

# THE DEVELOPMENT AND FEASIBILITY OF GAMIFIED DIGITAL INTERVENTION AIMING TO PROMOTE PHYSICAL ACTIVITY IN EARLY CHILDHOOD

Anni Pakarinen



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#### **ABSTRACT**

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### THE DEVELOPMENT AND FEASIBILITY OF GAMIFIED DIGITAL INTERVENTION AIMING TO PROMOTE PHYSICAL ACTIVITY IN EARLY CHILDHOOD

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This study aimed to develop a gamified digital intervention aiming to promote physical activity in early childhood. A further aim was to evaluate the feasibility of the intervention among the target group in child health clinics. The study consists of two phases.

The development phase – a cross-sectional correlational study explored developmental factors associated with active play behaviour of 2.5-year-old toddlers (n = 717). Data were collected in child health clinics and consisted of the assessment of child's neurological development and preference to participate in active play. Data were analyzed statistically. The results showed that delayed gross motor skills, self-help skills and auditory perception were negatively associated with a child's preference to participate in physically active play. A quantitative systematic review explored previous gamified digital interventions that enhanced the physical activity self-efficacy of children. Data were collected from five electronic databases and analyzed narratively and statistically. The results showed that the gamified digital interventions are effective in enhancing the physical activity self-efficacy of children. The results from a correlational study and systematic review, together with National Physical Activity Recommendations, contributed to the development of the intervention.

The feasibility and piloting phase – a mixed-method post-test feasibility study – evaluated the usability and acceptability of the intervention from the perspective of public health nurses (n = 5) and families with a child either 1.5 or 4 years old (n = 15). Data were collected using questionnaires and interviews, and analyzed statistically and with deductive qualitative content analyses. The results showed that the intervention was usable and acceptable. Suggestions for further development of the intervention consisted of simplifying the intervention, adding more gamified elements to be more attractive to children and adding more precise feedback for the parents. Based on these results, the intervention was modified and a cluster-randomized controlled study was planned to evaluate the effectiveness of the intervention.

**Keywords:** early childhood, physical activity, digital intervention, gamification.

#### TIIVISTELMÄ

Anni Pakarinen

#### VARHAISLAPSUUDEN FYYSISTÄ AKTIIVISUUTTA EDISTÄVÄN PE-LILLISEN DIGITAALISEN INTERVENTION KEHITTÄMINEN JA SO-VELTUVUUS

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Tämän tutkimuksen tarkoituksena oli kehittää pelillisyyttä hyödyntävä digitaalinen interventio lasten fyysisen aktiivisuuden edistämiseen lastenneuvoloissa, sekä arvioida intervention soveltuvuutta lasten, perheiden ja terveydenhoitajien näkökulmasta. Tutkimus koostuu kahdesta vaiheesta.

Kehittämisen vaiheessa, korrelatiivinen poikkileikkaustutkimus tutki 2,5-vuotiaiden lasten (n=717) kehityksen ja liikunnallisen leikin välisiä yhteyksiä. Aineisto kerättiin lastenneuvoloissa ja se koostui lasten neurologisen kehityksen arvioinneista ja liikunnalliseen leikkiin osallistumisen arvioinneista. Aineisto analysoitiin tilastollisin menetelmin. Tulosten mukaan motorinen kehitys, omatoimisuus ja kuullun ymmärtäminen olivat yhteydessä lapsen liikunnalliseen leikkiin osallistumiseen. Kvantitatiivisen systemaattisen katsauksen tarkoituksena oli tarkastella aiempia pelillisiä interventioita lasten fyysisen aktiivisuuden minäpystyvyyden edistämisen näkökulmasta. Aineisto kerätiin viidestä sähköisestä tietokannasta ja analysoitiin narratiivisesti ja tilastollisin menetelmin. Tulosten mukaan peli-interventiot ovat tehokkaita lasten fyysisen aktiivisuuden minäpystyvyyden edistämisessä. Korrelatiivisen tutkimuksen ja katsauksen tulokset sekä kansalliset lasten liikunnan suositukset toimivat intervention kehittämisen pohjana.

Soveltuvuuden ja pilotoinnin vaiheessa, monimenetelmäinen soveltuvuustutkimus arvioi intervention käytettävyyttä ja hyväksyttävyyttä terveydenhoitajien (n=5) sekä 1,5- ja 4-vuotiaiden lasten ja heidän perheidensä (n=15) näkökulmasta. Aineisto kerättiin kyselyin ja haastatteluin sekä analysoitiin tilastollisin menetelmin ja laadullisella deduktiivisella sisällön analyysilla. Tulosten mukaan interventio oli käytettävä ja hyväksyttävä. Tutkittavat toivat esiin intervention parantamisehdotuksia, jotka liittyivät intervention sujuvuuden ja pelillisten elementtien lisäämiseen sekä vanhemmille osoitetun yksityiskohtaisemman palautesysteemin luomiseen. Soveltuvuustutkimuksen tulosten perusteella interventiota muokattiin ja intervention vaikuttavuuden tutkimus suunniteltiin satunnaistettuna kontrolloituna tutkimuksena.

**Avainsanat:** varhaislapsuus, fyysinen aktiivisuus, digitaalinen intervention, pelillistäminen

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#### **ABBREVIATIONS**

CONSORT- Consolidated Standards of Reporting Trials of Electronic and

EHEALTH Mobile HEalth Applications and onLine TeleHealth

GRADE Grades of Recommendation Assessment, Development and

Evaluation

ISPOR International Society for Pharmacoeconomics and Outcomes

Research

MET Metabolic equivalent

MRC Medical Research Council

MVPA Moderate-to-vigorous physical activity

OR Odds ratio

PDAP Parental Self-Efficacy for Healthy Dietary and Physical Activ-

ity Behaviours in Preschoolers Scale

PHN Public health nurse

PICO patient/intervention/comparison/outcome

RCT Randomized controlled trial SUS System Usability Scale

TIDieR Template for Intervention Description and Replication

#### LIST OF ORIGINAL PUBLICATIONS

This doctoral thesis is based on the following publications, which are referred to in the text by the roman numerals I–IV.

- I Pakarinen A, Kauhanen L, Liuksila P-R, Aromaa M, Hautala L, Kallio H, Sillanpää M, Salanterä. A preference for active play and neurological development in toddlers. (Submitted)
- II Pakarinen A, Parisod H, Smed J, Salanterä S. (2017). Health game interventions to enhance physical activity self-efficacy of children: a quantitative systematic review. *Journal of Advanced Nursing*, 73(4), 794–811. doi 10.1111/jan.13160.
- III Pakarinen A, Parisod H, Aromaa M, Hamari L, Leppänen V, Linden I, Smed J, Salanterä S. A gamified application aiming to promote the health of families with small children a feasibility study. (Submitted)
- IV Pakarinen A, Flemmich M, Parisod H, Selänne L, Hamari L, Aromaa M, Leppänen V, Löyttyniemi E, Smed J, Salanterä S. (2018). Protocol for a digital intervention for the effective health promotion of small children a cluster randomized trial. *Journal of Advanced Nursing*, 2018;00, 1–15. doi: 10.1111/jan.13561.

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#### 1 INTRODUCTION

The basis for physical activity behaviour develops very early on in childhood. Longitudinal studies show that physical activity behaviour tends to track into adolescence and adulthood (Craigie et al. 2011, Telama et al. 2014). In addition to this tracking, physical activity has many beneficial effects on children's health, growth and development (Timmons et al. 2012). However, physical inactivity among small children (2–5 years old) is a global concern and there is an urgent need to develop effective physical activity interventions for small children (Goldfield et al. 2012).

During early childhood, different factors determine how physically active children are (Eisenmann & Wickel 2009), and for example, motor skills (Iivonen et al. 2013), enjoyment (Dowda et al. 2011), preference for physical activity and physical activity self-efficacy (Sterdt et al. 2014) are positively associated with the physical activity of small children. Also, parents have a meaningful role in their small children's lives. Evidently parents' encouragement and support is very important from the perspective of the child's physical activity (Xu et al. 2015, Carson 2016), indicating that family-centred interventions may have the potential to increase the physical activity of children (Xu et al. 2015).

For the families of today, digital media offers a preferred and familiar way to communicate and get information (Feng & Xie 2015). Digitalization of health care offers possibilities to use digital methods for health-promotive purposes (Lupton 2014a). This is often called "digital health" and it encompasses a wide range of technologies that are used for health care, health education and health promotion purposes. The use of mobile devices, applications, websites and different platforms offers access to health information over the Internet, as well as new ways to monitor and measure individuals, and share personal information within health care (Lupton 2014b). Digital health interventions enable a family-centred approach and reach a wide range of families (Braun et al. 2013, Tate et al. 2013). The child-friendly approach – for instance, using gamification in digital health interventions – supports the participation of children (Baranowski et al. 2008, Parisod et al. 2014, Quelly et al. 2016).

When developing interventions for health promotion purposes, evidence and theory should guide the development process, and the feasibility and effectiveness should be evaluated before the implementation of the intervention (Thabane et al. 2010, Craig et al. 2013, Eldridge et al. 2016). The aim of this study was to develop a gamified digital intervention aiming to promote the physical activity of small children and to evaluate the feasibility of the intervention. The study comprises two phases. The aim of the development phase was to strengthen the evidence and

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theory base for the intervention. The aim of the feasibility and piloting phase was to evaluate the feasibility of the intervention among the target group to guide the modification of the intervention and the protocol for the evaluation study.

#### 2 LITERATURE REVIEW

#### 2.1 Promoting physical activity in early childhood

Early childhood (concerning children from birth to five years of age) can be divided into three age periods: infancy (aged 0–1), toddlerhood (aged >1–3) and preschool age (aged >3–5) (American Academy of Pediatrics 2016). In this study the participants include both toddlers and preschoolers.

In the following chapters, the need for physical activity interventions in early childhood is rationalized through describing the significance of physical activity for health and the physical activity behaviour of children. In addition, factors related to physical activity and evidence from earlier physical activity interventions are described in order to understand the basis for future interventions. This literature review focuses (for the most part and where applicable) on children under school age: toddlers and preschoolers. Throughout the literature review, both the toddlers and preschoolers are referred to as *children* or *small children*, since in the reviewed literature, the distinction between toddlers or preschoolers was not always applicable. However, the detailed ages of the children are mentioned where applicable or relevant.

#### 2.1.1 The significance of physical activity for health

Early childhood is a period when children acquire important motor skills with which they can participate in physical activities, both in childhood and later in life (Fisher et al. 2005, Sheridan et al. 2010, Gallahue 2012, Timmons et al. 2012, Laukkanen et al. 2014, Payne & Isaacs 2017). Small children do not generally participate in organized physical activities and spend most of their time at home and in day care settings (Venetsanou & Kambas 2010, Cardon et al. 2011). Thus, during this age period, active play – also called *physically active play* and *exercise play* – can be considered a form of physical activity (Pellegrini et al. 2007, Sheridan et al. 2010). *Active play*, defined as physical activity in a playful context (Pellegrini et al. 2007). *Active play* usually refers to free-flow play which follows the child's preferences and is distinguished from more structured physical activity (Brady et al. 2008, Sheridan et al. 2010). Offering children possibilities to participate in active play promotes children's overall physical activity (Burdette & Whitaker 2005, Sheridan et al. 2010, Veitch et al. 2010).

Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure" (Caspersen et al. 1985). Physical activity can be described through different dimensions, such as frequency (sessions / unit of time), duration (the amount of time spent doing physical activity), quality (aerobic, balance or muscle strengthening activity) and intensity (energy expenditure) (Must & Tybor 2005). Intensity levels are further divided to light intensity activity (e.g. slow walking), moderate-to-vigorous intensity activity (e.g. dancing) and vigorous intensity activity (e.g. running), according to how much energy is expended during the activity (Caspersen et al. 1985, Pate et al. 2008). In contrast to physical activity, inactivity, often referred to as *sedentary behaviour*, is activity that does not increase energy expenditure above the resting (e.g. sitting) level (Pate et al. 2008). The basis for physical activity behaviour develops early on in childhood and tends to track into adolescence and adulthood (Craigie et al. 2011, Telama et al. 2014). Physical activity has many beneficial effects on children's health (Timmons et al. 2012).

Physical activity has, most importantly, beneficial effects on physical health. Physical activity reduces the risk of being overweight and of obesity (Jiménez-Pavón et al. 2010, Vale et al. 2010) and was positively associated with lower adiposity, especially activity at the vigorous level (Collings et al. 2013). Physical activity improves cardiometabolic health indicators – like waist circumference, insulin resistance, blood lipids and blood pressure (Ekelund et al. 2012, Timmons et al. 2012) – and was positively associated with bone and skeletal health (Timmons et al. 2012). Higher levels of physical activity were also positively associated with improved motor skill development (Fisher et al. 2005, Bürgi et al. 2011, Timmons et al. 2012, Laukkanen et al. 2014) and predicted better bone health during school age (Janz et al. 2010).

In addition to physical health, physical activity is evidenced to have beneficial effects on psychosocial health (Timmons et al 2012). Physical activity increased social competence and externalizing behaviour, and more active children were more outgoing and less socially withdrawn when compared to their less active peers (Timmons et al. 2012). Physical activity also has beneficial effects on cognitive development (Etnier et al. 2006, Ahn & Fedeva 2011, Carson et al. 2016). Higher levels of physical activity were associated with better self-regulation (Becker et al. 2014), the ability to sustain attention (Palmer et al. 2013) and early academic achievement, like reading and mathematics skills (Becker et al. 2014), and literacy skills (Kirk et al. 2013).

To gain health benefits, there is a set of international and national physical activity recommendations for children that state an estimated amount (duration and frequency), intensity and quality of physical activity that children should accumulate (Janssen & LeBlanc 2010, Skouteris et al. 2012). The World Health Organization gives recommendations for children aged 5-17 years old. According to the recommendations, children should accumulate at least 60 minutes of moderate-to-vigorous intensity physical activity (MVPA) daily, and vigorous intensity activities should include muscle and bone strengthening activities at least three times per week (WHO 2010). National recommendations may differ slightly between the countries, for example, in the United States children under five years of age should accumulate at least 60 minutes of structured physical activity each day and up to several hours of unstructured daily physical activity (NASPE 2009). In the United Kingdom and Australia, children under five years of age should accumulate at least 180 minutes of light-to-vigorous intensity physical activity each day (Department of Health, Australia 2017, Department of Health and Social Care, UK 2011). While recommendations state the amount, intensity and quality of physical activity, they also give recommendations for inactivity, such as the maximum time per day spent in sedentary activities, since inactivity is known to be an independent risk factor associated with poor health outcomes and increased risk of mortality (Ekelund et al. 2016). In Finland, physical activity recommendations for children under school age state that children should accumulate at least 180 minutes of light-to-vigorous intensity (at least one hour of MVPA and two hours of light-to-moderate physical activity) daily. Physical activity should include versatile physical activities and children should not be sedentary for more than 60 minutes at a time (Ministry of Social Affairs and Health, 2016).

#### 2.1.2 Physical activity behaviour in early childhood

Even with the evidence of the positive effect of physical activity on health and determined physical activity recommendations, the amount of physical inactivity in small children is a global concern (Kohl et al. 2012). It is therefore particularly important to implement physical activity interventions during early childhood (Goldfield et al. 2012). When developing interventions for effective physical activity promotion in early childhood, we should first understand the physical activity behaviour of children, and the determinants and correlates for physical activity (Sallis et al. 2000, Bauman et al. 2012, Hinkley et al. 2012), as well as identify the elements of success found in earlier physical activity interventions (Ling et al. 2017).

Evidence shows that most small children (2–6 years old) do not reach the physical activity recommendations, and most of their daily activities involve low-intensity and sedentary activities (Tucker 2008, Reilly et al. 2010, Gubbels et al. 2010, Hnatiuk et al. 2014). Results from objectively measured physical activity (measured

using an accelerometer) among four- to five-year-olds showed that 7 % of the children engaged in MVPA for 60 min per day and 26 % met the recommended 120 min of total activity per day (Cardon & De Bourdeaudhuij 2008). In other studies, 39 % of five-year-old children spent the recommended 60 min in MVPA per day (Brasholt et al. 2013) and 20 % of the three-year-old Finnish children spent the recommended 120 min in light-to-vigorous activity per day (Soini et al. 2014, 2015). Results from direct observation data (using OSRAC-P) showed that threeto five-year-old children engaged in MVPA less than 3 % of the observed time and were sedentary for more than 80 % of the observed time during the observation (Pate et al. 2008). Moreover, the evidence seems to support that boys are more active than girls (Cardon & De Bourdeaudhuij 2008, Pate et al. 2008, Dolinsky et al. 2011, Hinkley et al. 2012, Soini et al. 2014, 2015). However, on the contrary, some studies showed the opposite results to some of these results, and in the study by Obeid et al. (2011) all the study participants (3-5 years old) met the national recommendations (120 min of total physical activity per day) and in the study by Hnatiuk et al. (2012) 90.5 % of the 1.5-year-old children met the recommendations: 180 minutes of total physical activity per day. The variance of the children's physical activity levels is considerable high and in some cases even contradictory, indicating that the physical activity behaviour during early childhood is subject to change and dependable on different factors.

#### 2.1.3 Determinants and correlates for physical activity

Different factors – such as physical, psychological, social and environmental factors – are regarded as determinants (factors with a causal relationship) and correlates (factors associated with physical activity) for physical activity (Bauman et al. 2002, Eisenmann & Wickel 2009, Bauman et al. 2012). Related to physical factors, children's weight status seems to be associated with their physical activity behaviour. Normal weight children were more physically active and performed better in aerobic fitness, agility and dynamic balance than their obese peers (Niederer et al. 2013). During early childhood, children acquire important motor skills for participating in physical activities, both during childhood and later in life (Fisher et al. 2005, Sheridan et al. 2010, Gallahue 2012, Timmons et al. 2012, Laukkanen et al. 2014, Payne & Isaacs 2017). Children with better motor skills were more physically active than their peers with poorer motor skills (Williams et al. 2008, Cliff et al. 2009, Kambas et al. 2012, Iivonen et al. 2013). Also, children with physical disabilities participated in less physical activity compared to their typically developing peers (Shikako-Thomas et al. 2008).

Psychological factors, like intrapersonal factors, influence children's physical activity behaviours. Shyness, anxiety, a lack of interest or a lack of ability to follow rules hindered willingness to participate in physical activities among children (Dwyer et al. 2008). Children's enjoyment (Dowda et al. 2011) and preference for physical activity, physical activity self-efficacy, perceived competence and attitudes (Sallis et al. 2000, Sterdt et al. 2014), motivation and perceived barriers (Sterdt et al. 2014) were associated with children's physical activity.

Social factors, especially during early childhood, include parents and other caretakers. The family provides basis for the child's socialization, wherein health behaviours begin (Nicklas et al. 2001, Hills et al. 2007, Tucker 2008). Parental support and encouragement was positively associated with children's physical activity (Gustafson & Rhodes 2006, Loprinzi & Trost 2010, Zecevic et al. 2010, Dowda et al. 2011, Grigsby-Toussaint et al. 2011, Trost & Loprinzi 2011, Østbye et al. 2013, Sterdt et al. 2014, Xu et al. 2015, Carson 2016), but parental rules, such as those restricting rough games inside, and other constraints were negatively associated with physical activity (Hinkley et al. 2012). Encouragement and support from day care personnel (Gubbels et al. 2010, Nicaise et al. 2011, Hodges et al. 2012) and peers (Gubbels et al. 2010, Ward et al. 2017) had a positive impact on children's physical activity behaviour. Role modelling, such as parents being physically active themselves (Sallis et al. 2000, Hinkley et al. 2008, Spurrier et al. 2008, Fuemmeler et al. 2011) and with their children, increased the physical activity levels of children (Sallis et al. 2000, Grigsby-Toussaint et al. 2011). Also, parental self-efficacy (Smith et al. 2010, Xu et al. 2015, Nixon et al. 2012, Bohman et al. 2016, Parekh et al. 2017) and parents' perception of their child's competence were positively associated with the child's physical activity (Loprinzi & Trost 2010). Thus, parents should acknowledge their important role in children's physical activity promotion, and foster and enable physical activity behaviour in their children.

Environmental factors have an impact on children's physical activity behaviours. Day care settings are meaningful places where children spend a relatively large amount of time and evidence shows that the intensities of children's physical activity vary between different settings (Grøntved et al. 2007, Pate et al. 2008, Tucker 2008, Dowda et al. 2009). According to earlier studies, offering children the opportunity for outdoor activities and free-flow play (Hannon & Brown 2008, Brown et al. 2009, Sugiyama et al. 2012) positively impacted on their physical activity behaviour (Gubbels et al. 2010, Hodges et al. 2012). Time spent outdoors (Sallis et al. 2000, Hinkley et al. 2008, Brown et al. 2009, Dolinsky et al. 2011, Sterdt et al. 2014) and the overall physical environment – such as larger playgrounds (Spurrier et al. 2008, Dowda et al. 2009, Nicaise et al. 2011), the greenness of playgrounds (Grigsby-Toussaint et al. 2011, Nicaise et al. 2011) and the availability of

equipment (Hannon & Brown 2008, Pate et al. 2008, Spurrier et al. 2008, Brown et al. 2009, Dowda et al. 2011, Nicaise et al. 2011, Sugiyama et al. 2012, Broekhuizen et al. 2014), especially portable and manipulative playground equipment, like wheeled toys (Hannon & Brown 2008, Brown et al. 2009, Nicaise et al. 2011) – and lower use of electronic media (Dowda et al. 2009) increased children's physical activity.

#### 2.1.4 Elements of success in physical activity interventions

Even with the urgent need for physical activity interventions in early childhood (Goldfield et al. 2012), there are a relatively small amount of interventions that target this age group. Reviews and meta-analyses exploring the effectiveness of interventions promoting the physical activity of children mostly report evidence related to school-aged children (Salmon et al. 2007, Van Sluijs et al. 2007, Metcalf et al. 2012). Meta-analyses by Metcalf et al. (2012) showed that physical activity interventions only resulted in a small effect on children's overall activity levels. Reviews by Van Sluijs et al. (2007) and Salmon et al. (2007) showed only small or limited evidence for interventions that involved children under 12 years old. Some evidence of an effect was shown for environmental interventions (Van Sluijs et al. 2007) and for interventions delivered in the school setting that involved activity breaks or family- and theory-based interventions (Salmon et al. 2007). A review that explored physical activity interventions among preschool-aged children, found a small-to-moderate effect on general physical activity and a moderate effect on MVPA. Evidence of an effect was shown for interventions implemented in an early-learning environment, led by teachers, that involved outdoor and unstructured activity or lasted less than four weeks (Gordon et al. 2013).

Evidence from individual studies targeting under school-aged children is mixed. A study of an eight-week intervention which integrated physical activity into the preschool curriculum (Move and Learn) found a significant effect on MVPA in three- to five-year-old children (Trost et al. 2008). A study of an 18-week teacher-led activity lesson intervention (Mighty Moves), implemented in pre-school settings among three- to five-year old children (Bellows et al. 2013) and another study of a 24-week physical activity intervention in a nursery with home-based health education among four-year-old children (Reilly et al. 2006), found a significant effect on gross motor skills, but not on the physical activity levels of children. In contrast, a study by Fitzgibbon et al. (2005) among three- to five-year old children found in no intervention effects in a 14-week teacher-led activity lesson intervention.

As previously described, significant associations exist between parents' behaviours and the physical activity of small children, thus, the role of parents as health promoters should be acknowledged when developing interventions (Goldfield et al. 2012). In a meta-analysis exploring healthy lifestyle interventions in preschoolaged children, interventions targeting parents with parenting skill training and behavioural change strategies resulted in greater effects (Ling et al. 2017), and in a few reviews exploring physical activity interventions, family-centred interventions resulted in positive outcomes related to children's physical activity behaviour (Timperio et al. 2004, Salmon et al. 2007). Further, a study by Sääkslahti et al. (2004), found significant effects on four-year old children's active outdoor play in a three-year family-centred intervention including annual parent meetings, physical activity sessions with children and delivery of print materials. And a study of a 10-week activity and educational intervention, implemented in SureStart children's centres among three- to five-year old children and their parents, found significant intervention effects for sedentary time and physical activity in children (O'Dwyer et al. 2012). Parental self-efficacy was found to be in association with children's physical activity behaviour (Smith et al. 2010, Xu et al. 2015, Nixon et al. 2012, Bohman et al. 2016, Parekh et al. 2017) and parents who had high sense of self-efficacy were more likely to have their children meet the physical activity guidelines (Smith et al. 2010). Thus, family-centred interventions, improving parenting practices and enhancing parental self-efficacy may have potential to increase the physical activity of children (Xu et al. 2015).

The family-centred approach is an empowering collaborative and respectful partnership between families and care providers, where families' individual strengths and needs are noted and their decision-making is supported (Dalvand et al. 2014). At its best, the family-centred approach also supports the participation of children and values their role as health promotive actors in their own life (Christensen 2004, Montgomery-Andersen & Borup 2012, Coyne et al. 2016). To support children's active participation in health discussion, health care providers and parents should give children the space and opportunity to bring out their views and tailor the responses and care to meet children's individual needs and competencies (Coyne et al. 2016).

One meaningful setting for the implementation of family-centred interventions in Finland is child health clinics, since they reach a wide range of small, under schoolaged children and their families (STM 2009, Government Decree 338/2011). Families attend to health examinations in child health clinics, where the child's health, growth and development are assessed and the family receives health guidance. The assessment and promotion of families' health behaviours, like physical activity, also form one meaningful part of the health examinations (Mäki et al. 2017). Thus, public health nurses (PHNs) have a significant role in promoting the health literacy

of families and supporting their competencies, participation and motivation to take actions toward promoting their health (Government Decree 338/2011, Sørensen et al. 2012). Recent advances in health technology provide the opportunity to develop and implement innovative and child-friendly digital interventions (Baranowski et al. 2008, Quelly et al. 2016). Digital interventions enable a family-centred approach, reach a wide range of families and are cost-effective (Braun et al. 2013, Tate et al. 2013). Digital health interventions have been shown to be a feasible and effective method for promoting children's healthy behaviour (Parisod et al. 2014, Turner et al. 2015, Quelly et al. 2016). However, the evidence on digital health interventions among small children and their families is scarce.

#### 2.2 Digital interventions to promote physical activity in childhood

Digital media – such as software, video games, websites, social media and databases – has a significant impact on society and culture (Dewar 2000). Digital media offers a natural and preferred media for today's children (Brown 2011, Radesky et al. 2015, Kabali et al. 2015, Chassiakos et al. 2016). People around the world are using digital media even more and, for example, in Europe, over 85 % of the population is using the Internet (Internet World Stats 2017) and in the USA, 98 % of the households with under eight-year-old children have a mobile device (Rideout 2017), providing a good ground for implementing interventions for families with small children. Even small children use mobile devices daily to play games, access applications and watch videos (Brown 2011, Radesky et al. 2105, Kabali et al. 2015, Chassiakos et al. 2016). Thus, gamification – defined as "the use of game design elements in non-game contexts" (Deterding et al. 2011a) – is one potential method of intervention that supports the participation of children. Game design elements may include reward systems (points, levels, leader boards), narratives, playful contexts and feedback systems (Deterding et al. 2011a, 2011b). Gamification can increase the enjoyment of and engagement in health interventions among children (Hamari et al. 2014) and also increase their attractiveness (Parisod et al. 2014).

In the following chapters, the evidence from family-centred digital and gamified interventions, used to promote the physical activity of children, is explored. The emphasis, where applicable, is on children under school age: toddlers and preschoolers (referred as "children" or "small children"). The focus will be on the description of interventions, their evidence, development and feasibility. This exploration is based on a narrative analysis of original publications. A literature search was conducted using international electronic databases (PUBMED/MED-LINE, CINAHL and EMBASE) in March 2018. The following search terms were

used in different combinations: *child/preschooler/toddler, parent/family, digital/internet/web-based/mobile/game and physical activity* (see Appendix 1). The search was limited to publications from 2008 to 2018 and publications written in English. A manual search of the reference lists of screened articles was used to complete the literature review.

#### 2.2.1 Evidence from previous digital interventions

The systematic literature search identified 17 individual studies reporting on altogether nine different digital interventions aimed at promoting the physical activity of children (E-health4Uth Healthy Toddler, EMPOWER, Healthy Start, HFHK, HomeStyles, InFANT Extend, MINISTOP, NAP SACC UK, Time2bHealthy). Some of the studies reported on the same intervention and were related to the protocol of the intervention (Knowlden et al. 2012, Raat et al. 2013, Delisle et al. 2015), the feasibility of the intervention (Jones et al. 2011, Knowlden et al. 2014) or to different time points related to the intervention results (Knowlden et al. 2015, 2016, 2017) (Table 1).

All the interventions were family-centred interventions with children under six years of age, implemented during the last five years in three different continents. Most interventions were home based (EMPOWER, HomeStyles, InFANT Extend, MINISTOP, Time2bHealthy). Two of the interventions were implemented at both home and childcare centres (Healthy Start, NAP SACC UK), and one was an intervention targeting parents at home and in child health clinic settings (Ehealth4Uth Healthy Toddler). A further intervention was a one-time intervention, implemented in research settings to evaluate the feasibility of a website (HFHK).

All the interventions were combined interventions with the focus on the promotion of physical activity and healthy nutrition. A few also targeted the sleeping habits of children (Time2bHealthy, HFHK and HomeStyles). Most of the interventions were web-based interventions involving websites with healthy information (Healthy Start, HFHK, InFANT Extend, HomeStyles, NAP SACC UK, Time2bHealthy). One was delivered using a mobile application (MINISTOP) and one through web-based education material, such as audio-visual lessons and interactive worksheets (EMPOWER). Another had an eHealth module with the ability to enter information on a child's health habits, receive tailored feedback and advice online from health professionals in a child health clinic, based on the results (E-health4Uth Healthy Toddler). Interventions also consisted of some other elements, such as social activity through online discussion boards (EMPOWER), Facebook groups (Healthy Start, Time2bHealthy, InFANT Extend, NAP SACC UK), goal setting (HomeStyles, NAP SACC UK, Time2bHealthy), the ability to discuss with

a health professional online (InFANT Extend, MINISTOP, Time2bHealthy), and the possibility to receive tailored online feedback, based on the entered health behaviours (E-health4Uth Healthy Toddler, HomeStyles, MINISTOP, NAP SACC UK). In other aspects, like the dose of the intervention, interventions were rather heterogeneous, as described in Table 1.

The effectiveness of the interventions as regards to physical activity, inactivity or physical activity mediators (like self-efficacy) were measured from right after the intervention (Davies et al. 2014) to a two-year follow-up (Knowlden et al. 2017) and the results were mixed. According to the results in randomized controlled trials (RCTs), the intervention had significant effects on physical activity behaviours in a one-month follow-up (Knowlden et al. 2015) and two years after the intervention (Knowlden et al. 2017). The same intervention also had significant effects on mediators (like the environment), expectations and self-efficacy in all the follow-up measurement points from one month to the two-year follow-up (Knowlden et al. 2015, 2016, 2017). Notably, one intervention resulted in having no effect on the physical activity of the children (Deslisle-Nyström et al. 2017, Parekh et al. 2017) and one study only found significant effects related to physical activity and outdoor play among one sub-group of children (van Grieken et al. 2017). Apart from abovementioned results, drawing conclusions related to efficacy for the rest of the interventions was impossible since one of the studies only reported on the feasibility of the intervention (Davies et al. 2014) and the rest of the studies were protocols of RCTs (Bélanger et al. 2016, Campbell et al. 2016, Byrd-Bredbenner et al. 2017, Hammersley et al. 2017) or studies of the feasibility of RCTs (Kipping et al. 2016). A more detailed description of the interventions can be found in Table 1.

 Table 1. Description of the digital interventions.

Interven- tion	Time2bHealthy	EMPOWER	E-health4Uth Healthy Toddler	НГНК	MINISTOP	Healthy Start	InFANT Ex- tend	NAP SACC UK	HomeStyles
Author, year, country	Jones et al. 2011, Hammersley et al. 2017, Australia	Knowlden et al. 2012, 2014, 2015, 2016, 2017, USA	Raat et al. 2013, van Grieken et al. 2017, Neth- erlands	Davies et al. 2014, USA	Delisle et al. 2015, Delisle- Nyström et al. 2017, Parekh et al. 2017, Sweden	Bélanger et al. 2016, Can- ada	Campbell et al. 2016, Australia	Kipping et al. 2016, UK	Byrd-Bredbenner et al. 2017, USA
Description of the intervention	Online program: *Six interactive modules including information on healthy nutrition, physical activity, screen-time and sleep: *Videos and activi- ties *Ability to set goals *Tailored feedback is provided by a di- etitian via the web- site regarding the goals set *Facebook group moderated by the dietitian *Reminders deliv- ered by emails	Web-Based education: *Audio visual lessons *Interactive worksheets *Online discussion boards	Web-based intervention with face to face counseling: *eHealth module with tailored feedback and advice to parents regarding their child's nutritional habits and physical activity before regular well-child visits *Tailored feedback and advice is based on the answers that parents provide in the assessment questionnaire of the eHealth module *During a regular well-child visit at 18 and 24 months of age, discussion of the advice combined with face-to-face counselling provided by the health care professional (e.g. Community physician or nurse).	Web-Based intervention:  *Website with nine different webpages.  *Two web pages related to family history and child temperament, four webpages related to child lifestyle factors: eating habits, physical activity, sedentary activity and sleep habits, three webpages related to environmental factors, like family practices, family function and the built environment.  *Physical activity related webpages included recommendations, age-appropriate suggestions and encourages parents to role modelling	egies for	material for	Web-based intervention: *E-mail news-letters sent to parents containing web-links to the Melbourne In-FANT Program website. *Facebook group moderated by nutritionist	Web-based intervention for parents: *Website including questionnaire about family health behaviour *Text messages or emails including tai- lored feedback on target behaviour *Ability to set and review goals related to health behaviours *Tailored tips and suggestions through text messages, emails or Facebook *Two face to face training sessions to nursery staff	Web-based intervention: *Website with 12 instructional guides in the form of four-page mini- magazines *Goal-setting and monitoring (goal trackers) *Information and tips about healthy nutrition, physical activity and sleep *Reminders deliv- ered by phone, text messaging, and/or email *In-home, face-to- face, individual- ized learning facil- itated by trained home visitation staff

Aim	To promote healthy lifestyles of over- weight, or at risk of overweight, pre- school-aged chil- dren	To assist mothers in helping children achieve four child behaviours posited to prevent child-hood obesity (physical activity, fruit and vegetable consumption, sugarfree beverage intake, and screen time).	To promote child's healthy nutrition (eat breakfast daily and consume fewer sweetened beverages) and physical activity behaviours (increase physical activity and spend less screenbased time).	To promote the change in parental self-efficacy related to risk factors for childhood obesity.	children achieve healthy body fatness through in- creasing phys- ical activity and improving dietary behav- iour.	educators to integrate phys- ical activity and healthy eating in the daily lives.	To increase children's fruit and vegetable consumption and physically active time and to decrease consumption of sweetened drinks and sedentary time.	To increase knowledge, self-effi- cacy and motivation of parents and nursery staff to pro- mote healthy eating and physical activity behaviour of chil- dren.	To motivate parents to change their home environments and lifestyle behavioural practices (diet, exercise, and sleep) to be more supportive of their preschool children's optimal health and weight.
Target group	Parents with over- weight 2-5-year-old children (target sample 160 partici- pants).	Mothers with 4-6-year-old children (n=57, 29 in intervention and 28 in control group).	Parents with 1,5 and 2- year-old children (n=2102, 1008 in intervention and 1094 in control group)	Parents with 2-5-year- old children (n=15)	Parents with 4,5-year-old children (n=281, 143 in intervention and 138 in control group).	Parents and their 3-5- year-old chil- dren (target sample 735 children).	First-time parents with 1,5-3-year-old children (target sample 540 parents).	Parents and their 2-4- year-old children and nursery staff (target number of nurseries is 12).	Parents with 2-5- year-old children (target sample 210 parents).
Setting	Home-based intervention	Home-based intervention	Home-and child health care-based intervention	Participants screening and reading the webpage in research settings	Home-based intervention	Homes and Childcare centres	Home-based intervention	Homes and Nurseries	Home-based intervention
Dose (frequency and dura- tion)	11-week intervention with six 30-minute modules dedicated to topics of nutrition, physical activity, screen-time and sleep. Modules are completed over a two-week period.	Six-week intervention with five 10- to 15-minute modules, dedicated to each of the four child behaviours and one booster session to reinforce the content of the previous four modules.	The duration of well-child visit was approximately 20 minutes	One-time intervention with participants screening and reading the webpage in re- search settings	Six-month in- tervention with twelve topics (every other week) of themes on healthy foods, physical activ- ity and seden- tary behav- iour.	Six to eight months inte- grated to daily routines of child cen- tres	1,5-year intervention and one emailed newsletter in every 3 months starting when child is 1,5-year-old.	One-year intervention.	12 to 18-month intervention with twelve 15-minute sessions to review

Design,	RCT	RCT	RCT	One group pre-test and	RCT	RCT	RCT	RCT (feasibility	RCT
and main	* study results not	*1-month post-	*Follow-up, when child	post-test feasibility	*6-month	* study re-	* study results	study)	* study results not
result of	yet available (study	test: significant	was 36 months old: signif-	study	post-test:	sults not yet	not yet availa-	* study results not	yet available
the inter-	protocol)	effects for child	icant effect in one sub-	*After one time use of	no significant	available	ble (study pro-	yet available (study	(study protocol).
vention re-		physical activity	group (non-Dutch chil-	webpage: 62 % of par-	effects for	(study proto-	tocol).	protocol).	
lated to		and physical ac-	dren) in time spent being	ents reported improve-	child physical	col).			
physical		tivity mediators	active or playing outdoors	ment in self-efficacy	activity.				
activity		*1-year follow-	compared with the control	on physical activity of					
		up: significant	group.	children					
		effects for physi-							
		cal activity me-							
		diators *2-year							
		follow-up: sig-							
		nificant effects							
		in child physical							
		activity and							
		physical activity							
		mediators.							

#### 2.2.2 The development of digital interventions

The Medical Research Council (MRC) offers a comprehensive framework for complex interventions (Craig et al. 2013). Digital interventions may be considered complex because they include various stakeholders, target various outcomes and are often complicated in nature (Eysenbach et al. 2011). The MRC framework includes four phases. The first phase includes recommendations for the development of interventions using the best available evidence and appropriate theory guiding the content, methods and implementation of the intervention (Craig et al. 2013). Also, other frameworks guide the development of digital interventions like the user-centred design process, which is a general framework for all kinds of designs and devices (Barnum 2010). Participatory design principles are recommended to ensure the sustainable implementation of interventions (McIntyre 2008). There are also frameworks more focused on game and application design processes, like that presented by Novak (2012).

There are common principles in these frameworks, including needs assessment, user participation and the multidisciplinary expertise of the development team. In health interventions, the development team is recommended to consist of experts from several fields, ranging from content experts in health and behavioural sciences to experts in technological and graphical design (Baranowski et al. 2013, 2016). Needs assessment may include the evaluation of previous evidence related to the health issue in concern through literature reviews or empirical research and exploration of the needs among the targeted users through empirical research, for example, surveys and interviews. Iterative development through user participation may include evaluating the perceptions and ideas of the target group concerning the intervention at different phases of the development process (Barnum 2010, Novak 2012).

Most of the included interventions were based on recent, evidence-based guide-lines and recommendations for child health-related behaviour (E-health4Uth Healthy Toddler, EMPOWER, HFHK, HomeStyles, MINISTOP, NAP SACC UK, Time2bHealthy). Some were also based on up-to-date research literature (Healthy Start, HFHK, HomeStyles), explorations of publicly available websites containing healthy lifestyle information (HFHK, Time2bHealthy), earlier interventions targeting young children (MINISTOP) and the best available knowledge from practice (Healthy Start). One intervention was an adapted version of the same intervention implemented in the USA, but extended with a digital component (NAP SACC UK). There was no information about the evidence base of the In-FANT Extend intervention.

All interventions were based on social cognitive theory expect one (Healthy Start). Many of the interventions were also based on a social-ecological model (Ehealth4Uth Healthy Toddler, Healthy Start, HFHK, HomeStyles, NAP SACC UK). In addition to these, one intervention was also based on the theory of planned behaviour and McGuire's communication model (Ehealth4Uth Healthy Toddler). Parental self-efficacy was the most targeted psychological mediator for behaviour change in the included interventions (Ehealth4Uth Healthy Toddler, EMPOWER, Healthy Start, HFHK, HomeStyles, InFANT Extend, MINISTOP, NAP SACC UK, Time2bHealthy).

An iterative development process was implemented in some of the interventions through a pilot study with concept testing (MINISTOP), a usability study with usability and functionality testing (HFHK) and feasibility testing with the prototype (MINISTOP). Most of the interventions used participatory design principles and involved target group of parents (Healthy Start, HomeStyles, MINISTOP, NAP SACC UK, Time2bHealthy), children and health care providers, like paediatricians (HomeStyles), nursery managers, health visitors and public health staff (NAP SACC UK), as well as social workers (HomeStyles) and early years teachers (NAP SACC UK).

Many of the interventions were developed using content expertise, like that of dieticians (HomeStyles, MINISTOP, NAP SACC UK) and that of experts on physical activity (HomeStyles, MINISTOP), child development (HomeStyles), behavioural science (HomeStyles, MINISTOP), the medical field (MINISTOP) and education (Healthy Start, HomeStyles). Also, researchers (HomeStyles, Healthy Start), community groups and government representatives (Healthy Start) were involved in the development process. For the technical development experts from engineering (MINISTOP), computer technology and graphic design (HomeStyles) were consulted. One study did not report more precisely on the development process of the interventions, but indicated that the intervention was developed by the research team (EMPOWER) and two of the studies did not give any description of the development process (E-health4Uth Healthy Toddler, InFANT Extend).

#### 2.2.3 The feasibility of digital interventions

Feasibility testing shows whether a developed intervention is relevant and appropriate for further testing and implementation, and shows what kind of changes or modifications are needed. Feasibility studies are also an important part of planning RCTs, for example, they are used to estimate the number of eligible patients, response rates to questionnaires and adherence rates (Arain et al. 2010, NETSCC

2018) and to identify possible problems and challenges regarding the implementation of future studies (Bowen et al. 2009, Thabane et al. 2010, Craig et al. 2013, Peters et al. 2013, Eldridge et al. 2016). Feasibility testing is usually implemented in real-life settings in order to evaluate the feasibility of the intervention among the target group and in its intended context. There are different issues to evaluate in feasibility testing, like usability, acceptability, demand, practicality and limited effectiveness (Bowen et al. 2009).

In the included studies, feasibility (pilot) studies were conducted in five out of the nine interventions (Jones et al. 2011, Raat et al. 2013, Knowlden et al. 2014, Davies et al. 2014, Delisle et al. 2015). The Healthy Start intervention was piloted (Belangér et al. 2016), but the study has not been published, thus, no further information can be found out about the conduct and results of the pilot study. Jones et al. (2011) tested the acceptability and potential efficacy of the intervention in a one-group pre-post-test 10-week pilot study among 40 mother-child dyads. According to the results, the Time2bHealthy intervention was acceptable, had a high level of retention and was potentially efficacious (Jones et al. 2011). A pilot study by Raat et al. (2013) showed that the E-health4Uth Healthy Toddler intervention was generally appreciated by parents regarding the understandability, usefulness and applicability of the advice they received from the eHealth module. Knowlden et al. (2014) conducted their feasibility study as a process evaluation and tested the program fidelity, dose delivered, dose received, context, reach and recruitment among targeted parents. The results suggested that the EMPOWER intervention was equivalent and administered as planned. The feasibility of the HFHK intervention was tested as a pre-post-test design study. They tested the limited effectiveness of the intervention with a parental self-efficacy survey and perceptions of the intervention, satisfaction with the intervention, and needs for the further development of the intervention were assessed with an open-ended interview among 15 parents. The results indicated that 92 % of parents had some degree of improvement in self-efficacy on at least one risk factor for childhood obesity. All participants found the website readable and the information useful; no suggestions for improvements were made (Davies et al. 2014). The content and feasibility of the MINISTOP intervention was tested in a pilot study among 19 parents and the results of the study guided the final development of the intervention, but no further information on the results were found from the article (Delisle et al. 2015).

#### 2.2.4 A summary of the findings in previous digital interventions

Based on the findings of this literature review, digital and family-centred interventions offer potential methods for promoting the physical activity of small children.

All the nine interventions included in this review were web-based interventions that also involved other intervention elements, such as the promotion of healthy nutrition. Most of the interventions included websites with information on healthy behaviour, but also elements that enabled parents to enter information concerning family practices and the health behaviour of children, and to receive tailored feedback and advice based on their behaviour. All the interventions were evidence and theory based and most of the studies reported using content expertise in the development process. The development of the interventions was mostly iterative and followed participatory design principles. Target groups, such as parents and health care providers, were involved at least in some phases of the intervention development. The target groups perceived these kinds of intervention to mostly be useful and feasible methods to promote the health behaviour of children and families.

There were also some limitations to the identified interventions. First, feasibility and piloting testing was only conducted in five out of the nine interventions. This lack of testing may influence the sustainable implementation of the interventions in the future, since feasibility studies bring important insights regarding the relevance and appropriateness of interventions among targeted users in targeted settings (Bowen et al. 2009, Craig et al. 2013, Peters et al. 2013). Second, not all the included interventions targeted at parents and the participation of children were supported during development or during the intervention implementation. The development of digital interventions involving small children as health promotive actors would be a welcome addition to the field of family-centred health promotion (Christensen 2004, Montgomery-Andersen & Borup 2012, Coyne et al. 2016). Third, no study reported on using gamification in its intervention. However, the studies included goal setting, monitoring and feedback systems, which are often perceived as such elements (Deterding et al. 2011a, 2011b).

Since earlier studies have showed gamification to be a potential method for use among school-aged children (Parisod et al. 2014), this area needs more exploration among small children in the future. Moreover, the evaluation of the effectiveness of child-centred interventions would be of interest. The use of digital health promotive interventions among small children is still at an early stage. However, this literature review showed that digital interventions have been implemented during recent years, indicating that this area is an evolving area for exploration in the future.

#### 3 THE AIMS OF THE STUDY

This study is part of a larger project, wherein we developed a gamified digital intervention to promote the health literacy skills of small, under school-aged children in child health clinics. The overall aim of this study was to develop the physical activity component of the intervention and to evaluate the feasibility of the intervention with special reference to the physical activity component. The study comprises six sub-studies and two phases: 1) the development phase and 2) the feasibility and piloting phase.

The specific aims of the sub-studies were:

#### Phase I: The development phase

Sub-study I: To explore the developmental factors associated with the active play behaviour of toddlers (Paper I).

Sub-study II: To explore gamified digital interventions to enhance the physical activity self-efficacy of children (Paper II).

Sub-study III: To describe the development of the physical activity component of the intervention (Papers I, II, III, Summary).

#### Phase II: The feasibility and piloting phase

Sub-study IV: To evaluate the feasibility of the intervention among families with small children and PHNs in child health clinics (Paper III).

Sub-study V: To describe the modification of the physical activity component of the intervention (Paper IV, summary).

Sub-study VI: To describe the protocol for the evaluation study (Paper IV).

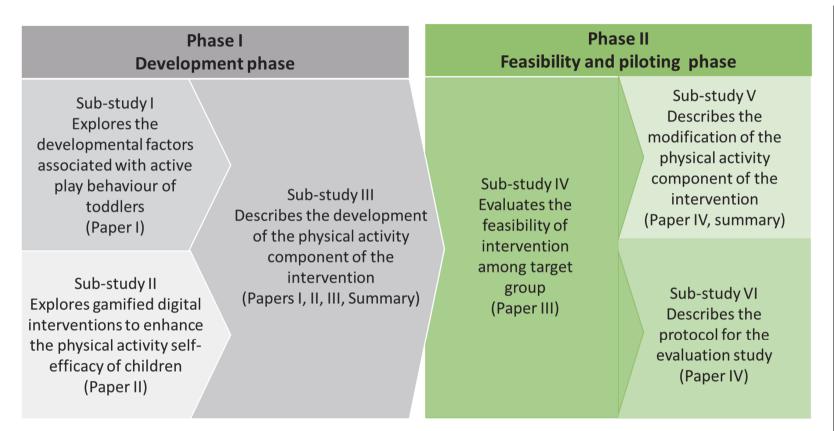


Figure 1. Overall design of the study.

#### 4 MATERIALS AND METHODS

### 4.1 The WellWe intervention for promoting the health of small children

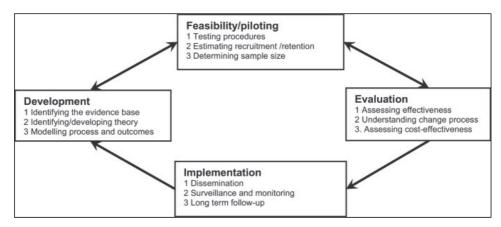
An intervention called the WellWe intervention approached health considering four aspects: physical activity, nutrition, family resources and daily rhythm. Each has a theoretical basis of its own. The development of the intervention followed the methodological framework for complex interventions (Craig et al. 2013). This study focuses on the development and feasibility of the physical activity component of the intervention.

In the WellWe intervention, families with small children used the web-based WellWe application with personal computers or mobile devices in order to assess and enter information on their current health behaviour (physical activity and nutrition), family resources and daily rhythm. Families used the application before they entered the extensive health examination in child health clinics. During the health examination, PHNs used the information in the application to facilitate family- and child-centred health discussion with families.

The iterative development and formative testing of the application, following Novak's (2012) framework and participatory design principles (McIntyre 2008), is described in Papers III and IV, and in the study by Pakarinen et al. (2017). During the formative testing, first, a testable alpha version of the application was tested among health care professionals (n = 26). The data were collected through semi-structured group interviews to assess the ease of use, relevance and visualization of the application. The beta version of the application was tested among health care personnel from child health clinics (n = 5) and the research group's and their acquaintance's children (n = 3). The data from health care personnel were collected through informal group discussion in order to assess the usability, functionality, usefulness, understandability and visualization of the application. The data from children were collected through informal discussion and observation in order to assess the visualization and understandability of the application (Pakarinen et al. 2017).

#### 4.2 The methodological and theoretical approach of the study

The methodological framework for the study was the MRC's framework for complex interventions (Fig 2). The MRC framework includes four phases. In the first phase, the framework recommends using the best available evidence and appropriate theory to develop interventions systematically. In the second phase, feasibility and pilot testing are recommended. This phase produces meaningful information on the procedures, recruitment and retention of the intervention, as well as guiding the determining of the sample size for the clinical trial. In the third phase, the evaluation study evaluates the effectiveness of the intervention in order to further assist and monitor the process of the implementation of the intervention in the fourth phase. This study comprises the first two phases from the MRC framework: the development phase, and the feasibility and piloting phase (Craig et al. 2013).



**Figure 2**. Medical Research Council's (MRC) framework for complex interventions (Craig et al. 2013).

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Theory-guided interventions are evidenced to lead to more effective outcomes, especially in behavioural interventions (Lubans et al. 2008, Nixon et al. 2012). Behavioural theories or conceptual models provide the basis for understanding health behaviour (Baranowski et al. 2003). Theory can guide the development of interventions by identifying the theoretical constructs to be targeted or the mechanisms underlying behaviour change techniques (Webb et al. 2010). The theoretical framework for the intervention was the *mediating variable model* (Baranowski et al. 1997, 1998), which specifies that behaviours should be addressed through mediators that are evidenced to be the determinants of desirable behaviours (Baranowski et al. 1997).

The mediating variable model has been proposed as a framework for designing interventions for physical activity and healthy nutrition promotion (Baranowski et al. 1997, 1998). In the model, mediating variables (later referred to as *mediators*), derived from theoretical or conceptual models, are seen to be in a cause–effect relationship between an intervention and a behavioural outcome. According to the model, interventions affecting the changes in mediators result in changes in behavioural outcomes. Interventions are more likely to be effective if the selected mediators are strongly associated with the desired behaviour (Baranowski et al. 2003).

Since self-efficacy is an important personal factor in behaviour change (Bandura 1986a, 1986b), and has been found as one of the key determinants for physical activity engagement in children in many previous studies (Sallis et al. 2000, Lubans et al. 2008, Plotnikoff et al. 2013, Sterdt et al. 2014), it was chosen as a theory base for the physical activity component of the intervention. *Self-efficacy* refers to the belief in one's competence at behaving in certain predictable ways, even when facing obstacles and barriers. It refers to the capacity and actions which an individual has an influence upon (Bandura 1994, 1997). Based on the theoretical framework (the mediating variable model [Baranowski et al. 1997, 1998]) the intervention aims to affect the mediator (physical activity self-efficacy) in order to promote the physical activity behaviour of children (see Fig. 3).



Figure 3. Theoretical framework for the physical activity component of the WellWe-intervention

# 4.3 The design of the study

### Phase I: The development phase

In Sub-study I, we identified the evidence base for the intervention and conducted a cross-sectional correlational study (Mann 2003) in order to explore the active play behaviour of toddlers (Paper I). In Sub-study II, we identified the theory base for the intervention and conducted a quantitative systematic review (Higgins & Green 2011) in order to explore previous gamified digital interventions that aimed to enhance the physical activity self-efficacy of children (Paper II). In Sub-study

III, these previous studies, together with national physical activity recommendations (Ministry of Social Affairs and Health 2005), contributed to the development of the physical activity component of the intervention (Papers I, II, III, summary).

### Phase II: The feasibility and piloting phase

In Sub-study IV, we used a mixed method (e.g. Kelle 2006, Brannen 2017) posttest design (Grove et al. 2012) to explore the feasibility of the intervention (Bowen et al. 2009). We evaluated the feasibility from the perspective of public health nurses (PHNs) and families with 1.5- and 4-year-old children. The usability of the intervention was explored using quantitative methods (Pakarinen et al. 2017) and the acceptability of the intervention was explored using qualitative methods (Paper III). In Sub-study V, the feasibility study contributed to the modification of the physical activity component of the intervention (Paper IV, summary) and protocol for the evaluation study (Paper IV). In Sub-study VI, we planned a trial study to evaluate the effectiveness of the intervention (Craig et al. 2013) and followed the guideline of the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) statement (Eysenbach et al. 2011) (Paper IV).

 Table 2. Summary of the methodological approaches of the study.

Phase	Sub- study	Design	Setting	Subjects and sources	Data collection	Data analyses	Reported in
	Ι	Cross-sectional correlational study	Child health clinics in the city of Turku (n=19)	Children aged 2.5 y (n=717)	Data-records of child's neurologi- cal development (Lene test) and child's preference to active play (Questionnaire)	Descriptive statistics, Cross- tabulations, Fisher's exact tests, Multivariable logistic re- gression analysis	Paper I
Develop- ment phase	П	Quantitative system- atic review	Electronic databases (n=5) and manual search	Studies meeting the eligibility criteria (n=5)	Systematic literature search	Descriptive statistics, narrative analysis	Paper II
	III	Development of the physical activity com- ponent of the inter- vention	Multidisciplinary group of experts	Papers I, II and physical activity recommendations for children	Data extraction	Data synthetization and convertion	Papers I, II, III, summary
	IV	Mixed-method post- test feasibility study	Child health clinics (n=5) in the Southwest Finland	PHNs (n=5), families (n=15) with 1.5- or 4- year-old children	Usability scale (PHNs and families), Interviews (PHNs), Semistructured questionnaire (families)	Descriptive statistics and de- ductive qualitative content analyses	Paper III (see also Pakari- nen et al. 2017)
Feasibility and pilot- ing phase	V	Modification of the physical activity com- ponent of the inter- vention	Multidisciplinary group of experts	Paper III and physical activity recommendations for children	Data extraction	Inductive content analyses	Paper IV, summary
	VI	Protocol for the evaluation study (protocol for controlled trial)	Identifying the setting that best represents targeted context for the intervention	Families with 4-year-old children and sample size calculated with power analyses	Identifying the instrument to re- flect physical activity self-efficacy	Choosing relevant statistical analyses to assess the effectiveness of the intervention	Paper IV

# 4.4 Samples and settings

### Phase I: The development phase

Identifying the evidence base (Sub-study I)

Data used for the cross-sectional correlational study were collected during 2007– 2011 in child health clinics (n = 19) in the city of Turku, Finland. The total sample consisted of data collected from 2.5-year-old toddlers (n = 717: girls = 368, boys = 349), who attended a 2.5-year-old health examination in child health clinics. The data consisted of information on a child's neurological development, as evaluated by PHN (n = 30), and preference to participate in active play, as evaluated by the child's parents at home and by early years teachers in public nurseries. Public nurseries (later referred to as nurseries) are public-based services that municipalities in Finland provide for all small, under school-aged children. Early years teachers are persons with an official education in child care and education, who work with children daily. According to the inclusion criteria, the data of children were eligible 1) if a child and his or her parent(s) had participated in the regular 2.5-year-old health examination in a child health clinic in the city of Turku, 2) if a family's mother tongue was Finnish and 3) if the child's preference to participate in active play was assessed by both his or her parents and early years teachers (Paper I).

*Identifying the theory base (Sub-study II)* 

Data used for the quantitative systematic review was acquired through a systematic literature search strategy (Higgins & Green 2011). Relevant literature was searched for from 1996 until October 2014 from the following electronic databases: Medline [Ovid], the Cumulative Index to Nursing and Allied Health Library (CINAHL Plus) [Ebscohost], PsychINFO [Ovid], EMBASE [Ovid] and the Cochrane Library [Wiley Online]. The strategy is described in more detail, including the search terms, in Paper II (Table 2). The search was updated in June 2016, using the same search strategy, to ensure the most recent relevant literature was screened. Also, a manual literature search was implemented by going through the references of the included studies. From the total of 122 studies retrieved from the databases, we included five articles in the review (Paper II).

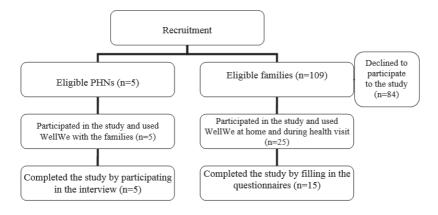
Developing the physical activity component of the intervention (Sub-study III)

The development of the physical activity component of the intervention was based on previous evidence (Paper I) and theory (Paper II), as well as on national recommendations for physical activity for children (Ministry of Social Affairs and Health 2005), and it was developed in a multidisciplinary group of representatives from the fields of nursing, medicine, physical activity, information technology and graphic design.

# Phase II: The feasibility and piloting phase

Evaluating the feasibility of the intervention (Sub-study IV)

The data for the feasibility study were collected during October to November 2015. Following the purposive critical case sampling method, we sought the cases that represented the intended setting of the intervention (Patton 2015) and conducted the study in five child health clinics from four municipalities, located in Southwest Finland. The data were collected during the extensive 1.5- and 4- year health examinations in child health clinics, after participants had tested the intervention. Participating PHNs (n = 5) were instructed regarding the study protocol, after which they attempted to recruit all eligible families (n = 109) by sending them an information letter. According to the eligibility criteria, families were recruited if they could communicate in the Finnish language and participated in the extensive 1.5- or 4-year health examination in one of the five studied child health clinics during the data collection period. Altogether 25 families used the application at home and during the health examination, and 15 families participated in the study by answering the study questionnaires (Fig. 4) (Paper III).



**Figure 4**. Study participation flow in Sub-study IV.

*Modifying the physical activity component of the intervention (Sub-study V)* 

The modification of the physical activity component of the intervention was based on the results of the feasibility study (Paper III). The modification was designed in the multidisciplinary group of representatives from the fields of nursing, medicine, physical activity, information technology and graphic design (Summary, Paper IV).

Planning the evaluation study (Sub-study VI)

We planned the design, setting, eligibility criteria, allocation ratio and delivery of the intervention and the recruitment based on the feasibility study. The sample size was estimated based on a power calculations and feasibility study to consider the expected attrition rates (Craig et al. 2013). We also planned the method, type and mechanism in order to generate the random allocation of participants (Eysenbach et al. 2011) (Paper IV).

### 4.5 Data collection and instruments

### Phase I: The development phase

*Identifying the evidence base (Sub-study I)* 

The data used for the cross-sectional correlational study (Paper I) was collected during 2007–2011 in the child health clinics. The data consisted of information on a child's neurological development, assessed by PHNs in child health clinics, and the child's preference to participate in active play, assessed by parents at home and by early years teachers at a nursery.

Children's neurological development was assessed by the PHNs in child health clinics using the Lene test (later referred to as *Lene*). Lene is a neurodevelopmental screening tool for children aged between two to six years of age. Lene covers all the major areas of neurological development: attention-behaviour development, motor-perceptual development and language development. The validity (structural, concurrent and predictive) and reliability (internal consistency) of Lene have been shown to be acceptable (Valtonen 2004, 2007, 2009). In this study we used a version of Lene (Lene2) designed for two- to three-year-old toddlers, which takes about 30 minutes to administer. Lene2 consists of 12 items, and some of the items include tasks for the toddlers: visual perception tasks (four tasks), hearing tasks, gross motor competence tasks (five tasks), interactional skills tasks, attention and motivation tasks, expressive speech tasks, understanding speech and concepts tasks (four tasks), auditory perception tasks (four tasks), eye-hand co-ordination

tasks (three tasks), play skills tasks and self-help skills tasks. The items are scored on scale of 0–3, indicating either *normal development* (score 0), *suspect/mild delay* (score 1), *moderate/severe delay* (score 2) or *refusal to complete the task* (score 3). All the participating PHNs were trained to administer Lene by the developer herself.

Children's preference to participate in active play was collected in child health clinics during normal health examinations and using questionnaires administered by the parents and early years teachers. The questionnaire consists of 31 items assessing how children perform different developmental skills/behaviours at home (assessed by parents) and at nursery (assessed by early years teachers). The items are scored on scale of 0–2, indicating *mostly / most of the time* (score 0), *variably* (score 1) or *not yet* (score 2). In this study we used an item representing the physical activity behaviour of toddlers – "preference to participate in active play" – which featured in the questionnaire using the following statement: "willingness to participate in active play" (Paper I).

### Identifying the theory base (Sub-study II)

A systematic literature search for the quantitative systematic review was done using literature from 1996 until 28 June 2016 and stored on the following electronic databases: Medline [Ovid], the Cumulative Index to Nursing and Allied Health Library CINAHL Plus) [Ebscohost], PsychINFO [Ovid], EMBASE [Ovid] and the Cochrane Library [Wiley Online]. The identification of the studies was made by two independent reviewers following a priori established eligibility criteria (Table 1 and Figure 1, Paper II). According to the criteria, based on participant/intervention/comparison/outcome (PICO) strategy (Santos et al. 2007), we included controlled studies with participants under 18 years old (*P*), comparing a gamified digital intervention (*I*) with a no-game-intervention condition (*C*) and measuring physical activity self-efficacy (*O*). Following Cochrane Collaboration's guidelines (Higgins & Green 2011), quality appraisal was made by two reviewers independently using Cochrane Collaboration's tool for assessing risk of bias (Higgins et al. 2011).

The data were extracted using a predetermined data extraction plan and compiled in tables for the analyses. First, we extracted information concerning the authors, publication year, country, design, aim, setting, sample, outcomes and the main results of the studies. Second, we collected data related to the intervention by adapting the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al. 2014). We extracted information concerning the materials, procedures, duration and dose of the intervention. Third, we extracted information concerning the elements of intervention related to physical activity self-efficacy. Furthermore,

we used the Grades of Recommendation Assessment, Development and Evaluation (GRADE) approach to grade the quality of evidence for physical activity self-efficacy. The GRADE approach is used in systematic reviews to estimate the level of quality of evidence. The GRADE approach provides a framework with which to rate the quality of evidence as either *high*, *moderate*, *low* or *very low*, in order to reflect the extent of confidence on the reported study findings (Higgins & Green 2011, Guyatt et al. 2011) (Paper II).

Developing the physical activity component of the intervention (Sub-study III)

The results from the previous studies (Papers I, II) and recommendations (Ministry of Social Affairs and Health 2005) formed the data source for the development of the physical activity component of the intervention. Based on the key findings from these sources, the content elements (the representation of the intervention) and activity elements (the action in the intervention) for the physical activity component of the intervention were created (Papers I, II, III, Summary).

# Phase II: The feasibility and piloting phase

Evaluating the feasibility of the intervention (Sub-study IV)

The usability of the intervention was assessed among families and PHNs during the feasibility study. The data were collected by using the System Usability Scale (SUS) immediately after the testing of the intervention. The SUS is a valid and reliable tool to evaluate the usability of a wide range of technologies, like products, systems and services. The SUS consists of ten statements (items), which are scored using a five-point Likert scale. The scores range from  $1 = strongly \ disagree$  to  $5 = strongly \ agree$ , and SUS total scores have a range of 0 to 100 (100 being the best possible score) (Brooke 1996, Pakarinen et al. 2017).

The acceptability of the intervention was assessed during the same feasibility study. The data from the families were collected using a semi-structured nine-item questionnaire developed for the study (see Table 1 in Paper III). The data were collected immediately after the testing of the intervention. The data from the PHNs were collected with interviews using an interview frame with similar themes. The PHNs were interviewed individually after the data collection with families had ended. The interviews were audiotaped and transcribed verbatim (Paper III).

Modifying the physical activity component of the intervention (Sub-study V)

The results from the feasibility study (Paper III) formed the data source for the modification of the physical activity component of the intervention. We used the

results relevant to the physical activity. In this phase the physical activity component was updated by modifying the content elements and activity elements in the intervention (Summary, Paper IV).

Planning the evaluation study (Sub-study VI)

To evaluate the intervention effectiveness related to the primary outcome, physical activity self-efficacy, we searched for validated instruments. After choosing the optimal instrument, we conducted an official translation process and translated it into Finnish language following the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) protocol. The ISPOR protocol is a 10-step process that includes principles of good practice and guides the translation and cultural adaptation of instruments (Wild et al. 2005). We also planned the time points for outcome measurement (Eysenbach et al. 2011).

# 4.6 Data analysis

### Phase I: The development phase

Identifying the evidence base (Sub-study I)

The data from the cross-sectional correlational study was analysed statistically using SAS software (version 9.3 for Windows). We used descriptive statistics to estimate the prevalence of children who participated in active play. We used crosstabulations and Fisher's exact tests to investigate the associations between the explanatory variables (areas of neurological development) and the response variables (preference to participate in active play). In neurological development, we combined the classes of *suspect or mild delay* and *moderate or severe delay*, since the number of children in the latter class was small. For *preference to participate in active play*, we combined the classes of *variably* and *not yet*, since the number of children in the latter class was small. We also evaluated the difference between the parents' and early years teachers' assessments by computing the proportion of agreement (*P*) (Grant 1991) and tested which of the explanatory variables were in association with the disagreement using Fisher's exact tests and multivariable logistic regression analysis. In the analyses, *p*-values <0.01 were interpreted as being significant (Paper I).

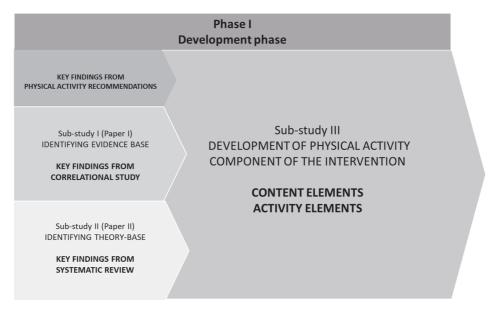
*Identifying the theory base (Sub-study II)* 

In the systematic literature review, the extracted data was analysed using the narrative approach and statistical analyses in order to address the research questions (Popay et al. 2006). Meta-analysis was not applicable because of the heterogeneity

of the studies (Higgins & Green 2011). Instead of a meta-analysis, the effectiveness of the individual studies was estimated against statistical significance, based on the pre–post change in physical activity self-efficacy scores. The quality of evidence was assessed according to the GRADE criteria (Higgins & Green 2011, Guyatt et al. 2011) (Paper II).

Developing the physical activity component of the intervention (Sub-study III)

All the key findings from the previous studies (Papers I, II) and recommendations (Ministry of Social Affairs and Health 2005) were converted in to content elements (the representation of the intervention) and activity elements (the action in the intervention) for the physical activity component of the intervention. The analysis process is visualized in Figure 5 (Papers I, II, III, Summary).



**Figure 5**. The analyses process of the physical activity component development.

# Phase II: The feasibility and piloting phase

Evaluating the feasibility of the intervention (Sub-study IV)

The usability data, collected using the SUS, were analyzed using descriptive statistics. First, we estimated the mean values, ranging from 1 to 5, for each item in the SUS using SPSS (version 23 for IBM). Second, we calculated the total SUS scores from mean values, using specific SUS-calculation formula in Excel. Following the calculation formula, each item was given a score contribution ranging from 0 to 4. For items 1, 3, 5, 7 and 9 the score contribution is the mean value, minus 1. For items 2, 4, 6, 8 and 10, the contribution is 5 minus the mean value.

Finally, the total SUS scores, ranging from 0 to 100, were obtained by multiplying the sum of the score contributions by 2.5 (Brooke 1996). To interpret the results of total SUS scores, we followed adjective ratings for SUS scores, as reported in Bangor et al. (2009) (Pakarinen et al. 2017).

The acceptability data collected using the semi-structured questionnaire were analysed using directed content analyses (Hsieh & Shannon 2005). We used an analysis frame with categories reflecting the acceptability of the intervention: attractiveness, suitability, perceived appropriateness and satisfaction (Bowen et al. 2009). The parents' and PHNs' answers were analysed separately through a systematic classification process ranging from coding to the identification of themes. All the words, terms and sentences relevant to our study aim were highlighted, coded and ordered into categories according to the analysis frame (Hsieh & Shannon 2005) (Paper III).

*Modifying the physical activity component of the intervention (Sub-study V)* 

The results from the feasibility study (Paper III) served as data for the modification of the physical activity component of the intervention. The data relevant to the physical activity component were first summarized using inductive content analyses (Vaismoradi et al. 2013) and then compared with the content elements and activity elements in the physical activity component. Second, the physical activity component was updated by removing, changing or adding content and activity elements (Summary, Paper IV).

Planning the evaluation study (Sub-study VI)

Identified instruments and measurements guided the plan for the statistical methods used to compare groups for outcomes (Eysenbach et al. 2011) and to test the validity of the instrument among Finnish parents (Wild et al. 2009) (Paper IV).

### 4.7 Ethical considerations

The study was conducted following ethical principles and responsible conduct for research (TENK 2012). The ethical principles of research in the humanities and social and behavioural sciences, respecting the autonomy, integrity, anonymity and confidentiality of the participants, were followed throughout the study. The autonomy of the study participants was respected through voluntary participation and with the relevant information required to give informed consent. Participants were informed about the voluntary nature of the study, the possibility to withdraw from the study at any time and the possible benefits and harms for them of study participation. They were given the opportunity to consider their participation and to ask

questions from the researcher before giving consent. The anonymity and confidentiality of the participants were respected through careful data management. The collected data were stored and analysed using codes and without any identification information. Recognition of the participants, child health care clinic, municipality or individual participant was also made impossible when reporting the results (TENK 2012, Vanclay et al. 2013, World Medical Association 2013).

When children participate in a study, their vulnerability should be given thorough consideration (ETENE 2003, Lagström et al. 2010, Graham et al. 2013, Vanclay et al. 2013, World Medical Association 2013). The same ethical principles concern children (Vanclay et al. 2013, World medical association 2013), but special attention and reflection should be given to the assumptions, values, beliefs and practices that influence the research process and impact on children. Everyone involved, researchers and other stakeholders, are considered to have the responsibility to respect the equitability, dignity and integrity of children (ETENE 2003, Lagström et al. 2010, Graham et al. 2013). Hereafter, the specific ethical issues concerning Sub-studies I, IV and VI are discussed in more detail.

### *Identifying the evidence base (Sub-study I)*

The study was approved by the Institutional Review Board of the city of Turku. The study subjects or their parents were not personally contacted since neither approval by an ethical committee nor informed consent by study subjects are required for studies that are based on statistical data files provided for scientific research purposes without identification information (Personal Data Act 523/1999). The data were collected during a routine health examination in child health clinics and using Lene, which is a normal procedure to assess 2.5-year-old children's development during health examinations in Finland. Thus, our study did not cause any special ethical considerations from the perspective of the integrity of the children (ETENE 2003, Lagström et al. 2010, Graham et al. 2013).

### Evaluating the feasibility of the intervention (Sub-study IV)

The study was approved by the Ethics Committee of the University of Turku, Finland (6/2015/26). The permission to conduct the study was granted by the Social and Health Board. Participants were given relevant information about the study in written and verbal formats. Participation was voluntary and written informed consents were acquired from the PHNs and legal guardians of the participating children. The use of instruments during data collection followed research ethics with respect to immaterial rights. Even though the participants were adults, children were indirectly involved in the study by participating in the intervention with their parents. Special attention to the children was given by respecting their voluntary involvement, equitability, dignity and integrity (Graham et al. 2013).

Planning the evaluation study (Sub-study VI)

The study was approved by the Ethics Committee of the University of Turku, Finland (64/2016). The permission to conduct the study was granted by the head nurses of the municipalities (May 2017). Participants have been given the relevant information about the study in written and verbal formats. Participation is voluntary and written informed consents are being acquired from the PHNs and legal guardian of the participating families. Even though the participants are adults, children are indirectly involved in the study by participating in the intervention with their parents. Special attention to the children is given by respecting their voluntary involvement, equitability, dignity and integrity (Graham et al. 2013).

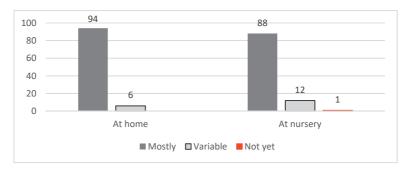
The results of the study will be reported following the dictates of the CONSORT-EHEALTH statement (Eysenbach et al. 2011) and TIDieR (Hoffmann et al. 2014). The use of instruments during data collection follow research ethics with respect to immaterial rights. Permission to use the instrument has been obtained from the original developer. The study protocol is being reported in a trial register (Clinicaltrials.gov: NCT03278288).

# 5 RESULTS

The results are presented here according to the study phases and following the study aims. First, the results from the development phase are presented, ranging from the evidence (Sub-study I) and theory base (Sub-study II) to the development of the physical activity component of the intervention (Sub-study III). Second, the results from the feasibility and piloting phase are presented, ranging from the usability and acceptability of the intervention among the target group (Sub-study IV) and modification of the physical activity component of the intervention (Sub-study V) to the protocol for the evaluation study (Sub-study VI).

# 5.1 The active play behaviour of toddlers

In Sub-study I (Paper I), active play behaviour and its associations with the neurological development of children (n=717, mean age 2.5) were explored. Active play behaviour was assessed in two different settings (at home and at the nursery) and neurological development was assessed during health examinations in child health clinics. Toddlers showed a preference to participate in active play both at home (94 %) and at the nursery (88 %) (Fig. 6). Significant associations between active play behaviour and neurological development were found in toddlers at the nursery. The results indicated that toddlers with delayed gross motor performance (32 %, p < 0.005), delayed auditory perception (27 %, p < 0.006) and a lack of self-help skills (24 %, p < 0.002) showed lower levels of preference to participate in active play (Table 3, Paper I). No significant associations between reports of active play behaviour and delayed neurological development were identified among toddlers at home.



**Figure 6.** Prevalence (%) of toddlers with preference to participate in active play at home and at nursery (mostly, variable, not yet).

Analyses of the differences in the assessments of the toddlers' preference for active play between assessments by parents and early years teachers showed that the proportion of agreement was 88 % (609/696) in responses concerning toddlers' showing a preference to participate in active play *most of the time* (P = 0.875; 95 % CI [0.848–0.899]) and 19 % (21/108) in responses concerning toddlers' showing a variable preference to participate in active play or not yet showing a preference to participate in active play (P = 0.194; 95 % CI [0.125–0.282]). The difference between the assessments was significant (12 %, 87/717, p < 0.001) and the prevalence of toddlers who variably participated in active play or who did not yet participate in active play was twice as common at the nursery (12 %, 85/717) as it was at home (6 %, 44/717) (Fig. 6).

The developmental factors associated with disagreeing assessments were toddlers' gross motor competence (p = 0.005), auditory perception (p < 0.001) and self-help skills (p < 0.001). Further analyses showed that self-help skills had an independent association with disagreement (OR 3.1; 95 % CI [1.3–7.4], p = 0.001), while gross motor competence and auditory perception were not significant (p values  $\ge 0.010$ ). Toddlers with a delay in self-help skills had two times higher odds than others of being classified into a different group regarding their preference for active play. Altogether 24 % of children with a delay in self-help skills (18/74) were assessed to variably participate in active play or to not yet participate in active play at nursery, while the same factor was 5 % (4/74) at home. Key findings from this study that contributed to the development of the intervention are summarized in Figure 7.

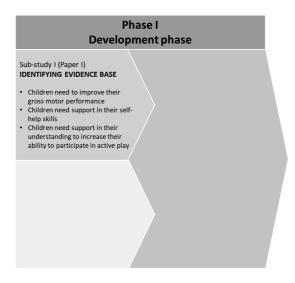


Figure 7. Key findings from the correlational study for the intervention.

# 5.2 Gamified interventions to promote physical activity

In Sub-study II (Paper II), we explored previous gamified digital interventions aiming to enhance the physical activity self-efficacy of children. From a total of 122 studies retrieved from the databases, we identified five articles as eligible for inclusion in the review. According to the quality assessment (Higgins et al. 2011), the quality of the studies was at a medium level (Paper II, Table 3). The studies were conducted between the years 2005 and 2015. Participants of the studies were school-aged children (ages ranging from 9 to 19 years old) and all the interventions were school based, excepting one home-based intervention (Direito et al. 2015). The duration of the interventions varied from 6 to 36 weeks, leading to differences between the doses of the interventions (4.5 to 75 hours).

The interventions consisted of commercially available exergames (Nintendo Wii games) (Gao et al. 2012, Staiano et al. 2013, Lwin & Malik 2014) and game-based applications (*Zombies, Run*) (Direito et al. 2015). In one study, the intervention was an educational game, developed for the purposes of the study (Goran & Reynolds 2005). Two of the interventions also consisted of other materials and methods, like classroom lessons, family-centred activities (Goran & Reynolds 2005) and written health education materials (Lwin & Malik 2014). Family-centred activities were delivered in the form of homework assignments, designed to reinforce and enact behaviour, skills and knowledge related to physical activity and to build awareness of the need for environmental changes to promote the physical activity of children (Goran & Reynolds 2005).

Interventions included elements that were thought to enhance physical activity self-efficacy through fostering mastery experiences (Gao et al. 2012, Staiano et al. 2013, Lwin & Malik 2014) and vicarious experiences (Gao et al. 2012), through verbal persuasion (Gao et al. 2012, Staiano et al. 2013) and through overcoming barriers to physical activity (Goran & Reynolds 2005). A detailed description on the elements enhancing physical activity self-efficacy is summarized in Table 3.

**Table 3.** The elements in games enhancing the physical activity self-efficacy.

Elements in interventions		Construct of physical activity self-efficacy
•	Playing the game repeatedly and performing physical activities during gameplay (Lwin & Malik 2014) Playing the game through practice and in own difficulty level (Gao et al. 2012)	Mastery experiences
•	Having control over the gameplay (Staiano et al. 2013)	
•	Role modelling the figures in the screen (Gao et al. 2012)	Vicarious experiences
•	Receiving simultaneous feedback (Gao et al. 2012) Encouragement through motivating statements (Staiano et al. 2013)	Verbal persuasion
•	Lessons about overcoming barriers to be physically active (Goran & Reynolds 2005)	Overcoming the barriers for physical activity

Three of the interventions were considered effective regarding the physical activity self-efficacy of children (Gao et al. 2012, Staiano et al. 2013, Lwin & Malik 2014). One study reported a marginally significant increase in physical activity self-efficacy (Goran & Reynolds 2005), while another intervention was not considered effective (Direito et al. 2015). Notably, the quality of evidence according to GRADE criteria was considered low for physical activity self-efficacy (Paper II, Table 6). The characteristics of the intervention studies are summarized in Table 4. The key findings of the self-efficacy enhancing elements that contribute the intervention are represented in Figure 8.

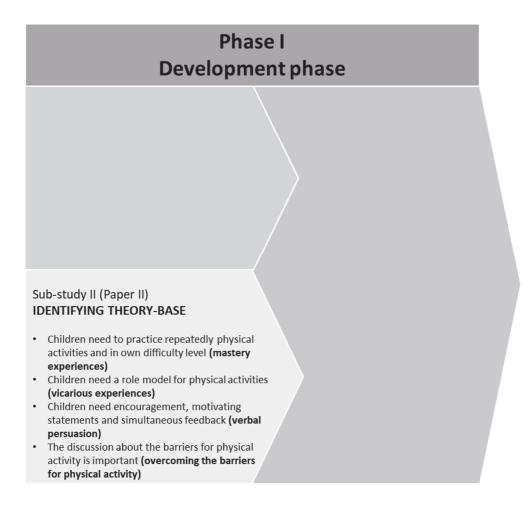


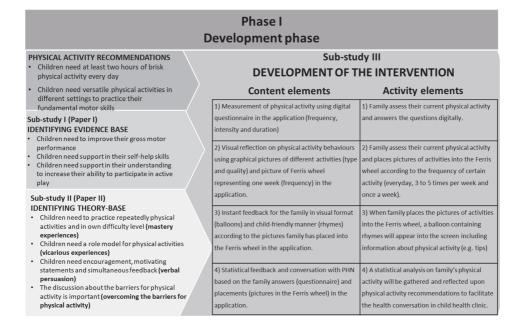
Figure 8. Key findings from the systematic review for the intervention.

**Table 4.** The characteristics of intervention studies.

Study	Design and aim of the study	Participants and settings	Characteristics of interventions (materials, procedures, duration and dose)	Effectiveness of the interventions re- lated to physical activity self-efficacy
Direito et al., 2015, New Zealand	RCT To examine the effects of the intervention on cardiorespiratory fitness, physical activity, enjoyment, satisfaction and self-efficacy.	n= 51 Age: 14-17 y, Mean age: 15.7 y Home-setting	Intervention consisted of game-based application (Zombies, Run).  Gameplay during free time. Participants were instructed and encouraged to use the application 3 times per week by principal investigator.  8-week intervention with gameplay 1-3 times per week for 30–60 minutes.  Gameplay on average 6h to 18h.	No intervention effects on physical activity self-efficacy compared to the comparison group.  Physical Activity Self-Efficacy Scale (PASES) by Bartholomew et al. (2006).
Gao et al., 2012, USA	Quasi-experimental To examine the effects of the intervention on daily physical activity and physical activity correlates.  RCT	n=101 Age: 9-11 y, Mean age: 10.36 y School (n=1) n=122	Intervention consisted of Wii exergame: Dance Dance Revolution (DDR). Gameplay during school recess periods. Participants were instructed and monitored by researchers and research assistants.  36-week intervention with gameplay 3 times per week for 30 minutes. Gameplay altogether 54 h.	Significant improvements in self-effi- cacy; change score 0.52 (F 1.99 = 6.50, p<0.05) compared to control condition. Physical Activity Confidence Scale by Norman et al. (2005). Marginal improvement in self-effi-
Goran & Reyn- olds, 2005, USA	To develop and examine the effects of the intervention physical activity and obesity.	Mean age: 9.5 y School (n=4)	Intervention consisted of interactive educational learning game (CD-ROM). Intervention included also 4 classroom lessons and 4 family-centred activities. Gameplay during school lessons. No further information on the provider of the intervention.  8-week intervention with 8 sessions of gameplay for 45 minutes. Gameplay altogether 6 h.	Marginal improvement in self-effi- cacy; adjusted mean value among boys $9.7 \pm 0.5$ vs. $8.7 \pm 0.5$ and among girls $9.3 \pm 0.4$ vs. $8.7 \pm 0.4$ (p=0.06) compared to control condition. Self-Efficacy Scale by Saunders et al. (1997).
Lwin & Malik, 2014, Singa- pore	RCT To examine the effects of the intervention on the physical activity intention and behaviour.	n=398 Mean age: 10.2 y School (n=3)	Intervention consisted of three Wii exergames: Dance Dance Revolution (DDR), Wii Tennis and Wii Boxing. Intervention included also written health education materials.  Gameplay during Physical education lessons. Participants were guided by the teachers.  6-week intervention with gameplay 1 time per week for 45 minutes. Gameplay altogether 4.5 h.	Significant improvements in self-effi- cacy; adjusted mean value 3.93 vs. 3.61 (SE 0.07, p<0.01) compared to control condition. Adapted questionnaire from Armitage and Conner (2001) and Lwin (2009).
Staiano et al., 2013, USA	RCT To examine the effects of the intervention on weight loss and psychosocial outcomes in overweight and obese adolescents.	n=54 Age: 15–19 y School (n=1)	Intervention consisted of Nintendo Wii exergame.  Gameplay during lunch periods or after school. Participants were led by an adult coordinator and observed by a supervisor.  20-week intervention with gameplay 5 times per week for 30–60 minutes.  Gameplay altogether 75 h.	Significant improvements in self-effi- cacy; mean value 43.29 $\pm$ 13.40 vs. 35.30 $\pm$ 8.76 (p=0.05) compared to con- trol condition. Exercise Confidence Survey by Sallis et al. (1988).

# 5.3 Development of the physical activity component of the intervention

In Sub-study III, the key findings from the previous studies (Papers I, II), together with the national physical activity recommendations for children (Ministry of Social Affairs and Health 2005), formed the data source and contributed to the development of the physical activity component of the intervention. The intervention was developed in a multidisciplinary group of representatives from the fields of nursing, medicine, physical activity, information technology and graphic design. Following the analysis process (see Fig. 5 in Section 4.6: "Data analysis"), altogether nine key findings from data sources were converted into four content elements (the representation of the intervention) and four activity elements (the actions in the intervention) (see Fig. 9). Hereafter the content elements and activity elements are described in more detail.



**Figure 9.** Visualization of the evidence and theory base for the intervention and description of physical activity component of the intervention.

The first content and activity element consisted of the measurement of physical activity. To be able to give feedback and discuss the amount of the child's physical activity and whether the activity is versatile enough for the child, it needs to be measured. We adapted a questionnaire to measure the physical activity of the children and their parents based on physical activity recommendations for adults (UKK Institute 2009) and children (Ministry of Social Affairs and Health 2005)

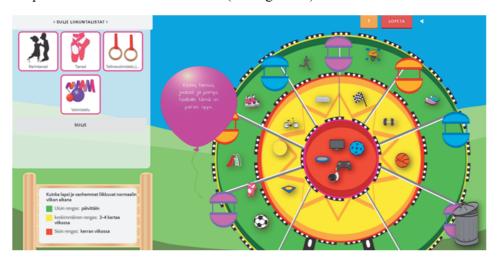
and on a questionnaire used in previous studies among school-aged children (Raitakari et al. 1996). The questionnaire included questions about the intensity, frequency and duration of the child's physical activity. The permission to use and adapt the original questionnaire was acquired from the developer himself (Raitakari). Also, experts from the physical activity field were consulted when adapting the questionnaire. First, we removed the term *sweating* from the answering options for an intensity question since small children rarely sweat, even at high-intensity physical activity levels. Second, the answering options in a frequency question were modified to include one week instead of one month (which was used in the original version), since evidence shows that it is more reliable to recall the previous week than longer periods (Biddle et al. 2011). Third, we added answering options in a duration question to also include options for over one hour of physical activity in order to comply with the physical activity recommendations for small children (Ministry of Social Affairs and Health 2005). We also included separate questions for parents to measure their physical activity with a general question, since parents are key role models for children (see Table 5). When answering the questions, the family is supposed to assess their current physical activity behaviour.

**Table 5.** Questionnaire in the application measuring physical activity of families.

Questions for parents	Answering options
How often you are physically active at least half	At least 5 times per week
an hour during a week so, that you get out of	1-3 times per week
breath or you sweat somewhat?	Less than once a week
What describes most the way your child is phys-	She/he won't get out of breath
ically active?	She/he gets out of breath somewhat
	She/he gets out of breath clearly
How often is your child physically active during	Not at all
a week?	1–2 times per week
	3–4 times per week
	5–6 times per week
	Every day
What is the child's average duration of one phys-	Less than 20 minutes
ical activity episode per day? (if your child has physical activity episodes every day, inform the	20–40 minutes
nean duration by counting all episode's dura- ions together)	40–60 minutes
	1–1.5 hours
	1.5–2 hours
	2 hours or more

The second content and activity element measured physical activity behaviour in a way that supports the child's participation. We designed a child-friendly element for the intervention: a visual reflection of physical activity behaviours. To support both a child's understanding of different physical activities and role modelling of different physical activities, and to enable her or his participation in the

intervention, altogether 51 graphical physical activity pictures (e.g. dancing) were designed for the application. The pictures were grouped into seven different physical activity categories (*ball games, daily exercise, dance & gymnastics, sedentary activities, water sports, winter sports, other physical activities*). The family is supposed to assess their current physical activity and place different pictures relevant to them onto a Ferris wheel. The Ferris wheel represents one week and distinct colour circles in the wheel indicate the different frequencies of physical activities (green for *every day*, yellow for 3–5 *times per week* and red for *once a week*). The idea is that both the child's and parents' pictures representing physical activities are placed on the same Ferris Wheel (see Figure 10).



**Figure 10.** An example of family user interface showing the physical activity pictures and the Ferris wheel representing one week.

The third content and activity element involved instant feedback for the family in a visual format, giving the family information on a physical activity and reflecting their physical activity behaviour. The feedback appears on the screen in the format of a balloon containing a child-friendly rhyme. Altogether 28 different rhymes were designed. Besides increasing the awareness of the desired physical activity for health, this element was designed to support the child's understanding, to encourage and motivate her or him to be physically active. When the family places the pictures of activities onto the Ferris wheel, a balloon containing a rhyme appears on the screen. A rhyme includes information about the physical activity. The rhymes included encouraging and motivating statements, tips and notifications (see the balloon in Fig. 10 and for examples of the rhymes, see Table 6). The pictures and the rhymes were designed based on physical activity recommendations for children (Ministry of Social Affairs and Health 2005) and other relevant literature.

**Table 6.** An example of the rhymes in the balloons.

Liikunnan iloa, monta mieluista kiloa.	Physical activity gives you joy, many armfuls of joy.
Hypi, pyöri, tee kuperkeikkaa,	Jump, rotate, do somersaults,
se kehittää sun motoriikkaa!	it will develop your motor skills!
Pyöräilyä, juoksua, hyppimistä huimaa, luiden lujuutta ja lihasten voimaa.	Biking, jogging, jumping crazy, gives strength for your bones and muscles.
Jos pelata tahdot sä pelejä,	If you want to play games,
valitse hauskoja liikuntapelejä,	choose fun video games,
wii, pleikkari ja tanssimatto,	Wii, PlayStation and dancing mat,
niillä pelatessa kasvaa kunto.	playing with them you will be fit.

The fourth content and activity element reflected upon all the content elements. We designed the statistical user interface to facilitate a family-and-child—centred health discussion in a child health clinic, discussing the child's physical activity behaviours. This user interface was designed to only be seen by PHNs (i.e. it was a professional user interface). The statistics are based on the family's answers to the questionnaire and their placement of pictures on the Ferris wheel in the application. The statistics from the application enable the discussion between the PHN and the family to be tailored according to the needs and situation of each child and family. The visualization also enables the child to participate into the discussion about physical activity. The statistical analysis visualizes the family's physical activity behaviours compared to the physical activity recommendations.

The first part of the statistics shows the frequency of the activity according to the questionnaire using a colour code: a green square for if the recommendations are met, a yellow square for if they are not met but a family member is physically active during some days of the week and a red square for inactivity. The second part of the statistics shows the intensity of the activity according to the placements on the Ferris wheel. Each of the pictures represents a certain intensity and is coded according to its MET value (Ainsworth et al. 1993, 2000): green bars represent vigorous intensity activities (MET >6) and moderate-to-vigorous intensity activities (MET = 4–6), yellow bars represent light intensity activities (MET = 2–3) and red bars represent inactivity (MET  $\leq 1$ ). The third part of the statistics shows the quality of the activity: the light blue part of the pie chart represents aerobic training activity and the purple part of the pie chart represents balance and muscle strengthening activity (Fig. 11).



**Figure 11.** An example of the statistical user interface in the application (professional user interface).

To conclude, the results of this sub-study included altogether eight content and activity elements, derived from previous studies. See Table 7 for a summary of the elements.

**Table 7.** Summary of content and activity elements in the intervention.

CONTENT ELEMENT OF THE INTERVENTION	ACTIVITY ELEMENT OF THE INTERVENTION
1) Measurement of physical activity using digital questionnaire in the application (frequency, intensity and duration)	Family assess their current physical activity and answers the questions digitally.
2) Visual reflection on physical activity behaviours using graphical pictures of different activities (type and quality) and picture of Ferris wheel representing one week (frequency) in the application.	2) Family assess their current physical activity and places pictures of activities into the Ferris wheel according to the frequency of certain activity (everyday, 3 to 5 times per week and once a week).
3) Instant feedback for the family in visual format (balloons) and child-friendly manner (rhymes) according to the pictures family has placed into the Ferris wheel in the application.	3) When family places the pictures of activities into the Ferris wheel, a balloon containing rhymes will appear into the screen including information about physical activity (e.g. tips)
4) Statistical user interface and discussion with PHN based on the family answers (questionnaire) and placements (pictures in the Ferris wheel) in the application.	4) An analysis on family's physical activity will be gathered and reflected upon physical activity recommendations to facilitate the health discussion in child health clinic.

# 5.4 The feasibility of the intervention among the target group

In Sub-study IV (Paper III, see also Pakarinen et al. 2017), we evaluated the feasibility of the whole intervention with regard to its usability and acceptability (its attractiveness, suitability, perceived appropriateness and satisfaction) as perceived by the target group – the families with 1.5- and four-year-old children (n = 15) – and PHNs from the child health clinics (n = 5). The results are described with special reference to the physical activity component of the intervention.

# **Usability**

Altogether five PHNs and 15 families with 1.5- to four-year-old children participated in the study. The usability was evaluated with the SUS for both groups. The usability of the intervention was satisfactory with the total mean SUS score of 65.2. The usability was perceived as good among PHNs (mean SUS score: 71.5) and as satisfactory among families (mean SUS score: 58.8). The results are described in more detail in the paper by Pakarinen et al. (2017).

### Acceptability

### Attractiveness

The children liked the pictures and visualization of the application. However, some of the children got bored soon. Some parents indicated that there was too little gamification in the application to attract children and 1.5-year-old participants were too small to participate according to their parents. PHNs perceived the statistics in the application as useful and informative. They liked to work with families with such a colourful and visual tool. They preferred discussions using the family user interface when discussing physical activity behaviours. According to PHNs, some families were interested in exploring the statistical graphs instead of the family user interface.

### Suitability

In general, families perceived the functionality of the application to be clear and its use to be easy. However, some of the functions were experienced as awkward and difficulties with technical use occurred. Some families experienced that there were not enough physical activity pictures and the physical activity questionnaire was perceived to be difficult to fill in. For example, families stated that it was hard to estimate the duration of children's physical activity. The PHNs also perceived the use of the application to be easy. A few PHNs perceived that their technical skills were insufficient, causing difficulties in the use of the application during the health discussion. They were still optimistic and felt that, in time and with practice,

they would learn to use the application more fluently. Some PHNs faced difficulties in interpreting the physical activity results, since the pictures of physical activities of both the child and the parents were placed onto one Ferris wheel. They perceived that the physical activity questionnaire was good way to assess physical activity of each member of the family.

### Perceived appropriateness

Some families experienced the application to be more informative than traditional, paper-based questionnaires. They perceived that placing pictures of physical activities and seeing them visually on the Ferris wheel activated them to ponder and initiate discussions about their current health behaviour. They also valued the fact that the rhymes included short facts about healthy behaviour. Some families perceived the application to be appropriate for its purposes. But some families perceived that their awareness of healthy behaviour was sufficient, and they did not see it as a valuable tool for them. They also felt that using the application was too time consuming in their busy everyday life with small children. They preferred traditional paper-based questionnaires. Even though there were a few negative comments on the appropriateness of the application, families generally felt that it could be an effective way to get information on families' behaviours and situation, especially among families with challenging situations. The PHNs perceived the application was a good tool to facilitate the discussions. They thought that it was rather easy to detect each family's individual situation, strengths and needs. The physical activity statistics were very informative and easy to interpret. However, some of the PHNs said that they did not spend so much time with the physical activity component if they saw that a family had adequate amounts of physical activity. In such a situation they just indicated that everything was ok for the family and spent more time with other components of the application.

### Satisfaction and ideas for further development

Almost half of the families (n = 7) thought they would use the application in the future. They suggested that it could also be used with school-aged children. Suggestions for future development included the possibility to assess the family member's behaviour separately, in order to comment or explain about issues in a textual format and to get individual feedback. They also wished that the application would be simpler, fluent and require less time to use it. More gamified elements were also suggested in order to better attract children. The PHNs felt they could use the application in their daily work. Suggestions for future development included the possibility to see the family user interface and statistics in one window and to monitor the behaviours of children and parents separately. The PHNs wished for more gamified elements, and simplifying and easing its use in order to save the time.

→ More gamified elements to better attract

children (families, PHNs)

A summary of the acceptability according to the participants is described in Table 8. A feasibility study contributed to the modification of the intervention. The key issues to be modified are summarized in Figure 12.

**Table 8.** Summary of acceptability of the intervention.

Attractiveness	Suitability
<ul> <li>+ Colours, pictures and visualization were attractive</li> <li>+ The physical activity statistics were informative, useful and easy to interpret</li> <li>- Some children got bored soon when using the application</li> <li>- Not enough gamified elements to attract children</li> <li>- 1.5-year-old participants were too small to participate</li> </ul>	<ul> <li>Functionality was clear and use was easy</li> <li>Statistics were useful and informative</li> <li>Physical activity questionnaire was good way to assess physical activity of family members</li> <li>Some functions were awkward</li> <li>Some difficulties with the technical use</li> <li>Not enough physical activity pictures</li> <li>Physical activity questionnaire was difficult to fulfil</li> <li>Difficulties in interpreting the physical activity results, because of combined re-</li> </ul>
	sults (PHN)
Perceived appropriateness	sults (PHN)  Satisfaction and ideas for further develop-
	• •
+ Visuality activated families to ponder and initiate discussions about their health behaviours	Satisfaction and ideas for further develop-
+ Visuality activated families to pon- der and initiate discussions about	Satisfaction and ideas for further development  Half of the families (n=7) and all the PHNs (n=5) thought they could use the application
<ul> <li>Visuality activated families to ponder and initiate discussions about their health behaviours</li> <li>Easy to detect each family's individual situation, strengths and needs and</li> </ul>	Satisfaction and ideas for further development  Half of the families (n=7) and all the PHNs (n=5) thought they could use the application in the future  + Application could also be used with

ing situation

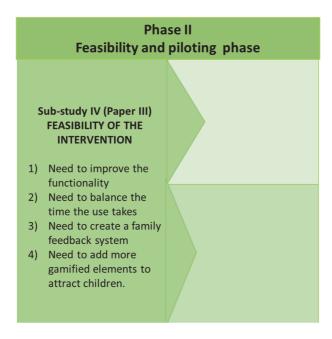
Some families felt they did not need

Application was too time consuming in the otherwise busy everyday life

these kind of applications

with small children

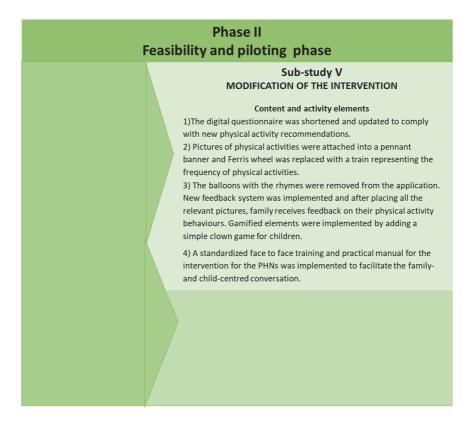
<sup>+=</sup> positive perceptions, -= negative perceptions,  $\rightarrow=$  ideas for further development



**Figure 12.** The key improvement needs of the physical activity component of the intervention.

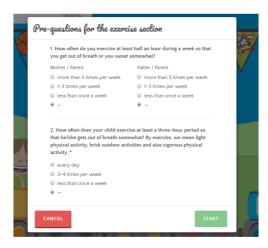
# 5.5 Modification of the physical activity component of the intervention

In Sub-study V, the key improvement needs from the feasibility study contributed to the modification of the intervention. In addition, since new physical activity recommendations for children (Ministry of Social Affairs and Health, 2016) were published after the feasibility study, we modified the content and activity elements where needed to comply with the new recommendations. The modifications are the main results of this sub-study (see Figure 13). Hereafter, the modifications are described in more detail.



**Figure 13.** The modification of design elements and activities in the intervention.

The first content and activity element, the measurement of physical activity using a questionnaire, was shortened and modified to comply with the new physical activity recommendations. We combined three questions assessing the child's physical activity into one question and, instead of asking about the intensity, frequency and duration of child's physical activity separately, we monitored whether the child was physically active enough to meet the physical activity recommendations or not. In addition, instead of just having an option for two hours of physical activity per day, the question was modified to also include an option for three hours per day. The basic idea of the family answering the questionnaire remained the same (Fig. 14).



**Figure 14.** The questionnaire to measure the physical activity of children.

The second content and activity element, the visual reflection on physical activity behaviours, was modified the most in order to attract children. However, physical activity pictures, categories and the idea of placing the pictures onto a picture remained the same. But, to attract children and improve the functionality, physical activity pictures were attached to a pennant banner and the Ferris wheel was replaced with a train. Each of the train carriages represents a different frequency. The frequencies were renamed to ease the picture placements, and a green train carriage represented everyday activities, a yellow train carriage represented something done a few times per week, a red train carriage represented something done once a week and blue train carriage represented something done now and then (Fig. 15).



Figure 15. The family user interface.

The third content and activity element, instant feedback for the family in a visual format, was modified to improve the functionality and lessen the time required to use the application. The balloons with the rhymes were removed and replaced with a feedback system. After all the relevant pictures are placed into the train carriages by the family, they receive feedback on their physical activity behaviour. The feedback is based on physical activity recommendations (Ministry of Social Affairs and Health, 2016) and self-efficacy theory (Bandura 1994). The feedback includes notification or cheering, fact-based information and tips on how to strengthen the physical activity self-efficacy (Fig. 16). In addition, to attract children, more gamified elements were designed. This included an avatar (a girl and a boy), who is sitting in the train. After the feedback, a child can play a short clown game. In the game, the child can accessorize her or his avatar with funny hair. The idea is that in the end, the avatar would look like a cute clown (Fig. 17).



Figure 16. Feedback for the family on their physical activity behaviours.

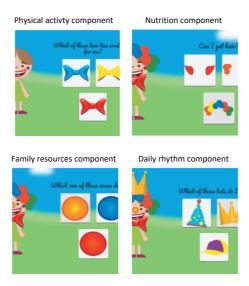


Figure 17. The clown game pictures from all the WellWe-application components.

The fourth content and activity element, the statistical user interface and the health discussion with a PHN using the professional user interface, remained the same (see Fig. 6, Paper IV). However, we realized that more emphasis should be put on the training of the PHNs. Thus, we planned a two-hour face-to-face training for the PHNs and made a practical manual for the intervention. The face-to-face training and manual included more information on physical activity and its promotion. It aimed to facilitate a family- and child-centred approach and to give PHNs tools with which to promote the physical activity self-efficacy of children. A description of the content of the training and the practical manual is visualized in Table 9 (Paper IV).

**Table 9.** Areas in focus and main content of the training and the practical manual for PHNs.

AREA IN FOCUS	MAIN CONTENT OF THE TRAINING
Practical use	Practical information how to sign in to the Application and how to see families' results
Family interface	<ul> <li>Practical information, how family uses the physical activity component of the Application</li> <li>Short description about the family feedback and the base for that</li> </ul>
PHN interface (the statistical interface) and interpretation of results	Description on the statistics with example pictures and how to interpret the results:         Amount and frequency of the physical activity of the family         Intensity of the physical activity of the family (sedentary, light, MVPA, vigorous)         The type of the physical activity of the family (aerobic, balance and muscle strengthening activity)
Physical activity self-efficacy and its promotion	How PHN can support parental self-efficacy     Parents can support child's mastery experiences     Parents serve as role models for their children     Parents are the supporters and encouragers for their children     The enjoyment and positive experiences are essential for physical activity

# 5.6 Protocol for the evaluation study

In Sub-study VI (Paper IV), we planned the study to evaluate the effectiveness of the WellWe intervention. All the earlier sub-studies, especially the feasibility study, contributed to the protocol for the evaluation study. The key methods for the protocol of the evaluation study are described in Figure 18. Hereafter, the protocol of the planned study is described.

# Study design and setting

The evaluation study was designed as a two-arm cluster RCT with a four-month follow-up. The study will be conducted in four municipalities and in a total of 15 child health clinics, located in Southwest Finland.

### Sampling and randomization

Since the feasibility study showed that 1.5-year-old children were too young to participate to the intervention, we decided to focus on the extensive health examination of four-year-old children. Eligible participants were families with a four-year-old child attending the extensive health examination at child health clinics during the data collection period. The total sample size has been estimated with power calculations, resulting in the target of 176 families (two groups of 88 families). The randomization was performed as cluster randomization with a 1:1 allocation and with two clusters randomly allocated to the intervention arm and two clusters to the usual care arm. The random allocation to the intervention and control groups is conducted at a municipal (cluster) level. Randomization was performed in two phases (Fig. 7, Paper IV). The participants randomized to the intervention group will receive the intervention. Participants randomized to the control group will attend the usual extensive health examination (Paper IV).

# Intervention delivery

The intervention will consist of two parts: first, using the application at home and second, during the extensive health examination at a child health clinic. The use of the application at home will last approximately 30 to 40 minutes. The consumed time depends on the individual family and whether the child is participating or not. During the extensive health examination, the application and its results will be used by the PHNs in order to facilitate the health guidance and discussion with the family. The discussion will last approximately 15 to 20 minutes.

Participating PHNs will be the intervention providers. The PHNs allocated to the intervention group will receive training in the study protocol, a standardized two-hour training and a practical manual for the intervention delivery. They will also

have a full access to application during the data collection period. The PHNs allocated to the control group will be the implementers of the study and they will receive training on how to recruit families and implement the data collection. A description of intervention delivery is visualized in Paper IV, Figure 8.

#### Data collection

Data is being collected at baseline and will be collected both immediately after the intervention and at follow-up, four months after intervention. Parental self-efficacy in health behaviour was chosen as the primary outcome of the evaluation study. Parental self-efficacy will be measured using a 21-item version of the Parental Self-Efficacy for Healthy Dietary and Physical Activity Behaviours in Preschoolers Scale (PDAP). The instrument is an 11-point Likert scale and it has been validated among Swedish parents with five-year-old children (Bohman et al. 2016). We followed ISPOR protocol and translated the instrument into Finnish (Wild et al. 2005).

### Data analyses

The results will be analysed using SAS (version 9.4 or later). Descriptive statistics will be used for the numerical and categorical data. Comparisons for category variables will be conducted using Fisher's exact test and the chi-square test. Comparisons for numerical variables will be conducted using two independent sample T-tests or the Mann Whitney U-test (non-normal data). Hierarchical linear mixed models will be used to compare the mean changes in the sum variable for the PDAP. The probability level will be set at 0.05 (two-sided) to prove the significance of the difference. The reliability and validity of the Finnish PDAP will be evaluated by analysing the internal consistency (Cronbach's alpha) and content validity of the instrument (DeVellis 2012).

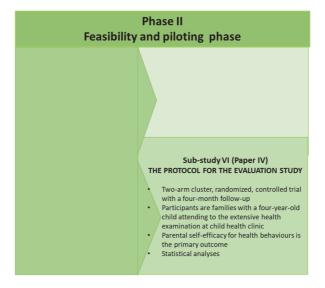


Figure 18. The key methods of the protocol for the intervention evaluation.

# 5.7 A summary of the study results

Evidence of small children's physical activity behaviour, especially inactivity (Tucker 2008, Reilly et al. 2010, Gubbels et al. 2010, Kohl et al. 2012, Hnatiuk et al. 2014, Ekelund et al. 2016), indicates that there is an urgent need for physical activity interventions for children during early childhood (Goldfield et al 2012). This study aimed to develop a digital gamified intervention to promote the physical activity of small children. Further, another aim was to evaluate the feasibility of the intervention among the target group. Following the MRC framework for complex interventions (Craig et al. 2013), this study was divided into two phases: the development phase, and the feasibility and piloting phase.

During the development phase, the evidence and theory base for the intervention was strengthened by conducting a correlational study and a systematic review. The correlational study (Sub-study I) explored the associations between active play and neurological development of toddlers. The results indicated that gross motor skills, self-help skills and auditory perception are positively associated with the child's preference to participate in active play. When considering the theory base for the intervention, the mediating variable model (Baranowski et al. 1997, 1998) was chosen as a framework for the intervention. According to the model, interventions affecting the changes in mediators are more likely to be effective, especially if the selected mediators are strongly associated with the desired behaviour (Baranowski et al. 2003). Since, previous studies indicated that physical activity self-efficacy

was an important psychological mediator for physical activity in children (Sallis et al. 2000, Lubans et al. 2008, Plotnikoff et al. 2013, Sterdt et al. 2014), it was chosen as a mediator in the intervention. Following this framework, the systematic review (Sub-study II) explored previous gamified interventions to promote children's physical activity self-efficacy. The main aim in this was to identify self-efficacy enhancing elements in the interventions (see Table 3). The results from two sub-studies (I, II) and physical activity recommendations for children, as well as knowledge and experience from a multidisciplinary group of experts from various fields of health and technology, contributed to the development of the content for the intervention. Through a systematic development process and expertise in programming and graphic design, the gamified intervention was developed (Substudy III).

During the feasibility and piloting phase, the feasibility of the intervention was evaluated (Sub-study IV) from the perspective of families with small children and PHNs in child health clinics. The study assessed the usability, attractiveness, suitability, perceived appropriateness and satisfaction of the intervention. According to the usability results, intervention was perceived as good in the PHNs' opinions and as satisfactory in the families' opinions. The families perceived the intervention as being less acceptable than the PHNs (see Table 8). A few important issues, required to improve the content and technicalities of the intervention, were identified. The feasibility study gave us important information on the user experience that we used to guide the modification of the intervention (Sub-study V). The intervention was modified quite extensively, in particular the graphical user interface and the feedback system for families were renewed completely. The user interface of the PHNs was modified much less. The feasibility study also contributed to the plan for the evaluation study (an RCT), influencing the sampling, recruitment and implementation of the intervention (Sub-study VI). The summary of the study results is visualized in Figure 19.

Phase I Development phase				
PHYSICAL ACTIVITY RECOMMENDATIONS  Children need at least two hours of brisk physical activity every day		Sub-study III DEVELOPMENT OF THE INTERVENTION		
Children need versatile physical activities in different settings to practice their fundamental motor skills	Content elements  1) Measurement of physical activity using digital	Activity elements  1) Family assess their current physical activity		
Sub-study I (Paper I) IDENTIFYING EVIDENCE BASE  Children need to improve their gross motor	questionnaire in the application (frequency, intensity and duration)	and answers the questions digitally.		
performance Children need support in their self-help skills Children need support in their understanding to increase their ability to participate in active play	using graphical pictures of different activities (type and quality) and picture of Ferris wheel	<ol> <li>Family assess their current physical activity and places pictures of activities into the Ferris wheel according to the frequency of certain activity (everyday, 3 to 5 times per week and</li> </ol>		
Sub-study II (Paper II) IDENTIFYING THEORY-BASE  Children need to practice repeatedly physical activities and in own difficulty level (mastery experiences)  Children need a role model for physical activities (vicarious experiences)  Children need encouragement, motivating	3) Instant feedback for the family in visual format (balloons) and child-friendly manner (rhymes) according to the pictures family has placed into	once a week).  3) When family places the pictures of activities into the Ferris wheel, a balloon containing rhymes will appear into the screen including information about physical activity (e.g. tips)		
Chimeren need encouragement, mouvaing statements and simultaneous feedback (verbal persuasion)     The discussion about the barriers for physical activity is important (overcoming the barriers for physical activity)	based on the family answers (questionnaire) and placements (pictures in the Ferris wheel) in the	4) A statistical analysis on family's physical activity will be gathered and reflected upon physical activity recommendations to facilitate the health conversation in child health clinic.		

#### Phase II Feasibility and piloting phase Sub-study V MODIFICATION OF THE INTERVENTION Content and activity elements 1)The digital questionnaire was updated to comply with new physical activity recommendations. 2) Pictures of physical activities were attached into a pennant Sub-study IV (Paper III) banner and Ferris wheel was replaced with a train representing the FEASIBILITY OF THE frequency of physical activities. INTERVENTION 3) The balloons with the rhymes were removed from the application. New feedback system was implemented and after placing all the 1) Need to improve the relevant pictures, family receives feedback on their physical activity functionality behaviours. Gamified elements were implemented by adding a 2) Need to balance the time simple clown game for children. the use takes 4) A standardized face to face training and practical manual for the 3) Need to create a family intervention for the PHNs was implemented to facilitate the familyfeedback system and child-centred conversation. 4) Need to add more gamified elements to Sub-study VI (Paper IV) attract children. THE PROTOCOL FOR THE EVALUATION STUDY Two-arm cluster, randomized, controlled trial with a four-month Participants are families with a four-year-old child attending to the extensive health examination at child health clinic Parental self-efficacy for health behaviours is the primary outcome

Figure 19. Summary of study results.

## 6 DISCUSSION

#### 6.1 Discussion of results

The overall aim of this study was to develop the physical activity component of the intervention and to explore the feasibility of the intervention with special reference to the physical activity component. The results of this study are discussed from the perspectives of the development and the feasibility of the intervention.

### The development of the physical activity component of the intervention

Identifying the evidence base (Sub-study I)

The results on the associations of neurological development and preference for active play among 2.5-year-old toddlers (Paper I) showed that most of the toddlers participated willingly in active play at home (as assessed by their parents). However, their participation was reported to be less common in nursery settings (as assessed by the early years teachers). Participation was positively associated with gross motor competence, auditory perception and self-help skills. Toddlers with delayed development in these areas participated less in active play than toddlers with normal development at nursery. This finding is in accordance with earlier studies, which show that motorically skilled children were more physically active than their less motorically skilled peers (Williams et al. 2008, Cliff et al. 2009, Kambas et al. 2012, Iivonen et al. 2013) and that physically disabled children participated in less physical activity than their normally developed peers (Shikako-Thomas et al. 2008).

There is no study reporting associations of self-help skills and auditory perception with the physical activity of small children. However, the results of one qualitative study exploring the parent's perceptions on their small children are somewhat similar. A study by Dwyer et al. (2008) found that shyness and the ability to follow rules were personal factors that lowered children's preference to participate in physical activities (Dwyer et al. 2008). When reflecting upon delayed self-help skills and auditory perceptions, these may be considered as a manifestation of these personal factors (e.g. shy children are rarely regarded as being capable of self-help). Notably, there were no associations between a preference for active play and the delayed development of toddlers at home, indicating that no matter what, toddlers are physically active at home.

There is no clear explanation for this finding. However, there are few different options which can be discussed regarding this issue. Firstly, the results may indicate that since parents have a strong bond with their child and cherish her or him, their perceptions of their child's skills may also be biased towards being too positive. Still, this assumption is comforting from the perspective of the physical activity promotion of children, since parents' perceptions of their child's competencies are positively associated with the child's physical activity (Loprinzi & Trost 2010). On the other hand, because one can assume that parents have more time to spend with their child than early years teachers and are willing to foster the child's abilities and development, children are encouraged and supported in active play. The latter conception is confirmed by findings from previous studies on the positive associations of parental support and encouragement with children's physical activity (Gustafson & Rhodes 2006, Loprinzi & Trost 2010, Zecevic et al. 2010, Dowda et al. 2011, Grigsby-Toussaint et al. 2011, Trost & Loprinzi 2011, Østbye et al. 2013, Sterdt et al. 2014, Xu et al. 2015, Carson 2016).

The third main finding indicates that the difference between the assessments of parents and early years teachers was statistically significant. Assessments differed most strongly among toddlers with delayed self-help skills. This leads to a question of how well or how similarly the term "preference for active play" is interpreted by parents and early years teachers. Also, it can lead to the idea that early years teachers are better educated about and experienced in children's active play behaviour, indicating that their assessment is more reliable.

On the contrary, as discussed above, there is a possibility that children are supported and encouraged more at home than in nursery settings, indicating that their physical activity behaviour may differ in these two settings. There is also evidence from studies on environmental factors' associations with children's physical activity behaviour, which may confirm the findings of this study. Previous studies support the idea that children's physical activity behaviour varies in different settings (Grøntved et al. 2007, Pate et al. 2008, Tucker 2008, Dowda et al. 2009), and it can be assumed that home and nursery environments offer very different opportunities for active play (like outdoor activities, free-flow play and play equipment), which is evidenced to be positively associated with child's physical activity behaviour (Sallis et al. 2000, Hannon & Brown 2008, Hinkley et al. 2008, Pate et al. 2008, Spurrier et al. 2008, Brown et al. 2009, Gubbels et al. 2010, Dolinsky et al. 2011, Dowda et al. 2011, Nicaise et al. 2011, Hodges et al. 2012, Sugiyama et al. 2012, Sterdt et al. 2014, Broekhuizen et al. 2014).

### Identifying the theory base (Sub-study II)

Previous studies showed self-efficacy to represent one meaningful psychological mediator affecting the physical activity behaviour of children (Sallis et al. 2000,

Lubans et al. 2008, Plotnikoff et al. 2013, Sterdt et al. 2014). Digital health interventions are a potential method to promote the health of children (Turner et al. 2015, Quelly et al. 2016) and gamification can increase the enjoyment of and engagement with these interventions (Hamari et al. 2014) and the attractiveness of these interventions (Parisod et al. 2014). Thus, the previous gamified digital interventions to enhance the physical activity self-efficacy of children were explored using the systematic review (Paper II).

According to the results from five different interventions, physical activity self-efficacy improved significantly in most of the included studies. The first three school-based interventions employed a commercially available active game, like games played with Nintendo Wii® and Dancing mat. These interventions were effective at improving the physical activity self-efficacy of children (Gao et al. 2012, Staiano et al. 2013, Lwin & Malik 2014). The fourth intervention employed a game-themed mobile application, but this home-based intervention was not effective (Direito et al. 2015). The fifth intervention was a school-based intervention employing a sedentary educational game. The intervention resulted in marginal improvements in physical activity self-efficacy (Goran & Reynolds 2005). Notably, the participants of the studies were school-aged children, with the mean age being approximately nine years old. None of the interventions were family centred. This finding is in accordance with recent literature, which showed a lack of studies that explore family-centred interventions among small children using a gamified approach.

Even though the amount of identified studies was small, the quality of the evidence was low and the interventions were heterogeneous, we could still make an analysis of self-efficacy enhancing elements in the gamified interventions. This analysis provided us with information to guide the development of the intervention. The literature review on family-centred digital interventions also showed that self-efficacy is a key mediator in physical activity interventions. These interventions introduced parental self-efficacy, which was one of the key mediators in family-centred interventions (Raat et al. 2012, Davies et al. 2014, Delisle et al. 2015, Knowlden et al. 2015, Belangér et al. 2016, Campbell et al. 2016, Kipping et al. 2016, Byrd-Benner et al. 2017, Hammersley et al. 2017). The evidence supports this approach, since parental self-efficacy is correlated positively with child's physical activity behaviour (Smith et al. 2010, Xu et al. 2015, Nixon et al. 2012, Bohman et al. 2016, Parekh et al. 2017).

Developing the physical activity component of the intervention (Sub-study III)

The evidence and theory base is meaningful from the perspective of the systematic development and implementation of the intervention (Craig et al. 2013) and the effectiveness of the intervention (Lubans et al. 2008, Nixon et al. 2012). Exploring

physical activity behaviour, associative factors (Sallis et al. 2000, Bauman et al. 2012, Hinkley et al. 2012) and earlier physical activity interventions in small children (Ling et al. 2017) can guide us to develop more sustainable interventions for small children.

The development of the physical activity component of the intervention was based on previous evidence from a correlational study on children's active play behaviour and neurological development (Paper I). This approach may be called *needs assessment* and it is recommended when developing digital interventions (McIntyre 2008, Barnum 2010, Novak 2012). There are different possibilities to implement needs assessment to explore the target group and health issue concerned, for instance, literature reviews and empirical studies (Barnum 2010, Novak 2012). The findings from the correlational study guided the development of the content for the intervention, and like in many digital interventions for small children (Raat et al. 2013, Knowlden et al. 2015, Davies et al. 2014, Byrd-Bredbenner et al. 2017, Delisle et al. 2015, Kipping et al. 2016, Jones et al. 2011), our intervention was also based on national physical activity recommendations (Ministry of Social Affairs and Health 2005). Basing our intervention on empirical evidence and current recommendations for physical activity, provided sound evidence, and can be considered a strength of the intervention.

The theoretical framework for the intervention (the mediating variable model of Baranowski et al. 1997, 1998) and evidence from previous physical activity studies (Sallis et al. 2000, Lubans et al. 2008, Plotnikoff et al. 2013, Sterdt et al. 2014) directed us to choose physical activity self-efficacy as the core mediator for the intervention (Bandura, 1986). The concept of self-efficacy is derived from Bandura's social cognitive theory, which was one of the guiding theories in previous family-centred digital interventions for small children (Jones et al. 2011, Raat et al. 2013, Davies et al. 2014, Delisle et al. 2015, Knowlden et al. 2015, Campbell et al. 2016, Kipping et al. 2016, Byrd-Bredbenner et al. 2017). The development of the physical activity component of the intervention was based on previous evidence from a systematic review of gamified interventions and their self-efficacy enhancing elements (Paper II). The findings from the review provided theorybased elements and contributed to the development of the intervention. Previous digital interventions for small children were also based on previous research literature (Bélanger et al. 2016, Davies et al. 2014, Byrd-Bredbenner et al. 2017) and earlier interventions targeting young children (Delisle et al. 2015).

The physical activity component of the intervention was developed in a multidisciplinary group of representatives from the fields of nursing, medicine, physical activity, information technology and graphic design, which is recommended by leading experts from the field of game research (Baranowski et al. 2013, 2016).

Depending on the needed expertise in the intervention, a different kind of content expertise is needed during the development process, as in previous digital interventions for children by dieticians (Delisle et al. 2015, Kipping et al. 2016, Byrd-Bredbenner et al. 2017), experts in physical activity (Delisle et al. 2015, Byrd-Bredbenner et al. 2017), child development (Byrd-Bredbenner et al. 2017), behavioural science (Delisle et al. 2015, Byrd-Bredbenner et al. 2017), the medical field (Delisle et al. 2015), education (Bélanger et al. 2016, Byrd-Bredbenner et al. 2017), engineering (Delisle et al. 2015), computer technology and graphic design (Byrd-Bredbenner et al. 2017). In this study, experts from the physical activity field were consulted when developing the physical activity questionnaire for the application.

Usually, the development process of digital interventions is iterative, consisting of several different phases. Development following participatory design principles is recommended in order to evaluate the perceptions and preferences of the target group (McIntyre 2008, Barnum 2010, Novak 2012). Even though the iterative process of this intervention has not been described in detail in this summary, it included many phases among various groups, like children, health professionals and PHNs in child health clinics (a more detailed description can be found in Papers III and IV, and in Pakarinen et al. 2017). The same kind of processes were also described in previous digital interventions for small children, and the participatory research varied from concept testing (Delisle et al. 2015) to usability studies (Davies et al. 2014) among parents (Jones et al. 2011, Delisle et al. 2015, Bélanger et al. 2016, Kipping et al. 2016, Byrd-Bredbenner et al. 2017), paediatricians, social workers (Byrd-Bredbenner et al. 2017), nursery managers, public health staff (Kipping et al. 2016) and early years teachers (Kipping et al. 2016). Only one study included children in the development process (Byrd-Bredbenner et al. 2017).

Although previous digital interventions were targeted at parents, the aim of these interventions was to promote the health of children. All the materials, mostly websites, were developed for parents and child participation was not supported, nor considered. This is may be considered a limitation since even small children are capable of understanding health messages and their participation in the interventions should be supported (Christensen 2004, Montgomery-Andersen & Borup 2012, Coyne et al. 2016). This intervention was developed considering and fostering children's active participation, and for that reason, gamified elements and a child-friendly user interface were implemented in the application. Also, a child's comprehension of the functionality of the application and the pictures in the application was assured by involving children during the development process (Pakarinen et al. 2017).

#### Feasibility and piloting the intervention

Evaluating the feasibility of the intervention (Sub-study IV)

After the intervention was developed, its feasibility was tested in real-life settings, as recommended (Bowen et al. 2009). In this study the setting was child health clinics and the participants were families with small children and the PHNs in child health clinics. The aim of feasibility studies is to evaluate the relevance, appropriateness and development needs of the intervention (Bowen et al. 2009, Thabane et al. 2010, Craig et al. 2013, Peters et al. 2013, Eldridge et al. 2016). Our study (Paper III, see also Pakarinen et al. 2017) evaluated the usability and acceptability of the intervention with a survey and interview. Feasibility studies may be conducted among a small number of participants since the effectiveness is not usually evaluated (Barnum 2010). Feasibility studies may also evaluate the effectiveness of the intervention, but then it is called *limited* or *potential efficacy*, and power calculations for sample size are not usually implemented (Bowen et al. 2009), as was the case in previous studies evaluating the limited effectiveness of interventions (Jones et al. 2011, Davies et al. 2014). As characterized in feasibility studies, different approaches can be implemented to evaluate the feasibility of the intervention. Previous studies, consisting of digital family-centred interventions, evaluated their acceptability (Jones et al. 2011), content (Delisle et al. 2015), understandability, usefulness and applicability (Raat et al. 2013) Also, satisfaction, needs for further development (Davies et al. 2014), fidelity, dose, context, reach and recruitment (Knowlden et al. 2014) of the digital interventions were evaluated.

According to the results of our feasibility study, the intervention was considered potentially usable and acceptable among the target group. This is in line with previous studies which evaluated the usability and acceptability of digital interventions among families (Jones et al. 2011, Raat et al. 2013, Davies et al. 2014). The studies showed that interventions involving webpages were generally appreciated by parents, and that the information and advice they received was applicable, understandable, useful (Raat et al. 2013) and readable (Davies et al. 2014). In our study, families, in general, experienced the intervention as an easy and valuable tool to reflect upon their own health behaviour. However, some families felt the application was too time consuming and not appropriate enough for their purposes. But, even these families perceived that the intervention could be a good tool for families with challenging situations. Some functions seemed to be too complicated and technical problems occurred during the use of the application with some devices. In the PHNs' opinions, the application was easy to use for detecting the individual needs of the families and for initiating discussions about family health, which is a good feature in tools used by health care professionals. Families in need of targeted support should be detected early enough to reduce health inequalities

in the future (Pillas et al. 2014). Both, the families and the PHNs, perceived the intervention could be a welcomed addition to current child health work. Also, needs for future development were provided by both, the families and the PHNs, so that the intervention would better suit their purposes. These are discussed in more detail in the next paragraph.

Modifying the physical activity component of the intervention (Sub-study V)

The piloting of an intervention should guide the modification and the plan for the effectiveness evaluation of the intervention. These phases are needed before implementing interventions in real-life settings (Bowen et al. 2009, Craig et al. 2013). The results of our feasibility study guided the modification of the intervention, like in previous studies (Delisle et al. 2015). The key improvement needs concerned improving the functionality and simplifying the system to balance the time required to the use the application, as well as creating a family feedback system. Since our intervention aims to support also the participation of children and to promote their role as health promotive actors (Christensen 2004, Montgomery-Andersen & Borup 2012, Coyne et al. 2016), one main finding was that many of the children were not actually participating into the intervention, neither in the use of the application, nor in discussions in child health clinics. Suggestions on this issue were made by parents and PHNs. They indicated that children 1.5 years of age were too small to participate and that gamified elements were not fully implemented from the perspective of the children. This may have been due the families and their children were not involved enough early in the development process. These key improvement needs were implemented during the modification of the intervention (see Fig. 13).

#### Planning the evaluation study (Sub-study VI)

Feasibility studies are meaningful from the perspective of the sustainable use and implementation of interventions in intended settings (Bowen et al. 2009, Craig et al. 2013, Peters et al. 2013). Different approaches are taken in feasibility studies (Bowen et al. 2009) and, in addition to usability and acceptability (which were in focus in our feasibility study), potential effectiveness may also be evaluated to guide the future research and implementation of an intervention (Bowen et al. 2009, Craig et al. 2013). Previous studies on digital interventions showed them to have a high level of retention and they were potentially efficacious (Jones et al. 2011, Knowlden et al. 2014).

In addition to the modification, our feasibility study also contributed to the plan for the effectiveness study. It showed that the recruitment of families might be a challenge, since only every fourth family that was contacted, used the application and only 15 % of the families completed the questionnaires. This is a limitation

that needed careful consideration when planning the recruitment of families for the evaluation study. In addition to the recruitment, careful planning was also made regarding the outcomes to be measured, and in order not to expel families from participating in an evaluation study with an exhausting amount of questionnaires, we choose to include only the minimal amount of questionnaires in the study. Since previous studies showed parental self-efficacy to be positively associated with a child's physical activity, we decided to include parental self-efficacy as the main outcome of the evaluation study. Also, previous studies strengthen this choice, since parental self-efficacy was the most targeted psychological mediator for behaviour change in the digital interventions aiming to promote the physical activity of small children (Jones et al. 2011, Raat et al. 2013, Davies et al. 2014, Delisle et al. 2015, Knowlden et al. 2015, Bélanger et al. 2016, Campbell et al. 2016, Byrd-Bredbenner et al. 2017, Kipping et al. 2016).

Digitalization is a rising area in health care, thus there is a considerably big challenge to implement digital solutions so that they become fluently embedded in one's working routines. Health care providers prefer digital tools that are simple and intuitive to use (Mendiola et al. 2015). The implementation of digital solutions in health care settings should be well planned in order to foster their sustainable use (Pereira et al. 2014). Evaluation studies contribute to this body of evidence (Craig et al. 2013). For example, our feasibility study showed that some of the PHNs had difficulties using the intervention fluently during the health visits. This was the main reason that we decided to produce a practical manual and implement a face-to-face training session for the implementation of the intervention for PHNs in the evaluation study.

The strengths of this study include the systematic process of the intervention development and piloting, following the MRC's guidance for complex interventions (Craig et al. 2013). As an evidence- and theory-based intervention, it represents one potential method to promote the health of small children. Evaluating the effectiveness of the intervention in real-life settings will show whether the WellWe intervention is worth implementing in child health clinic settings to promote the health of children.

# 6.2 The validity and reliability of the study

The strengths of this study include the use of various methodological approaches to develop an evidence- and theory-based intervention and to test its feasibility among the target group in the intended setting for the intervention. This methodological triangulation increases the validity of the research, produces more comprehensive data and enhances the understanding of studied phenomena (Bekhet &

Zauszniewski 2012). In the following subsections, the strengths and limitations of the study are discussed, reflecting upon the validity and reliability of the data collection, instruments and results.

#### The development and piloting phase

*Identifying the evidence base (Sub-study I)* 

In Sub-study I, a cross-sectional correlational study, data included assessments of toddlers' active play behaviour and neurological development from three different assessors. PHNs at child health clinics used Lene (Valtonen et al. 2004) to assess the neurological development of children. Lene is an instrument that is subjective by nature, since the assessment is dependent on the interpretations of PHNs. Previous studies among four- to six-year children showed that the structural validity of Lene (the Spearman correlation coefficient) varied from r = 0.27-0.82 (Valtonen et al. 2004, 2007) and internal consistency of Lene (Cronbach's alpha) varied from 0.69 to 0.85 (Valtonen et al. 2004, 2009). Even though the validity of Lene showed it to be at acceptable levels (Bland & Altman 1997), the test-retest or interrater reliability of the instrument has not been evaluated (Valtonen et al. 2004). Thus, these issues can be considered a limitation in this study. However, before the data collection, the PHNs were given the same training by the developer herself (R.V.), thus, it can be assumed that assessments between the assessors have been rather parallel.

Also, the subjective ratings of toddler's preference for active play, conducted by parents and by early years teachers, can be considered another limitation form the perspective of data collection. The instrument used was developed to complement Lene in child health clinics and to give the PHNs an idea of how a child is behaving in everyday settings at home and in nursery settings (Valtonen et al. 2004). Our study showed that parent's and early years teacher's assessments differed significantly and the various possible reasons for this have already been discussed above. In addition to those discussions, it can be asked whether parents and early years teachers are reliable sources to assess a child's physical activity behaviour. However, earlier studies indicate that both the parents (especially the mothers [Telama et al. 2014]), and the early years teachers in nursery settings (Chen et al. 2002) can be considered capable and valid sources for assessing small children's physical activity behaviour.

When considering the limitations of the results, one can argue that, since a relatively small proportion (26 %) of the population was included in the study, the results may be biased. But, this possible limitation could be vitiated as our statistical analyses showed that there were no statistically meaningful differences between these two groups (participants and non-participants). The strengths of the

study include the generalizability of the results, because of the representativeness of the participating toddlers. The nursery settings in which toddlers were assessed are publicly accessible places, to which children from all social strata have similar access. Child health clinics in turn, reach a wide range of Finnish families with under school-aged children, since 99.5 % of families attend health examinations regularly (Leino et al. 2007). All in all, with the limitations and strengths in mind, one should be cautious when interpreting results and drawing too strict conclusions about the associations of the physical activity behaviour and neurological development of toddlers.

#### Identifying the theory base (Sub-study II)

In Sub-study II, the data for the systematic review was gathered rigorously following Cochrane's protocol in order to ensure the validity and reliability of the data collection (Higgins et al. 2011). The strengths of data collection include the comprehensive data search from five different databases that used a pre-determined eligibility criterion and conducting the search using two independent reviewers. The validity and reliability of results were ensured by assessing the quality of the included studies using the Cochrane Collaboration tool to assess the risk of bias by two independent reviewers (Higgins et al. 2011) and assessing the quality of the evidence using the GRADE tool (Higgins & Green 2011, Guyatt et al. 2011). When considering the limitations of the results, the heterogeneity of the included studies and inability to conduct meta-analyses can be considered to lower the validity of the results. Meta-analyses can provide accurate estimates of the effectiveness of results (Liberati et al. 2009). Also, because some of the included interventions involved elements other than game elements, the drawing of exclusive conclusions about the relationship between game elements and outcomes was not so strong. Moreover, the lack of high quality studies and the low quality of the evidence diminished the reliability of results. But these were limitations that we were not able affect on. The strengths of the results include the fact that our review was the first review to explore health game interventions from the perspective of physical activity self-efficacy in children.

#### Developing the physical activity component of the intervention (Sub-study III)

In Sub-study III, the physical activity component of the intervention was developed. The strengths of the development phase include the systematic process, following the MRC framework for complex interventions (Craig et al. 2013) and basing the intervention on theory (the mediating variable model from Baranowski et al. 1997, 1998), evidence, Sub-studies I and II, and from national physical activity recommendations for children (Ministry of Social Affairs and Health 2005). The strengths also include the multidisciplinary group of experts from health, physical

activity, medical, information technology and graphic design fields, whose involvement in this development phase increased the validity of the content of the intervention. The participation of the multidisciplinary group was assured by regular meetings and discussions between the researchers in the group. Although the data collection and analyses followed a systematic approach and the validity of the content was ensured in the multidisciplinary group, the nature of this kind of innovation process may still be considered rather loose. When giving the emphasis to the free flow of ideas and interpretations, the end-product always has the appearance of its creators. Thus, with a different developer team, the physical activity component of the intervention might have had different content and essence. However, this may be neither a limitation nor a strength.

#### Feasibility and the piloting phase

Evaluating the feasibility of the intervention (Sub-study IV)

In Sub-study IV, the feasibility study, data was collected using a structured usability questionnaire (using the SUS) among two groups (n = 25): using a semi-structured acceptability questionnaire among parents (n = 15) and an interview among PHNs (n = 5). The SUS, which was used to assess usability, is a valid and reliable tool to evaluate the usability of wide range of technologies (Brooke 1996). An acceptability questionnaire was developed for the purposes of the study. The interview frame included the same themes as the questionnaire. Limitations of the data collection include the fact that the acceptability questionnaire was not piloted, thus, the questions may have been interpreted differently by participants. But, this may not be a major limitation since the questions were quite straightforward, exploring the pros and cons of the intervention and the ideas for further development needs. Because of the possibility to repeat the questions and ask clarifying questions if needed, this limitation did not exist in interviews with PHNs. In addition, even though the predetermined analysis frame guided the analyses process regarding the acceptability of the intervention, there is still the possibility for misinterpretation of the collected data. However, as with the acceptability questionnaire, the interpretation of the data was quite straightforward, thus the likelihood of interpreting the data in many various ways is unlikely. Still, this limitation would have been avoided if two researchers had analysed the results independently. Another limitation of the data collection involved inadequate data, caused by missing questions concerning relevant background information of the families and PHNs, such as questions concerning the socio-economic status of the families and working experience of the PHNs. Because of this lack of information, more comprehensive results could not be provided, which could have been used to compare the perceptions of experienced or less experienced PHNs for example. However, this was a

good learning experience for a novice researcher: to consider relevant and adequate questions more carefully before data collection.

One limitation from the perspective of the results includes the small sample size, which has decreased the generalizability of the results. However, given the nature of this feasibility study – which explored the usability and acceptability of the intervention from the perspective of families and PHNs in child health clinic settings and sought out cases that best represented similar cases – the sample size may have been adequate (Patton 2015). In addition, the sample sizes of previous feasibility studies evaluating digital interventions were also small, varying from 15 to 40 participants (Jones et al. 2011, Davies e al. 2014, Delisle et al. 2016). Notably, the low participation rate (15 out of 105 recruited) may have biased the results and, thus, it can be considered a limitation. The bias in the results is caused by the rather homogeneous group of participants who take part in these kinds of studies in general. Also, another bias in the results may include the overly positive perceptions of the intervention as perceived by the PHNs, since the same PHNs were also involved in the development process of the intervention. The same PHNs and study participants had the possibility to have a deeper understanding of the use and purpose of the intervention, possibly leading to more positive perceptions than if PHNs using the intervention for the first time had been studied.

*Modifying the physical activity component of the intervention (Sub-study V)* 

In Sub-study V, the physical activity component of the intervention was modified. The data used as a base for the modification was the main results from the feasibility study. In addition, since the physical activity recommendations were renewed since the first version of the intervention, those recommendations also provided issues to be modified. The same multidisciplinary group of experts from various fields that was involved in the development phase was involved in the modification process. This is a strength and has quite possibly increased the validity of the content of the intervention. The same limitations that were present in the development phase of the intervention were present in this phase. Thus, even the data collection and analyses was conducted systematically, the results are still results derived from an innovation process with the emphasis on the free flow of the ideas and interpretations and may not lead to the same kind of results as those that would be gained from some other team of researchers. Even with this possible limitation, the intervention development rigorously followed the MRC framework for complex interventions, leading to more systematic processes and to an evidence- and theory-based intervention (Craig et al. 2013).

Planning the evaluation study (Sub-study VI)

In Sub-study VI, a plan for the evaluation study was designed. The feasibility study provided the base for the protocol regarding the design, setting, eligibility criteria, allocation ratio, delivery of the intervention and recruitment. This is in accordance with the MRC framework for complex interventions and may be considered a strength of this study. To ensure the validity of results, the study sample size was estimated, based on a power calculations and the feasibility study (Craig et al. 2013). To ensure the validity and reliability of the data collection, validated instruments are to be used to evaluate the intervention's effectiveness for promoting physical activity self-efficacy. Since the instrument was in English, we used a valid process to translate the questionnaire into Finnish. To ensure the validity and reliability of the translation, an official translation process, following the ISPOR protocol, was chosen (Wild et al. 2005). Also, the reliability and validity analyses of the instrument are to be conducted during the evaluation study, since the questionnaire will be being used for the first time among the Finnish population. The plan for the randomization systematically followed the guidelines of the CONSORT-EHEALTH statement, thus ensuring the validity of the data collection (Eysenbach et al. 2011). Careful design of the data collection also included the consideration of how to avoid contamination and systematic bias in the data. Thus, randomization was conducted at the municipal level (Craig et al. 2013).

Even with a rigorous process to ensure the validity and reliability of the study, some limitations will exist, which are difficult to avoid. The first limitation includes the impossibility of blinding the intervention providers (the PHNs), the researchers and the research assistants. This was due to the fact that the same people were involved in the training of the intervention providers. However, the blinding of the participating families was possible. A second limitation includes the fidelity of the intervention. Even though the intervention providers (the PHNs) have been given a standardized training session on the implementation of the intervention, there is no possibility to control their actual implementation of the intervention (for example, the discussions with the families).

## 6.3 Implications and future research

During this study a digital gamified intervention aiming to promote the physical activity of small children was developed and the feasibility of the intervention was tested following a systematic process and basing the intervention on evidence and theory. This study consisted of several sub-studies, which altogether contributed to the development and modification of the intervention and the plan for the evaluation study. But, since this study is the sum of its parts, the sub-studies can be

considered individual studies with their own contributions to practice and research. Hereafter, the implications for practice and suggestions for research are summarized.

### **Practical implications**

- Children with developmental delays should be encouraged to participate in active play in a way that supports their ability and comprehension, both at home and in nursery settings.
- Children with a lack of gross motor competence need special attention, since
  motor skills are important from the perspective of a child's physical activity.
  Motor skills may be supported by offering children various equipment and enabling their free-flow play and outside activities.
- Children with a lack of self-help skills or delayed auditory perception need support and encouragement, especially in nursery settings. These children may be supported better by implementing physical activities in small groups.
- Parents play a key role in promoting the physical activity of small children.
   This should be emphasized in the child health clinics during family health visits. The family-centred approach in health promoting interventions can support parental self-efficacy in promoting their child's physical activity.
- Digital interventions offer one potential method to be used in health care settings to promote the physical activity of children. A gamified approach in interventions may support the participation of small children, fostering the child's role as a health promotive actor. Active videogames are potential methods to enhance the physical activity self-efficacy of school-aged children.

#### Suggestions for future research and development of interventions

- The results of this study indicated that delays in a child's neurological development are associated with the child's physical activity behaviour during early childhood. This finding needs more exploration and the associations of children's neurological development and physical activity should be studied with validated instruments. Furthermore, these associations should be measured both in home and nursery settings.
- This study showed that previous studies have not evaluated gamified interventions among small children and previous gamified interventions among school children mostly employed commercially available games. There is a need to develop and evaluate gamified interventions among small children.

- The previous evidence shows that the physical activity self-efficacy of children
  is positively associated with physical activity. The results of this study on selfefficacy supporting elements in games can be used when developing physical
  activity promotive interventions for children.
- The previous evidence shows that parental self-efficacy is positively associated with child's physical activity. This study translated an instrument to measure parental self-efficacy into Finnish, following a validated back-translation process. The evaluation study will test the reliability and validity of the instrument on the Finnish population. This provides the possibility to study parental self-efficacy and its associations with children's physical activity in Finnish families.
- The previous studies indicate that there is a need for family-centred digital health interventions that are intended for parents and their small children. Overall the results of this study indicate that the WellWe intervention is potentially feasible and worth further evaluation. The WellWe intervention may be more appreciated by families with challenging situations, but this finding needs more exploration. A future evaluation study will show whether the WellWe intervention was effective in promoting the parental self-efficacy and family-centred approach to health examination. The results will contribute to the plan for the intervention's implementation.
- This study provided a systematic process for the development and testing of a gamified digital intervention targeting small children and their families in health care settings. The evidence- and theory-based development process that this study described in detailed may guide the development of future digital health interventions intended for children and families in health care settings. Some recommendations can be made based on the learning experiences of this study:
  - The development of digital interventions requires a multidisciplinary group of experts from different fields of health and information technology and graphics.
  - The development of digital interventions requires careful exploration of the needs of the target group and the health issue in concern, and basing the intervention on theory and evidence increases the possibility of achieving more sustainable use and effective results.
  - The development of digital interventions requires special attention to be paid on the target group and following participatory research methods in order to better meet the needs of the target group and suit the purposes

- of the stakeholders in health care settings. If one is developing interventions for children, their perceptions and ideas regarding the intervention should be taken into consideration early on in the development process.
- Participatory research methods should guide the developers when testing the intervention among the target group in several phases of the development process and when modifying the intervention based on the results of the testing.

## 7 SUMMARY AND CONCLUSIONS

This study described a development process and feasibility testing of a gamified digital intervention to promote the physical activity of small children. The development rigorously followed a methodological framework and the intervention was based on evidence and theory. The physical activity component of the intervention was based on evidence which showed that the motor skills, self-help skills and comprehension of children should be supported in order to foster their preference for physical activity participation. Evidence from earlier interventions supported the family-centred and gamified approach of the intervention and showed that elements supporting the physical activity self-efficacy of children can be embedded in digital interventions.

The feasibility and piloting phase showed that innovative interventions are needed and the intervention was acceptable from the perspective of small children, their parents and the PHNs in child health clinics. Feasibility studies offer important information for researchers and developers to design and modify interventions in order to better meet the needs and preferences of the target group. Feasibility studies are also an integral part of planning the evaluation studies and implementation of the intervention. Thus, evidence- and theory-based interventions following formative testing among the target group are an essential part of implementing new digital interventions in health care settings in order to promote the health of small children. This was the first study to employ a child-centred and gamified approach in a digital intervention to promote the physical activity of children in early childhood. The main findings of this study are summarized in Table 10.

Table 10. Summary of main findings of the study.

AIMS	MAIN FINDINGS							
DEVELOPMENT PHASE								
Sub-study I aimed to explore the developmental factors associated with active play behaviour of toddlers	Nearly 90 % of toddlers participated in active play at home and nursery settings. At nursery settings, active play behaviour was significantly in association with delayed gross motor performance and auditory perception, and lack of self-help skills. No significant associations between reports of active play behaviour and delayed neurological development were identified among toddlers at home.							
Sub-study II aimed to explore gamified digital interventions to enhance the physical activity self-efficacy of children	Interventions were targeted at school-aged children, were mostly school-based and included commercially available games. They were effective as regards of physical activity self-efficacy of children, but the quality of evidence was considered low for physical activity self-efficacy. Interventions included elements enhancing physical activity self-efficacy, through fostering mastery experiences and vicarious experiences, verbal persuasion and overcoming barriers for physical activity.							
Sub-study III aimed to describe the develop- ment of the physical ac- tivity component of the intervention	Previous studies formed the evidence and theory base for the intervention. All together four content- and four activity elements were designed for the physical activity component of the intervention: 1) Measurement of physical activity using digital questionnaire. 2) Visual reflection on physical activity behaviours of family using graphical pictures and placing them into Ferris wheel to show the frequency of the behavior. 3) Instant feedback (information about physical activity) for the family in visual format and child-friendly manner according to the pictures family has placed into the Ferris wheel. 4) Statistical user interface and health discussion with PHN based on the family physical activity monitored with the application.							
	FEASIBILITY AND PILOTING PHASE							
Sub-study IV aimed to evaluate the feasibility of intervention among target group	Usability of the intervention was perceived good among PHNs (mean SUS-score 71.5) and satisfactory among families (mean SUS-score 58.8). Overall, the intervention was perceived potentially acceptable. PHNs perceived that intervention facilitated them to detect individual needs of the families to support their health. Families perceptions varied: Some families would have preferred paper-based questionnaire and they felt that it didn't increase their health-related knowledge. Other families found the application informative and they thought it was a good tool to realize their own behaviors. Main development needs as perceived by the target group were the need to improve the functionality, to balance the time the use takes, to create a family feedback system and to add more gamified elements to attract children.							
Sub-study V aimed to describe the modifica- tion of the physical ac- tivity component of the intervention	Feasibility study contributed to the modification of physical activity component of the intervention: 1) To facilitate the use and improve functionality, digital questionnaire was shortened, and instant feedback system was modified to be more comprehensive. 2) To attract children, pictures of physical activities were designed to be more child-friendly and gamified elements were added by designing g a simple clown game for children. 3) To improve the intervention fidelity and implementation from the perspective of PHNs, a standardized face to face training and practical manual for the PHNs was designed.							
Sub-study VI aimed to describe the protocol for the evaluation study	Feasibility study, together with previous evidence and theory, contributed to the plan for the effectiveness evaluation of the intervention: 1) Intervention delivery and the training of the PHNs. 2) Recruitment plan facilitating the participation and decision to use limited number of questionnaires. 3) Decision to include families with 4-year-old children for the intervention. 4) Decision to include parental self-efficacy as main outcome							

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## REFERENCES

- Ahn, S., & Fedewa, A. L. (2011). A meta-analysis of the relationship between children's physical activity and mental health. Journal of Pediatric Psychology, 36(4), 385-397.
- Ainsworth, B. E., Haskell, W. L., Whitt, M. C., Irwin, M. L., Swartz, A. M., Strath, S. J., ... & Ja-cobs, D. R. (2000). Compendium of physical activities: an update of activity codes and MET intensities. Medicine and Science in Sports and Exercise, 32(9; SUPP/1), S498-S504.
- Ainsworth, B. E., Haskell, W. L., Leon, A. S., Jacobs, J. D., Montoye, H. J., Sallis, J. F., & Paffenbarger, J. R. (1993). Compendium of physical activities: classification of energy costs of human physical activities. Medicine and Science in Sports and Exercise, 25(1), 71-80.
- American Academy of Pediatrics (2016). Ages & Stages. Retrieved from https://www.healthychildren.org/English/ages-stages/Pages/default.aspx. (2/2018).
- Arain, M., Campbell, M. J., Cooper, C. L., & Lancaster, G. A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Medical Research Methodology, 10(1), 67.
- Bandura, A. (1986a). Social foundations of thought and action: A social cognitive theory. Englewood Cliffs, NJ, US: Prentice-Hall, Inc.
- Bandura, A. (1986b). The explanatory and predictive scope of self-efficacy theory. Journal of Social and Clinical Psychology, 4(3), 359-373.
- Bandura, A., & Wessels, S. (1994). Self-efficacy. In V. S. Ramachaudran (Ed.), Encyclopedia of human behavior (Vol. 4, pp. 71-81). New York: Academic Press.
- Bandura, A. (1997). Self-efficacy: The exercise of control. New York, NY, US: W H Freeman/Times Books/ Henry Holt & Co.
- Bangor, A., Kortum, P., & Miller, J. (2009). Determining what individual SUS scores mean: Adding an adjective rating scale. Journal of Usability studies, 4(3), 114-123.
- Baranowski, T., Lin, L. S., Wetter, D. W., Resnicow, K., & Hearn, M. D. (1997). Theory as medi-ating variables: why aren't community interventions working as desired?. Annals of Epidemiolo-gy, 7(7), S89-S95.
- Baranowski, T., Anderson, C., & Carmack, C. (1998). Mediating variable framework in physical activity interventions: How are we doing? How might we do better?. American Journal of Preventive Medicine, 15(4), 266-297.
- Baranowski, T., Cullen, K. W., Nicklas, T., Thompson, D., & Baranowski, J. (2003). Are current health behavioural change models helpful in guiding prevention of weight gain efforts?. Obesity, 11(S10).

- Baranowski, T., Buday, R., Thompson, D. I., & Baranowski, J. (2008). Playing for real: video games and stories for health-related behaviour change. American Journal of Preventive Medicine, 34(1), 74-82.
- Baranowski, T., Buday, R., Thompson, D., Lyons, E. J., Lu, A. S., & Baranowski, J. (2013). Developing games for health behaviour change: Getting started. GAMES FOR HEALTH: Re-search, Development, and Clinical Applications, 2(4), 183-190.
- Baranowski, T., Blumberg, F., Buday, R., DeSmet, A., Fiellin, L. E., ... & Mellecker, R. (2016). Games for health for children—Current status and needed research. Games for Health Journal, 5(1), 1-12.
- Barnum, C. M. (2010). Usability testing essentials: ready, set... test!. Elsevier.
- Bauman, A. E., Sallis, J. F., Dzewaltowski, D. A., & Owen, N. (2002). Toward a better understanding of the influences on physical activity: the role of determinants, correlates, causal variables, mediators, moderators, and confounders. American Journal of Preventive Medicine, 23(2), 5-14.
- Bauman, A. E., Reis, R. S., Sallis, J. F., Wells, J. C., Loos, R. J., Martin, B. W., & Lancet Physical Activity Series Working Group. (2012). Correlates of physical activity: why are some people physically active and others not? The Lancet, 380(9838), 258-271.
- Becker, D. R., McClelland, M. M., Loprinzi, P., & Trost, S. G. (2014). Physical activity, self-regulation, and early academic achievement in preschool children. Early Education & Development, 25(1), 56-70.
- Bekhet, A. K., & Zauszniewski, J. A. (2012). Methodological triangulation: An approach to understanding data. Nurse Researcher.
- Bélanger, M., Humbert, L., Vatanparast, H., Ward, S., Muhajarine, N., Chow, A. F., ... & Leis, A. (2016). A multilevel intervention to increase physical activity and improve healthy eating and physical literacy among young children (ages 3-5) attending early childcare centres: the Healthy Start-Départ Santé cluster randomised controlled trial study protocol. BMC Public Health, 16(1), 313.
- Bellows, L. L., Davies, P. L., Anderson, J., & Kennedy, C. (2013). Effectiveness of a physical activity intervention for Head Start preschoolers: a randomized intervention study. American Journal of Occupational Therapy, 67(1), 28-36.
- Biddle SJ & Asare M. (2011). Physical activity and mental health in children and adolescents: a review of reviews. British Journal of Sports Medicine, 45(11), 886–895.
- Biddle, S. J., Gorely, T., Pearson, N., & Bull, F. C. (2011). An assessment of self-reported physical activity instruments in young people for population surveillance: Project ALPHA. International Journal of Behavioral Nutrition and Physical Activity, 8(1), 1.
- Bland, J. M., & Altman, D. G. (1997). Statistics notes: Cronbach's alpha. BMJ, 314(7080), 572.

- Bohman, B., Rasmussen, F., & Ghaderi, A. (2016). Development and psychometric evaluation of a context-based parental self-efficacy instrument for healthy dietary and physical activity behaviours in preschool children. International Journal of Behavioural Nutrition and Physical Activity, 13(110), 1-9.
- Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., ... & Fernandez, M. (2009). How we design feasibility studies. American Journal of Preventive Medicine, 36(5), 452-457.
- Brady, L. M., Gibb, J., Henshall, A., & Lewis, J. (2008).
  Play and Exercise in Early Years: physically active play in early childhood provision. UK Government, Department of Culture, Media and Sport, London, UK.
- Brannen, J. (Ed.). (2017). Mixing methods: Qualitative and quantitative research. Routledge.
- Brasholt, M., Chawes, B., Kreiner-Møller, E., Vahlkvist, S., Sinding, M., & Bisgaard, H. (2013). Objective assessment of levels and patterns of physical activity in preschool children. Pediatric Research, 74(3), 333.
- Braun, R., Catalani, C., Wimbush, J., & Israelski, D. (2013). Community health workers and mo-bile technology: a systematic review of the literature. PloS one, 8(6), e65772.
- Broekhuizen, K., Scholten, A. M., & de Vries, S. I. (2014). The value of (pre) school play-grounds for children's physical activity level: a systematic review. International Journal of Behavioural Nutrition and Physical Activity, 11(1), 59.
- Brooke, J. (1996). SUS-A quick and dirty usability scale. Usability evaluation in industry, 189(194), 4-7.
- Brown, A. (2011). Media use by children younger than 2 years. Pediatrics, 128(5), 1040-1045.
- Brown, W. H., Pfeiffer, K. A., McIver, K. L., Dowda, M., Addy, C. L., & Pate, R. R. (2009). Social and environmental factors associated with preschoolers' nonsedentary physical activity. Child Development, 80(1), 45-58.
- Burdette, H. L., & Whitaker, R. C. (2005). Resurrecting free play in young children: looking beyond fitness and fatness to attention, affiliation, and affect. Archives of Pediatrics & Adolescent Medicine, 159(1), 46-50.
- Bürgi, F., Meyer, U., Granacher, U., Schindler, C., Marques-Vidal, P., Kriemler, S., & Puder, J. J. (2011). Relationship of physical activity with motor skills, aerobic fitness and body fat in preschool children: a cross-sectional and longitudinal study (Ballabeina). International Journal of Obesity, 35(7), 937.
- Byrd-Bredbenner, C., Martin-Biggers, J., Koenings, M., Quick, V., Hongu, N., & Worobey, J. (2017). Home-Styles, a web-based childhood obesity prevention program for families with preschool children: protocol for a randomized controlled trial. JMIR Research Protocols, 6(4).

- Campbell, K. J., Hesketh, K. D., McNaughton, S. A., Ball, K., McCallum, Z., Lynch, J., & Crawford, D. A. (2016). The extended Infant Feeding, Activity and Nutrition Trial (InFANT Extend) Program: a clusterrandomized controlled trial of an early intervention to prevent childhood obesity. BMC Public Health, 16(1), 166.
- Cardon, G. M., & De Bourdeaudhuij, I. M. (2008). Are preschool children active enough? Objectively measured physical activity levels. Research Quarterly for Exercise and Sport, 79(3), 326-332.
- Carson, V., Hunter, S., Kuzik, N., Wiebe, S. A., Spence, J. C., Friedman, A., ... & Hinkley, T. (2016). Systematic review of physical activity and cognitive development in early childhood. Journal of Science and Medicine in Sport, 19(7), 573-578.
- Caspersen C.J., Powell K.E. & Chrostenson G.M. (1985). Physical activity, exercice, and physical fitness: definition and distinction for health-related research. Public Health Reports 100(2), 126-131.
- Chassiakos, Y. L. R., Radesky, J., Christakis, D., Moreno, M. A., & Cross, C. (2016). Children and adolescents and digital media. Pediatrics, 138(5), e20162593.
- Chen, X., Sekine, M., Hamanishi, S., Wang, H., Hayashikawa, Y., Yamagami, T., & Kagamimori, S. (2002). The validity of nursery teachers' report on the physical activity of young children. Journal of Epidemiology, 12(5), 367-374.
- Christensen, P. (2004). The health-promoting family: a conceptual framework for future re-search. Social Science & Medicine, 59(2), 377-387.
- Cliff, D. P., Okely, A. D., Smith, L. M., & McKeen, K. (2009). Relationships between fundamental movement skills and objectively measured physical activity in preschool children. Pediatric Exercise Science, 21(4), 436-449.
- Collings, P. J., Brage, S., Ridgway, C. L., Harvey, N. C., Godfrey, K. M., Inskip, H. M., ... & Ekelund, U. (2013). Physical activity intensity, sedentary time, and body composition in preschoolers—. The American of Clinical Nutrition, 97(5), 1020-1028.
- Coyne, I., Hallström, I., & Söderbäck, M. (2016). Reframing the focus from a family-centred to a childcentred care approach for children's healthcare. Journal of Child Health Care, 20(4), 494-502.
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2013). Developing and evaluating complex interventions: the new Medical Research Council guidance. International Journal of Nursing Studies, 50(5), 587-592.
- Craigie, A. M., Lake, A. A., Kelly, S. A., Adamson, A. J., & Mathers, J. C. (2011). Tracking of obesity-related behaviours from childhood to adulthood: a systematic review. Maturitas, 70(3), 266-284.
- Dalvand, H., Rassafiani, M., & Bagheri, H. (2014). Family Centred Approach: A literature the review. Journal of Modern Rehabilitation, 8(1), 1-9.

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- Davies, M. A., Terhorst, L., Nakonechny, A. J., Skukla, N., & El Saadawi, G. (2014). The development and effectiveness of a health information website designed to improve parents' self-efficacy in managing risk for obesity in preschoolers. Journal for Specialists in Pediatric Nursing, 19(4), 316-330.
- Delisle, C., Sandin, S., Forsum, E., Henriksson, H., Trolle-Lagerros, Y., Larsson, C., ... & Timpka, T. (2015). A web-and mobile phone-based intervention to prevent obesity in 4-year-olds (MINISTOP): a population-based randomized controlled trial. BMC Public Health, 15(1), 95.
- Delisle-Nyström, C. D., Sandin, S., Henriksson, P., Henriksson, H., Trolle-Lagerros, Y., Larsson, C., ... & Silfvernagel, K. (2017). Mobile-based intervention intended to stop obesity in preschool-aged children: the MINISTOP randomized controlled trial, 2. The American Journal of Clinical Nutrition, 105(6), 1327-1335.
- Department of Health. Australia (2017). Australian 24-Hour Movement Guidelines for the Early Years (Birth to 5 years). Retrieved from http://www.health.gov.au/internet/main/publishing.nsf/co
  - tent/F01F92328EDADA5BCA257BF0001E720D/\$ File/Birthto5years\_24hrGuidelines\_Brochure.pdf (2/2018)
- Department of Health and Social Care, UK (2011). Physical activity guidelines for early years (under 5s) for children who are capable of walking. Retrieved from https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/213738/dh\_128143.pdf (2/2018)
- Deterding, S., Dixon, D., Khaled, R., & Nacke, L. (2011). From game design elements to gamefulness: defining gamification. In Proceedings of the 15th international academic MindTrek conference: Envisioning Future Media Environments (pp. 9-15). ACM.
- Deterding, S., Sicart, M., Nacke, L., O'Hara, K., & Dixon, D. (2011, May). Gamification. using gamedesign elements in non-gaming contexts. In CHI'11 extended abstracts on human factors in computing systems (pp. 2425-2428). ACM.
- DeVellis, R. F. (2016). Scale development: Theory and applications (Vol. 26). Sage publications.
- Dewar, J. A. (2000). The information age and the printing press: looking backward to see ahead. Ubiquity, 2000(August), 8.
- Direito, A., Jiang, Y., Whittaker, R., & Maddison, R. (2015). Apps for IMproving FITness and increasing physical activity among young people: the AIMFIT pragmatic randomized controlled trial. Journal of Medical Internet Research, 17(8).
- Dolinsky, D. H., Brouwer, R. J. N., Østbye, T., Evenson, K. R., & Siega-Riz, A. M. (2011). Peer reviewed: correlates of sedentary time and physical activity among preschool-aged children. Preventing Chronic Disease, 8(6).

- Dowda M., Brown, W.H., McIver, K.L., Pfeiffer, K.A., O'Neill, J.R., & Addy, C.L. (2009). Policies and characteristics of the preschool environment and physical activity of young children. Pediatrics, 123(2):e261– e266
- Dowda, M., Pfeiffer, K. A., Brown, W. H., Mitchell, J. A., Byun, W., & Pate, R. R. (2011). Parental and environmental correlates of physical activity of children attending preschool. Archives of Pediatrics & Adolescent Medicine, 165(10), 939-944.
- Dwyer, J., Needham, L., Simpson, J. R., & Heeney, E. S. (2008). Parents report intrapersonal, interpersonal, and environmental barriers to supporting healthy eating and physical activity among their preschoolers. Applied Physiology, Nutrition, and Metabolism, 33(2), 338-346.
- Dyer, A. (2005). Two-year follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. The Journal of Pediatrics, 146(5), 618-625.
- Eisenmann, J. C., & Wickel, E. E. (2009). The biological basis of physical activity in children: revisited. Pediatric Exercise Science, 21(3), 257-272.
- Ekelund, U., Luan, J. A., Sherar, L. B., Esliger, D. W., Griew, P., Cooper, A., & International Children's Accelerometry Database (ICAD) Collaborators. (2012). Moderate to vigorous physical activity and sedentary time and cardiometabolic risk factors in children and adolescents. JAMA, 307(7), 704-712.
- Ekelund, U., Steene-Johannessen, J., Brown, W. J., Fagerland, M. W., Owen, N., Powell, K. E., ... & Lancet Sedentary Behaviour Working Group. (2016). Does physical activity attenuate, or even eliminate, the detrimental association of sitting time with mortality? A harmonised meta-analysis of data from more than 1 million men and women. The Lancet, 388(10051), 1302-1310.
- Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. PLoS One, 11(3), e0150205.
- ETENE National Advisory board social Welfare and health care ethics. (2003). Perspectives on Medical Children. Retrieved research in http://etene.fi/documents/1429646/1559090/Ty%C3%B6ryhm%C3%A 4n+loppuraportti+N%C3%A4k%C3%B6kulmia+l%C3%A4%C3%A4ketieteellisist%C3%A4+tutkimuksista+lapsilla.pdf/431c583a-bcea-4719-96b9-7b609e44bf65/Ty%C3%B6ryhm%C3%A4n+loppuraportti+N%C3%A4k%C3%B6kulmia+l%C3%A4%C3%A4ketieteellisist%C3%A4+tutkimuksista+lapsilla.pdf.pdf (3/2018)
- Etnier, J. L., Nowell, P. M., Landers, D. M., & Sibley, B. A. (2006). A meta-regression to examine the relationship between aerobic fitness and cognitive performance. Brain Research Reviews, 52(1), 119-130.

- Eysenbach, G., & Consort-EHEALTH Group. (2011). CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. Journal of Medical Internet Research, 13(4).
- Fedewa, A. L., & Ahn, S. (2011). The effects of physical activity and physical fitness on children's achievement and cognitive outcomes: a meta-analysis. Research Quarterly for Exercise and Sport, 82(3), 521-535.
- Feng, Y., & Xie, W. (2015). Digital divide 2.0: the role of social networking sites in seeking health information online from a longitudinal per-spective. Journal of Health Communication, 20(1), 60-68.
- Fisher, A., Reilly, J. J., Kelly, L. A., Montgomery, C., Williamson, A., Paton, J. Y., & Grant, S. (2005). Fundamental movement skills and habitual physical activity in young children. Medicine & Science in Sports & Exercise, 37(4), 684-688.
- Fitzgibbon, M. L., Stolley, M. R., Schiffer, L., Van Horn, L., KauferChristoffel, K., & Dyer, A. (2005). Twoyear follow-up results for Hip-Hop to Health Jr.: a randomized controlled trial for overweight prevention in preschool minority children. The Journal of Pediatrics, 146(5), 618-625
- Fuemmeler, B. F., Anderson, C. B., & Mâsse, L. C. (2011). Parent-child relationship of directly measured physical activity. International Journal of Behavioural Nutrition and Physical Activity, 8(1), 17.
- Gallahue, D. L., Ozmun, J. C., Goodway J. D. (2012).
  Understanding Motor Development: Infants, Children, Adolescents, Adults. New York: McGraw-Hill.
- Gao, Z., Huang, C., Liu, T., & Xiong, W. (2012). Impact of interactive dance games on urban children's physical activity correlates and behavior. Journal of Exercise Science & Fitness, 10(2), 107-112.
- Goldfield, G. S., Harvey, A., Grattan, K., & Adamo, K. B. (2012). Physical activity promotion in the preschool years: a critical period to intervene. International Journal of Environmental Research and public health, 9(4), 1326-1342.
- Goran, M. I., & Reynolds, K. (2005). Interactive multimedia for promoting physical activity (IMPACT) in children. Obesity, 13(4), 762-771.
- Gordon, E. S., Tucker, P., Burke, S. M., & Carron, A. V. (2013). Effectiveness of physical activ-ity interventions for preschoolers: a meta-analysis. Research Quarterly for Exercise and Sport, 84(3), 287-294.
- Government Decree, 338/2011. (2011). On maternity and child health clinic services, school and student health services and preventive oral health services for children and youth. Retrieved from http://www.finlex.fi/fi/laki/alkup/2011/20110338. (3/2018).
- Graham, A., Powell, M., Taylor, N., Anderson, D., & Fitzgerald, R. (2013). Ethical research involving children. Florence: UNICEF Office of Research-Innocenti.
- Grant, J. M. (1991). The fetal heart rate trace is normal, isn't it?: Observer agreement of categorical assessments. The Lancet, 337(8735), 215-218.

- Grigsby-Toussaint, D. S., Chi, S. H., & Fiese, B. H. (2011). Where they live, how they play: Neighborhood greenness and outdoor physical activity among preschoolers. International Journal of Health Geographics, 10(1), 66.
- Grove, S., Burn, N., & Grey, J. (2012). The practice of Nursing Research, Appraisal, Synthesis and Generation of Evidence, Chapter 4, Examining Ethics in Nursing Research.
- Grøntved, A., Pedersen, G. S., & Froberg, K. (2007).Physical Activity among Preschool Children. University of Southern Denmark, 1-7.
- Gubbels, J. S., Kremers, S. P., Van Kann, D. H., Stafleu, A., Candel, M. J., Dagnelie, P. C., ... & De Vries, N. K. (2011). Interaction between physical environment, social environment, and child characteristics in determining physical activity at child care. Health Psychology, 30(1), 84.
- Gustafson, S. L., & Rhodes, R. E. (2006). Parental correlates of physical activity in children and early adolescents. Sports Medicine, 36(1), 79-97.
- Guyatt, G., Oxman, A. D., Akl, E. A., Kunz, R., Vist, G., Brozek, J., ... & Rind, D. (2011). GRADE guidelines: 1. Introduction—GRADE evidence profiles and summary of findings tables. Journal of Clinical Epidemiology, 64(4), 383-394.
- Hamari, J., Koivisto, J., & Sarsa, H. (2014, January). Does gamification work? -a literature review of empirical studies on gamification. In System Sciences (HICSS), 2014 47th Hawaii International Conference on (pp. 3025-3034). IEEE.
- Hammersley, M. L., Jones, R. A., & Okely, A. D. (2017). Time2bHealthy–An online childhood obesity prevention program for preschool-aged children: A randomised controlled trial proto-col. Contemporary Clinical Trials, 61, 73-80.
- Hannon, J. C., & Brown, B. B. (2008). Increasing preschoolers' physical activity intensities: an activityfriendly preschool playground intervention. Preventive Medicine, 46(6), 532-536.
- Higgins, J. P., Altman, D. G., Gøtzsche, P. C., Jüni, P., Moher, D., Oxman, A. D., ... & Sterne, J. A. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ, 343, d5928.
- Higgins J.P.T. & Green S. (eds) (2011) Cochrane Handbook for Systematic Reviews of Interventions Version 5\_1\_0. The Cochrane Collaboration.
- Hills, A. P., King, N. A., & Armstrong, T. P. (2007). The contribution of physical activity and sedentary behaviours to the growth and development of children and adolescents. Sports Medicine, 37(6), 533-545.
- Hinkley, T., Crawford, D., Salmon, J., Okely, A. D., & Hesketh, K. (2008). Preschool children and physical activity: a review of correlates. American Journal of Preventive Medicine, 34(5), 435-441.
- Hinkley, T., Salmon, J., Okely, A. D., Hesketh, K., & Crawford, D. (2012). Correlates of preschool children's physical activity. American Journal of Preventive Medicine, 43(2), 159-167.

- Hnatiuk, J., Ridgers, N. D., Salmon, J., Campbell, K., McCallum, Z., & Hesketh, K. (2012). Physical activity levels and patterns of 19-month-old children. Medicine and Science in Sports and Exercise, 44(9), 1715-1720.
- Hnatiuk, J. A., Salmon, J., Hinkley, T., Okely, A. D., & Trost, S. (2014). A review of preschool children's physical activity and sedentary time using objective measures. American Journal of Preventive Medicine, 47(4), 487-497.
- Hodges, E. A., Smith, C., Tidwell, S., & Berry, D. (2013). Promoting physical activity in preschoolers to prevent obesity: a review of the literature. Journal of Pediatric Nursing: Nursing Care of Children and Families, 28(1), 3-19.
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Lamb, S. E. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ, 348, g1687.
- Hsieh, H. F., & Shannon, S. E. (2005). Three approaches to qualitative content analy-sis. Qualitative Health Research, 15(9), 1277-1288.
- Iivonen, K. S., Sääkslahti, A. K., Mehtälä, A., Villberg, J. J., Tammelin, T. H., Kulmala, J. S., & Poskiparta, M. (2013). Relationship between fundamental motor skills and physical activity in 4-year-old preschool children. Perceptual and motor skills, 117(2), 627-646.
- Internet World Stats. (2017). Retrieved from http://www.internetworldstats.com/stats.htm (3/2018).
- Jacobs, Jr., H. J. Montoye, and J. F. Sallis. (1993). Compendium of physical activities: classification of energy costs of human physical activities. Medicine & Science in Sports & Exercise. 25:71–80.
- Janssen, I., & LeBlanc, A. G. (2010). Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. International Journal of Behavioral Nutrition and Physical Activity, 7(1), 40.
- Janz KF, Letuchy EM, Eichenberger Gilmore JM, Burns TL, Torner JC, Willing MC, Levy SM. (2010). Medicine & Science in Sports & Exercise, 42(6):1072– 1078.
- Jiménez-Pavón, D., Kelly, J., & Reilly, J. J. (2010). Associations between objectively measured habitual physical activity and adiposity in children and adolescents: Systematic review. Pediatric Obesity, 5(1), 3–18.
- Jones, R., Wells, M., Okely, A., Lockyer, L., & Walton, K. (2011). Is an online healthy lifestyles program acceptable for parents of preschool children?. Nutrition & Dietetics, 68(2), 149-154.
- Kabali, H. K., Irigoyen, M. M., Nunez-Davis, R., Bu-dacki, J. G., Mohanty, S. H., Leister, K. P., & Bonner, R. L. (2015). Exposure and use of mobile media devices by young children. Pediatrics, 136(6), 1044-1050.

- Kambas, A., Michalopoulou, M., Fatouros, I. G., Christoforidis, C., Manthou, E., Giannakidou, D., ... & Zimmer, R. (2012). The relationship between motor proficiency and pedometer-determined physical activity in young children. Pediatric Exercise Science, 24(1), 34-44.
- Kelle, U. (2006). Combining qualitative and quantitative methods in research practice: purposes and advantages. Qualitative Research in Psychology, 3(4), 293-311.
- Kirk, S. M., Vizcarra, C. R., Looney, E. C., & Kirk, E. P. (2014). Using physical activity to teach academic content: a study of the effects on literacy in head start preschoolers. Early Childhood Education Journal, 42(3), 181-189.
- Kipping, R., Jago, R., Metcalfe, C., White, J., Papadaki, A., Campbell, R., ... & Nicholson, A. (2016). NAP SACC UK: protocol for a feasibility cluster randomised NAP SACC UK: protocol for a feasibility cluster randomised controlled trial in nurseries and at home to increase physical activity and healthy eating in children aged 2–4 years. BMJ Open, 6(4).
- Knowlden, A., & Sharma, M. (2012). A feasibility and efficacy randomized controlled trial of an online preventative program for childhood obesity: Protocol for the EMPOWER intervention. JMIR Research Protocols, 1(1).
- Knowlden, A. P., & Sharma, M. (2014). Process evaluation of the enabling mothers to prevent pediatric obesity through web-based learning and reciprocal determinism (EMPOWER) randomized control trial. Health Promotion Practice, 15(5), 685-694.
- Knowlden, A. P., Sharma, M., Cottrell, R. R., Wilson, B. R., & Johnson, M. L. (2015). Impact evaluation of enabling mothers to prevent pediatric obesity through web-based education and reciprocal determinism (EMPOWER) randomized control trial. Health Education & Behavior, 42(2), 171-184.
- Knowlden, A., & Sharma, M. (2016). One-year efficacy testing of enabling mothers to prevent pediatric obesity through web-based education and reciprocal determinism (EMPOWER) randomized control trial. Health Education & Behavior, 43(1), 94-106.
- Knowlden, A. P., & Conrad, E. (2017). Two-Year Outcomes of the Enabling Mothers to Prevent Pediatric Obesity Through Web-Based Education and Reciprocal Determinism (EMPOWER) Randomized Control Trial. Health Education & Behaviour, 1090198117732604.
- Kohl 3rd, H. W., Craig, C. L., Lambert, E. V., Inoue, S., Alkandari, J. R., Leetongin, G., ... & Lancet Physical Activity Series Working Group. (2012). The pandemic of physical inactivity: global action for public health. The Lancet, 380(9838), 294–305.
- Lagström, H., Pösö, T., Rutanen, N., & Vehkalahti, K. (2010). Lasten ja nuorten tutkimuksen etiik-ka. Helsinki: Yliopistopaino.
- Laukkanen, A., Pesola, A., Havu, M., Sääkslahti, A., & Finni, T. (2014). Relationship between habitual physical activity and gross motor skills is multifaceted in 5-to 8-year-old children. Scandinavian Journal of Medicine & Science in Sports, 24(2).

References

Leino, T., Koskenniemi, E., Saranpää, P.-R., Strömberg, N., Kilpi, T. (2007). Vaccination coverage still very high. Finnish Medical Journal, 62(8), 739–743.

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- Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gøtzsche, P. C., Ioannidis, J. P., ... & Moher, D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Medicine, 6(7), e1000100.
- Ling, J., Robbins, L. B., Wen, F., & Zhang, N. (2017). Lifestyle interventions in preschool children: A meta-analysis of effectiveness. American Journal of Preventive Medicine, 53(1), 102-112.
- Loprinzi, P. D., & Trost, S. G. (2010). Parental influences on physical activity behaviour in preschool children. Preventive Medicine, 50(3), 129-133.
- Lubans, D. R., Foster, C., & Biddle, S. J. (2008). A review of mediators of behaviour in interventions to promote physical activity among children and adolescents. Preventive Medicine, 47(5), 463-470.
- Lubans, D. R., Morgan, P. J., Cliff, D. P., Barnett, L. M., & Okely, A. D. (2010). Fundamental movement skills in children and adolescents. Sports Medicine, 40(12), 1019-1035.
- Lupton, D. (2014a). Health promotion in the digital era: a critical commentary. Health Promotion International, 30(1), 174-183.
- Lupton, D. (2014b). Critical perspectives on digital health technologies. Sociology Compass, 8(12), 1344-1359.
- Lwin, M. O., & Malik, S. (2014). Can exergames impart health messages? Game play, framing, and drivers of physical activity among children. Journal of Health Communication, 19(2), 136-151.
- Mann, C. J. (2003). Observational research methods. Research design II: cohort, cross sectional, and case-control studies. Emergency Medicine Journal, 20(1), 54-60.
- McIntyre, A. (2008). Participatory action research. Thousand Oaks, California: Sage Publications, Inc.
- Mellecker, R. (2016). Games for health for children— Current status and needed research. Games for Health Journal, 5(1), 1-12.
- Mendiola, M. F., Kalnicki, M., & Lindenauer, S. (2015). Valuable features in mobile health apps for patients and consumers: content analysis of apps and user ratings. JMIR mHealth and uHealth, 3(2).
- Metcalf, B., Henley, W., & Wilkin, T. (2012). Effectiveness of intervention on physical activity of children: systematic review and meta-analysis of controlled trials with objectively measured outcomes (EarlyBird 54). BMJ, 345, e5888.

- Ministry of Social Affairs and Health. (2005). Varhaiskasvatuksen liikunnan suositukset. "Physical activity recommendations in early childhood" Retrieved from https://www.google.fi/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwjTstTw3KDaAhVqP5oKHdYJDJEQFgh-BMAI&url=http%3A%2F%2Fwww.ukkinstitutit.f%2Ffilebank%2F1721-Varhaiskasvatuksen\_liikunnan\_suositukset\_2005.pdf&usg=AOvVaw0TJaqzOREwUf-3Wr6\_6gxt (2/2018)
- Ministry of Social Affairs and Health. (2016). Iloa, leikkiä ja yhdessä tekemistä: varhaisvuosien fyysisen aktiivisuuden suositukset. "Physical activity recommendations in early childhood" Retrieved from http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/75405/OKM21.pdf (2/2018).
- Montgomery-Andersen, R., & Borup, I. (2012). Family support and the child as health promoting agent in the Arctic-" the Inuit way". Rural and Remote Health, 12(2), 1977.
- Montigny, F., & Lacharité, C. (2005). Perceived parental efficacy: Concept analysis. Journal of Advanced Nursing, 49(4), 387-396.
- Must, A., & Tybor, D. J. (2005). Physical activity and sedentary behaviour: a review of longitudinal studies of weight and adiposity in youth. International Journal of Obesity, 29(S2), S84.
- Mäki, P., Wikström, K., Hakulinen, T., & Laatikainen, T. (2017). Terveystarkastukset lastenneuvolassa ja kouluterveydenhuollossa: Menetelmäkäsikirja.
- NASPE -National Association for Sport and Physical Education. (2009). Active Start: A Statement of Physical Activity Guidelines for Children From Birth to Age 5. 2nd ed. AAHPERD Publications, Oxon Hill, Md., USA.
- NETSCC -National Institute for Health Research Trials and Studies. (2018). Coordinating Centre. Definition of feasibility studies. Retrieved from http://www.netscc.ac.uk/glossary/. (4/2018)
- Nicaise, V., Kahan, D., & Sallis, J. F. (2011). Correlates of moderate-to-vigorous physical activity among preschoolers during unstructured outdoor play periods. Preventive Medicine, 53(4-5), 309-315.
- Nicklas, T. A., Baranowski, T., Baranowski, J. C., Cullen, K., Rittenberry, L., & Olvera, N. (2001). Family and child-care provider influences on preschool children's fruit, juice, and vegetable consumption. Nutrition Reviews, 59(7), 224-235.
- Niederer, I., Bürgi, F., Ebenegger, V., Marques-Vidal, P., Schindler, C., Nydegger, A., ... & Puder, J. J. (2013). Effects of a lifestyle intervention on adiposity and fitness in overweight or low fit preschoolers (Ballabeina). Obesity, 21(3).

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- Nixon, C. A., Moore, H. J., Douthwaite, W., Gibson, E. L., Vogele, C., Kreichauf, S., ... Summerbell, C. D. (2012). Identifying effective behavioural models and behaviour change strategies underpinning preschooland school-based obesity prevention interventions aimed at 4-6-year-olds: a systematic review. Obesity Reviews: An Official Journal of the International Association for the Study of Obesity, 13
  Suppl 1, 106–117. http://doi.org/10.1111/j.1467-789X.2011.00962.x
- Novak, J. (2012). Game development essentials: an introduction. (3rd ed.) Cengage Learning.
- O'Dwyer, M. V., Fairclough, S. J., Knowles, Z., & Stratton, G. (2012). Effect of a family focused active play intervention on sedentary time and physical activity in preschool children. International Journal of Behavioural Nutrition and Physical Activity, 9(1), 117.
- Obeid, J., Nguyen, T., Gabel, L., & Timmons, B. W. (2011). Physical activity in Ontario preschoolers: prevalence and measurement issues. Applied Physiology, Nutrition, and Metabolism, 36(2), 291-297.
- Østbye, T., Malhotra, R., Stroo, M., Lovelady, C., Brouwer, R., Zucker, N., & Fuemmeler, B. (2013). The effect of the home environment on physical activity and dietary intake in preschool children. International Journal of Obesity, 37(10), 1314.
- Pakarinen, A., Parisod, H., Linden, I., Aromaa, M., Smed, J., Leppänen, V., & Salanterä, S. (2017). Usability of a Gamified Application to Promote Family Wellbeing in Child Health Clinics. In P. Tuomi & A. Perttula (Eds.), CEUR Workshop Proceedings 1857 (pp. 141–149). Tampere University of Technology.
- Palmer KK, Miller MW, Robinson, LE. (2013). Acute Exercise Enhances Preschoolers' Ability to Sustain Attention. Journal of Sports & Exercise Psychology, 35, 433–437.
- Parekh, N., Henriksson, P., Delisle Nyström, C., Silfvernagel, K., Ruiz, J. R., Ortega, F. B., ... & Löf, M. (2017). Associations of Parental Self-Efficacy With Diet, Physical Activity, Body Composition, and Cardiorespiratory Fitness in Swedish Preschoolers: Results From the MINISTOP Trial. Health Education & Behaviour, 1090198117714019.
- Parekh, N., Henriksson, P., Delisle Nyström, C., Silfvernagel, K., Ruiz, J. R., Ortega, F. B., ... & Löf, M. (2017). Associations of Parental Self-Efficacy With Diet, Physical Activity, Body Com-position, and Cardiorespiratory Fitness in Swedish Preschoolers: Results From the MINISTOP Trial. Health Education & Behaviour, 1090198117714019.
- Parisod, H., Pakarinen, A., Kauhanen, L., Aromaa, M., Leppänen, V., Liukkonen, T. N., ... & Salanterä, S. (2014). Promoting children's health with digital games: A review of re-views. GAMES FOR HEALTH: Research, Development, and Clinical Applications, 3(3), 145-156.
- Pate, R. R., McIver, K., Dowda, M., Brown, W. H., & Addy, C. (2008). Directly observed physical activity levels in preschool children. Journal of School Health, 78(8), 438-444.

Pate, R. R., O'neill, J. R., & Lobelo, F. (2008). The evolving definition of sedentary". Exercise and Sport Sciences Reviews, 36(4), 173-178.

- Patton M. (2015). Qualitative research & evaluation methods: Integrating theory and practice (4th ed). CA: Thousand Oaks, Sage.
- Payne, V. G., & Isaacs, L. D. (2017). Human motor development: A lifespan approach. Routledge.
- Pereira, P., Duarte, E., Rebelo, F., & Noriega, P. (2014, June). A review of gamification for health-related contexts. In International conference of design, user experience, and usability (pp. 742-753). Springer, Cham.
- Personal Data Act (523/1999). Ministry of Justice, Finland. Retrieved from http://www.finlex.fi/fi/laki/alkup/1999/19990523?se arch%5Btype%5D=pika&search%5Bpika%5D=tietosuoja%20523%2F1999 (1/2018)
- Peters, D. H., Adam, T., Alonge, O., Agyepong, I. A., & Tran, N. (2013). Implementation re-search: what it is and how to do it. BMJ, 347, f6753.
- Pillas, D., Marmot, M., Naicker, K., Goldblatt, P., Morrison, J., & Pikhart, H. (2014). Social inequalities in early childhood health and development: a European-wide systematic review. Pediatric Research, 76(5), 418.
- Plotnikoff, R. C., Costigan, S. A., Karunamuni, N., & Lubans, D. R. (2013). Social cognitive theories used to explain physical activity behavior in adolescents: a systematic review and meta-analysis. Preventive Medicine, 56(5), 245-253.
- Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., ... & Duffy, S. (2006). Guidance on the conduct of narrative synthesis in systematic reviews. A product from the ESRC methods programme Version, 1, b92.
- Pellegrini, A. D., Dupuis, D., & Smith, P. K. (2007). Play in evolution and development. Developmental Review, 27(2), 261-276.
- Pellegrini, A. D., & Smith, P. K. (1998). The development of play during childhood: forms and possible functions. Child Psychology and Psychiatry Review, 3(2), 51-57.
- Quelly, S. B., Norris, A. E., & DiPietro, J. L. (2016). Impact of mobile apps to combat obesity in children and adolescents: A systematic literature review. Journal for Specialists in Pediatric Nursing, 21(1), 5-17.
- Raat, H., Struijk, M. K., Remmers, T., Vlasblom, E., van Grieken, A., Broeren, S. M., ... & L'Hoir, M. P. (2013). Primary prevention of overweight in preschool children, the BeeBOFT study (breastfeeding, breakfast daily, outside playing, few sweet drinks, less TV viewing): de-sign of a cluster randomized controlled trial. BMC public health, 13(1), 974.
- Radesky, J. S., Schumacher, J., & Zuckerman, B. (2015). Mobile and interactive media use by young children: the good, the bad, and the unknown. Pediatrics, 135(1), 1-3.

- Raitakari, O. T., Taimela, S., Porkka, K. V. K., Leino, M., Telama, R., Dahl, M., & Viikari, J. S. A. (1996). Patterns of intense physical activity among 15-to 30year-old Finns. Scandinavian Journal of Medicine & Science in Sports, 6(1), 36-39.
- Reilly, J. J., Kelly, L., Montgomery, C., Williamson, A., Fisher, A., McColl, J. H., ... & Grant, S. (2006). Physical activity to prevent obesity in young children: cluster randomised controlled trial. BMJ, 333(7577), 1041.
- Reilly, J. J. (2010). Low levels of objectively measured physical activity in preschoolers in child care. Medicine and Science in Sports and Exercise, 42(3), 502-507.
- Rideout, V. (2017). The Common Sense Census: Media Use by Kids Age Zero to Eight. Robb, M., Ed.
- Sallis, J. F., Prochaska, J. J., & Taylor, W. C. (2000). A review of correlates of physical activity of children and adolescents. Medicine & Science in Sports & Exercise, 32(5), 963-975.
- Salmon, J., Booth, M. L., Phongsavan, P., Murphy, N., & Timperio, A. (2007). Promoting phys-ical activity participation among children and adolescents. Epidemiologic Reviews, 29(1), 144-159.
- Santos, C. M. D. C., Pimenta, C. A. D. M., & Nobre, M. R. C. (2007). The PICO strategy for the research question construction and evidence search. Revista Latino-Americana de Enfermagem, 15(3), 508-511.
- Sheridan, M., Howard, J., & Alderson, D. (2010). Play in Early Childhood: From Birth to Six Years. Routledge.
- Shikako-Thomas, K., Majnemer, A., Law, M., & Lach, L. (2008). Determinants of participation in leisure activities in children and youth with cerebral palsy: systematic review. Physical & Occupational Therapy in Pediatrics, 28(2), 155-169.
- Skouteris, H., Dell'Aquila, D., Baur, L. A., Dwyer, G. M., McCabe, M. P., Ricciardelli, L. A., & Fuller-Tyszkiewicz, M. (2012). Physical activity guidelines for preschoolers: a call for research to inform public health policy. Medical Journal of Australia, 196(3), 174-6.
- Smith, B. J., Grunseit, A., Hardy, L. L., King, L., Wolfenden, L., & Milat, A. (2010). Parental influences on child physical activity and screen viewing time: a population based study. BMC public health, 10(1), 593
- Soini A. (2015). Always on the move? Measured physical activity of 3-year-old preschool children. Jyväskylä: University of Jyväskylä.
- Soini, A., Tammelin, T., Sääkslahti, A., Watt, A., Villberg, J., Kettunen, T., ... & Poskiparta, M. (2014). Seasonal and daily variation in physical activity among three-year-old Finnish preschool children. Early Child Development and Care, 184(4), 589-601.

- Spurrier, N. J., Magarey, A. A., Golley, R., Curnow, F., & Sawyer, M. G. (2008). Relationships between the home environment and physical activity and dietary patterns of preschool children: a cross-sectional study. International Journal of Behavioural Nutrition and Physical Activity, 5(1), 31.
- Staiano, A. E., Abraham, A. A., & Calvert, S. L. (2013). Adolescent exergame play for weight loss and psychosocial improvement: a controlled physical activity intervention. Obesity, 21(3), 598-601.
- Sterdt, E., Liersch, S., & Walter, U. (2014). Correlates of physical activity of children and adolescents: A systematic review of reviews. Health Education Journal, 73(1), 72–89.
- STM. (2009). Neuvolatoiminta, koulu- ja opiskeluterveydenhuolto sekä ehkäisevä suun terveydenhuolto. Asetuksen (380/2009) perustelut ja soveltamisohjeet. Sosiaali- ja terveysministeriön julkaisuja 2009:20.
- Sugiyama, T., Okely, A. D., Masters, J. M., & Moore, G. T. (2012). Attributes of child care centers and outdoor play areas associated with preschoolers' physical activity and sedentary behavior. Environment and Behavior, 44(3), 334-349.
- Sääkslahti, A., Numminen, P., Salo, P., Tuominen, J., Helenius, H., & Välimäki, I. (2004). Ef-fects of a three-year intervention on children's physical activity from age 4 to 7. Pediatric Exercise Science, 16(2), 167-180.
- Sørensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., & Brand, H. (2012). Health literacy and public health: a systematic review and integration of definitions and models. BMC public health, 12(1), 80.
- Tate, E. B., Spruijt-Metz, D., O'Reilly, G., Jordan-Marsh, M., Gotsis, M., Pentz, M. A., & Dunton, G. F. (2013). mHealth approaches to child obesity prevention: successes, unique challenges, and next directions. Translational Behavioural Medicine, 3(4), 406-415.
- Telama R, Yang X, Leskinen E, Kankaanpää A, Hirvensalo M, Tammelin T. (2014). Tracking of physical activity from early childhood through youth into adulthood. Medicine & Science in Sports & Exercise, 46, 955–962.
- TENK (2012). Finnish Advisory Board on Research Integrity. Responsible conduct of research and procedures for handling allegiations of misconduct in Finland. Retrieved from ttp://www.tenk.fi/sites/tenk.fi/files/HTK\_ohje\_2012.pdf. (3/2018).
- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., ... & Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology, 10(1), 1.
- Timmons, B. W., LeBlanc, A. G., Carson, V., Connor Gorber, S., Dillman, C., Janssen, I., ... & Tremblay, M. S. (2012). Systematic review of physical activity and health in the early years (aged 0–4 years). Applied Physiology, Nutrition, and Metabolism, 37(4), 773-792.

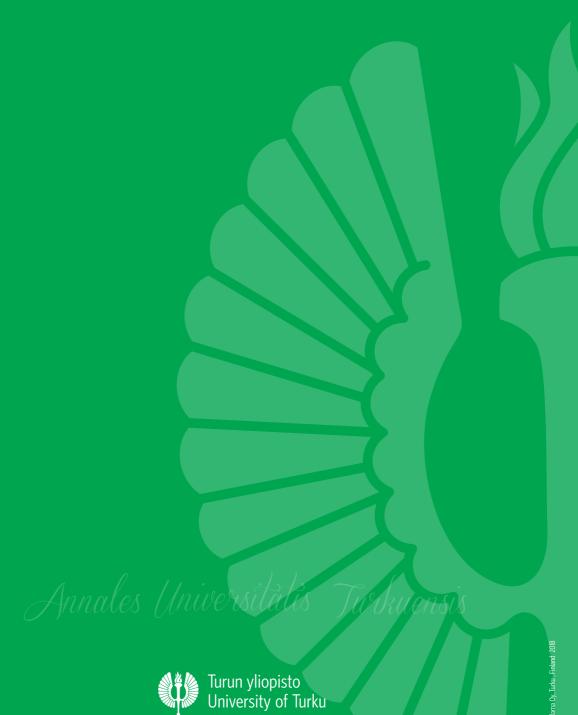
- Timperio, A., Salmon, J., & Ball, K. (2004). Evidencebased strategies to promote physical activity among children, adolescents and young adults: review and update. Journal of Science and Medicine in Sport, 7(1), 20-29.
- Trost, S. G., Fees, B., & Dzewaltowski, D. (2008). Feasibility and efficacy of a "move and learn" physical activity curriculum in preschool children. Journal of Physical Activity and Health, 5(1), 88-103.
- Trost, S. G., & Loprinzi, P. D. (2011). Parental influences on physical activity behaviour in children and adolescents: a brief review. American Journal of Lifestyle Medicine, 5(2), 171-181.
- Tucker, P. (2008). The physical activity levels of preschool-aged children: A systematic review. Early Childhood Research Quarterly, 23(4), 547-558.
- Turner, T., Spruijt-Metz, D., Wen, C. F., & Hingle, M. D. (2015). Prevention and treatment of pediatric obesity using mobile and wireless technologies: a systematic review. Pediatric Obesity, 10(6), 403-409.
- UKK Institute. (2009). Physical activity recommendations for adults (18–64years). Retrieved from http://www.ukkinstitutti.fi/liikuntapiirakka/liikuntapiirakka-aikuisille (3/2018).
- Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nursing & Health Sciences, 15(3), 398-405.
- Vale, S., Santos, R., Soares-Miranda, L., Moreira, C., Ruiz, J. R., & Mota, J. (2010). Objectively measured physical activity and body mass index in preschool children. International Journal of Pediatrics, 2010, 1-6
- Valtonen, R., Ahonen, T., Lyytinen, P., & Lyytinen, H. (2004). Co-occurrence of developmental delays in a screening study of 4-year-old Finnish children. Developmental Medicine and Child Neurology, 46(7), 436-443.
- Valtonen, R., Ahonen, T., Lyytinen, P., & Tolvanen, A. (2007). Screening for developmental risks at 4 years of age: Predicting development two years later. Nordic Psychology, 59(2), 95.
- Valtonen, R., Ahonen, T., Tolvanen, A., & Lyytinen, P. (2009). How does early developmental assessment predict academic and attentional–behavioural skills at group and individual levels?. Developmental Medicine & Child Neurology, 51(10), 792-799.
- Vanclay, F., Baines, J. T., & Taylor, C. N. (2013). Principles for ethical research involv-ing humans: ethical professional practice in impact assessment Part I. Impact Assessment and Project Appraisal, 31(4), 243-253.

- Van Grieken, A., Vlasblom, E., Wang, L., Beltman, M., Boere-Boonekamp, M. M., L'Hoir, M. P., & Raat, H. (2017). Personalized web-based advice in combination with well-child visits to prevent overweight in young children: Cluster randomized controlled trial. Journal of medical Internet research. 19(7).
- Van Sluijs, E. M., McMinn, A. M., & Griffin, S. J. (2007). Effectiveness of interventions to pro-mote physical activity in children and adolescents: systematic review of controlled trials. BMJ, 335(7622), 703.
- Veitch, J., Salmon, J., & Ball, K. (2010). Individual, social and physical environmental correlates of children's active free-play: a cross-sectional study. International Journal of Behavioral Nutrition and Physical Activity, 7(1), 11.
- Venetsanou, F., & Kambas, A. (2010). Environmental factors affecting preschoolers' motor development. Early childhood education journal, 37(4), 319-327.
- Ward, S., Bélanger, M., Donovan, D., Boudreau, J., Vatanparast, H., Muhajarine, N., ... & Carrier, N. (2017). "Monkey see, monkey do": Peers' behaviours predict preschoolers' physical activity and dietary intake in childcare centers. Preventive medicine, 97, 33-39.
- Webb T, Joseph J, Yardley L, Michie S. Using the Internet to Promote Health Behaviour Change: A Systematic Review and Meta-analysis of the Impact of Theoretical Basis, Use of Behaviour Change Techniques, and Mode of Delivery on Efficacy. J Med Internet Res 2010, 12(1):e4
- Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., & Erikson, P. (2005). Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in health, 8(2), 94-104.
- Williams, H. G., Pfeiffer, K. A., O'neill, J. R., Dowda, M., McIver, K. L., Brown, W. H., & Pate, R. R. (2008). Motor skill performance and physical activity in preschool children. Obesity, 16(6), 1421-1426.
- World Health Organization. (2010). Global recommendations on physical activity for health. Geneva: WHO; 2010. ISBN, 1011132395, 60.
- World Medical Association. (2013). Declaration of Helsinki. Retrieved from https://www.wma.net/policiespost/wma-declaration-of-helsinki-ethical-principlesfor-medical-research-involving-human-subjects/ (3/2018).
- Xu, H., Wen, L. M., & Rissel, C. (2015). Associations of parental influences with physical activity and screen time among young children: a systematic review. Journal of Obesity, 2015.
- Zecevic, C. A., Tremblay, L., Lovsin, T., & Michel, L. (2010). Parental influence on young children's physical activity. International Journal of Pediatrics, 2010.

# **APPENDICES**

# Appendix 1 Literature search from databases.

Database	Date	Search terms	Limitations	Articles	Articles	Articles	Duplicates	Articles	Articles
				identified	excluded	included	removed	excluded	included
				through	based on	based on		based on full-	based on full-
				database	title and	title and		text	text
				search	abstarct	abstract			
Pubmed 13th Mars 2018	13th March	Search ((child OR children OR toddler* OR pre-school age* OR preschooler*	2008-2018	115	93	22		8	11
	2018	OR preschool age* OR "Child, Preschool" [Mesh] OR "Child" [Mesh]) AND							
		(family OR families OR parent OR parents OR "Family" [Mesh] OR							
		"Parents" [Mesh]) AND ("mobile app" OR "mobile application" OR "health							
		application" OR "health app" OR mHealth* OR mobile health* OR health							
		game* OR health-game* OR "gamified app" OR "gamified application" OR							
		gamified* OR digital game* OR web-based game* OR web-based game* OR web-							
		based* OR internet-based* OR digital*) AND ("physical							
		activity")) Filters: published in the last 10 years							
2018	13th March	( child OR children OR toddler* OR preschool* OR pre-school* OR pre-school	2008-2018, english	66	57	6	3	2	1
	2018	age* OR preschooler* OR preschool age* ) AND ( family OR families OR							
		parent OR parents ) AND ( "mobile app" OR "mobile application" OR "health							
		application" OR "health app" OR mHealth* OR "mobile health" OR "health							
		game*" OR "health-game*" OR "gamified app" OR "gamified application" OR							
		gamified OR "digital game*" OR "Web-based game*" OR "web-based" OR							
		"internet-based" OR "digital" ) AND ( "physical activity" OR exercise* OR							
		activit*)							
Embase	13th March		2008-2018,	272	248	24	14	9	1
	2018	('child':ti,ab,kw OR 'children':ti,ab,kw OR 'toddler*':ti,ab,kw	title/abstract/keywords						
		OR 'preschool*':ti,ab,kw OR 'pre-school*':ti,ab,kw OR 'pre-school							
		age*':ti,ab,kw OR 'preschooler*':ti,ab,kw OR 'preschool age*':ti,ab,kw) AND							
		('family':ti,ab,kw OR 'families':ti,ab,kw OR 'parent':ti,ab,kw							
		OR 'parents':ti,ab,kw) AND ('mobile app':ti,ab,kw OR 'mobile							
		application':ti,ab,kw OR 'health application':ti,ab,kw OR 'health app':ti,ab,kw							
		OR 'mhealth*':ti,ab,kw OR 'mobile health':ti,ab,kw OR 'health game*':ti,ab,kw							
		OR 'health-game*':ti,ab,kw OR 'gamified app':ti,ab,kw OR 'gamified							
		application':ti,ab,kw OR 'gamified':ti,ab,kw OR 'digital game*':ti,ab,kw OR 'web-							
		based game*':ti,ab,kw OR 'web-based':ti,ab,kw OR 'internet-based':ti,ab,kw							
		OR 'digital':ti,ab,kw) AND ('physical activity':ti,ab,kw OR 'exercise*':ti,ab,kw							
		OR 'activit*':ti,ab,kw) AND [2008-2018]/py							
Manual search from	March 2018								4
reference lists of									
screened articles									



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