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STUDY PROTOCOL

A RANDOMIZED CONTROLLED TRIAL ON THE ISLAMIC-BASED PROGRAM USING FAMILY APPROACHES IN PREVENTING ADOLESCENTS' SMOKING BEHAVIOR IN INDONESIA: A STUDY PROTOCOL

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Abstract

Background: Smoking is a significant problem especially among Indonesian adolescents. A number of smoking prevention programs have been developed and implemented, but most of them do not work significantly for the Indonesian adolescents who are mostly Muslim.

Objective: The aim of this article is to outline a study protocol for measuring the effects of Islamic-based program using family approaches on the prevention of adolescents' smoking behavior.

Methods: The study will use a cluster randomized controlled trial conducted in three junior high schools, in Aceh Province, Indonesia. A total of 150 students will be involved in this study, where each school will be represented by 50 students. Each school group will be given the respective treatments. The first group will receive health-based intervention program, the second group will receive Islamic-based intervention program, and the last group will act as a control group receiving no intervention. The outcomes include the knowledge about smoking, attitudes toward smoking, smoking intention and smoking behavior of the adolescents. All outcomes will be measured using validated questionnaires.

Discussion: If the Islamic-based intervention using family approach is effective, then this approach could be implemented not only in Indonesia but also in other countries with the same social characteristics.

Trial registration: Australian New Zealand Clinical Trial Registry, ACTRN 12620000465954

KEYWORDS

smoking; prevention; adolescence; Islamic; Indonesia

BACKGROUND

Smoking is one of the causes of various health problems. Cigarette smoke contains more than 5000 chemicals (Gatto et al., 2017). Previous studies have shown that smokers are at risk for heart disease, stroke and various types of cancer (Duncan, Pearson, & Maddison, 2018). Although various studies have proven that smoking is harmful to health, the number of smokers is in continuous increase in Indonesia, where this country is one of the top three countries with the highest number of smokers in the world. A study on nine countries in North and Southeast Asia shows that Indonesia is one of three countries with high smoking rate among men (the other countries are the Maldives and Bangladesh) (Sreeramareddy, Pradhan, Mir, & Sin, 2014). In 2007, the prevalence of active smokers was at 34.2%, then increased by 34.7% in 2010, and followed by another increase by 36.3% in 2013 (Department of Health of Indonesia, 2013).

The problem of smoking is also experienced by adolescents who are the nation's next generation. A national survey in 2006 Indonesia that included 3,737 students aged 13 to 15, shows that 37.7% of them were smokers, 13.5% were current smokers, 11.8% were cigarette smokers, and 3.8% others reported to smoke tobacco. It was also reported that 95.1% of Indonesian teenagers, who said they had never smoked, had a desire to start smoking in the next 12 months (Centers for Disease Control and Prevention, 2009). Furthermore, in 2014, the Global Youth Tobacco Survey (GYTS) in Indonesia showed that 20.3% of 13- to 15-year-old students were using tobacco products, 19.4% were smoking tobacco, 18.3% were smoking cigarettes, and 2.1% were using smokeless tobacco (WHO Regional Office for South-East Asia, 2014). Smoking is not only a major national problem in Indonesia, but also in Aceh Province. The prevalence of daily smoking over the age of 15 in Aceh Province is 31.9%. While the active smoker (daily and occasionally) in Aceh Province is 37.1%. The prevalence is higher than the national average which is only 34.7%. The prevalence of indoor

smoking of the 15-year-old population in Aceh Province has reached 78.3% (Department of Health of Indonesia, 2010).

The data above show that the problem of smoking requires optimal prevention. This is very important because even though the adolescents have an initial smoking attempt, 50% of them continue to smoke in the future (Thomas, Baker, & Thomas, 2016). Adolescents who only attempt to smoke at the age of 10-14 are predicted to actively smoke in the next two years (Sargent, Gabrielli, Budney, Soneji, & Wills, 2017). A previous study showed that the smoking experience during adolescence is a predictor of their smoking status in the future (Sargent et al., 2017).

The high smoking rate of among adolescents is caused by various factors including psychological factors, especially with various challenges these adolescents have to face. Adolescents entering secondary school, aged 12-13, must adapt to school culture and increasing academic demands, causing some of them to experience a decline in self-esteem and increase in anxiety, which are risk factors for smoking initiation (O'Loughlin et al., 2017). A previous research also reported psychological distress related to smoking behavior (Lawrence, Mitrou, & Zubrick, 2011). Thus, in order to make it effective, the intervention program for the smoking behavior prevention must consider psychological stress factors (Kilibarda, Mravcik, Oechsler, & Martens, 2017).

There is a link between psychological problems and smoking behavior owing to the fact that some teenagers tend to consider smoking can help them in adapting to the occurring physical, cognitive and emotional changes. Smoking is also falsely appraised as an escape from the experienced negative feelings (Garey et al., 2017). As supported by a previous research, adolescents with smoking behavior have lower self-esteem and self-image, where smoking is associated with depression problems (Chaiton, Cohen, O'Loughlin, & Rehm, 2009). In addition to psychological problems, the high smoking behavior among adolescents is due to the influence of friends and the easy access of obtaining cigarettes (Urrutia-Pereira, Oliano, Aranda, Mallol, & Solé, 2017). Friends influence may change the disinterest of the adolescent in smoking. As reported by a previous study, the peer pressure triggers smoking behavior (Shaheen, Oyebode, & Masud, 2018). Therefore, it is important to give more prevention on the psychological distress and the influence of peers, to induce more self-confidence and the ability to avoid smoking (Duncan et al., 2018). In order to achieve it, family and religious approaches can be used in the prevention program. Family is the first educational tool during a childhood period. It further affects the child's ability to face various challenges including the invitation to smoke (McGee et al., 2015).

The importance of family role in smoking prevention is stem from continuous interaction. A conflict in the family increases the risk of early smoking initiation in adolescents, while the warmth and intimacy offer a protection against smoking initiation (Rajesh, Diamond, Spitz, & Wilkinson, 2015). Parental constructive communication encourages children's healthy behavior. In addition, the absence of at home smoking exposure and the knowledge on smoking harmful effect had been reported as a protective factor against smoking behavior in adolescents (Urrutia-Pereira et al., 2017). Other studies also show that smoking has a significantly related with family factors (Backhaus et al., 2017; Eugen, Cornelia, & Aurelia, 2015; Joung, Han, Park, & Ryu, 2016; Saari, Kentala, & Mattila, 2014). Parental involvement in the smoking prevention is important to reduce the risk of smoking through

parenting practices (Bird, Staines-Orozco, & Moraros, 2016; Hiemstra, de Leeuw, Engels, & Otten, 2017; McGee et al., 2015). Furthermore, involving families in smoking prevention efforts had been reported to be strategic, helping adolescents not to start smoking (Bird et al., 2016). Family coaching, focusing on setting rules and expectations, is an important and universal element of smoking prevention programs for adolescents in various communities (Stanton, Highland, Tercyak, Luta, & Niaura, 2013). Other than family, the aforementioned religious approach can also be used in smoking prevention. A study by Naing et al. (2004) suggested that Islamic teaching had effectively prevented smoking and drug addiction. Another previous research shows that smoking is also associated with religious factors (Hussain, Walker, & Moon, 2019). In addition, research in China found the relationship of the involvement in religious activities with smoking behavior (Wang, Koenig, & Al Shohaib, 2015).

Based on the explanations above, the important role of family and religion in the smoking prevention has been clearly portrayed. This research is expected to have contribution in reducing the prevalence of smokers, which will ultimately improve the quality of life. This research will be conducted in Aceh, where the majority of the people are Muslims, approximately 98%. The Islamic-based intervention is expected to be effective with the people in Aceh. This is also supported with the fact that Aceh Province has implemented Islamic Sharia regulations since 2000 (Regional Regulation of the Special Province of Aceh Number 5 of 2000 concerning the Implementation of Islamic Sharia). Furthermore, the fatwa of the Islamic Scholar Committee in Aceh also supports the prevention of smoking (Majelis Permusyawaratan Ulama Aceh, 2014).

Based on the literature review, the previous research on smoking prevention among the adolescent, for the most part, had only been carried out in Western countries (Crone, Spruijt, Dijkstra, Willemsen, & Paulussen, 2011). Therefore, this research, taking place in Aceh, will provide a new and useful information on smoking prevention, especially in the development of smoking intervention programs for Muslim adolescents. Even though the number of smokers has been very alarming, the smoking prevention development in Indonesia, especially in Aceh, is poorly studied. Currently, there is no study explore about the incorporation of family-focused and Islamic-based approaches to prevent smoking behavior. Therefore, this study is expected to have significant contribution to prevent smoking behavior among adolescents, especially in Muslim countries which share the same characteristics. The objective of this paper was to outline a study protocol for developing smoking prevention program. The adolescents' knowledge, attitudes, smoking intentions and smoking behavior are taken as the success parameters.

METHODS

Study Design
This study will be conducted using a Cluster Randomized Controlled Trial (RCT), testing the effectiveness of smoking prevention intervention programs for adolescents.

Setting
This study will be conducted in three schools in Aceh Besar Regency, representing a moderate life condition, between city and village life. These schools are in suburban area, having good public transportation and located less than 20 km from the Aceh Province Capital. Total

population in the district is 409.109 inhabitants, with the average household size of 4, poverty of 15.41%, and labor force participation rate of 59.17% (Central Aceh Statistics, 2019).

Participants
Participants of this study will include 150 students from three junior high schools in Aceh Besar Regency, Aceh Province, Indonesia. The participant will be determined by simple randomization using a randomization table created by computer software and divided into three groups with 50 participants for each group. The number of samples was determined using a medium effect size with a power of .08, confidence level at 95% and an alpha of .05 with a value of $d = .60$. The inclusion criteria include male, aged 11-14, having a family member (at least a mother) and living with the family, able to communicate in Indonesian Language, not experiencing communication problems and willing to be respondents.

Interventions
This study includes three intervention programs for three groups of participants. Each group will receive different kind of intervention. The intervention for the three groups is explained below.
1. Group A (Health-based intervention program using family approach). Intervention for this group consists of six sessions for six weeks with 90 minutes for each session. The first session includes introduction about smoking phenomena, the next session is about prevalence of smoking and smoking rules, the third session is about health effects of smoking, the next session is about stress managements, the fifth session is about smoking refusal skills and the last session is closing. The sessions will be delivered to adolescents by face to face activities in classroom, the intervention will be administered by health educators and psychiatric health nurses. The methods include lecture, demonstration, discussion, storytelling and role playing. The media for intervention includes booklet and manual guide sheet which are designed specifically for this study. At the end of each session, the researchers will hand the material with the same topic to students and ask them to give it to their parents as a guideline for planning of action at home.

2. Group B (Islamic based intervention program using family approach). Intervention for this group consists of six sessions, 90 minutes sessions per week for six weeks. The first session includes introduction about smoking phenomena among Muslim, the next session is about Islamic perspective about healthy living, the third session is about Islamic perspective of smoking, the next session is about stress managements based on Islamic teaching, the fifth session includes smoking refusal skills using Islamic approach, and the last session is closing. The intervention will be delivered face-to-face by health educators, psychiatric health nurses and Islamic Scholars. The methods include lecture, demonstration, discussion, storytelling, and role playing. The media for intervention includes booklet and manual guide sheet which are designed specifically for this study. At the end of each session, the researcher will hand the material with the same topic to student to give it to their parents as a guideline for planning of action at home. The intervention adherence will be assessed by researchers using observation form which is designed specifically for this study.

3. Group C (Control group). In the group C, the participants will not receive any kinds of intervention. This group will be the control group in this study.

Training for Program Providers
The program providers include health educators, Islamic scholars and the mental health nurses. Prior to the program implementation, the program providers will have one-day training in order to obtain the optimal results. The training is also to ensure that all program providers will have the same perception on how to carry out the intervention program. The training also aims to get the support from policymakers, including from the schools and the community. The training includes several activities, such as introduction, effective teaching methods and a review of available resources. The researchers are actively involved in the training activities to share the knowledge and experience with the program providers.

Data Collection and Outcome Measurement
The research assistants will collect data in the classroom in each school. The data will be collected using self-report questionnaire which will be measured at each of three data collection time-points including one week before intervention, two weeks after completing the intervention, and four weeks after completing the intervention.

Knowledge about health effect of smoking will be assessed by self-report questionnaire, which include 30 multiple-choice questions. Each question is presented in a multiple-choice format with four possible options for each answer, one point will be scored for each correct answer. The total score for this scale will range from 0 to 30 with higher scores representing greater knowledge.

Attitudes toward smoking will be assessed by using self-report questionnaire designed specifically for this study. It includes 25 statements which are presented in a five-point Likert scale format, with responses ranging from 0 (strongly disagree) to 4 (strongly agree) for positively worded items, and 0 (strongly agree) to 4 (strongly disagree) for negatively worded items. Scores are summed to obtain a total score for smoking attitude, which range from 0 to 100. A higher score indicates that the individual is more likely to smoke.

The questionnaire about knowledge and attitude is designed specifically for this study. The validity will be assessed by three experts including Islamic scholar, psychiatric health nurse, and community nurse. The content validity index (CVI) score of .9 will be used as the excellent standard for the questionnaire. Interrater reliability will be conducted by a test-retest to measure the correlation between the same person's score as well as the application of internal consistency to evaluate the interrelatedness among items or sets of items in the scale. The criteria score is $\geq .7$.

Smoking intention and smoking behavior will be assessed using questionnaire adapted from a previous study. The Cronbach's alpha of smoking intention and smoking behavior questionnaire were .84 and .88 (Tahlil, Woodman, Coveney, & Ward, 2013). Smoking intention includes three questions, each question with five response categories, ranging from 0 for "certain not to smoke" to 4 for "certain to smoke". The three questions include, whether they would smoke tobacco next year, during senior high school, and when older or when over 50 years of age. Higher score indicates that the individual is more intent to smoke.

Smoking behavior will be measured using three questions, including the number of cigarettes smoked in the last seven days, in the last 30 days, and in the participants' lifetime. To assess cigarette smoking frequency in the last seven days, response categories are "never tried a

cigarette, not even one puff" (score 0), "one puff or two puffs" (score 1), "just one cigarette" (score 2), "two cigarettes" (score 3), and "three to five cigarette" (score 4).

The frequency of cigarettes smoked in the last 30 days consists of response categories including: I did not smoke cigarettes during the past 30 days (score 0), less than one cigarette per day (score 1), one cigarette per day (score 2), two to five cigarette per day (score 3), six to ten cigarettes per day (score 4), 11 to 20 cigarettes per day (score 5), and more than 20 cigarettes per day (score 6). Finally, for assessing frequency of lifetime cigarette smoking, the responses include I did not smoke any cigarette (score 0), less than one cigarette (score 1), one cigarette (score 2), two to five cigarettes (score 3), six to ten cigarettes (score 4), 11 to 20 cigarettes (score 5), 21 to 60 cigarettes (score 6), 61 to 100 cigarettes (score 7), and more than 100 cigarettes (score 8). Higher score indicates higher frequency of smoking.

Data Analysis
Data will be analyzed using SPPS version 21 for window. Descriptive statistics will be performed to explain frequency, percentage, mean and standard deviation. Differences between groups at baseline of the outcome variables will be assessed using Analysis of variance (ANOVA) for smoking knowledge and attitude, and using chi-squared tests for smoking intention and behavior.

Ethical Approval
This study was approved by the Research Ethics Committee of the Faculty of Nursing, Universitas Syiah Kuala with number 113003101118. Participants have the right to refuse to be involved in the study. They will be given detailed information about the research and confidentiality will be guaranteed. Written consent to participate in this study will be obtained from participants' parents.

DISCUSSION

The high smoking prevalence among Indonesian adolescents especially in Aceh is a significant problem, requiring an effective prevention program to be developed for solving this phenomenon. Therefore, we have developed an Islamic-based intervention program using a family approach to prevent the smoking behavior among adolescents.

The primary objective of this study is to examine the effectiveness of the Islamic-based smoking prevention program using a family approach on adolescents' knowledge, attitudes, intentions and behavior on smoking activities. The intervention will be delivered by trained teachers, health worker's / health educators, Islamic leaders and mental health nurses. It is expected that this intervention will be culturally fit and effective for preventing smoking behaviors among adolescents. The results of this study could be a reference for other places in the world, which experienced similar problem and have the same social characteristics.

This study gives a very meaningful contribution because there is limited study on smoking interventions in Indonesia, especially in Aceh. Based on the review of various reported studies, we have learned that the development of smoking prevention efforts among adolescents is mostly conducted in western countries, where the family-focused and Islamic-based approaches are not widely reported. Hence, this study is expected to fill the gap of knowledge in the prevention of smoking behavior among adolescents, especially for Muslim adolescents.

CONCLUSION

Based on the explanation above and the results of the Focus Group Discussion (FGD) with the students in Aceh, we designed an Islamic-based program using family approaches for preventing the adolescents from smoking behavior. This study is expected to be a reference for health professionals to prevent smoking among adolescents.

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