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The Effect of a Zero Tolerance Program Applied to Parents of Children at High Risk of Secondhand Smoke Exposure on the Child's Urine Cotinine Level According to Exposure Feedback: A Study Protocol for a Randomized Controlled Trial

İkinci El Tütün Duman Maruziyet Riski Yüksek Çocukların Ebeveynlerine Uygulanan Sıfır Tolerans Programının Maruziyet Geri Bildirimi Vermeye Göre Çocuğun İdrar Kotinin Düzeyine Etkisi: Randomize Kontrollü Deneyin Çalışma Protokolü

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ABSTRACT

Objective: This study protocol is aimed at comparing the effect of exposure feedback according to a Zero Tolerance Program (Sıfır Tolerans Programı, SToP) on urinary cotinine levels in children aged 5 and younger (0-5 age).

Methods: This study protocol is planned as an active control group, single-blind (participant), randomized control trial, and stratified block randomization (1:1). The study is planned to be carried out between April 2023 and April 2024 and includes 58 participants in total from the SToP group (n = 29) and the secondhand smoke (SHS) exposure feedback group (n: 29), which is the active control group. The primary outcome is the urinary cotinine level of children, which will be measured by a cotinine-sensitive rapid test kit. The Knowledge Form on Exposure to SHS, Attitude Form on Exposure to Secondhand Smoke, Beliefs about Third-Hand Smoke Scale, and Secondhand Smoke Exposure Risk Algorithm will be used to measure secondary outcomes. Secondhand smoke exposure feedback, reminder objects, informative materials, and telephone messages will be given to the SToP group. The active control group will only take SHS exposure feedback.

Results: The difference in the children's urinary cotinine level, parents' knowledge, attitudes, and beliefs, and children's exposure risk between the SToP group and SHS exposure feedback group will be evaluated after the interventions. Findings will be presented in terms of our hypotheses.

Conclusion: This study protocol will show whether there is a viable intervention for parents on how SToP intervention, which is a sustainable program for children at high risk of SHS exposure, can reduce exposure.

Keywords: Child, cotinine, education, parents, secondhand smoke

ÖZ

Amaç: Bu çalışma protokolünün amacı ebeveynlere uygulanan Sıfır Tolerans Programı'na (SToP) göre maruziyet geri bildirimi vermenin çocukların idrar kotinin düzeyine etkisinin karşılaştırılmasıdır.

Yöntemler: Aktif kontrol gruplu, tek kör (katılımcı), randomize kontrollü deney olan bu çalışma protokolünde tabakalı blok randomizasyon (1:1) yapılacaktır. Nisan 2023- Nisan 2024 tarihleri arasında yürütülmesi planlanan çalışmaya SToP girişim grubu (n:29) ve aktif kontrol grubu olan ikinci el sigara dumanı maruziyet geribildirim grubundan (n:29) toplamda 58 katılımcı dâhil edilmesi planlanmıştır. Birincil sonuç için kotinin duyarlı hızlı test kiti, ikincil sonuçlar için ise İkinci El Dumana Maruz Kalmaya İlişkin Bilgi formu, İkinci El Dumana Maruz Kalmaya İlişkin Tutum formu, Üçüncü El Sigara Dumanına Yönelik İnançlar (ÜESDYİ) Ölçeği ve İkinci El Sigara Dumanı Maruz Kalma Risk Algoritması (İESDM-RA) kullanılacaktır.

Bulgular: SToP grubu ile ikinci el sigara dumanı maruziyet geribildirim grubu arasındaki çocukların idrar kotinin düzeyi, ebeveynlerin bilgi, tutum ve inançları ve çocukların maruz kalma riskindeki fark, müdahalelerden sonra değerlendirilecektir. Bulgular hipotezlerimiz doğrultusunda sunulacaktır.

Sonuç: Bu protokol ikinci el sigara duman maruziyet riski yüksek çocuklar için sürdürülebilir bir program olan SToP girişimlerinin maruziyeti nasıl azaltılabileceği konusunda ebeveynlere uygulanabilir bir müdahale olup olmadığını gösterecektir.

Anahtar Kelimeler: Çocuk, kotinin, eğitim, ebeveynler, ikinci el sigara dumanı

INTRODUCTION

Among non-smokers, exposure to secondhand smoke (SHS) is estimated to kill an additional 600 000 people each year. Nearly half of children regularly breathe air polluted by cigarette smoke, and more than 40% of children have at least 1 parent who smokes.[1] According to World Health Organization, SHS is a mixture of the smoke from the burning tip of a cigarette and the smoke exhaled by a smoker. When SHS contaminates the air, especially in enclosed spaces, it is inhaled by everyone, exposing both smokers and non-smokers to its harmful effects.[2]

Children are the group most exposed to SHS, especially due to adults who smoke in the home environment.[3] The rate of children under 15 years exposed to SHS at home ranged from 4.5% to 79.0% and was 61.2% in Turkey.[4] Quitting smoking was the most effective way to protect children from the negative effects of SHS. In one meta-analysis, interventions such as education and counseling on smoking cessation were provided to parents to prevent children's exposure to SHS, but most parents continued to smoke after the interventions.[5] In this context, the focus should not only be on parents quitting smoking but also on interventions such as education and counseling to minimize the harm of SHS in children. Two meta-analysis studies found that although interventions such as counseling, home visits, brochures, and SHS exposure feedback with biomarkers such as saliva or urine protected children from SHS and reduced smoke pollution in the home, SHS exposure in children still remained.[6,7] In many studies with multiple interventions such as posters, home visits, and counseling, it has not been determined which of the interventions to reduce SHS exposure is more effective.[5-9] Also, among smoking parents, parents' perception and avoidance of SHS exposure behaviors[10] and knowledge and attitudes toward SHS exposure[11] were found to be lower.

In Turkey, within the scope of the Ministry of Health and Green Crescent's practices, such as the Smoke-Free Airspace Control System[12] and Green Detector,[13] the prevention of tobacco use in public spaces is seriously inspected. However, since the home living environment cannot be controlled, individuals' own awareness is important in protecting against SHS exposure. For this reason, it has been stated that families should be made aware of the fact that especially babies should not come into direct or indirect contact with cigarette smoke in the home environment.[14] In this regard, it is recommended to question SHS exposure during the follow-up of infants and 5-year-old children and to inform parents about the health hazards and possible effects of SHS exposure.[15] However, no intervention programs have been found to prevent SHS exposure in infants and children who spend the majority of their lives in the home environment.

Enforcement of smoke-free laws protects vulnerable groups, especially children, against SHS in the home. However, smoke-free house rules are not sufficient to completely protect children from exposure to SHS, especially in homes with smokers.[16] The inability to control SHS exposure, the lack of sustainable policies, and interventions for SHS exposure in the home environment increase the risk of SHS exposure, especially for children aged 5 years and younger. In recent studies, interventions such as SHS exposure feedback, reminder objects, informational materials, and telephone messages have been found to reduce SHS exposure in children.[6,7,9] In this context, it is important to adopt a *"Zero Tolerance"* approach to ensure that there are sustainable interventions that will minimize SHS exposure in the home environment, such as reminders and warnings to family members about the harms of SHS exposure. The *Zero Tolerance Program* (SToP), which includes exposure feedback, reminders such as magnets, informative materials such as brochures, and informative telephone messages, is designed for parents of children aged 5 and younger at high risk of exposure to SHS. Therefore, this study protocol for a randomized controlled trial will aim to compare the effect of a SToP applied to parents of children at high risk of exposure to secondhand smoke on the child's urinary cotinine level according to exposure feedback. This study will also examine the impact of SToP and exposure feedback interventions on parents' knowledge and attitudes about SHS, parents' beliefs about thirdhand smoke (THS), and children's risk levels for SHS exposure.

Population, Intervention, Comparison, Outcomes, and Study were used to create hypotheses, with a significance level of 0.05.[17] The following are the hypotheses:

- **H_0:** The urinary cotinine level of children aged 5 and younger in the SToP group will not be different from the SHS exposure feedback group.
- **H_1:** Parents in the SToP groups will have more **a)** knowledge and **b)** positive attitudes about SHS than those in the SHS exposure feedback group. **c)** Children of parents in SToP groups will have a lower risk of SHS exposure than in the SHS exposure feedback group.

- **H_1:** The SToP interventions will positively affect parents' beliefs about THS more than the SHS exposure feedback intervention.

METHODS

Study Design

This study protocol for a randomized controlled trial was designed as a single-blind (participant) randomized controlled trial with an active control group (Figure 1 and 2). Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT),[18] Consolidated Standards of Reporting Trials (CONSORT),[19] and Template for Intervention Description and Replication (TIDieR)[20] checklists and guides will be used in this protocol study.

Study Setting and Population

The study was planned to be carried out between April 2023 and April 2024 in the 9 nolu Şehit HemşireCanan AKKUŞ Family Health Center (FHC) located in the district of Antalya Muratpaşa district of Antalya province was preferred because it has a heterogeneous socio-demographic and sociocultural structure. The population of the research will be the parents of children aged 5 years and younger who reside in the Muratpasa district of Antalya province, are registered with the FHC and are exposed to SHS.

Inclusion Criteria

- Parents of children aged 5 and younger who scored 3 (high risk) or 4 (very high) according to the Secondhand Smoke Exposure

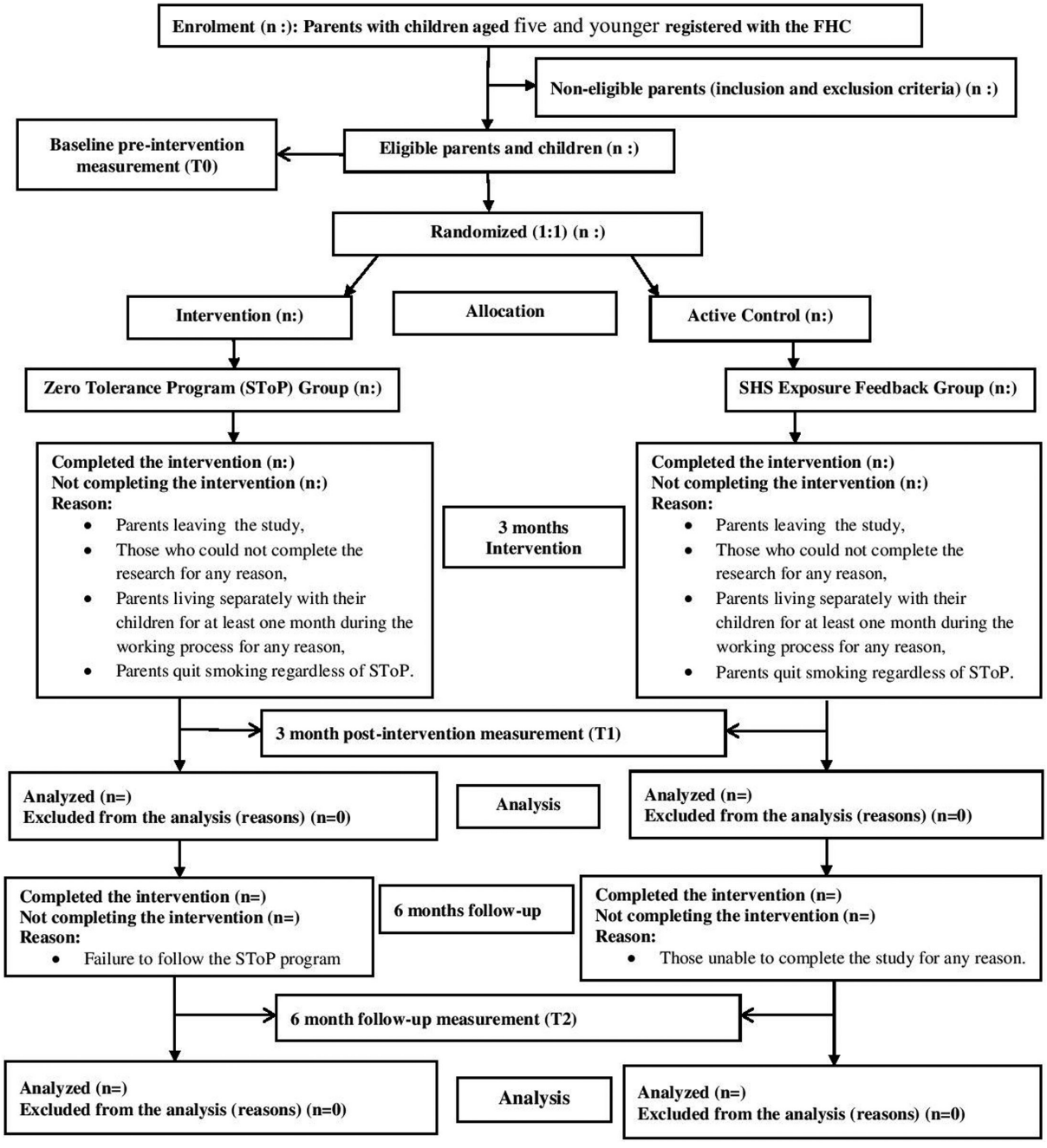

Figure 1. Zero Tolerance Program Consolidated Standards of Reporting Trials flow chart.

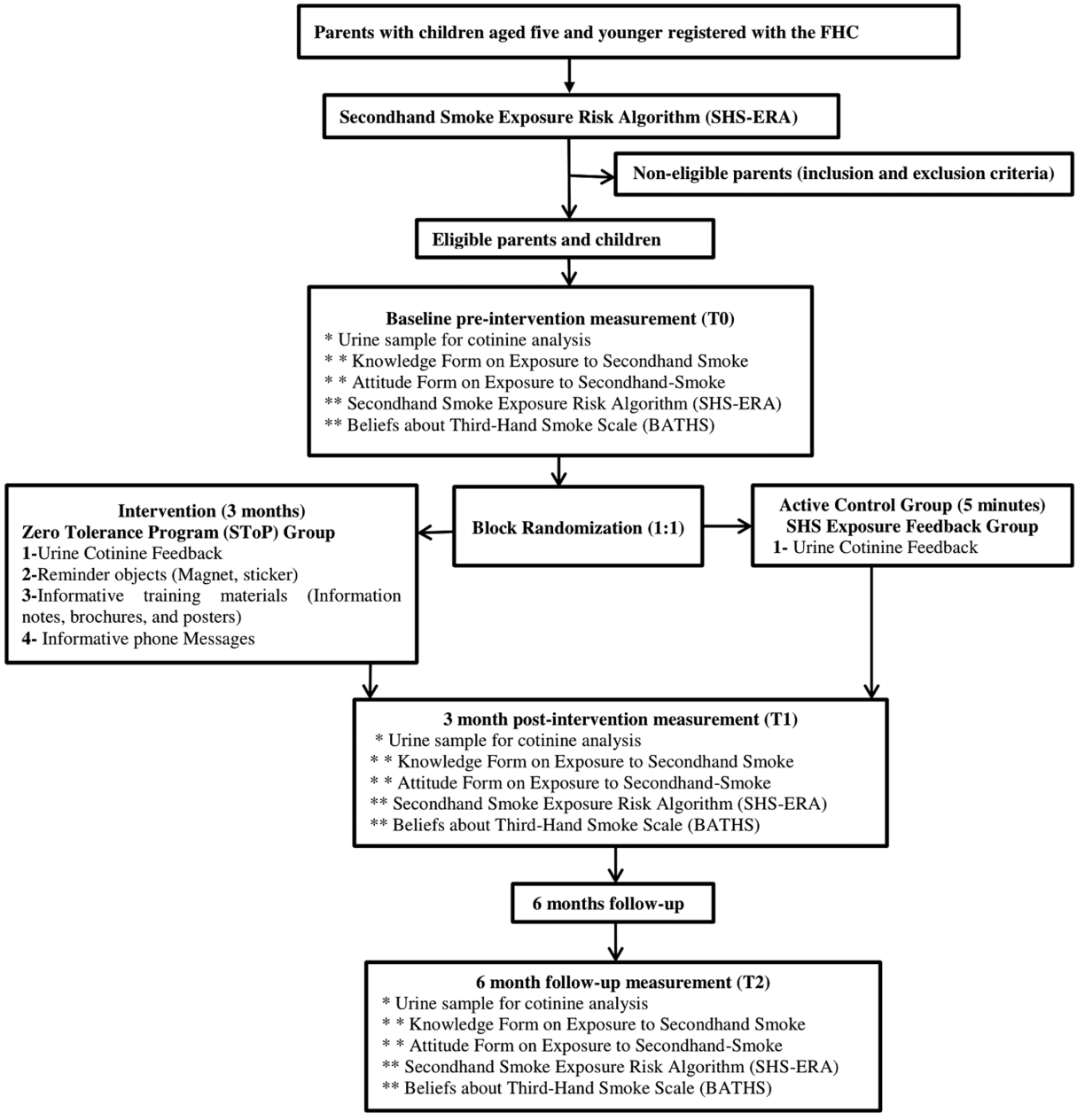

Figure 2. Flow chart of the Zero Tolerance Program study. *Primary outcome; **Secondary outcome.

Risk Algorithm (SHS-ERA; Figure 3). This age group was preferred because they spend more time at home. In addition, routine follow-up for this age group in Turkey is carried out by nurses in family health centers.

Children who have been exposed to secondhand smoke in the past 7 days.

- Parents who voluntarily agreed to participate in the study.

Exclusion Criteria

- Paid caregivers.
- Those who do not speak Turkish.
- Parents of children with asthma will not be included because it may be confusing as they may display more specific behavior.

Withdrawal Criteria

- Who wants to leave the research.
- Those who could not complete the research for any reason.
- Parents living separately with their children for at least one month during the working process for any reason.
- Parents quit smoking, regardless of SToP.

Sample Size

In a study, it was found that interventions to reduce SHS exposure had a high degree of effect on urinary cotinine levels.[21] The effect size of this study was used as a guide for sample calculation. Sample size calculation was performed in the G*Power 3.1.9.7 program with 0.8 effect size, 0.05 alpha values, and 80% power in the different analysis calculations between the *t*-test and the mean of 2 independent groups. For each group, 26 participants (52 in total) were calculated. The average loss rate of 10% is added, and the inclusion of participants for each group of 29 required was determined. It is planned to reach 58 participants in total.

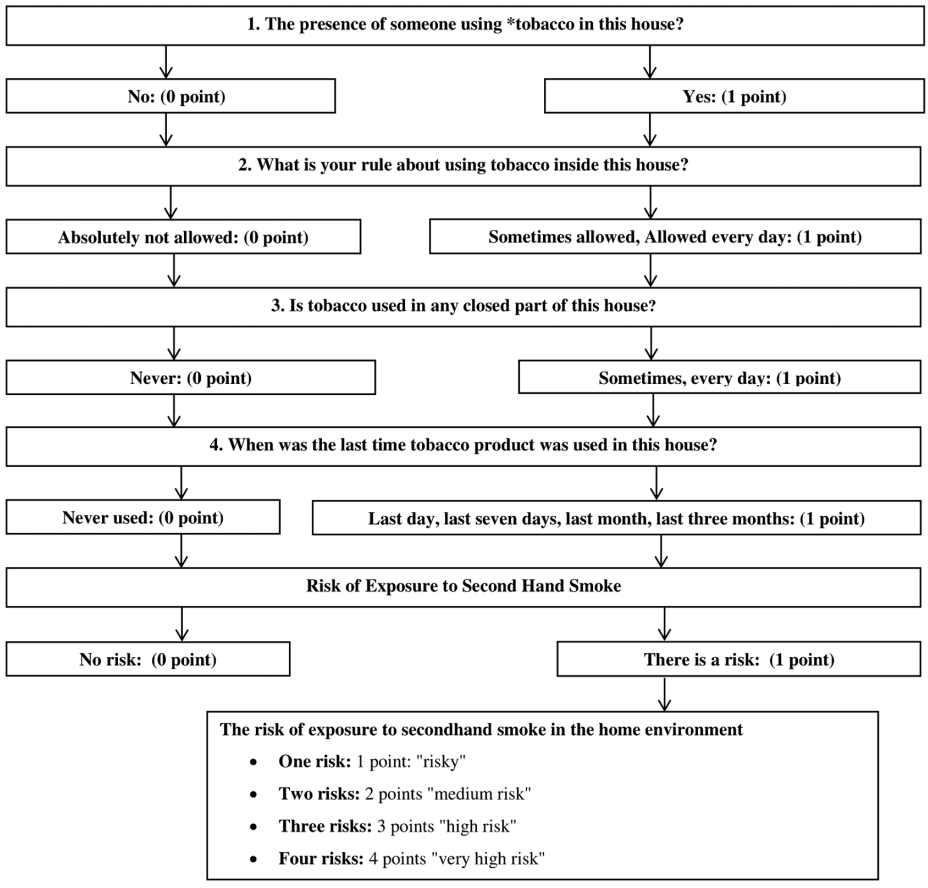

Figure 3. Secondhand Smoke Exposure Risk Algorithm. *All participants define the tobacco product used as cigarette.

Randomization and Blinding

According to the SHS risk algorithm, high (3 points) and very high (4 points) SHS exposure will be considered stratified, and stratified block randomization (1 : 1) will be made. In order to control the selection bias, randomization will be made in the mobile application of the *"Statistics and Sampling"* program by the consultant researcher, who does not meet the parents, and will be delivered to the researcher in closed envelopes. The block size is planned to be eight. Since the intervention will be made by the researcher, it is not possible to blind the researcher. However, since the intervention will be made in both groups, the participant (parent) will be blinded.

Urine cotinine values are objective data and will be read by the 2 intern nurses in FHC, who do not know which group the participant is in. Scales for SHS and THS are subjective data. These data will be collected by self-report from parents via e-survey. Therefore, bias in outcome measurements can be avoided. The data obtained will be transferred to the database by the researcher as groups A and B and analyzed by a statistician who does not know which group the participants are in. Thus, statistician blinding will be provided.

Interventions Group/Zero Tolerance Program Group

The SToP interventions, consisting of 4 components (exposure feedback, reminder objects, informative materials, informative telephone text messages), were evaluated by 10 experts consisting of public health nurses, pediatric nurses, and pediatricians who have studied the subject, and a content validity index (CVI) of 0.99 was found. Table 1 indicates the characteristics of the intervention. The intervention will take approximately 15-20 minutes.

Exposure Feedback

The cotinine concentration value of the urine samples taken from the children who came to the FHC during the pretest, posttest, and follow-up stages of the study will be measured with the cotinine-sensitive rapid test kit. The cotinine concentration value of the cotinine-sensitive rapid test kit assay can be determined within 5 minutes. As soon as the concentration value is determined by 2 intern nurses by the funded The Scientific and Technological Research Council of Turkey, 1002-A Rapid Support Program (Number: 222S724), the parents will be informed face-to-face. Scholars were selected and trained by researchers among intern nurses. Parents will be told by the researcher what the cotinine-sensitive rapid test kit score and color scale mean. The intervention will take nearly 5 minutes.

Reminder Objects

The magnets and stickers created by the researcher will be hung on the refrigerator, phone, stroller, baby room, and entrance door of the house. For example, sticking *"Zero Tolerance* to Smoking," *"No smoking in my house," "No smoking in this house"* magnets on the entrance door of the house where everyone can see them. At the same time, magnets and stickers will be prepared to correct known mistakes about cigarettes, which will be posted on places that will attract the attention of individuals, such as the door of the house, the baby carriage, the children's room, and white goods. It will be given to the parents who come to the FHC by the researcher.

Table 1. The Characteristics of the Interventions

	Intervention Components to be Applied in the Study			
Characteristic	**Exposure Feedback**	**Reminder Objects**	**Informative Materials (Information Notes and Brochures)**	**Informative Telephone Text Messages**
Time	Pretest: T0 Posttest (third month): T1 Follow-up test (sixth month): T2	Once after T0	One face-to-face meeting after T0. Informing parents about the phone number and hours they can call the researcher if they have questions about SHS and THS exposure.	Informative phone text message once a week after T0
Content and implement	**1**.Evaluation of urinary cotinine with urine cotinine rapid test kit **2.** Explaining what the test result means—giving feedback	**1.** Preparation of magnets and labels (stickers). **2.** Ensuring that magnets and stickers are hung on the refrigerator, baby stroller, baby room, and entrance door of the apartment by the parent. For example; On the entrance door of the house: "ZERO TOLERANCE" to smoke magnet; "No smoking in my house" label.	**1.** Preparation of informative notes and posters (harms of SHS and THS, diseases caused, how to protect, etc.). For example: "Breathing the air in a room where people smoked the day before may harm the health of babies and children." For example: tell guests who come to the house and smoke that there is no smoking in the house. **2.** Giving brochures and posters of the Green Crescent and the Ministry of Health to parents regarding passive exposure.	**1.** Reminder message contents related to SHS and THS are prepared and sent to parents every week.
Target		**1.** Ensuring knowledge and attitude change. **2.** Perceving the false facts about SHS and THS exposure.	**1.** Increasing the level of knowledge. **2.** Ensuring positive attitude/behavior change. **3.** Ensuring that children are protected from SHS and THS exposure in the home environment.	**1.** Increasing the levels of knowledge, attitudes, and beliefs regarding SHS and THS exposure **2.** Raising awareness about the harms of smoke.
Interventions Group/Zero Tolerance Program Group (SToP)	✓	✓	✓	✓
Active Control Group/SHS Exposure Feedback Group	✓	×	×	×
Practitioner	Researchers and project's scholars (intern nurse).	Researchers	Researchers	Researchers
location and type of Intervention	Family Health Center- face to face.	Family Health Center—face-to-face	Family Health Center and Telephone	Telephone

SHS, Secondhand smoke; THS, thirdhand smoke.

Informative Materials (Information Notes and Brochures)

Information notes and brochures will be used as informative material. Informative brochures prepared by the Turkish Green Crescent Society and the Republic of Turkey Ministry of Health will be used. Informative materials will be sent to parents by the researcher via message once a week. The content of each piece of informative material will be different from the others. Informative notes created by the researcher will include topics such as the harms of SHS and THS, the diseases they cause, and how to protect them. For example, "*Opening windows or using a ventilator will not remove all cigarette smoke particles in a room.*" The purpose of the informative materials is to increase the level of knowledge, attitudes, and beliefs in parents about SHS and THS and to increase their awareness about the harms of cigarette smoke. In addition, phone calls will be made when the parents need them. The phone call is planned to last between 5 and 10 minutes. Parents in the SToP group who receive phone support will be told how to protect their children from SHS and THS at home. For example, information will be given on issues such as "telling the smoking guests that there is no smoking in the house."

Informative Telephone Text Messages

Educational and informative text messages about SHS and THS exposure harms and how parents wiil protect their children will be sent to parents via telephone once a week for 12 weeks. Text messages will be sent to only parents in the SToP group. The text messages were created by the researcher in line with the relevant literature. The content of each message will be different from each other. The purpose of these informative messages is to increase the level of knowledge, attitudes, and beliefs about SHS and THS in parents and to increase their awareness about the harms of cigarette smoke.

Sample text messages:

- In babies and children growing up in an environment where tobacco is used, diseases can become the most progressive.
- The harmful substances in tobacco smoke can remain on clothes for a long time and harm children.

- Breathing the air in a room where people smoked the day before may harm the health of babies and children.
- Opening windows or using a ventilator will not remove all cigarette smoke particles from a room.
- In order to build trust in parents, they will be told that they can call the researcher by phone whenever they need. The phone number and hours at which the parents can reach the researcher regarding their questions regarding SHS and THS exposure will be informed.

Active Control Group/Secondhand Smoke Exposure Feedback Group

The secondhand smoke exposure feedback group consists of 1 part. Only the exposure feedback intervention in the SToP group will be implemented in the active control group. The intervention will take nearly 5 minutes. Table 1 indicates the characteristics of the intervention.

Data Collection

Descriptive characteristics of the participants (age, gender, and education level), the number of children aged 5 and younger at home, and their age and gender will be included in the household descriptive form. The "Fagerström Test for Nicotine Dependence" will be used to determine the degree of nicotine addiction of the participants.

Secondhand Smoke Exposure Risk Algorithm

This form will be used to select children at "high" and "very high" risk of SHS exposure at home. The SHS-ERA form, which was prepared by the researcher based on the relevant literature,[22-25] includes 4 questions (Figure 3). These questions included the presence of smokers in households, rules for using tobacco at home, tobacco use status in the interior and exterior parts of the house where tobacco is used, whether it is time to use tobacco at home. The first 2 questions were created by referencing the studies of the Global Adult Tobacco Survey (GATS).[25] The presence of a tobacco user among the people living in the house was accepted as exposure.[22] Although tobacco use in the house is questioned in the GATS study,[25] it is not questioned which indoor part of the house tobacco product is used. In the third question created to determine the exposure risk, any closed part of the house, such as the living room, hall, kitchen, and areas covered with materials such as glass, PVC windows or blinds were accepted as "indoor areas." Areas such as gardens, balconies, and terraces that are not covered with materials such as glass, PVC windows or blinds were considered "open spaces."

The fourth question in this section was formed by considering the GATS study and the recommendations of the American Academy of Pediatrics. In the GATS study, the frequency of tobacco use in the home is evaluated in the categories of daily, weekly, monthly, less than a month, and never.[25] The American Academy of Pediatrics recommends asking the question "Has anyone smoked anywhere in your home in the past 3 months?" to determine children's exposure to secondhand smoke.[26]

For the content validity of the questions formed, the CVI was calculated by taking the opinions of 9 experts who had research or projects on the subject using the Davis Technique.[27] The CVI value of this part of the questionnaire was found to be 0.86. The answers were given to evaluate the exposure frequency and risk intensity of children aged 5 and younger in the home environment. They were given 1 point if they included risk and 0 points if they did not. Having at least 1 score was considered a "risk." The risk intensity is scored between 0 and 4 in total. A score of 1 or above indicates the presence and intensity of risk. Face-to-face interviews with participants who match the inclusion criteria will be conducted to gain their informed consent and basic data.

Outcome criteria

Children's urine cotinine test kit values are the primary outcome. Parents' knowledge and attitudes about SHS exposure and parents' beliefs about THS exposure are secondary outcomes. Also, child risk level, according to SHS-ERA, is another secondary outcome.

Primary outcome criteria

One primary outcome was detected in this study.

Urinary Cotinine Level

A urine sample taken at any time will be analyzed with a cotinine-sensitive rapid test kit to assess the urinary cotinine level that indicates the child has been exposed to SHS. Urine samples will be tested according to the manufacturer's instructions.[28] The test has over 99% sensitivity in detecting cotinine, with a cut-off level of 200 ng/mL, a minimum detection time of 2-8 hours, and a maximum detection time of 1-7 days. After the test is immersed in the urine collection container for 10 seconds, the result becomes clear within 5 minutes. If the test is negative, the control (C) and test (T) lines appear. If the test is positive, only the C line appears. If the C and T lines are not visible or the C line is visible, it means that the test is invalid. Each test sample will be read and recorded by 2 independent observers. The use of test kits does not require special equipment and can be easily performed with minimal training.[28] Each test sample will be read and recorded by 2 independent intern nurses.

Secondary Outcomes Criteria

Four secondary outcomes were detected in this study.

Knowledge Form on Exposure to Secondhand Smoke

The form is based on the literature.[11,26,29] The form consists of 13 items. For each item, the participants—right, wrong, I don't know—can choose one of the options. Each item is scored between 0 and 1, according to the answer given. Accordingly, scores ranging from 0 to 13 are taken. A high score indicates good knowledge. The content validity index was obtained from 9 people who are experts in the fields of public health, child health, measurement, and evaluation using the Davis technique.[27] The CVI was 0.99. The Kuder–Richardson (KR-20) value was 0.85**.**

Attitude Form on Exposure to Secondhand Smoke

The form was developed by researchers in line with the literature.[11,26,30] The form consists of 6 statements. Participants: *"Strongly agree," "I agree," "I am undecided," "I do not agree," "I strongly disagree"* can choose one of the answer options. The CVI was obtained from 9 people who are experts in the fields of public health, child health, measurement, and evaluation using the Davis technique.[27] The CVI was 0.99. The KR-20 value was 0.84. Since the answers of the participants focused on a certain area, their choices were recategorized and classified as positive and negative attitudes. Positive attitude statements will be given 1 point and negative attitude statements will be given 0 (zero) points. Accordingly, a score between 0 and 6 can be obtained. A high score indicates a positive attitude.

Secondhand Smoke Exposure Risk Algorithm

The SHS-ERA will be remeasured as a secondary outcome to see if the risk level of children has changed with the interventions made.

Beliefs about Third-Hand Smoke Scale

The scale was developed by Haardörfer et al in 2017 to determine beliefs about third hand smoke (BATHS). In the sub-items of the scale, there are 5 items related to the effect of THS on health and 4 items related to the persistence of THS in the environment. The Cronbach's alpha value of the scale is 0.91. In scoring the scale using a five-point Likert: 5: strongly agree, 4: agree, 3: not sure, 2: disagree, 1: strongly disagree. A score is obtained by dividing the total score of the scale by the number of items. If the score obtained from each item is close to 5, it is interpreted that the individual believes in the effects of THS on the environment and health, and if it is closer to 1, the individual does not believe in the effects of THS on the environment and health.[31] The Turkish validity and reliability study of the scale was carried out by Odacı and Kitiş.[32] The Cronbach alpha value of the Turkish scale was 0.83.

Statistical Analysis

The statistics to be used in the study are summarized in Table 2.

Ethical Committee Approval

Ethics committee approval was obtained for the study from the Akdeniz University Faculty of Medicine Clinical Research Ethics Committee (Date: July 20, 2022; Number: KAEK-462). Official permission was obtained from the Antalya Provincial Health Directorate for the study to be conducted in the Family Health Center (Date: September 19, 2022; Number: E-67910779-799). In September 2022, the study protocol was registered on ClinicalTrials.gov (NCT05545748). This study was conducted in accordance with the principles Declaration of the Helsinki. Before the interview, the researcher will provide the participant with information about the research and obtain written and verbal consent using an informed consent form. Participants will have the right to leave the interview at any time. The study has no risk for the participants.

Validity and Reliability

The SPIRIT,[18] CONSORT,[19] and TIDieR[20] checklists and guides were used in this protocol. Interventions will be carried out in accordance with the intervention plan. The cotinine-sensitive rapid test used in the present study to detect SHS exposure is valid and reliable.[33]

Knowledge Form on Exposure to Secondhand Smoke, Attitude Form on Exposure to Secondhand Smoke, and SHS-ERA were evaluated by taking the opinions of 9 experts in the fields of public health, child health, measurement, and evaluation. The CVI was calculated by using Davis technique.[27] The CVI of the Knowledge Form on Exposure to Secondhand Smoke was 0.99 and of KR-20 value was 0.85. The CVI of Attitude Form on Exposure to

Table 2. Statistical Analyses to be Used

Variable/Outputs	Hypothesis	Measurement Outputs	Analysis Method
	Sample calculation and power analysis		G*Power program
	Content relevance of the SToP	Expert opinions	R program; Scope content index and Weighted Kappa Analysis/Evaluation with Dawis technique and CVI calculation
	Whether the data show normal distribution or not		Shapiro–Wilk and Kolmogorov–Smirnov tests
	Validity and reliability of data collection tools		Kuder–Richardson 20 (KR-20) for the reliability of the attitude and knowledge forms. Cronbach alpha (α) analysis for THS reliability
*Urine cotinine concentration level at 6 months, 3 months, and baseline	**H_0:** The urinary cotinine level of children aged 5 and younger in the Zero Tolerance Program (SToP) group will not be different from the SHS exposure feedback group	Cotinine-sensitive rapid test kit results	Chi-square test for discrete variables and independent group *t*-test for continuous variables to compare intervention and comparison groups at baseline and detect differences between groups at 3-month follow-up. Analysis of varriance to compare mean urinary cotinine concentration between and within groups. Effect size (d), Confidence interval.
**Parents' knowledge on SHS at 6 months, 3 months and baseline	**H_1:** Parents in the SToP groups will have more knowledge about SHS than those in the SHS exposure feedback group	Knowledge Form on Exposure to Secondhand Smoke	Odds Ratio in frequency, percentage (%), chi-square, and 2 × 2 chi-square analysis for categorical variables, and Bonferroni correction to determine the group with the difference in multieyed chi-square will be applied. The difference in continuous variables will be analyzed by independent groups *t*-test. Cohen's d will be given for effect size.
**Parents' attitudes on SHS at 6 months, 3 months and baseline	**H_1:** Parents in the SToP groups will have more positive attitudes about SHS than those in the SHS exposure feedback group	Attitude Form on Exposure to Secondhand Smoke	
**Risk of exposure of the child to SHS	**H_1:** Children of parents in SToP groups will have a lower risk of SHS exposure than in the SHS exposure feedback group	Secondhand Smoke Exposure Risk Algorithm (SHS-ERA)	
**Parents' beliefs on THS at 6 months, 3 months and baseline	**H_1:** SToP interventions will positively affect parents' beliefs about THS more than the SHS exposure feedback intervention	Beliefs about Third-Hand Smoke Scale (BATHS)	

The data will be analyzed using the licensed Statistical Package for Social Science Statistics (SPSS) Base version 23.0 software (IBM Corp.; Armonk, NY, USA) of Akdeniz University Faculty of Medicine, Department of Biostatistics.CVI, Content validity index; SHS, secondhand smoke; THS, thirdhand smoke*Primary outcome.**Secondary outcome.

Secondhand Smoke was 0.99, and the KR-20 value was 0.84. The CVI of SHS-ERA was 0.86. The Turkish validity and reliability study of the BATHS was carried out by Odacı and Kitiş.[32] The Cronbach alpha value of the Turkish scale was 0.83. The measurement tools to be used in the research are valid and reliable. Blinding and randomization will be used to lessen the possibility of bias in the results. The cotinine-sensitive rapid test will be evaluated independently by 2 nursing interns. In addition, there will be no risk of bias in outcome measures, as all secondary measures will be measured by them independently of the researchers.

DISCUSSION

In many countries, policies toward not using tobacco products are implemented in many public places, such as hospitals and schools.[34] However, the lack of strong policies regarding the privately owned home environment increases children's risk of SHS exposure.[4] Even smoke-free home rules are not enough to fully protect children from exposure to SHS.[16]

It has been determined that many interventions, such as messages to parents, brochures, SHS exposure feedback, and telephone support to protect children from SHS exposure, reduce SHS exposure in children, but SHS exposure continues in children due to the lack of continuity of the interventions.[6,7,9] In this context, there is a possibility that programs such as SToP that include sustainable interventions that affect parents' knowledge and attitudes about SHS will reduce the risk of SHS exposure in children. The SToP developed for this study provides parents with both objective and subjective evidence of SHS exposure. It also gives information to parents about false facts. In addition, prevention of SHS exposure is kept on the agenda with reminder materials.

Biomarkers, which are accepted as the gold standard in determining SHS exposure, have disadvantages such as being costly, time-consuming, and not accessible to everyone.[35] For this reason, the use of cotinine-sensitive rapid test kits that can detect SHS exposure on-site without the need for a laboratory environment and without the use of special equipment can enable SHS exposure to be determined as soon as possible. Therefore, a cotinine-sensitive rapid test kit such as NicAlert will be used in this protocol study. We think that this concrete result will have a striking effect on parents regarding their child's SHS exposure.

We think that cotinine-sensitive rapid test kits will be preferred more in future studies because they can evaluate SHS exposure in the fastest way, are not time-consuming, do not require a laboratory environment, and are economical. This raises the possibility of fully using SToP interventions in many future studies. We also believe that the sustainability of SToP interventions may affect parents' knowledge, attitudes, behaviors, and beliefs. The SToP may contribute to helping health professionals understand the possible risk of children's exposure. In this protocol study, it will be evaluated whether giving only SHS exposure feedback to the active control group will be sufficient to prevent exposure. Thus, the effects of different interventions can be revealed.

Implications

The SHS exposure based on the biomarkers and questionnaires used in this protocol study can be easily assessed during periodic examinations, especially by family nurses and physicians. Urinary cotinine test kits used in the study can even be used by parents to evaluate their childrens' SHS exposure. SToP interventions can be easily used by all healthcare professionals who may care children. Objective (urine cotinine) and subjective (exposure risk level) exposure feedback, informative telephone text messages, informative materials, and reminder objects used in this study can be standardized and disseminated. In addition, parents' beliefs about THS exposure may be positively affected. In short, with SToP, children aged 5 and younger may be more likely to be protected from the health risks associated with SHS and THS that they may encounter in the future.

Limitations

Because the participants will be drawn from just 1 regional FHC, the possible results cannot be generalized to all children. The SToP, however, can be applied broadly to lessen any form of tobacco exposure, according to our predictions.

The study protocol has been registered on ClinicalTrials.gov in September 2022.

ClinicalTrials.gov link: https://clinicaltrials.gov/ct2/show/NCT05545748

ClinicalTrials.gov number: NCT05545748

Ethics Committee Approval: Ethics committee approval was obtained for the study from the Akdeniz University Faculty of Medicine Clinical Research Ethics Committee (Date: July 20, 2022; Number: KAEK-462). Official permission was obtained from the Antalya Provincial Health Directorate for the study to be conducted in the Family Health Center (Date: September 19, 2022; Number: E-67910779-799).

Informed Consent: Before the interview, the researchers provided the participant with information about the research and obtain written and verbal consent using an informed consent form.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – S.G., E.A.; Design – S.G., E.A.; Supervision – S.G.; Resources – E.A.; Materials – S.G., E.A.; Data Collection and/or Processing –S.G., E.A.; Analysis and/or Interpretation – S.G., E.A.; Literature Search – S.G., E.A.; Writing Manuscript – S.G., E.A.; Critical Review – S.G., E.A.

Declaration of Interests: The authors declare that they have no competing interest.

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Hasta Onamı: Araştırmacılar, görüşmeden önce katılımcıya araştırma hakkında bilgi vermiş ve bilgilendirilmiş onam formu kullanarak yazılı ve sözlü onam almıştır.

Hakem Değerlendirmesi: Dış bağımsız.

Yazar Katkıları: Fikir – S.G., E.A.; Tasarım – S.G., E.A.; Denetleme – S.G.; Kaynaklar – E.A.; Malzemeler – S.G., E.A.; Veri Toplanması ve/veya İşlemesi – E.A., S.G.; Analiz ve/veya Yorum – S.G., E.A.; Literatür Taraması – S.G., E.A.; Yazıyı Yazan – S.G., E.A.; Eleştirel İnceleme S.G., E.A.

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Supplementary Table 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents* (*Continued*)

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	16, 19
	2b	All items from the World Health Organization Trial Registration Data Set	N.A
Protocol version	3	Date and version identifier	16
Funding	4	Sources and types of financial, material, and other support	16,19
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	16,19
	5b	Name and contact information for the trial sponsor	N.A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N.A
	5d	Composition, roles, and responsibilities of the coordinating center, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N.A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3,4,5
	6b	Explanation for choice of comparators	4,5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study setting (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5,6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centers and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	6,7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8,9,10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	8,9,10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)	8,9,10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8,9,10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12
Participant timeline	13	Time schedule of enrollment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1,2,3
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrollment to reach target sample size	6,7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions	7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	7

(*Continued*)

Supplementary Table 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents* (*Continued*)

Section/item	Item No	Description	Addressed on page number
Blinding (masking)	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	7
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10,11,12,13,14,15, Figure 1, 2,3
	18b	Plans to promote participant retention and complete follow-up, including a list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	10,11,12,13,14,15, Figure 1,2
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	N.A
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	N.A
	20c	Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Figure 1.
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N.A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N.A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N.A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N.A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	16
Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N.A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N.A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N.A
Dissemination policy	31a	Plans for investigators and sponsors to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18,19
	31b	Authorship eligibility guidelines and any intended use of professional writers	N.A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N.A

(*Continued*)

Supplementary Table 1. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents* (*Continued*)

Section/item	Item No	Description	Addressed on page number
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorized surrogates	N.A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N.A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.