

Title:

Feasibility of Mobile Health Game “Fume” in Supporting Tobacco-related Health Literacy among Early Adolescents: A Three-Armed Cluster Randomized Design

Heidi Parisod^a, MHS; Anni Pakarinen^a, MHS; Anna Axelin^a, PhD; Eliisa Löyttyniemi^b, PhD; Jouni Smed^c, PhD; Sanna Salanterä^{a,d}, PhD, Professor of Clinical Nursing Science

^aDepartment of Nursing Science, University of Turku, Turku FI-20014, Finland

^bDepartment of Biostatistics, University of Turku, Turku FI-20014, Finland.

^cDepartment of Future Technologies, University of Turku, Turku FI-20014, Finland

^dTurku University Hospital, Turku FI-20521, Finland

Corresponding author:

Heidi Parisod

Postal address:

Department of Nursing Science

University of Turku

Turku FI-20014

Finland

Phone: +358 45 121 3567

E-mail: heidi.parisod@utu.fi

Abstract

Objective: New interventions supporting health literacy and a tobacco-free lifestyle in adolescence are needed to narrow the widening gap in existing health inequalities. Health games offer potential and could be utilized for example in school healthcare, but more research is needed to increase the understanding of the effects of game elements in health interventions. The aim of this feasibility study is to determine the short-term effectiveness of the tobacco-related mobile health game *Fume* and a non-gamified website in comparison with a no-intervention control group, regarding tobacco-related health literacy among 10 to 13-year-old early adolescents. In addition, we compare the demand for and acceptability of *Fume* to that of the website.

Methods: In total, 151 early adolescents participated in this single-blinded, three-armed cluster randomized trial. The participants from three municipalities in southwest Finland were randomly allocated between a group with access to the health game *Fume* (n = 61), a group with access to the website (n = 47), and a group with no intervention (n = 43). The intervention groups first participated in a 20-minute training session with *Fume*/the website, and then had two weeks to use *Fume*/the website based on their own interest. Short-term effectiveness was measured by primary (anti-smoking self-efficacy) and secondary (smoking outcome expectations, attitudes towards tobacco use, tobacco-use motives, motivation to decline tobacco use in the future, and knowledge about tobacco) outcomes derived from the theory-based determinants of tobacco-related health literacy and evaluated with self-assessment questionnaires at baseline and post-intervention (after a two-week follow-up). For evaluating the demand, the actual use of *Fume*/the website was tracked during the two-week period. Regarding acceptability, the raised interest

towards *Fume*/the website and opinions about the interventions were evaluated post-intervention. Differences were tested with the McNemar, Fisher exact, and non-parametric tests.

Results: Statistically significant favorable changes during the study period were found for positive ($P = .002$) and negative ($P = .02$) smoking outcome expectations and attitudes towards cigarette smoking ($P = .01$) within the group using *Fume*. No statistically significant changes were detected within the website or control groups. Statistically significant differences were not found for the change in outcome variables among the three groups. The number of visits ($P < .001$), number of separate visit days ($P < .001$) and total duration of use ($P < .001$) were larger for the group using *Fume* than for that using the website. *Fume* sparked more interest in early adolescents than the website did ($P < .001$). There were no statistically significant differences in opinions about *Fume* and those regarding the website.

Conclusions: The intervention with embedded game elements, the health game *Fume*, was found to be more feasible as a tobacco-related health education intervention than the non-gamified website among early adolescents in light of demand and acceptability (raised interest). Even though no change in anti-smoking self-efficacy was found, the results of this feasibility study demonstrated favorable short-term changes with *Fume* in some other theory-based determinants of tobacco-related health literacy.

Trial Registration: ClinicalTrials.gov NCT02717910

Keywords: Tobacco, Health education, Health literacy, Health game, Adolescent, Feasibility studies, Randomized controlled trial

1. Introduction

Adolescents' use of non-conventional tobacco products, such as snus (smokeless moist powder tobacco), has increased [1,2]. Also, even though the current trend of cigarette smoking is decreasing, 12% of 15-year-olds still smoke at least once a week [3]. Cigarette smoking is largely associated with a lower socio-economic background [4]. To narrow the widening gap of health inequalities, support of health literacy [5,6] (i.e., motivation and ability to access, understand, and use health information) already among young people [7-9] needs attention. Most commonly, interventions designed to address youngsters' health literacy are targeted at adults, such as parents, and interventions focusing on children and adolescents themselves are still scarce [10].

Developments in digital technology and patterns of adolescents' technology use [11] have encouraged the development of new health education methods to reach adolescents in school healthcare and other settings. The majority of adolescents (92%) report going online daily, and nearly three out of four have access to a smartphone. Other than for information-seeking purposes, adolescents mainly utilize these mobile devices for messaging and sharing visual material in social media and gaming [11].

Interest in gamified interventions has increased during the last decade [12,13]. Game elements (e.g., goals, rules, and opponents) are used in health education interventions to influence motivational, psychological, and behavioral outcomes [13], such as promoting participant engagement and influencing health behaviors. Previous studies have demonstrated the potential of health games in adolescent tobacco prevention [14-17], but more research with experimental

study designs is needed to strengthen the understanding of the effects of game elements in the context of health interventions [18,19]. Furthermore, little is known regarding how gamified health interventions are actually being used [19], especially among adolescents.

The aim of this feasibility study is to determine the short-term effectiveness of the tobacco-related mobile health game *Fume* and that of a non-gamified website in comparison with a no-intervention control group regarding tobacco-related health literacy among 10 to 13-year-old early adolescents. In addition, we compare the demand for and acceptability of *Fume* to that of the website.

2. Methods

2.1 Study design

We conducted a feasibility study using a single-blind, three-armed cluster randomized design in spring 2016 (Figure 1). The measurement points were at baseline and post-intervention (after a two-week follow-up) with the same participants.

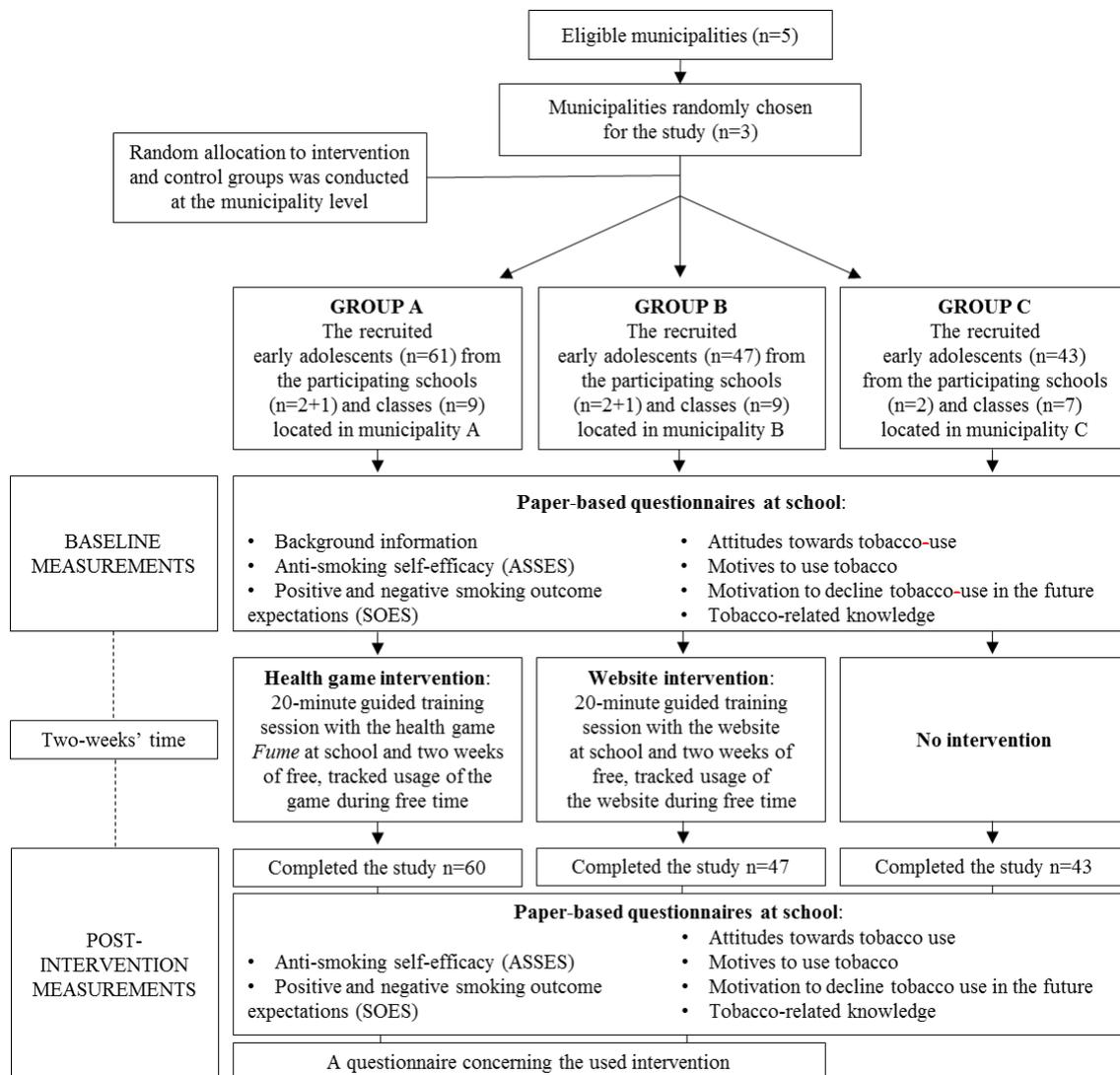


Figure 1. The study design and flow of participants

This study was pre-assessed and approved of by the Ethics Committee of the University of Turku (reference number: 11/2016). Permission to conduct the study was received from the participating municipalities in March 2016 before contacting the schools and starting recruitment of the participating early adolescents.

2.2 Recruitment of the municipalities and randomization

Three municipalities meeting the eligibility criteria were randomly chosen for the study. The eligibility criteria required that the municipality: (1) have more than 10,000 inhabitants [20], (2) have at least 11.4% adolescent tobacco prevalence [21], and (3) be located in southwest Finland. Random allocation was done in clusters, dividing the participants between three groups: the health game group (Group A), the website group (Group B), and the no-intervention control group (Group C). This was done at the municipal level using computer-assisted randomization to prevent contamination between participants in different groups.

2.3 Determination of sample size and recruitment of the participating early adolescents

The sample size concerning the participating early adolescents was determined in advance with a power calculation based on previously recognized [22] early adolescents' average anti-smoking self-efficacy scores (mean = 3.57, SD = 0.49). The calculations indicated that having at least 30 participants in each group would give 80% power to detect mean differences of 10% (0.357) in anti-smoking self-efficacy between groups at the end of the study ($\alpha = .05$; 2-sided). Since cluster randomized trials require larger sample sizes to achieve the same statistical power as an individually randomized trial [23], we aimed to have sample sizes that were 50% or higher than indicated based on the power calculation.

To be eligible for participation, early adolescents had to: (1) be from 10 to 13 years old, (2) understand and be able to communicate in Finnish, Swedish, or English, and (3) have daily access to either a smartphone or a tablet computer during their free time. They were recruited from eight public schools (medium size and large), and 25 classes (grades 4–6) participated in

this study. We started the recruitment with two schools in each of the municipalities. Due to a low recruitment level of early adolescents at the time of the data collection, recruitment for the health game and the website groups was extended, and two additional schools were included in the study at a later phase.

A researcher (HP) introduced the study to the early adolescents in the participating classes during a school day in oral and written form. The early adolescents were blinded to the intervention of interest. Since the randomization was done before the introduction, they were only informed about the kind of intervention they would receive if they participated in the study. They also received detailed information about how to access and use either the health game (Group A) or the website (Group B) and what kind of data would be collected and how it would be collected. Participation was voluntary, and the adolescents had a week to decide to participate. A written informed consent was required from both the participating early adolescent and one guardian.

2.4 Health game intervention (Group A)

The early adolescents in Group A used a mobile health game called *Fume* (version 1.1.0; see Video 1). *Fume* was developed [24] by a multidisciplinary research group that included researchers from nursing science, medicine, and information technology. The health game was first modeled using theoretical and empirical knowledge on tobacco-related health literacy, views of adolescents and other previous research literature. The game was further designed with a game company (NordicEdu) specializing in applied games. Then the game was produced using an iterative process that included four iteration rounds and testing sessions in 2015. During these testing sessions, alpha and beta versions of the game were tested by adolescents 9 to 16 years old

(session 1: n = 16; session 3: n = 10; session 4: n = 44) and health promotion professionals (session 2: n = 3). The design of the game was revised based on observations on the usability of the game and feedback. The version of *Fume* (version 1.1.0) used in this study contains five minigames, a story, and additional textual information concentrating on the topic of tobacco. The game elements included the opponent (time limited), rules, goals, scores, levels, and personal high scores. A detailed description of *Fume* and its development process is presented in Parisod et al. 2017 [24].

The health game intervention consisted of a 20-minute guided training session on *Fume* at school and two weeks of free usage. During the training sessions, the participants played through the game at least once. Then the free-of-charge game was downloaded to each early adolescent's mobile device (smartphone or tablet using the Android, iOS, or Windows operating system), and they were instructed to use *Fume* based on their own interest during the free time. At the time of this study, *Fume* was not yet available from mobile stores, which prevented the participants in the other groups to have access to it.

2.5 Website intervention (Group B)

The early adolescents in Group B used a website (Figure 2) containing the exact same story and textual information as *Fume* (version 1.1.0) and graphics from the game (pictures and video clips). However, the materials were presented in a static form without game elements. The website was created using the WordPress publishing platform. Access to the website required logging in with a personal username and password provided to the participants. The website

intervention was implemented using the same protocol as the health game intervention (a 20-minute training session plus two weeks of free usage).

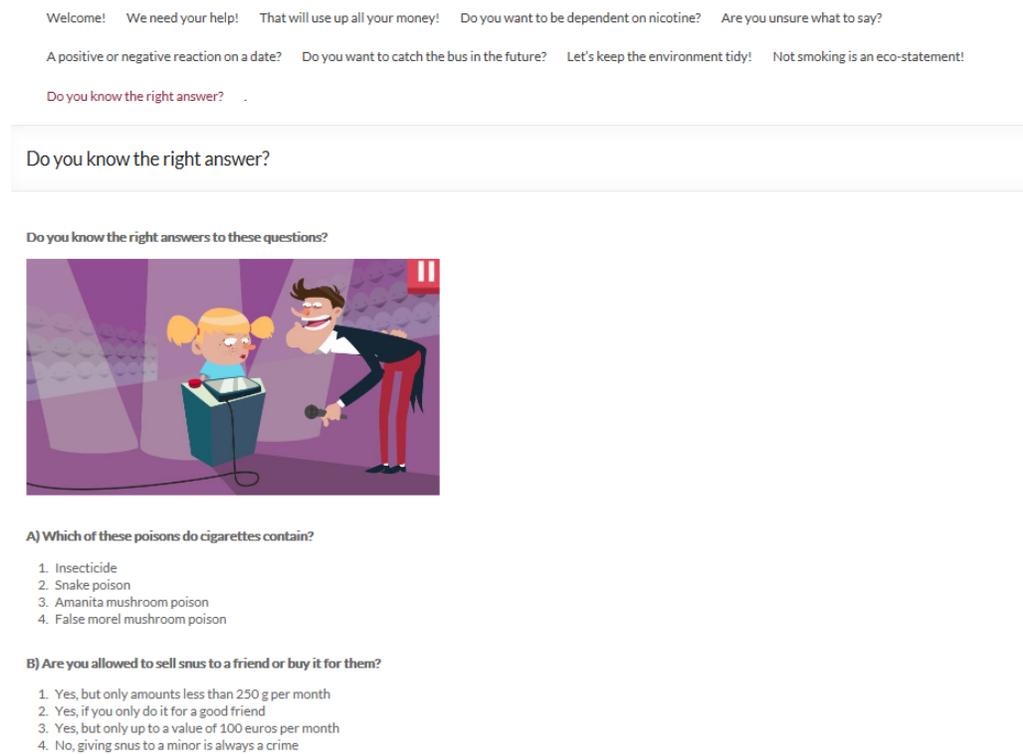


Figure 2. Screenshot of the website

2.6 Outcome measures

2.6.1 Background information

A background information questionnaire developed for this study was completed at baseline during a school day. The paper-based questionnaire included questions about the participant and external factors that could potentially influence tobacco-related health literacy.

2.6.2 Short-term effectiveness

Paper-based instruments derived from the theory-based determinants of tobacco-related health literacy [25] were used at baseline and post-intervention (after a two-week follow-up) with the same early adolescents. The determinants were used instead of actual tobacco-related health literacy due to a lack of health literacy instruments suitable for young populations [26]. Anti-smoking self-efficacy was considered to be the primary outcome. The instruments are presented in Table 1. Knowledge about tobacco was evaluated with open-ended questions (*'What are the possible consequences of cigarette smoking/snus use?'*), which were operationalized for the purpose of statistical analysis (*'Describe any consequences: yes/no'*). An additional response option to the questions concerning snus (*'I don't know what snus is'*) was also included.

Table 1. The instruments used for measuring the theory-based determinants of health literacy

Instrument	Instrument type	Validation results	Items	Possible range
Anti-smoking Self-efficacy scale (ASSES) [22]	A 4-point Likert-scale questionnaire	Cronbach's alpha ^a .90; ICC score ^b .85, CVI score .92 ^c [22]	Includes 15 questions regarding self-efficacy to decline cigarette smoking	15–60 (sum); 60 refers to the highest level of self-efficacy
Smoking Outcome Expectation scale (SOES) [22]	A 4-point Likert-scale questionnaire that includes two sub-scales: Positive Smoking Outcome Expectations sub-scale (POS-SOES) and Negative Smoking Outcome Expectations sub-scale (NEG-SOES)	POS-SOES: Cronbach's alpha ^a .78; ICC score ^b .90, CVI score 1.0 ^c [22] NEG-SOES: Cronbach's alpha ^a .76; ICC score ^b .85, CVI score .86 ^c [22]	POS-SOES: Includes three questions concerning perceptions about positive outcomes of cigarette smoking NEG-SOES: Includes three questions concerning perceptions about negative outcomes of cigarette smoking	POS-SOES: 3–12 (sum); 3 refers to the most favorable result NEG-SOES: 3–12 (sum); 12 refers to the most favorable result
Attitudes towards tobacco use^d	A 4-point Likert-scale questionnaire that includes two sub-scales: Attitudes towards cigarette smoking, and Attitudes towards snus use	N/A ^e	Attitudes towards cigarette smoking: includes one question regarding cigarette smoking Attitudes towards snus use: includes one question regarding snus use	Attitudes towards cigarette smoking: 1–4; 1 refers to the most negative attitudes towards cigarette smoking Attitudes towards snus use: 1–4; 1 refers to the most negative attitudes towards snus use
Tobacco-use motives^d	A 4-point Likert-scale questionnaire that includes two sub-scales: Cigarette smoking motives and Snus use motives	Cigarette smoking motives: Cronbach's alpha ^{a,f} at baseline .85; Cronbach's alpha ^{a,f} post-intervention .86 Snus use motives: Cronbach's alpha ^{a,f} at baseline .92; Cronbach's alpha ^{a,f} post-intervention .93	Cigarette smoking motives: includes three questions regarding different motives to smoke cigarettes (to show others how tough, cool, or adult-like you are) Snus use motives: Includes three questions regarding different motives to use snus (to show others how tough, cool, or adult-like you are)	Cigarette smoking motives: 3–12 (sum); 3 refers to the lowest motives to smoke cigarettes Snus use motives: 3–12 (sum); 3 refers to the lowest motives to use snus

Motivation to decline tobacco use in the future^d	A 4-point Likert-scale questionnaire that includes two sub-scales: Motivation to decline cigarette smoking in the future and Motivation to decline snus use in the future	N/A ^e	Motivation to decline cigarette smoking in the future: includes one question regarding cigarette smoking Motivation to decline snus use in the future: includes one question regarding snus use	Motivation to decline cigarette smoking in the future: 1–4; 1 refers to the highest motivation to decline cigarette smoking Motivation to decline snus use in the future: 1–4; 1 refers to the highest motivation to decline snus use
--	---	------------------	--	--

^a Cronbach’s alpha is an indicator of internal consistency.

^b ICC=Infraclass correlation coefficient is an indicator of test-retest reliability.

^c CVI=Content validity index is an indicator of content validity.

^d Instrument was developed for the use of this study based on research knowledge, evaluated by a multidisciplinary group of experts, and piloted with early adolescents (n=7).

^e N/A= Not available. Cronbach’s alpha could not be calculated, as the sub-scales include only one item each.

^f Cronbach’s alpha calculated based on the data of this study.

2.6.3 Demand

The actual use of *Fume*/the website was tracked during the two-week study period for the purpose of estimating the demand for the intervention. With *Fume*, a random individual code generated for each downloaded game application, log files, and GameAnalytics were used. With the website, tracking was done using individual usernames and a user-tracking plug-in on the website. The following data was collected: number of visits (game application openings or website logins), number of separate visit days, and total duration (minutes) of game play/website usage.

2.6.4 Acceptability

Raised interest and opinions were evaluated using early adolescents’ self-assessments post-intervention. Raised interest was evaluated with a dichotomous question (*Did Fume/the website provoke discussions among your friends?*). The early adolescents’ opinions about *Fume*/the

website was assessed with a 4-point Likert-scale question (*'What was your opinion of Fume/the website?'*).

2.7 Statistical analysis

We used descriptive statistics (number of observations, percentage, median, and range) to characterize the background information and the outcome measures of all randomized participants using the intention-to-treat principle at baseline and post-intervention (after a two-week follow-up). Confidence intervals (95%) were also calculated. To evaluate change in the theory-based determinants of health literacy within the groups, comparisons between baseline and post-intervention were performed with McNemar's test and the non-parametric Wilcoxon Signed Ranks test. To evaluate change over the study period between the groups, changes were first calculated in each group and then tested with Fisher's exact and non-parametric tests (Mann-Whitney U and Kruskal-Wallis tests). The same tests were used with background information and data concerning demand and acceptability. Non-parametric tests were used, while normal distribution assumptions were not met based on the Shapiro-Wilk test. If the Kruskal-Wallis test indicated a statistically significant result, the Mann-Whitney U test was performed for pair-wise testing. The Cronbach's alpha for the tobacco-use motives questionnaire developed for this study was also calculated.

We performed supplementary analyses, as statistically significant unbalance was observed between the intervention and control groups in background information concerning experiences of being offered cigarettes; the smoking habits of parents, other relatives, and authorities; the use of snus by authorities; and early adolescents' values concerning money. New subgroups were

formed (see Appendix B). The participating early adolescents were divided into these subgroups based on combined information about the original group and the above background information (*'consider the following example: health game group + has been offered cigarettes, health game group + has not been offered cigarettes,' etc.*). Differences between these new subgroups regarding changes in the following outcomes were tested with the Kruskal-Wallis test: positive smoking outcome expectations, negative smoking outcome expectations, and attitudes towards cigarette use. These kinds of procedures and non-parametric tests were used because normal distribution assumptions were not met.

P values under .05 (two-tailed) were considered significant. The statistical program SPSS® Statistics for Windows, version 23.0 (IBM Corp, Armonk, NY, USA), was used with the exception of the confidence intervals (95%). The confidence intervals (95%) for proportions were calculated with JMP® Pro, version 12.2 for Windows (SAS Institute Inc., Cary, NC, USA), and for medians with SAS® System, version 9.4 for Windows (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1 Participant characteristics

In total, 151 early adolescents participated in this study (Group A, health game group, $n = 61$; Group B, website group, $n = 47$; Group C, no-intervention control group, $n = 43$). Information on the participating adolescents is presented in tables 2, 3, and 4. There were some differences between the groups: experiences of being offered cigarettes ($P = .02$); cigarette smoking habits

of parents ($P = .01$), other relatives ($P = .01$), and authorities ($P = .003$); snus use habits of authorities ($P = .01$), and early adolescents' values concerning money ($P = .04$).

Table 2. General information on the participating early adolescents

Background factors	Group A n=61	Group B n=47	Group C n=43	P value ^a	
Age in years median (range)	11 (10-13)	11 (10-13)	11 (10-13)	.65	
Gender: Female n (%)	32 (52.5%)	20 (42.6%)	27 (62.8%)	.17	
Native language: Finnish n (%)	61 (100.0%)	46 (97.9%)	43 (100.0%)	.60	
Mother's native language: Finnish n (%)	60 (100.0%)	44 (93.6%)	43 (100.0%)	.05	
Father's native language: Finnish n (%)	59 (100.0%)	44 (95.7%)	42 (100.0%)	.18	
Has a chronic disease n (%)	7 (11.5%)	3 (6.4%)	7 (16.3%)	.35	
Allowance €/week median (range)	5.00 (2.00-20.00)	5.00 (2.00-10.00)	3.60 (0.60-10.00)	.05	
Gaming frequency n (%)	Daily players	40 (65.6%)	22 (46.8%)	24 (55.8%)	.07
	Weekly players	14 (23.0%)	23 (48.9%)	16 (37.2%)	
	Occasional players	7 (11.5%)	2 (4.3%)	3 (7.0%)	
Parents restrict gaming n (%)	35 (57.4%)	30 (63.8%)	29 (67.4%)	.56	
Has been offered cigarettes n (%)	13 (21.3%)	2 (4.3%)	3 (7.1%)	.02	
Has been offered snus n (%)	3 (5.9%)	0 (0.0%)	1 (2.9%)	.24	
Has tried cigarette smoking n (%)	4 (6.7%)	1 (2.1%)	1 (2.3%)	.51	
Smokes currently n (%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	1.00	
Has tried using snus n (%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	1.00	
Uses snus currently n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1.00	
Often sees others smoking cigarettes n (%)	46 (75.4%)	37 (78.7%)	36 (83.7%)	.57	
Often sees others using snus n (%)	5 (10.0%)	4 (8.9%)	2 (5.9%)	.86	
Often sees cigarette waste n (%)	58 (95.1%)	45 (95.7%)	42 (97.7%)	.88	
Often sees snus waste n (%)	14 (27.5%)	20 (44.4%)	8 (23.5%)	.11	
Remembers receiving health education about cigarettes during current school year n (%)	34 (55.7%)	32 (68.1%)	20 (46.5%)	.12	
Remembers receiving health education about snus during current school year n (%)	17 (33.3%)	12 (26.7%)	13 (38.2%)	.51	

^a Between-group comparisons were performed with the Kruskal-Wallis test and the Fisher's exact test.

Table 3. Tobacco use in the vicinity of the early adolescent

Members in the vicinity	Group A		Group B		Group C		<i>P</i> value ^a	
	Smokes cigarettes n (%)	Uses snus n (%)	Smokes cigarettes n (%)	Uses snus n (%)	Smokes cigarettes n (%)	Uses snus n (%)	Smokes cigarettes	Uses snus
Parents	24 (39.3%)	1 (1.6%)	20 (42.6%)	4 (8.5%)	29 (67.4%)	2 (4.7%)	.01	.26
Siblings	6 (9.8%)	0 (0.0%)	6 (12.8%)	1 (2.1%)	8 (19.0%)	2 (4.7%)	.43	.19
Other relatives	26 (42.6%)	1 (1.6%)	25 (53.2%)	2 (4.3%)	10 (23.3%)	0 (0.0%)	.01	.49
Friends	12 (19.7%)	3 (4.9%)	6 (12.8%)	3 (6.4%)	6 (14.0%)	0 (0.0%)	.61	.32
Authority figure (e.g., sports coach, teacher)	1 (1.6%)	0 (0.0%)	9 (20.0%)	6 (12.8%)	2 (4.7%)	1 (2.3%)	.003	.01
Idols	6 (9.8%)	2 (3.3%)	2 (4.4%)	1 (2.1%)	2 (4.7%)	1 (2.3%)	.54	1.00
Someone else in the vicinity	7 (11.5%)	2 (3.3%)	5 (10.6%)	2 (4.3%)	4 (9.3%)	2 (4.7%)	1.00	1.00

^a Between-group comparisons were performed with Fisher's exact test

Table 4. The number of early adolescents that chose the value in question among the three most important ones to them

Values	Group A	Group B	Group C	<i>P</i> value ^a
Health n (%)	55 (90%)	42 (89%)	41 (95%)	.58
Friends' acceptance n (%)	38 (62%)	32 (68%)	27 (63%)	.81
Athletic achievements n (%)	27 (44%)	26 (55%)	20 (47%)	.52
Nature conservation n (%)	16 (26%)	20 (43%)	20 (47%)	.07
Money n (%)	18 (30%)	5 (11%)	7 (16%)	.04

^a Between group comparisons were performed with the Fisher's exact test.

3.2 Short-term effectiveness: changes over the study period within each group

Of the 151 recruited early adolescents, 150 completed both the baseline and post-intervention measurements. Observations for one participant were missing from the health game group (Group A) at post-intervention because the participant was absent from school on the day the post-intervention measurements took place. The measured health literacy-related outcome variables are presented for the different groups at baseline and post-intervention in Table 5. No statistically significant changes were found within the groups in anti-smoking self-efficacy. There were statistically significant favorable changes within the health game intervention group (Group A) for positive ($P = .002$, early adolescents with favorable change $n = 20$, 33.3%) and

negative ($P = .02$, $n = 25$, 41.7%) smoking outcome expectations, and attitudes towards cigarette smoking ($P = .01$, $n = 9$, 15.0%). No statistically significant changes were found within the website intervention group (Group B) or the no-intervention control group (Group C).

Table 5. Outcome values for the theory-based determinants of tobacco-related health literacy at baseline and after two weeks, and P -values for the within-group comparisons

Outcome variables		Group A			Group B			Group C		
		Baseline	Post-test	P value ^a	Baseline	Post-test	P value ^a	Baseline	Post-test	P value ^a
Anti-smoking self-efficacy (ASSES)	median	55	57	.32	56	56	.60	57	56	.46
	95% CI	53, 56	53, 58		54, 57	53, 58		54, 58	55, 58	
	range	15–60	38–60		28–60	25–60		39–60	21–60	
Positive smoking outcome expectations (POS-SOES)	median	3	3	.002	3	3	.37	3	3	.10
	95% CI	3, 4	3, 3		3, 4	3, 3		3, 4	3, 3	
	range	3–11	3–7		3–9	3–9		3–6	3–6	
Negative smoking outcome expectations (NEG-SOES)	median	11	12	.02	12	12	.41	11	12	.54
	95% CI	11, 12	12, 12		11, 12	12, 12		11, 12	10, 12	
	range	7–12	3–12		3–12	3–12		3–12	4–12	
Attitudes towards cigarette smoking	median	1	1	.01	1	1	.56	1	1	.26
	95% CI	1, 1	1, 1		1, 1	1, 1		1, 1	1, 1	
	range	1–3	1–3		1–3	1–3		1–2	1–2	
Attitudes towards snus use	median	1	1	1.00	1	1	.16	1	1	1.00
	95% CI	1, 1	1, 1		1, 1	1, 1		1, 1	1, 1	
	range	1–3	1–2		1–3	1–3		1–3	1–3	
Motives to smoke cigarettes	median	3	3	.96	3	3	.77	3	3	.66
	95% CI	3, 3	3, 3		3, 3	3, 3		3, 3	3, 3	
	range	3–6	3–6		3–9	3–8		3–6	3–5	
Motives to use snus	median	3	3	.34	3	3	.68	3	3	.32

	95% CI	3, 3	3, 3		3, 3	3, 3		3, 3	3, 3	
	range	3–6	3–6		3–9	3–8		3–4	3–6	
Motivation to decline cigarette smoking in the future	median	1	1	.10	1	1	.56	1	1	.08
	95% CI	1, 1	1, 1		1, 1	1, 1		1, 1	1, 1	
	range	1–3	1–3		1–2	1–3		1–2	1–2	
Motivation to decline snus use in the future	median	1	1	1.00	1	1	1.00	1	1	.32
	95% CI	1, 1	1, 1		1, 1	1, 1		1, 1	1, 1	
	range	1–2	1–2		1–1	1–1		1–3	1–3	
Doesn't know what snus is	n	10	5	.13	2	1	1.00	9	7	.50
	%	16.4%	8.3%		4.3%	2.1%		20.9%	16.3%	
	95% CI	9.2%, 27.6%	3.6%, 17.8%		1.2%, 14.2%	0.4%, 11.1%		11.4%, 35.2%	8.1%, 30.0%	
Can't mention any consequences of cigarette smoking	n	2	2	1.00	0	1	N/A ^b	0	1	N/A ^b
	%	3.3%	3.3%		0.0%	2.1%		0.0%	2.3%	
	95% CI	0.9%, 11.2%	0.9%, 11.2%		N/A ^b	0.4%, 11.1%		N/A ^b	0.4%, 12.1%	
Can't mention any consequences of snus use	n	31	24	.12	25	22	.38	23	22	1.00
	%	50.8%	40.0%		53.2%	46.8%		53.5%	51.2%	
	95% CI	38.6%, 62.9%	28.1%, 51.9%		39.2%, 66.7%	33.3%, 60.8%		38.9%, 67.5%	36.8%, 65.4%	

^a Within-group comparisons between two time points were performed with McNemar's test for categorical variables and Wilcoxon Signed Ranks test for numerical variables.

^b N/A=Not available

3.3 Short-term effectiveness: changes over the study period between the groups

No statistically significant differences in changes were found between the groups (A–C) in anti-smoking self-efficacy or other outcome variables (positive or negative smoking outcome expectations, attitudes towards tobacco use, motives to use tobacco, motivation to decline tobacco in the future, and knowledge about tobacco). (See Appendix A.)

3.4 Supplementary analyses

Supplementary analyses were performed to test differences between the formed subgroups (combined information about intervention/control groups and background information) in the change of positive and negative smoking outcome expectations and attitudes towards cigarette smoking. No statistically significant differences were detected between any of the subgroups for the tested outcome variables. (See Appendix B.)

3.5 Comparisons of the demand between the interventions

The usage data for the health game group (Group A) and the website group (Group B) during the two-week study period are presented in Table 6. The early adolescents in the health game group visited *Fume* (4 times on average) statistically significantly ($P < .001$) more frequently than the early adolescents in the website group visited the website (once on average). The actual use of *Fume* was also significantly more frequent in light of the other outcome measures (visit days $P < .001$ and the total usage in minutes $P < .001$) compared to that of the website.

Table 6. The demand for the interventions

Outcomes		Group A (n=40) ^a	Group B (n=39) ^b	<i>P</i> value ^c
Number of visits (game application openings or website logins)	median	4	1	< .001
	95% CI	4, 8	1, 2	
	range	2–50	1–9	
Number of separate visit days	median	3	1	< .001
	95% CI	2, 3	1, 1	
	range	1–10	1–7	
Total duration (minutes) of game play/website usage	median	19	9	< .001
	95% CI	16, 26	8, 11	
	range	0–219	0–36	

^a Data was missing from 21 participants due to technical challenges.

^b Data was missing from 8 participants due to technical challenges.

^c Between-group comparisons were performed with the Mann-Whitney U test.

3.6 Comparisons of the acceptability between the intervention groups

The results concerning interest and opinions of the health game group (Group A) and the website group (Group B) are presented in Table 7. *Fume* raised more interest than the website ($P < .001$). The early adolescents reported that they mainly discussed their achieved high scores and what they thought about the game, but also about *Fume*'s tobacco-related content. Their opinions about the interventions did not differ significantly ($P = .19$).

Table 7. Acceptability of the interventions

Outcomes			Group A	Group B	<i>P</i> value ^a
Discussed <i>Fume</i>/the website with their friends	Yes	n	42	13	< .001
		%	70.0%	27.7%	
		95% CI	57.5%, 80.1%	16.9%, 41.8%	
Opinion of <i>Fume</i>/the website	Very boring	n	0	3	.19
		%	0.0%	6.4%	
		95% CI	N/A ^b	2.2%, 17.2%	
	Somewhat boring	n	13	8	
		%	22.0%	17.0%	
		95% CI	13.4%, 34.1%	8.9%, 30.1%	
	Somewhat nice	n	31	28	
		%	52.5%	59.6%	
		95% CI	40.0%, 64.7%	45.3%, 72.4%	
	Very nice	n	15	8	
		%	25.4%	17.0%	
		95% CI	16.1%, 37.8%	8.9%, 30.1%	

^a Between-group comparisons were performed with Fisher's exact test.

^b N/A=Not available

4. Discussion

The popularity of gamification has resulted in an increased amount of gamified health interventions [12]. Even though the inclusion of game elements is mainly seen as beneficial, some studies in educational contexts have demonstrated some negative outcomes [13]. In our study, the inclusion of game elements did not have a negative influence. On the contrary, the favorable changes regarding the theory-based determinants of tobacco-related health literacy (positive and negative smoking outcome expectations, and attitudes towards cigarette smoking)

were achieved within the group using *Fume*. These kinds of changes were not detected in the group using the non-gamified counterpart of *Fume*, on the website, or in the control group with no intervention.

Based on the achieved results and knowledge about adolescents' mobile device use patterns [11], a mobile version of a health game seems to be feasible with this population when used outside of school hours. Presenting tobacco-related health education in the form of a game resulted in greater use and interest in the intervention. The time the early adolescents spent with *Fume* in their free time was more than double compared to that of the website group, and they found *Fume* more interesting, as it provoked more discussion among them. Adolescents' use of digital health material has been shown to be affected by peer use [27]. Thus, besides the actual immersive game elements, discussions about *Fume* that took place among the early adolescents may have motivated them to continue using the game.

Both the higher degree of usage and discussions with peers may have functioned as mechanisms that improved the effects achieved with *Fume*. The discussions about *Fume* may have inspired early adolescents to look for additional information about tobacco products and to share negative thoughts about tobacco products with each other. One challenge with gamified interventions has been that the achieved favorable changes in health outcomes have been only temporal [28]. This means that maintaining discussions about the game could function as a booster to inspire the continuing use of the game and conversations about tobacco, which can generate long-term effects. Strengthening the understanding of these mechanisms (specific game elements that increase effectiveness and generate long-term effects) requires further research.

There are still a few issues that need further improvement. There were no statistically significant changes in our primary outcome of anti-smoking self-efficacy. However, the early adolescents' self-efficacy scores were high already at baseline, and that hindered the achievement of favorable changes. In future studies, testing *Fume* with a group of early adolescents with lower tobacco-related health literacy could be conducted. In this feasibility study, *Fume* was used only for a short period and as a stand-alone intervention. Debriefing sessions that were not included at this point are expected to reinforce the desirable outcomes [29]. To promote early adolescents' tobacco-related health literacy comprehensively, inclusion of debriefing sessions, expanded content, and further development of the game intervention are needed.

All of the favorable health literacy-related results of *Fume* were connected to cigarettes, not snus. Furthermore, over half of the early adolescents were not able to mention any consequences of snus use at baseline. *Fume* contains only a small amount of textual information about tobacco products. It may be that the early adolescents needed some kind of support to interpret the more unfamiliar snus-related content of the game. These results and adolescents' increased use of snus [1] highlight the need for putting more emphasis on health education about snus in general. In addition, the design of *Fume* could be improved to better support early adolescents' snus-related health literacy. For example, new minigames dealing with factual information about snus could be added.

Fume (version 1.1.0) covers both conventional cigarettes and snus. In addition, some information about electronic cigarettes is included. The game was developed to meet the needs of Finnish early adolescents, but it can be considered applicable to countries with a similar tobacco culture

as well. Some modifications to the content of *Fume* may be needed when using it as a health education intervention in other cultural contexts. In addition, updates are required in the future based on the trends in adolescents' tobacco-use habits.

5. Limitations

The study has some limitations. We used cluster randomization [23] at the municipal level to prevent contamination between early adolescents in different groups. For practical reasons, the early adolescents were recruited after randomization, but they were blinded to the main intervention of interest. We also conducted the statistical tests individually instead of in clusters due to the low number of clusters allocated to each arm. However, this study can be considered as a pilot for future research evaluating the long-term effectiveness of *Fume*.

The percentage of participants among the schools varied widely (between 8% and 43%). However, we collected comprehensive background information to be able to evaluate the homogeneity of our sample. Mostly there were no differences between the groups, but some differences existed. We conducted supplementary analyses to account for these confounding factors, but no statistically significant differences between the subgroups were found.

Some usage data was missing concerning both *Fume* (n = 21) and the website (n = 8) due to technical difficulties in downloading the game and tracking the usage. Even though the data was not available for all the participants, all the early adolescents in the intervention groups participated in the guided training sessions. Thus, it was verified that they used the intervention at least once.

6. Conclusions

The intervention with embedded game elements, the health game *Fume*, was found to be more feasible among early adolescents than its non-gamified counterpart, the website, in light of demand and acceptability (raised interest). The results also demonstrated favorable short-term changes with *Fume* in regard to positive and negative smoking outcome expectations and attitudes towards cigarette smoking. The promising findings encourage further development and testing of *Fume* as an intervention supporting tobacco-related health literacy in early adolescents.

Authors' contributions

HP, AP, JS, and SS participated in designing the health game *Fume* used in the study, and HP developed the website used as control intervention. All authors contributed to the design of the study. HP recruited the participants and collected the data. AA, JS, and SS supervised the conducting of the study and data collection. HP and EL did the power calculation and randomization and analyzed the data. HP drafted the manuscript, and all authors contributed to its revision.

Acknowledgements

We would like to thank all the early adolescents who participated in this study, the school personnel, and research assistants Johanna Nyman, Magda Flemmich, and Aarne A. Röyskö. This study was supported by the University of Turku, the City of Turku, the Research Foundation of Pulmonary Diseases, the TYKS Foundation, the Finnish Association of Nursing Research, and the Juho Vainio Foundation. The funding sources were not involved in conducting or reporting the study.

Conflicts of Interest

The health game *Fume* was developed by the authors in cooperation with the rest of the research group and the game company NordicEdu. The University of Turku owns the game.

Summary table

What was already known on the topic

- New interventions to support health literacy and a tobacco-free life in adolescence are needed to narrow the widening gap of health inequalities.
- Health games hold potential for tobacco-related health education among adolescents and could be utilized for example in school healthcare.
- Further research using experimental study designs is needed to strengthen the understanding of the effects of game elements within health interventions.

What this study adds to our knowledge

- Embedding game elements in tobacco-related health education resulted in greater use and interest in the intervention among 10- to 13-year-old early adolescents compared to its non-gamified counterpart, the website intervention.
- Some favorable short-term effects in regard to the theory-based determinants of tobacco-related health literacy were also achieved with the health game *Fume*. These kinds of changes were not detected within the website group or the no-intervention control group.

References

- [1] Kinnunen JM, Pere L, Lindfors P, Ollila O, Rimpelä A. 2015. Nuorten terveystapatutkimus 2015. Nuorten tupakkatuotteiden ja päihteiden käyttö 1977–2015. Report no. 2015:31. Helsinki, Ministry of Social Affairs and Health. Available from:
https://www.julkari.fi/bitstream/handle/10024/126379/URN_ISBN_978-952-00-3592-1.pdf?sequence=1.
- [2] Kann L, McManus T, Harris WA, Shanklin SL, Flint KH, Hawkins J, Queen B, Lowry R, O'Malley Olsen E, Chyen D, Whittle L, Thornton J, Lim C, Yamakawa Y, Brener N, Zaza S. 2016. Youth risk behavior surveillance—United States, 2015. *MMWR Surveillance Summaries* 65(6), 1–174. DOI: 10.15585/mmwr.ss6506a1.
- [3] Inchley J, Currie D, Young T, Samdal O, Torsheim T, Augustson L, Mathison F, Aleman-Diaz A, Molcho M, Weber M, Barnekow V. (Eds.). 2016. Growing up Unequal: Gender and Socioeconomic Differences in Young People's Health and Well-Being. Health Behaviour in School-aged Children (HBSC) study: international report from the 2013/2014 survey. Copenhagen, WHO Regional Office for Europe. Available from:
http://www.euro.who.int/__data/assets/pdf_file/0003/303438/HSBC-No.7-Growing-up-unequal-Full-Report.pdf.
- [4] Pampel FC, Mollborn S, Lawrence EM. 2014. Life course transitions in early adulthood and SES disparities in tobacco use. *Social Science Research* 43, 45–59. DOI: 10.1016/j.ssresearch.2013.08.005.

[5] Bennett IM, Chen J, Soroui JS, White S. 2009. The Contribution of Health Literacy to Disparities in Self-Rated Health Status and Preventive Health Behaviors in Older Adults. *Annals of Family Medicine* 7(3), 204-211. DOI: 10.1370/afm.940.

[6] Stringhini S, Sabia S, Shipley M, Brunner E, Nabi H, Kivimäki M, Singh-Manoux A. 2010. Association of socioeconomic position with health behaviors and mortality. The Whitehall II study. *JAMA* 303(12), 1159–1166. DOI:10.1001/jama.2010.297.

[7] Manganello. 2008. Health literacy and adolescents: a framework and agenda for future research. *Health Education Research* 23(5), 840-847. DOI: 10.1093/her/cym069.

[8] Brown SL, Teufel JA, Birch DA. 2007. Early adolescents perceptions of health and health literacy. *Journal of School Health* 77(1), 7-15. DOI: 10.1111/j.1746-1561.2007.00156.x.

[9] DeWalt DA, Hink A. 2009. Health Literacy and Child Health Outcomes: A Systematic Review of the Literature. *Pediatrics* 124, S265-S274. DOI: 10.1542/peds.2009-1162B.

[10] Velardo S, Drummond M. 2017. Emphasizing the child in child health literacy research. *Journal of Child Health Care* 21(1), 5–13. DOI: 10.1177/1367493516643423.

[11] Lenhart A, Smith A, Anderson M, Duggan M, Perrin A. 2015. *Teens, Technology and Friendships*. Washington, DC: Pew Research Center. Available from: <http://www.pewinternet.org/2015/08/06/teens-technology-and-friendships/>.

[12] Kharrazi H, Lu AS, Gharghabi F, Coleman W. 2012. A Scoping Review of Health Game Research: Past, Present, and Future. *Games for Health Journal* 1(2), 153-164. DOI: 10.1089/g4h.2012.0011.

[13] Hamari J, Koivisto J, Sarsa H. 2014. Does Gamification Work? — A Literature Review of Empirical Studies on Gamification. *System Sciences (HICSS), Proceedings of the 47th Hawaii International Conference on System Science*, 3025-3034. DOI: 10.1109/HICSS.2014.377.

[14] Tingen M, Gramling L, Bennett G, Gibson EM, Renew MM. 1997. A pilot study of preadolescents using focus groups to evaluate appeal of a video-based smoking prevention strategy. *Journal of Addictions Nursing* 9(3), 118–124.

[15] Andrews JA, Gordon JS, Hampson SH, Christiansen SM, Gunn B, Slovic P, Severson HH. 2011. Short-term efficacy of click city®: tobacco: changing etiological mechanisms related to the onset of tobacco use. *Prevention Science* 12(1), 89–102. DOI: 10.1007/s11121-010-0192-3.

[16] Andrews JA, Gordon JS, Hampson SH, Gunn B, Christiansen SM, Slovic P. 2014. Long-term efficacy of click city®: tobacco: a school-based tobacco prevention program. *Nicotine & Tobacco Research* 16(1), 33–41. DOI: 10.1093/ntr/ntt106.

[17] Rath JM, Williams V, Rubenstein R, Smith L, Vallone D. 2015. Assessing the impact of an interactive mobile game on tobacco-related attitudes and beliefs: the truth campaign's "Flavor Monsters". *Games for Health Journal* 4(6), 480–487. DOI: 10.1089/g4h.2015.0005.

[18] Alahäivälä T, Oinas-Kukkonen H. 2016. Understanding persuasion contexts in health gamification: A systematic analysis of gamified health behavior change support systems literature. *International Journal of Medical Informatics* 96, 62-70. DOI: 10.1016/j.ijmedinf.2016.02.006.

[19] Brown M, O'Neill N, van Woerden H, Eslambolchilar P, Jones M, John A. 2016. Gamification and Adherence to Web-Based Mental Health Interventions: A Systematic Review. *JMIR Mental Health* 3(3), e39. DOI: 10.2196/mental.5710.

[20] Population Registration Center. 2015. Kuntien asukasluvut äänestysalueittain helmikuussa 2015. Available from: <http://vrk.fi/kuntien-asukasluvut-aaenestysalueittain-helmikuu-2015>.

[21] Sotkanet.fi. 2013. Alcohol, tobacco and addiction: Daily smokers, as % of all pupils in 8th and 9th year of comprehensive school. Statistical information on welfare and health in Finland. National Institute for Health and Welfare. Available from: <https://www.sotkanet.fi/>.

[22] Chen CJ, Yeh MC, Tang FI, Yu S. 2015. The Smoking Outcome Expectation Scale and Anti-Smoking Self-Efficacy Scale for Early Adolescents: Instrument Development and Validation. *The Journal of School Nursing* 31(5), 363-373. DOI: 10.1177/1059840514560352.

[23] Puffer S, Torgerson DJ, Watson J. 2005. Cluster randomized controlled trials. *Journal of Evaluation in Clinical Practice* 11(5), 479–483. doi:10.1111/j.1365-2753.2005.00568.x.

[24] Parisod H, Pakarinen A, Axelin A, Danielsson-Ojala R, Smed J, Salanterä S. 2017. Designing a health-game intervention supporting health literacy and a tobacco-free life in early adolescence. *Games for Health Journal*, [Epub ahead of print]. DOI: 10.1089/g4h.2016.0107.

[25] Parisod H, Axelin A, Smed J, Salanterä S. 2016. Determinants of tobacco-related health literacy: a qualitative study with early adolescents. *International Journal of Nursing Studies* 62, 71-80. DOI: 10.1016/j.ijnurstu.2016.07.012.

[26] Perry EL. 2014. Health literacy in adolescents: an integrative review. *Journal for Specialists in Pediatric Nursing* 19(3), 210–218. DOI: 10.1111/jspn.12072.

[27] Ho J, Corden ME, Caccamo L, Tomasino KN, Duffecy J, Begale M, Mohr DC. 2016. Design and evaluation of a peer network to support adherence to a web-based intervention for adolescents. *Internet Interventions* 6, 50-56. DOI: 10.1016/j.invent.2016.09.005.

[28] Parisod H, Pakarinen A, Kauhanen L, Aromaa M, Leppänen V, Liukkonen TN, Smed J, Salanterä S. 2014. Promoting Children's Health with Digital Games: A Review of Reviews. *Games for Health Journal* 3(3), 145-156. DOI: 10.1089/g4h.2013.0086.

[29] de Freitas S, Oliver M. 2006. How can exploratory learning with games and simulations within the curriculum be most effectively evaluated? *Computers & Education* 46, 249–264. DOI: 10.1016/j.compedu.2005.11.007.

Appendices

Appendix A: Table presenting change in the outcome values regarding the theory-based determinants of tobacco-related health literacy in each group and *P*-values for between-group comparisons

Outcome variables		Change in Group A	Change in Group B	Change in Group C	<i>P</i> value
Anti-smoking self-efficacy (ASSES)^a	median	0	0	0	.65
	95% CI	0, 1	-1, 1	0, 1	
	range	-13–45	-22–17	-18–7	
Positive smoking outcome expectations (POS-SOES)	median	0	0	0	.37
	95% CI	0, 0	0, 0	0, 0	
	range	-8–2	-3–3	-3–2	
Negative smoking outcome expectations (NEG-SOES)^a	median	0	0	0	.52
	95% CI	0, 1	0, 0	0, 1	
	range	-9–4	-9–9	-8–7	
Attitudes towards cigarette smoking	median	0	0	0	.25
	95% CI	0, 0	0, 0	0, 0	
	range	-2–1	-1–1	-1–1	
Attitudes towards snus use	median	0	0	0	.70
	95% CI	0, 0	0, 0	0, 0	
	range	-1–1	-1–0	-1–1	
Motives to smoke cigarettes	median	0	0	0	.81
	95% CI	0, 0	0, 0	0, 0	
	range	-2–3	-3–4	-3–1	
Motives to use snus	median	0	0	0	.49
	95% CI	0, 0	0, 0	0, 0	
	range	-3–3	-3–3	0–2	
Motivation to decline cigarette smoking in the future	median	0	0	0	.05
	95% CI	0, 0	0, 0	0, 0	
	range	-2–1	-1–1	0–1	
Motivation to decline snus use in the future	median	0	0	0	.63
	95% CI	0, 0	0, 0	0, 0	
	range	-1–1	0–0	0–1	
Doesn't know what snus is	median	0	0	0	.44
	95% CI	0, 0	0, 0	0, 0	
	range	-1–1	-1–0	-1–0	
Can't mention any consequences of cigarette smoking	median	0	0	0	.71
	95% CI	0, 0	0, 0	0, 0	
	range	-1–1	0–1	0–1	
Can't mention any consequences of snus use	median	0	0	0	.44
	95% CI	0, 0	0, 0	0, 0	
	range	-1–1	-1–1	-1–1	

^a Contrary to others, negative numerical change represents unfavorable change in this determinant of health literacy

Appendix B: Table presenting *P* values for between-subgroup comparisons for the differences in change (supplementary analyses)

Subgroups formed	<i>P</i> value ^a		
	Change in positive smoking outcome expectations	Change in negative smoking outcome expectations	Change in attitudes towards cigarette smoking
D1: Health game group + has been offered cigarettes D2: Health game group + has not been offered cigarettes D3: Website group + has been offered cigarettes D4: Website group + has not been offered cigarettes D5: No-intervention control group + has been offered cigarettes D6: No-intervention control group + has not been offered cigarettes	.32	.27	.51
E1: Health game group + parents smoke cigarettes E2: Health game group + parents do not smoke cigarettes E3: Website group + parents smoke cigarettes E4: Website group + parents do not smoke cigarettes E5: No-intervention control group + parents smoke cigarettes E6: No-intervention control group + parents do not smoke cigarettes	.85	.37	.25
F1: Health game group + relatives smoke cigarettes F2: Health game group + relatives do not smoke cigarettes F3: Website group + relatives smoke cigarettes F4: Website group + relatives do not smoke cigarettes F5: No-intervention control group + relatives smoke cigarettes F6: No-intervention control group + relatives do not smoke cigarettes	.33	.55	.56
G1: Health game group + authorities smoke cigarettes G2: Health game group + authorities do not smoke cigarettes G3: Website group + authorities smoke cigarettes G4: Website group + authorities do not smoke cigarettes G5: No-intervention control group + authorities smoke cigarettes G6: No-intervention control group + authorities do not smoke cigarettes	.58	.28	.71
H1: Health game group + authorities use snus H2: Health game group + authorities do not use snus H3: Website group + authorities use snus H4: Website group + authorities do not use snus H5: No-intervention control group + authorities use snus H6: No-intervention control group + authorities do not use snus	.72	.41	.34
I1: Health game group + money among the top three values I2: Health game group + money not among the top three values I3: Website group + money among the top three values I4: Website group + money not among the top three values I5: No-intervention control group + money among the top three values I6: No-intervention control group + money not among the top three values	.33	.66	.46

^a Between-subgroup comparisons were performed with the Kruskal-Wallis test