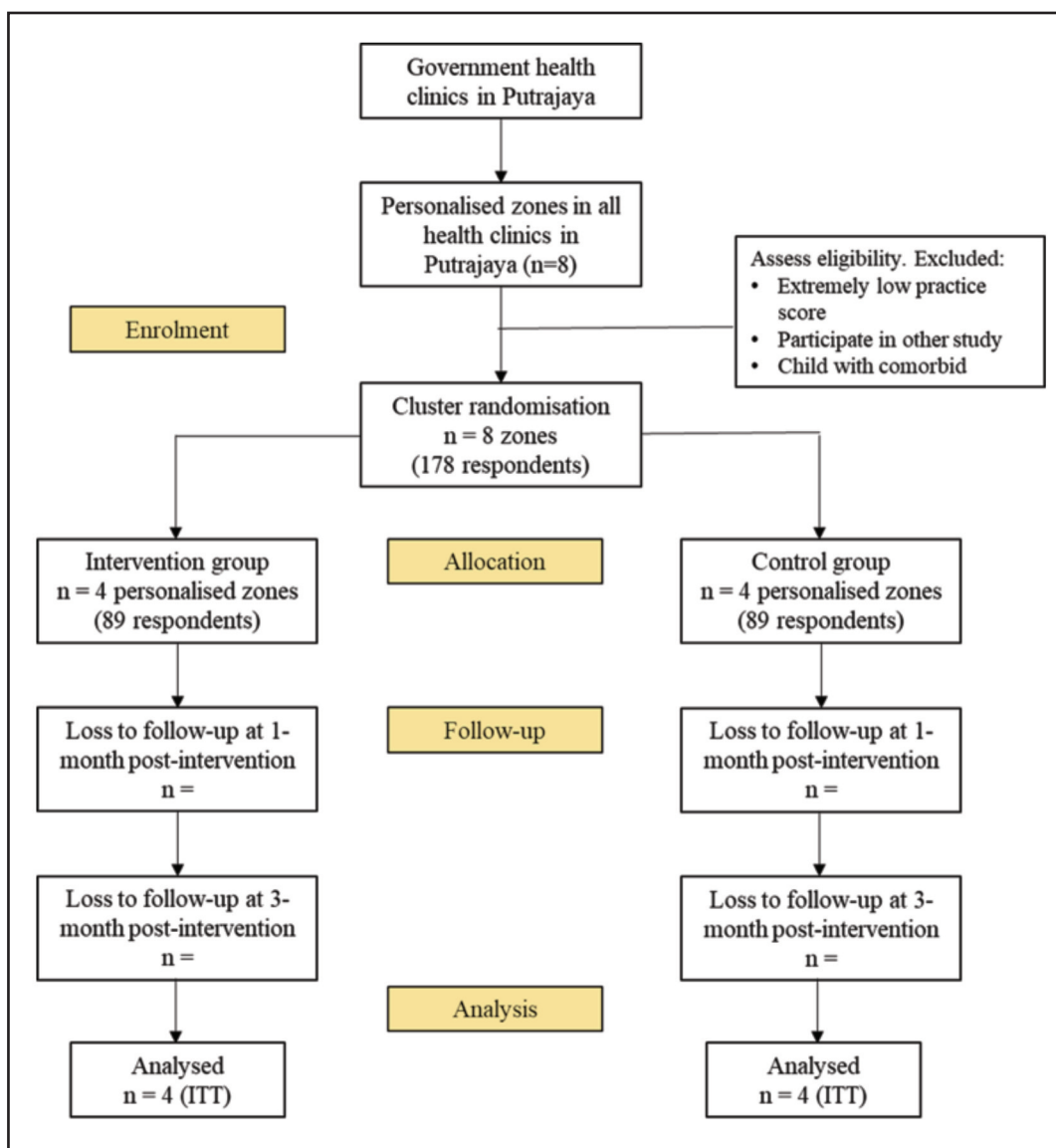


Fig. 1: Flowchart based on CONSORT extension for cluster trial 2012.

personalised health team during their visit to the health clinic. The existing health education is based on child health record book checklist and standard advice based on child's age group. To keep the control group blinded, they were informed that once they participate in the study, health education module will be given at any time within the six months of participation. Participants in the control group received all the health educational videos on completion of data collection (wait-list).

Data collection

In view of various restrictions at health clinics due to COVID-19 pandemic, data collection was conducted online. Each registered participant was assigned a unique code number and link to the online questionnaire via individual WhatsApp. Data were collected at three timepoints: baseline (T0), one month after the intervention (T1), and three months after the intervention (T2). The questionnaires were adapted from existing self-report scales to assess the injury preventive practice and its associated factors, including the sociodemographic background of the participants. To minimise loss in follow-ups in cases where online questionnaire is not feasible, telephone interview was conducted. Reminders were also sent in form of short messaging system (SMS) to prompt participants to answer the questionnaire in a timely manner.

Quality control

The questionnaire has been reliably tested among 30 parents of children under seven years attending government health clinics and analysed by SPSS to compute the Cohen's Kappa and Intraclass Correlation Coefficient value. Internal consistency of the questionnaire was assessed using Cronbach's Alpha test. The findings were used to finalise the questionnaires before administration to actual respondents.

Outcome assessment

The primary outcome measure of the study is the change in parent's preventive practice score, which refers to the total injury preventive practice score. It was calculated based on 30 items in the last section where it consists of three components: teaching own children, safety proofing, and parental supervision. This outcome was compared between the intervention and control group, and within each group at baseline, one-month and three-month post-intervention.

The secondary outcome measure of the study consists of the IMB construct score change, including the knowledge, motivation, and behavioural skills of the parents. Knowledge change refers to changes in total knowledge score as measured in the questionnaire, which assess respondents' level of knowledge in the developmental stage of children and risk factors for unintentional childhood injuries. Motivation change refers to the summation of score calculated in the questionnaire where it consists of attitude, beliefs, and subjective norms of the respondents towards injury preventive practice. Behavioural skills score change refers to self-efficacy components in the questionnaire where the score calculated is based on the five statements. Higher score indicates higher self-efficacy in preventing childhood injuries.

Data analysis

Final data were entered and analysed using the computer software Statistical Package for Social Sciences (SPSS) version 23. No identifying information was recorded, and data were encrypted with password to ensure safety and confidentiality. Prior to the analysis, data were screened for out-of-range values, error, or missing data, and they were handled using multiple imputations. Additionally, sensitivity analysis was conducted in form of intention-to-treat (ITT) principle to ensure robustness and validity of the study outcome. Descriptive statistical analysis was used to describe the sociodemographic characteristics of all the participants, knowledge, motivation, behavioural skills, and injury preventive practice score. Univariate statistical analysis was performed to compare the baseline differences between the intervention and control group. An independent t-test was used to compare the means of two groups in normally distributed continuous variables, while Wilcoxon-Mann-Whitney test was conducted to compare the medians between two groups of non-normally distributed continuous data. For categorical variables, Chi-square and Fisher's Exact tests were used to compare the differences. Generalised Linear Mixed Model (GLMM) analysis was used in this study to determine the effectiveness of the health education intervention on the parent's preventive practice against childhood injury between the intervention and control groups. The results of the analysis are presented as 95% confidence interval, and the level of significance in this study is set at alpha value of 0.05.

DISCUSSION

The study anticipated to be able to determine the effect of the health education intervention on the injury preventive practice. The mean score for preventive practice is expected to be higher immediately after the intervention as compared to the baseline score and to be sustained at three-month follow-up.

The result of this study provides an insight on the effectiveness of theory-based intervention to parents of young children in improving their preventive practices to reduce unintentional childhood injuries. The use of educational video as interventional method can effectively supplement existing health education at the primary care setting and help to sustain parents' motivation and self-efficacy to improve their injury preventive practices.

This is an experimental study where the variables and environment of the intervention conducted are in controlled environment. Therefore, the limitations to this study include caution interpretation of the generalisability of the study findings. Furthermore, cluster randomisation may cause selection bias if randomisation done prior to recruitment of participants as the researcher knows about the allocation. However, this can be minimised by adhering to CONSORT flow whereby the randomisation is done only on completion of participant recruitment. Lastly, the outcome measure is that the parental preventive practice, which is self-reported, imposed risk of social desirability or recall bias compared to observed behaviour practice.³⁵

In summary, the implementation of the intervention to the parents is expected to improve the parents' knowledge, motivation, and practice to prevent unintentional childhood injuries. The health education module developed in this study can be taught to the health staff to standardise their knowledge and transfer of information to the parents during visit. The intervention module can be used to complement existing health education activities in the government health clinics.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was registered under National Medical Research Registry (NMRR) and approved by the Malaysian Research Ethical Committee board (Reference: NMRR-20-1819-54615, Date: 15/10/2020). This study protocol was also registered with the Thai Clinical Trial Registry with the registration number TCTR20200629002, Date: 15/06/2020. Written informed consent was obtained from respondents before collecting data. All the personal details of the respondents and information gained by the study will be kept confidential and will be used for research purposes only.

CONFLICT OF INTEREST

The authors declare no competing interests.

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