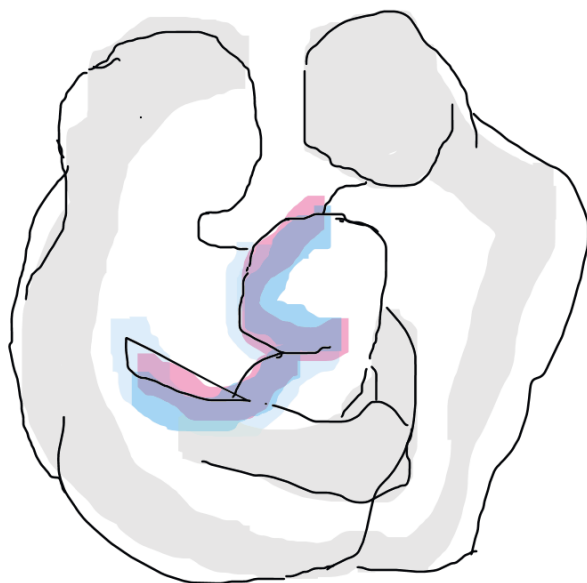


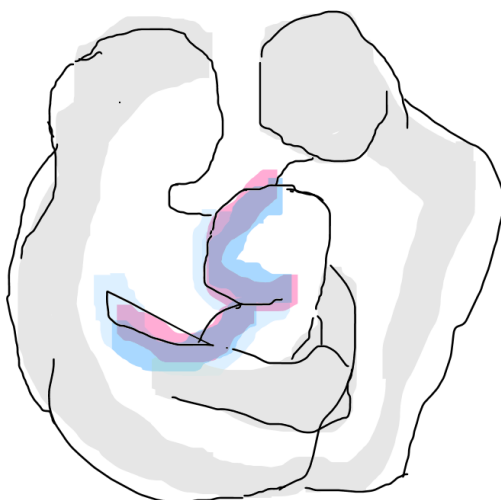
MINISTOP 2.0: a smartphone app
integrated in primary child health care to
promote healthy diet and physical activity
behaviors and prevent obesity in
preschool-aged children

Christina Alexandrou



MINISTOP 2.0: a smartphone app integrated in primary child health care to promote healthy diet and physical activity behaviors and prevent obesity in preschool-aged children

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Linköping 2023



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To my beloved daughter Alice and husband Stefan – I love you both so
much!

“There’s some good in this world, Mr. Frodo, and it’s worth fighting for!”

Samwise Gamgi

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ABSTRACT

Background

Childhood overweight and obesity is currently estimated to affect 39 million children under the age of five worldwide. After the COVID-19 pandemic, further increases have been observed in several countries including Sweden, where an increased incidence was observed in 3- and 4-year-old children, especially in disadvantaged areas. This development emphasizes the urgent need for population-based childhood obesity prevention interventions, and Swedish primary child health care provides an ideal setting for primary preventive efforts during the preschool years. However, thus far, previous child health care-based obesity prevention interventions have demonstrated limited effectiveness. As previous interventions also have been face-to-face delivered and thus resource-demanding; new, and scalable ways of delivering interventions also need to be evaluated. Mobile health or mHealth refers to the use of mobile devices for medical and public health practice and provides opportunity for development and dissemination of digital interventions for various purposes and populations at scale. This thesis reports the results of the MINISTOP 2.0 project, which covers the development and evaluation of the MINISTOP 2.0 digital intervention, from adaptation and translation of the intervention to Somali, Arabic and English (Paper I), to evaluation of real-world effectiveness within the Swedish primary child health care setting (Paper II) followed by exploration of user experiences and implementation aspects (Paper III) and a cost-consequence analysis of the intervention costs (Paper IV).

Aim

The overall aim of this thesis was to evaluate whether a 6-month parent-oriented mHealth intervention (MINISTOP 2.0 app), embedded in the routine services of Swedish primary child health care, can be used to improve diet and physical activity behaviors, and decrease the prevalence of overweight and obesity in 2.5-to-3-year-old children.

Methods

The MINISTOP 2.0 project utilized a hybrid type 1 effectiveness-implementation study design to enable simultaneous evaluation and exploration of intervention effectiveness, user experiences and implementation aspects.

Paper I: A qualitative exploration of user requirements in an app-based parental support intervention was conducted through three focus group interviews with Somali- (n = 5), Arabic- (n = 4), and Swedish-speaking

parents (n = 6), and individual interviews with child health care nurses (n = 15). Data was analyzed using thematic analysis.

Paper II: A two-arm parallel randomized controlled trial was conducted at 19 child health care centers located in six Swedish regions. Participating parents (n = 552) were invited during their routine visit at 2.5/3-years at their primary child health care center. All baseline and follow-up procedures were conducted by the nurses. Parents that were randomized to the control group received standard care, while the intervention group received access to the MINISTOP 2.0 app for six months, alongside standard care. Prior to randomization, nurses measured the child's height and weight for assessment of BMI, and parents answered a questionnaire about their child's intake of fruit and vegetables, sweet and savory treats, and sweet drinks; time spent in moderate-to-vigorous physical activity (MVPA) and screen time; and parental self-efficacy (PSE) for promoting healthy diet, physical activity, and screen time behaviors. These baseline procedures were then repeated at a 6-month follow-up visit to the child health care center.

Paper III: A qualitative exploration of user experiences, acceptability, and feasibility of the MINISTOP 2.0 intervention was conducted through individual interviews with parents (n = 24) with diverse backgrounds, and with child health care nurses (n = 15). Data was analyzed using content analysis.

Paper IV: Data on all costs related to the MINISTOP 2.0 intervention, including costs for app and interface upkeep as well as salary costs for introduction and dissemination of the app by nurses, was collected retrospectively. A cost-consequence analysis was then performed to estimate the costs of the intervention.

Results

Paper I: Parents expressed several challenges related to promoting healthy eating behaviors, such as worrying about their child not eating enough, and difficulties balancing different food cultures. There were also requests for the app content to be accessible through alternative modes of delivery (e.g., audio/video) for parents with low literacy. Nurses underlined the importance of supporting parents early with health behavior interventions, and the value of a shared digital platform, available in several languages, to facilitate communication with parents.

Paper II: Seventy-nine percent of the participating parents (n = 552) were mothers and 62% had a university degree. Among the children, 24% had two foreign-born parents. Children in the intervention group had lower intakes of sweet and savory treats (-6.97 g/day; p = 0.001), sweet drinks (-31.52 g/day; p < 0.001), and screen time (-7.00 min/day; p = 0.012) compared to the control group at follow-up. Parents in the intervention group also reported higher total PSE (0.91; p = 0.006), PSE for promoting healthy diet behaviors (0.34; p = 0.008) and PSE for promoting healthy physical

activity behaviors (0.31; $p = 0.009$) compared to the control group. For children's MVPA or BMI z-score, no statistically significant effect was observed between groups. Finally, parents also reported high satisfaction with the app, and 54% reported using the app once a week or more.

Paper III: Findings indicated that the app was well accepted and appreciated, as it increased knowledge and awareness around current health behaviors. Furthermore, evidence-based information available in one place and from a trusted source, was highly valued, especially when living in a country with a different culture than your own. The app was also acknowledged as a feasible support tool and a suitable complement to the standard care offered during visits. Finally, due to the accessibility in different languages and the possibility of disseminating the app at scale, both nurses and parents described the app as an appropriate tool for reaching larger populations of parents as well as parents in need of additional support.

Paper IV: The total cost for the MINISTOP 2.0 intervention was 437 439 SEK based on the 277 families in the intervention group. The cost for child health care nurses introducing and registering families for the app represented only 9% of the total cost per family, which was considerably lower in comparison to other similar childhood obesity prevention interventions. Also, notably, for upscaling, sharing running costs for the user interface for larger populations of children, would result in much lower total costs per family.

Conclusions

Overall, qualitative findings for adapting the intervention highlighted the need for early access to information, as well as the importance of adapting interventions to also be accessible for parents with migrant background and parents with lower literacy. When disseminated through primary child health care, the MINISTOP 2.0 intervention resulted in statistically significant reduced intakes of sweet and savory treats, sweet drinks, and screen time in children (primary outcomes) as well as increased PSE for promoting healthy diet and activity behaviors (secondary outcome). The app was well accepted and perceived as a feasible support tool for parents. Furthermore, accessibility in different languages was also appreciated. Finally, the relatively low salary costs in comparison to face-to-face interventions suggest that the MINISTOP 2.0 app and caregiver interface may be an affordable preventive effort for early promotion of healthy lifestyle behaviors in children when scaled up on a population level. Altogether, the results from the papers in this thesis support the large-scale implementation of the MINISTOP 2.0 app within the Swedish primary child health care setting for promotion of healthy lifestyle behaviours in 2.5-to-3-year-old children.

SVENSK SAMMANFATTNING

Bakgrund

De senaste decennierna har övervikt och obesitas bland barn ökat och för närvarande beräknas ca 39 miljoner barn under fem års ålder vara drabbade av övervikt eller obesitas globalt. Efter COVID-19 pandemin observerades även en ökad prevalens i flera länder inklusive Sverige, där man såg en ökad förekomst bland barn i förskoleåldern, särskilt i utsatta områden. Eftersom övervikt och obesitas under barndom och ungdom är associerat med ökad risk för obesitas, kardiometabola sjukdomar samt olika former av cancer senare i livet, kommer den ökade prevalensen av övervikt och obesitas innebära en stor framtida folkhälsoutmaning. Barn, unga och vuxna med obesitas utsätts även oftare för mobbning och diskriminering vilket i sin tur kan bidra både till en sämre mental och fysisk hälsa samt en lägre livskvalitet överlag. Att motverka uppkomst av övervikt och obesitas bland barn med hjälp av tidiga primärpreventiva insatser bör därmed prioriteras.

MINISTOP 2.0 projektet

Den här avhandlingen sammanfattar resultat från MINISTOP 2.0 projektet, där det primära syftet var att utvärdera ett digitalt app-baserat stöd-verktyg (MINISTOP 2.0 appen) riktat till föräldrar i syfte att främja hälsosamma levnasvanor bland barn i 2.5-till-3-års åldern. Inom projektet genomfördes totalt fyra delstudier. **Studie I** undersökte användarbehov via fokusgruppintervjuer med föräldrar av olika härkomst (somalisk-, arabisk- och svensktalande) och enskilda intervjuer med barnhälsovårds (BHV) sköterskor i syfte att uppdatera och anpassa MINISTOP appen innan översättning till somaliska, arabiska och engelska. Kort därefter, utvärderades appen via en kontrollerad randomiserad studie inom barnhälsovården (**Studie II**). Studien pågick under ca 2,5 års tid, från november 2019 till april 2022 och totalt deltog 552 föräldrar med sitt barn, från 19 olika barnhälsovårdscentraler i södra Sverige. Hälften av deltagarna lottades slumpmässigt till att använda MINISTOP 2.0 appen under en period på 6 månader i kombination med standardvård, medan den andra hälften lottades till enbart standardvård. Parallellt med denna studie, intervjuades också föräldrar av olika härkomst i syfte att undersöka deras användarupplevelse av appen efter att de använt den i 6 månader (**Studie III**). BHV-sköterskor som hjälpt till att rekrytera familjer i studien intervjuades också kring sina upplevelser av att arbeta med och rekommendera appen som ett föräldrastöd för goda levnadsvanor. Avslutligtvis, efter att alla 552 deltagare i studien följts upp, genomfördes även en retrospektiv ekonomisk utvärdering (**Studie IV**) av kostnaderna associerade med interventionen inom barnhälsovården.

Huvudresultat och slutsats

Utifrån intervjuresultat från **Studie I** anpassades appen så att innehållet också blev tillgängligt i videoformat på olika språk, i syfte att underlätta för föräldrar med begränsad läskunnighet. Vidare, visade resultat från den randomiserade kontrollerade studien (**Studie II**) att barn till föräldrar som hade fått använda appen under sex månader hade ett lägre intag av sötsaker och snacks och sockersötade drycker, samt något mindre skärmtid jämfört mot barn till föräldrar som enbart fått standardvård. Föräldrar som använt appen rapporterade också en stärkt tilltro till sin förmåga att främja hälsosamma levnadssvanor hos sina barn. De här resultaten förstärktes ytterligare av intervjufynd från **Studie III** där både föräldrar och sköterskor uppskattade att appen var tillgänglig på olika språk, samt att den innehöll relevant och tillförlitlig information om levnadssvanor för barn samlat på ett och samma ställe. Både föräldrar och sköterskor ansåg även att appen var ett lämpligt stödverktyg för föräldrar på BVC. I **Studie IV** drogs slutsatsen att appen var en relativt prisvärd förebyggande insats om den skalas upp på befolkningsnivå, eftersom de totala kostnaderna och särskilt lönekostnaderna för barnhälsovårdspersonal var låga i jämförelse med tidigare primärpreventiva insatser för att förebygga övervikt och obesitas hos barn i förskoleåldern. Sammantaget stödjer resultaten från delstudierna i denna avhandling, en storskalig implementering av MINISTOP 2.0 appen inom den svenska barnhälsovården för att främja hälsosamma levnadssvanor hos barn i 2,5- till 3-årsåldern.

LIST OF PAPERS

- I. **Alexandrou C**, Müssener U, Thomas K, Henriksson H, Löf M. Adapting a Parental Support App to Promote Healthy Diet and Physical Activity Behaviors (MINISTOP) for a Multi-Ethnic Setting: A Qualitative Study on the Needs and Preferences of Parents and Nurses within Swedish Child Health Care. *Nutrients*. 2021;13(7):2190.
- II. **Alexandrou C**, Henriksson H, Henström M, Henriksson P, Delisle Nyström C, Bendtsen M, Löf M. Effectiveness of a Smartphone App (MINISTOP 2.0) integrated in primary child health care to promote healthy diet and physical activity behaviors and prevent obesity in preschool-aged children: randomized controlled trial. *Int J Behav Nutr Phys Act*. 2023;20:22.
- III. **Alexandrou C**, Rutberg S, Johansson L, Lindqvist AK, Müssener U, Löf M. User experiences of an app-based mHealth intervention (MINISTOP 2.0) integrated in Swedish primary child health care among Swedish-, Somali-, and Arabic-speaking parents and child health care nurses: a qualitative study. *Manuscript under review*
- IV. **Alexandrou C**, Löf M, Brown V, Delisle Nyström C. Cost-consequence analysis of a mHealth obesity prevention intervention in Swedish primary child health care: the MINISTOP 2.0 trial. *Manuscript*

PAPERS NOT INCLUDED IN THIS THESIS

Henriksson H, **Alexandrou C**, Henriksson P, Henström M, Bendtsen M, Thomas K, Müssener U, Nilsen P, Löf M. MINISTOP 2.0: a smartphone app integrated in primary child health care to promote healthy diet and physical activity behaviours and prevent obesity in preschool-aged children: protocol for a hybrid design effectiveness-implementation study. *BMC Public Health*. 2020;20:1756.

ABBREVIATIONS

App	Mobile application
BCT	Behavior change technique
BMI	Body mass index
BMI z-score	Body mass index standard deviation score
mHealth	Mobile health
MVPA	Moderate-to-vigorous physical activity
PSE	Parental self efficacy
RCT	Randomized controlled trial
SCT	Social cognitive theory
SD	Standard deviation

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INTRODUCTION

The public health challenge of childhood overweight and obesity

Overweight and obesity in children – global prevalence and health consequences

The global prevalence of overweight and obesity in adults has increased nearly threefold the past forty years [1–3]. Correspondingly, childhood overweight and obesity increased by 47% between 1980 and 2013 [3,4], and recent data indicates further increases during the COVID-19 pandemic in several countries [5–7]. This is concerning, especially when considering that globally, 39 million children under the age of five already are estimated to have either overweight or obesity [1–4]. Development of overweight and obesity early in life is a major global public health challenge as these conditions tend to track throughout childhood and into adulthood [8,9]; a review and meta-analysis showed that children and adolescents with obesity were five times more likely to have obesity in adulthood, compared to children with normal weight [8]. Childhood obesity is also associated with increased risk of cardiometabolic disease as well as certain cancers later in life [8,10–15]. Notably, the global burden of non-communicable diseases (NCDs) currently accounts for the majority of premature deaths and morbidity worldwide, with cardiovascular diseases as the main contributor [16,17]. Moreover, children, adolescents, and adults with obesity are often subject to social stigmatization through various forms of discrimination during their lifespan, further contributing to adverse mental and physical health and lower quality of life [17–20]. Clearly, childhood overweight and obesity, already in the preschool years, are major global public health challenges, and preventive efforts need to be a public health priority going forward.

Overweight and obesity also a public health issue among young children in Sweden

The prevalence of childhood and pubertal overweight and obesity in Sweden has also increased during the last decades [21–23]. For example, between 1980 and 2000, there was a twofold increase in the prevalence of overweight among 10-year-olds in Sweden, while the prevalence of obesity in the same age group increased fourfold [23]. Although some reports thereafter have indicated a stabilization or decline [24,25], a study with data from 2018 concluded that the prevalence of overweight and obesity

among 4-year-olds in Sweden remained at high levels and requested preventive actions [26]. Furthermore, even though Sweden never went into formal lockdown, the prevalence of overweight and obesity among 4-year-old children have been reported to increase during the first year of the COVID-19 pandemic, from 11% in 2018, to 13.3% in 2020 [26–30]. Correspondingly, another report comparing the incidence of childhood overweight and obesity before and during the pandemic, showed an increased incidence among 3- and 4-year-old children in Sweden [31], where the prevalence of for example obesity in 3-year-old girls increased from 2.8% to 3.9% [31]. This increase was also more evident in child health care centers located in socioeconomically disadvantaged areas [31]. Even though these recent findings may represent temporarily and reversible changes due to the COVID-19 pandemic, childhood overweight and obesity among preschool aged children (2–5 years) still remains a public health issue in Sweden.

The socioeconomic gradient of childhood obesity

When viewing the health of a population one also needs to consider the socioeconomic gradient in health, where health disparities tend to accumulate more in socioeconomically vulnerable populations such as individuals with lower income, shorter education, lower literacy, and migrant background [32–35]. This gradient in health is also reflected in childhood overweight and obesity rates, where there are clear structural inequalities in prevalence depending on the socioeconomic conditions of different areas and communities [27,28,36–38]. Noteworthy, a recent report from the child health care services in Stockholm showed that the prevalence of overweight and obesity among 4-year-old children was up to three times higher in low vs. high socioeconomic areas (6.5% vs. 18.5%) [28], further highlighting the urgency of counteracting this development with effective preventive efforts.

Determinants of childhood overweight and obesity and types of interventions

Although development of childhood overweight and obesity is preventable [39,40], the factors related to its development are often a result of complex interactions between social, environmental, behavioral, and genetic factors [35,41–43] and therefore also require a complex and multilevel response [35,44]. While genetic and early-life factors such as e.g., maternal gestational weight gain, birth weight and breastfeeding status, are important determinants for explaining the variation in height and weight during infancy and early childhood, environmental, psychosocial, and behavioral factors also play a large role in the development of childhood overweight and obesity [45,46]. Environmental and psychosocial factors also influence behavioral factors such as for example parental ability to promote healthy diet,

physical activity, sleep, and screen time behaviors in their children [45]. This is concerning, especially when set in relation to the recent years increased engagement in obesogenic behaviors such as physically inactive and sedentary lifestyles [47,48] and dietary patterns characterized by high intakes of processed foods rich in salt and added sugars [49]. For instance, in Sweden, a significant increasing trend in screen time was observed in 4-to-6-year-old children between 2018 and 2020, with a lower proportion of children watching < 1h of screen time per day [50]. In addition, an increased proportion of 4-to-6-year-old children that had 3-4 h of daily screen time was also observed [50]. Furthermore, it is estimated that only 20% and 30% of Swedish preschool-age children reach the national recommendations of physical activity and intake of fruit and vegetables respectively [51,52]. Consequently, there is a need for primary preventive efforts and interventions supporting families in promoting healthy lifestyle behaviors both on an individual as well as on a community level.

Primary child health care and primary prevention

Primary child health care – a key arena for primary prevention

Swedish primary child health care provides an ideal setting for early preventive population level health efforts and interventions; their overall goal is to work towards and contribute to the best possible physical, mental, and social health of children, through early prevention of ill-health, promotion of health behaviors, and monitoring of each child's growth and development [53,54]. Notably, in Sweden, primary child health care is also free of charge and voluntary [53,54]. Despite the voluntary aspect, the coverage is high; approximately 99% of families with a child aged 0 – 5 years attend visits regularly, which also indicates a high level of trust for the setting [55].

Previous childhood obesity prevention interventions within primary child health care settings

Overall, results from previous childhood obesity prevention interventions within primary child health care settings have shown moderate effects on children's BMI [56–60]. For instance, for the Swedish setting, Döring et al. evaluated a parental support intervention (n = 1355 families) within primary child health care, where parents in the intervention group received one group session and eight individual motivational interviewing (MI) sessions, starting from when their child was 9 months up to the age of 4 years [61]. Although the evaluation showed no statistically significant difference between groups in terms of primary outcomes, i.e., children's BMI, overweight prevalence and waist circumference at 4 years, a small yet significant effect was observed for the secondary outcome – children's and mother's diet and physical activity habits [61]. Similarly, Derwig et al. did

not observe any statistically significant effect on children's BMI between groups, after evaluating the effectiveness of a child-centered dialogue on healthy lifestyle behaviors at the age of 4 years [62]. The intervention was delivered through a 10-minute dialogue with the child and caregiver, where the nurse held a structured conversation on health behaviors and BMI while showing different illustrations of health behaviors [62]. Additionally, in a recent review of obesity prevention interventions delivered by health care professionals during the first 1000 days of life ($n = 46$), only four interventions had an effect on both children's weight/adiposity outcomes as well as on a behavioral outcome, while an additional six interventions had an effect only on children's weight/adiposity outcomes. However, notably, despite the lack of effect on weight/adiposity outcomes in the majority of the interventions, many still had an effect on behavioral outcomes ($n = 22$) [63]. Although these findings collectively suggest a positive impact of obesity prevention interventions on children's lifestyle behaviors, they also underline the need for further research to investigate whether the effectiveness of primary preventive interventions for obesity in preschool aged children can be enhanced. Finally, as previous studies primarily focused on face-to-face intervention deliveries, which may be challenging to scale up due to high staff costs, there is also a need for other ways of delivering obesity prevention interventions that are more scalable.

Addressing health inequalities: a fundamental aspect when developing population-based interventions

As described earlier, evidence indicates that the prevalence of overweight and obesity often is unequally distributed across socioeconomic groups within countries, with widening socioeconomic inequalities as a consequence [36]. Furthermore, a recent review concluded that reaching disadvantaged families with health behavior interventions is challenging [64], and some of the barriers that were suggested to hinder families from accessing and engaging with interventions were linguistic, but also cultural [65,66]. From a public health perspective, vulnerable population groups need to be prioritized when developing interventions [67], however, in order to practically achieve this, interventions and efforts also need to be adapted, translated, and designed to promote inclusiveness and reach of those in most need of support [68,69]. If bypassed, future health efforts and interventions instead risk contributing to widening health gaps [68,69].

mHealth – potential for adapted and accessible health behavior interventions at scale

Definition of mHealth and other related concepts

Digital health is an umbrella term used for eHealth and other areas of advanced computing sciences, such as for example artificial intelligence and big-data [70]. eHealth in turn refers to the use of information and communication technologies as a support within health and health care related settings [70]. During the 58th World Health Assembly in 2005, the World Health Organization (WHO) urged member states to begin the work with setting up strategic plans for implementation and use of eHealth technologies, as eHealth was acknowledged a cost-effective and secure way of supporting health care settings [71]. Thereafter, the Swedish government in collaboration with the Swedish Association of Local Authorities and Regions developed a vision for eHealth in 2016, with the aim of by 2025, becoming the best in the world at utilizing the possibilities of digitization and e-health in order to make it easier for individuals to achieve good and equal health and welfare [72].

Mobile health or mHealth is a separate area within the eHealth discipline, defined by WHO as the “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” [73]. As mobile phones are widely used and accepted worldwide, the field of mHealth provides a broad range of use within both primary prevention and health promotion, with many possibilities for developing and disseminating health behavior interventions for different purposes and populations [74]. Advantages compared to traditional face-to-face interventions include remote delivery of care at any time and place. mHealth interventions are also suitable for primary prevention if properly adapted, as they may be relatively easy to scale up [75].

A shift in the use of mHealth

The COVID-19 pandemic brought forward a shift in the way health care is delivered [69,76]. Although there were indications of an increased need for mHealth solutions before the pandemic, the recommendation and use of such technologies within routine care was limited [77], and barriers associated with their adoption included both scepticism and lack of trust for their effectiveness among health care professionals [69,76]. Nevertheless, during the pandemic, communication and remote delivery of care became a necessity [76]. Although Sweden did not have as many restrictions compared to other countries; for instance, preschools and schools were kept open – children’s lifestyle behaviors were still affected with an increased

incidence and prevalence of obesity among preschool-aged children as a result [28,29,31]. Possible reasons for this development are that parents, regardless of the absence of a formal lockdown, were urged to keep their children at home for minor cold symptoms or due to shortage of staff [31,78,79]. Additionally, some parents also kept their children at home out of fear; this was observed primarily in socioeconomically disadvantaged areas [31]. All in all, the pandemic underlined the importance of having the option of recommending and using mHealth and other digital solutions in routine care practice. Nevertheless, in relation to this, it is also important to highlight that mHealth solutions should not solely replace any current available care, but rather be used in a way that they complement and strengthen standard care. Additionally, in the context of child health care, mHealth solutions should be viewed as part of the bigger picture for prevention and treatment of childhood obesity, where parents are presented with the option of additional support between visits to child health care, or as an additional component in childhood obesity treatment programs. Finally, with mHealth solutions providing comprehensive information and support without requiring extensive staff resources, there is a potential for health care providers to help them reallocate more resources in terms of in-person contact to families that need that the most.

Health literacy, health equity and the potential of mHealth

Health literacy is a term with definitions on both a personal and organizational level [80]. On a personal level, health literacy is defined as “the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others” [80], while health literacy on the organizational level is defined as “the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others” [80]. Thus, through its aim of working towards more equitable health services, health literacy is also linked to health equity [80–82]. On that account, mHealth interventions have been suggested to also contribute to increased health literacy, if designed or adapted to meet the varying levels of literacy in populations [83,84]. However, if not adapted to promote accessibility and inclusiveness, mHealth interventions may also contribute to increased health inequalities [81,83,85]. Therefore, going forward it is suggested that features and content in mHealth interventions are developed in collaboration with low-literacy and low-health literacy populations, followed by a systematic measure of their effect [86]. With that said, the potential effect of an mHealth intervention for promotion of health behaviors in vulnerable population groups during the preschool age has yet to be investigated.

A brief introduction to the MINISTOP mHealth intervention

The name MINISTOP is an acronym for Mobile Based Intervention Intended to Stop Obesity in Preschoolers. This thesis reports the results of the MINISTOP 2.0 project [87], where the primary aim was to evaluate whether a parental support intervention (MINISTOP 2.0 app) for promotion of healthy lifestyle behaviors in preschool aged children, would be an effective and feasible support tool to use within the Swedish primary child health care setting. The MINISTOP 2.0 project is a continuation of a previous population-based trial [88,89] which evaluated the efficacy of an app-based parental support intervention (MINISTOP 1.0 app) in parents of 4-year-old children ($n = 15$). This trial was conducted between 2013 and 2015 in the general population of Östergötland in Sweden, and utilized objective and accurate outcome measures such as air-displacement plethysmography for measuring children's body-composition, and [90] accelerometry (ActiGraph wGT3X-BT) for measuring children's physical activity [89,91–96]. Overall, the main results from the MINISTOP 1.0 trial [89] showed no group difference in children's fat mass index, however, children in the intervention group demonstrated a statistically significant higher composite score of six dietary and physical activity behaviors at follow-up (OR: 1.99; 95% CI 1.20 – 3.30; $p = 0.008$). Noteworthy, this effect was also more pronounced in children with a higher fat mass index [89]. Additionally, the MINISTOP 1.0 trial also reported a similar effect size as more labor-intensive face-to-face interventions for prevention of childhood overweight and obesity within child health care and kindergarten settings [59,61].

Adapting the MINISTOP intervention to increase future accessibility and reach

After completing the MINISTOP 1.0 trial, several Swedish primary child health care units expressed interest to implement the MINISTOP 1.0 app within routine practice. However, before implementing the app at scale, real-world effectiveness also needed to be proven; the 1.0 version had been evaluated in a rigorous efficacy-trial where parents had interacted with and received the app by the research team. Furthermore, the 1.0 version was available only in Swedish which was a limitation for accessibility and reach, as 24% of children in Sweden have foreign-born parents [97]. Thus, the app first needed to be adapted and translated before being introduced and evaluated within the primary child health care setting. Subsequently, in 2019, the work of modifying and extending the MINISTOP 1.0 app into a 2.0 version was initiated, through adaptations and translation of the intervention content to Somali, Arabic and English, which during that point in time, were the languages spoken by the majority of the foreign-born population in Sweden [98]. These adaptations, together with an evaluation of real-world effectiveness, were then combined into a research project (MINISTOP 2.0) addressing research questions that needed to be answered before implementation at scale.

Bridging the gap between research and clinical practice

Implementation research

Implementation research is an emerging field within health research, as the mechanisms behind successful implementation of interventions and programs are complex [99,100]. Further, there is a gap between research and clinical practice where it is common for public health or clinical interventions to be conducted, but not adopted and implemented after the trial ends, despite showing promising effects [99]. Implementation research is focused on bridging this gap. It is conducted within real-world conditions and focuses on all aspects related to implementation, such as for example different factors affecting implementation processes but also the results of intervention/program implementation [99]. It is also focused on working with promoting large scale implementation of interventions, as well as how interventions may be successfully sustained over time [99].

Hybrid study designs

Although the interest of using mHealth and other digital care solutions is increasing among both health care providers and patients, it is also a relatively new way of delivering care, hence there are yet no clear guidelines for how health care setting may integrate and disseminate digital tools in routine practice [101]. Hybrid study designs [102] are becoming increasingly common when evaluating the clinical effectiveness of programs within real-world settings, as they enable simultaneous collection of data on effectiveness outcomes and implementation aspects. Thus, utilizing hybrid designs has been proposed to speed up the research process, from development and effectiveness evaluation to implementation within clinical settings [102]. Currently, there are three common types of hybrid effectiveness-implementation study designs: type 1, type 2, and type 3 [102]. The MINISTOP 2.0 project is based on a hybrid type 1 effectiveness-implementation design which means that it is mainly focused on evaluating effectiveness, but also collects data on implementation aspects to facilitate and inform future implementation [87]. Hybrid type 2 designs on the other hand, have an equal focus on both effectiveness and implementation outcomes, while hybrid type 3 study designs primarily focus on implementation [102].

Research aims

The overall aim of this thesis was to evaluate whether a parent-oriented mHealth intervention (MINISTOP 2.0 app) embedded in the routine services of primary child health care, can be used to improve diet and physical activity behaviors, and decrease the prevalence of overweight and obesity in preschool-age children.

The specific aims of my PhD project were:

- 1) To investigate user-requirements (parents and primary child health care nurses) in terms of content and technical features and thereafter modify, extend, and translate the MINISTOP 1.0 app into a 2.0 version (**Paper I**)
- 2) To evaluate the effectiveness of a 6-month mHealth intervention (MINISTOP 2.0 app), embedded in the routine services of Swedish primary child health care, targeting parents with 2.5-to-3-year-old children on: i) children's intake of fruits, vegetables, sweet and savory treats, sweet drinks, and time spent in moderate-to-vigorous physical activity (MVPA) and screen time (primary outcomes) and ii) parental self-efficacy (PSE) for promoting healthy dietary, physical activity and screen time behaviors in children, and children's body mass index (BMI) (secondary outcomes) (**Paper II**)
- 3) To explore and describe user experiences as well as acceptability and feasibility of the MINISTOP 2.0 app-based intervention in a diverse group of parents (end-users) and Swedish child health care nurses (implementers) (**Paper III**)
- 4) To evaluate the costs of the MINISTOP 2.0 intervention, when delivered through Swedish primary child health care, by means of a cost-consequence analysis (**Paper IV**)

METHODS

The MINISTOP 2.0 project: from development to cost-consequence at scale

Study design and setting (Paper I-IV)

The MINISTOP 2.0 project covers the development and evaluation of the MINISTOP 2.0 digital intervention, from adaptation and translation of the intervention to multiple languages (Paper I), to evaluation of real-world effectiveness within the Swedish primary child health care setting (Paper II) followed by exploration of user experiences and implementation aspects such as intervention feasibility and acceptability (Paper III), to finally concluding with a cost-consequence analysis of the intervention cost per family (Paper IV). A summary of the aims, study design and timeline for the papers included in this thesis are presented in **Table 1**. For Paper II and Paper III, the MINISTOP 2.0 project utilized a hybrid type 1 effectiveness-implementation study design [102] to enable parallel evaluation of effectiveness outcomes and implementation aspects of the MINISTOP 2.0 app-based intervention. The effectiveness outcomes (Paper II) were evaluated through a randomized controlled trial (RCT), while user experiences and implementation aspects (Paper III) were explored qualitatively through individual interviews with parents (end-users) and child health care nurses (implementers).

The study design and statistical analyses plan for the randomized controlled trial (Paper II) have been described in detail in a study protocol that was published in 2020 (Clinicaltrials.gov NCT04147039) [87]. The results from the included studies were reported according to relevant guidelines and checklists. Thus, qualitative findings (Paper I, Paper III) within the MINISTOP 2.0 project have been reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [103], while reporting of quantitative results followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Paper II) [104] and the TIDieR checklist (Paper II) [105]. Finally, data on costs and consequences (Paper IV) were reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist [106].

Table 1. Overview and timeline of the papers included in this thesis.

Paper, method	Aim(s) and timeline for data collection	Participants	Data collection	Data analyses
Paper I Qualitative, formative	Sep 2019: To investigate user-requirements (parents and primary child health care nurses) in terms of content and technical features and thereafter modify, extend, and translate the MINISTOP 1.0 app into a 2.0 version	Parents speaking Somali (n=5), Arabic (n=4) and Swedish (n=6) Child health care nurses (n=15)	Semi-structured focus group interviews with the parents. One focus group per language. The focus groups were conducted at a child health care center in Ryd, Linköping together with translators. Semi-structured individual interviews were conducted with the nurses. All interviews were conducted over the phone and were audio recorded	Thematic analysis, Inductive latent approach
Paper II Quantitative, RCT	Nov 2019 – Apr 2022: To assess the effectiveness of the MINISTOP 2.0 app-based intervention on: i) children's intake of fruits, vegetables, sweet and savory treats, sweet drinks, MVPA and screen time (primary outcomes) and ii) PSE for promoting healthy diet and physical activity behaviors in children, and children's BMI (secondary outcomes)	Participants (All, n=552; Intervention group, n=277; Control group, n=275) in the MINISTOP 2.0 trial	Nurses disseminated a questionnaire at baseline and after six months assessing primary and secondary outcomes. Nurses also measured children's height and weight for assessment of BMI, using standardized procedures	Intention-to-treat analyses according to the study protocol [87]. Linear regression on complete cases, followed by an imputed data analysis. The secondary outcome BMI was analyzed using quantile regression. Finally, Bayesian analyses were also conducted for all outcomes.
Paper III Qualitative, evaluation	Sep 2020 – Mar 2022: To explore and describe user experiences as well as acceptability and feasibility of the MINISTOP 2.0 app-based intervention in a diverse group of parents (end-users) and Swedish child health care nurses (implementers)	Parents speaking Somali (n=9), Arabic (n=5), Swedish (n=9) and English (n=1); as well as child health care nurses (n=15) that participated in the MINISTOP 2.0 trial	Semi-structured individual interviews. All interviews were conducted over the phone and were audio recorded. When needed, an interpreter was used	Content analysis, latent inductive approach
Paper IV Quantitative, cost-consequence	Nov 2022 – Dec 2022: To evaluate the costs of the MINISTOP 2.0 intervention when delivered through Swedish primary child health care, by means of a cost-consequence analysis	Participants (n=277) in the intervention group of the MINISTOP 2.0 trial	Data on all costs related to the MINISTOP 2.0 intervention were collected retrospectively from trial records as well as from the human resource departments for the participating child healthcare centers	A cost-consequence analysis was conducted using the Ersatz add-in for Microsoft Excel. A Monte Carlo simulation was used to estimate total intervention cost and cost per participant during the intervention

Abbreviations: RCT, randomized controlled trial; MVPA, moderate-to-vigorous physical activity; PSE, parental self-efficacy; BMI, body mass index

Participants and recruitment (Paper I-IV)

Paper I: In order to explore needs of support and user requirements within the MINISTOP app, purposive sampling of parents for participation in a focus group interview was conducted in September 2019. The recruitment of parents was conducted at Familjecentralen Ryd, a child health care center located in a socioeconomically and culturally diverse area of Linköping. Parents speaking Somali ($n = 5$) and Arabic ($n = 4$) were approached with the help of Somali- and Arabic-speaking bridge-builders, i.e., individuals with specific cultural backgrounds, employed by health care services in Sweden to facilitate communication with individuals with migrant background. Parents speaking Swedish ($n = 6$) were recruited by a child health care nurse at the child health care center. Additionally, 15 child health care nurses were also recruited for an individual interview in September 2019, from child health care centers ($n = 24$) that had expressed interest in participating in the upcoming MINISTOP 2.0 trial (November 2019). The invitation for the nurses with the study and consent information, was sent via e-mail.

Paper II: The parents ($n = 552$) participating in the MINISTOP 2.0 trial with their child were recruited from 19 child health care centres, located in six Swedish regions (Skåne, Stockholm, Uppsala, Västmanland, Västra Götaland and, Östergötland) between November 2019 and September 2021. As the MINISTOP 2.0 trial was conducted within the primary child health care setting, all study procedures (recruitment, outcome measures, randomization) were performed by the child health care nurses at the primary child health care centers. A flowchart of the MINISTOP 2.0 trial, from recruitment to follow-up at six months is shown in **Figure 1**.

Paper III: For the qualitative exploration of user experiences and implementation aspects such as intervention feasibility and acceptability, parents in the intervention group of the MINISTOP 2.0 trial that were Swedish- ($n = 9$) and English-speaking ($n = 1$) were recruited after they had completed the trial, through a web-based evaluation questionnaire sent out in conjunction with the 6-month follow-up. Parents that were Somali- ($n = 9$) and Arabic-speaking ($n = 5$) were instead approached and recruited through bridge-builders and health-communicators to ensure that they fully understood the study and consent information. Child health care nurses ($n = 15$) that had participated in the recruitment of the MINISTOP 2.0 trial were invited by e-mail to participate in an individual interview about disseminating and using the app in their practice. Altogether, the recruitment of parents and child health care nurses for an interview was conducted between September 2020 and March 2022.

Paper IV: For the evaluation of costs for the MINISTOP 2.0 trial, a cost-consequence analysis was conducted [107], where data on participants in the intervention group ($n = 277$) of the trial was used, while data on costs related to the intervention was collected retrospectively in November and December of 2022.

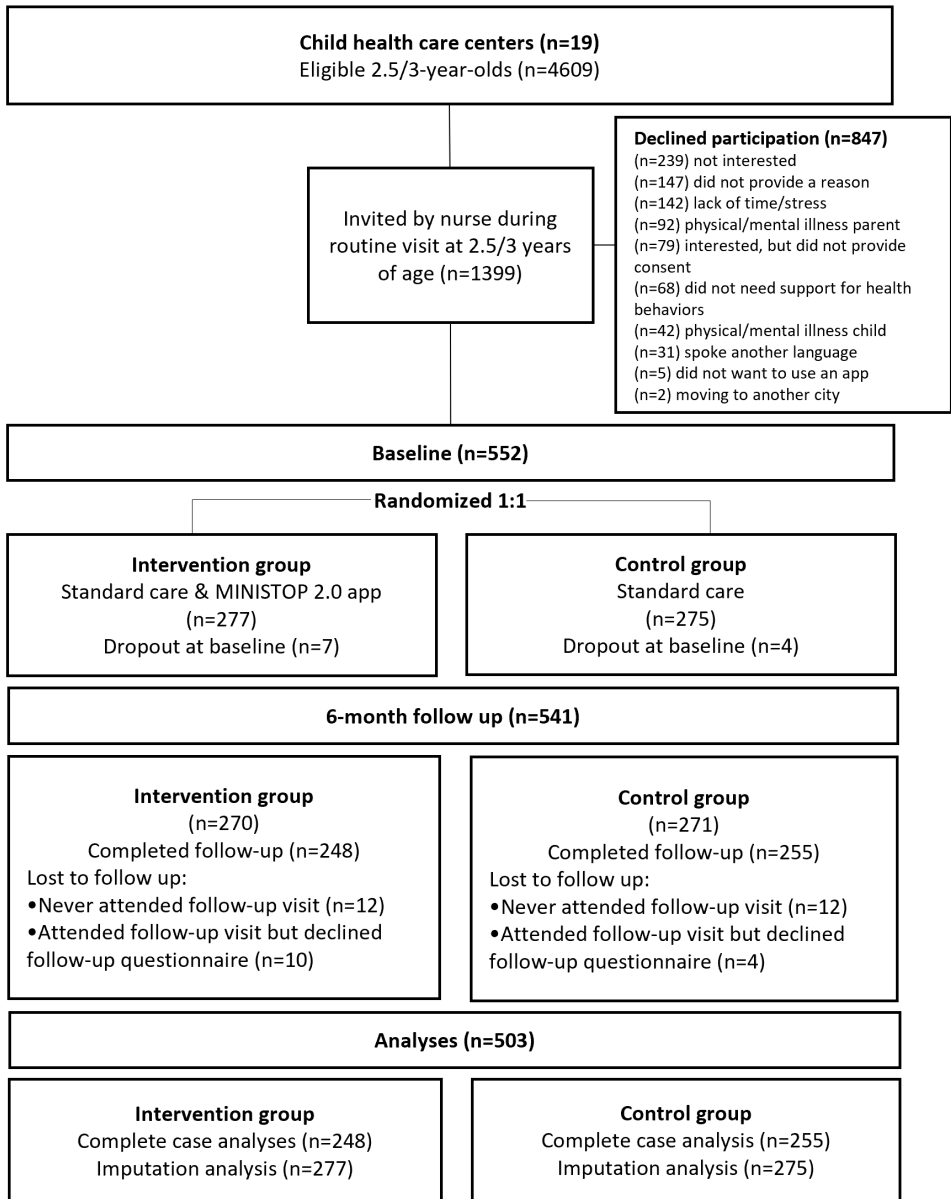


Figure 1. Flowchart of the recruitment and data collection in the MINISTOP 2.0 randomized controlled trial (Paper II).

The MINISTOP 2.0 intervention

Following the baseline procedures in the MINISTOP 2.0 trial (Paper II), participating parents were randomized by their nurse at a 1:1 ratio, either to the intervention or control group. Parents in the intervention group received immediate access to the MINISTOP 2.0 app for six months, in addition to the standard care offered within Swedish primary child health care at ages 2.5 and 3 years [108].

Intervention development, overall content, and main features

The MINISTOP intervention is an app-based mHealth program delivered over a period of 6-months, aiming to support parents in promoting healthy diet and physical activity behaviors in preschool-aged children. The intervention was first developed in 2013 (MINISTOP 1.0 app version) by a multidisciplinary team of researchers with expertise in nutrition, behavioral science, medicine, engineering, psychology, and physical activity [88]. As part of this thesis, the intervention was further adapted and translated into Somali, Arabic and English (MINISTOP 2.0 app version), to make it more accessible (**Figure 2**) [87,109]. The MINISTOP 2.0 app is based on the MINISTOP 1.0 technical platform, developed by ScientificMed Tech AB, and is both Android and iOS compatible. It delivers an extensive program of information based on current recommendations on diet [110], physical activity, and screen time [111,112] for preschool aged children, through the gradual introduction of 13 themes, where a new theme of information is introduced every two weeks. The themes are: 1) healthy everyday food, 2) healthy breakfast, 3) healthy snacks, 4) physical activity and screen time, 5) sweets and snacks, 6) fruit and vegetables, 7) beverages, 8) snacking, 9) fast food, 10) sleep, 11) meals outside the home, 12) foods as a reward/on special occasions and 13) dental health. The app also includes a feature for registration, monitoring and feedback of children's weekly intakes of fruits, vegetables, sweets, savory treats, and sweet drinks as well as time spent being physically active and in front of screens. Screenshots with examples of the theme content and the registration feature in the app are presented in **Figure 3**.

Intervention ties to theory

The content and features of the MINISTOP app-based intervention are informed by social cognitive theory (SCT) [113]. SCT is a behavior change theory that revolves around the concept of human agency, i.e., the ability of individuals to regulate and control their actions, thought processes and motivation in order to influence their life situation or a specific behavior. Self-efficacy, a term which refers to an individual's belief in their ability to perform a specific behavior, is a key concept within SCT, and also regarded a major influencer of human agency [113]. Reciprocal determinism is

another central concept through which SCT is often illustrated and refers to how continuous bidirectional interactions between an individual's pre-existing skills and knowledge, behaviors, and their living and social environment, influences their behaviors [113]. In SCT, individuals are believed to learn by observing the behaviors or actions of others, i.e., through modelling of behavior [113]. This is known as observational or vicarious learning. However, learning new behaviors is not limited to observing others, they may also be acquired through instructions on how to conduct a specific behavior from a source such as media or the internet. SCT is further based on constructs such as behavioral capability, reinforcements, and expectations, where behavioral capability refers to an individual's actual knowledge and skills to perform a certain behavior and reinforcements refer to internal or external responses that may affect an individual's behavior, either positively or negatively [113]. Expectations, which often are based on previous experiences, also influences whether we will be successful in altering our behavior.

Behavioral interventions are commonly grounded in a behavior change theory in combination with specific behavior change techniques (BCT's) [114]. While behavior change theory is used to help explain the mechanisms of action behind human behavior and behavior change, BCT's are applied to and used in interventions to target and facilitate behavior change for a specific behavior [114]. The features and content of the MINISTOP 2.0 intervention are developed to increase parental self-efficacy (PSE), skills, and knowledge on healthy lifestyle behaviors for children, by building on BCT's such as providing general information, shaping knowledge, identification of self as role model, identification of barriers, action planning, self-monitoring of behavior and feedback on behavior. The health information feature of the intervention (gradually introduced themes 1-13) is focused on supporting parents create healthy food environments through information on healthy diet and feeding practices for preschool-aged children, and information for understanding and being more responsive towards their child's hunger and satiety cues [115,116]. The importance of setting healthy boundaries and being role models for healthy lifestyle behaviors is also emphasized and exemplified in different ways, through practical tips and strategies. The app also includes educational videos with tips on healthy snacks and indoor and outdoor activities for a child aged 2-to-3 years while the registration feature in the app enables parents to monitor key behaviors in their children and receive weekly feedback on their registrations. This feature was also developed to help increase parental insight and awareness in terms of recommended and healthy amounts of fruit, vegetables, sweets, snacks, sweet drinks, physical activity, and screen time for a preschool-aged child, through hands-on registration.

Intervention adaptations prior to translation

Although the findings from the qualitative exploration of user-requirements among parents and child health care nurses (Paper I) are part of the results of the MINISTOP 2.0 project, the same findings were also used to adapt and extend the MINISTOP intervention into a 2.0 version prior to dissemination and evaluation within primary child health care [87,109]. A brief description of the interview findings and the adaptations made to the content and features of the app is therefore included below.

One of the main interview findings was the necessity of the information feature in the app (themes 1-13) to also be accessible for individuals with low literacy. Subsequently, a collaboration with health-communicators (Flyktingmedicinskt centrum, Norrköping) was established, to create videos of the text content in each theme. Another interview finding (Paper I) were concerns among parents regarding children not eating enough for a healthy development and growth. Although this was expressed among parents, it was also confirmed by the nurses to be one of the more common areas of parental concern. To address this, more information (text and videos) on strategies for healthy feeding practices, emphasizing the importance of trusting childrens hunger and satiety cues and enabling children to self-regulate their intake of food, was added. As this concern also seemed to go hand in hand with limited knowledge on healthy amounts/intakes of foods, sweets and snacks for children aged 2-to-3 years, more and improved pictures of average portion sizes, recommended daily intakes of fruit and vegetables as well the maximum weekly intake of sweets, snacks and sweet drinks, were also added to increase parental knowledge and awareness through practical examples. Furthermore, part of the meal and snack recipes in the app were adapted to also include domestic and culturally familiar food items. Finally, in order to promote inclusiveness and representation, pictures of children and families from different cultures were added to illustrate the video and text content throughout the app.

Control group (Paper II)

The control group received the standard care offered by Swedish primary child health care at ages 2.5 and 3 years [108]. This included a conversation about health behaviors and a pamphlet with healthy lifestyle behavior information.

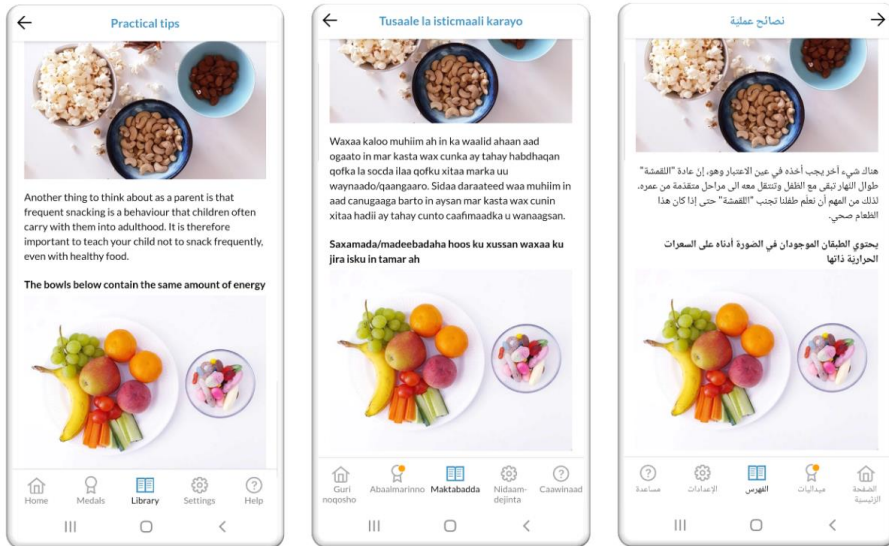


Figure 2. Screenshots from the MINISTOP 2.0 app showing an example of a theme text in English, Somali, and Arabic.

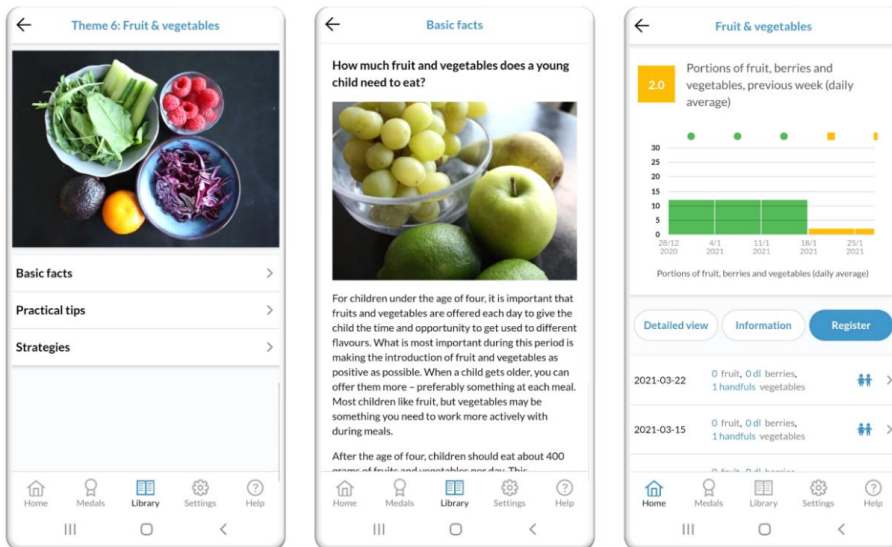


Figure 3. Screenshots with examples from the information feature (themes 1-13) and the registration feature in the MINISTOP 2.0 app. The app is available in Swedish, Somali, Arabic and English

Methods

Participant demographics (Paper I-IV)

Parents participating in the focus group interviews exploring user-requirements (Paper I) and in the individual interviews exploring user-experiences (Paper III) filled out a questionnaire assessing age, country of birth, educational attainment, occupation, spoken languages, and number and age of children, before the start of the interview. For the child health care nurses (Paper I, III), information about their age, professional expertise, and years of working experience was collected. Parents participating in the MINISTOP 2.0 trial (Paper II, IV) filled out questions at baseline assessing age (child, parents), sex (child, parents), height and weight (parents), educational attainment (parents), country of birth (child, parents, grandparents) as well as languages spoken at home (parents).

Qualitative studies (Paper I, III)

Paper I: To adapt the MINISTOP app into a 2.0 version for effectiveness evaluation within primary child health care, parental user-requirements first needed to be explored, in order to target the most relevant features and areas for update. A qualitative approach was chosen, and data was collected using semi-structured interview guides developed within the research group. Parents speaking Somali, Arabic and Swedish were recruited for participation in a focus group interview, and one focus group per language was conducted (Somali (n = 5); Arabic (n = 4); Swedish (n = 6)). All focus group interviews were conducted at the premises of a child health care center in Linköping (Familjecentralen Ryd) by C Alexandrou and H Henriksson. For the focus group interviews with the Somali- and Arabic-speaking parents, a translator was also present in the room. The child health care nurses (n = 15) were interviewed individually over the phone by C Alexandrou.

The interview guide used in the focus groups with the parents was designed to capture parental needs of support for promoting healthy diet and activity behaviors in children aged 2-to-3 years (Supplementary material, Table S1; Paper I). The guide also included questions to explore parental preferences of supportive content and features for promoting healthy lifestyle behaviors in their children. The interview guide used for the individual interviews with the nurses aimed to capture current health behavior promoting routines used within primary child health care and explore the current conditions for using mHealth tools within routine practice (Supplementary material, Table S2; Paper I). Additionally, both parents and nurses were shown screenshots of the MINISTOP 1.0 app [89] during the interviews and were thereafter asked to provide feedback on the content, features, and layout of the app.

Paper III: Semi-structured interview guides, developed by the research group, were used. The interview guides included both specific questions regarding the features and content of the app (parents, nurses) and caregiver interface (nurses) alongside more wide and open questions regarding the informants' overall user experience in relation to their current health behaviors (parents) and daily practice (nurses). Probing questions were used to clarify, and to help the informants to further elaborate their answers. All interviews were audio recorded and transcribed verbatim by an external transcribing firm.

Parents were recruited between September 2020 and March 2022. Interviews were conducted over the phone by C Alexandrou, who was also responsible for coordinating the recruitment and data collection in the MINISTOP 2.0 trial. C Alexandrou had no previous relationship with the parents as the recruitment and data collection in the trial was conducted by the child health care nurses. Informed verbal consent was obtained and recorded at the beginning of each interview. When needed, interviews with Somali- and Arabic-speaking parents were conducted together with a translator. Interviews were on average 48 minutes long and lasted between 32 to 74 minutes. Interviews conducted together with a translator ($n = 7$) were in general longer in duration.

Nurses were recruited between May 2021 and January 2022 and interviews were conducted by C Alexandrou and M Fagerström, a female PhD student and physiotherapist with expertise in implementation research. The nurses had no previous relationship with M Fagerström, however, due to the coordinating nature of her role in the trial, C Alexandrou had met the nurses earlier when introducing the intervention. Nurses were emailed an invitation to participate in an interview, which also included information about voluntary participation and the right to withdraw at any timepoint. Informed verbal consent was recorded at the start of each interview and interviews lasted on average 49 minutes (range: 27 to 67 minutes).

Quantitative study (RCT, Paper II)

Primary outcomes: children's health behaviors

The MINISTOP 2.0 trial is the second evaluation of the MINISTOP app [87]. The first MINISTOP trial (MINISTOP 1.0 app) was conducted by the research team and intervention efficacy was evaluated using accurate and objective methodologies [89]. However, as the MINISTOP 2.0 trial was an effectiveness trial, the aim was to evaluate the effect of the intervention on children's diet and physical activity behaviors, when disseminated within a real-world setting. Subsequently, outcome measures needed to be feasible to conduct by the nurses at primary child health care centers and also be respectful of the timeframe of the visit. Thus, a short questionnaire was

used to assess children's lifestyle behaviors at baseline and at the 6-month follow-up. The questionnaire was based on validated questions on health behaviors [117] used by the Swedish National Board of Health and Welfare [118], that were modified to fit 2-to-3-year-old children, and included questions on children's intakes of key dietary indicators such as vegetables, fruits and berries, sweet and savory treats, and sweet drinks (primary outcomes, Paper II). All indicators were assessed as the number of average standardized portions per day during the past month, and the questions were worded as follows: *"How many portions of fruits or berries (fresh, frozen, tinned etc.) does your child eat per day? One portion equals 1 normal size fruit or 1 dl of berries or fruit pieces. Think back over the past month"*. Standardized weights from the Swedish Food Agency's database [119] were then used to convert the reported average standardized portions of dietary indicators per day into grams per day.

The questionnaire also included questions assessing children's physical activity behaviors as time spent in moderate-to-vigorous physical activity (MVPA) and screen time (primary outcomes, Paper II). Both MVPA and screen time were assessed separately on a weekday and weekend day as minutes per day, and the questions were worded as follows: *"On a normal weekday, how much time does your child spend doing physical activity that causes their heart to beat faster and sometimes makes them out of breath? Think back over the past month"*. For the analyses, a weighted average for time spent in MVPA and screen time respectively on weekdays and weekend days was calculated as follows: (MVPA weekday * 5) + (MVPA weekend day * 2) divided by 7.

Secondary outcome: children's body mass index (BMI)

Nurses measured children's height and weight using standardized procedures, both at the baseline and 6-month follow-up visit at the child health care center. Children were weighed without shoes, in light clothing and height was measured using a wall-mounted stadiometer. BMI was calculated as weight divided by height squared (kg/m^2) and the extended international age and sex specific body mass index (IOTF) cut-offs by Cole and Lobstein [120] were then used for classification into weight status categories (i.e., underweight, normal weight, overweight and obesity). BMI standard deviation scores (BMI z-scores; secondary outcome; Paper II) were also calculated using a formula with BMI LMS coefficients [121] corresponding to the extended IOTF cut-offs [120].

Secondary outcome: PSE

In order to assess PSE for promoting healthy lifestyle behaviors, questions from the previously validated Parental Self-Efficacy for Promoting Healthy Physical Activity and Dietary Behaviors in Children Scale (PSEPAD) Questionnaire were used [122]. The included questions covered PSE for 1)

promoting healthy dietary behaviors, 2) promoting healthy physical activity behaviors and, 3) limiting screen time in children. Parents rated their self-efficacy on a scale from 0-10, where 10 was the highest perceived self-efficacy. In addition to scores for each separate question, a total PSE score was also created for the analyses, where the maximum possible score was 30.

App usage and satisfaction

Data on app usage and satisfaction was collected among participants in the intervention group of the MINISTOP 2.0 trial after the 6-month follow-up, using an online questionnaire. The questionnaire included questions assessing the number of themes (theme 1-13) the parents had taken part of, how frequently they had used the app, which features they had used, and whether they found the content and features in the app to be supportive and useful for promoting healthy diet and activity behaviors in their child.

Cost-consequence analysis (Paper IV)

A retrospective approach was utilized to collect data on all costs related to the MINISTOP 2.0 intervention, and Microsoft Excel (Office 365) was used to develop the costing protocol. Unit costs were collected from the MINISTOP 2.0 trial records, and labor costs were collected from the human resource departments for the participating child health care centers. Intervention costs were defined in a steady state, meaning that costs related to intervention development or evaluation were excluded and costs for the intervention were estimated over the intervention period, i.e., November 2019 to April 2022. The Ersatz boot-strap add-in by Epigear [123] for Microsoft Excel was utilized to calculate the 95% uncertainty levels (95% UL) for all parameters using a Monte Carlo simulation (1000 iterations). Total intervention cost and cost per participant were estimated. All intervention costs were presented in 2022 Swedish Krona. In the base case analysis, no discounting to costs and effects was applied due to the intervention duration of six months. Sensitivity analyses then applied a 3% discount rate, as is common in the Swedish setting [124].

Analyses

Qualitative data analysis (Paper I, III)

Exploration of user-requirements prior to trial start (Paper I) and user-experiences after the 6-month follow-up in the trial (Paper III) were analyzed using two different qualitative methodologies: thematic analysis [125] (Paper I) and content analysis [126] (Paper III).

Thematic analysis (Paper I)

Initial reflective notes were made by C Alexandrou after each interview. All interviews were then transcribed verbatim by an external transcribing firm and the interview transcripts were analyzed using thematic analysis [125] with an inductive latent approach to enable exploration of deeper underlying meanings in the data [127]. During the analysis process, the transcripts were first carefully read by C Alexandrou and U Müssener, a female researcher with expertise in qualitative methodology, in order to acquire a first comprehensive understanding. Quotations were then selected and marked throughout the transcripts, and preliminary themes emerged through an iterative analysis process of reading and re-reading the quotations in search of patterns. The process of coding into themes was initiated by C Alexandrou under supervision of U Müssener, and ongoing discussions between the two led to the formation of four final themes. The themes were further discussed among all authors until final agreement on the content and quotations included was reached.

Content analysis (Paper III)

Content analysis with an inductive latent approach inspired by Graneheim and Lundman [126] was used to analyze, explore, and acquire a deeper understanding of the data. All transcripts were first fully read by C Alexandrou (parents, nurses) and L Johansson (nurses), a female researcher and physiotherapist, to obtain an overview of the information in the interviews. A coding process was then initiated separately by C Alexandrou (parents, nurses) and L Johansson (nurses), where data was divided into meaning units that were condensed into smaller meaning units, and then further abstracted into codes. To ensure that the interpretation of data was correct C Alexandrou and L Johansson reviewed each other's codes. The codes were additionally reviewed by S Rutberg, a female researcher and physiotherapist with expertise in qualitative methodology, who also supported the analysis process through regular discussions with C Alexandrou. When agreement around the coding datasets was reached, C Alexandrou proceeded with sorting the condensed meaning units and codes into preliminary sub-categories that were close to the text. Categories for all the data were then identified, by reading and rereading the condensed meaning units, codes, and preliminary categories several times. Finally, themes and sub-themes emerged through interpretation of the underlying meaning of the categories. The theme content was then jointly discussed with all authors until final consensus was reached.

Statistical analyses (Paper II)

Intervention effectiveness (Paper II)

All analyses were intention-to-treat and conducted according to the analysis plan in the study protocol [87]. At first, analyses of complete cases were conducted, under the assumption that any missing data was missing completely at random (MCAR). Further, attrition analyses were conducted to support the MCAR assumption. Sensitivity analyses with missing data imputed were also conducted using multiple imputations with chained equations (200 imputed data sets with 30 iterations) [128]. To detect differences between the intervention and control group for the primary outcomes (vegetables and fruits, sweet and savory treats, sweet drinks, MVPA, and screen time) as well as for the secondary outcome PSE, linear regression was used. For group differences in BMI z-scores (secondary outcome), quantile regression (10th, 50th and 90th percentile) was used. Regression models for all outcomes were adjusted for their respective baseline value, as well as for the child's sex and age at baseline. A random intercept for each child health care center was also added to all regression models, to account for clustering of data points within centers. Further, to investigate whether the effect of the intervention on primary and secondary outcomes differed depending on parental country of birth (i.e., both parents born in Sweden, or; one parent born in Sweden and one parent born outside Sweden, or; both parents born outside Sweden), and parental education (primary school, highschool, university) interaction analyses were also performed. For these analyses, an interaction term between group allocation and country of birth and level of education respectively, was included. A 0.05 level of significance (two-sided) was used for null-hypothesis testing. Additionally, Bayesian analyses were also conducted to create a robust base for scientific inference in terms of the effectiveness of the intervention [129]. All statistical analyses were conducted in RStudio version 4.1.3 (The R Foundation for Statistical Computing).

Sample size and power calculations (Paper II)

Inclusion of 360 participants would provide 80% power ($\alpha = 0.05$) to detect a 0.30 standard deviation (SD) difference in outcomes between groups. This corresponded to e.g., a difference of 25 g in fruit and vegetable intake or a 0.4 kg/m² difference in BMI. A maximum loss to follow-up and/or dropout rate was estimated to 25-30%, based on previous experiences [61,89]. In order to account for this, at least 500 participants needed to be recruited.

Ethics

The MINISTOP 2.0 project (Paper I-IV) was approved by the Swedish Ethical Review Authority (ref no 2019-02747; 2020-01526). For the MINISTOP 2.0 trial (Paper II, Paper IV), written informed consent was collected from all participating parents by the primary child health care nurses prior to baseline assessments and randomization. For the qualitative studies (Paper I, Paper III) parents and nurses received verbal information about the study aims and procedures before providing written informed consent. The verbal information was provided by C Alexandrou together with Somali- and Arabic-speaking bridge-builders and health communicators. Verbal informed consent was also recorded upon the start of each individual interview.

RESULTS

Characteristics of participating parents, children, and nurses (Paper I-IV)

Paper I: Characteristics of informants (parents, nurses) that participated in focus group interviews and individual interviews exploring user requirements for the MINISTOP app, are presented in **Table 2**. Briefly, all parents except for one Swedish-speaking parent were female. The Swedish- (n = 6) and Somali-speaking parents (n = 5) were all born in Sweden and Somalia respectively, while the Arabic-speaking parents (n = 4) were born in Iraq (n = 3) and Syria (n = 1). The number of average years of education was 5.5 years among the Somali-speaking parents (mean age: 34 years), 13.5 years for the Arabic-speaking parents (mean age: 31 years), and 14.5 years for the Swedish-speaking parents (mean age: 36 years). The child health care nurses were on average 47 years old and had an average of 7.5 years of professional experience within primary child health care.

Paper II: Overall, 1399 parents from 19 child health care centers were invited and informed about the study, and 552 parents consented to participate with their child (**Figure 1**). After completion of baseline assessments 277 and 275 parents were randomized to the intervention and control group respectively. There were no statistically significant differences in baseline characteristics between groups, except for a slightly higher intake of vegetables and a lower intake of sweet and savory treats among children in the intervention group. However, this was accounted for as all regression models were adjusted for their respective baseline outcome value. Both groups had low attrition rates (**Figure 1**) with 6.9% in the intervention group and 5.8% in the control group lost to follow-up respectively. Furthermore, only 3.6% of participants in the intervention group and 1.5% of participants in the control group had missing questionnaire data at follow-up. Baseline characteristics of the parents and children participating in the MINISTOP 2.0 trial are presented in **Table 3**. In summary, 71% of parents were born in Sweden, 9% were born in another European country, and 20% were born outside of Europe. Among the foreign-born parents, 32% were from North Africa and the Middle East, 19% from Sub-Saharan Africa, and 17% from Central Europe. Almost all (97%) participating children were born in Sweden, however, on a household level, 24% of children had two foreign-born parents. Furthermore, 73% of children were 2.5 years and 23% were 3 years at baseline. Finally, 74% of children were classified with normal weight, 16% with overweight, 5% with obesity and 6% with underweight.

Paper III: When exploring user experiences and feasibility of the MINISTOP 2.0 app parallel to the ongoing MINISTOP 2.0 trial, the interviewed parents (n=24; 23 mothers, one father) were Swedish- (n = 9), Somali- (n = 9), Arabic- (n = 5) or English-speaking (n = 1). All Somali speaking parents (n = 9) were born in Somalia, while the Arabic speaking parents (n = 5) were born in different countries (Egypt, Iraq, Lebanon, Morocco, and Syria). Level of education ranged from two up to 22 years (mean: 12.5 years of education). Parents were between 22 and 53 years old (mean: 36 years) and number of children ranged from one up to seven children (mean: 3 children). Nurses (n = 15) were between 34 and 58 years old (mean: 43.7 years) and their years of working experience within the profession ranged from one up to twelve years (mean: 7.1 years).

Paper IV: The cost-consequence evaluation for the MINISTOP 2.0 intervention was based on the MINISTOP 2.0 randomized controlled trial. Thus, for participant characteristics, see **Table 3**.

User-requirements for refinement of the MINISTOP 2.0 intervention (Paper I)

Overall, four themes were identified in the data collected through focus group interviews with parents speaking Somali, Arabic and Swedish and individual interviews with Swedish primary child health care nurses (**Figure 4**). A full version of the themes is available in Paper I. **Table 2** presents a summary of the participating parents and nurses characteristics.

Table 2. Characteristics of participating parents¹ and child health care nurses (Paper I).

	Somali Focus Group (n = 5)		Arabic Focus Group (n = 4)		Swedish Focus Group (n = 6)	
	Mean	Range	Mean	Range	Mean	Range
Age (years)	34	23 - 41	31.2	29 - 34	35.8	30 - 42
Education (years)	5.5	1 - 11	13.5	12 - 15	14.5	14 - 15
Years in Sweden	9.8	6 - 19	8.7	6 - 14	-	-
Number of children	5.2	2 - 7	1.3	1 - 2	1.3	1 - 3
Enrolled with one or more children in Swedish daycare (years)	6.8	2 - 16	1.3	1 - 1.5	2.1	1.5 - 4.5
Child health care nurses (n = 15)						
	Mean	Range				
Age (years)	46.9	34 - 61				
Years in the profession	7.5	1.5 - 15				

¹All parents in the Swedish- and Somali-speaking focus groups were born in Sweden and Somalia respectively. In the Arabic-speaking focus group, three of the parents were born in Iraq, and one parent in Syria. Additionally, all participants, except for one parent in the Swedish focus group, were female.

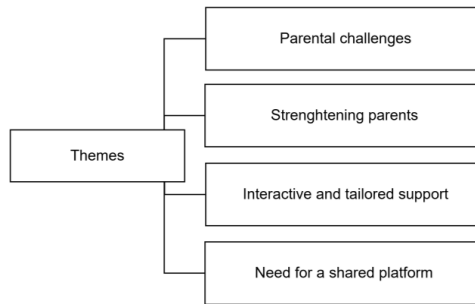


Figure 4. Overview of the four main themes identified in the data from the focus group interviews with parents speaking Somali, Arabic and Swedish, and the individual interviews with child health care nurses (Paper I).

Themes I-IV (Paper I) – a brief summary

The first theme “*Parental challenges*” revolved around the challenges parents expressed in relation to promoting healthy diet and physical activity behaviors in their children. Despite already receiving information from primary child health care, parents expressed a need for more parental strategies and support on how to promote healthy eating behaviors in their children. Parents also expressed worrying about their child not eating enough, as well as difficulties balancing different food cultures. In the second theme “*Strengthening parents*”, nurses underlined the importance of targeting parents early with information promoting healthy lifestyle behaviors in order to strengthen them in their parenting role. Nurses also discussed how parents often struggled with setting boundaries for healthy eating. At the same time, healthy lifestyle behaviors and BMI was expressed as a sensitive topic to talk about with parents. Nurses also connected parental feeding practices such as pressure-to-eat, with a limited knowledge on portion sizes for small children among parents. The third theme “*Interactive and tailored support*” summarized user requirements expressed among both parents and nurses. In addition to information and strategies for healthy lifestyle behaviors, parents were also interested in receiving information supporting parental mental health and wellbeing, but also an app that would follow their child’s development with age-appropriate information, starting already from infancy. Finally, parents also brought up the importance of being able to access the information in the app through alternative modes of delivery (e.g., audio/video) when having limited literacy. The fourth theme “*Need for a shared platform*” went beyond the features in the app and focused on the possible benefits of a shared platform for parents and nurses to use together. Nurses discussed the potential of tailoring their advice and support to families, by following their registrations on health behaviors. If such a shared digital tool also was available in different languages it would further facilitate communication with parents.

Intervention effectiveness on children's health behaviors (Paper II)

Children's health behaviors (primary outcomes)

The effect of the intervention on primary outcomes are presented in **Figure 5**. At follow up, statistically significant positive effects were observed on mean intakes of sweet and savory treats (-6.97 g/day; 95% CI -11.14 to -2.81; $p=0.001$), sweet drinks (-31.52 g/day; 95% CI -49.05 to -13.98; $p<0.001$) and average time spent in front of a screen (-7.00 min/day; 95% CI -12.46 to -1.55; $p=0.012$). For MVPA (-4.14 min/day; 95% CI -12.83 to 4.54; $p=0.349$) and intake of vegetables and fruits/berries at follow-up (9.69 g/day; 95% CI -1.75 to 21.15; $p=0.097$) no statistically significant effect was observed. However, when intakes of vegetables and fruits/berries were analyzed separately, there was a small statistically significant positive effect on the intake of vegetables (2.91 g/day; 95% CI 0.02 to 5.79; $p=0.049$). The effect of the intervention on outcomes did not differ depending on parental country of birth or education, with the exception of an interaction between parental country of birth and group allocation, where the intervention had a statistically significant positive effect on children's intake of sweet and savory treats (-10.90 g/day; 95% CI -21.00 to -0.79; $p=0.036$) when both parents were born outside of Sweden.

Results from Bayesian analyses further supported the effect of the intervention on primary outcomes (Additional file 2: Figure S2; Paper II). In summary, the probability of the intervention having any effect on the intake of fruit and vegetables compared to the control group was 94.6%. Similarly, for intakes of sweet and savory treats, the probability of the intervention having any effect was 99.9%, while the probability of an intervention effect for sweet drinks was $\geq 99.9\%$. Finally, the probability of an intervention effect on MVPA and screen time was 82.4% and 99.3% respectively, compared to the control group.

PSE (secondary outcome)

The intervention effects on PSE are presented in **Figure 5**. Compared to the control group, parents in the intervention group reported a statistically significantly higher PSE score for promoting healthy diet behaviors (0.34; 95% CI 0.09 to 0.59; $p=0.008$) and physical activity behaviors (0.31; 95% CI 0.08 to 0.55; $p=0.009$) at follow-up. The total PSE score was also statistically significantly higher in the intervention group at follow-up (0.91; 95% CI 0.26 to 1.55; $p=0.006$).

Children's BMI (secondary outcome)

The quantile regression analyses revealed no statistically significant effect on children's BMI z-score at follow-up (50th percentile: 0.0; 95% CI -0.09 to 0.09; and 90th percentile: 0.04; 95% CI -0.03 to 0.11; both $p > 0.05$).

Attrition and sensitivity analyses

After modelling baseline characteristics against the reason for missing follow-up data, no associations between baseline characteristics and missing data at follow-up were observed. Similarly, no associations were observed when missingness for each primary outcome was modelled separately. Furthermore, findings from normal regression and Bayesian analyses on imputed data were not different from the findings from normal regression and Bayesian analysis on complete cases, for all outcomes (Additional file 3: Table S1; Paper II).

App usage and satisfaction

Objective analytics data revealed a relatively high parental engagement with the registration feature in the app; on average, parents registered their child's lifestyle behaviors 1.04 ± 1.94 days/week. Moreover, self-reported data on app usage (**Table 4**) revealed that 79% of parents fully agreed to somewhat agreed that they were satisfied with the app; 76% of parents fully agreed to somewhat agreed that the app had given them insight into their child's diet and physical activity behaviors; and 65% of parents fully agreed to somewhat agreed that the app had supported them in promoting healthy lifestyle behaviors. In terms of app usage, 54% of parents reported that they had used the app once a week or more, while 67% reported that they had partaken in the majority of the themes (≥ 7 -8 themes).

Table 3. Baseline characteristics of participating parents and children (n=552).

	All		Intervention		Control	
	N	% or M (SD) ¹	N	% or M (SD)	N	% or M (SD)
Parental characteristics²						
Age (years)	539	34.1 (5.0)	270	34.0 (4.9)	269	34.1 (5.1)
Female	428	78.8	218	80.4	210	77.2
Male	115	21.2	53	19.6	62	22.8
Education (%)						
Primary school (≤ 9 years)	27	5.0	15	5.6	12	4.4
Highschool (12 years)	177	32.6	81	30.0	96	35.3
University	338	62.4	174	64.4	164	60.3
Country of birth (%)						
Sweden	390	71.3	200	73.0	190	69.6
Europe	50	9.1	27	9.8	23	8.4
Outside of Europe	107	19.6	47	17.2	60	22.0
BMI (kg/m ²)	532	25.5 (5.0)	265	25.5 (5.1)	267	25.5 (4.8)
PSE total score ³	543	22.5 (4.6)	271	22.7 (4.8)	272	22.3 (4.3)
PSE diet	543	7.7 (1.7)	271	7.7 (1.8)	272	7.6 (1.6)
PSE physical activity	543	7.8 (1.7)	271	7.9 (1.7)	272	7.8 (1.7)
PSE screen time	543	7.0 (2.1)	271	7.2 (2.2)	272	6.9 (2.0)
Children's characteristics						
Boys	279	50.5	131	47.3	148	53.8
Girls	273	49.5	146	52.7	127	46.2
2.5 years at baseline (%)	403	73.0	203	73.3	200	72.7
3.0 years at baseline (%)	149	27.0	74	26.7	75	27.3
Country of birth (%) ⁴						
Sweden	535	97.4	270	97.8	265	97.1
Europe	6	1.1	3	1.1	3	1.1
Outside of Europe	8	1.5	3	1.1	5	1.8
BMI (kg/m ²)	549	16.8 (1.5)	277	16.9 (1.5)	272	16.8 (1.5)
2.5 years	401	16.8 (1.4)	203	16.9 (1.4)	198	16.7 (1.4)
3.0 years	148	16.7 (1.9)	74	16.7 (1.9)	74	16.8 (1.9)
BMI z-score (SD) ⁵	549	0.47 (1.0)	277	0.51 (1.0)	272	0.43 (1.0)
BMI classification (%) ⁶						
Thinness (I, II)	32	5.8	14	5.1	18	6.6
Normal weight	404	73.6	200	72.2	204	75.0
Overweight	88	16.0	50	18.0	38	14.0
Obesity (I, II)	25	4.6	13	4.7	12	4.4
Vegetables and fruit/berries (g/day)	541	214.7 (74.8)	270	220.3 (74.5)	271	209.2 (74.9)
Vegetables (g/day)	541	43.7 (19.4)	270	46.2 (18.7)	271	41.1 (19.7)
Fruit/berries (g/day)	541	171.1 (64.8)	270	174.1 (65.1)	271	168.0 (64.5)
Sweet and savory treats (g/day)	541	24.4 (26.0)	270	21.9 (24.1)	271	26.8 (27.5)
Sweet drinks (g/day)	543	87.7 (124.1)	271	82.5 (127.6)	272	92.8 (120.5)
MVPA (min/day)	539	117.7 (57.0)	269	114.9 (58.2)	270	120.4 (55.9)
MVPA, weekday (min/day)	541	118.7 (61.2)	270	116.2 (62.6)	271	121.2 (59.8)
MVPA, weekend (min/day)	540	114.9 (57.2)	270	112.0 (57.3)	270	117.8 (57.1)
Screen time (min/day)	541	70.0 (39.7)	270	67.2 (39.1)	271	72.8 (40.1)
Screen time, weekday (min/day)	542	62.3 (39.2)	270	59.8 (38.4)	272	64.9 (39.8)
Screen time, weekend (min/day)	541	89.6 (49.1)	270	85.9 (49.7)	271	93.2 (48.3)

Abbreviations: M, mean; SD, standard deviation; PSE, parental self-efficacy; BMI, Body Mass Index; MVPA, moderate-to-vigorous physical activity.

¹Characteristics presented as percentages (%) or as mean and standard deviation (M \pm SD).

²Characteristics of the participating parent, i.e., the parent that filled out the baseline questionnaire and activated and used the MINISTOP 2.0 app on their mobile phone, if randomized to the intervention group.

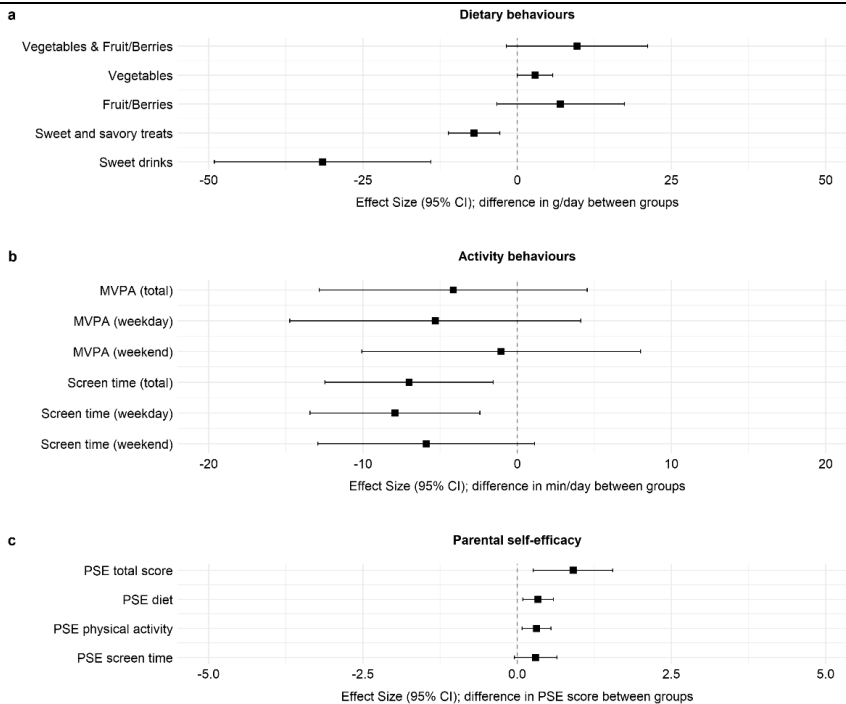
³Mean PSE score for promoting healthy lifestyle behaviors (diet, physical activity, screen time). Score range for each question: 1-10 [122].

⁴When considering country of birth for the whole family (i.e., also parents), 61.2% of children had parents that were both born in Sweden, 23.6% had two foreign-born parents, and 15.2% had one parent that was born in Sweden and one foreign-born parent.

⁵BMI standard deviation scores (BMI z-scores) calculated using the extended international age and sex specific body mass index (IOTF) cut-offs by Cole and Lobstein 2012 [120].

⁶BMI classification according to Cole and Lobsteins revised cut-offs 2012 [120]: Thinness II, ISO-BMI <17.0 kg/m²; Thinness I, ISO-BMI =17.0-18.5 kg/m²; Normal weight, ISO-BMI = 18.5-24.9 kg/m²; Overweight, ISO-BMI = 25.0-29.9 kg/m²; Obesity I, ISO-BMI = 30.0-34.9 kg/m²; Obesity II, ISO-BMI = 35.0-39.9 kg/m².

Figure 5. Results from the complete case analysis (n=503) showing the effect of the intervention on primary and secondary outcomes at follow-up. The effect of the intervention on primary outcomes is shown in a) vegetables and fruit/berries, sweet and savory treats, and sweet drinks (g/day), and in b) moderate-to-vigorous physical activity (MVPA) and screen time (min/day) whereas c) shows the effect of the intervention on the secondary outcome parental self-efficacy (PSE) for promoting healthy lifestyle behaviors at follow-up. All models were adjusted for the respective baseline outcome, the child's sex and age at baseline, and random intercepts were added for child health care center site.



	Complete case analysis		
	N	Coefficient (95% CI)	P value
Vegetables and fruit/berries (g/day)	501	9.69 (-1.75 to 21.15)	0.097
Vegetables (g/day)	501	2.91 (0.02 to 5.79)	0.049
Fruit/berries (g/day)	501	7.02 (-3.32 to 17.36)	0.183
Sweet and savory treats (g/day)	501	-6.97 (-11.14 to -2.81)	0.001
Sweet drinks (g/day)	503	-31.52 (-49.05 to -13.98)	<0.001
MVPA (min/day)	498	-4.14 (-12.83 to 4.54)	0.349
MVPA, weekday (min/day)	499	-5.31 (-14.74 to 4.12)	0.269
MVPA, weekend (min/day)	501	-1.04 (-10.07 to 7.99)	0.821
Screen time (min/day)	499	-7.00 (-12.46 to -1.55)	0.012
Screen time, weekday (min/day)	502	-7.92 (-13.43 to -2.41)	0.005
Screen time, weekend (min/day)	500	-5.89 (-12.91 to 1.13)	0.099
PSE total score ¹	503	0.91 (0.26 to 1.55)	0.006
PSE diet	503	0.34 (0.09 to 0.59)	0.008
PSE physical activity	503	0.31 (0.08 to 0.55)	0.009
PSE screen time	503	0.30 (-0.05 to 0.64)	0.089

Abbreviations: CI, confidence interval; MVPA, moderate-to-vigorous physical activity; PSE, parental self-efficacy.

¹Mean PSE score for promoting healthy lifestyle behaviors (diet, physical activity, screen time). Score range for each question: 1-10 [122]

Table 4. Participating parents' (n=154) self-reported satisfaction and usage of the MINISTOP 2.0 app.

	Fully agree	Agree	Agree to some extent	Disagree	Strongly disagree	Do not know		
Questions, acceptability:	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
I am satisfied with the app	31 (20.1)	56 (36.4)	35 (22.7)	13 (8.4)	8 (5.2)	11 (7.1)		
The app has given me insight into what my child's diet and activity habits look like	35 (22.7)	42 (27.3)	40 (26.0)	16 (10.4)	5 (3.2)	16 (10.4)		
The app has supported me in creating healthy diet and activity habits for my child	31 (20.1)	34 (22.1)	35 (22.7)	22 (14.3)	11 (7.1)	21 (13.6)		
It was easy to understand the features in the app	83 (53.9)	48 (31.2)	8 (5.2)	3 (1.9)	1 (0.6)	11 (7.1)		
I perceived the content in the app as factually correct	82 (53.2)	52 (33.8)	5 (3.2)	1 (0.6)	0 (0.0)	14 (9.1)		
I found the diet and activity registration feature in the app helpful	36 (23.4)	34 (22.1)	33 (21.4)	15 (9.7)	18 (11.7)	18 (11.7)		
I received useful tips/information from the messages/push notifications	28 (18.2)	49 (31.8)	36 (23.4)	13 (8.4)	8 (5.2)	20 (12.9)		
I would recommend other parents to use the MINISTOP 2.0 app	30 (19.5)	40 (26.0)	35 (22.7)	18 (11.7)	9 (5.8)	22 (14.3)		
	Everyday	More than three times per week	Two-three times per week	Once weekly	Two-three times per month	Once per month	Less than once per month	Never
Questions, app usage ¹ :	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
How actively did you use the app?	3 (2.2)	31 (22.3)	17 (12.2)	24 (17.3)	21 (15.1)	14 (10.1)	25 (18.0)	4 (2.9)
	All 13 themes	11-12 themes	9-10 themes	7-8 themes	5-6 themes	3-4 themes	1-2 themes	None
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
How many themes did you take part of? ²	38 (27.3)	14 (10.1)	18 (12.9)	23 (16.5)	22 (15.8)	13 (9.4)	5 (3.6)	6 (4.3)

¹n=139

²The MINISTOP 2.0 app included 13 themes with information, practical tips, and strategies for promoting healthy diet, physical activity, screen time, sleep and dental care behaviors for children aged 2-3 years.

User-experiences, feasibility, and acceptability of the MINISTOP 2.0 intervention (Paper III)

Paper III explored user experiences and feasibility of the MINISTOP 2.0 app-based intervention app among parents and child health care nurses. Two themes, based on two sub-themes respectively, were identified in the analyses (**Figure 6**). Overall, findings indicated that the app was well accepted and appreciated among parents as it increased knowledge and awareness around current health behaviors. Furthermore, evidence-based information available in one place and from a trusted source was highly valued, especially when living in a country with a different culture than your own. The app was also identified as a feasible support tool, and a suitable complement to the standard care offered during visits. Finally, due to the accessibility in different languages and the possibility of disseminating the app at scale, both nurses and parents described the app as an appropriate tool for reaching larger populations of parents as well as parents in need of additional support. **Table 5** includes extra citations from the interview transcripts that were not included in the manuscript.

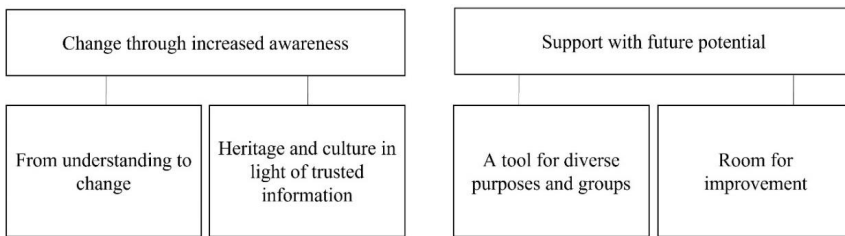


Figure 6. Overview of the themes and sub-themes.

Change through increased awareness

The app facilitated behavior change among parents through increased awareness, and, depending on previous experiences and current health behaviors, the app enabled insights into habits grounded in cultural background and heritage. Further, having support from an evidence-based tool was experienced as valuable and facilitated both trust and behavior change.

From understanding to change

A red thread throughout the interviews were the parents' perceptions of insight in relation to their family's current diet and physical activity behaviors after using the app. The app contributed to increased knowledge and insight that led to many smaller changes in everyday behaviors such as learning to identify healthier foods in the supermarket, increasing the intake of vegetables during meals, drinking water instead of sweetened

drinks, decreasing the frequency of intake of sweet treats, as well as keeping a more mindful disposition of time spent in front of screens and in active play during the day. Although some parents perceived themselves as already knowledgeable, using the app was still described as worthwhile, as it brought both new inspiration and useful repetition. Others expressed how the app had provided insight on for example dietary behaviors they had carried forward, not being aware that these were unhealthy.

“So, I used to give him different kinds of treats during the day, and I used to feel that it’s okay. But after using this app, it helped me understand some things that I used to do were not good for his health. Like giving him biscuits every day ... because biscuits contain sugar, and that is not okay.”
(Arabic/English-speaking mother, 28 years)

Visualization of lifestyle behaviors was expressed as both valuable and necessary to improve habits and parents shared how the registration feature increased awareness of what their children ate by making it more concrete. Specifically, registration in combination with supporting information provided an opportunity to work with and adjust current behaviors. For some, registration provided more structure to everyday life, however, daily, or long-term registration was not necessary for positive insights or new routines. Reaching the recommendation by the end of the week was motivating and described as a receipt for having healthy behaviors. Even so, not reaching the recommendations was sometimes also perceived as helpful, as it led to increased awareness over the behavior and subsequent change. Likewise, registration of “bad days” provided insight and was described as a strong motivator to do better.

“It was a bit painful, but in a good way I think, when it turned red [goal not reached]. It made you think ‘yes, but now it’s time to get it together’.”
(Swedish-speaking mother, 39 years)

Furthermore, the tone in the feedback messages, where positive reinforcement was used instead of pointers, was also described to facilitate behavior change. Nevertheless, the registration feature was not appreciated by everyone; some had mixed feelings, but thought it was good that the opportunity existed, others perceived it as stressful or unnecessary for behavior change and felt more affected by the information in the app.

Using the information feature was described as developing; it provided a good foundation of knowledge that led to new routines around food intake and eating behaviors as well as a sense of having control. The app was also appreciated for its holistic approach, where it both increased knowledge and awareness on health behaviors through general information, but also provided tips and strategies on how to set healthy boundaries and handle challenging situations.

Moreover, parents appreciated the novelty of the comprehensiveness of the app, i.e., that it gathered relevant information about health behaviors for preschool-aged children that otherwise would require visiting many different webpages, and how that also facilitated learning and understanding. Access to trustworthy information in one place was also appreciated by the nurses, who brought up how common it was for parents to search for information online, sometimes ending up on pages with questionable content.

“Overall, it felt like the app was very thought through. There was not only [information] about “this is good to eat”, but you also got suggestions ... if the child was not interested [in food, vegetables etc.], how to proceed and so on.”

(Swedish-speaking mother, 37 years)

Although parents in general had a good understanding of healthy and unhealthy foods, parents expressed a need for relevant information and examples regarding age-appropriate portion sizes, and healthy quantities of sweet and savory treats, and sweet drinks. Thus, for some, information about learning, understanding, and trusting the child's hunger and satiety cues in combination with portion picture examples, increased awareness; for others it confirmed that the child was eating enough and helped reduce worries when eating meals perceived as too small by the parent. Moreover, strategies for healthy eating behaviors, such as starting with a smaller portion instead of serving a large portion at once, was also expressed as valuable knowledge that provided relief.

“For example, in the mornings, before I had used this app, my daughter has a hard time eating in the morning. When she didn't eat anything [breakfast] before preschool, I used to worry and think ‘maybe she's really hungry’. But when I read in the app that if the child is alert and playing, then it's fine.”

(Somali-speaking mother, 35 years)

Depending on previous knowledge, the physical activity content in the app also influenced parents on different levels. For instance, not everyone were aware of the recommendation on physical activity for 2-to-3-year-old children and described this information as helpful, as it made them more mindful about this. Others were inspired by the age-appropriate tips on active play for children and appreciated the tips on how to be more active together with their child.

“I also thought that [the information on] active play was very good. That you got a little bit about ‘what is active play’? And ‘what counts as active play’? After all, you want your child to be active and healthy. And here, you got something to relate to.”

(Swedish-speaking mother, 36 years)

Further, the tips on active indoor play were described as especially inspiring and novel. Through information and video-examples, the app helped normalize active indoor play and shift the parents' level of tolerance regarding this, and parents described how they consciously began allowing and enabling more active indoor play because of this.

Heritage and culture in light of trusted information

The app included features to reach, inform and inspire parents, and depending on heritage and cultural background the app influenced awareness on different levels. For some of the parents, insights acquired from the information in the app generated discussions on the importance of receiving information from a trusted source to be able to identify sub-optimal health behaviors that were common in their culture, but also to keep the habits that were good. As parents often relied on information from within their own social or cultural circle, i.e., from individuals with the same way of life and similar food and eating behaviors as themselves, information from a trusted source was described as a prerequisite for questioning one's habits and heritage. Parents also expressed how they had gained increased awareness regarding common practices for healthy diet and eating behaviors in their culture compared to research-based recommendations after using the app and highlighted how this was both motivating and reassuring when making lifestyle changes.

"Before [using the app], you didn't have much knowledge or experience, and you felt quite new. But after watching the videos, you feel like you have knowledge to base your actions on. And that's more motivating ... that your actions are now based on knowledge and facts".

(Somali-speaking parent, 36 years (with interpreter))

Nurses also expressed a need to bridge and be able to communicate better with parents around common cultural dietary behaviors and practices in relation to evidence-based recommendations. Reaching through to parents when there were linguistic barriers was described as challenging. Furthermore, recommendations and information adapted to the Swedish way of eating and living, inflicted additional communication challenges. Thus, having access to a translated evidence-based support tool, where parents had the opportunity to read through and process the information in their own pace was described as a possible means to bridge certain cultural differences.

"So [for parents] from other cultures, you live in a different way, and it will be very difficult if you have to fully adapt, as I think maybe you think differently about breakfast, lunch, dinner, snacks, that it might be harder for them to comply ... because it's a little different from how they live culturally."

(Child health care nurse, 34 years, 5.5 years in profession)

Further, nurses also discussed how early introduction of sweets and sweet drinks was more common and acceptable in some cultures, but also difficult to approach and influence during the short time of the visit at the child health care center. Nurses also underlined how socioeconomic vulnerability was a strong predictor and influencer of lifestyle behaviors; however often also conjoined with being new to the country. In line with this, parents also described how it was common and accepted in their culture to give children sweet treats and sweet drinks both more frequently and from a young age and suggested the app could be useful for increasing knowledge about this.

“Because if I think about my children, that they weren’t allowed to eat anything sweet until they were a year old, even maybe a little longer. But if I were new to the country ... or just arrived in Sweden, then I would accept the idea that “Yes, but it doesn’t matter that they get sweets already from six months ... we have that in our culture, that you should ... the children should get to taste everything to get used to it later.”

(Arabic/Swedish-speaking mother, 33 years)

Support with future potential

The app was acknowledged as a preventive tool with potential for reaching diverse groups and purposes. It could be disseminated nationally through child health care to reach all parents, but also to reach specific population groups that would benefit from additional support. From a health promotive perspective, the app had room for improvement in terms of functioning as a more long-term support of parents, starting from infancy with healthy food introduction.

A tool for diverse purposes and groups

Parents talked about the preventive potential of the app, and how it could fill the need for reaching families early with supportive health behavior information on a population level. Dissemination of the app through child health care was viewed as both important, relevant, and logical as they reach most families. Child health care was also described as the most natural forum to turn to for support regarding questions on child nutrition and development and parents acknowledged the app to be especially useful for first-time parents or for parents that in general felt unsure about healthy lifestyle behaviors.

“I think that this [the app] is a good first effort to both identify and visualize certain patterns that often are quite easy to correct.”

(Swedish-speaking mother, 39 years)

Notably, parents highlighted that dissemination through child health care would benefit the use of the app, as most parents had high trust in them,

and a recommendation from them carried weight. Although some parents were open to also use the app if it was offered through other more commercial channels or forums, a connection with child health care was preferred.

"I would prefer for the app to be offered through child health care, because that would catch my interest more, that 'oh, maybe this is something very important for my child' ... it feels safer when offered through them."

(Somali-speaking mother, 37 years (with interpreter))

The preventive potential of the app was further confirmed by the nurses who discussed the benefits of having an evidence-based digital support tool as a complement to their daily practice. The content in the app was expressed as already in line with the message that primary child health care strives to convey, and thus it would be an advantage both for parents and nurses in the long run if everyone gained access to the app. Further, nurses acknowledged the need for supportive information about healthy eating behaviors as many parents worried about this and the app would be an appropriate support to offer parents in addition to the conversations about healthy dietary behaviors during the visits. However, the app would not replace the nurses' conversation, instead it would be something to use at home for deepened knowledge and insight. Both nurses and parents viewed the information in the app as equivalent to the information in the health conversations, albeit more comprehensive and accessible when needed.

"It's almost like we would stand behind them [the parents] a little bit every day for a period, I think, by getting the app. Because it's hard to absorb everything we [child health care nurses] say when they're here for a short visit and the kids are all over the place. So, I absolutely think that it [the app] can be a good complement, because it is evident that you can't change anything after a short conversation."

(Child health care nurse, 38 years, 12 years in profession)

Apart from prevention, suggestions for expanded use of the app as part of child obesity treatment programs were expressed among both groups of informants. However, nurses also discussed the organizational challenges of using the app for treatment purposes, as that would require additional education, time, and resources. Regardless, the opportunity for follow-up of health behaviors and BMI by using the app as common ground for conversation, feedback, and advice during visits was highlighted as beneficial from a treatment perspective. The need for a practical and accessible digital tool to offer families where the child had overweight or obesity was also underlined due to the perceived lack of such support tools, where the registration feature especially, was mentioned as potentially beneficial. Registration could also provide opportunity for the nurses to follow the family's

entries through the caretaker interface and based on that, target and support the family's current needs.

"You could then use it as a tool to say 'download this app, and then you use it for a couple of months, and then we'll meet. And then we can look together at what changes you have made and what it has led to' and so on."

(Child health care nurse, 56 years, 2.5 years in profession)

"It would be good [registration linked to child health care center] because then the nurse can see how the child is eating. It would be beneficial for the child's health."

(Somali-speaking mother, 37 years (with interpreter))

Both informant groups described the accessibility of the app in different languages as a valuable addition for primary child health care; speaking another language should not be a barrier for accessing information available to everyone else. Further, the increased future possibilities of reaching parents in need of an interpreter during the visits was brought up as especially valuable by the nurses, as informing about healthy lifestyle behaviors took longer time when a third part was involved. Most importantly, the app included a feature which enabled parents with limited literacy to also access the information content in the app through videos. Parents also expressed appreciation for this feature and shared how they had preferred watching the content in the app instead of reading it, as that was difficult for them. Even so, nurses also described a large interest in using the Swedish language version of the app among migrant parents that had begun learning Swedish. Thus, having both options was helpful.

Room for improvement

Suggestions of how the health promotive potential of the app and its features could be improved were also expressed among both groups of informants. Parents expressed a strong interest in using an app that would follow their child's development throughout childhood, and not be limited to the preschool years. Additionally, both parents and nurses discussed the potential benefits of using/offering the app already from birth, as a support for healthy food introduction. Further, different ages were associated with different challenges, and thus there was a need for age-relevant and supportive information for all developmental stages during childhood. Parents for example discussed how older children were naturally more open to impressions from peers and the outside world in general, and how that posed additional challenges when setting boundaries for e.g., healthy diet and screen time behaviors. Therefore, access to information and strategies on how to maintain healthy habits as the child grew older were important.

“Most three-year-olds are quite intense and energetic, but then you enter another [phase]. When the children are five, six years old, maybe there will be an increased inactivity, and above all an increased availability of screens for example. There might also be a need to boost and get a little more [support] on how to handle these habits.”

(Swedish-speaking mother, 39 years)

Some parents expressed a need for access to the app in its present form, for a longer period than the current six months, as the time needed for behavior change was individual. Having supportive information and tips to go back to for inspiration was considered helpful and parents requested being able to visit the app freely from time to time when needed. The opportunity of continued use of the app could also result in a different, more relaxed use, when knowing how features like the registration worked, and that it was available for a longer time.

“It would be great for us to know ... well, that you can keep it, that it doesn't have to be for a specific period.”

(Somali-speaking mother, 22 years (with interpreter))

Another suggestion for improvement was making the app even more interactive to keep parents interested and motivated throughout the intervention period. Thus, although the regular content updates every two weeks was expressed as enough among some parents, others requested more frequent updates. Parents described that if they felt like they gained something new every time they entered the app, like for instance a recipe for a healthy snack or meal, it would most likely increase the chances of them engaging further with the information and features in the app. Moreover, although parents appreciated the parenting advice and strategies already available in the app, these were also described as focused on diet and activity behaviors. As children's psychosocial development was perceived as equally important but also strongly linked to their physical health, inclusion of parental strategies in general was suggested. Overall, parents were curious and expressed a need for more information and support regarding parenting and parenting styles in general, i.e., how to be with your child as well as how to be more involved and promote your child's emotional and psychosocial development at different ages.

“You can add more about the emotional and psychological things concerning the health of a child. This would be very helpful, because many parents also struggle with how to connect with their children, and how to behave with their children.”

(Arabic/English-speaking mother, 28 years)

Table 5. Extra citations related to the main findings (Paper III).

Citations related to increased awareness on healthy diet and eating behaviors for children:

"Our children used to drink cordial every day. Only in the afternoons, but every day and it's not...it's unnecessary really."

(Swedish-speaking mother, 38 years, 2 children)

"Because I thought, 'No, but they eat vegetables'. Then when you started registering you saw 'perhaps they don't eat as much as I thought they did'. So, there has been much more fruit and vegetables and berries and so on."

(Swedish-speaking mother, 38 years, 2 children)

"I liked the overall perspective in the app, that you both got facts and concrete tips and then that you got to register yourself. It made it a bit more hands-on."

(Swedish-speaking mother, 36 years, 2 children)

"The information you have in the app is currently nowhere to be found as collected. You didn't have to look up seven different pages to get the information, because it provided both facts and tips. It was so comprehensive, both regarding food and lifestyle in general, screen time and active play. So, this app provided what I had been looking for, all in one place."

(Swedish-speaking mother, 36 years, 2 children)

"I already knew about diet or food, what it means. But what I have learned is the size of the portion to give to the child. Instead of giving a lot at once, giving a little, and then if the child wants more, you can add more."

(Somali-speaking mother, 22 years, 2 children)

"Sometimes it's hard to know how much sugar is ok...now I am more aware about amounts, how much I can give."

(Arabic/Swedish-speaking mother, 38 years, 2 children)

"And if he ate a smaller portion...it's very individual of course, but then you could still feel that 'yes, sometimes you have a day where you eat more and sometimes you eat less'."

(Swedish-speaking mother, 36 years, 2 children)

Citations related to the preventive potential of the app and the dissemination of the app through primary child health care:

"It will be a preventive tool, if it can be offered through child health care services and be available in that way."

(Swedish-speaking mother, 39 years, 2 children)

"Involving child health care is key for people to access the app."

(English-speaking mother, 43 years, 3 children)

"Especially that it's from professionals. Like, when I used to use Google for information, there was a lot of mixed information. Like, at least to learn the basic tips for the healthy living for the children."

(Arabic/English-speaking mother, 28 years, 1 child).

"For myself... when I had my first one [child], I didn't want to listen to just anyone, but from somewhere where I knew the information was safe. When you get this from your child health care center...then you are assured that you get it [right] from the beginning...basic level."

(Arabic/Swedish-speaking mother, 33 years, 2 children)

Intervention cost per participant and on population level at scale (Paper IV)

Table 6 provides a tabular presentation of the costs and consequences for all primary outcomes of the MINISTOP 2.0 intervention. On average it took eight minutes for child health care nurses to introduce and register the family for the MINISTOP 2.0 app at the routine visit at primary child health care, and the salary cost per family was 49 SEK (95% UL: 46, 53) (**Table 6**). The salary cost for the total number of consults (introduction of MINISTOP) was 288 SEK (95% UL: 268, 309) for 2019, 8 276 SEK (95% UL: 7 670, 8 842) for 2020, and 5 216 SEK (95% UL: 4 827, 5 602) for 2021. The total cost of the MINISTOP intervention in the base case analysis was 437 439 SEK (95% UL: 418 993, 455 849) and the total cost of the intervention per participant was 1 579 SEK (95% UL: 1 513, 1 646). Sensitivity analyses were conducted using a 3% discount rate and the total cost of the MINISTOP intervention was then 418 514 SEK (95% UL: 400 761, 435 991) while the total cost of the intervention per participant was 1 511 SEK (95% CI: 1 447, 1 574) (Supplementary Table 1; Paper IV).

Figure 7 illustrates a comparison of the total cost for the MINISTOP 2.0 intervention in relation to six other childhood obesity interventions in preschool-aged children [130–135]. The total cost per child in the MINISTOP 2.0 trial was 1 579 SEK, which was the second lowest cost per child. The only intervention with a lower total cost per child was the Chat-SMS intervention [131], which was a short message service (SMS) delivered intervention. Noteworthy, in the MINISTOP 2.0 trial, the percentage of salary costs for staff to introduce and register families for the app was only 9% in relation to the total intervention cost per family. In comparison, the salary costs for staff in the other six interventions was: 69% (HBT); 80% (POI-Comb); 75% (Nourish); 51% (INFANT); 92% (Chat-Tele); and 56% (Chat-SMS).

Table 6. Cost-consequence results for the MINISTOP 2.0 intervention [136] in Swedish krona¹.

	Comparison		Intervention	
	Mean (SEK)	95% UL	Mean (SEK)	95% UL
MINISTOP app and interface up-keep total cost (2019-2022)	N/A	N/A	400 196	381 969, 418 149
Salary cost for training of CHC nurses to use MINISTOP ²	N/A	N/A	23 464	21 808, 25 068
Salary cost for the CHC nurse to provide MINISTOP at the routine visit to one family ³	N/A	N/A	49	46, 53
Cost for the total number of consults per year for MINISTOP at CHC ^{3,4}				
2019	N/A	N/A	288	268, 309
2020	N/A	N/A	8276	7670, 8842
2021	N/A	N/A	5216	4827, 5602
Total cost of the MINISTOP intervention ¹	N/A	N/A	437 439	418 993, 455 849
Total cost of the MINISTOP intervention per participant ¹	N/A	N/A	1 579	1 513, 1 646
MINISTOP 2.0 effectiveness trial, primary outcomes ⁵	Coefficient (95% CI) ⁶		P value	
Vegetables & fruit/berries (g/day)	10.01 (-1.39 to 21.40)		0.085	
Vegetables (g/day)	3.09 (0.20 to 5.98)		0.036	
Fruit/berries (g/day)	7.06 (-3.23 to 17.35)		0.178	
Sweet and savory treats (g/day)	-6.48 (-10.76 to -2.20)		0.003	
Sweet drinks (g/day)	-31.89 (-49.54 to -14.23)		<0.001	
MVPA (min/day)	-3.78 (-12.37 to 4.81)		0.388	
Screen time (min/day)	-7.33 (-12.77 to -1.90)		0.008	

Abbreviations: SEK, Swedish krona; UL, Uncertainty level; CHC, child health care; CI, confidence interval; MVPA, moderate-to-vigorous physical activity.

¹No discount rate applied.

²65 nurses participated in the MINISTOP 2.0 trial and received a one-hour training session from the research team.

³This is based on that MINISTOP takes eight minutes on average, to introduce and register families for the MINISTOP app.

⁴The number of baseline consults per year: 2019 = 6; 2020 = 168; 2021 = 103.

⁵All participants (n=552); Intervention group (n=277); Control group (n=275).

⁶Results from the imputed data analysis of the MINISTOP 2.0 trial. All regression models were adjusted for the respective baseline outcome, the child's sex and age at baseline, and random intercepts were added for child health care center site.

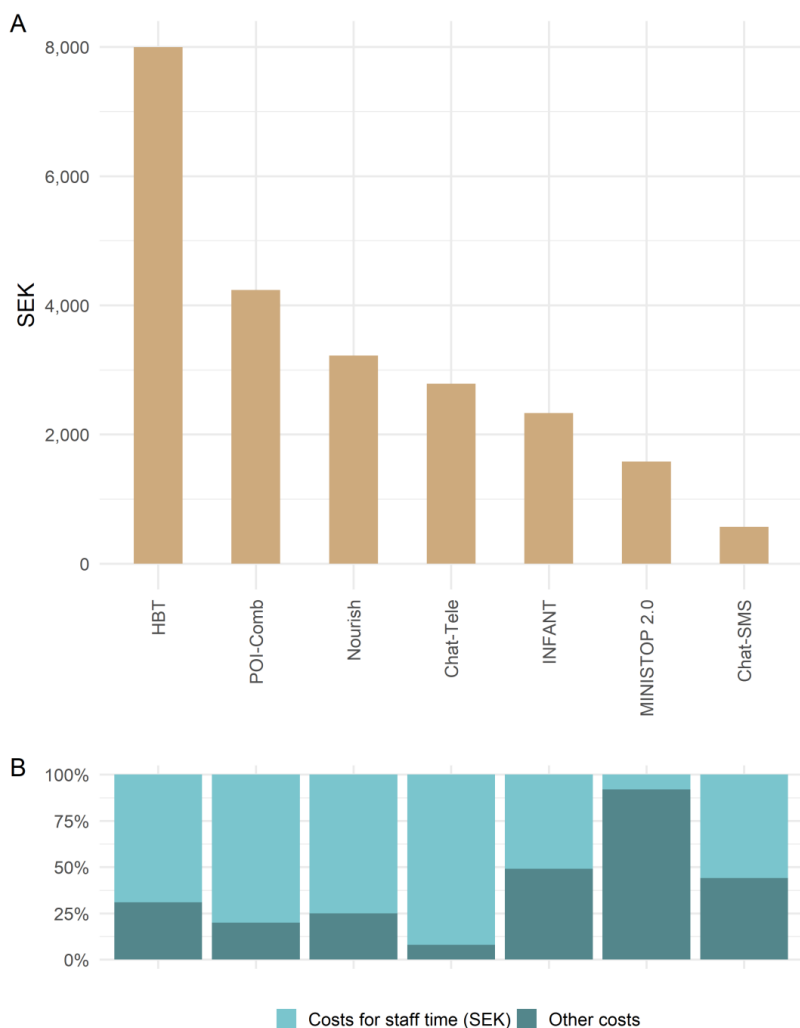


Figure 7. Comparison of the total cost for the MINISTOP 2.0 intervention in relation to similar interventions. A) Total cost per child in the MINISTOP 2.0 trial versus six other childhood obesity prevention trials [130] in the preschool age. B) The costs for staff and other costs, as a percentage of total cost per child for each intervention. Other costs for the MINISTOP 2.0 intervention represent the cost for the app and interface upkeep, while the other studies include equipment and travel costs. The MINISTOP 2.0 intervention only had 9% costs for staff time while the staff cost for the other interventions were: 69% (HBT); 80% (POI-Comb); 75% (Nourish); 92% (Chat-Tele); 51% (INFANT); and 56% (Chat-SMS). The bars in B) follow the same order as in A).

DISCUSSION

This thesis reports the results of the MINISTOP 2.0 project which aimed to investigate the real-world effectiveness of a mHealth intervention within Swedish primary child health care. The MINISTOP 2.0 project was also conducted with the aim to inform and facilitate a future large-scale implementation of the app within the Swedish primary child health care setting, where information about user experiences and implementation aspects such as feasibility, acceptability, and cost of the intervention would also be required. The thesis work was initiated with the development and adaptation of the MINISTOP intervention to other languages (Paper I), followed by the effectiveness-implementation and cost-consequence evaluation within primary child health care (Paper II-IV).

Results discussion

Intervention development: from MINISTOP 1.0 to 2.0 (Paper I)

Overall, the qualitative interviews in Paper I showed that parents shared several challenges related to healthy diet behaviors in their children – for example worrying about their child not eating enough. As worrying may contribute to more controlling parental feeding practices such as pressure to eat, it is an important parameter to target in parental interventions promoting healthy diet and feeding practices in children [137–139]. Findings also highlighted the importance of early introduction of health behavior efforts and interventions to reassure and strengthen parents in their parenting role. Furthermore, the importance of adapting interventions to different languages and cultures was underlined, as language was identified as a common barrier for communication between parents and nurses. Most importantly, although accessibility of the app in multiple languages was important, the information also needed to be accessible for parents with limited literacy. Thus, parents highlighted the need of adding videos or audio-files of the information provided in the themes of the app. Additionally relating to this, nurses also brought up the importance of adding many picture examples for parents with low literacy. Literature also suggest that if mHealth interventions are designed to be accessible for e.g., low-literacy and other vulnerable populations, it could positively influence health literacy [83,140–143]. The findings from the focus group interviews with parents and individual interviews with nurses were used to adapt the MINISTOP 1.0 app into a 2.0 version. These adaptations have also been described in more detail in the methods section of this thesis as well as in the “Implications” section of Paper I [109].

Effectiveness on children's health behaviors (Paper II: primary outcomes)

The MINISTOP 2.0 intervention showed statistically significant positive effects on children's health behaviors at follow-up. Compared to the control group, children in the intervention group had lower intakes of sweet and savory treats and sweet drinks, and less screen time. The intervention showed no statistically significant effect on children's MVPA and intake of fruit and vegetables. However, when analyzing children's intakes of vegetables and fruits/berries separately, children in the intervention group had a small yet statistically significant higher intake of vegetables compared to the control group at follow-up.

As previously mentioned in the discussion of Paper II, there have been no previous evaluations of app-based mHealth interventions promoting healthy lifestyle behaviors in parents of preschool-aged children. Healthy lifestyle behavior interventions comparable to the MINISTOP 2.0 intervention, i.e., targeting parents of preschool-age children through child health care settings, have either been web-based [144,145] or face-to-face delivered [146]. For instance, Van Grieken *et al.* [144] evaluated a web-based intervention where personalized advice was offered to parents prior to visits at health youth centers in the Netherlands at either 18- or 24-months of age. They observed small improvements on children's health behaviors, such as lower intakes of sweet drinks and less screen time when analyzing subgroups of children, however no statistically significant intervention effect was observed for the entire group [144]. Another web-based intervention, developed and evaluated by Helle *et al.* [145] showed that children in the intervention group were more frequently served vegetables and fruits and were less likely to have screen time during meals compared to the control group at follow-up. This intervention delivered online monthly videos of healthy eating over a period of six months, and targeted parents of 6-month-old children in Norway [145]. Noteworthy, our results in terms of the primary outcome screen time, where an effect size of 7 min per day less screen time was reported in the intervention group, is comparable to results from the INFANT trial; a much more resource-intensive and face-to-face delivered intervention [132,146]. Briefly, the INFANT intervention targeted parents of infants aged 4 months and was delivered as 2h-sessions with a dietitian every three months. The intervention group reported 10 min per day less screen time compared to the control group at both follow-ups (2- and 3.5-years post-intervention, i.e., at 3.6 and 5 years respectively) [146]. In summary, although some of the effects on above health behaviors may be viewed as modest, together they suggest a beneficial effect of interventions targeting children's health behaviors, when disseminated to parents through health care settings and health care professionals.

Effectiveness on PSE (Paper II: secondary outcome)

According to social cognitive theory [113], self-efficacy is an important dimension of human agency, and also linked to behavior change. In the MINISTOP 2.0 trial (Paper II), parents in the intervention group reported statistically significant higher PSE for promoting healthy diet and physical activity behaviors in their children at follow-up compared to the control group. As parents are key actors for promoting healthy diet and activity behaviors in children, this was an important finding which also further strengthened the interventions' potential of being an effective support tool. Our results on PSE (Paper II) are also in line with results from other similar studies. For instance, alongside improvements in child feeding pressure-to-eat practices and a reduced intake of discretionary foods, an internet-based childhood obesity prevention program by Hammersley *et al.*, also resulted in improved nutrition self-efficacy among parents in the intervention group [147]. The intervention was directed towards parents of preschool aged children with overweight and obesity and delivered an internet-based healthy lifestyle program over a period of 11 weeks [147]. Moreover, in a kindergarten based randomized controlled trial by Möhler *et al.* [148] PSE was a positive predictor of children's intakes of fruits and vegetables. Derwig *et al.* also observed a positive effect on maternal PSE for promoting healthy physical activity behaviors, following their face-to-face delivered intervention which was a child-centered dialogue also set in primary child health care [149]. Collectively, these findings as well as available literature suggest that targeting PSE may be important for health promotion in children during the preschool years [148,150–152].

Potential explanations for the lack of effect on children's MVPA (primary outcome) and BMI (secondary outcome)

Despite several statistically significant positive intervention effects on children's health behaviors, there was no statistically significant difference for MVPA or children's BMI between groups at follow-up. There are several possible reasons for this. For example, the participating children were only 2.5-to-3-years old. At this age, children have a more intermittent movement pattern [153], which also makes it difficult for parents to estimate MVPA throughout the day. Furthermore, it is also difficult for parents to engage children this young in planned or structured play or activities. Moreover, even though the intervention included information on physical activity, active play, screen time and sedentary behavior, the main focus of the themes in the app was promotion of healthy dietary behaviors.

Children's BMI was defined as a secondary outcome beforehand as changes in children's body weight might take longer than six months i.e., the duration of the intervention, to observe. Furthermore, children from all BMI categories were included in the study, as the primary outcomes were

intervention effects on children's lifestyle behaviors, and not treatment of childhood obesity. Our results on children's BMI are also in line with the results from other primary prevention studies within child health care settings [62,144] where no significant effects were observed on BMI-z score in Swedish 4-year-olds after a child-centered health dialogue within Swedish primary child health care [62], or in 3-year-olds in the Netherlands after parents had received web-based information on healthy lifestyle behaviors prior to health youth center visits [144]. Thus, to conclude, the null effect for BMI was not unexpected. Moreover, improving obesity-related lifestyle behaviours (primary outcome) and PSE can be considered as first steps, as lifestyle behaviours tend to track throughout childhood [154,155]. Consequently, it can be speculated that providing parents with relevant knowledge and tools such as the MINISTOP 2.0 app, may produce beneficial effects on BMI later in childhood; this could also be a topic for future research.

App usage, user experiences and implementation of the MINISTOP 2.0 intervention (Paper II, III)

Objective data on app usage indicated a quite high usage of the registration feature in the app (1.04 ± 1.94 days/week) among participants in the intervention group [136]. This was further supported by questionnaire data assessing the use of the app and its features after the intervention (**Table 4**), where 54% of the responding parents reported using the app at least once per week or more [136]. Moreover, qualitative interview findings (Paper III) from both parents and nurses indicated that the app was regarded a feasible support tool and a suitable complement to the standard care offered within primary child health care. The app was well accepted and appreciated for its comprehensive content, which included relevant, up to date, and evidence-based information in one place. Parents expressed that taking part of the information and registration feature in the app helped increase awareness in terms of healthy diet and physical activity behaviors. This was also in line with findings from another qualitative study exploring user perceptions of mobile health apps, where tracking of health behaviors, especially when presented graphically, was also described to increase awareness [156].

Parents also reported trusting the information in the app, and that dissemination through child health care added another level of trust to the intervention. Further, when living in a country with culturally different child feeding practices, dietary patterns, and customs than your own, being able to trust health information was acknowledged as especially important. These findings were also in line with findings from another qualitative study investigating barriers and facilitators of use of mHealth apps within health care [157], where patients preferred being recommended or prescribed

health apps by their physician as this often meant that the app and its content originated from a trusted source. Notably, the role of health care providers in the adoption of mHealth interventions has previously been discussed [158], and despite the fact that there is a pronounced need for mHealth tools within health care settings, health care professionals may often be hesitant to recommend health apps to patients in their routine practice [158]. This was suggested to be due to professionals being concerned in terms of the clinical effectiveness of mHealth tools [158]. However, when effectiveness is proven, it also facilitates adoption within routine practice [158]. Altogether, the results show high usage of the app among parents and that parents, as well as nurses were satisfied with the app and acknowledged its' potential as a support for promotion of healthy lifestyle behaviours in preschool aged children.

Intervention cost when scaled up on population level (Paper IV)

The total cost for the MINISTOP 2.0 intervention, when disseminated within primary child health care, was 437 439 SEK, while the cost per participating family ($n = 277$) was 1 579 SEK. The intervention cost was particularly low in terms of salary cost for staff, which only represented 9% of the total cost. For comparison, the salary cost ranged from 51% to 92% in other similar childhood obesity prevention interventions (**Figure 7**) [130]. This is also an important aspect to consider; when scaled up, interventions with high salary cost are more expensive compared to interventions with lower salary costs. To illustrate, if the MINISTOP 2.0 intervention was to be disseminated at scale within a middle-sized Swedish region such as e.g., Region Östergötland ($n = 5000$), the cost per child would be much lower (≈ 129 SEK per child), as the major costs for upkeep of the app and interface would be shared by 5000 instead of only 277 children in the study. Although calculated in a hypothetical scenario, this is not a high cost, especially when set in relation to the societal costs for overweight and obesity for Swedish 6-year-old children over a lifetime, which were recently estimated to 2.1 billion SEK for overweight, and 1.8 billion SEK for obesity respectively [159]. Furthermore, evidence suggests that interventions targeting prevention of childhood obesity during the preschool years also may be cost-effective long-term, as they increase the chances of better metabolic health in adulthood through early introduction and maintenance of health behaviors [160]. Moreover, the main acceleration of weight among adolescents with obesity, has also been suggested to occur between 2 to 6 years of age [161], further underlining the importance of health behavior efforts and interventions being introduced early in life.

Methodological discussion

Overall study design

A strength of this thesis (Paper I-IV) was the use of different methods, both quantitative (Paper II, IV) and qualitative (Paper I, III), to assess the effectiveness, feasibility, acceptability, user experiences and cost of the MINISTOP 2.0 intervention. In order to achieve this, the MINISTOP 2.0 project utilized an overarching hybrid type 1 effectiveness-implementation study design [102], where intervention effectiveness was evaluated through a RCT within primary child health care, while implementation aspects were explored qualitatively in both end-users (parents) and implementers (child health care nurses). The use of hybrid study designs [102], where effectiveness and implementation aspects are assessed simultaneously is becoming increasingly common; from a public health perspective they are highly interesting, as they enable faster evaluation and subsequent implementation of interventions within clinical or community-based settings [102]. Hybrid designs may also add another dimension or depth to study results as they often employ a mixed-methods approach [102,162]. The MINISTOP 2.0 project was based on both qualitative and self-reported quantitative outcome data [87]. Although self-reported data often is viewed as a limitation, it should be noted that, while efficacy trials are concerned with internal validity, effectiveness trials are more focused on external validity, i.e., the generalizability of interventions to the desired setting or population [163]. As the efficacy of the MINISTOP intervention had previously been evaluated in the MINISTOP 1.0 trial [89] using objective and accurate methodologies, the focus for this second trial was the evaluation of the intervention within a real-world setting using relevant, time-efficient, and feasible outcome measures [87,136].

Quantitative methods (Paper II, IV)

Paper II: A major strength of the effectiveness evaluation of the MINISTOP 2.0 intervention was the use of a RCT study design. RCT's are considered the gold standard [164] for evaluating intervention effectiveness, as they allow for comparison of outcome results against a comparator intervention or treatment; in our case – against standard child health care. The process of randomizing participants to either a control or intervention group also decreases bias by reducing the differences in baseline characteristics between groups [164]. Thus, randomization increases the chances of the observed intervention effects being attributed to the intervention as opposed to specific participant characteristics. Upon completion of baseline assessments, nurses in the MINISTOP 2.0 trial randomized parents to the intervention or control group using opaque envelopes that had been computer generated (R 3.6.1.) for each study site by the research group; thus, nurses had no influence over which family was randomized to each group. The

randomization was successful, as there were no statistically significant differences in baseline characteristics of the participating parents and children, other than a slightly higher intake of vegetables and lower intake of sweet and savory treats among children in the intervention group. Nevertheless, this difference was accounted for, as all outcomes were adjusted for the baseline value in the analyses. Blinding of participants, assessors, or both, is another strength of RCT study design [164], however, due to the nature of the MINISTOP 2.0 intervention, where nurses registered parents for access to the app through a caregiver interface, blinding of assessors or participants was not possible. Although this in theory, could pose a risk of bias, where nurses could have provided additional information on healthy diet and physical activity behaviors to parents in the control group knowing they would not receive the app, there are no reasons to believe that this occurred. All nurses were pre-trained in the study protocol and to the best of the research team's knowledge they followed all study procedures. Moreover, it is worth mentioning that if this indeed happened, it would have diluted rather than enhanced the intervention effect.

Additional strengths of the MINISTOP 2.0 trial were that all statistical analyses followed a pre-designed analyses plan, carefully designed in collaboration with a statistician and published in a study protocol [87]. Moreover, all analyses were intention-to-treat, and comprehensive attrition and sensitivity analyses were performed to rule out any major biases due to missing data. As 503 families completed follow-up, statistical power to detect differences in outcomes between groups was also reached; in order to reach 80% power ($\alpha = 0.05$), a minimum of 360 participants needed to complete the study [87,136]. Moreover, Bayesian analyses [129] of all outcomes further strengthened our results by creating a robust base for scientific inference for the effectiveness of the intervention. In comparison to classical statistics, Bayesian statistics do not assign the same weight to p-values or reject null hypothesis at a specific level of significance, but rather investigates the probability of the intervention having an effect on outcomes in relation to prior set distributions [165]. As such, the effect of an intervention can also be interpreted more continuously and provide an indication of the strength of the effect, as opposed to simply accepting or rejecting it [165]. Finally, the low attrition rate in the trial (8.9%; Figure 1) is an additional strength worth mentioning. Overall, the reasons for missingness were either due to not attending the follow-up visit at the child health care center (6.4%) or attending the visit but declining to answer the follow-up questionnaire (2.5%).

Paper IV: The cost-consequence analysis of the MINISTOP 2.0 intervention included several strengths contributing to the generalizability of the results to the Swedish general population and primary child health care setting. For instance, the effectiveness outcomes were based on data

collected from 19 child health care centers in six different Swedish health care regions [136]. Further, due to the evaluation of the intervention within the primary child health care setting, the analysis was also based on relevant cost data. This is also the first cost evaluation of a digital support tool within the Swedish primary child health care setting. As such, the digital format of the intervention may facilitate future comparison of costs for similar digital interventions and health care settings. A possible limitation was the retrospective collection of cost data; however, this cost-consequence analysis was made possible after the end of the MINSTOP 2.0 trial thanks to a collaboration with Deakin University. Although the retrospective collection of cost data prevented us from performing a cost-effectiveness analysis, data on costs and consequences has been suggested to be equally informative and are often easier to interpret for decision makers, compared to data on cost-effectiveness [107].

Qualitative methods (Paper I, III)

Methods for data collection (Paper I, III)

The two qualitative studies included in this thesis shared both methodological similarities and differences. Similarities included collecting data from two different groups of informants, i.e., parents and nurses, as well as the use of bridge-builders and health communicators when approaching and recruiting parents speaking Somali and Arabic. This was also a study strength, as it helped us approach and interview individuals that otherwise would have been difficult for us as researchers to recruit. In both studies, translators were also used during the focus group and individual interviews with Somali- and Arabic-speaking parents. Although the use of translators could be viewed as a limitation, it was also necessary in order for us to hear the voices of parents with limited Swedish and English. The main methodological difference was the collection of data through both focus group interviews (parents) and individual interviews (nurses) for Paper I, while for Paper III, data was collected through individual interviews with all informants (parents, nurses).

The reason for conducting focus group interviews for Paper I was to utilize the dynamics of parents sharing the same language and cultural background discussing together, as this could facilitate more open discussions in terms of ideas and experiences. Indeed, when assembling focus group interviews, informants should be recruited based on certain shared characteristics that are relevant for the study aim [166,167]. At this stage in the MINISTOP 2.0 project we were interested in exploring user requirements among parents representing the current largest languages spoken in Sweden (Swedish, Somali, Arabic) in order to afterwards adapt and translate the MINISTOP intervention before evaluation within primary child health care. Thus, one focus group per language was conducted to capture

experiences, attitudes, and feelings through interactions between the parents [166]. Ideally, after the first set of focus groups, repeated focus groups [166] with parents could have been conducted (Paper I). However, due to time constraints within the project and difficulties recruiting parents, this was not possible at the time being. Although this is a study limitation, the interview findings still provided several ideas for improvement and adaptation of the app.

For Paper III, individual interviews instead of focus groups, were conducted with parents, in order to deeper explore each parent's experience of using the app. Compared to focus group interviews, individual interviews allow for more interview time with each person [166]. In both studies, nurses were also interviewed individually to elicit more in-depth information regarding their work of promoting healthy lifestyle behaviors in families and their perceptions of parental challenges and need of support (Paper I), but also their experiences of working with and disseminating the app to parents within the MINISTOP 2.0 trial (Paper III).

Methods for data analysis (Paper I, III)

Two different qualitative methods were used to analyze data: thematic analysis [125,127] (Paper I) and content analysis [126] (Paper III). Having the opportunity of testing two different analysis methods during my PhD studies was valuable for my development in qualitative research and writing. Common for both thematic and content analysis is to condense and summarize large amounts of text data by "thematizing" meanings in e.g., interview transcripts or other text sources relevant to the research question [125–127,168,169]. The methods also share many similarities in terms of data analysis, such as systematic coding and searching for meanings, patterns, and overarching themes in the data set (thematic analysis) [125,127] or systematic coding of the content in a data set into preliminary categories and categories that are later abstracted into themes (content analysis) [126,169]. Differences between the methods include the researcher considering both latent and manifest data in thematic data analysis, while in content analysis, the researcher is advised to first choose between analyzing the data using either a latent or manifest approach before proceeding further with the analysis [168]. Thematic analysis also offers a more theoretically flexible approach as it is not grounded in a specific theoretical framework [125,168]. In comparison to content analysis, which is grounded in a constructivist/interpretivist research paradigm and a relativist ontology, thematic analysis can be underpinned by both constructivist and realist research paradigms [125,168,170]. Nevertheless, in this thesis, an inductive latent approach was undertaken for both methods [171]. Analyzing data inductively, refers to the process whereby the analysis is data driven, and where the primary aim is not to relate or connect data to previous findings

in the field, but rather be open to and search for new information and hypotheses [168]. The term “latent” refers to the underlying meanings of the findings, instead of just the “manifest”, i.e., apparent or factual meanings in the text [168]. Unraveling the latent meanings of qualitative findings involves a lot of interpretative work for the researcher, and thus falls under a more constructivist/interpretivist paradigm. As the ontological assumptions for relativism include the existence of multiple realities based on individual social interactions and experiences, as opposed to one single truth (realism), the process of interpreting and summarizing findings is also recognized as value dependent, i.e., dependent on the values of the individual researcher [172,173].

Trustworthiness (Paper I, III)

Within qualitative methodology, the term trustworthiness is used as the equivalent to internal and external validity in quantitative research, as these cannot be applied to qualitative findings [174,175]. Trustworthiness is a way of ensuring that qualitative findings can be trusted, i.e., that they were collected, analyzed, and reported using a precise and consistent procedure. Thus, the data collection and analysis process within qualitative research are described in detail and discussed based on their credibility, transferability, dependability, and conformability [126,174,175]. This allows the reader to judge whether the research process and findings are credible, and whether they are transferable to other populations of interest.

For both studies (Paper I, III), trustworthiness [126,174,175] in terms of credibility was achieved through investigator triangulation during both the data collection and analyses processes. Furthermore, data source triangulation by inclusion of informants with interrelated perspectives (parents, nurses) also contributed to data richness and the credibility of the findings. Credibility was further endorsed by inclusion of quotations from the interview transcripts which increased the transparency of the findings. Trustworthiness in terms of dependability was achieved by following a pre-defined systematic data collection procedure as well as by using a semi-structured interview guide for all interviews. Moreover, a description of the participant characteristics, intervention, and intervention setting also facilitated transferability of the findings for the reader. Finally, the nurses that were interviewed in both studies represented many different geographic and socioeconomic areas in Sweden which also increased the transferability of the findings to the Swedish primary child health care setting.

Study population

Paper II, IV: The MINISTOP 2.0 trial was a multicenter study ($n = 19$), where parents ($n = 552$) were recruited by child health care nurses ($n = 65$) between November 2019 and September 2021. In comparison to single-center trials, inclusion of participants from multiple child health care centers located in different geographic and socioeconomic areas, enabled recruitment of a more diverse study population, which also increased the generalizability of the study findings to the general population in Sweden. Additionally, although the educational attainment of parents in the MINISTOP 2.0 trial was higher in comparison to the Swedish general population (62% vs. 44% had a university degree) [176], it was lower compared to the parental level of education in the first efficacy trial (MINISTOP 1.0; 70%) [89]. Further, in comparison to the first efficacy trial [89], the study population ($n = 552$) was also more diverse with regards to parental country of birth. Thus, although 97.4% of children in the MINISTOP 2.0 trial were born in Sweden, 24% of children compared to 9% (MINISTOP 1.0) had two foreign-born parents [89,136]. This figure is highly comparable to the Swedish general population, where 24% of children have foreign-born parents [97]. It is also worth noting that, among the participating foreign-born parents, 51% were from countries in North Africa, Sub-Saharan Africa and the Middle East [136]. In terms of children's characteristics, approximately 21% were classified with overweight (16%) or obesity (4.6%) which was higher compared to the prevalence of overweight and obesity in 4-year-olds in the general population (11%) [26]. A reason for this could be that, although nurses were instructed to offer the app to all eligible families regardless of the child's BMI, nurses might still have prioritized recruiting families where the child had either overweight or obesity, due to the nature of the intervention. To summarize, conducting the trial recruitment in a real-world setting such as primary child health care, enabled reach and inclusion of a more diverse population of parents and children, both in terms of parental education, country of birth and children's BMI. Together with the low attrition rate (9%), the generalizability of the effectiveness outcomes to the general population of Swedish 2.5-to-3-year-old children can be considered as high.

Paper I, III: The MINISTOP intervention was adapted based on the interview findings from parents with diverse backgrounds. Participating parents for the focus group interviews in Paper I were recruited from a child health care center located in a socioeconomically vulnerable area of Linköping. Although the study sample was small, the parents represented families that the MINISTOP intervention aimed to reach and support going forward, i.e., parents speaking Somali and Arabic, with limited Swedish, and in some of the cases, with limited literacy; and thus provided valuable information.

The parents recruited for an individual interview in Paper III shared similar characteristics to parents in Paper I, and were recruited in a similar manner, through bridge-builders and health-communicators. Finally, the child health care nurses in both studies had varying degrees of professional experience and also shared many different experiences of working with families with varying needs of support, as they represented diverse socioeconomic and geographic areas in Sweden.

Ethical reflections

The MINISTOP 2.0 project received ethical approval from the Swedish Ethical Review Authority (ref no 2019-02747) and all studies included in the project (Paper I-IV) were conducted according to the guidelines of the Declaration of Helsinki [177]. Parents that participated with their child in the MINISTOP 2.0 trial provided written informed consent during the routine visit to their child health care center, and all study and consent information was available in Swedish, Somali, Arabic and English. Parents were also informed by their nurse that they could withdraw their consent at any time without providing an explanation, or without it affecting their child's or their own care.

Normally, the procedure of obtaining consent for children is that both parents provide written informed consent, however after the first months of recruitment in the MINISTOP 2.0 trial, nurses expressed concern that collecting consent from both parents sometimes hindered recruitment of families that they considered would benefit from using the MINISTOP 2.0 app, to the study. Often, only one of the parents would attend the visit to the primary child health care center, and the nurse would not be able to randomize or provide access to the app until the consent form was brought back signed by the other parent as well. Collecting the second consent could take time due to time restraints of the families, or that the other parent was abroad for a longer time. Since nurses also described that families who would benefit from using the app sometimes would not return with the signature from the other parent, this was also regarded an ethical dilemma. Therefore, an amendment to the ethical approval was submitted to the Swedish Ethical Review Authority (ref no 2020-01526) where permission to collect written consent from only one parent, i.e., the parent that attended the visit at the child health care center, was applied for. This request was also approved. Further, although information on diet and physical activity could be a trigger for eating disorders, the risk of this was considered to be unlikely, as the intervention content was focused on healthy eating and active play for preschool-aged children, and not in any way on weight loss, dieting or caloric restriction. Instead, the use of an app with information on health behaviors could benefit the everyday lifestyle behaviors of the participating families. Finally, the questionnaire data that was

collected by the nurses during the baseline and follow-up visit was continuously collected by the research team during the trial period, and stored in a secure server at Linköping University in accordance with the European General Data Protection Regulation (GDPR). The registration data collected within the MINISTOP 2.0 app was also collected and stored in accordance with GDPR.

Future perspectives of the MINISTOP 2.0 intervention

Next step – large scale implementation (MINISTOP 3.0)

Overall, the MINISTOP 2.0 project showed promising results; the app had a positive effect on children's health behaviors as well as on PSE [136]. Furthermore, objective data on app usage indicated high participant engagement with the app [136], while qualitative findings of user experiences revealed that the app was well accepted, appreciated, and feasible to use within primary child health care (Paper III). Finally, the results from cost-consequence analyses with relatively low total costs, especially for salary, in comparison to more traditional face-to-face delivered interventions, suggest that the app may represent an affordable childhood obesity prevention intervention, if scaled up on a population level. Consequently, the next step involves large scale implementation of the app within the Swedish primary child health care setting. In fact, the work of implementing the MINISTOP intervention at scale has already been initiated. This large-scale implementation will also be studied using scientific methodology (funded by a grant from the Swedish Cancer Society as well as a grant for a PhD position at Karolinska Institutet). Notably, this work also covers the costs of improving the app further based on the collective feedback from the participating parents and nurses from Paper III, into a MINISTOP 3.0 version.

Other suggestions for future research

Even though the next step for the MINISTOP concept - the MINISTOP 3.0 project, has already been initiated, there are also some other suggestions for future research. One interesting aspect to highlight is related to the theme *“Need for a shared platform”* in Paper I, which addresses the health promotive potential of the app, if nurses could tailor their advice during the visits, based on each families registrations in the app. Additionally, in Paper III, in the theme *“A tool for diverse purposes and groups”* nurses also brought up the potential of using the app as part of childhood obesity treatment programs, if adapted for this purpose. Notably, during the MINISTOP 2.0 trial [136], the caregiver interface was used by the nurses to register and provide access to the app for parents in the intervention group, however, despite the above findings in the interviews, the actual readiness

of monitoring and providing feedback on families registrations, evaluated through the actual use of the caregiver interface to review registrations (preliminary findings, not reported in this thesis), appeared to be very low. An explanation for this could be that the nurses participating in the interviews might have been more motivated to use the app in their daily practice. Further, nurses also expressed having limited time for each family during visits. Clearly, the need, potential, and readiness for shared features between parents and health care professionals are relevant topics for future research. Preferably, they should include both applications related to prevention and treatment.

Some final words going forward

In order to close the societal health equity gap, public health interventions and efforts need to be reviewed and adapted to make sure they target and support vulnerable population groups such as individuals with lower education or migrant background [69,178,179]. In the field of mHealth, this requires careful design and evaluation of features and content promoting inclusivity and accessibility for all [69]. A digital support for parents such as the MINISTOP 2.0 app provides opportunity to standardize the information on health behaviors disseminated to families on a national level and thus may also contribute to a more equal health care, where families have access to the same information and advice, in a language they understand. Currently, the MINISTOP 2.0 app is available in four languages, but could easily be translated to more languages in the near future; suggestions from within child health care of translating the app to Tigrinya and Polish have already been made. Moreover, as mHealth interventions are scalable to larger populations, the MINISTOP 2.0 intervention also has potential to contribute to increased health literacy and food literacy in the general population. The effect of interventions such as the MINISTOP 2.0 app on health literacy and food literacy, could also be the scope for future research. With that said, the app may serve as an effective and feasible complement to the standard care already offered at child health care centers in Sweden, by supporting parents of 2.5-to-3-year-old children between visits.

CONCLUSIONS

- Qualitative findings for adapting a parental support intervention such as the MINISTOP 2.0 app, highlighted the need for early access to information to strengthen parents, as well as adapting and translating parental support interventions with relevant features and content to also be accessible for migrant parents and parents with shorter education and low literacy.
- An app-based 6-month parental support intervention promoting healthy lifestyle behaviors in 2.5-to-3-year-old children (the MINISTOP 2.0 app) resulted in statistically significantly reduced intakes of sweet and savory treats, sweet drinks, and screen time in children (primary outcomes) as well as increased PSE for promoting healthy diet and activity behaviors in children (secondary outcome). However, no statistically significant effect was observed on children's BMI and MVPA.
- A qualitative exploration of user experiences of the MINISTOP 2.0 intervention (app and caregiver interface) among parents and nurses, found that the app was well accepted and perceived as a feasible support tool for parents within primary child health care. Furthermore, accessibility in different languages (Swedish, English, Somali, Arabic) was highly appreciated.
- A cost-consequence analysis of the intervention costs showed relatively low total costs, especially staff costs, in comparison to face-to-face interventions, and suggests that the MINISTOP 2.0 app and caregiver interface may be an affordable preventive effort for early promotion of healthy lifestyle behaviors in children when scaled up on a population level.

Altogether, the results from the papers in this thesis support the large-scale implementation of the MINISTOP 2.0 app within the Swedish primary child health care setting, for promotion of healthy lifestyle behaviours in 2.5-to-3-year-old children.

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