

# A HEALTH GAME AS AN INTERVENTION TO SUPPORT TOBACCO-RELATED HEALTH LITERACY AMONG EARLY ADOLESCENTS

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#### **ABSTRACT**

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The aim of this study was to develop and evaluate the feasibility of a health game intervention supporting tobacco-related health literacy in 10 to 13-year-old early adolescents. The study had two phases. During the development phase, we explored the determinants of tobacco-related health literacy with a qualitative descriptive study with early adolescents (n=39, focus groups, data analyzed using thematic analysis). We also conducted a review of reviews (n=15, narrative synthesis) of existing evidence on health games among children and adolescents. Furthermore, we explored the views of (n=39, focus groups and n=83, online questionnaire, thematic analysis) and collected feedback from adolescents (n=10+44 questionnaires, statistical analysis) while producing a health game called *Fume*. In the second phase, we evaluated feasibility (demand, acceptability, short-term effectiveness) of *Fume* using validated instruments, questionnaires and by tracking its actual use. We conducted the study with 151 early adolescents using a single-blind, three-armed cluster randomized design. The McNemar, Fisher's exact, and non-parametric tests were used to test differences within and between groups.

The results gathered during the development phase suggest that supporting tobacco-related health literacy among early adolescents requires being aware of the multidimensional nature of the determining factors, and paying attention to the mediating role of the interpretation process of health messages. Based on existing literature health games hold potential among children and adolescents, but further research is needed. The adolescent participants pointed several aspects regarding the acceptability of Fume during its development process, including the game's positive approach to tobacco non-use, and its high-quality graphics. The feasibility study with the game showed that, compared to a non-gamified website, there was a higher usage rate for *Fume* during the two-week study period ( $P \le 0.001$  for all the values) as well as greater interest in Fume ( $P \le 0.001$ ). The opinions of adolescents about the interventions did not differ in a statistically significant way. Favorable changes were found within the Fume group regarding positive (P=0.002) and negative (P=0.02) smoking outcome expectations and attitudes towards cigarette smoking (P=0.01). We did not find statistically significant differences in the changes of the theory-based determinants of tobacco-related health literacy between the *Fume*, website and control groups.

The gathered results highlight several aspects of tobacco-related health literacy as well as of health games. *Fume* was found to be more feasible among early adolescents than the non-gamified website, but there is still room for improvement.

Keywords: health literacy, health games, tobacco, adolescents, intervention study

#### TIIVISTELMÄ

Heidi Parisod

#### TERVEYSPELI TUPAKKAAN LIITTYVÄÄ TERVEYDEN-LUKUTAITOA TUKEVANA INTERVENTIONA VARHAISNUORILLA

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Tämän tutkimuksen tarkoituksena oli kehittää ja arvioida terveyspeliä tupakkaan liittyvää terveydenlukutaitoa tukevana interventiona 10–13 -vuotiailla varhaisnuorilla. Tutkimus toteutettiin kaksivaiheisena. Kehittämisvaiheessa tarkastelimme varhaisnuorten (n=39, fokusryhmähaastattelut) näkökulmasta tupakkaan liittyvää terveydenlukutaitoa määrittäviä tekijöitä laadullisella kuvailevalla tutkimuksella. Koostimme yhteenvedon kirjallisuuskatsauksissa (n=15) esitetystä tutkimusnäytöstä koskien terveyspelejä lasten ja nuorten terveyden edistämisen menetelmänä. Lisäksi tarkastelimme nuorten näkemyksiä (n=39, fokusryhmähaastattelu ja n=83, kysely, temaattinen analyysi) ja keräsimme nuorilta palautetta (n=10+44 kyselyt, tilastolliset analyysimenetelmät) terveyspelin nimeltä *Fume* kehitysprosessin aikana. Tutkimuksen toisessa vaiheessa arvioimme *Fumen* soveltuvuutta (käyttö, hyväksyntä, lyhytaikainen vaikuttavuus) terveysohjauksen menetelmänä. Osatutkimus toteutettiin ryppäittäin satunnaistetulla, kokeellisella tutkimusasetelmalla. Tähän osatutkimukseen osallistui 151 varhaisnuorta. McNemar, Fisher's exact ja ei-parametrisiä testejä käytettiin ryhmien välisten ja sisäisten erojen analysointiin.

Kehittämisvaiheen tulosten perusteella tupakkaan liittyvän terveydenlukutaidon tukeminen edellyttää terveydenlukutaitoa määrittävien tekijöiden monimuotoisuuden ja terveysviestien tulkintaprosessin roolin huomioimista. Terveyspelit osoittautuivat aiemman kirjallisuuden perusteella potentiaalisiksi lapsilla ja nuorilla, mutta tutkimusta tarvitaan lisää. Nuorten näkemykset toivat esille, että *Fumen* kehittämisessä huomiota tulee kiinnittää muun muassa tupakoimattomuuden positiivisten puolien korostamiseen ja korkealaatuisiin peligrafiikoihin. Soveltuvuustutkimuksessa kahden viikon ajanjaksona *Fumen* käyttö ( $P \le 0.001$  kaikille arvioille) ja nuorten kiinnostus *Fumea* kohtaan ( $P \le 0.001$ ) olivat suurempaa verrattuna eipelillistettyyn internetsivustoon. Varhaisnuorten mielipiteet interventioista eivät eronneet toisistaan tilastollisesti merkitsevästi. Havaitsimme myönteisiä muutoksia *Fumea* käyttäneessä ryhmässä seuraavissa muuttujissa: positiiviset (P=0.002) ja negatiiviset (P=0.02) savukkeisiin liittyvät mielikuvat ja asenteet savukkeiden polttamista kohtaan (P=0.01). Emme havainneet tilastollisesti merkitseviä eroja tapahtuneissa muutoksissa *Fume*-, internetsivusto- ja kontrolliryhmien välillä.

Tutkimus tuotti uutta tietoa tupakkaan liittyvän terveydenlukutaidon tukemisesta ja terveyspeleistä. Tutkimus osoitti, että *Fume* on soveltuvampi interventio varhaisnuorilla kuin ei-pelillistetty internetsivusto, mutta peli vaatii jatkokehitystä.

Avainsanat: terveydenlukutaito, terveyspelit, tupakka, nuoret, interventiotutkimus

### TABLE OF CONTENTS

ABS	TRA	CT		4
TIIV	ISTE	LMÄ		5
LIST	OF 1	FIGUR	ES AND TABLES	8
ABB	REV	IATIO	NS	9
LIST	OF (	ORIGI	NAL PUBLICATIONS	10
1	INTI	RODU	CTION	11
2	REV	TEW C	F LITERATURE	12
	2.1 2.2 2.3	Health Health	ectives on tobacco use in adolescence	15
3	2.4 AIM	Health	y	20
4	MA	ΓERIA	LS AND METHODS	27
	4.1	Materi 4.1.1	ials and methods used in the development phase	
		4.1.2	Data analysis methods used in the sub-studies in the development phase	
	4.2	Design	n of Fume	33
	4.3	Materi 4.3.1	ials and methods used in the piloting and feasibility phase  Study design, data collection and participants in the cluster randomized trial	
		4.3.2	Implementation of the interventions in the cluster randomize trial	ed 37
	4.4	4.3.3 4.3.4	Instruments used in the cluster randomized trial Statistical analysis methods used in the randomized trial	38
5	4.4 RES		l considerations	
	5.1	The er	ntity of the determinants of tobacco-related health literacy is limensional	
	5.2		rongest evidence supports the use of active video games	
	5.3		cing acceptability requires balancing between different element	
	5 1		cted to the health content and gaming experience	
	5.4	ine ne	ealth game Fume is a feasible intervention	49

#### Table of contents

		5.4.1 The actual use of and interest in Fume higher than that of	f the
		website	50
		5.4.2 Use of Fume resulted in favorable short-term effects	56
	5.5	Summary of the main results	57
6		CUSSION	
	6.1	Discussion of the results	59
	6.2	Validity and reliability of the study	63
		6.2.1 Validity and reliability of the data collection	64
		6.2.2 Validity and reliability of the instruments	65
		6.2.3 Validity and reliability of the results	67
	6.3	Suggestions for future research	69
	6.4	Practical implications	70
7	COl	NCLUSIONS	72
ACI	KNOV	WLEDGEMENTS	73
REF	ERE	NCES	76
APF	END	ICES	87
ORI	GINA	AL PURLICATIONS 1_4	93

### LIST OF FIGURES AND TABLES

Figure 1.	The overall study design
Figure 2.	Testing sessions conducted during the game production
Figure 3.	The design of sub-study V
Figure 4.	Theoretical model of the determinants of tobacco-related health
	literacy in early adolescents as recognized based on the early
	adolescents' (n=39) descriptions
Figure 5.	Conclusions made based on the review of reviews
Figure 6.	Elements included in adolescents (n=83+39) expectations towards a
г. д	tobacco-related health game
Figure 7.	Early adolescents' usage of Fume (Group A) and of the website
г. о	(Group B)
Figure 8.	Early adolescents' (Group A) usage of Fume by gender
_	Early adolescents' (Group A) usage of Fume by age
Figure 10.	Early adolescents' (Group A) usage of Fume by previous gaming habits 52
Figure 11.	Discussions about Fume among early adolescents (Group A) by gender 53
Figure 12.	Discussions about Fume among early adolescents (Group A) by age53
Figure 13.	Discussions about Fume among early adolescents (Group A) by
_	previous gaming habits
Figure 14.	Early adolescents' (Group A) opinions about Fume by gender 54
Figure 15.	Early adolescents' (Group A) opinions about Fume by age 55
Figure 16.	Early adolescents' (Group A) opinions about Fume by previous
	gaming habits
Figure 17.	Summary of the main results
Table 1.	Study designs, samples, data collections and analysis methods of the
	sub-studies, and papers reporting the results
Table 2.	Design of Fume (version 1.1.0)
Table 3.	Determinants of tobacco-related health literacy recognized based on
	the early adolescents' descriptions
Table 4.	Evidence level and quality of the literature concentrating on active
	video games included in the review of reviews
Table 5.	Evidence level and quality of the literature concentrating on sedentary
	games included in the review of reviews
Table 6.	The feedback gathered in the testing sessions 3 and 4
Table 7.	Descriptive statistics for the baseline values of theory-based
	determinants of tobacco-related health literacy for all the participants
	(n=151) in sub-study V
Table 8.	Reliability of the used instruments

#### **ABBREVIATIONS**

AMSTAR Measurement Tool to Assess Systematic Reviews

ASSES Anti-Smoking Self-Efficacy Scale
CEBM Centre of Evidence Based Medicine

CI Confidence interval

CINAHL Cumulative Index to Nursing and Allied Health Literature

GPS Global Positioning System MRC Medical Research Council

NEG-SOES Negative Smoking Outcome Expectations Sub-scale

PEGI Pan-European Game Information

POS-SOES Positive Smoking Outcome Expectation Sub-scale

RCT Randomized controlled trial

RQ Research question

SAS Statistical Analysis System

SD Standard deviation

SOES Smoking Outcome Expectation Scale
SPSS Statistical Package for Social Sciences

WHO World Health Organization

WHO FCTC World Health Organization's Framework Convention on

Tobacco Control

#### LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications, which are referred to in the text with the numbers 1–4.

- 1. Parisod H, Axelin A, Smed J & Salanterä S. 2016. Determinants of tobaccorelated health literacy: a qualitative study with early adolescents. International Journal of Nursing Studies 62, 71–80.
- 2. Parisod H, Pakarinen A, Kauhanen L, Aromaa M, Leppänen V, Liukkonen T, Smed J, Salanterä S. 2014a. Promoting children's health with digital games: A review of reviews. Games for Health Journal 3(3), 145–156.
- 3. Parisod H, Pakarinen A, Axelin A, Danielsson-Ojala R, Smed J & Salanterä S. 2017a. Designing a health-game intervention supporting health literacy and a tobacco-free life in early adolescence. Games for Health Journal 6(4), 187–199.
- 4. Parisod H, Pakarinen A, Axelin A, Löyttyniemi E, Smed J & Salanterä S. 2018. Feasibility of Mobile Health Game "Fume" in Supporting Tobaccorelated Health Literacy among Early Adolescents: A Three-Armed Cluster Randomized Design. International Journal of Medical Informatics 113, 26–37.

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#### 1 INTRODUCTION

A few years ago, when I worked as a nurse, I noticed that the methods used for tobacco-related health education with adolescents were not always in line with the media use habits and devices the adolescents were used to dealing with in their free-time. I got interested about the potential of digital devices that adolescents already use actively for communication, searching for information and entertainment (Lenhart et al. 2015) and how these devices could be better utilized in health education as well. Later, during my master's studies in nursing science, I learned about the possibilities games can offer besides their traditional purpose that is entertainment. The literature on health games suggests that a gamified approach could offer new means to adolescent health education (Baranowski et al. 2008) and offer possibilities to increase engagement and motivation (Hamari et al. 2014). Interest in health games was increasing (Kharrazi et al. 2012) at that time I started to work with my doctoral thesis. There was still research work to be done on this topic.

During my nursing career, I worked with people who were willing to quit smoking. I often heard these patients say that they wished they had never started to smoke. Recent trends in tobacco use show an unequal proportion of smokers across different socio-economic groups (Helldán & Helakorpi 2015; Casetta et al. 2016; THL 2017a). The widening gap in tobacco use based on background increases the health burden of those in more vulnerable positions in society (Braveman et al. 2010). Actions are currently being taken to reduce the demand for tobacco and thus narrow this gap. Providing equal possibilities of a tobacco-free lifestyle for adolescents before tobacco use becomes an addictive unhealthy habit is one of the key approaches (WHO 2017a).

Health literacy has raised the interest of practitioners, researchers and policymakers. It is considered a pivotal concept for public health goals, such as guaranteeing individuals with equal opportunities to achieve and maintain health, and narrowing the health disparities. Researchers and policymakers has given attention to the large variation in health literacy among individuals, and support for health literacy is being highlighted in current health policies (WHO 2013).

Adolescence is considered a crucial time for the development of health literacy and setting the base for a healthy lifestyle. The approach used to support health literacy in adults is likely unsuitable for adolescents due to their state of development (Christie & Viner 2005). For example, adolescents generally have more difficulty in understanding abstract concepts, such as nicotine addiction (Roditis et al. 2016). Despite its importance, health literacy is still poorly understood from the perspective of adolescents, and the amount of evidence-based health literacy interventions targeted at adolescent populations is scarce (Velardo & Drummond 2017). With this thesis, I aim to contribute to filling the presented knowledge gaps.

#### 2 REVIEW OF LITERATURE

In this chapter, I describe existing literature on tobacco use, health literacy, to-bacco-related health education and health game interventions from the perspective of adolescents. In reviewing the literature, I am to provide a basis for the study as a whole and justify its viewpoints. Three systematic literature searches were conducted using PubMed (Medline), CINAHL, the Cochrane Library and the Web of Science databases to generally review evidence on tobacco-related health education interventions, and specifically on tobacco-related health literacy and health game interventions among adolescent populations (see Chapters 2.3 and 2.4). In addition, the literature was searched for related to the main concepts using PubMed (Medline) and CINAHL databases. The search was supplemented with searches of webpages of relevant organizations, guidelines, national legislation and from the internet in general. Manual searches were also conducted using reference lists of the included publications.

#### 2.1 Perspectives on tobacco use in adolescence

Every adolescent should be provided with opportunities to pursue a healthy life (UN 1989), and living tobacco-free is part of a healthy lifestyle. The definition of *tobacco products* includes cigarettes, snus (moist powder tobacco) and other consumable products that consist wholly or partly of tobacco and contain highly addictive and toxic nicotine (Tobacco Act 549/2016). Nicotine can also be inhaled with electronic cigarettes, which are also covered by the Tobacco Act (549/2016).

Along with other countries, Finland has signed the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) and has committed to implementing evidence-based measures aiming at reducing the demand for tobacco. These actions include, for example, communication strategies that increase public awareness about the dangers of tobacco (WHO 2017a). Finland is also one of the first countries in the world that is aiming to be a tobacco-free nation and declaring this aim in the national tobacco legislation (Tobacco Act 549/2016).

#### Hazardous and addictive tobacco

Cigarettes contain thousands of harmful chemicals besides toxic and highly addictive nicotine. Smoking cigarettes endangers the smoker as well as those exposed to the tobacco smoke. Cumulated evidence has strengthened the understanding that smoking has a negative impact on almost every organ of the body. (U.S. Department of Health and Human Services 2014.) Cigarette smoking has been distinctly shown to cause serious health risks and diseases, such as many kinds of neoplastic, cardio-vascular and respiratory diseases, and premature deaths (Jha et al. 2013; U.S. Department of Health and Human Services 2014). For example, in the United States, smoking and exposure to tobacco smoke has caused more than 87% of lung cancer deaths, 61% of pulmonary disease deaths and 32% of coronary heart disease

deaths. In addition to daily and heavy smoking, even intermittent and light smoking has been shown to be harmful to health (Tobacco dependence and cessation: Current Care Guidelines 2012). Intermittent smoking significantly increases the risk for coronary heart disease compared to that of non-smokers (Willett et al. 1987; Luoto et al. 2000). Daily light smoking has been shown to increase the risk of chronic obstructive pulmonary disease (Hukkinen et al. 2012).

Snus is a smokeless tobacco product that is held in the mouth between the gum and lip (Norwegian Institute of Public Health 2014). Snus has been demonstrated to be harmful to health as well (Lee 2013; Norwegian Institute of Public Health 2014; Heikkinen et al. 2015), and it is prohibited to sell it, otherwise supply or pass it on in Finland (Tobacco Act 549/2016). Daily use of snus may expose the user to a 3 to 5 times larger amount of nicotine than daily cigarette smoking (Heikkinen et al. 2015). The exposure varies based on the nicotine content of the snus and depending on how long it is kept in the mouth. Besides nicotine, snus includes carcinogenic tobacco-specific nitrosamines as well as other carcinogenic substances. (Norwegian Institute of Public Health 2014.) The use of snus negatively influences oral health (Heikkinen et al. 2015) and increases the risk of pancreatic, esophageal and oral cavity cancer (Norwegian Institute of Public Health 2014). The use of snus is also related to other increased health risks, such as the risk of heart failure and fatal acute myocardial infarction (Lee 2013). Snus is often associated with athletes, and it may enhance, for example, concentration and aerobic performance. However, snus has several harmful effects to cardiovascular health, muscular strength and anaerobic performance, and thus, to sports performance. (Chagué et al. 2015.)

Electronic cigarettes (or e-cigarettes) are battery-powered devices than are used for vaporizing liquid solution into aerosol. The liquid often consists of propylene glycol and/or glycerin and flavors with or without nicotine. (Schaller et al. 2013.) Evidence shows that electronic cigarettes may contain the same toxicants and carcinogens as conventional cigarettes (Besaratinia & Tommasi 2014). In addition, the heating of the liquids in electronic cigarettes can result in the formation of new compounds not originally included in the liquid (Uchiyama et al. 2013). The most common adverse effect caused by electronic cigarettes is irritation of the mouth and throat (Hartmann-Boyce et al. 2016). Electronic cigarettes can also cause other harmful effects, especially for the respiratory system (Huang et al. 2017). There is still limited research on the long-term effects of electronic cigarettes (Hartmann-Boyce et al. 2016), and electronic cigarettes cannot be recommended for smoking cessation (Kalkhoran & Glantz 2016). Instead, it has been shown that the use of electronic cigarettes among adolescents is associated with future conventional cigarette smoking (Primack et al. 2015). Based on the current national legislation, it is prohibited to sell, otherwise supply or pass on both electronic cigarettes and conventional cigarettes to under 18-year-old children and adolescents (Tobacco Act 549/2016).

Tobacco causes physiological, psychological and social addiction, which is classified as a disease. Tobacco addiction is largely habitual by its nature but is mainly caused by nicotine (especially physiological addiction). Nicotine causes changes

to the nicotine receptors in the central nervous systems and, thus, withdrawal symptoms if the exposure is discontinued (Tobacco dependence and cessation: Current Care Guidelines 2012). Nicotine dependence can evolve quickly, especially among adolescents (DiFranza et al. 2007; O'Dell 2009; Tobacco dependence and cessation: Current Care Guidelines 2012), and even intermittent smoking can cause addiction (DiFranza et al. 2007). DiFranza and colleagues (2007) showed that over half of adolescents lost autonomy by the time they smoked 7 cigarettes per month. It has been suggested that adolescents experience nicotine rewards more strongly than adults, but withdrawal symptoms not as strongly, due to differences in the nervous system (O'Dell 2009).

Besides the health burdens that affect individuals directly, tobacco causes approximately 1.5 billion euros of economic loss to society in a year. The economic loss is caused by direct costs, such as health care costs, and indirect costs, such as sickness-related costs and loss of labor input. (Vähänen 2015.) Tobacco also has a harmful impact on the environment due to the cultivation, production, distribution and consumption of tobacco products. The harmful impacts include, for example, deforestation, loss of biodiversity, emitted greenhouse gases, indoor pollution caused by toxic residue from tobacco smoke and environment pollution due to cigarette butts and toxic third-hand smoke materials (i.e. chemical residual of tobacco smoke that clings to different surfaces). In addition, the cultivation of tobacco plants requires large quantities of chemicals that lead to harmful environmental effects and put the farmers' health in danger, especially in low- and middle-income countries. (WHO 2017b.)

#### Tobacco experimentation among adolescents

The first tobacco experimentation usually takes place in early adolescence when young people are becoming independent and separating from their parents, while they are also increasingly being influenced by peers (Christie & Viner 2005). Weekly cigarette smoking is still rare among 11-year-olds (Inchley et al. 2016). However, 3.9% of 4<sup>th</sup> and 5<sup>th</sup> grade students (approximately 10 to 12-year-old early adolescents) report experimenting with cigarette smoking in Finland. Of the same age group, 2.0% have tried using snus and 3.2% have tried electronic cigarettes. (THL 2017a.) Over two-thirds of those who try cigarettes end up becoming daily smokers (Birge et al. 2017). Tobacco intake at a young age also predicts tobacco use in adulthood (Paavola et al. 2004).

The reasons for tobacco-experimentation in early adolescence are typical for this age group. Early adolescents experiment with tobacco as they want to try something new, belong to a group (Puuronen 2012; Kinnunen et al. 2016), look "cool," and test something that is forbidden and exciting (Puuronen 2012). Early adolescents' thinking is also on a concrete level (Christie & Viner 2005). Thus, they have difficulties understanding the true meaning of abstract concepts such as nicotine addiction (Roditis et al. 2016). *Early adolescence* is defined in this study as the period from 10 to 13 years old.

#### The changing tobacco use habits of adolescents

Adolescents' tobacco use habits are changing. The use of conventional cigarettes has decreased among adolescent populations during the last decades, but at the same time, the use of snus is becoming more acceptable among adolescents. According to the results of the national School Health Promotion study, daily cigarette use among 8th and 9th graders (approximately 14 to 16-year-olds) has decreased from 15.0% to 6.9% in 2008–2017. During the same time period, the use of snus among adolescents of the same age has increased from 1.4% to 4.5%. (THL 2017a.) In addition, other tobacco products are increasingly becoming of interest in adolescent populations. For example, experimentation with electronic cigarettes has increased among Finnish 12 to 18-year-old adolescents from 17.4% to 25.0% between 2013 and 2015 (Kinnunen et al. 2016).

There are large differences in tobacco use habits at the population level based on socioeconomic status (Helldán & Helakorpi 2015), income (Casetta et al. 2016) and educational level (Helldán & Helakorpi 2015; THL 2017a). In 2017, the daily smoking rate of adolescents in upper secondary school (academic track) was 3.4%, and for adolescents in vocational school (vocational track) the rate was 23.2%. The rates for daily snus use were 3.7% and 10.3%, respectively. (THL 2017a.) Moor and colleagues (2015) showed that, in addition to family factors, academic achievements and school satisfaction also explain the association between socioeconomic status and regular smoking among adolescents. In addition, parents' educational levels and their own achieved socioeconomic status and life course roles (e.g., becoming a parent or being married) explain the disparities in adult smoking (Pampel et al. 2014). These differences in tobacco use based on socioeconomic background raise a public health concern as they highlight that there is a greater health burden on those in more disadvantaged positions in the society (Braveman et al. 2010).

#### 2.2 Health literacy as a key factor for achieving equality in health

Health literacy is highlighted in current health policies and is thus gaining increasing attention among researchers, policymakers and practitioners. Health literacy is considered as one of the key factors regarding the goals of public health, such as achieving equality in health and narrowing health inequalities. It also is central in supporting individuals' active roles in the promotion of their own health and health-related decision making. (WHO 2013.) Still, about half of the population in Europe has limited health literacy, it varies greatly between individuals (Sørensen et al. 2015). The pieces of literature specifically concentrating on adolescent populations show similar results (Sansom-Daly et al. 2016). The lower levels of health literacy are connected to socioeconomic background factors, such as financial deprivation, and low social status and education (Sørensen et al. 2015).

Previous studies have demonstrated the association between low health literacy and tobacco use in youth (Lloyd et al. 2013; Vozikis et al. 2014; Sudo & Kuroda

2017) and adult (e.g., Suka et al. 2015; Stewart et al. 2015) populations. On the other hand, there are also results showing that adolescents (Mazanov & Byrne 2007; Dermota et al. 2013) and young adults (Dermota et al. 2013) using tobacco are better informed about tobacco-related issues and have a better understanding of tobacco-specific information than non-users. The reason for this may be that tobacco-users are exposed to tobacco-related information more commonly (Dermota et al. 2013).

In this study, *health literacy* is defined based on the definition of the World Health Organization (WHO) (WHO 1998) as an early adolescent's motivation and ability to access, understand and apply health information in ways that promote and maintain good health. Health literacy is considered as a context and content-specific concept that can be divided into different levels (Nutbeam 2009). According to Nutbeam (2000), *functional health literacy* refers to the lowest level of health literacy and to the ability to achieve and understand factual health information. The second level, *interactive health literacy*, consists of an individual's capacity, motivation and self-confidence to act independently on the knowledge achieved. The third level, *critical health literacy*, refers to the skills needed to take social and political actions to address the determinants of health. Improvements in all the three levels of health literacy are considered to be essential in enabling individuals to make healthy lifestyle choices, improve community health and take actions to change public policies related to health.

#### Health literacy and adolescents

Adolescents and even young children encounter and process health-related information and make decisions that influence their health. Support of health literacy already in childhood and adolescence is essential in regard to guaranteeing equal opportunities for health and attaining public health goals (WHO 2013). In addition to basic education, nurses and other health professionals hold a central position (Dennis et al. 2012) and have a crucial role in supporting health literacy-related capacities and motivation of children and adolescents (Velardo & Drummond 2017). Health professionals are also responsible for providing easily accessible and understandable information (Velardo & Drummond 2017).

It is suggested that the special characteristics of children and adolescents, such as developmental differences and vulnerability to influences, highlight the need for health literacy research focusing especially on their perspective (Bröder et al. 2017). Still, most of the existing health literacy research examines the topic from an adult perspective (Perry 2014; Bröder et al. 2017), and the theoretical assumptions of health literacy are still poorly understood from the perspective of adolescents (Velardo & Drummond 2017). There are a few adolescent-specific, general health literacy models and conceptual frameworks available that consider the development of health literacy with slightly different approaches. Three of these existing models and frameworks applicable to early adolescents and the nursing context are presented by Manganello (2008), Paek et al. (2011), and Wharf Higgins et al. (2009), and the determinants of health literacy presented in these models and frameworks are elaborated on in Article 1. In general, it is suggested that the nature

of health literacy among adolescent populations is multidimensional. Still, most of the existing models have a strong focus on individual determinants of health literacy, and the contextual factors are less emphasized. The current approaches to health literacy are heterogeneous (Bröder et al. 2017). However, it has been presented that, due to the context- and content-specific nature, the approach to health literacy varies depending on the purpose of its use (Nutbeam 2009). For the abovementioned reasons, the special needs of adolescents and the theoretical assumptions of health literacy still require further consideration (Bröder et al. 2017; Velardo & Drummond 2017).

As with theoretical models and conceptual frameworks, no consensus exists on what the most accurate instrument measuring health literacy among adolescents is (Ormshaw et al. 2013). The existing validated health literacy instruments contain both instruments developed specifically for adolescents and previously adult-focused instruments (e.g. TOFHLA and REALM) validated for the use of adolescent populations (Ormshaw et al. 2013; Perry 2014). These also cover instruments measuring self-reported health literacy and instruments with task-performance-oriented questions, as well as instruments measuring functional health literacy or a more complex construct. Both instruments measuring general health literacy and some health topic specific health literacy instruments also exist. Choosing an appropriate instrument to meet the needs of the target group as well as the conceptualization of health literacy used in the study remains a challenge. (Ormshaw et al. 2013.) There are, according to my knowledge, only two instruments (Schmidt et al. 2010; Levin-Zamir et al. 2011) covering partly tobacco-specific questions. However, both of these instruments were developed to measure a broader range of health topics, not solely tobacco-related health literacy.

## 2.3 Health education as a strategy to support tobacco-related health literacy

Health literacy can be supported with *health education* that, according to the definition of WHO, consists of consciously constructed communication strategies (WHO 1998). School is a convenient setting for implementing health education interventions supporting health literacy (Perry 2014) and reaching early adolescents equally regardless of their backgrounds (Basic Education Act 628/1998). In Finland, student welfare services, such as school health care, have a central role in providing tobacco-related health education to children and adolescents (MSAH & Stakes. 2002; MSAH 2004; 2009). Tobacco as a topic is required to be addressed in meetings with the school health personnel, such as the school health nurse, in a suitable manner considering the developmental stage of the child or adolescent (MSAH 2004). Health education about tobacco is recommended to be emphasized during the last grades of primary school (approximately 4<sup>th</sup>—6<sup>th</sup> grades) (MSAH & Stakes. 2002).

Municipalities are responsible for implementing and guaranteeing a suitable environment for tobacco-related health education and other actions aiming to reduce

the demand for tobacco (Substance Abuse Prevention Act 523/2015; Tobacco Act 549/2016). Recent statistics show that implementation of these tobacco-related interventions is executed only moderately in the school context in Finland, and implementation varies between regions. (THL 2017b.)

#### Evidence on health literacy interventions targeted at adolescents

In general, there are some scientifically evaluated health literacy interventions for young target groups. Still, the amount of research literature examining these interventions is limited. Most commonly, these interventions are implemented in educational context instead of health care context and focus on the development of general health literacy. (Perry 2014.)

The systematic literature search I conducted specifically on tobacco-related health literacy interventions resulted in a low amount of literature as well. I conducted the literature search systematically (Appendix A) using four international databases (PubMed/Medline, CINAHL, Cochrane Library, Web of Science) in December 2017. The inclusion criteria stipulated that the research literature should be on tobacco-related health literacy interventions and should have under 18-year-old children or adolescents as the target group. At the abstract level, the inclusion criteria were tightened, and studies (n=7) concentrating solely on media literacy were excluded. Media literacy is included as part of some health literacy models (see, e.g., Manganello 2008), but media literacy as a concept has a narrower focus than health literacy. Media literacy is generally defined as "the ability to understand, analyze, evaluate and create media messages" (Primack et al. 2009).

The literature search on tobacco-related health literacy interventions finally resulted only in two studies. The first study, by Hubbard and Rainey (2007), evaluated a textbook-based intervention among secondary school students (n=669) using a quasi-experimental design. During one semester, the researchers evaluated the intervention's effects on students' health-related (tobacco, nutrition and physical activity) concepts and health literacy-related skills. The intervention was developed based on a national framework that was "designed to support schools in meeting the essential goal of enabling students to acquire the concepts and skills necessary to achieve health literacy." The study showed that both the concepts and skills improved statistically significantly (P<0.001) in the intervention group. The other study, by Bousamra and colleagues (2008), evaluated a physician-led, smoking-related intervention called Drive Cancer Out, aiming to support health literacy among adolescents. A more specific approach to health literacy used in the intervention was not described by the authors. The intervention included a 15- to 20minute slide presentation with the focus especially on the causes of smoking as well as a small group education. In small groups, the adolescents could, for example, see and handle preserved lungs with emphysema and cancer, meet a cancer survivor and sign a pledge to never smoke. The intervention was evaluated using pre-post measurements with 473 fifth grade students. Students rated the intervention positively. The results showed that students' basic medical knowledge of the physical consequences of smoking was at good level already at baseline. The test scores varied from 86% (one week before) to 89% (one week after the intervention). Of the participants, 97% considered smoking to be dangerous before the intervention and 98.5% after the intervention.

#### Evidence on tobacco-related health education interventions in school contexts

Due to the limited amount of research on tobacco-related health literacy interventions, I conducted another systematic literature search to gain more knowledge on tobacco-related interventions. The aim of this literature search was to review existing research evidence on school-based tobacco-related health education interventions without specific theoretical assumptions. I systematically searched for literature (Appendix A) from four international databases (PubMed/Medline, CI-NAHL, Cochrane Library, Web of Science) in October 2017. As inclusion criteria, I focused on literature reporting on under 18-year-old children or adolescents, tobacco-related health education (preventive approach) and school contexts (e.g. school health care, classes). I limited the search to systematic reviews and meta-analyses published during the last 10 years in English. I used a review of reviews approach to be able to examine the existing literature comprehensively. In total, 14 systematic reviews and meta-analyses were included.

The evidence shows that health education provided at schools can support a to-bacco-free lifestyle in young populations (Sherman et al. 2009; Jackson et al. 2011; Saraf et al. 2012; Teesson et al. 2012; Champion et al. 2013; Thomas et al. 2013; 2015; Peirson et al. 2016), although the evidence is not convergent (Sherman et al. 2009; Saraf et al. 2012; Thomas et al. 2013; 2015; de Kleijn et al. 2015; Flynn et al. 2015; Hodder et al. 2017). Addressing the social pressures of tobacco-experimentation can enhance the effectiveness of the interventions (Champion et al. 2013; Thomas et al. 2013; 2015), but conflicting results also exist (Hodder et al. 2017). Based on the positive findings, using an approach that supports adolescents' social competences or a combination that covers both social competences and influences is most beneficial. Interventions focusing on communication of information or social influences only seem not to be effective. (Thomas et al. 2013; 2015.)

Inclusion of supplementary components to school-based interventions, such as community (Saraf et al. 2012; Khayyati et al. 2015) or family-based (Saraf et al. 2012; Champion et al. 2013; Thomas et al. 2016) components, can strengthen the effectiveness of these interventions. However, conflicting results also exist (Thomas et al. 2013; 2015). The use of additional booster sessions may increase the effectiveness of an intervention (Champion et al. 2013; Thomas et al. 2013), especially regarding the long-term effects of the intervention (Thomas et al. 2015).

Peer-led interventions seem to have a positive effect (Saraf et al. 2012; MacArthur et al. 2015), but there is also evidence favoring adult health educators (Sherman et al. 2009; Thomas et al. 2013; 2015). In addition, it may be that, in some cases, the use of peer-educators may even result in negative effects. Peer-led interventions may enhance the use of tobacco among high-risk adolescents, i.e., those that have pro-smoking attitudes or friends who smoke. (MacArthur et al. 2015.)

There is evidence that tobacco-related interventions are more effective on girls than boys (Thomas et al. 2015), although, universal interventions are not optimal in preventing girls from smoking (de Kleijn et al. 2015). With girls, the use of mass media in addition to school-based program components may be beneficial (de Kleijn et al. 2015). In general, the use of digital methods can strengthen positive outcomes of school-based interventions (Champion et al. 2013).

#### 2.4 Health games as health education interventions

Digitality is already a natural part of everyday life for today's adolescents. Adolescents use digital devices actively for communication, searching for information and entertainment (Lenhart et al. 2015). It has been demonstrated that adolescents react positively to web-based tobacco-related interventions (Bowen et al. 2012; Calabro et al. 2017). The perceived interactivity of adolescents and entertainment targeting them are also associated with more favorable tobacco-related outcomes (Khalil et al. 2017), which supports the use of digital interventions. Previous studies, conducted mainly in adults, support the use of digital health literacy interventions, such as computer and multimedia programs (Jacobs et al. 2016). More efficient utilization of digital innovations is also emphasized in health promotion policies (MSAH 2016).

Still, adolescents' engagement with digital interventions remains a challenge. It has been pointed out that only short usage periods of digital tobacco-related interventions may not be sufficient in light of the preferred outcomes (Nădășan et al. 2016). Bowen and colleagues (2012) found out that, despite adolescents' positive attitudes towards the smoking preventive web-based *SmokingZine* intervention, only about half of the adolescents signed in to the website, and 80% of them only signed in once.

#### Digital game playing of adolescents

Digital games are a set of activities that are played according to certain rules to achieve the goal of the game (Smed & Hakonen 2003) using a digital platform such as a computer or a mobile device. Adolescents are interested in digital games, and they play games actively for entertainment (Inchley et al. 2016; Mäyrä et al. 2016). The most popular digital game genres among adolescents are puzzle games. In 2015, 57% of Finnish active players aged 10 to 19 years reported playing these kinds of games. The other top favorite game genres among them were adventure games (50.6%) and sports games (41.6%). Of the same population, 12.4% reported playing educational games. The games were frequently played (88.4% of active players) using mobile devices. (Mäyrä et al. 2016.)

Both girls and boys play digital games. In 2015, 42.7% of 10 to 19-year-old girls and 54.4% of boys of the same age reported playing games actively in Finland. However, some differences exist in the game culture between girls and boys, and

their preferences vary (Suoninen 2013). For example, sports games are more popular among boys than girls; in 2015, 63.9% of boys played these kinds of games. Among girls, the percentage was 18.3%. (Mäyrä et al. 2016.) In general, girls' game playing is often occasional by nature, and they play for short periods at once. Boys tend to spend more time on playing. They also prefer playing against their friends or other players and compare achievements with each other. Also, especially boys like to discuss their game playing either in the game environment or by using other means of communication. (Suoninen 2013.)

#### Possibilities of games in health promotion

The elements included in games (such as points, levels, leaderboards, feedback and narrative) are considered to increase player's engagement and motivation (Hamari et al. 2014). Thus, games have drawn health practitioners' and researchers' attention and raised their interest about the possibilities to use games for health promotive purposes (Kharrazi et al. 2012). Games that have an instrumental purpose besides solely entertainment and are used to influence the player's health positively are called *health games* (Baranowski et al. 2016). In these games, the health-related goal is embedded into the game's design with design elements that aim to influence the targeted health behavior at the time of the game play or to influence determinants or precursors of the targeted behavior. In this way, the health games aim to promote the health of the player. (Baranowski et al. 2016.)

Active video games (or exergames) can be considered to be one type of health games, even though they often are commercial games developed for entertainment purposes. In these games, the motions of the player are used to control the game. Typically, active video games are played using consoles with sensors, such as the Nintendo® (Kyoto, Japan) Wii Balance Board™ or the Microsoft® (Redmond, WA, USA) Kinect® sensor. Mobile games utilizing, e.g., a Global Positioning System (GPS) or an accelerometer, and the tracking of one's movements can be considered to be an active video game as well. One example of a mobile game is  $Pokémon\ Go$  (Niantic Labs), which has motivated millions of people to walk since its release in 2016. When played, the player attains a higher level of physical activity than he or she would without playing (Liu & Ligmann-Zielinska 2017; Marquet et al. 2017).

Commercial active video games have been used for other purposes besides entertainment, for example, for promoting physical activity or for supporting motor skill development or rehabilitation (Kharrazi et al. 2012). Active video games can also be developed with other objectives. In addition to influencing health at the time of game play, active video games can be used for influencing, for example, health knowledge or psychological domains of the player. One example of this is *Alien Health*, that is an active video game using the Microsoft® Kinect® sensor. It is designed to teach adolescents about nutrition while playing the game. (Johnson-Glenberg et al. 2014.)

Other type of health games (referred to here as sedentary health games) are controlled using some type of game controller or a mobile device, usually while seated. From their beginning, sedentary health games have usually been developed for

instrumental purposes and cover a variety of health issues, such as sexual health, pediatric cancer and diabetes. Games have been used for prevention, treatment and rehabilitation as health education interventions. (Kharrazi et al. 2012; Baranowski et al. 2016.) An example of this type of health game is *Escape from Diab*, which is a computer game aiming to reduce risk for Type 2 diabetes and obesity among youth (Thompson et al. 2010; Ledoux et al. 2016). Commercial entertaining games have been used for health purposes as well, for example, as a pain distraction method during painful procedures (Nilsson et al. 2013). The possibilities of both active video games and sedentary health games for children' and adolescents' health promotion are further explored in Article 2.

#### Health game development

Typically, game production is an iterative process that proceeds from an idea and initial concept document to a published version of the game (gold version). New updated versions are published when needed. The production requires expertise, e.g., in gameplay, character, story, art and sound design. (Novak 2007.) In games that are developed for health purposes, the health-related goal is embedded into the design and overall goal of the game. Development of health games requires expertise from game fields and knowledge about the health topic in question, health theories and the context in which the game will be implemented, as well as expertise on health intervention development. (Baranowski et al. 2013.)

The intended target group of the health game is central regarding the usability, understandability, acceptability and viability of the developed health game (Baranowski et al. 2013). However, it has been shown that excessive involvement of the target group is not beneficial considering the effectiveness of the health game intervention. The most beneficial role of the target group seems to be that of informant rather than co-designer. (DeSmet et al. 2016.) Health game research and the amount of available health games have increased during recent years. Still, further research on health game development, and on optimal design elements and target group involvement, is needed (Baranowski et al. 2016).

#### The current evidence on tobacco-related health game interventions

I conducted a systematic literature search using PubMed (Medline), CINAHL, the Cochrane Library and the Web of Science in September 2017 to identify previous research on digital tobacco-related health game interventions with a preventive approach and that targeted adolescent populations. I limited the search to studies conducted within the past 10 years and peer-reviewed scientific original publications written in English. A variety of headings and keywords connected to tobacco, adolescents and games was used (see Appendix A). After screening the titles, abstracts and full papers, 8 papers were included.

In total, 5 scientifically evaluated digital tobacco-related health game interventions were found (see Appendix B). These were *Click City®: Tobacco* (Andrews et al. 2011; 2014), *Flavor Monsters* (Rath et al. 2015), *Fun without Smokes* (Cremers et al. 2012; 2014; 2015), *HeadOn* (Marsch et al. 2007) and an online quiz game (Ip

et al. 2014). Two of the games were stand-alone interventions. The rest (n=3) were larger web-based interventions that included a game or games as part of the intervention. One of the stand-alone game interventions was a mobile health game and the other was a web-based game. Four of the interventions concentrated solely on tobacco, while one targeted a broader scope of substances. The interventions were based on various theories, including the Prototype/Willingness model, the Theory of Reasoned Action/the Theory of Planned Behavior, the I-Change Model and the Elaboration Likelihood Model, and theoretical knowledge on social influences, social competencies, affect heuristic, optimism bias and cumulative risks. The game interventions had been developed in the USA (n=3), China (n=1) and the Netherlands (n=1). The game interventions were evaluated (see Appendix C) using experimental or quasi-experimental designs in school (n=2) and out-of-school contexts (n=3). The sample sizes varied from 272 to 3213 participants and the age of the participants from 10 to 24 years.

Two of the web-based interventions (Click City®: Tobacco and HeadOn) implemented in a school context and including game or games as part of the interventions were more effective in supporting tobacco non-use than the control interventions (Andrews et al. 2011; 2014; Marsch et al. 2007). Andrews and colleagues (2014) showed that intentions and willingness to smoke increased less among students in the Click City®: Tobacco program from baseline (5th grade) to 6th grade (P<0.05 and P<0.05, respectively), and from baseline to 7th grade (P<0.05 and P<0.01, respectively) than among those in the usual curriculum. Favorable changes have also been shown in tobacco-related outcomes with both of the standalone health games; the mobile Flavor Monsters (Rath et al. 2015) and the webbased quiz game (Ip et al. 2014). Rath and colleagues (2015) found statistically significant (P=0.000) favorable differences in anti-tobacco attitudes and beliefs at the three-month follow-up among the participants playing the game. Contrary to the others, the web-based out-of-school intervention with a game as part of the larger intervention (Fun without Smokes) was not effective in supporting tobacco non-use among 10 to 12-year-olds (Cremers et al. 2015).

With *Flavor Monsters*, the favorable effects were observed with those participants who mastered at least the first level of the game. The higher levels mastered were a predictor of more favorable effects. (Rath et al. 2015.) Similarly, the most favorable effects of the quiz game were connected to answering all the quiz questions included in the game (Ip et al. 2014). The amount and type of tobacco-related information included in *Flavor Monsters* game did not influence the engagement and length of play in participants aged 13 to 24 years (Rath et al. 2015). More frequent *Fun without Smokes* website visits were achieved with primary school-aged children when using prompts announcing new tobacco-related games on the website (Cremers et al. 2015).

#### 2.5 Gaps in the knowledge of current literature

Health literacy is essential in regard to guaranteeing equal opportunities for health and supporting adolescents' equal possibilities of a tobacco-free lifestyle regardless of the background of the adolescent. Existing literature on health literacy has focused largely on the adult perspective, and health literacy among early adolescents remains poorly understood despite its importance. The amount of scientifically evaluated health literacy interventions targeting adolescent populations also remains low.

Based on the existing literature on tobacco-related health education interventions, there is still a need to find methods that increase early adolescents' interest towards the interventions and engagement, and thus, effectiveness of the interventions. Moreover, methods that are equally effective with both girls and boys are needed. Health games hold potential for these purposes. Still, the current evidence on tobacco-related health games especially among early adolescents and as stand-alone health game interventions is limited. Further research is also needed about health game development and adolescents' involvement in the development process.

#### 3 AIMS OF THE STUDY

The overall aim of this study was to develop and evaluate the feasibility of a health game intervention supporting tobacco-related health literacy in 10 to 13-year-old early adolescents. The study (Figure 1) was carried out in two phases based on the Medical Research Council's (MRC's) framework for complex interventions (Craig et al. 2008): the development phase, and the feasibility and piloting phase. The development phase was further supplemented with elements from game production process (Novak 2007).

The sub-aims and research questions (RQ) addressed were as follows:

**Development phase:** The aim was to strengthen theoretical knowledge and evidence, and produce a health game aimed at supporting tobacco-related health literacy in early adolescents.

**RQ1:** What do the descriptions given by early adolescents disclose about the determinants of tobacco-related health literacy? (Sub-study I)

**RQ2:** What does previous evidence reveal about the potential of health games in general, in regard to promoting health among children and adolescents? (Substudy II)

**RQ3:** How can the acceptability of a tobacco-related health game be enhanced according to the views of adolescents? (Sub-studies III–IV)

**Feasibility and piloting phase:** The aim was to evaluate feasibility (demand, acceptability and short-term effectiveness) of the developed health game intervention.

**RQ4:** Is the developed health game a feasible intervention in supporting to-bacco-related health literacy in early adolescents compared to a non-gamified website? (Sub-study V)

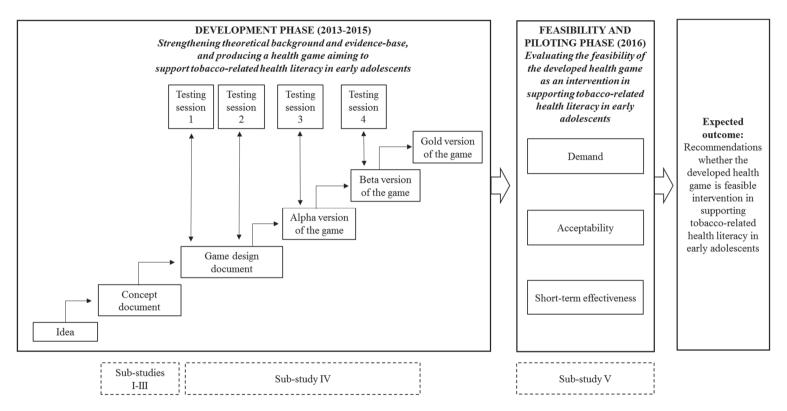


Figure 1. The overall study design

#### 4 MATERIALS AND METHODS

Various materials and methods (Table 1) were used when addressing the research questions (RQ1-4). The MRC's framework for complex interventions (Craig et al. 2008) with additional elements from game production process (Novak 2007) was used as the methodological framework of this study. I as the primary investigator together with the rest of the research group chose MRC's framework (Craig et al. 2008) as it is a comprehensive guide that assists developing effective evidencebased and theory-based interventions that are appropriate for the intended purposes. It also assists paying attention to the complexity of health interventions. As a whole, the framework consists of four phases including 1) development, 2) feasibility and piloting, 3) evaluation and 4) implementation that are covered with gathering best available evidence and conducting series of empirical studies. (Craig et al. 2008.) This study focuses on the first two phases of the framework (Craig et al. 2008) that cover strengthening the evidence- and theory-base of the developed intervention (development phase) and evaluating its feasibility (piloting and feasibility phase). Feasibility studies are important part of health intervention development as they enable testing key uncertainties of the developed intervention and gather evidence for its appropriateness (Craig et al. 2008; Bowen et al. 2009). Feasibility evaluation can focus for example on the acceptability (i.e. how the target group reacts to the intervention), demand (i.e. how the intervention is for example actually being used) and limited effectiveness-testing (i.e. to test the effectiveness of the intervention for example with intermediate outcomes and short follow-up period) (Bowen et al. 2009) as done in this study.

In this chapter, I present the materials and methods used in this study in two parts: first, for the sub-studies under the development phase, and then, for the piloting and feasibility phase. After this, I concentrate on the ethical considerations relevant for this study.

#### 4.1 Materials and methods used in the development phase

The development phase consists of sub-studies I–IV. The study designs, participants, and data collection and analysis methods used in these sub-studies are presented next.

## 4.1.1 Study designs, data collection and participants in the sub-studies in the development phase

#### A qualitative descriptive study on tobacco-related health literacy (I)

We conducted a qualitative descriptive (Sandelowski 2000) study (sub-study I) in 2014 with 10 to 13-year-old early adolescents (4<sup>th</sup> to 6<sup>th</sup> graders). Our aim was to strengthen theoretical knowledge on tobacco-related health literacy from the perspective of early adolescents. The informant recruitment, setting and data collection are described in detail in Article 1. In brief, we collected the data from two schools in southern Finland using focus groups (Krueger & Casey 2009). We chose the participating schools purposively (the strategy of maximum variation) (Patton 1990) to include both adolescents following the general curriculum and those with special educational needs. We created ten focus groups at the schools and divided the participating early adolescents (n=39; girls n=26, boys n=13) into the groups based on school, school day's schedule, age and gender. I, as the primary investigator, monitored and audiotaped the focus groups. I used an interview guide that contained questions about the early adolescents' thoughts and experiences regarding tobacco-related health communication, especially, when it came to accessing, understanding and using tobacco-related information.

Table 1. Study designs, samples, data collections and analysis methods of the sub-studies, and papers reporting the results

Phase	RQª	Sub- study	Design	Sample	Data collection	Analysis method	Reported in
	RQ1	I	Qualitative descriptive	10 to 13-year-old early adolescents (n=39)	Focus groups	Deductive thematic analysis	Article 1
	RQ2	II	Review of reviews	Systematic reviews and other review articles reporting a systematic search (n= 15)	Systematic literature search	Narrative synthesis	Article 2
DEVELOPMENT PHASE	RQ3	descript	Qualitative	13 to 16-year-old adolescents (n=83)	Online, open-ended questionnaire	Inductive thematic analysis	- Article 3
			descriptive	Same sample as in sub-study I	Same data collection method as in sub-study I	Deductive thematic analysis	
		IV	Quantitative	10 to 13-year-old adolescents (n=10)	Semi-structured questionnaire	Statistical methods (descriptive statistics)	Article 3
		descriptive	9 to 16-year-old adolescents (n=44)	Structured questionnaire	Statistical methods (descriptive statistics)		
FEASIBILITY AND PILOTING PHASE	RQ4	V	Single-blinded, three-armed cluster randomized trial	10 to 13-year-old early adolescents (n=151)	ASSES and SOES instruments, structured questionnaires and tracked intervention usage	Statistical methods (descriptive statistics, McNemar's test, Wilcoxon Signed Ranks test, Fisher's exact test, Mann-Whitney U test and Kruskal-Wallis test)	Article 4, summary (see also Parisod et al. 2017b)

<sup>&</sup>lt;sup>a</sup> RQ=The research question to which we sought answers with the sub-study or sub-studies

#### A review of reviews on health games (II)

We analyzed reviews of health games (sub-study II) to identify and summarize existing evidence on the effectiveness of digital games in general in health promotion among children and adolescents (under 18 years of age). We chose this approach (Becker & Oxman 2009; Smith et al. 2011) so that we could examine the topic comprehensively and summarize the existing evidence. The literature search, inclusion and exclusion criteria, data extraction, and quality and level of evidence assessment of the included literature are described in Article 2. Briefly, we conducted a systematic literature search in May 2013 from five international electronic databases: the Cochrane Library, PubMed (Medline), Embase, CINAHL, and PsychInfo. We updated the search in August 2013 and performed a supplementary search using Google Scholar. We limited the search to systematic reviews (including meta-analyses) and other type of review articles that reported a systematic search. Another reviewer and I independently screened the literature following the inclusion and exclusion criteria, which was determined a priori. The screening process proceeded from titles and abstracts to full texts. We discussed any discrepancies at each step to achieve a consensus.

We included a total of 15 review articles and extracted the data following the review questions. We scored all the included systematic and non-systematic reviews with the AMSTAR checklist (Shea et al. 2007). We also used the AMSTAR scores for evaluating the quality of the included systematic reviews. We decided on the level of evidence of the included literature by applying the guideline of the Centre for Evidence-Based Medicine (CEBM) (Centre for Evidence-Based Medicine 2009).

#### A qualitative descriptive study on adolescents' expectations (III)

We used a qualitative descriptive study design (sub-study III) to increase our understanding of both 13 to 16-year-old adolescents (7<sup>th</sup> to 9<sup>th</sup> graders, later referred as "older adolescents") and 10 to 13-year-old early adolescents (4<sup>th</sup> to 6<sup>th</sup> graders) in regard to their expectations towards tobacco-related health education and a health game intervention. We focused both on older and early adolescents as it was expected that older adolescents would have pervasive experiences on the topic (such as regarding peers' tobacco experimentations and tobacco-related health education), and thus, valuable views regarding the development of the intervention. We also considered the early adolescents an important group as they represented the target group of the health game to be developed.

We collected the data for this study in two parts before producing the health game. In the first part in 2013, we used an online questionnaire including background and open-ended questions with older adolescents. We shared the questionnaire on social media using an open Facebook page and snowball sampling (Goodman 1961; Sadler et al. 2010). We continued the data collection with the same questionnaire in a junior high school located in southern Finland to achieve saturation. We chose the participating adolescents at the school purposively (Patton 1990) and used age

as the inclusion criterion. Altogether 83 older adolescents (girls n=38, boys n=45) participated in this study.

We conducted the second part of the data collection in 2014 with early adolescents. We collected the data during the same focus groups that were used to collect data for sub-study I. Thus, the same early adolescents (girls n=26, boys n=13) participated in this sub-study as well. We included questions about the health game to be developed in the interview guide for this sub-study. A more detailed description of the data collection procedures is presented in Article 3.

#### Gathering feedback of the produced health game (IV)

We used the data gathered with sub-studies I-III and additional relevant information to model a mobile health game called *Fume*. The game production process (Novak 2007) proceeded from the concept document to a game design document and alpha, beta and gold versions of the game. We exposed the design to adolescents and health promotion professionals, and asked for their feedback during four iteration rounds and testing sessions in 2015 (Figure 2). We revised the game design between each iteration round based on the feedback. The development process of *Fume* and the four testing sessions is presented in more detail in Article 3.

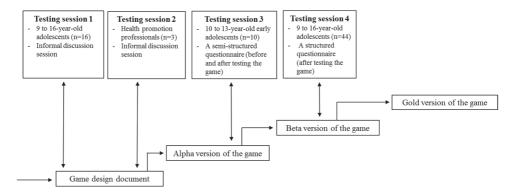


Figure 2. Testing sessions conducted during the game production

The feedback in testing sessions 1 and 2 was received during informal discussion sessions. In sessions 3 and 4, we collected data to evaluate success and recognize further development needs of the design of *Fume* from the adolescents' perspective. We used the alpha version of the game (the first playable version) in testing session 3. Early adolescents aged 10 to 13 (n=10; girls n=4, boys n=6) tested the alpha version. They filled out a questionnaire developed for the testing session partly before (background information and expectations towards *Fume*) and partly after (views about *Fume*) the game testing. We carried out testing session 4 with the beta version of the game (a complete version). Adolescents aged 9 to 16 (n=44; girls n=20, boys n=24, N/A n=2) from a school located in southern Finland participated in testing the game. They answered a short questionnaire including one 5-point Likert-scale question evaluating the game post-testing.

## 4.1.2 Data analysis methods used in the sub-studies in the development phase

#### Qualitative data analysis (I, III)

We used thematic analysis (Braun & Clarke 2006) for analyzing the textual data of the qualitative descriptive studies (sub-studies I and III) focusing on the content of the adolescents' descriptions. We chose thematic analysis as it is a flexible method independent of theory and epistemology (Braun & Clarke 2006). It is considered suitable for producing a descriptive summary that employs a relatively low level of interpretation (Vaismoradi et al. 2013).

The analytic process in sub-study I was deductive, and it is described in detail in Article 1. We did the coding following a coding frame. The frame included a combination of the determinants of health literacy presented in three previous adolescent-specific models applying to the nursing context; Manganello (2008), Wharf Higgins et al. (2009) and Paek et al. (2011). We analyzed the remaining data not fitting into the pre-existing coding frame inductively. As the primary researcher, I first coded the data, and then, formed initial themes. The coding as well as the initial themes were further refined based on constructive criticism and feedback provided by the rest of the research group. We named the themes with expressions that embodied the early adolescents' descriptions after a consensus.

In sub-study III, we first analyzed the 13 to 16-year-old older adolescents' descriptions inductively. I, as the primary researcher, coded the data in a data-driven manner. I also grouped the coded data extracts using tables and mind-maps to form initial sub-themes and further initial major themes. The initial coding and themes were repeatedly reviewed by the rest of the research group and refined based on the discussions. We ensured the relationship between the themes and the raw data and reviewed the formed themes against internal homogeneity and external heterogeneity. The final version of the themes was defined and named at the end of the iterative analysis process. Then, we analyzed the data set concerning the 10 to 13-year-old early adolescents' views deductively, following the themes formed based on the older adolescents' descriptions. The deductive analysis process proceeded in a similar manner as in sub-study I. The analysis process of sub-study III is presented as a whole in Article 3.

#### Narrative synthesis (II)

We applied a narrative synthesis method (Popay et al. 2006) in the review of reviews (sub-study II). We chose this approach as a statistical pooling, such as statistical meta-analysis was not considered feasible due to the variety of outcomes, instruments and interventions used in the included systematic reviews and reviews. We first organized the assessed AMSTAR scores (for systematic and non-systematic reviews), the level of evidence and the quality of the systematic reviews, as well as other extracted data using tabulation and grouping. Then, we compared the results and characteristics of the included literature and identified patterns. We assessed the robustness of the synthesis based on the AMSTAR scores, the quality

of the included systematic reviews and the level of evidence, before we drew conclusions about the results.

#### Statistical analysis (IV)

We used descriptive statistics with the data that we collected in testing sessions 3 and 4. We used frequencies, percentages, means and standard deviations (SD) when applicable to characterize the adolescents' feedback on the tested game. We performed the analysis with Statistical Package for the SPSS® Statistics for Windows, version 23.0 (IBM Corp, Armonk, NY, USA).

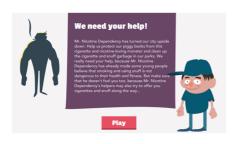
#### 4.2 Design of *Fume*

We produced the first published version (gold version, version 1.1.0) of the mobile health game called *Fume* at the end of the development phase. The production was done in cooperation with a game company (NordicEdu) specialized in applied games. We designed *Fume* to address the determinants of tobacco-related health literacy that founded on existing theoretical health literacy models, conceptual frameworks and early adolescents' (n=39) descriptions (sub-study I). This set of determinants is referred in this thesis as "theory-based determinants of tobacco-related health literacy". Other relevant theoretical and scientific literature was used to supplement the theoretical design of the game (see Article 3, Figure 4). In the game, we also included other design elements identified in the early and older adolescents' descriptions (sub-study III), compromising on some issues. For example, we left some elements for the next, expanded versions of the game due to limited resources. We made some revisions to the design of the game based on the feedback gathered in testing sessions 1–4. See Article 3 for more information about the production process.

The goal of *Fume* is to support tobacco-related health literacy and a tobacco-free lifestyle with a preventive approach. *Fume* (version 1.1.0) consists of five minigames including short tasks that concentrate on tobacco-related topics. The animated scenes in the minigames are founded on adolescents' descriptions (substudies I and III). The scenes illustrate the positive sides of tobacco non-use and negative consequences of tobacco use to the player. The game application introduces the minigames to the player in a random order. Short textual information about the topics is available from the start screen of the application as well. The goal of the player in the game is to perform the given tasks within the given time limit. The game gives feedback to the player based on performance and choices made in the game. More detailed information about *Fume* (version 1.1.0) is available in Table 2 and Article 3.

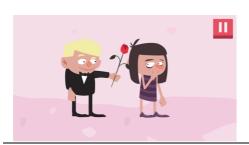
Table 2. Design of Fume (version 1.1.0)

#### Screen shots of Fume









#### Description of the design of Fume

- The game concentrates on the topic of tobacco with a humoristic, partly exaggerated style, but still based on evidence-based information about tobacco
- Playing the game through takes from few minutes to tens of minutes depending on the player's performance
- The content of the game is introduced at the beginning with a story in an adolescent-oriented manner
- Short textual information connected to the topics included in the game is available from the start screen besides the minigames
- The goal of the player in the game is to complete the minigames and tasks given within given time limit or the player loses one of the given three lives
- The minigames concentrate on: sports performance and health (bus minigame), the environment (environment minigame), nicotine addiction and financial side of tobacco use (piggy bank minigame), peer pressure ("Do you want one" minigame) and various facts about tobacco (quiz minigame)
- The minigames are designed to address the following theory-based determinants of tobacco-related health literacy: knowledge, social skills, attitudes, beliefs/perceptions, experiences, motives, self-efficacy, role expectations and interpretation of health messages
- The minigames have different endings depending on the choices made in the game and player's performance
- The feedback about the choices and performance is given to the player with scores and animations

#### 4.3 Materials and methods used in the piloting and feasibility phase

The piloting and feasibility phase includes one sub-study (V). The study design, data collection procedures and analysis methods we used as well as participants taking part in this sub-study are presented in this section.

## 4.3.1 Study design, data collection and participants in the cluster randomized trial

We conducted a single-blind, three-armed cluster randomized trial (Puffer et al. 2005) (sub-study V) in spring 2016 (ClinicalTrials.gov identifier: NCT02717910). This feasibility study concentrated on comparing the short-term effectiveness on early adolescents of *Fume* and a non-gamified website with a no-intervention control group. We used the outcomes derived from the theory-based determinants of tobacco-related health literacy (sub-study I, Article 1) for evaluating the short-term effectiveness. Anti-smoking self-efficacy was considered as the primary outcome. We also compared the demand for and acceptability of *Fume* and the website. The study design is presented in Figure 3 and a detailed description of the study procedures in Article 4.

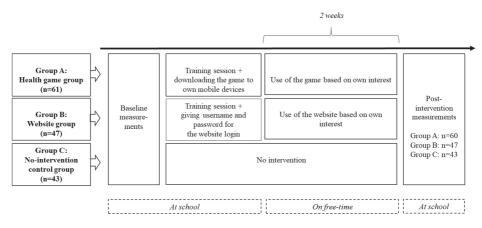


Figure 3. The design of sub-study V

In brief, we randomly chose three municipalities for the study. The eligibility criteria for the municipalities were: 1) to have more than 10 000 inhabitants (Population Registration Center 2015), 2) to have high (11.4% or higher) adolescent to-bacco prevalence (Sotkanet.fi. 2013) and 3) to be located in southwestern Finland. We randomly allocated the early adolescents into three groups: the health game intervention group (group A), the website intervention group (group B) and the no-intervention control group (group C) in clusters at the municipality level. This was done to prevent contamination between the participants in different groups. The early adolescents were blinded to the intervention of interest.

#### **Data collection**

We used paper-based questionnaires for measuring the outcomes at baseline and at a two-week follow-up (post-intervention) with the same participants. We evaluated the demand for the interventions by tracking the actual use of *Fume* with the GameAnalytics tool and the website with a user-tracking plugin during the two-week study period. We evaluated the acceptability with questionnaires concentrating on early adolescents' opinions and their interest towards the interventions at post-intervention. All the participating early adolescents also filled out a background information questionnaire at baseline. More detailed information about the data collection of this sub-study is presented in Article 4.

#### Participating early adolescents

We used power calculation and methodological literature on cluster randomized trials (Puffer et al. 2005) to estimate the sample size. We made the calculation using the primary outcome (anti-smoking self-efficacy) and early adolescents' average anti-smoking self-efficacy scores measured by Chen et al. (2015). We used a power level of 0.80 and a significance level of 0.05 (2-sided). The calculation indicated that we would need at least 30 participants in each group (A–C) to detect mean differences of 10% in anti-smoking self-efficacy between the groups at the end of the study. We aimed at higher sample sizes (at least 45 participating early adolescents in each group) as it is recommended to have 50% or larger samples with cluster than individually randomized trials due to possible correlation between the individuals within a cluster (Puffer et al. 2005).

We recruited the participating early adolescents from eight medium-sized or large schools (at least 100 students and/or 6 classes) located in the three participating municipalities. The eligibility criteria for the early adolescents included that he or she must: 1) be 10 to 13 years old, 2) be able to communicate either in Finnish, Swedish or English, and 3) have daily access either to a smart phone or a tablet computer in their free-time.

In total, 151 early adolescents participated in this sub-study. We nearly achieved the aimed sample sizes, as there were 61 participants in the health game group, 47 in the website group and 43 in the no-intervention control group. Of the participating early adolescents, 79 were girls and 72 were boys. Altogether, 43.0% (n=65) of them did not remember receiving health education about cigarettes and 72.2 % (n=109) about snus during the current school year. More detailed background information about the participating early adolescents is presented in Article 4 (Tables 2-4.)

#### 4.3.2 Implementation of the interventions in the cluster randomized trial

#### **Health game group (Group A)**

The participating early adolescents in the health game group (group A) received the *Fume* intervention. First, they took part in a short, face-to-face training about *Fume*, which we provided to them at school. The early adolescents tested the game for the first time during the training. We also instructed them during the training to address any problems they had in using the game. We downloaded the game to their mobile devices (smart phones or tablet computers) at school or they did it via a private invitation link at home (this depended on the mobile operating system of the device). *Fume* was only available for research use at the time of the study to prevent early adolescents in other groups from having contact with it. Then, the early adolescents had two weeks to use *Fume* based on their own interest in their free-time. An individual code was generated automatically for each downloaded game application. Each game application had two accounts. One was meant for the early adolescent participating in this study, the other one was, e.g., for family members who wanted to test the game. We used the individual code and account meant for the participating early adolescent for tracking the usage of the game.

#### Website group (Group B)

The early adolescents in the website group (group B) received intervention via a website. The website had similar content to that that was in *Fume*, but was nongamified. Both interventions included the same story that introduced the content to the user, the same tobacco-related content and the same graphics. The website intervention was implemented using the same protocol as the health game intervention (training session at school and two weeks of usage based on own interest) apart from downloading. Using the website required a user name and password that we gave to the participants. Each early adolescent had a different user name, which allowed us to track website use individually. We also offered the early adolescents an extra guest user name and password for, e.g., family members wanting to test the website.

#### **Control group with no intervention (Group C)**

The early adolescents in the control group (group C) received no intervention. Still, they participated in the baseline and post-intervention measurements (Figure 3).

#### 4.3.3 Instruments used in the cluster randomized trial

In sub-study V, we used two previously developed instruments (Chen et al. 2015), the Anti-Smoking Self-Efficacy Scale (ASSES) and the Smoking Outcome Expectation Scale (SOES) (Chen et al. 2015), and three short, structured questionnaires

developed for this study for measuring outcomes related to the theory-based determinants of tobacco-related health literacy (see Article 4, Table 1). We developed the questionnaires based on the results gathered in sub-study I and piloted them with early adolescents (n=7) before conducting this sub-study. In addition, we used an open-ended question (*What are the possible consequences of cigarette smoking/snus use?*) and an alternative answer option concerning the questions about snus (*I don't know what snus is*) for evaluating knowledge about tobacco. We operationalized the answers to the open-ended question for statistical analyses (describes any consequences: yes/no). We also developed and used a background questionnaire and a short questionnaire measuring acceptability of *Fume* and the website. The questionnaire contained a structured, 4-point Likert-scaled question concerning early adolescents' opinions (*What is your opinion of Fume/the website?*) and a dichotomous question evaluating raised interest towards the interventions (*Did Fume/the website provoke discussions among your friends?*).

#### **Anti-Smoking Self-Efficacy Scale (ASSES)**

ASSES measures early adolescent's self-efficacy to accomplish anti-smoking behavior including refusal skills, rejection of offers, resistance to temptation and pressure, and implementation of smoking bans (referred to as anti-smoking self-efficacy). The instrument consists of 15 items with 4-point Likert scale answer options. The total ASSES score varies from 15 to 60. ASSES was developed for and validated with 10 to 12-year-old early adolescents. Based on psychometric testing, ASSES has good validity and reliability. (Chen et al. 2015.)

#### **Smoking Outcome Expectation Scale (SOES)**

SOES assesses one's judgement of the likely consequences of cigarette smoking (referred to as smoking outcome expectations). It consists of two sub-scales that concentrate separately on positive (POS-SOES) and negative outcome expectations (NEG-SOES). The positive outcome expectations refer to positive perceptions related to the outcomes of smoking, such as smoking representing maturity and courage. On the contrary, the negative outcome expectations refer to perceptions connected to the adverse effects of smoking. Both the sub-scales have three 4-point Likert scale items each, and the scores of both POS-SOES and NEG-SOES vary from 3 to 12. As with ASSES, SOES was also validated with early adolescents and it was found to have good validity and reliability. (Chen et al. 2015.)

#### 4.3.4 Statistical analysis methods used in the randomized trial

We performed the statistical analyses in sub-study V mainly with Statistical Package for SPSS® Statistics for Windows, version 23.0 (IBM Corp, Armonk, NY, USA). 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). We used frequencies, percentages, medians and ranges when applicable to

characterize the collected background information on the participants and the outcome measures.

We examined the frequency distributions with the Shapiro-Wilk test and used non-parametric tests due to skewed distributions. We performed various statistical tests (McNemar's test, Wilcoxon Signed Ranks test, Fisher's exact test, Mann-Whitney U test and Kruskal-Wallis test) using the intention-to-treat principle. We set the level of statistical significance at P < 0.05 with all the tests. Confidence intervals (95%) were calculated to provide information on the estimated effect sizes and their precision. We also calculated the Cronbach's alpha for the tobacco use motives questionnaire developed for this study and translated versions of ASSESS and SOES instruments.

We performed both within and between group analyses. We used McNemar's test with categorical data to evaluate change over the study period (baseline–post-intervention) within groups A, B and C). The non-parametric Wilcoxon Signed Ranks test was used for within-group testing when the dependent variable was on interval scale. We used Fisher's exact test with categorical data for testing differences between the independent groups (A–C). The non-parametric tests (Mann-Whitney U and Kruskal-Wallis tests) were used when the dependent variable was on interval scale. Before we performed the between-group comparisons for outcomes, we first calculated the changes in each group. We used the Mann-Whitney U test for pairwise testing if the Kruskal-Wallis test indicated a statistically significant difference between the three (A–C) groups.

We conducted supplementary subgroup analyses and used the same tests presented above for these purposes. We tested the differences in the change in positive and negative smoking outcome expectations, and attitudes towards eigarette use between subgroups with combined information about the original groups (A–C) and background information (experiences of being offered eigarettes, parents', other relatives' and authorities' eigarette smoking habits, authorities' snus use habits and early adolescents' values concerning money) (see Article 4). These supplementary analyses were performed as we observed statistically significant unbalance between the intervention and control groups in the abovementioned background factors. We also performed subgroup analyses, reported in this summary (see also Parisod et al. 2017b), based on age, gender and previous gaming habits with the data (actual use, interest, opinions) from the health game group (Group A).

#### 4.4 Ethical considerations

We followed good research practices founded on the principles of research integrity (Finnish Advisory Board on Research Integrity TENK 2012; ALLEA 2017) throughout the study. The study was designed, conducted and reported with meticulousness, accountability, accuracy and honesty. The research participants and participating organizations were respected.

This study addresses two special topics from the ethical point of view. First, the study participants were adolescents. We carefully considered the unique aspects of research involving minors (Caskey & Rosenthal 2005) at every step of the research process. Second, the use of digital games for health promotion purposes raises some ethical questions regarding their possible limitations besides the known advantages (Parisod et al. 2014b; Reid Chassiakos et al 2016; Hyrynsalmi et al. 2017). These issues are discussed in more detail in this section.

#### Research integrity

We applied and received ethical pre-approval from the Ethics Committee of the University of Turku separately for sub-studies I, III and V. We obtained permission to conduct the studies at schools from each of the participating municipalities according to their policies as well as from the participating schools' principals. We requested and received the permission to translate and use the ASSES and SOES instruments from the copyright holders by email.

We verbally informed all the participants in sub-studies I, III–V, with the exception of those recruited via social media, about the study and its purpose. This information stated that participation was voluntary and what participation would actually entail. Participants were also informed about the confidentiality procedures. In sub-studies I, III and V, all the participating adolescents and their guardians also received the information in written form with contact details. The information letters were separately written to adolescents and their caregivers using language fitting for the different purposes. For sub-study III, involving social media, separate information letters for the adolescents and their guardians were attached to the study's open Facebook page. At schools (I, III and V), the information letters were distributed during a school day, and the adolescents had a week to discuss the study with their guardians before making decision about their participation.

We required written informed consent from each participating adolescent in substudies I and III, and from both the adolescent and one of the guardians in substudy V. In sub-study IV, participation in the testing sessions and a completed feedback form on the game was considered as consent.

Adolescents could answer the questionnaires (III and IV) and participate in the focus groups (I and III) anonymously. We also maintained confidentiality in substudy V by coding the data with individual numbers given to the early adolescents. We created a list to be able to combine the data from baseline and post-intervention from different data sources. In reporting the results, we ensured that either the individual adolescents, participating schools or municipalities could not be recognized from the results. We stored all the electronic data behind a password and the paper questionnaires in a locked space.

#### Adolescents as research participants

Most of the research participants in this study were adolescents, which required noticing some special ethical considerations (Caskey & Rosenthal 2005). The study was non-invasive and evaluated to have very low risks for adolescents. To-bacco as a topic is not among the most sensible ones and it is discussed commonly at school, but still some adolescents may feel uncomfortable talking about it. This was noted when forming the focus groups (Daley 2013). The early adolescents were divided into small groups (approximately 4 participants in each) in a way that in each of the groups there were only girls or only boys, and the age difference between the participants was a maximum of two years.

We respected adolescents' autonomy (Caskey & Rosenthal 2005) and their right to have their views taken into account (UN 1989). We asked for an active written informed consent primarily from the adolescents themselves and their guardians were informed about the study. With the younger group of adolescents, the 10 to 13-year-olds, guardians' consent was demanded. In sub-studies I and III, the guardians were offered a form that they could use to withdraw their child from the study (passive consent). In sub-study V, the active written informed consent was asked from one guardian per participant in addition to the early adolescent, as the data collection required using the participants' own mobile devices, and it was executed partly outside school hours. These procedures were based on the Convention on the Rights of the Child (UN 1989), Finnish law concerning human rights (The Constitution of Finland 731/1999) and research ethics guidelines (Finnish Advisory Board on Research Integrity TENK 2009).

#### **Ethical aspects on games as health promotion interventions**

In this study, we developed a health game and used it as an intervention in early adolescents. Games have several advantages that support their use in health education purposes, but some limitations also exist (Parisod et al. 2014b; Reid Chassiakos et al. 2016; Hyrynsalmi et al. 2017). The potential for games lies in their fun and attractive nature. Games are considered to offer new possibilities for health promotion by reaching audiences that are difficult to reach with more traditional messaging, and offering individualized feedback and support (Parisod et al. 2014b; Reid Chassiakos et al. 2016). Games can also motivate people to take part in different activities and to change behavior (Hamari et al. 2014). The immersive and powerful nature of games can be beneficial, but at the same time it raises some questions, especially concerning children and adolescents, that require consideration from an ethical perspective.

Children and adolescents as vulnerable groups are sensitive to various influences, and the role of adults is to advocate on their behalf. Children and adolescents may not have the capabilities to evaluate materials provided to them. For this reason, health game developers should pay attention to, e.g., criteria (National Audiovisual Institute 2016) and rating systems (such as Pan-European Game Information

(PEGI) age rating system, see www.pegi.info) on age-appropriate contents to protect the young users and limit the possibilities for inappropriate content. In addition, the rights of the child as a health care client or patient (Act on the Status and Rights of Patients 785/1992) should be respected. Thus, it may be questionable to disguise interventions with a game-like approach in health care context without expressing the actual intended purpose, even though the intention is to promote health.

Games are repeatedly discussed in the media and questions about potential adverse effects of digital game has been raised. Still, the undesirable effects are often overlooked in applied game research (Hyrynsalmi et al. 2017). From the point of view of the ethically sustainable use of health games, attention needs to be payed to the sedentary and screen time resulting from playing games, and associated health outcomes. For example, screen time in children and adolescents is considered as a risk for obesity due to connected unhealthy eating habits and reduced sleeping duration (Robinson et al. 2017). Some literature also suggests that digital media may have a negative impact on the cognitive development of children. However, the current evidence highlights the role of the age of the child, the content of the media and the social context where the media is used instead of considering all kinds of media use as harmful. (Anderson et al. 2017.)

Traditionally, guidelines concerning the use of games and other digital media among children and adolescents recommend limiting the screen time to a maximum of two hours per day (such as Ministry of Education and Culture & Nuori Suomi association 2008). However, there have been discussions about the outdated nature of these kinds of time limit-based recommendations, as the variety and possibilities of media use have changed tremendously during recent years. The new policy statement on media use among school-aged children and adolescents presented by the American Academy of Pediatrics (2016) recommends paying attention to the types and content of the media, media-free time and adequate sleep, physical activity and other behaviors essential for health instead of recommending strict time limits for children ages 6 years and older.

Another issue that raises discussions and ethical concerns is problematic gaming. In general, most players do not have game-related problems. Still, small number of adolescents has difficulties in controlling their playing (Männikkö et al. 2017). This kind of problematic and compulsive gaming is shown to be connected to fatigue, sleep interference, depression and anxiety symptoms (Männikkö et al. 2015). Even though problematic gaming is usually associated to entertaining games, such as role-playing games and massively multiplayer online games (Männikkö et al. 2017), this is an aspect that needs consideration regarding health games as well.

Based on the current literature, it can be stated that ethically sustainable use of games in the promotion of children's and adolescents' health starts already during the development phase. Moreover, ethically sustainability can be promoted by paying attention to the means of utilizing the health games and noticing the possible individual limitations of adolescents. Besides these recommendations, the use of

health games, such as in the school health care context, requires attention and evaluation skills from those recommending or utilizing the games. Even though, the amount of available health games has increased during recent years, many still lack evidence-based design and vary largely in quality (Watson et al. 2016; Reid Chassiakos et al. 2016). Thus, the label of "health game" is not self-evidently a guarantee of a reliable health intervention.

These abovementioned ethical issues were taken into consideration in this study during the development and evaluation of the health game Fume. For example, the game sessions of Fume were designed to be short to minimize sedentary time spent playing the game, and the content of the game was carefully created. The development process of Fume was designed based on the MRC's framework on complex interventions (Craig et al. 2008) as well as on research evidence and theoretical knowledge. Health care professionals, and health promotion and educational specialists were consulted during the development process, and the purpose of the study and aim of Fume was declared to the participating early adolescents. When evaluating the feasibility of Fume, both possible favorable and negative outcomes were noticed in the analyses.

#### 5 RESULTS

In this chapter, I present a summary of the results gathered in this study. I present the results according to the research questions (RQ1–4);

- What do the descriptions given by early adolescents disclose about the determinants of tobacco-related health literacy? (RQ1, sub-chapter 5.1),
- What does previous evidence reveal about the potential of health games in general, in regard to promoting health among children and adolescents? (RQ2, sub-chapter 5.2),
- How can the acceptability of a tobacco-related health game be enhanced according to the views of adolescents? (RQ3, sub-chapter 5.3), and
- Is the developed health game a feasible intervention in supporting tobaccorelated health literacy in early adolescents compared to a non-gamified website? (RQ4, sub-chapter 5.4).

## 5.1 The entity of the determinants of tobacco-related health literacy is multidimensional

The 10 to 13-year-old early adolescents' (n=39) descriptions disclosed that to-bacco-related health literacy in early adolescence is influenced by a multidimensional entity of various factors. We recognized both personal (connected to the early adolescent himself or herself) and external (stemming from other people and surroundings) determinants. In addition, the mediating factors connected to the interpretation process of the health messages can be seen as an additional dimension to the determinants of health literacy. The recognized determinants are listed in Table 3. An illustration of the theoretical model of the determinants is presented in Figure 4.

Table 3. Determinants of tobacco-related health literacy recognized based on the early adolescents' descriptions

	Determinants of tobacco-related health literacy according to the descriptions of early adolescents (n=39)
Personal factors	Age, knowledge, access to health information, media use, health status, social skills, attitudes, beliefs/perceptions, experiences, motives <sup>(a)</sup> , self-efficacy <sup>(a)</sup> , role expectations <sup>(a)</sup>
External factors	Peers, family/parents, school, media, societal factors, living environment, authorities <sup>(a)</sup> , idols <sup>(a)</sup> , random people <sup>(a)</sup> , socio-cultural atmosphere <sup>(a)</sup>
Mediating	Interpretation of health messages <sup>(a)</sup> , balancing the personal and external
factors(a	determining factors <sup>(a)</sup> , level of capacity to process conflicting information <sup>(a)</sup>

<sup>&</sup>lt;sup>a)</sup> Newly found determinant, not included in the previous (Manganello 2008; Wharf Higgins et al. 2009; Paek et al. 2011) adolescent-specific health literacy frameworks and models

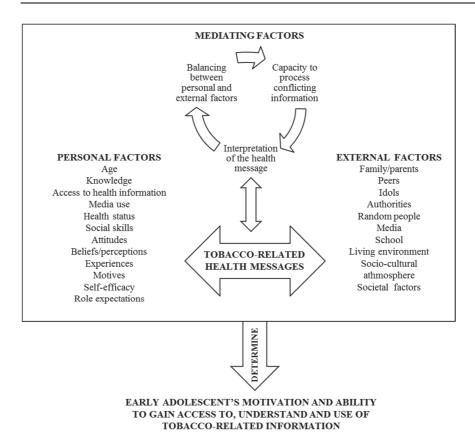


Figure 4. Theoretical model of the determinants of tobacco-related health literacy in early adolescents as recognized based on the early adolescents' (n=39) descriptions

The complex nature of the determinants manifested in the early adolescents' descriptions. Their descriptions propose that they observed and received various kinds of tobacco-related health messages in everyday life. Both personal factors and external factors stemming from the outside world seem to have influenced which kinds of health messages they were exposed to. The personal and external factors also seem to have had an impact on how they interacted with these health messages. In addition, the early adolescents described that they made individual interpretations of the health messages and reflected these interpretations in relation to personal (e.g. pre-existing perceptions) and external (e.g. the source of the health message) factors. When the interpretation conflicted with the personal and/or external factors, their ability to process the conflicting information depended on their cognitive capacities. In some cases, this interpretation process (referred as the mediating factor) may end up in confusion. This complex and multidimensional entity of different factors (Figure 4) determines early adolescents' motivation and ability to gain access to, understand, and use tobacco-related information, i.e. tobaccorelated health literacy based on the results of this qualitative descriptive study. The results are described in more detail in Article 1.

#### 5.2 The strongest evidence supports the use of active video games

The previous evidence (until August 2013) gathered with the review of reviews showed that health games have potential in children's and adolescents' health promotion. The largest amount highest level of quality of the previous evidence supports the use of active video games in physical activity promotion (Table 4). The potential for health games used in health education (e.g. related to asthma, diabetes and dietary habits) was also demonstrated (Table 5). However, we could not make firm conclusions about these kinds of sedentary health games due to the low amount of literature and heterogeneity of the evaluated interventions, health issues and measured outcomes. A summary of the conclusions we made based on the results is presented in Figure 5 and more detailed results in Article 2.

Table 4. Evidence level and quality of the literature concentrating on active video games included in the review of reviews

	Quality A, high (AMSTAR scores 9-11)	Quality B, medium (AMSTAR scores 5-8)	Quality C, low (AMSTAR scores 0-4)
Evidence level 1 (Meta-analysis or systematic reviews including only RCTs)		Peng et al. 2011	
Evidence level 2 (Systematic reviews of all study designs)	LeBlanc et al. 2013	Barnett et al. 2011; Biddiss & Irwin 2010; Guy et al. 2011; Lu et al. 2013; Peng et al. 2012	
Evidence level 3 <sup>(a)</sup> (Reviews)	Daley 2009; Foley & Maddison 2010; Papastergiou 2009; Sween et al. 2014		

<sup>&</sup>lt;sup>a)</sup> AMSTAR checklist is designed for evaluating quality of systematic reviews. With reviews, the AM-STAR scores were not used for quality evaluation

Table 5. Evidence level and quality of the literature concentrating on sedentary games included in the review of reviews

	Quality A, high (AMSTAR scores 9-11)	Quality B, medium (AMSTAR scores 5-8)	Quality C, low (AMSTAR scores 0-4)
Evidence level 1 <sup>(a)</sup> (Meta-analysis or systematic reviews including only RCTs)		Hieftje et al. 2013	
Evidence level 2 (Systematic reviews of all study designs)		DeShazo et al. 2010; Guy et al. 2011	
Evidence level 3 <sup>(b)</sup> (Reviews)	Ceranoglu 2010; Papastergiou 2009		

a) The quality of one systematic review of RCTs, Lawrence et al. 2010, could not be evaluated as it resulted not including any studies.

# Conclusions about health games in the promotion of children's health based on the level of evidence and quality of previous literaure<sup>(a)</sup>

#### Active video games

- Active video games appears to be effective in achieving light- to moderate physical activity intensity levels (1B, 2A-B, 3), especially if playing requires both upper and lower body movements (1B, 2B, 3).
- It appears that playing increases energy expenditure (1B, 2A-B, 3), heart rate (1B, 2B) and oxygen consumption (1B, 2B).
- It appears that playing alone is not enough for meeting the recommendations of daily amounts of physical activity (1B, 2A-B, 3)
- The intensity may decrease after an initial period (2B) and vary based on the game played, and the player's skills and choices made during the game play (2B).
- Favorable changes in the outcomes may be achieved with overweight and obese children (2A–B, 3).
- Playing may improve motor skill proficiency and movement cues in children with movement difficulties (2A).

#### Sedentary health games

- It appears that playing games can result in improvements in self-management behaviors related to asthma (1B) and diabetes (1B, 2B), and in dietary habits (1B, 2B, 3).
- Games may be effective in improving nutritional knowledge (2B), and might possibly support positive attitudes and skills in general (3).
- The results also suggest that games might possibly be helpful in psychotherapy, especially if traditional therapy has failed (3).

Figure 5. Conclusions made based on the review of reviews

b) AMSTAR checklist is designed for evaluating quality of systematic reviews. With reviews, the AMSTAR scores were not used for quality evaluation.

a) Numbers 1-3 refer to the level of evidence adapted from CEBM guidance, and letters A-C to the quality of the literature based on AMSTAR scores.

## 5.3 Enhancing acceptability requires balancing between different elements connected to the health content and gaming experience

The views of the 13 to 16-year-old adolescents (n=83) and the 10 to 13-year-old early adolescents (n=39) suggest that acceptability of a tobacco-related health game can be enhanced by finding a balance between different design elements connected to the health content and gaming experience (see Figure 6 and Article 3). Adolescents' views revealed that, on one hand, they expected the approach to the topic of tobacco in the game to be delicate, positive and carried out from adolescent-oriented perspective. On the other hand, they expected the game to effectively support a negative impression of tobacco use. Moreover, they pointed out that the gaming experience should not be forgotten while concentrating on the health content. They expected the game to be a high-class game, and to provide a stimulating, intellectually challenging and individualized gaming experience. More detailed results are presented in Article 3.

#### ADOLESCENTS' EXPECTATIONS TOWARDS A TOBACCO-RELATED HEALTH GAME

#### ELEMENTS CONNECTED TO THE HEALTH CONTENT

#### APPROACH OF THE GAME

- Approaches the health topic from adolescents" perspective
- Supports delicately a tobaccofree lifestyle
  - Uses a positive rather than a negative-only approach

## IMPRESSION THE GAME SUPPORTS

- Supports impression of tobacco use as a poor choice effectively enough and in a memorable manner

#### Finding a balance

#### ELEMENTS CONNECTED TO THE GAMING EXPERIENCE

#### **GAMING EXPERIENCE**

- Has high production values
- Provides a stimulating experience
- Provides an intellectually challenging experience
  - Provides an individualized experience

Figure 6. Elements included in adolescents (n=83+39) expectations towards a to-bacco-related health game

The feedback gathered from adolescents during the testing sessions supported the abovementioned notions about acceptability. We included most of the elements presented by the adolescents in the design of the developed health game called *Fume* (see Figure 3 in Article 3). The feedback gathered with the alpha and beta

versions of the game was positive, but pointed out some additional notions regarding acceptability (Table 6), namely that, to enhance acceptability of the health game, attention needs to be payed to the difficulty levels. The difficulty of the game should meet the needs of adolescents with different gaming backgrounds. The content of the game also needs to be versatile. This was considered important regarding the viability of the game.

Table 6. The feedback gathered in the testing sessions 3 and 4

Testing session	Used material(s)	Participants	Summary of the feedback
3	Alpha version of the game	10 to 13-year- old early ado- lescents, n=10	<ul> <li>Early adolescents evaluated the game on 5-point Likert scale (1=boring, 5=very fun):         <ul> <li>Before testing the game:</li></ul></li></ul>
4	Beta version of the game	9 to 16-year- old adoles- cents, n=44	- Adolescents evaluated the game on 5-point Likert scale (1=boring, 5=very fun):  o After testing the game: Mean 4.3 (SD 0.81)

#### 5.4 The health game *Fume* is a feasible intervention

The results of the cluster randomized trial showed that the health game *Fume* is more feasible as an intervention in supporting tobacco-related health literacy in early adolescents than the non-gamified website in light of demand and acceptability (interest). The early adolescents used *Fume* more in their free-time than they visited the website ( $P \le 0.001$ ). They were also more interested in *Fume*, as it provoked more discussion among them compared to the website ( $P \le 0.001$ ). We did not find statistically significant differences between the early adolescents' opinions about the interventions (P=0.19). These results are presented in more details in the following sub-sections and Article 4 (see also Parisod et al. 2017b).

We detected favorable changes (baseline–post-intervention) in the following theory-based determinants of tobacco-related health literacy within the health game group using *Fume*: positive (P=0.002) and negative smoking outcome expectations (P=0.02), and attitudes towards cigarette smoking (P=0.01). We did not find

any statistically significant changes within the website or no-intervention control groups. Neither did we find statistically significant differences between the groups (A–C) in changes over the study period in the health literacy-related outcome variables. I present these results more closely in the following sub-sections (see also Article 4).

We collected comprehensive background information on the early adolescents (n=151) participating in this three-armed cluster randomized trial (see Article 4, Tables 2-4). We noticed some differences between the groups (A–C) in the background factors at baseline. The three groups varied in experiences of being offered cigarettes (P=0.02), parents' (P=0.01), other relatives' (P=0.01) and authorities' (P=0.003) cigarette smoking habits, authorities' snus use habits (P=0.01) and early adolescents' values concerning money (P=0.04). We performed supplementary analyses due to these observed unbalances. These results are also presented in the following sub-sections and Article 4.

#### 5.4.1 The actual use of and interest in Fume higher than that of the website

#### Actual use

The early adolescents used *Fume* more than the website ( $P \le 0.001$  for all the outcome values) in their free-time, according the usage data we tracked during the two-week period (Figure 7). The early adolescents in the health game group (Group A, n=40, N/A n=21) visited *Fume* an average (median) of 4 times (95% CI 4, 8; range 2–50), as the early adolescents in the website group (Group B, n=39, N/A n=8) visited the website an average of 1 time (95% CI 1, 2; range 1–9). The early adolescents (Group A) visited the *Fume* application an average of 3 separate days (95% CI 2, 3; range 1–10), as those using the website used the site 1 day on average (95% CI 1, 1; range 1–7). The total duration of game play with *Fume* (Group A) was 19 minutes on average (95% CI 16, 26; range 0–219) and total website usage (Group B) was 9 minutes on average (95% CI 8, 11; range 0–36).

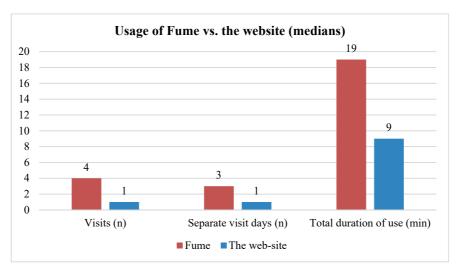


Figure 7. Early adolescents' usage of Fume (Group A) and of the website (Group B)

We did not find statistically significant differences with the current sample in the usage of *Fume* between girls and boys (visits P=0.47, visit days P=0.45 and total duration of game play P=0.92). Neither did we find statistically significant differences with early adolescents of different ages (visits P=0.76, visit days P=0.51 and total duration of game play P=0.36) nor among adolescents with different gaming habits (visits P=0.26, visit days P=0.17 and total duration of game play P=0.73), see Figures 8–10.

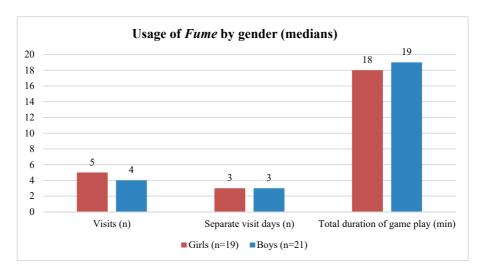


Figure 8. Early adolescents' (Group A) usage of Fume by gender

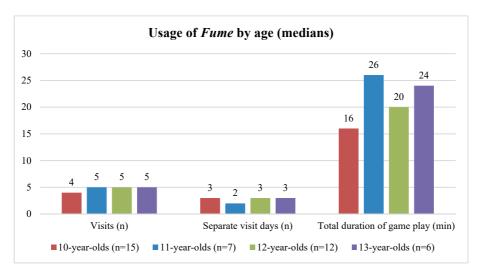


Figure 9. Early adolescents' (Group A) usage of Fume by age

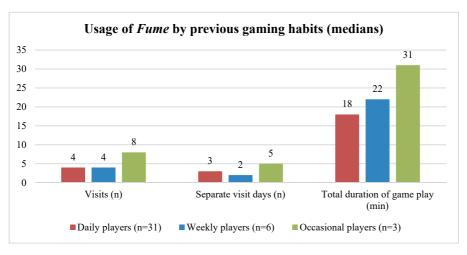


Figure 10. Early adolescents' (Group A) usage of Fume by previous gaming habits

#### Interest

The early adolescents were more interested in *Fume* than in the website ( $P \le 0.001$ ). Of the early adolescents in the health game group (Group A, n=61), 42 (70.0%; 95% CI 57.5–80.1%) reported discussing *Fume* and its content with their friends. In the website group (Group B, n=47), this number was 13 (27.7%; 95% CI 16.9–41.8%). When we asked the early adolescents in the health game group (Group A) about the topics they discussed, they reported discussing the minigames and scenes included in *Fume* (n=18), tobacco in general (n=2), use of *Fume* and achieved high scores (n=11), and their opinions about the game (n=14). We did not find statistically significant differences in interest in *Fume* (Group A) between girls and boys (P=1.00), early adolescents of different ages (P=0.25) or adolescents with different gaming habits (P=0.84) based on the current sample (Figures 11–13).

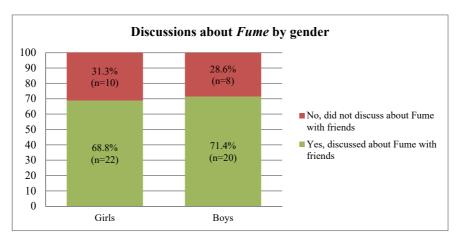


Figure 11. Discussions about Fume among early adolescents (Group A) by gender

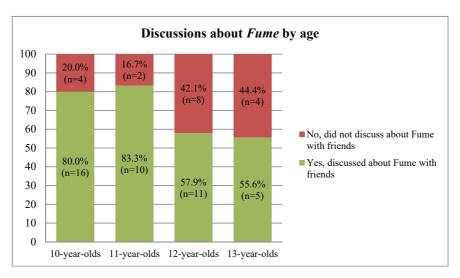


Figure 12. Discussions about Fume among early adolescents (Group A) by age

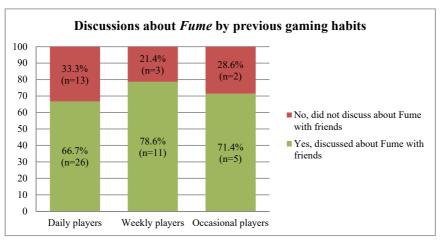


Figure 13. Discussions about Fume among early adolescents (Group A) by previous gaming habits

#### **Opinions**

Of the early adolescents in the health game group (Group A), 15 (25.4%; 95% CI 16.1-37.8%) considered *Fume* as "very nice". In the website group (Group B), this number was 8 (17.0%; 95% CI 8.9-30.1%). We did not find statistically significant differences (P=0.19) in early adolescents' opinions about *Fume* (Group A) and the website (Group B) (see Article 4, Table 7). The early adolescents' opinions about *Fume* (Group A) did not differ in a statistically significant way when comparing girls and boys (P=0.74), early adolescents of different ages (P=0.07) or previous gaming habits (P=0.64), according to subgroup analyses with the current sample (Figures 14-16).

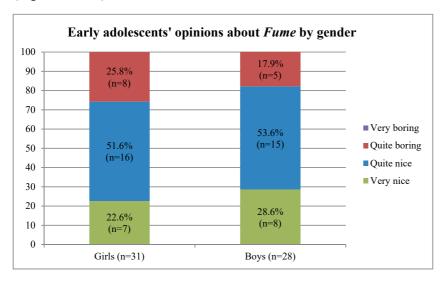


Figure 14. Early adolescents' (Group A) opinions about Fume by gender

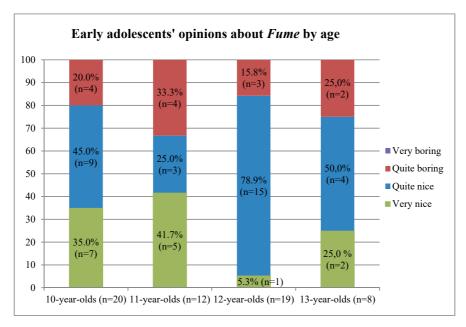


Figure 15. Early adolescents' (Group A) opinions about Fume by age

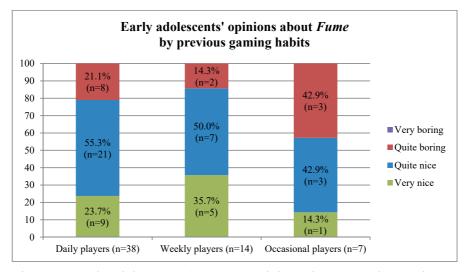


Figure 16. Early adolescents' (Group A) opinions about Fume by previous gaming habits

#### 5.4.2 Use of Fume resulted in favorable short-term effects

#### The theory-based determinants of tobacco-related health literacy at baseline

Of all the early adolescents (n=151), 21 (13.9%; 95% CI 9.3, 20.3%) did not know what snus is, 79 (52.3%; 95% CI 44.4, 60.1%) could not mention any consequences of snus use and 2 (1.3%; 95% CI 0.4, 4.7%) could not mention any consequences of tobacco use at baseline. The other measured theory-based determinants of tobacco-related health literacy were at good levels already at baseline (Table 7). The baseline values are presented separately for the early adolescents in different groups (A–C) in Article 4, Table 5.

Table 7. Descriptive statistics for the baseline values of theory-based determinants of tobacco-related health literacy for all the participants (n=151) in substudy V

All the participating early adolescents (n=151)

	Baseline		
OUTCOME VARIABLES	Median	95% CI	Range
Anti-smoking self-efficacy (ASSES)	56	54, 56	15-60
Positive smoking outcome expectations (POS-SOES)	3	3, 3	3–11
Negative smoking outcome expectations (NEG-SOES)	11	11, 12	3–12
Attitudes towards cigarette smoking	1	1, 1	1-3
Attitudes towards snus use	1	1, 1	1-3
Motives to smoke cigarettes	3	3, 3	3–9
Motives to use snus	3	3, 3	3–9
Motivation to decline eigarette smoking in the future	1	1, 1	1–3
Motivation to decline snus use in the future	1	1, 1	1-3

#### Change in the theory-based determinants of tobacco-related health literacy

We found statistically significant favorable changes (baseline–post-intervention) within the health game group (Group A) for positive (P=0.002) and negative smoking outcome expectations (P=0.02), and attitudes towards cigarette smoking (P=0.01). We did not detect statistically significant changes for anti-smoking self-efficacy, attitudes towards snus use, motives to smoke cigarettes or use snus, motivation to decline cigarette smoking or snus use in the future or knowledge about tobacco-products (what snus is, and consequences of snus use and cigarette smoking) within the health game group. We did not find statistically significant changes in any of the theory-based health literacy-related outcome variables within the website group (Group B) or the no-intervention control group (Group C).

We did not find statistically significant differences between the groups (A–C) in changes for any of the theory-based health literacy-related outcome variables (anti-

smoking self-efficacy, positive or negative smoking outcome expectations, attitudes towards cigarette smoking or snus use, motives to smoke cigarettes or use snus, motivation to decline cigarette smoking or snus use in the future or knowledge about cigarettes or snus).

We performed supplementary analyses accounting the confounding factors as we observed statistically significant unbalance in some of the background factors at baseline. We tested differences between the formed subgroups with combined information about the original groups (A–C) and background factors (experiences of being offered cigarettes, parents', other relatives' and authorities' cigarette smoking habits, authorities' snus use habits and early adolescents' values concerning money). We did not found statistically differences between the subgroups for any of the tested outcome variables (change in positive and negative smoking outcome expectations and attitudes towards cigarette smoking).

#### 5.5 Summary of the main results

The main findings of this study are summarized in Figure 17.

#### **DEVELOPMENT PHASE (2013-2015)**

Strengthening theoretical knowledge and evidence, and producing a health game intervention aiming at supporting tobacco-related health literacy in early adolescents

### RQI: What do the descriptions given by early adolescents disclose about the determinants of tobacco-related health literacy? (Sub-study I)

→Various personal and external factors, but also mediating factors connected to the interpretation process of tobacco-related health messages seem to determine tobacco-related health literacy in early adolescents. The role of the interpretation process of health messages requires further attention.

## RQ2: What does previous evidence reveal about the potential of health games in general, in regard to promoting health among children and adolescents? (Sub-study II)

→ The strongest evidence supports the use of active video games in children's and adolescents' physical activity promotion. Games are suitable for other health promotion purposes as well, but more research especially on sedentary health games is needed to make firm conclusions.

## RQ3: How can the acceptability of a tobacco-related health game be enhanced according to the views of adolescents? (Sub-studies III–IV)

→ There is need to find a balance between different design elements connected to the health content (the used approach and impression about tobacco supported) of a tobacco-related health game to enhance acceptability among adolescents. At the same time, the elements supporting the gaming experience should not be forgotten. The different gaming backgrounds of the adolescents need to be noted as well.

#### FEASIBILITY AND PILOTING PHASE (2016)

Evaluating feasibility of the developed health game as an intervention supporting tobacco-related health literacy in early adolescents

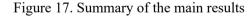
RQ4: Is the developed health game a feasible intervention in supporting tobacco-related health literacy in early adolescents compared to a nongamified website? (Sub-study V)

- ⇒ The early adolescents used *Fume* more in their free-time ( $P \le 0.001$ ) and they were more interested in it ( $P \le 0.001$ ) than in the website, but their opinions about *Fume* and the website did not differ (P=0.19)
- → Favorable short-term changes were detected with Fume in positive (P=0.002) and negative (P=0.02) smoking outcome expectations and attitudes towards cigarette smoking (P=0.01). No statistically significant changes were found within the web-site or control groups. No statistically significant differences were found between the groups.

The developed health game Fume is more feasible than a non-gamified website as a tobacco-related health literacy intervention with early adolescents.

Fume can be further strengthened based on the gathered results, but it can be recommended to be utilized in health education of early adolescents.





#### 6 DISCUSSION

#### 6.1 Discussion of the results

In this study, we developed and evaluated feasibility of a health game intervention in supporting tobacco-related health literacy in 10 to 13-year-old early adolescents. I discuss next the main results gathered with this study.

## The multidimensional entity of the determinants of tobacco-related health literacy in early adolescents

We learned from early adolescents that tobacco-related health literacy is influenced by a complex and multidimensional entity of different factors concerning both the adolescent him- or herself and the outside world. In addition, mediating factors connected to the interpretation process of health messages seemed to determine their health literacy as well. These results suggest that there is a need to pay careful attention to the unique needs of early adolescents regarding health literacy. For example, the non-age specific model of Nutbeam (2008) considering health literacy from health promotive perspective refers only to personal skills and knowledge as the determining factors. Many of the existing adolescent-specific health literacy models are largely focused on individual determinants of health literacy as well (Bröder et al. 2017). This kind of approach to health literacy seems insufficient with adolescents based on our results.

The results revealed that adolescents pay attentively attention to different health messages stemming from the outside world. For example, idols and random people that the early adolescent encounters may influence on his or her health literacy. Previously, idols' smoking status has been demonstrated to influence smoking of young people (Salameh et al. 2014). The results of this study present that besides idolizing and modelling idols can act as a source of tobacco-related health information. Early adolescents seemed to pay attention to not only written and oral health information they receive but also non-verbal health messages (e.g. careful observations of tobacco-using idols' appearance or performance) they encounter. The early adolescents were also well aware of the tobacco policies and actions taken at societal level. This highlights the importance of the political actions (Tobacco Act 549/2016; WHO 2017a) taken to reduce the demand of tobacco and promote tobacco-free environments.

Our results also point out the important role of interpretation process of the health messages. Early adolescents seemed to reflect the information content of the different health messages they encounter in relation to for example their pre-existing perceptions about tobacco. This cognitive interpretation process and capacity to process conflicting information seemed to eventually determine what kind of value the health message had to them. The previous social ecological model of adolescent health literacy presented by Wharf Higgins and colleagues (2009) is grounded on the idea of learning as a social process. They describe that, in general, learning

takes place while connecting, finding meanings and interacting with others. Still, the set of determinants presented in the model of Wharf Higgins et al. (2008) or in other previous adolescent-specific health literacy models and frameworks (Manganello 2008; Paek et al. 2011) do not include interpretation process among the determining factors of health literacy.

Another adolescent-oriented health literacy model examining health literacy in educational context as a learning outcome (Paakkari et al. 2012) refers partly to a similar kind of perspective as the interpretation process recognized in our results. Paakkari and Paakkari (2012) include theoretical knowledge, practical knowledge, critical thinking, self-awareness and citizenship as the components of health literacy. Recognizing the role of critical thinking as part of health literacy, and thus, supporting criticality besides capabilities to interpret conflicting health messages could contribute positively to the development of tobacco-related health literacy in adolescents. The approach of this model to health literacy is educational and approaches used to support health literacy in health care are different than in educational context. Still, it could provide important notions to for example school health care.

Based on the knowledge gained with this study, I argue that the current health literacy models and conceptual frameworks do not cover sufficiently all the determinants of health literacy with adolescents. Similar notions have also been presented previously (Bröder et al. 2017). Especially, the mediating role of the interpretation process should be better recognized as one of the determinants of health literacy. Although, this study examined health literacy from tobacco-specific perspective in early adolescents, our findings may be also applicable to other health contents and contexts. Further examination of the recognized theory-based determinants is needed.

## The previous evidence on the potential of health games in children and adolescents

The previous evidence gathered with the review of reviews on health games in children and adolescents demonstrated the positive effects active video games have in regards of physical activity promotion. The research literature on sedentary health games and from other health topic perspectives than physical activity promotion was scarcer. Still, the literature suggested that health games could work for example for health education purposes with children and adolescents. The literature review conducted specifically on tobacco-related health games (Marsch et al. 2007; Andrews et al. 2011; 2014; Cremers et al. 2012; 2014; 2015; Ip et al. 2014; Rath et al. 2015) presented in this summary strengthened the evidence. The literature suggested that a health game could work for tobacco-related health education purposes. Still, the existing research literature especially on tobacco-related health games as stand-alone interventions was limited.

The amount of health game research literature has increased since we conducted the review of reviews and new reviews and meta-analyses have been published. For example, Gao and colleagues published a meta-analysis about active video

games in 2015. The results of this meta-analysis are in line with our findings and show the positive effects active video games have especially on physical activity of children and adolescents. In addition, they also demonstrated the potential of active video games in influencing the psychological outcomes, such as self-efficacy. Another meta-analysis (DeSmet et al. 2014) strengthens the knowledge about sedentary health games developed for health educational purposes. These results show that health games have positive effects on healthy lifestyles and their determinants, knowledge above all.

Several research needs are still highlighted in the literature. Increasing understanding on the most appropriate game design elements with children and adolescents and research about optimal participatory design approaches are required (Baranowski et al. 2016). The literature also implies that there is need for studies concentrating on the development process of health games and describing the design features more in details to advance empirical evaluations of the health games (DeSmet et al. 2014). Further research applying rigorous randomized controlled trial designs are also needed for acquiring stronger evidence on the effectiveness of health games (Baranowski et al. 2016). We aimed at contributing to these recognized research needs with our study.

The next step in health game research, as intervention research in general, is implementation after the effectiveness evaluation (Craig et al. 2008). Traditionally implementation of new health interventions into health care context require strong evidence (Nursing Research Foundation 2013; Honkanen et al. 2016). Complex intervention studies with long follow-ups can take time (Lakshman et al. 2014). This is challenging with health games and other digital health technology that are evolving rapidly. Use of health care experts for validating and evaluating the reliability of digital interventions implemented into health care can be used to strengthen the research evidence (Ruck et al. 2016). Nurses' and other health care professionals are here in central position. In our study, we conducted a testing session during the development of *Fume* with health promotion professionals working with tobacco prevention of adolescents. In addition, strength of the development of *Fume* also was that our multidisciplinary research team included members with health professional backgrounds. As a future goal, conducting process evaluation (Moore et al. 2015) with health games in health care context could benefit the health game field. This kind of evaluation would strengthen understanding of both mechanisms influencing the effectiveness and implementation process of health games, and related contextual factors from health care perspective.

#### Suggestions based on the views of adolescents for designing health games

We learned from adolescents that they have several notions regarding the health game design. Paying attention to different elements connected to the health content, such as positive approach to tobacco non-use in the game, and to the gaming experience, such high-quality graphics, seemed to contribute to the acceptability of *Fume*. Previous studies suggest that adults tend to use negative, disease-oriented approach in tobacco-related health education (Marck et al. 2014; Hall et al. 2015).

Paying attention to the positive, health-oriented perspective in tobacco-related health education pointed by the adolescents require attention.

Adolescents' views also suggested that difficulty levels meeting the needs of different kinds of gamers need consideration as well. These issues pointed by adolescents indicate that they reflect health games against their previous gaming experiences with commercial, entertaining games. On the other hand, adolescents had also high expectations towards the health content as well. Previously, it has been pointed that including adolescents as co-designers to health game development may influence negatively to the effectiveness of the game (DeSmet et al. 2016). However, noticing the requirements presented by adolescents is important as attitudes towards and perceived usefulness of health games are essential in regards playing intentions (Hamari & Keronen 2017).

An interesting aspect was that early adolescents' evaluations in testing session 3 indicated slightly more positive opinions towards *Fume* after testing the game than what they expected it to be beforehand. This suggests that adolescents may have preconceptions of health games that may influence (Hamari & Keronen 2017) their health game use. This is an aspect that needs attention in the health games field in order to reach the target audience and enhance acceptability, support viability of the health game, and to accomplish the desirable outcomes.

#### Demonstrated feasibility of the tobacco-related health game intervention

This study strengthened the current evidence that positive health-related outcomes can be achieved with games and that inclusion of game elements into the intervention do not influence the outcomes negatively. Favorable effects regarding positive and negative smoking outcome expectations, and attitudes towards cigarette smoking were demonstrated already after short use of *Fume*. Based on previous studies (Ip et al. 2014; Rath et al. 2015), the mechanism behind the achieved effects with *Fume* may lie in its larger use than of the website version. On the other hand, the discussions taken place among the early adolescents may have inspired them looking for additional information on tobacco-products and share thoughts and experiences, and thus, strengthen the effects of *Fume*. Further research examining these possible mechanisms is needed.

The results showed that embedding game-elements into the intervention resulted in greater use and interest towards the intervention. We did not found differences in usage or interest between girls and boys. Previously, it has been showed that engagement (Ip et al. 2014; Rath et al. 2015) is pivotal in regards of the desired outcomes with health games. The positive reactions of early adolescents point out the possibilities for achieving longer-term effects with *Fume*. The subgroup analyses based on gender also suggest that *Fume* could meet the presented need (Thomas et al. 2015) regarding finding tobacco-related health education methods that are equally effective for both genders. However, further evaluations with larger sample sizes and longer follow-up are needed to confirm our findings.

Based on our background data, a large number of early adolescents reported not remembering receiving health education especially about snus during the current school year. The implementation activity of tobacco-related interventions in Finnish comprehensive schools (THL 2017b) also points the need for improvements. Our results showed that a mobile health game can work as a health education intervention in early adolescents while played outside school hours and it holds potential in supporting the health education provided by the school health nurses and other health professionals.

The results pointed that snus and its negative health effects are still rather unfamiliar to early adolescents. Our results together with the information about the increased use of snus among adolescents (THL 2017a) highlight the need for paying more attention to snus in health education. An important notion is that we did not achieve any favorable results with snus-related outcomes. When reflecting these results with the three-level hierarchy of health literacy presented by Nutbeam (2000), it may be that *Fume* as a stand-alone intervention functioned better in supporting interactive (i.e. capacity, motivation and self-confidence to act on the knowledge) than functional health literacy (i.e. ability to understand factual health information). In its current form, Fume contains only little textual information about tobacco-products. It may be that the early adolescents might have needed different kinds of support for the more unfamiliar content related to snus. Minigames dealing with factual information on snus or other additional intervention components could strengthen Fume from the snus-related perspective. On the other hand, it needs to be noted that too large amounts of text-based information may weaken acceptability of the health game based on the views presented by the early adolescents in this study and previous results (Marsac et al. 2015). These notions could be taken into consideration when further developing *Fume*.

The achieved favorable changes were measured only after two-week follow-up and the longer-term effects were not evaluated. In addition, we could not demonstrate the effectiveness of *Fume* compared to the website or no intervention. Based on previously gathered evidence, use of boosters (Champion et al. 2013; Thomas et al. 2013), debriefing sessions (de Freitas & Oliver 2006) and family- (Saraf et al. 2012; Champion et al. 2013; Thomas et al. 2016) and community-based (Saraf et al. 2012; Khayyati et al. 2015) components could strengthen the *Fume* intervention. Prompts (Cremers et al. 2014) announcing updated contents and new available levels, or other kinds of reminders could function as boosters and maintain engagement and interest towards *Fume* for longer time period. These can also be considered as suggestions for future development of *Fume* intervention.

#### 6.2 Validity and reliability of the study

This study consisted of five sub-studies applying variety of designs, and data collection and analysis methods. This methodological triangulation (Bekhet & Zauszniewski 2012) can be considered strength of this study. In addition, we followed the MRC's framework for complex interventions (Craig et al. 2008) that guides

developing evidence- and theory-based interventions. I discuss next other aspects of validity and reliability, as well as the strengths and limitations, of our study from the perspectives of data collection procedures, used instruments and achieved results. Validity of the qualitative sub-studies (I and III) is discussed in terms of credibility, authenticity, criticality and integrity (Whittemore et al. 2001).

#### 6.2.1 Validity and reliability of the data collection

#### **Development phase**

We used focus groups (Krueger & Casey 2009) for collecting the data in the substudy I. Several actions were taken to demonstrate the validity of the data. We piloted the interview guide with the first group of early adolescents to ensure that the questions presented were appropriate for its purposes and understandable by them. No changes were required based on the piloting. We employed data triangulation and purposive sampling utilizing the strategy of maximum variation (Patton 1990) in this qualitative descriptive study. In this way we were able to the gather data from both early adolescents following general curriculum and early adolescents with special education needs. We ensured both credibility and authenticity by audiotaping the discussions, writing field notes and providing verbatim transcriptions. We recognized that the presence of the researcher and peers might have influenced the participating early adolescents, and thus, authenticity of their descriptions. This was noted already when designing the data collection. Thus, we formed the focus groups noticing the special needs of early adolescents (Daley 2013) and the early adolescents were divided into small groups based on age and gender. The early adolescents were also given opportunity to write their thoughts on post-it-notes besides discussion. We continued the data collection until saturation was achieved, in other words, until no new information was attained.

We ensured reliability of the data collection in the review of reviews (II) by using rigorous review protocol (Smith et al. 2011). We conducted the literature search systematically from five international databases using search strategy containing inclusion and exclusion criteria chosen *a priori*. We did the literature review in a team. Our team included researches with both previous experience in conducting systematic literature reviews and expertise on the topic under review. We performed the literature search and screening process by three independent reviewers, I among others. However, despite the comprehensive literature search and rigorous review process we used, there might be some relevant literature on the topic not included in the review.

We collected the data in sub-study III using both an online questionnaire and focus groups. Similarly as in the sub-study I, also here we used triangulation (Carter et al. 2014) to provide comprehensive understanding on the topic, gain multiple perspectives from adolescents and demonstrate richness of the data. We piloted the online questionnaire with four adolescents before conducting the data collection.

Some minor rewording was made based on the pilot. We carried out the data collection with the online questionnaire both through social media and in one junior high school to achieve data saturation. The public health nurse was the contact person during the data collection at school. We instructed her about the study using phone calls and emails.

We used questionnaires developed for the purpose of this study in the testing sessions with *Fume* (sub-study IV). We used the questionnaires for collecting feedback about the initial versions of the game for further development of the game intervention. Even though no previously validated instruments were used, the questionnaires were considered suitable for the purpose of this sub-study.

#### Feasibility and piloting phase

We noted several aspects in designing the cluster randomized trial (sub-study V) to enhance reliability. We estimated the sample size in advance based on power calculations and methodological literature (Puffer et al. 2005). We set the targeted sample size at 50% higher number than estimated based on calculations, because cluster randomized trials require larger samples to achieve the same statistical power as individually randomized trials (Puffer et al. 2005). The aimed sample size was well achieved after including two additional schools to the study.

We did the randomization at the level of municipalities to avoid contamination between participants in the intervention and control groups. In addition, *Fume* was not made available from the mobile stores at the time of the data collection to prevent early adolescents in the website or control groups to have contact with it. The study had also some limitations. We recruited the participating early adolescents after randomization due to practical reasons and only one municipality was allocated to each arm. Still, we collected the data during the same time period at all the schools, except at those two additional schools recruited afterwards. We also collected a comprehensive background data from the participating early adolescents to be able to evaluate homogeneity of the sample.

#### 6.2.2 Validity and reliability of the instruments

In this chapter, I concentrate on the validity and reliability of the instruments used in the sub-study V. ASSES and SOES are previously developed and tested instruments demonstrating both good validity and reliability (Chen et al. 2015). The original instruments in Chinese were validated in Taiwan with the same age early adolescents as the target group of this study. Later, translated Turkish versions of the instruments have been tested and shown to be valid and reliable tools with early adolescents (Bektas et al. 2017). We asked the original versions of ASSES and SOES and received them from Chen and colleagues.

We evaluated the face validity of ASSES and SOES to be good from the perspective of the theory-based determinants of health literacy (tobacco-related self-efficacy and beliefs/perceptions) used in this study (see article 1). During this study, the instruments were used for the first time in Finland. We conducted the translation of the original instruments and validation process using the back-translation method (Sperber 2004). The original Chinese instruments were first translated by a professional translator into Finnish. Then, another translator translated the Finnish versions back into Chinese. After this, the original and translated versions were compared by a native Chinese researcher to validate the translations. I discussed about the differences between these two translations with the Chinese researcher. Then, the findings of the validation and the Finnish versions of the instruments were evaluated by an expert group. We made some minor revisions to wording based on this evaluation (e.g. "I refuse" was changed to "I can refuse" as it was more in line with the original version of ASSES). In addition, we did a minor change in regards cultural validation (in ASSES item 10, the reference to a Chinese anime was changed to a music video of a Finnish popstar). We piloted the revised Finnish versions of ASSES and SOES with Finnish early adolescents (n=7). Based on the pilot, the translated versions were understandable, but the item 7 in ASSES seemed to confuse the adolescents. We made a minor addition ("...if I get instructions how to do it" was added). In addition, we added a sub-heading between POS-SOES and NEG-SOES items based on the pilot. We evaluated the reliability of the translated instruments with Finnish early adolescents using Cronbach's alpha (Table 8). The reliability of the Finnish version of ASSES varied from good to excellent, POS-SOES from poor to acceptable and NEG-SOES from acceptable to good based on baseline and post-intervention data.

We used an instrument developed for this study besides ASSES and SOES. We developed Tobacco use motives instrument based on the results gathered in substudies I and III. The instrument was designed to measure social motives early adolescents have regarding using tobacco. Face validity of the developed instrument was evaluated by a group of researchers familiar with the topic. The instrument contains two sub-scales; cigarette smoking motives and snus use motives. Both sub-scales include three items. We also piloted this instrument with early adolescents (n=7). No changes were required based on the pilot. The reliability (Table 8) of the cigarette smoking motives sub-scale was demonstrated to be good and of the snus use motive sub-scale excellent.

	Sub-scales	Cronbach's alpha	
Name of the instrument Finnish version of		At baseline	At post-intervention
ASSES Finnish version of	POS-SOES	0.89	0.91
SOES	NEG-SOES	0.71	0.71
Tobacco use	Cigarette smoking motives	0.85	0.86
motives	Snus use motives	0.92	0.93

Table 8. Reliability of the used instruments

We measured the following theory-based determinants of tobacco related health literacy using single questions: attitudes towards tobacco use and motivation to decline tobacco use in the future (separately cigarette smoking and snus use). In addition, we used one question to evaluate both early adolescents' opinion of *Fume* and the website, and their interest towards the interventions. These questionnaires developed for this study were used as no previous instruments meeting the purpose of this study were found.

#### 6.2.3 Validity and reliability of the results

#### **Development phase**

We used qualitative descriptive design (Sandelowski 2000) in sub-studies I and III to ensure authenticity and give voice to early adolescents. We enhanced credibility of the results by critically reflecting the analytic process and reviewing the initial codes and themes among our research group. We also supported authenticity and credibility by including quotations from adolescents' descriptions to the results.

The determinants of tobacco-related health literacy we recognized in the qualitative descriptive study (I) are theoretical as they are not tested with quantitative methods. For our knowledge, this was the first study describing these determinants among early adolescents. The use of adolescent-oriented perspective is a strength of this study as adolescent-specific features of health literacy are still poorly understood (Velardo & Drummond 2017). However, to strengthen the presented theoretical model, correlations and causalities of the presented determinants requires further research.

We enhanced reliability of the results and conclusions in sub-study II by evaluating the quality of the included systematic reviews and level of evidence of the included literature. We applied AMSTAR checklist (Shea et al. 2007) and the guideline of the CEBM (Centre for Evidence Based Medicine 2009) for these purposes. A limitation of this study is that there was some overlap between the included reviews and systematic reviews. Some original publications were included in several of the reviews and systematic reviews which may have biased the results. To minimize

the influence, we provided a comprehensive list of the original publications included in the review and systematic reviews in the article 2.

The generalizability of the results of sub-study IV can be argued as the samples were rather small (n=10 and n=44) and the participants were chosen purposively based on the age of adolescents. However, the aim of the sub-study IV was mainly to provide information for further development of the health game *Fume*, test the initial versions of the game and validate its content from adolescents' perspective. The acceptability evaluations of the adolescents in the both data collections were parallel that establish reliability of the results.

#### Feasibility and piloting phase

The cluster randomized design we used in the sub-study V is considered as a valid approach to study the effectiveness of health education interventions. This approach used for undertaking randomized controlled trial (RCT), allow testing the effectiveness in real contexts, such as at school, where individual randomization is difficult or even possible to implement without risk of contamination. (Puffer et al. 2005.) However, there were some limitations regarding the internal validity (Ferguson 2004) of this sub-study. We used the theory-based determinants of to-bacco-related health literacy as outcomes instead of measuring actual health literacy. We did this as there are no existing instruments concentrating specifically on tobacco-related health literacy and thus, meeting the purpose of this study. In addition, there is only very few general health literacy instruments intended for adolescent populations (Perry 2014). These instruments concentrated too broadly to health literacy and thus, we considered them as not adequate.

There were some issues that may have influenced the reliability of our results. First, the participation percentage of the early adolescents varied between schools widely (from 8% to 43%). This may have biased the results as it may be that those early adolescents with the most positive attitudes towards tobacco-related interventions have taken part to the study. However, the background information we gathered from the participating early adolescents supports the representativeness of our sample. The number of early adolescents that had tried cigarette smoking in our sample (4.0%) is in line with previous national results (3.9%) (THL 2017a). However, those who had experimented use of snus were fewer in our sample (0.7%) than previously demonstrated (2.0%) with this age group (THL 2017a).

Second, there were some usage data missing from the GameAnalytics tool related to the actual use of Fume (n=21) and from the user-tracking plug-in on the website (n=8). Due to this, we could not evaluate the usage amounts of all the participants in the intervention groups. Still, all the participating early adolescents in the intervention groups used Fume or the website at least once during the training sessions we conducted at school at the beginning of the study. In addition, we included all the data gathered concerning the acceptability and effectiveness of the interventions in the statistical analyses despite the missing usage data.

Third, we performed the statistical analyses at individual level instead of clusters. Performing analyses at the cluster level are recommended in cluster RCTs as participants within one cluster are more likely to respond similarly than participants from different clusters (Eccles et al. 2003). We made the decision to perform analyses at individual level due to the low number of clusters included in each arm. This may have influenced the reliability of the results and needs to be taken into consideration when interpreting the results of this pilot study.

We enhanced external validity (Ferguson 2004) and minimized possible Hawthorne Effect (McCarney et al. 2007) by using RCT design. The larger amount of involvement taken with those participants in the intervention groups may still have influenced the results. However, the attention payed to the early adolescents in both the *Fume* and website groups was similar. The participating early adolescents were blinded about the intervention of interest. Due to practical reasons, no double-blind procedures were implemented. These limitations need to be noted when generalizing the results.

#### 6.3 Suggestions for future research

This study strengthened the body of research literature on tobacco-related health literacy and health games as interventions in adolescent populations. Still, there is a need for future research on these topics. The following suggestions are presented:

- The presented determinants of tobacco-related health literacy were recognized based on a qualitative descriptive study. Further research confirming these findings and examining correlations and causalities of the presented theoretical determinants and health literacy is needed.
- The health game *Fume* was evaluated as an intervention supporting to-bacco-related health literacy in early adolescents. Further research examining the elements of *Fume* and how to support tobacco-related health literacy more comprehensively is needed. In addition, evaluating *Fume* with a longer follow-up would provide more evidence on its effectiveness.
- Understanding the mechanisms of the achieved effects with *Fume* require further examination. The early adolescents used *Fume* more than the website and it provoked more discussions among them. Research examining contribution of these mechanisms in light of the achieved effects is recommended. This would provide important information for further development of *Fume* and other similar kinds of interventions.
- The reactions towards *Fume* in early adolescents with different ages, gender and previous gaming habits did not differ based on our sample. Testing the demand, acceptability and effectiveness of Fume between these subgroups with larger samples would be needed to confirm our findings.

- The results of this study suggested that early adolescents' knowledge about snus is low. Evaluating the knowledge level and snus-related health literacy with larger population would confirm this finding and provide important information for the base of health policies.
- Fume is worthy to develop further based on the results. There were some elements that were designed to be included in Fume, but were decided to be excluded from the first version due to limited resources. Further, inclusion of debriefing sessions was left for future. Conducting formative research with these new elements would assist the further development of Fume intervention.
- The results support the use of *Fume* as an additional method for example in school health care. The school health nurses could utilize *Fume* for providing tobacco-related health education. Conducting process evaluation with *Fume* would contribute both the implementation of *Fume* itself, but also provide information to be used when planning commissioning processes of similar kinds of digital health interventions.

#### 6.4 Practical implications

The following practical implications for nursing and policymaking can be presented based on the results of this study:

#### Implications for nursing

- Support of tobacco-related health literacy seems to require using a multidimensional approach. Early adolescents could benefit of support connected to the interpretation process of various tobacco-related health messages. This could be noticed while providing health education about tobacco for example by school health nurses and others working with adolescents.
- Tobacco non-use as a topic could be approached from a positive perspective as it seems to speak to adolescents. The positive sides of tobacco non-use could be highlighted in tobacco-related health education with adolescents besides bringing up the negative consequences of tobacco use.
- Snus should be addressed more often in health education provided at school health care and other health care services.
- Fume could be utilized as new, adolescent-oriented tool for developing current tobacco-related health education practices and as a supplementary intervention in nursing with early adolescents. Fume could be suggested to the early adolescents before attending to the health visits. Fume could be then utilized as a starting point of adolescent-oriented discussions with e.g.

the school health nurse and the raised questions on tobacco could be discussed together. This kind of procedure exploiting a digital health game could support the school health personnel in fulfilling the recommendations regarding tobacco-related health education (MSAH & Stakes. 2002; MSAH 2004; 2009), but still save valuable time resources from the school health care.

#### Implications for policymaking

- Attention to the needs of early adolescents regarding tobacco-related health literacy and their knowledge-needs about snus should be payed when updating the school health care recommendations and guidelines.
- Adolescents have important notions that could help to develop the current tobacco-related health education practices towards more adolescent-oriented direction. Their participation in planning of the interventions, recommendations and guidelines could be noticed more actively.
- The possibilities of new digital health innovations, such as health games, could be better noticed in nursing recommendations, guidelines, education and practice.

72 *Conclusions* 

## 7 CONCLUSIONS

The results of this study suggest that tobacco-related health literacy in early adolescents is influenced by a multidimensional and complex set of personal, external and mediating factors. The mediating role of the interpretation process of health messages requires further attention. These determinants recognized in this study highlight the need for paying attention to the unique nature of health literacy in early adolescents. Still, future research confirming the qualitative findings is needed.

This study showed that the strongest evidence on health games in children and adolescents supports the use of active video games in physical activity promotion. Further research is needed especially on other types of health games even though their potential in health promotion of children and adolescents was also demonstrated based on previous research evidence. A new tobacco-related health game intervention named *Fume* targeted to early adolescents was developed and evaluated in this study. The results gathered during the development suggest that balancing the elements both connected to the health content and influencing gaming experience contributes to the acceptability of the intervention. Paying attention to the expectations of adolescents with different gaming backgrounds is also needed.

This study showed that the health game *Fume* is a more feasible as a tobaccorelated health literacy intervention among early adolescents than its non-gamified counterpart, a website intervention, as there was a higher usage rate for *Fume* as well as greater interest in the game intervention. Effectiveness of *Fume* compared to the website intervention and no intervention control group was not demonstrated, but favorable short-term changes in the following theory-based determinants of tobacco-related health literacy were achieved with *Fume*: in positive and negative smoking outcome expectations and attitudes towards cigarette smoking. This study also showed that inclusion of game-elements into the intervention did not influence negatively to the measured outcomes. Based on this study, there is still room for improvement of *Fume*, but it can already be recommended to be used in the health education of early adolescents.

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## **APPENDICES**

Appendix A: Search strategies for the literature reviews reported in this summary

Literature review topic	Keywords <sup>a</sup>	PubMed (Med- line) <sup>b</sup> All/Titles/ Abstracts	CINAHL <sup>b</sup> All/ Titles/ Abstracts	Cochrane Library <sup>b</sup> Titles/ Abstracts	Web of Science <sup>b</sup> Titles/ Abstracts	Abstracts af- ter duplicates removed	Total number of included papers
Tobacco- related health literacy interventions	("Health Literacy" [Mesh] OR "health literacy")  AND ("Child" [Mesh] OR "Adolescent" [Mesh] OR adolescent* OR child OR children) AND ("Tobacco Products" [Mesh] OR "Tobacco" [Mesh] OR "To- bacco Use" [Mesh] OR tobacco OR smoking OR cigarette* OR snus)	49/18/14	10/2/2	13/8/8	42/5/3	18	2
School-based tobacco- related health education interventions	(school[Title/Abstract]) AND (tobacco[Title/Abstract] OR smoking[Title/Abstract] OR cigarette*[Title/Abstract] OR snus[Title/Abstract]) AND (review[Title] OR meta-analysis[Title])	78/18/20	29/11/8	25/7/5	17/5/5	24	14
Tobacco- related health game interventions	("Tobacco Products" [Mesh] OR "Tobacco Use" [Mesh] OR "Tobacco" [Mesh] OR tobacco [Title/Abstract] OR smoking [Title/Abstract] OR cigarette* [Title/Abstract] OR snus [Title/Abstract]) AND ("Child" [Mesh] OR "Adolescent" [Mesh] OR adolescent* [Title/Abstract] OR child* [Title/Abstract])  AND ("Video Games" [Mesh] OR game*)	131/17/12	34/2/0	25/3/2	161/10/7	24	8

<sup>&</sup>lt;sup>a</sup>Variation of headings were used based on individual strategies of the databases. <sup>b</sup>The search was limited to last 10 years and peer-reviewed scientific original publications written in English

Appendix B: Details of the previous tobacco-related health game interventions

Name	Related publications	Country of origin	Target group	Aim	Guiding theory	Targeted theory-based mechanisms	Game's role in the inter- vention <sup>a</sup>	Platform	Short description of the game/game elements
Click City®: Tobacco	Andrews et al. 2011; 2014	The United States of America	5 <sup>th</sup> and 6 <sup>th</sup> graders	Prevent tobacco use, espe- cially cigarette use	Prototype/Willingness model and Theory of Reasoned Action/ the Theory of Planned Behavior. Components designed based on affect heuris- tic, optimism bias and cumulative risks were also included.	Social images, normative beliefs, descriptive norms, perceptions of risks (consequences of tobacco use and exposure to tobacco smoke, risk of addiction), optimism bias, cumulative risks	L	Web- based (intranet)	A web-based environ- ment that include the fol- lowing games: "Mr. Po- tato-head" game (choose between attributes that portray your social im- ages of smokers), "pong- like" game (bat away cigarettes), a smoking roulette game (avoid the word "addicted"), board game (shows what you miss as a smoker), hid- den objects game (rein- forces concepts from previous lessons)
Flavor Monsters	Rath et al. 2015	The United States of America	13 to 24- year-olds	Lower tobacco use, speci- fically flavored tobacco use	Theory of Planned Behavior	Knowledge, beliefs, attitudes	S	Mobile (iOs and Android)	A free mobile game application where Flavor Monsters are attacking American cities. The player needs to complete six levels and stop the monsters by using various tools and items.

<sup>&</sup>lt;sup>a</sup>The game is: S=a stand-alone intervention /L=part of a larger intervention

Appendix B (continues): Details of the previous tobacco-related health game interventions

Name	Related publications	Country of origin	Target group	Aim	Guiding theory	Targeted theory-based mechanisms	Game's role in the in- ter-ven- tion <sup>a</sup>	Platform	Short description of the game/game elements
Fun wit- hout Smokes	Cremers et al. 2012; 2014; 2015	The Nether- lands	10 to 13- year-olds	Prevent smoking	I-Change Model	Knowledge, attitude, social influences, self-efficacy, formation of action plans, intention to change	L	Web- based	A website where a game can be played among others. No further information about the game is available.
HeadOn	Marsch et al. 2007	The United States of America	6–8 graders	Prevent substance abuse, such as smoking	Social influences and social competencies	Knowledge, refusal, social and self- management skills training	L	Web- based	A computer-based program where the user can, among others, answer to a quiz to earn skills cards to be used in a card game called <i>Skills Challenge</i> . In this game, the player needs to play against various challenger by selecting appropriate skills cards.
"An online multiple- choice quiz game"	Ip et al. 2014	China	10 to 24- year-olds	Promote a smoke- free atti- tude	Elaboration Likelihood Model	Knowledge, enhancement of the probability of choosing the central path	S	Web- based	An online multiple- choice quiz game com- petition influenced by viral marketing cam- paigns. The goal is to obtain the highest score possible by answering to quiz questions and to be- come the champion.

<sup>&</sup>lt;sup>a</sup>The game is: S=a stand-alone intervention /L=part of a larger intervention

Appendix C: Details of the previous tobacco-related health game intervention studies

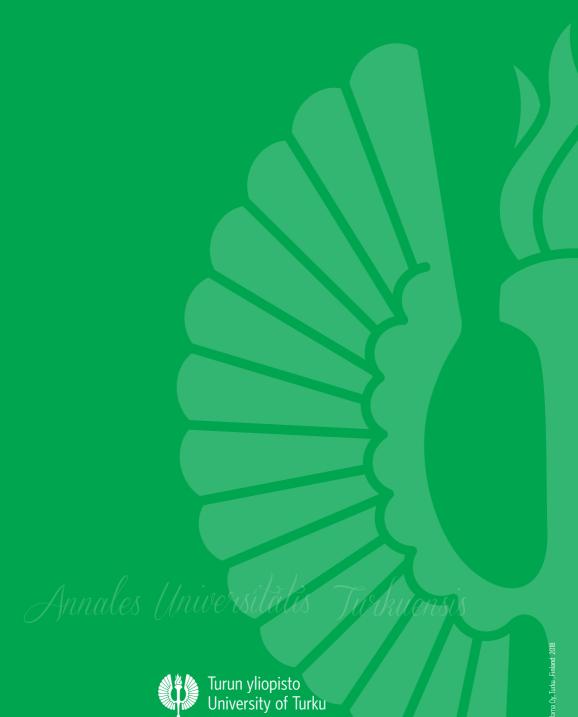
	Publi-	s of the previous tobacco-re	Study de-	ĺ	Description of the in-	Set-	
Name	cation	Aim of the study	sign	Sample	tervention as a whole	ting	Main results
Click City®: Tobacco	And- rews et al. 2011	Evaluate the short-term (base- line—one week) efficacy of the Click City®: Tobacco	RCT	n=2322 fifth grade stu- dents	Eight-session, online program including videos, games, quiz and other interactive tasks. The intervention also included a booster in the 6th grade, a guide for teachers and newsletters for parents. Data were gathered at baseline and after a week.	School	Students in the Click City®: To-bacco program decreased their intentions to use tobacco and their willingness to smoke if given opportunity from baseline to one week after the implementation statistically significantly (P<0.0001 others, intention to chew tobacco P<0.05) more than those in the usual curriculum. Within those schools using the Click City®: To-bacco program, social images of smokers and smoking became less favorable, perceptions of descriptive norms decreased, perceptions of the risks of the consequences of using tobacco, harms of tobacco use and secondhand smoke and risks of addiction increased. Optimism bias regarding getting addicted was reduced.
	And- rews et al. 2014	Evaluate the long-term (5 <sup>th</sup> -7 <sup>th</sup> graders) efficacy of the <i>Click City</i> ®: <i>Tobacco</i>	RCT	n=1168 fifth to seventh grade stu- dents	Same as above, but data were gathered at baseline (5 <sup>th</sup> grade), in 6 <sup>th</sup> grade and in 7 <sup>th</sup> grade.	School	Students in the <i>Click City®: To-bacco</i> program increased less their intentions and willingness to smoke from baseline to 6 <sup>th</sup> grade ( <i>P</i> <0.05 and <i>P</i> <0.05, respectively), and from baseline to 7 <sup>th</sup> grade ( <i>P</i> <0.05 and <i>P</i> <0.01, respectively) than those in the usual curriculum. Positive changes in other mechanisms were also observed.

Appendix C (continues): Details of the previous tobacco-related health game intervention studies

	Publi-	inues). Details of the previous to	Study		Description of the in-	Set-	
Name	cation	Aim of the study	design	Sample	tervention as a whole	ting	Main results
Flavor Mons- ters	Rath et al. 2015	1) To compare length of play, engagement and awareness of the brand of the tobacco-preventive campaign when using two versions of the game with different amount and type of tobacco-related information.  2) To explain the relationship between the "Flavor Monsters" gameplay and game-related tobacco knowledge, attitudes, and beliefs.	1) RCT 2) A single- group re- peated- measure s design	n=693 youth aged 13 to 24 years	The participants downloaded the game application to their mobile devices. Data were gathered at 1 week, 1 month and 3 months of follow-up.	Out- of- school	1) There were no statistically significant differences for engagement ( <i>P</i> =0.81), length of play ( <i>P</i> =0.10) or awareness of the brand ( <i>P</i> =0.67) between those using the two different versions of the game.  2) Gameplay was not a predictor of lower levels of intention to smoke. Statistically significant ( <i>P</i> =0.000) favorable differences (baseline–3 months) were observed in anti-tobacco attitudes and beliefs (Anti-Tobacco Industry Index) for those who mastered the levels 1, 2 or 3 or won the game. The level mastered in the game was statistically significant ( <i>P</i> =0.002) predictor of increase in Anti-Tobacco Industry Index scores at 3-month follow-up.
Fun without Smokes	Cremers et al. 2014	"Examine (1) whether prompts will stimulate primary school children to reuse a smoking prevention website, (2) whether the prompt content is related to its effect in terms of reuse, and (3) which individual characteristics of children are associated with a higher likelihood to respond to prompts and reuse an intervention website."	Cluster RCT	n=1124, age mean 10,35 years	A website with animated videos, games, computer tailored feedback letters and possibility to ask questions. Children logged in to the website using a personal username and password. Use of the website was tracked for a year.	Out- of- school	Use of prompts announcing new to-bacco-related games resulted in more frequent reuse of the website $(P=0.004)$ . Children in the prompt group used the intervention more than those in the no-prompt group $(P<0.001)$ . Children with low socioeconomic status reused the website more often $(P<0.001)$ than those with high socioeconomic status $(P=0.005)$ .
	Cremers et al. 2015	"Evaluate whether computer-tailored feedback messages, with and without prompt messages, are effective in de- creasing children's smoking intentions and smoking behavior after 12 and 25 months of follow-up."	Cluster RCT	n=3213 children aged 10 to 12 years	Same as above, but the data were gathered after 12 and 25 months of follow-up.	Out- of- school	No significant effects were observed in smoking intention in the groups using the website with prompts, without prompts or without intervention at all.

Appendix C (continues): Details of the previous tobacco-related health game intervention studies

Appendix C	ppendix C (continues): Details of the previous tobacco-related health game intervention studies									
Name	Publi- cation	Aim of the study	Study design	Sample	Description of the intervention as a whole	Setting	Main results			
HeadOn	Marsc h et al. 2007	Evaluate HeadOn program compared with Life Skills Training drug abuse prevention curriculum in a school-based evaluation across 4 middle school.	RCT/ quasi experi- mental (not speci- fied)	n=272, six to eight grade students	HeadOn computer-based prevention program with 15 sessions carried out during a school year	School	Students in the <i>HeadOn</i> program had greater accuracy in knowledge compared to the students in the Life Skills group ( <i>P</i> =0.0001). Students in both groups achieved positive outcomes in self-reported rates of cigarettes and alcohol, intention to use substances, attitudes, beliefs about prevalence and likelihood of refusing a drug offer. Students and teachers evaluated the <i>HeadOn</i> useful, and the students found it highly interesting.			
"An online multiple- choice quiz game com- petition"	Ip et al. 2014	Assess the efficacy of an online game-based viral marketing campaign in promoting a smoke-free attitude among Chinese adolescents.	A single- group repeated- measures design	n=928, aged 10 to 24 years	The game was available online. The participants could earn scores by answering to quiz questions or by recommending the game to others. The competition lasted for two months.	Recruit- ment of level-1 users was carried through schools, otherwise out-of- school	The number of participants holding negative attitudes towards smoking increased from 57% to 73% and those holding positive attitudes decreased from 26% to 12% during the campaign. Answering to all of the 20 quiz questions was associated with lower smoking intention in the future (OR=0,95; $P$ <0.01).			



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