

A Field Trial of an Educational Intervention to Promote Safe Behaviors in Pedestrians: Study Protocol

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Study protocol

Keywords: Safe behaviors, Educational intervention, Pedestrian, Field trial, Mix Method research

DOI: <https://doi.org/10.21203/rs.3.rs-178169/v1>

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Abstract

Background: Pedestrians are vulnerable in traffic, and unsafe behaviors often lead to their injury. The aim of this study is to investigate the effect of a theory-based training package (TBTP) on improving pedestrians' safe traffic behaviors.

Methods: This study is a protocol for a field trial with parallel arms to examine the effect of educational intervention on 204 pedestrians that are selected using multi-stage cluster sampling. In order to prepare a training package, a sequential exploratory mixed study will be performed in 4 phases: 1) A questionnaire will be designed using a qualitative study and constructs of the theory of planned behavior (TPB). 2) A cross-sectional study will be performed to evaluate the psychometrics of the questionnaire and current situation, 3) The training package will be designed based on the previous phase findings, results of related studies, opinions of a panel of experts and effective techniques for behavior and belief change. 4) The effect of training will be measured using pre and posttest to comparing the mean scores of different theory constructs on pedestrians' behavior between the intervention and control groups before and three months after the intervention. The between-group differences in terms of demographic variables, awareness, risk perception, beliefs, intention and behavior will be examined first. Paired t-test and ANCOVA will be applied to evaluate the effect of the intervention between the two groups.

Discussion: The present research provides good information about pedestrians' needs and evidence-based approach to promoting traffic culture, and reducing pedestrian injuries.

Trial registration: Iranian Registry of Clinical Trials ≠ IRCT20180228038896N1

1. Background

Statistics from the World Health Organization (WHO) suggest that one person dies on the world's roads every 24 seconds [1]. Pedestrians are one of the most vulnerable victims of road collisions. They are subject to direct damage and have no protective equipment [2]. If pedestrians are involved in a crash, the probability of a fatal outcome is 3.7 times higher [3]. According to the WHO, pedestrian fatalities comprise 22% of the total number of casualties due to road crashes worldwide; this rate is 34% in the Eastern Mediterranean region and 22% in Iran [4]. Although a reduction of 10% in annual deaths from 2011 to 2020 has been anticipated in Iran's strategic plans, this goal has not been achieved yet [1]. Studies conducted in Iran have shown that 30% of the accidents are pedestrian related and 23% of traffic fatalities involve pedestrians [4]. Following collisions, pedestrians are exposed to severe injuries, especially in the "head and neck" [5]. In addition to death, accidents cause great physical damage, economic burden, and financial and psychological effects on individuals and families, which increase the direct (costs of treatment and care) and indirect expenses (causing psychological problems and depression in family members, permanent or temporary loss of active workforce) [6].

Along with the inherent vulnerability of pedestrians, many factors have been identified in their vulnerability such as environmental factors [7, 8], social factors [9, 10], behavioral factors related to

pedestrian facilities [11] and behavioral factors unrelated to pedestrian facilities [12, 13]. Human behavior is the main factor in most cases and the road, vehicle, or environment has no role in causing a collision [14]. Studies suggest that the prevalence of these behaviors is increasing. Iran's statistics show that 38% of crashes in Tehran are due to unsafe behaviors of pedestrians like not using pedestrian overpasses. Zhuang and Wu reported that 65.7% of the pedestrians entered the street without looking for vehicles [10]. Another study showed that 16.4% of pedestrians ran when the traffic light was red and 6.3% of them passed through unsafe places [15]. Therefore, considering pedestrians unsafe behaviors, it is necessary to design and implement effective interventions.

Creating a safety culture is one of the recommended ways to reduce harms, a culture in which citizens perceive safety as an important element in life and behave in a way that prioritizes their own safety and that of the others [16]. Addressing this strategy requires alignment of structural, political, environmental and behavioral factors and change of social norms [17]. Injury prevention is an example of dealing with these multiple factors [18]. In road safety guidelines, the WHO has pointed to the role of educational activities for policymakers and executives and has identified them as motives for behavior change [19]. Most of the studies on pedestrian high-risk traffic behaviors have focused on determining the potential factors [20] and have used quantitative and descriptive research methods [21]. On the other hand, educational activities are often directed at children and adolescents [22]. In addition, a few studies have examined the effect of training on pedestrians, especially training based on theories. Furthermore, a study was only performed on male students excluding women and the general population [23]. In general, there is no good evidence about the effectiveness of safety training on adult pedestrians. Moreover, very few trials have been conducted in low- and middle-income countries [24]. Therefore, there is a need for more research in this field. The general purpose of this study is to design an educational intervention to promote pedestrian's safe behaviors. Its specific purposes include:

1. Designing a questionnaire for pedestrians' safe traffic behaviors based on the TPB structures.
2. Designing an educational intervention and evaluating its effect.

The research question is whether educational intervention has an effect on promoting the pedestrians' safe traffic behaviors.

This paper presents a protocol and follows the SPIRIT items (Standard Protocol: Recommendations for Intervention Trials and Guidelines 2013) for reporting [25].

2. Methods/design

Study design

This is an exploratory sequential mixed methods study. Findings of the qualitative study will be used to develop a quantitative tool. In the second phase, this tool will be implemented quantitatively and its reliability will be evaluated. Based on the results of the quantitative study, an educational intervention will be designed and implemented in the third phase. In the fourth phase, the effectiveness of the educational

intervention will be evaluated in a field trial and two parallel group. Figure 1 shows the flow diagram of the study.

Phase One: Developing a tool based on qualitative study findings

According to the literature, theory of planned behavior (TPB) is useful for examining the intention of pedestrians when crossing the street in potentially dangerous situations. Therefore, TPB is selected as the guiding theory of the study. In addition, the “risk perception” construct, which has a significant predictive according to several studies, is considered for the development of the model. According to the TPB guideline [26], a qualitative study will be conducted using directed content analysis to identify behavioral, normative, and control beliefs.

Semi-structured interviews will be conducted in the form of focused group discussions (FGD) to gain an in-depth understanding of the factors related to pedestrians’ behaviors. Interview questions will fall into the following three categories based on the TPB guideline:

1. What are the advantages/disadvantages of pedestrians' safe traffic behaviors?
2. Do any individuals or groups approve/disapprove of your safe traffic behavior? Who?
3. Which factors and situations make safe traffic behavior easy/difficult for you?

The FGDs and the data analysis will be done simultaneously. FGDs continues until data saturation is achieved [26, 27].

All FGDs will be transcribed and a content analysis will be performed [28]; first, the research questions will be reviewed and answers will be read over and over to achieve a deep understanding of pedestrians’ beliefs. Words, sentences, and paragraphs whose contents are relevant form a semantic unit. A code will be assigned to each semantic unit. The codes will then be examined and grouped based on meaning, similarities, and differences. Similar codes will be merged to form subgroups. This is a type of general grouping [29]. The relationship between general groups and main groups will be examined through continuous comparisons to determine conceptual and logical connections between them [30]. The MAXQDA software will be used to facilitate data organization and retrieval. The questions will be prepared according to the qualitative stage codes. The questionnaire will have several parts such as demographic information, pedestrians’ knowledge of traffic laws, risk perception, and TPB constructs.

Phase Two: Psychometrics of the questionnaire and determining the current situation

In this phase, the psychometric properties of the questionnaire will be evaluated in a cross-sectional study. In addition, information will be obtained about the characteristics of the target group, the status of behavioral, control, and normative beliefs, as well as their intention and safe crossing behavior. The predictive power of intention and safe behavior will also be examined. The reference population comprises 510 eligible pedestrians. The SPSS software will be used for preprocessing the data. Structural

Equation Modeling will be used for a more comprehensive analysis of theoretical relationships between factors and path analysis using variance-based software (Smart PLS).

Phase 3: Intervention design

To prepare the educational content, educational messages, posters and pedestrian educational videos will be reviewed in up-to-date scientific sources and reputable sites. These contents are examined in terms of target group, beliefs or behaviors, type of message, practical strategies for changing beliefs and behaviors, cognitive or emotional approach, and type of the movie (animated or real). If their goals are close to the present study, the techniques used to change beliefs and behaviors are scientific and close to the culture of the community being studied, the media will be used. Otherwise, the researcher will produce educational media. An educational material will be prepared, including training videos, stories, photos, posters and information about the basic method of safe traffic behaviors. Educational videos will be prepared according to text messages made by researcher and films of pedestrians across the city. Other educational contents will be provided using the results of previous sections. Media help better understanding and are effective in attitude change. A qualitative method will be applied to evaluate the suitability of the prepared materials in expert panel and a small group of people similar to the target group. Comments and views received from the target group will be applied to the videos as much as possible

Belief and behavior change techniques

Educational videos will be prepared based on the TPB and cross-sectional study findings. First, the constructs and beliefs requiring intervention will be identified. Then, the techniques used to change beliefs, feelings, risk perception, self-efficacy, norms and behavior will be defined according to a literature review [31] and experts' opinions. To change behavioral beliefs (benefits and costs), techniques demonstrating the behavior-health relationship and the possible negative consequences of the behavior will be used as high-risk behavior leads to injury. To change control beliefs, in addition to reasoning, safe behaviors in high-risk situations will be discussed. To increase the perception of danger, traffic camera videos will be used to show how pedestrians cross the street. Simple, practical, and effective behaviors will be suggested in order to increase response efficiency. To enhance self-efficacy, an easy, step-by-step behavior guide will be developed. At the same time, some information will be provided and cognitive needs of the participants will be answered. Alternative, safe, practical solutions will be ready for maximum management of high-risk situations.

Phase 4: Performing educational intervention

In this phase, a field trial will be designed to evaluate the efficiency of the prepared educational package. FTs are performed on healthy individuals with the aim of prevention [32]. The presence of a control group makes it possible to identify and distinguish between epidemiological and/or statistical correlations and cause-and-effect relationships [33]. The designed intervention is applied to the intervention group. The control group will not receive any interventions. For ethical reasons, all educational materials will be given

to the members of the control group at the end of the intervention. The field trial methodology is described below.

Inclusion and exclusion criteria

Eligibility is defined as interest in participating in the study, the ability to use social media, and visiting social networks at least once every three days. Other inclusion criteria are crossing the street during the last week and lack of language or communication problems. The exclusion criteria are lack of interest in sharing experiences and views, reluctance to participate in the study.

Setting and sample size

This study will be conducted in Yazd, a city in central of Iran, where the use of bicycles for transportation has been common since ancient times. However, with the growth of urbanization and motorized vehicles, an increase is seen in accidents, especially among adolescents and young adults. Therefore, the study population includes individuals aged 18–35 years old in this city, since the aim of the present study is to promote safe traffic behaviors in pedestrians. Considering a confidence level of 95%, Sigma of 18 [23], accuracy of 5%, test power of 80% (beta = 20), a minimum difference of 8 points between the two groups, and a non-response rate of 15%, and cluster correction, 102 subjects need to be enrolled in each group. Therefore, the researcher should recruit a total of 204 eligible participants in the study.

$$N = 2 \left[\frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right) S}{d} \right]^2$$

The subjects will be selected using multi-stage cluster random sampling. First, 6 healthcare centers will be randomly selected (two centers each from three areas of the city). Then, 2 blocks covered by each center will be randomly selected using statistical software. Three centers and their subset blocks as the control group and three other centers and their subset blocks as the intervention group. Finally, cluster sampling will be done inside the blocks and one of the numbers of the subjects aged 18–35 years registered in the integrated health system will be randomly selected. This person will be the starting point for sampling. Sampling continues among eligible individuals that are interested in participation in the study until the desired sample size is achieved (17 subjects).

Intervention

The purpose is increase awareness and risk perception, promote the pedestrians' beliefs, and consequently improve their intention and safe traffic behaviors. Media will be uploaded to the virtual group every night at an agreed time. Group discussion will be used for examination of the different aspects of the behavior and attitude. Today, Social networks facilitate communication and strengthen social interactions in the cyberspace [34]. These networks will be used to communicate with the target group and transfer educational material due to the availability of mobile phones, the wide use of social

networks by adult, ability to have group discussions and interactions with different users, the ability to publish different visual, audio and digital media. To choose the social network, participants will be asked a few questions when completing the pre-test. After obtaining their consent by care providers, they will be added to the virtual group. The trial will be conducted for 6 months and the activities are planned according to Table 1.

Table 1
Schedule of enrolment, interventions and assessments

Activity type / Study period (months)	M1	M2	M3	M4	M5	M6
1 Identifying eligible individuals	×					
2 obtaining inform consent	×					
3 Baseline evaluation	×					
4 Determining the intervention and control group	×					
5 Applying intervention to intervention group		×				
6 No intervention for control group						
7 Final Evaluation of intervention and control groups						×

Blinding

The questionnaires will be anonymous to promote participation and assure the participants of data anonymity and confidentiality. The participants who fill out the questionnaires will be blind to the group assignment. The evaluator will be blind to the type of intervention in each group. This study will be practically blind on two side.

Outcomes

Preliminary Outcome: In the intervention phase, the number of members' visits will be monitored randomly every day, the members who actively participate will be encouraged. Using probing questions, other members will be encouraged to participate and share their experiences and views as well.

Secondary Outcome: Study variables such as safe intent and behavior, attitude, subjective norms and perceived control are measured using a questionnaire on a Likert scale. According to the guideline for questionnaire development based on the TPB [35], the score of intent and behavior construct is obtained through the sum of answers. As for the scores of the constructs of attitude, subjective norms, and perceived control, the score of each belief is multiplied by its evaluation question; then, the results are summed. The sum of the results is the score of the construct. Then, the score of the construct will be weighed by the probable amplitude of the sum of scores.

Method and time of data collection

Data will be collected using a self-report questionnaire. This questionnaire will be given to participants in the intervention group and the control group at the beginning of the study and three months after the intervention.

Statistical methods

Since a 15% non-response rate has been considered for the FT stage and applied to the sample size, it is assumed that loss to follow-up and non-cooperation of the participants will be accidental. The SPSS software will be used for preprocessing the data and data analysis. To evaluate the effectiveness of the intervention, the difference in the mean scores between the two groups before and after the intervention will be examined using independent t-test, chi-square test, paired t-test and ANCOVA.

3. Discussion

This study is designed to improve pedestrians' safe traffic behaviors. According to our knowledge, a limited number of qualitative studies have investigated pedestrians' perceptions of the factors affecting safe traffic behavior and their beliefs in the city where the present study will be conducted; therefore, the results can be used to design educational interventions. Moreover, environmental advertising is costly and its effectiveness is questionable. On the other hand, teaching traffic rules and regulations is targeted at children who do not have sufficient cognition of the real road conditions, while the victims of accidents are young adults who have high-risk traffic behaviors. Therefore, this study will be conducted to determine the effect of TBTP on the safe traffic behaviors of young adult pedestrians. This program has some strengths like using a FT to evaluate the training program, using a mixed methods approach, preparing a TBTP, applying intervention to adult pedestrians, and conducting a study in the context of virtual networks. Since the intervention is applied in the community, the study has potential limitations. The need for providing Internet data for the participants in the intervention group, cultural differences, and the possibility of advertising about the victims of traffic accidents in the city are among these limitations. Another limitation is the use of a self-report questionnaire and memory error [36]. Other limitations is need for a larger sample size and more time as well as higher costs [32].

To reduce the likelihood of these limitations, a one-month Internet plan will be provided free of charge for intervention group participants who join a photo contest. Maximum participation will be enhanced regularly by a reward mechanism. The participants will be asked to refrain from posting the educational videos to family or friend groups until the end of the one-month intervention period. We anticipate that this theory based study will help to prioritize traffic safety issues and the necessity to improve the culture of citizens about safe traffic behaviors.

Abbreviations

WHO: World Health Organization; TPB: Theory of Planned Behavior; FT: Field Trial, TBTP: Theory-Based Training Package, FGD; Focused Group Discussion

Declarations

Ethics approval

The Ethics Committee of Tarbiat Modares University approved the protocol of this randomized controlled trial (IR.TMU.REC.1396.556). The trial is registered in the Iranian Registry of Clinical Trials (reference: IRCT20180228038896N1, Registered 2018-06-21, <https://en.irct.ir/trial/29869>). Participation is voluntary and they are free to leave the study at any time. Written consent will be obtained from all participants. The confidentiality of the information will be emphasized and only the analyzed data will be published.

Consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and material

Not applicable – this is a research protocol and does not contain any data.

Competing interests

This study will have no conflicts of interest

Funding

No funding was obtained for this study.

Authors' contributions

AH is the thesis supervisor and contributed to the conception and design of the study in cooperation with FZH, MAM, and ME. FZH drafted the manuscript, and AH, MAM, and ME revised the manuscript for intellectual content. FZH and AH finalized the manuscript. All authors read and approved the final manuscript.

Acknowledgements

Not applicable

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Figures

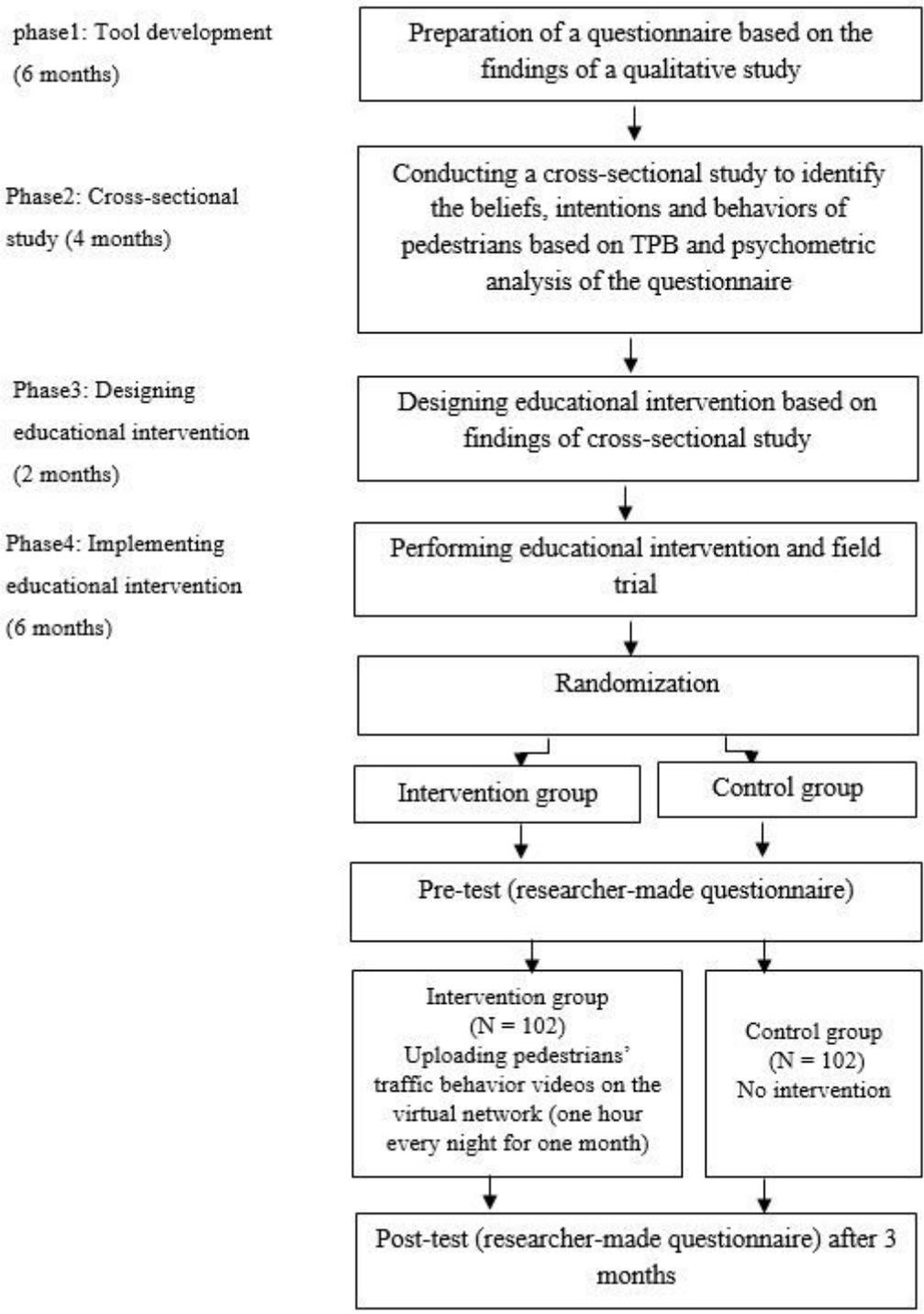


Figure 1

The flow diagram of study

Supplementary Files

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