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Feasibility, Acceptability and Preliminary Effectiveness of "First Breath", a Digital Behavioral Intervention for Expectant Fathers to Reduce Their Pregnant Spouses' Secondhand Smoke Exposure: a Pilot Randomized Controlled Trial

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Abstract

Background: Pregnant women are frequently exposed to secondhand smoke (SHS) inside the home. This study evaluated the feasibility, acceptability, and preliminary effectiveness of *First Breath*, a digital intervention designed to support expectant fathers in reducing their spouses' SHS exposure.

Methods: A pilot randomized controlled trial (RCT) was conducted. Eligible participants were Hebrew-speaking men, aged ≥18, who smoked at least one cigarette daily, and lived with a pregnant spouse (<25 weeks' gestation). Exclusion criteria included participation in a smoking cessation program, a spouse with a high-risk pregnancy or who smokes, or lack of internet access. Participants were randomized to receive *First Breath* or general SHS information (control) (via a WebApp). Questionnaires were completed at baseline and 12-week follow-up. The primary feasibility outcome was recruitment. Additional measures included engagement, satisfaction, changes in perceived spouses' SHS exposure and in smoking rules at home. Linear mixed-effects repeated measures models examined within- and between-group changes over time.

Results: Of 120 individuals screened, 69 (57.5%) were eligible and 45 (37.5%) were enrolled, with 42 (93%) completing follow-up. Mean WebApp engagement time was higher in the intervention group (~13 minutes) than in controls (~1 minute). Perceived spouses' SHS exposure decreased in the intervention group but increased in controls ($p_{interaction}$=0.026). The proportion reporting smoking only outdoors increased modestly in both groups (intervention: 82.6% to 90.5%; control: 81% to 85%; $p_{interaction}$=0.72).

Conclusions: *First Breath* was feasible among expectant fathers and showed preliminary effectiveness in reducing SHS exposure. Larger RCTs are warranted to evaluate its impact on prenatal SHS reduction.

Trial Registration: This study was registered at ClinicalTrials.gov (Identifier: NCT07003282). The initial release was on May 18, 2025, followed by the last release on September 8, 2025. The record was last updated on February 26, 2026.

Introduction

SHS exposure remains a significant concern among pregnant women. More than a third (38%) of non-smoking Israeli Jewish pregnant women were exposed to SHS in a biomonitoring study using urine cotinine.[1] Given the well-documented short- and long-term adverse effects of SHS exposure on maternal and fetal health,[2-4] promoting the reduction of SHS exposure during pregnancy represents a critical public health priority.

Implementing a complete smoke-free home (SFH), defined as allowing smoking only at least 10 meters away from the home, may be a promising approach to reduce prenatal SHS exposure. SFH rules were found to significantly reduce SHS exposure among children and adolescents.[5,6] SFH rules may also support reduced cigarette consumption and quit attempts.[7,8]

Interventions aimed at reducing prenatal SHS exposure have predominantly relied on written informational materials, educational sessions, and reminder-based approaches with limited use of digital tools, that may offer lower costs and reduce human resource demands.[9,10] Most existing interventions primarily target pregnant women, positioning them either as responsible for protecting themselves or as agents of change in their partners' smoking behaviours.[9,11,12] However, many pregnant women are reluctant to ask their spouses not to smoke at home, particularly in traditional households where men often dominate decision-making.[13-15]

Expectant fathers often report a strong sense of responsibility and concern for the health and well-being of both the pregnant woman and the fetus, while simultaneously lacking sufficient knowledge about SHS exposure harms and effective strategies for reducing household SHS. [15,16] Interventions that engage both spouses—while preserving men's autonomy and sense of self-determination regarding household smoking rules—may offer a promising strategy.[17]

Recent research has also suggested the use of nicotine replacement therapy (NRT) within the home as a strategy to reduce SHS exposure .[18] NRT may offer a practical harm-reduction alternative for individuals who are not ready to quit but aim to reduce SHS exposure within the household. Emerging evidence suggests that NRT is perceived as acceptable for temporary abstinence.[19,20] However, to the best of our knowledge, this approach has not been tested among expectant fathers.

First Breath is a digital, theory- and evidence-based, behavioral intervention designed to reduce prenatal SHS exposure. It involves both pregnant non-smoking women and expectant fathers who smoke and incorporates a gradual

approach to reducing SHS exposure in the home, including the use of NRT to support temporary abstinence, while increasing self-efficacy and motivation to implement a complete SFH. In a prior validation study among health professionals and potential end-users, *First Breath* was perceived as innovative, offering a stepwise and realistic approach to reducing SHS exposure and well-tailored to pregnant women and expectant fathers (Rodnay et al, unpublished observations).

As no previous study has assessed the feasibility of the *First Breath* intervention, a small-scale pilot study was warranted to determine whether the intervention "can be done, should we proceed with it, and if so, how".[21] Pilot studies can also identify potential problems in research design, sampling methods, and data collection, thereby informing the design and implementation of a subsequent full-scale trial.[22]

The primary aim of this pilot randomized controlled trial (RCT) was to assess the recruitment rate and acceptability of the components of *First Breath* targeting expectant fathers. Secondary aims were to: (1) evaluate the preliminary effectiveness of the intervention in promoting partial or complete SFH adoption; reducing SHS exposure; increasing knowledge and positively influencing attitudes toward SFH implementation; and (2) examine changes in participants' smoking behaviors, including smoking reduction and cessation, as well as the use of NRT to support temporary abstinence in the home.

Methods

Study design, setting and participants

A pilot feasibility RCT was conducted. The study was conducted in Israel in a community-based setting. Participants were recruited through social media, and the intervention was delivered remotely via a web-based application. The study was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines, including the extension for randomized pilot and feasibility trials.[23]

Originally, we planned a pilot clustered RCT in eight Women Health Centers, recruiting 10 expectant fathers from each center while they accompanied their pregnant spouse for prenatal visits (n=80 in total). Due to technical and budget constraints, recruitment was shifted to social media; however, the originally planned sample size was maintained.

No formal power calculation was performed, as recommended for feasibility pilot studies, where the aim is to estimate design parameters with adequate precision rather than to test effectiveness.[24,25] The original target of 80

participants (40 per arm) was retained after the change from cluster to individual randomization for three reasons. First, the feasibility parameters to be estimated, recruitment rate, follow-up rate, engagement, intervention completion, and re-entry, were unchanged, and the required precision for these estimates does not depend on the unit of allocation. Second, individual randomization removes the design effect inherent in the original plan of eight clusters of ten participants; assuming an intracluster correlation of 0.02-0.05, the clustered design would have yielded an effective sample size of approximately 55-68. Retaining n=80 therefore preserved, and slightly increased, the precision anticipated in the original protocol. Third, a sample of this size was intended to permit exploratory multivariable analysis of the preliminary effectiveness outcomes, allowing group × time models to be adjusted for a small number of prespecified covariates while keeping approximately 10-15 observations per estimated parameter for continuous outcomes and at least 10 events per variable for binary outcomes.[26,27] A sample of 40 per arm also exceeds published benchmarks for external pilot trials, including the median of 30 per arm observed in UK pilot trials[25] and the 35 per arm recommended for estimating a standard deviation, or 60-100 in total for estimating an event rate.[28]

Inclusion criteria included a) male; b) aged ≥18; c) smoking at least one combustible cigarette per day (dual users of combustible and electronic cigarettes were eligible); d) ability to understand Hebrew at a reasonable level; e) living with a pregnant spouse at <25 weeks' gestation.

Exclusion criteria included a) currently engaged in any smoking cessation program; b) high-risk pregnancy; c) pregnant spouse who currently smoked; d) no internet access at home.

Procedure

Recruitment

Participants were recruited via online ads posted on social media (Facebook and Instagram), with an option to leave their details through a secure form. They were contacted by a research assistant (RA), checked for eligibility, and if eligible, received a full explanation of the study. Those who were interested were invited to an online meeting where they provided informed consent and were randomized to either the intervention or control group.

Randomization and blinding

Participants were allocated 1:1 using the random allocation rule, equivalent to a single permuted block of 80. An allocation list containing exactly 40 intervention and 40 control assignments was created in Excel, assigned random numbers

using the RAND function, and sorted to produce a random order. The list was generated in advance by a team member not involved in recruitment and was not accessible to the RAs, who assigned participants consecutively in order of enrollment. As recruitment stopped before the planned 80 participants were reached, the fixed balance of the list was not realised; the achieved allocation was n= 23 intervention and n=22 control.

Participants were not informed of their group allocation. However, they received different digital content according to their assigned group. Research assistants were aware of group allocation because this information was required for follow-up procedures.

Intervention and Control Groups

Intervention group – Participants were given access to the *First Breath* WebApp. The intervention included five principal components: 1) a questionnaire on their perception of their spouse's SHS exposure, smoking habits at home and strategies used to reduce their spouse' SHS exposure; 2) an "SHS exposure score" (0-100) generated from the questionnaire and providing visual feedback on their spouse's SHS exposure level; 3) knowledge, practical tips and motivational tools to reduce SHS exposure (including videos, audio clips, small "bites" of information, an interactive exposure game, and a motivational letter from their unborn baby); 4) goal setting and action planning (allowing for a personalized action plan, selecting a goal ranging from "I will not change my home smoking rules, but I will do my best to minimize my spouses' SHS exposure" to "smoking is allowed only far from home" and a choice of various strategies such as "washing hands after each cigarette"); and 5) reminders sent two to three times a week during the 12-week follow-up period. The intervention is described in detail elsewhere (Rodnay et al., unpublished observations).

Control group – Participants were given access to a WebApp containing general information about prenatal SHS exposure harms and practical tools to reduce SHS exposure. Data were based on the Israel Cancer Association website (https://www.cancer.org.il/articles/5658/).

Supplementary file 1 presents the study timeline for both groups.

Data collection

Feasibility data was recorded by the RAs. Data regarding user engagement was extracted from reports generated via the WordPress platform. The questionnaires were developed specifically for this study and administered in Hebrew. English translations are provided in Supplementary Files 2a and 2b. Participants were

reimbursed for their time and effort after completing the questionnaires at baseline (100NIS, ~US$35) and 12-week follow-up (150NIS, ~US$50).

Primary outcome

As this was a feasibility pilot study the primary outcome was recruitment, [29] defined as the proportion of individuals responding to the advertisement who provided informed consent.

Secondary outcomes

Additional secondary feasibility outcomes included duration of recruitment, follow-up rate, engagement time with the WebApp (page-open time and repeated visits), intervention completion and WebApp re-entry rate.

At the 12-week follow-up only, acceptability of the WebApp was assessed using four study-specific items addressing satisfaction, ease of use, perceived reliability, and usability of the content, domains commonly included in evaluations of mHealth application usability.[30] Responses were rated on a four-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree).

Secondary effectiveness outcomes included: self-reported complete SFH; smoking allowed only outdoors (including near the home, e.g., on the balcony); smoking allowed only outside the car; changes in home smoking rules; NRT use at home; changes in perceived spouses' SHS exposure; smoking cessation; changes in the mean number of cigarettes smoked per day; and changes in knowledge and attitudes regarding prenatal SHS and SFH. A detailed definition of each outcome is presented in Supplementary file 3.

Additional covariates measured

Sociodemographic and other characteristics including age, marital status, number of children, religion and religiosity level, education, employment status, and spouse's pregnancy week. Other characteristics included intention and self-efficacy to reduce their spouses' SHS exposure (both measured on a Likert scale ranging from 1 (lowest) to 10 (highest), digital health literacy and intrahousehold male-led decision-making. Digital health literacy was measured using the HLS19-DIGI instrument, which was validated in Hebrew.[31] This included eight items, "How easy or difficult is it for you to…", rated on a five-point Likert scale from 1 (very easy) to 5 (very difficult), yielding a composite score (low (1.0–2.0), moderate (2.01–3.99), and high (4.0–5.0)). The categories were reversed and the score was dichotomized into low or moderate vs high. Intrahousehold male-led

decision-making was measured using three questions regarding whether they or their spouse typically makes decisions regarding their children's education, family outings, and major household purchases (adapted from Pandey et al.).[32] Responses were collapsed into a dichotomous variable indicating a "traditional family structure" if the participant responded "I mainly decide" to at least one item.

Home structure was categorized as a private home, an apartment building with a balcony and/or a yard, or an apartment building without a balcony/yard.

Smoking-related characteristics included the level of nicotine dependence (assessed using the Heaviness of Smoking Index (HSI) [source: NIH, https://datashare.nida.nih.gov/instrument/heaviness-of-smoking-index], categorized into low vs moderate or high dependence), number of previous quit attempts, past 30-day use of other tobacco or nicotine products, and past 30-day use of alcohol and illicit drugs.

Statistical analysis

All randomized participants were included in the analysis of feasibility outcomes. Secondary effectiveness outcomes were analyzed on an intention-to-treat basis, including all randomized participants with at least one available observation; the mixed effects repeated measures models used all available data under a missing-at-random assumption, without imputation. Descriptive comparisons at each time point were based on available cases, and the denominator is reported for every estimate. No per-protocol analysis was conducted, given the small sample.

Descriptive statistics were calculated for primary and secondary outcomes and presented as proportions with 95% confidence intervals (CIs). For the secondary effectiveness outcomes, comparisons between the intervention and control groups were conducted using Fisher's exact test for dichotomous variables, Chi-square tests for categorical variables, independent-samples *t* tests for normally distributed continuous variables, and Mann–Whitney *U* tests for continuous variables with non-normal distributions.

Changes over time in continuous outcomes (perceived spouse's SHS exposure, mean number of cigarettes smoked per day, knowledge and attitude scores) were analysed using a linear mixed model with an identity link. Fixed effects were group, time (baseline, 12 weeks), and the group × time interaction; a random intercept for participant accounted for the within-person correlation between the two assessments. With only two time points a random slope is not identifiable, so the model is equivalent to a compound symmetry covariance structure for the repeated measures. Parameters were estimated by restricted maximum likelihood, and denominator degrees of freedom were obtained using

the Kenward-Roger approximation to avoid anti-conservative inference in this small sample. Adjusted mean differences in change scores are reported with 95% CIs.
Missing outcome data were handled using linear mixed-effects models, which allow for the inclusion of participants with incomplete repeated measurements under the missing-at-random (MAR) assumption. All available outcome measurements were included in the analyses without imputation of missing values.

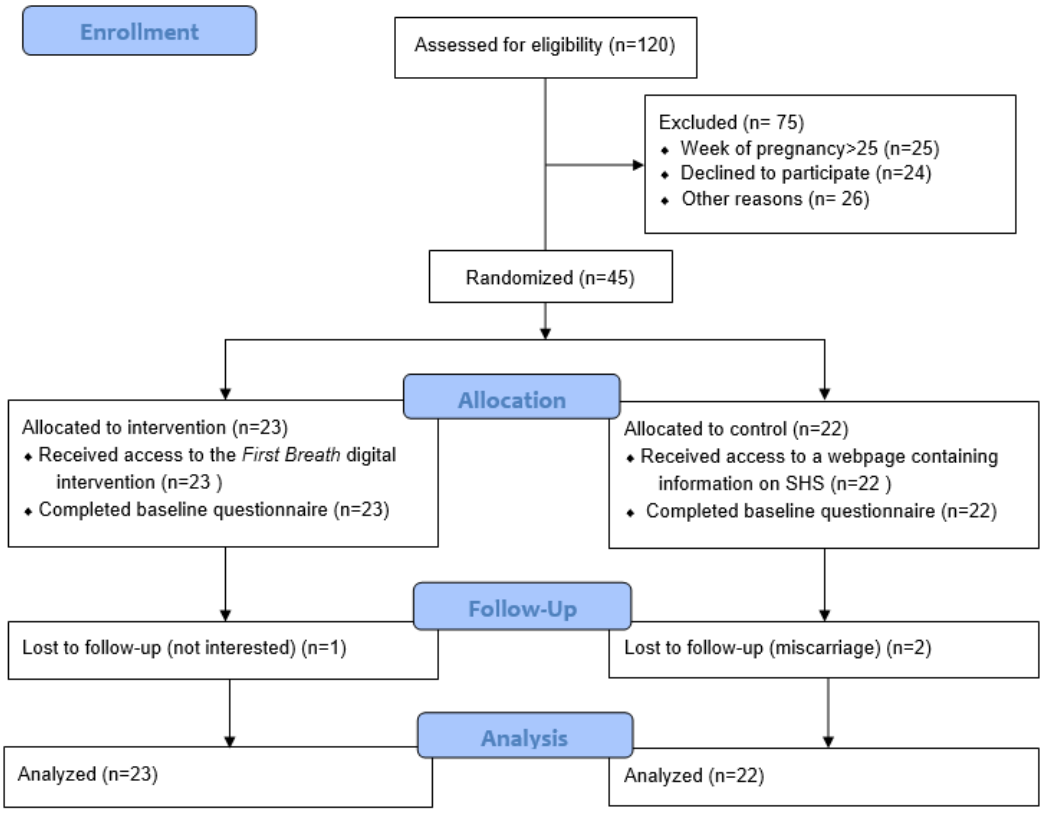
Results

Feasibility outcomes

A total of 120 responded to the advertisements. Of these, 27 were not interested in participating (22.5%), and 44 (36.7%) were ineligible. Reasons for ineligibility included the spouse being more than 25 weeks pregnant (n=25), not pregnant (n=7), smoking less than one regular cigarette per day (n=8), high risk pregnancy (n=2), and not speaking Hebrew (n=2). For four individuals the reason for non-enrollment was not documented. Therefore, 45 men (recruitment rate: 45/120 = 37.5%; Wilson 95% CI 29.4%-46.4%) were enrolled and randomized to the study groups with 23 allocated to the intervention group and 22 to the control group. Although the target sample size was 80 participants, recruitment was concluded after 45 participants due to time and budget constraints.

Participant recruitment lasted 118 days (from 30 March to 25 July 2025) corresponding to an average of 2.6 days per participant recruited. Almost all participants (n=42/45 = 93.3%; Wilson 95% CI 82.1%-97.7%), completed the follow-up questionnaire - 22 in the intervention group and 20 in the control group (Figure 1).

Figure 1: Participants flow diagram



Sociodemographic and other characteristics of the study sample, overall and by group, are presented in Tables 1 and 2.

Mean participant age was 31.8 ± 5 years. Most were married (82%, n=37), employed (98%, n=44), and had low/moderate digital health literacy (67%, n=30); 40% had one or more children (n=18). Approximately half lived in apartments with a balcony or a yard (53%, n=24). Most participants reported a low nicotine dependence level (73%, n=33) with a mean cigarette consumption of 12.2 ± 9.5 cigarettes/day; 60% (n=27) had previously attempted to quit. Smoking was generally not allowed indoors but was permitted in adjacent areas such as on a balcony (77.8%, n=35). More than half reported that smoking was allowed in the car (53.3%, n=24). Most reported smoking near their pregnant spouse (67%, n=30), although mean perceived spouses' SHS exposure was low (4.8±2.4). Mean motivation (9.1±1.5) and self-efficacy (8.0±2.1) to reduce SHS exposure were high. Baseline characteristics were generally similar between groups, although past 30-day illicit drug use was reported by four participants in the control group and none in the intervention group.

Table 1: Sociodemographic and other characteristics of the study sample, overall and by arm (n=45).

Variable	Overall (N= 45)	Intervention (N=23)	Control (N=22)
Age (mean [SD])	31.8 [4.98]	31.6 [5.31]	32.0 [4.71]
Married	37 (82.2%)	20 (87.0%)	17 (77.3%)
Has children	18 (40.0%)	10 (43.5%)	8 (36.4%)
Born in Israel	41 (91.1%)	19 (82.6%)	22 (100%)
Academic education	18 (40.0%)	9 (39.1%)	9 (40.9%)
Currently employed	44 (97.8%)	22 (95.7%)	22 (100%)
Non-religious	25 (55.6%)	11 (47.8%)	14 (63.6%)
Spouse in 1st trimester of pregnancy	21 (46.7%)	11 (47.8%)	10 (45.5%)
Intrahousehold male-led decision-making[1]	8 (17.8%)	5 (21.7%)	3 (13.6%)
Low/moderate digital health literacy[2]	30 (66.7%)	18 (78.3%)	12 (54.5%)

Missing: Academic education n=1

[1]Intrahousehold male-led decision-making - measured using three questions regarding whether they or their spouse typically makes decisions regarding their children's education, family outings, and major household purchases, recategorized to dichotomous variable indicating a "traditional family structure" if the participant responded "I mainly decide" to at least one item.

[2] Digital health literacy was assessed using the HLS19-DIGI instrument.[33] A composite score was calculated from eight items, each rated on a scale from 1 to 5 (from "very easy" to "very difficult"). The score was reversed and categorized as follows: low (1.00–2.00), moderate (2.01–3.99), and high (4.00–5.00).

Table 2: Home structure, smoking rules at home and in the car, smoking habits, perceived spouses' secondhand smoke (SHS) exposure, knowledge and attitudes regarding SHS and other characteristics of the study sample, overall and by arm (n=45).

Variable	Overall (N= 45)	Intervention (N=23)	Control (N=22)
Home structure			
Living in a private home	11 (24.4%)	5 (21.7%)	6 (27.3%)

Living in an apartment building with a balcony / yard	24 (53.3%)	14 (60.9%)	10 (45.5%)
Living in an apartment building without a balcony/yard	10 (22.2%)	4 (17.4%)	6 (27.3%)
Home smoking rules (n=44)			
Smoking is allowed indoors	8 (18.2%)	4 (17.4%)	4 (19.0%)
Smoking is allowed outdoors near the home	35 (79.5%)	19 (82.6%)	16 (76.2%)
Smoking is allowed only far from home	1 (2.2%)	0	1 (4.8%)
Car smoking rules (n=43)			
Smoking is allowed inside the car	24 (55.8%)	13 (59.1%)	11 (52.4%)
Smoking is allowed outside but near the car	13 (30.2%)	6 (27.3%)	7 (33.3%)
Smoking is allowed only far from the car	6 (14.0%)	3 (13.6%)	3 (14.3%)
Number of cigarettes per day (mean [SD])	12.2 [9.46]	10.4 [6.32]	14.0 [11.78]
Low nicotine dependance [1]	33 (73.3%)	18 (78.3%)	15 (68.2%)
NRT use	5 (11.1%)	2 (8.7%)	3 (13.6%)
Past smoking cessation attempts	27 (60.0%)	15 (65.2%)	12 (54.5%)
Other tobacco products use	17 (37.8%)	9 (39.1%)	8 (36.4%)
Alcohol consumption >5 times in the past 30 days	12 (26.7%)	6 (26.1%)	6 (27.3%)
Past 30-day Cannabis Use	13 (28.9%)	9 (39.1%)	4 (18.2%)
Past 30-day illicit drug use other than cannabis[2]	4 (8.9%)	0 (0.0%)	4 (18.2%)
Smoking near spouse			
Never\ Smoking only far from the pregnant spouse	15 (33.3%)	5 (21.7%)	10 (45.5%)
Additional household members who smoke	2 (4.4%)	2 (8.7%)	0 (0.0%)
Self-reported SHS exposure[3] (mean [SD])	4.78 [2.4]	5.1 [2.1]	4.5 [2.6]

Self-reported willingness to reduce SHS[3] (mean [SD]) (n=43)	9.1 [1.5]	9.2 [1.2]	9.0 [1.8]
Self-reported self-efficacy to reduce SHS[3] (mean [SD]) (n=42)	8.0 [2.1]	8.4 [1.5]	7.6 [2.5]
Knowledge score[4] (mean [SD])	59.2 [23.6]	58.70 [20.9]	59.9 [26.6]
Attitudes score[5] (mean [SD])	3.0 [0.5]	2.9 [0.6]	3.1 [0.4]

Abbreviations: SFH – Smoke-free Home, SHS- Secondhand Smoke, NRT – nicotine replacement therapy.

Missing: Home smoking rules n=1, Car smoking rules n=2, Willingness to reduce SHS n=2; Self-efficacy to reduce SHS n=3

[1]Dependence level, based on the Heaviness of Smoking Index. [34]

[2]Other substance use: Ecstasy, Cocaine, Yaba, and "party drugs" among others.

[3]All on scale of 1-10

[4]Knowledge was measured using 12 true/false/don't know statements, creating a composite score on a scale of 0-100.

[5]Mean composite attitude score was measured from 18 statements on a scale of 1- strongly disagree to 5-strongly agree.

Engagement

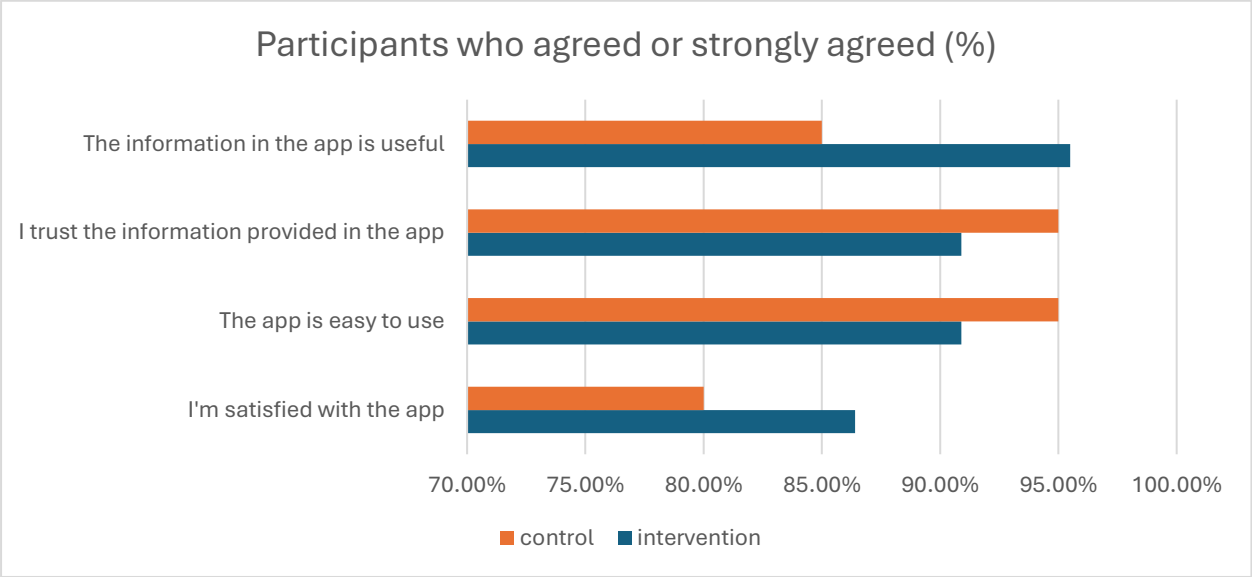
The intervention was delivered remotely through the First Breath web application, while control participants received access to a landing page. Mean engagement time was 13 minutes 33 seconds (range: 10 seconds–42 minutes) in the intervention group, compared with 1 minute 16 seconds (range: 10 seconds–3 minutes) in the control group. Five participants (22%) in the intervention group completed all intervention components and 14 (60.9%; Wilson 95% CI 40.8%-77.8%) re-entered the WebApp at least once. On average, participants in the intervention group accessed 27% of the content in the "Tools" section, 29% in the "Practical Tips" section, and 21% in the "Motivation" section. Few participants viewed the videos (22%, n=5) or listened to the audio clips (13%, n=3).

Among the selectable goals, six participants chose "I will not change my home smoking rules, but I will do my best to minimize my spouses' SHS exposure," five chose "smoking is allowed only far from home" (i.e., a complete SFH) and two chose "Smoking is allowed only outside the home in nearby areas". Nine participants did not selected a goal. The most frequently selected strategies were "washing the face and hands after each cigarette" and "when outdoors, moving at least 15 steps away from my spouse while smoking".

Acceptability

Acceptability ratings were high, with 80%–96% of participants in both groups agreeing or strongly agreeing that the WebApp was useful, trustworthy, and easy to use, and that they were satisfied with it. There were no significant differences in acceptability ratings between the intervention and control groups (Figure 2)

Figure 2: Acceptability of the WebApp by study group (n=42)



Secondary effectiveness outcomes (Table 3)

Self- report of home and car smoking rules and NRT use

At the 12-week follow-up, two participants (9.5%) in the intervention group and one participant (5.0%) in the control group reported a complete home smoking ban (p = 1.00). Furthermore, 19 participants (90.5%) in the intervention group and 17 (85.0%) in the control group reported that smoking is allowed only outdoors, including in adjacent places such as balcony or yard (p=0.67) (Supplementary File 4a).

In the intervention group, 4 participants (19.0%) reported a positive change in home smoking rules, while 17 (81.0%) reported no change. In the control group, 3 participants (15.8%) reported a positive change, while 16 (84.2%) reported no or negative change. Data on changes in home smoking rules were missing for 1 participant in each group.

Regarding car smoking rules, 17 participants from the intervention group (89.5%) and 14 participants (70%) in the control group reported that smoking is not allowed inside the car (p=0.24). Data on car smoking rules were missing for 3 participants (all in the intervention group).

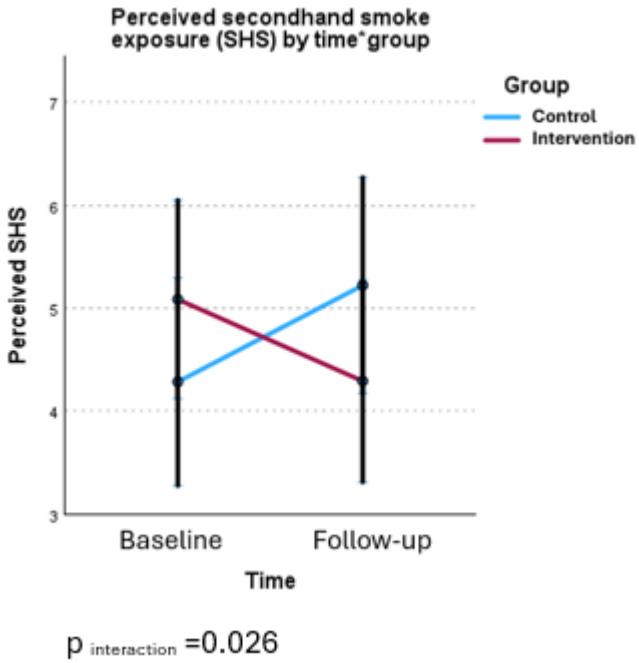
No significant time-by-group interaction was found for either smoking allowed only outdoors (included on a balcony and/or in a yard) ($p_{interaction}$=0.719) or smoking not allowed inside the car ($p_{interaction}$=0.137).

Few participants reported using NRT at home at follow-up: 1 participant (5.3%) in the intervention group and 3 participants (15.8%) in the control group (p = 0.60). Data on NRT use at home were missing for 4 participants: 3 in the intervention group and 1 in the control group.

Perceived SHS exposure

Mean perceived spouse's SHS exposure decreased in the intervention group from baseline to the 12-week follow up (from 5.1±2.2 to 4.3±2.1, n=22, p=0.18), whereas it increased in the control group (from 4.5±2.6 to 5.4±2.5,n=20, p=0.14). A significant time-by-group interaction was observed ($p_{interaction}$=0.026), after adjustment for baseline illicit drug use (Figure 3).

Figure 3: Change in perceived spouse SHS exposure over time by study group



Mean cigarette consumption (number of cigarettes per day)

Mean cigarette consumption decreased in the intervention group from 10.4±6.3 cigarettes/day at baseline to 8.8±5.8 at follow-up (n=22, p=0.01), and from 14.0±11.8 to 13.2±11.8 in the control group (n=19, p=0.10). There was no evidence of a differential change between groups ($p_{interaction}$=0.995) (Supplementary File 3b). Two participants in each group reported smoking cessation (p=1.00).

Changes in knowledge and attitudes scores

Mean knowledge score increased significantly in the intervention group (from 58.7± 20.9 to 74.6±21.6, n=22, p=0.002) and in the control group (from 59.9±26.6 to 74.9±21.3, n=20, p=0.003) with no significant time-by-group interaction ($p_{interaction}$=0.99). Mean attitude score increased from 2.9±0.6 to 3.2±0.5 in the intervention group (n=22, p=0.02) and from 3.1±0.4 to 3.3± 0.4 in the control group (n=20, p=0.12), with no significant time-by-group interaction ($p_{interaction}$ =0.53) (Supplementary Files 3c and 3d). Changes in the secondary effectiveness outcomes in both groups are presented in Table 3.

Table 3: Changes in the secondary effectiveness outcomes in the intervention and control groups over time.

Outcome variable	**Group**	**Baseline (n=45)** **n (%)**	**Follow-up (n=42)** **n (%)**	**p time[a]**	**p time*group[c]**
Self-report that smoking is allowed only outside the home	Intervention	19 (82.6%)	19 (90.5%)	0.500	0.719
	Control	17 (81.0%)	17 (85.0%)	1.000	
	p groups[b]	1.0	0.67		
Self-report that smoking is allowed only outside the car	Intervention	9 (39.1%)	17 (73.9%)	0.002	0.137
	Control	10 (45.5%)	14 (63.6%)	0.219	
	p groups[b]	0.37	0.24		
Self-reported perceived secondhand smoke exposure (mean± SD)[1]	Intervention	5.1±2.2	4.3 ±2.1	0.18	0.026
	Control	4.5 ±2.6	5.4 ±2.5	0.14	
	p groups[b]	0.31	0.18		
Number of cigarettes per day (mean± SD)	Intervention	10.4 ±6.32	8.80 ±5.8	0.01	0.995
	Control	14.0 ±11.78	13.22 ±11.8	0.1	
	p groups[b]	0.21	0.15		
Knowledge score (mean± SD)[2]	Intervention	58.70 ±20.9	74.6 ±21.6	0.002	0.993
	Control	59.9 ±26.6	74.9 ±21.3	0.003	
	p groups[b]	0.78	0.99		
Attitude score (mean ±SD)[3]	Intervention	2.9 ±0.6	3.2 ±0.5	0.02	0.527
	Control	3.1 ±0.4	3.3 ±0.40	0.12	
	p groups[b]	0.35	0.99		

[a]p-value for changes over time, from baseline to the 12-week follow-up, in each group; [b]p-value for between-groups differences (intervention vs control group) in each time point. [c]p-value for interaction between the trend of change over time and the group effect; after adjustment of past 30-days illicit drug use.

[11]Scale of 1-10. [2] Knowledge was measured using 12 true/false/don't know statements, creating a composite score on a scale of 1-100. [3]Mean composite attitude score from 18 statements measured on a scale of 1 to 5 (1- strongly disagree to 5 – strongly agree).

Discussion

This pilot RCT yielded encouraging findings regarding the feasibility and acceptability of the *First Breath* intervention. Although social media recruitment was challenging, it was nevertheless achievable. Follow-up retention was high in both groups, and participants reported high levels of satisfaction. Mean WebApp engagement was higher in the intervention group than in controls. Improvements in several secondary effectiveness outcomes were observed. However, improvements in home and car smoking rules, smoking behaviors, knowledge, and attitudes occurred in both groups. Notably, perceived spouses' SHS exposure decreased in the intervention group and increased in the control group, with a significant time-by-group interaction.

Knowledge regarding the health consequences of prenatal SHS exposure and strategies for SFH implementation was low at baseline for both groups, consistent with a previous qualitative study among expectant Israeli fathers who smoke.[16] In addition, awareness and uptake of NRT as a means to support temporary abstinence at home were limited. Although *First Breath* promoted NRT use at home as an aid to implementing an SFH, and prior literature suggested this approach may be feasible and acceptable among fathers,[20,35] only a small proportion of participants reported NRT use at follow-up. This is in agreement with previous findings from our study validating the *First breath* WebApp where end-users expressed negative attitudes toward using NRT for temporary abstinence (Guri-Scherman 2026, manuscript submitted for publication). These findings highlight the need for strategies to increase awareness of the health consequences of SHS exposure during pregnancy, promote SFHs, and improve understanding of the potential role of NRT in supporting temporary abstinence at home.

Previous studies suggest that while SFH rules are relatively common, smoke-free car rules are less consistently adopted, despite the potentially higher intensity of SHS exposure in cars.[36,37] Consistent with this pattern, most participants in the present study reported at baseline that smoking was allowed in the family car. Smoke-free car rules increased at follow-up in both groups, with a larger increase than that observed for SFH rules. This may partly reflect their lower prevalence at baseline, which provided greater scope for improvement, and is consistent with previous studies demonstrating substantial potential for change in car smoking restrictions and high parental support for prohibiting smoking in cars carrying children.[38] However, as the perceived feasibility or severity of smoking in cars was not assessed in the present study, the mechanisms underlying the greater observed change remain uncertain. Nevertheless, these findings underscore the importance of addressing cars as a distinct and high-risk

environment alongside efforts to promote comprehensive smoke-free policies. Legislation banning smoking in family cars, as implemented in several other countries, may further contribute to protect pregnant women from SHS exposure.[39,40]

Findings across almost all effectiveness outcomes indicate improvements in both groups. These results raise the question of whether the *First Breath* digital program provides added value beyond readily available online information about SHS. The improvements observed in both groups may be attributable to several factors. First, a participation bias cannot be ruled out, whereby involvement in the study itself may have increased participants' awareness and motivation to reduce SHS. Second, pregnancy is widely recognized as a natural trigger for health behavior change among expectant fathers, including smoking-related behaviors.[16,41] Further studies with larger sample sizes are needed to evaluate the differential effect of *First Breath* compared with an available online information on the implementation of SFH rules during pregnancy, and to assess whether its cost-effectiveness. Furthermore, incorporating user incentives may represent a promising strategy for improving engagement and, in turn, enhancing the effectiveness of the WebApp, as incentives such as rewards and reinforcement mechanisms have been shown to promote sustained engagement with digital health interventions. [42]Incorporating longitudinal tracking of progress - particularly the adoption and maintenance of strategies to reduce SHS exposure at home, may also encourage repeated WebApp use by allowing users to monitor improvements over time and reinforcing behavior change.[43]

Challenges in recruitment may partly reflect that it might be more difficult to reach male participants in health behavior change interventions, as they tend to be less engaged in health promotion programs.[44,45] In the context of pregnancy, men are also less exposed to relevant health information, as prenatal services are primarily oriented toward pregnant women.[46]

This study also identified challenges related to participant engagement, intervention completion, and sustained use of the *First Breath* WebApp. Low to moderate levels of digital health literacy were observed among most participants in the intervention group (78.3%). Digital health literacy may be relevant to engagement with digital interventions; however, the relationship between digital health literacy and engagement was not directly assessed in the present study, and therefore no conclusions regarding such an association can be drawn from these findings. Given previous evidence linking digital health literacy with health-related behaviors,[47] its potential role in engagement with digital interventions should be explored in future studies. Strategies to facilitate navigation and

engagement, such as brief instructional materials, videos, or eLearning modules, may also warrant consideration.[48]

Strength and limitations

To our knowledge, this pilot study is the first to evaluate the feasibility and acceptability of a digital intervention aimed at reducing SHS exposure among Israeli expectant fathers who smoke. *First Breath* adopts an innovative approach by engaging men directly—rather than indirectly through their pregnant partners—and by emphasizing SHS reduction rather than smoking cessation, through a gradual, stepwise modification of household smoking rules toward the ultimate goal of establishing a SFH. In addition, the intervention emphasizes user autonomy and choice in determining how to modify smoking practices at home, while fostering self-efficacy and strengthening motivation for behavior change. Notably, participants were successfully recruited from different geographic regions.

This study has several limitations. The sample size was relatively small, and some population minorities in Israel—including Arab populations, Ultra-Orthodox Jews, and new immigrants—were not represented, limiting generalizability of the findings. In addition, participants were mainly men with low levels of nicotine dependence who smoked outside but nearby the home (e.g., on balconies), resulting in relatively low baseline spouses' SHS exposure, which might make further changes, such as smoking only at a 10-meter distance from the home, harder to achieve.

In addition, reliance on self-reported estimation of spouses' SHS exposure rather than objective biomarkers such as urinary cotinine may introduce reporting bias. Furthermore, the relatively short follow-up period limits assessment of sustained changes in home and car smoking rules.

Conclusion

Findings from this pilot study indicate that the *First Breath* digital behavioral intervention is feasible and acceptable among expectant fathers who smoke. Improvements in home and car smoking rules, smoking behavior, knowledge, and attitudes were observed in both study groups, while *First Breath* showed preliminary evidence of an effect on perceived spouses' SHS exposure. These findings support further refinement of the *First Breath* WebApp intervention and evaluation in a larger, adequately powered RCT. Such efforts may ultimately contribute to more effective engagement of expectant fathers in reducing prenatal SHS exposure and creating SFHs.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. The study was approved by the Hebrew University - Hadassah Faculty of Medicine Ethics Committee (Approval No. 09032025).

Informed consent was obtained from all study participants prior to data collection. Each participant received a detailed explanation of the study, including its purpose and procedures, and was given sufficient time to ask questions. Participants were then directed to a digital informed consent form hosted on the secure REDCap platform, which provided information about the study. Participants were asked to click an "Approve" button to indicate their consent, with clicking this button constituting informed consent to participate in the study.

Consent for publication

Not applicable.

Availability of data and materials

The individual participant data, data dictionary, and statistical code are not available for sharing due to privacy and ethical considerations.

Trial registration

This study was registered at ClinicalTrials.gov (Identifier: NCT07003282). The initial release was on May 18, 2025, followed by the last release on September 8, 2025. The record was last updated on February 26, 2026.

Competing interests

YBZ had received fees for lectures from Pfizer, Novartis NCH and GSK Consumer Health (distributors of pharmacotherapy in Israel) in the past (2012 to July 2019).

YBZ receives a small monthly fee to provide clinical consultations in an online smoking cessation forum

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Authors' contribution

ALG contributed to the conceptualization, methodology, investigation, resources, and writing of the original draft. MR contributed to the

conceptualization, investigation, resources, and review and editing of the manuscript. YN contributed to validation, funding acquisition, supervision, and review and editing of the manuscript. WA contributed to data curation and review and editing of the manuscript. YBZ contributed to the conceptualization, investigation, data curation, funding acquisition, supervision, and review and editing of the manuscript. All authors reviewed and approved the final manuscript.

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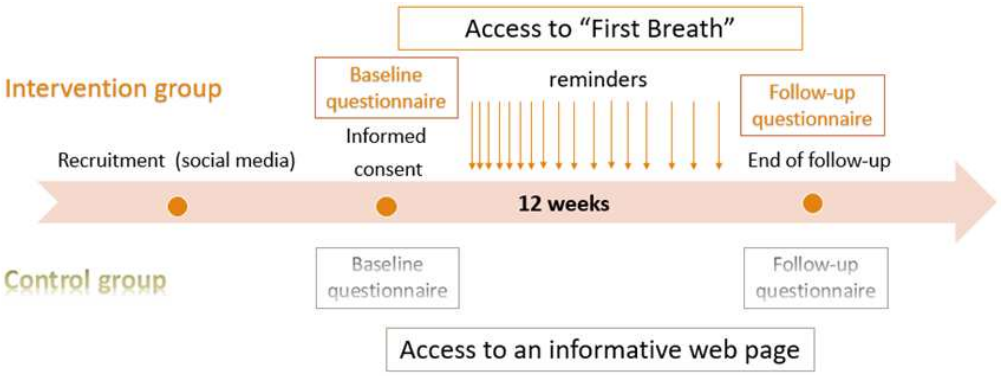
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Supplementary Files

Supplementary File 1: Study timeline and intervention procedures for the intervention and control groups



Supplementary file 2a: Baseline questionnaire (English version)

Part A: Sociodemographic Characteristics

1. What is your year of birth? ____

2. What is your marital status?

1. Married
2. Living with my partner but not married
3. Other: _____
4. Prefer not to answer

3. Do you have children?

1. Yes
2. No
3. Prefer not to answer

4. If yes, how many children do you have? ____

5. How old is your youngest child?

_____ years

6. In which country were you born?

1. Israel
2. Other: _____
3. Don't know
4. Prefer not to answer

7. What is your highest level of education?

1. 12 years of schooling or less (without a matriculation certificate)
2. Completed secondary education (12 years of schooling) with a matriculation certificate
3. Post-secondary non-academic education (e.g., practical engineering studies, advanced religious studies)
4. Bachelor's degree
5. Master's degree

6. PhD degree or higher
7. Don't know
8. Prefer not to answer

8. What is your current employment status?

1. Not employed
2. Employed part-time
3. Employed full-time
4. Prefer not to answer

9. What is your religion?

1. Jewish
2. Muslim
3. Christian
4. Druze
5. Other: _____
6. Don't know
7. Prefer not to answer

10. How would you describe your level of religiosity?

1. Very religious
2. Religious
3. Not very religious
4. Not religious
5. Don't know
6. Prefer not to answer

11. What type of residence do you live in?

1. Detached house (ground-level residence)
2. Apartment in a low-rise building (up to and including three floors)
3. Apartment in a multi-story building (four or more floors)
4. Other: _____

5. Don't know
6. Prefer not to answer

12. Does your home have any of the following?

a. A balcony

- Yes
- No
- Prefer not to answer

b. A garden or yard adjacent to the residence

- Yes
- No
- Prefer not to answer

c. A utility room with a window

- Yes
- No
- Prefer not to answer

d. An elevator (for apartment residents)

- Yes
- No
- Not applicable
- Prefer not to answer

13. How many people, including yourself, permanently reside in your household? __

14. Which trimester of pregnancy is your partner currently in?

1. First trimester (weeks 1–13 of pregnancy)
2. Second trimester (weeks 14–27 of pregnancy)
3. Third trimester (weeks 28–40 of pregnancy)
4. Don't know
5. Prefer not to answer

Part B: Smoking Habits and Substance Use

15. During the past week, how many conventional cigarettes (excluding electronic cigarettes) did you smoke per day, on average? _____

16. On a typical day, how long after waking up in the morning do you smoke your first cigarette?

1. Within 5 minutes
2. 6–30 minutes
3. 31–60 minutes
4. More than 60 minutes
5. Don't know
6. Prefer not to answer

17. During the past 30 days, have you used any of the following tobacco or nicotine products?

For each item, select: Yes / No / Prefer not to answer.

1. Electronic cigarettes, vaping products, or other electronic nicotine delivery devices (excluding heated tobacco products such as IQOS)
2. Heated tobacco products (e.g., IQOS)
3. Waterpipe (hookah)
4. Cigars or cigarillos
5. Tobacco pipes
6. Smokeless tobacco
7. Other: _____

18. During the past 30 days, how many times did you consume alcoholic beverages (e.g., wine, beer), excluding consumption for religious purposes?

1. Never
2. 1–2 times
3. 3–5 times

4. 6–9 times
5. 10–19 times
6. 20–29 times
7. More than 30 times
8. Don't know
9. Prefer not to answer

19. During the past 30 days, how many times did you use cannabis/marijuana for non-medical purposes?

1. Never
2. 1–2 times
3. 3–5 times
4. 6–9 times
5. 10–19 times
6. 20–29 times
7. More than 30 times
8. Don't know
9. Prefer not to answer

20. If you reported using cannabis/marijuana during the past 30 days, did you use cannabis/marijuana mixed with tobacco?

1. Yes
2. No
3. Don't know
4. Prefer not to answer

21. During the past 30 days, how many times did you use other drugs (excluding cannabis/marijuana), such as ecstasy, cocaine, yaba, or synthetic recreational drugs (sometimes referred to as "kiosk drugs" in Israel)?

1. Never
2. 1–2 times
3. 3–5 times

4. 6–9 times
5. 10–19 times
6. 20–29 times
7. More than 30 times
8. Don't know
9. Prefer not to answer

22. What are the current rules regarding cigarette smoking in your home?

1. Smoking is allowed anywhere inside the home.
2. Smoking is allowed only in certain rooms, such as the utility room, living room, or study, but not in other rooms.
3. Smoking is allowed in only one designated room, such as the living room or utility room, and is prohibited in all other rooms.
4. Smoking is allowed only outside the home in adjacent areas, such as the balcony or yard. Smoking is not allowed anywhere inside the home.
5. Smoking is allowed only at a distance from the home. Smoking is not allowed on the balcony or in the yard near the home, and smokers must remain at least 15 steps (10 meters) away from any window or door.
6. Don't know
7. Prefer not to answer

23. What are the rules regarding smoking in the vehicle used for family transportation?

1. Smoking is allowed inside the vehicle when my partner is present, even when the windows are closed.
2. Smoking is allowed inside the vehicle when my partner is present, but only when the windows are open.
3. Smoking is allowed inside the vehicle only when my partner is not present.
4. Smoking is allowed only outside the vehicle, near the vehicle.
5. Smoking is allowed only outside the vehicle, at a distance of at least 15 steps (10 meters) from the vehicle.
6. We do not have a vehicle.

7. Don't know
8. Prefer not to answer

24. Do you smoke in the presence of your partner?

1. I never smoke in the presence of my partner.
2. I smoke in the presence of my partner but maintain a substantial distance from her (by moving to another room or remaining at least 15 steps [10 meters] away when outdoors).
3. I smoke in the presence of my partner but maintain only a short distance from her (less than 15 steps [10 meters]).
4. I smoke in the presence of my partner without moving away from her.
5. Don't know
6. Prefer not to answer

25. During the past 6 months, have any other people who smoke lived in your household?

1. Yes
2. No
3. Don't know
4. Prefer not to answer

26. If yes, did these individuals smoke in the presence of your partner inside the home?

1. They never smoked in the presence of my partner.
2. Yes, they smoked in the presence of my partner but maintained a substantial distance from her (by moving to another room or remaining at least 15 steps [10 meters] away when outdoors).
3. Yes, they smoked in the presence of my partner but maintained only a short distance from her (less than 15 steps [10 meters]).
4. Yes, they smoked in the presence of my partner without moving away from her.
5. Don't know
6. Prefer not to answer

27. During the past 12 months, have you stopped smoking for at least 24 hours?

1. Yes
2. No
3. Prefer not to answer

28. On a scale from 1 to 10, to what extent do you think your partner is exposed to your cigarette smoke?

(1 = Not exposed at all; 10 = Extremely exposed)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

29. On a scale from 1 to 10, how strong is your desire to reduce your partner's exposure to cigarette smoke at home?

(1 = No desire at all to reduce her exposure; 10 = Very strong desire to reduce her exposure)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

30. On a scale from 1 to 10, how confident are you in your ability to reduce your partner's exposure to cigarette smoke at home?

(1 = Not at all confident in my ability to reduce her exposure; 10 = Extremely confident in my ability to reduce her exposure)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

32. How often do you use nicotine replacement products (such as nicotine gum or nicotine lozenges) to reduce your partner's exposure to cigarette smoke (at home, in the vehicle, or when you are near her)?

Nicotine replacement products are over-the-counter medications that provide nicotine without smoking, helping reduce the urge to smoke.

1. Always
2. Often
3. Sometimes
4. Rarely
5. Never
6. Don't know
7. Prefer not to answer

Part C: Digital Health Literacy

33. When searching for health-related information on the internet, how easy or difficult is it for you to perform the following tasks?

For each statement, select one response:

Very easy / Easy / Neither easy nor difficult / Difficult / Very difficult / Prefer not to answer

	Item Task
a.	Assess whether the information is reliable.
b.	Assess whether the information has a commercial purpose.
c.	Understand the information.
d.	Use the information to address a health-related problem.
e.	Assess whether the information is relevant to you.
f.	Find the exact information you are looking for.
g.	Browse several different websites to determine whether they provide similar information on the same topic.
h.	Use appropriate keywords and/or perform a precise search to find the information you are looking for.

Part D: Knowledge of the Health Risks of Secondhand Smoke Exposure and Smoke-Free Homes

34. Below are several statements. For each statement, please indicate whether you believe it is true or false.

These statements refer to situations in which a pregnant woman does not smoke, but her partner does.

Response options for each statement: **True / False / Don't know / Prefer not to answer**

Health Risks of Secondhand Smoke Exposure During Pregnancy

1. Exposure to secondhand smoke for less than 10 minutes once a week will not harm the unborn baby.

2. Exposure to secondhand smoke during pregnancy may harm the pregnant woman's health.
3. Exposure to secondhand smoke during pregnancy may impair the unborn baby's brain development.
4. Exposure to secondhand smoke is harmful only during the early stages of pregnancy (the first three months).
5. Exposure to secondhand smoke during pregnancy may cause preterm birth.
6. The baby is protected inside the womb, and cigarette smoke cannot reach the baby.
7. Exposure to secondhand smoke during pregnancy may cause miscarriage.
8. Exposure to secondhand smoke during pregnancy may result in the baby being born with a low birth weight.

Smoke-Free Homes

9. Moving just 2–3 steps away from a pregnant woman is sufficient to substantially reduce her exposure to secondhand smoke.
10. Opening a window is sufficient to substantially reduce exposure to secondhand smoke.
11. When I smoke on the balcony or in the garden while my partner is inside the home, she is not exposed to my cigarette smoke.
12. In a smoke-free home, nicotine gum or lozenges can be used instead of cigarettes when a smoker does not want to or cannot smoke, even if the smoker does not quit smoking entirely.

Part E: Attitudes Toward Establishing a Smoke-Free Home

35. Please indicate how strongly you agree or disagree with each of the following statements.

Response options for each statement: **Strongly disagree / Disagree / Neither agree nor disagree / Agree / Strongly agree / Prefer not to answer**

1. I know how to make my home smoke-free.
2. I know how and when to use nicotine replacement therapies (nicotine gum or lozenges) while I am at home.

3. I believe I am capable of making my home smoke-free.
4. I believe I am capable of using nicotine replacement therapies (nicotine gum or lozenges) when I am at home and unable to go outside.
5. I have the ability to refrain from smoking inside my home.
6. I am able to ask guests and visitors not to smoke inside my home.
7. I have set a goal to make my home smoke-free.
8. I consider it part of my responsibility as a partner and expectant father to ensure that our home is smoke-free.
9. Making my home smoke-free will improve the health of my partner and our unborn baby.
10. I believe I will succeed in making my home completely smoke-free.
11. Using nicotine replacement therapies (nicotine gum or lozenges) instead of smoking while I am inside the home will help substantially reduce my partner's exposure to secondhand smoke.
12. My partner supports making our home smoke-free.
13. People close to me (family and friends) support making our home smoke-free.
14. My residential environment (e.g., the floor on which I live, elevator, garden, or balcony) allows me to establish a smoke-free home.
15. I feel frustrated because it is difficult for me to go outside to smoke.
16. I intend to make my home smoke-free in the near future.
17. Making my home smoke-free is one of my highest priorities.
18. Whenever I am at home and feel the urge to smoke, it will be easy for me to remember that my home is smoke-free.

Part F: Decision-Making Processes Between Partners

36. When you and your partner make decisions about choosing activities to do together on weekends, who ultimately makes the decision?

1. Mainly me
2. Mainly my partner
3. Sometimes me and sometimes my partner

4. We make the decision together
5. Don't know
6. Prefer not to answer

37. Who makes decisions about major household purchases (e.g., a wardrobe or refrigerator)?

1. Mainly me
2. Mainly my partner
3. Sometimes me and sometimes my partner
4. We make the decision together
5. Don't know
6. Prefer not to answer

38. Who usually makes decisions regarding child-rearing in your household?

This question is presented only to participants who reported having children.

1. Mainly me
2. Mainly my partner
3. Sometimes me and sometimes my partner
4. We make the decision together
5. Don't know
6. Prefer not to answer

Supplementary file 2b: Follow-up questionnaire (English version)

Part A: Smoking Habits

1. During the past week, how many cigarettes did you smoke per day, on average? _____

2. On a typical day, how long after waking up in the morning do you smoke your first cigarette?

1. Within 5 minutes
2. 6–30 minutes
3. 31–60 minutes
4. More than 60 minutes
5. Prefer not to answer

3. During the past 30 days, have you used any of the following tobacco or nicotine products?

For each item, select: Yes / No / Prefer not to answer.

1. Electronic cigarettes, vaping products, or other electronic nicotine delivery devices (excluding heated tobacco products such as IQOS)
2. Heated tobacco products (e.g., IQOS)
3. Waterpipe (hookah)
4. Cigars or cigarillos
5. Tobacco pipes
6. Smokeless tobacco
7. Other: _____

4. During the past 30 days, how many times did you use cannabis/marijuana for non-medical purposes?

1. Never
2. 1–2 times
3. 3–5 times
4. 6–9 times
5. 10–19 times

6. 20–29 times
7. More than 30 times
8. Don't know
9. Prefer not to answer

5. If you reported using cannabis/marijuana during the past 30 days, did you use cannabis/marijuana mixed with tobacco?

1. Yes
2. No
3. Don't know
4. Prefer not to answer

6. What are the current rules regarding cigarette smoking in your home?

1. Smoking is allowed anywhere inside the home.
2. Smoking is allowed only in certain rooms, such as the utility room, living room, or study, but not in other rooms.
3. Smoking is allowed in only one designated room, such as the living room or utility room, and is prohibited in all other rooms.
4. Smoking is allowed only outside the home in adjacent areas, such as the balcony or yard. Smoking is not allowed anywhere inside the home.
5. Smoking is allowed only at a distance from the home. Smoking is not allowed on the balcony or in the yard near the home, and smokers must remain at least 15 steps (10 meters) away from any window or door.

7. What are the current rules regarding smoking in your vehicle?

1. Smoking is allowed inside the vehicle when my partner is present, even when the windows are closed.
2. Smoking is allowed inside the vehicle when my partner is present, but only when the windows are open.
3. Smoking is allowed inside the vehicle only when my partner is not present.
4. Smoking is allowed only outside the vehicle, near the vehicle.
5. Smoking is allowed only outside the vehicle, at a distance of at least 15 steps (10 meters) from the vehicle.

8. Do you currently smoke in the presence of your partner?

1. I never smoke in the presence of my partner.
2. I smoke in the presence of my partner but maintain a substantial distance from her (by moving to another room or remaining at least 15 steps [10 meters] away when outdoors).
3. I smoke in the presence of my partner but maintain only a short distance from her (less than 15 steps [10 meters]).
4. I smoke in the presence of my partner without moving away from her.

9. During the past 3 months, have any other people who smoke lived in your household?

1. Yes
2. No
3. Don't know
4. Prefer not to answer

10. If yes, did these individuals smoke in the presence of your partner inside the home?

1. They never smoked in the presence of my partner.
2. Yes, they smoked in the presence of my partner but maintained a substantial distance from her (by moving to another room or remaining at least 15 steps [10 meters] away when outdoors).
3. Yes, they smoked in the presence of my partner but maintained only a short distance from her (less than 15 steps [10 meters]).
4. Yes, they smoked in the presence of my partner without moving away from her.
5. Don't know
6. Prefer not to answer

11. During the past 3 months, have you stopped smoking for at least 24 hours?

1. Yes
2. No
3. Prefer not to answer

12. On a scale from 1 to 10, to what extent do you think your partner is exposed to your cigarette smoke?

(1 = Not exposed at all; 10 = Extremely exposed)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

13. On a scale from 1 to 10, how strong is your desire to reduce your partner's exposure to cigarette smoke at home?

(1 = No desire at all to reduce her exposure; 10 = Very strong desire to reduce her exposure)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

14. On a scale from 1 to 10, how confident are you in your ability to reduce your partner's exposure to cigarette smoke at home?

(1 = Not at all confident in my ability to reduce her exposure; 10 = Extremely confident in my ability to reduce her exposure)

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

15. During the past 4 weeks, how often have you felt guilty about exposing your partner to your cigarette smoke?

1. Never
2. 1–2 times
3. 3–4 times
4. Once a week or more (but less than once a day)
5. Once a day or more

16. How often do you use nicotine replacement therapies (such as nicotine gum or nicotine lozenges) to reduce your partner's exposure to cigarette smoke (at home, in the vehicle, or when you are near her)?

Nicotine replacement therapies are over-the-counter medications that provide nicotine without smoking, helping reduce the urge to smoke.

1. Always
2. Often
3. Sometimes
4. Rarely
5. Never

6. Don't know
7. Prefer not to answer

Part B: Knowledge of the Health Risks of Secondhand Smoke Exposure and Smoke-Free Homes

Same as Part D in baseline questionnaire.

Part C: Attitudes Toward Establishing a Smoke-Free Home

Same as Part E in baseline questionnaire.

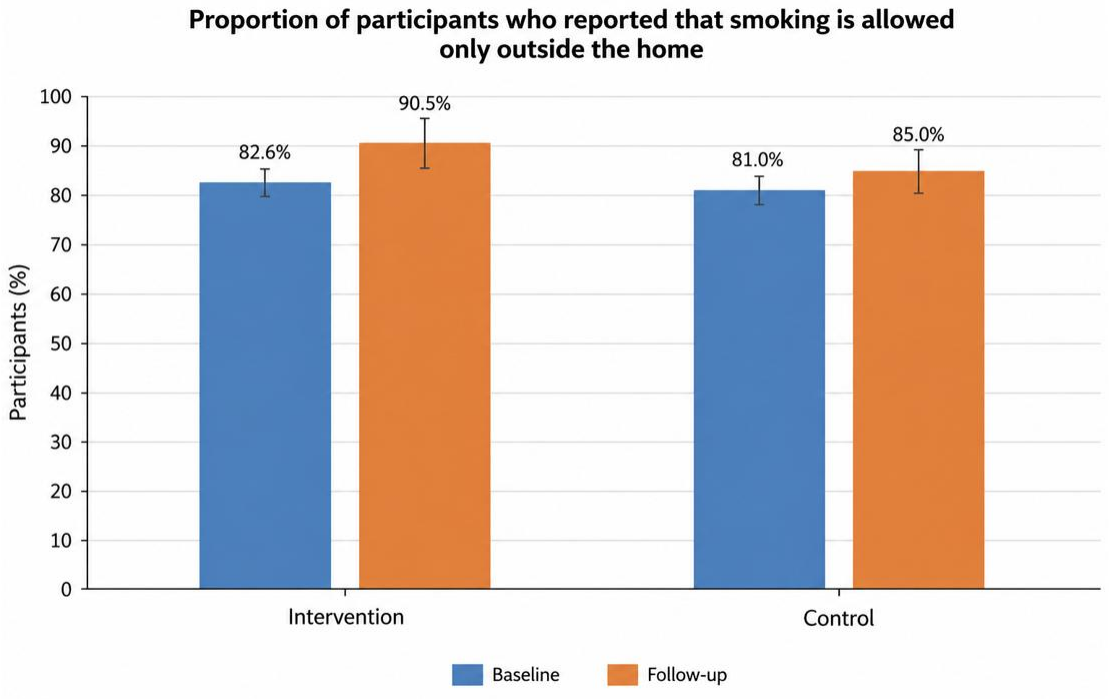
Supplementary File 3: Definitions for all secondary feasibility and effectiveness outcomes.

Outcome	Definition
Secondary feasibility outcomes	
Duration of recruitment	Number of participants recruited during the 118-day recruitment period and mean number of days per participant recruited.
Follow-up rate	Proportion of participants who completed the 12-week follow-up questionnaire.
Engagement time	Number of minutes spent on the *First Breath* WebApp (intervention group) or webpage (control group).
Intervention completion rate	Proportion of intervention participants who completed all components of the *First Breath* WebApp, including: 1) the questionnaire assessing perceived SHS exposure and home smoking rules; 2) goal setting; 3) action planning; and 4) accessing at least one component of the "Tools", "Tips" and "Motivation" sections.
WebApp re-entry rate	Proportion of intervention participants who accessed the WebApp more than once during the follow-up period.
Secondary effectiveness outcomes	
Self-reported complete smoke-free home	Proportion of participants who reported that smoking was allowed only at least 10 meters far from the home.
Self-report that smoking was allowed only outdoors	Proportion of participants who reported that smoking was allowed only outside the home, but was permitted near the home, e.g., on the balcony, porch or in a private garden.
Self-report that smoking was allowed only outside the car	Proportion of participants who reported that smoking was allowed only outside the car.
Self-reported change in smoke-free home rules	Change in home smoking rules between baseline and the 12-week follow-up, categorized as positive, no change, or negative based on five ordered categories: smoking allowed anywhere in the home; smoking allowed only in some rooms; smoking allowed only in one room; smoking allowed only outside but near the home; and smoking allowed only far from the home.

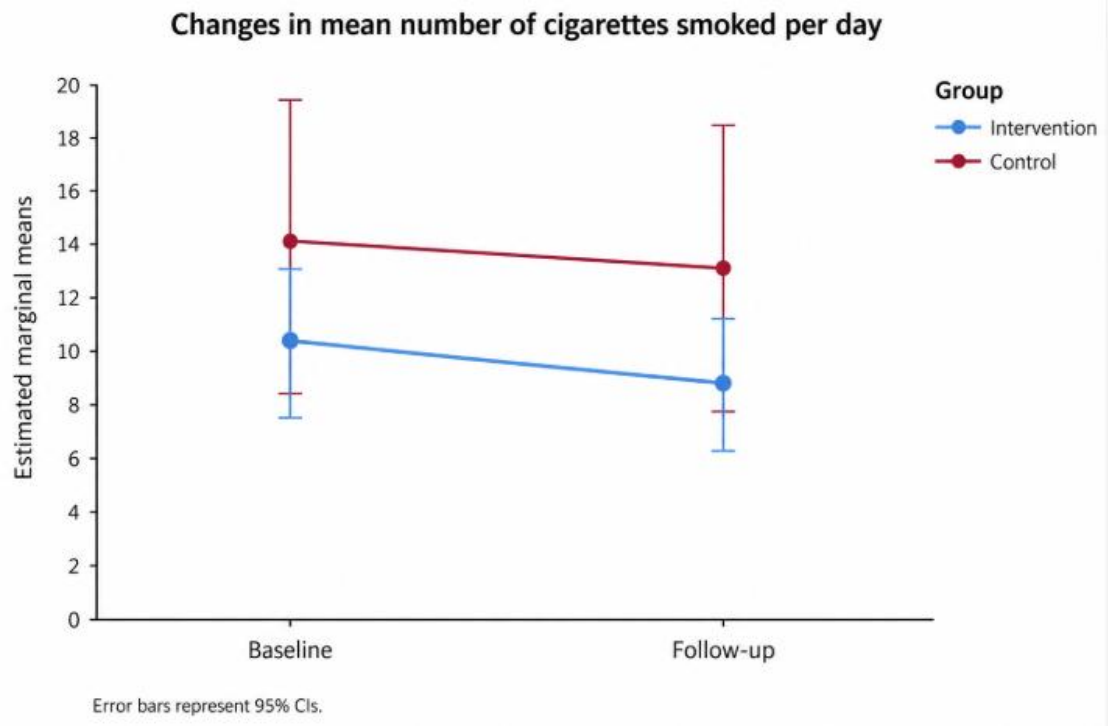
NRT use at home	Proportion of participants who reported using nicotine-replacement therapy (NRT) to support implementation of a smoke-free home at the 12-week follow up.
Change in perceived spouse SHS exposure	Change in perceived spouse SHS exposure score between the baseline and the 12-week follow up. Perceived SHS exposure was assessed using one question "In your opinion, to what extent is your spouse exposed to SHS from your smoking?", rated from 0 (not exposed at all) to 10 (very exposed).
Self-reportedf smoking cessation	Proportion of participants who reported having quit smoking at the 12-week follow-up.
Change in number of cigarettes smoked per day	Change in the mean number of cigarettes smoked per day between baseline and the 12-week follow up.
Change in knowledge regarding prenatal SHS and SFH	Change in participant's composite knowledge score between baseline and the 12-week follow up. Knowledge was assessed using 12 true/false/don't know statements, with "don't know" responses considered incorrect, yielding a composite score from 0 to 100;
Change in attitudes regarding prenatal SHS and SFH	Change in participant's mean composite attitude score between baseline and the 12-week follow-up/Attitudes were assessed using 18 items rated on a five-point Likert scale (1=strongly disagree to 5=strongly agree), based on the Theoretical Domains Framework (Atkins et al., 2017).

Supplementary File 4: Changes in the secondary effectiveness outcomes by study group

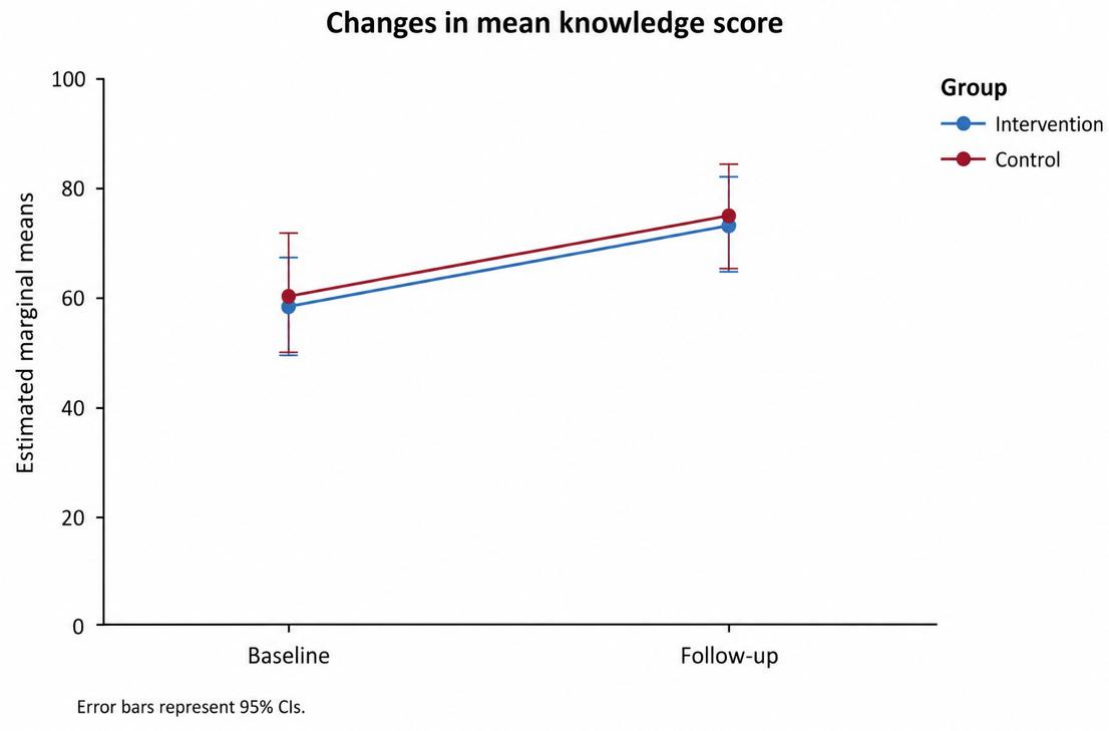
Supplementary Figure 4a: Change in smoking allowed only outdoors, including in areas adjacent to the home from baseline to 12-week follow-up, by study group.



Supplementary Figure 4b: Change in mean number of cigarettes smoked per day from baseline to 12-week follow-up, by study group.



Supplementary Figure 4c: Comparison of changes in knowledge score over time between the intervention and control groups.



Supplementary File 4d: Comparison of changes in attitude score over time between the intervention and control groups.

