

Screen-Free Time with Friends: Study Protocol for a Cluster-Randomized Controlled Trial to Promote Face-to-Face Interaction with Peers and Reduce Recreational Screen Use among Children Aged 9-11 Years

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Table of Contents

Original Manuscript..... 5

Supplementary Files..... 43

 Figures 44

 Figure 1..... 45

 Figure 2..... 46

 Figure 3..... 47

CONSORT (or other) checklists..... 48

 CONSORT (or other) checklist 0..... 49

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Abstract

Background: Children's leisure time has changed in recent decades, with more time spent on screen media and less time face-to-face with peers - potentially affecting their physical and mental well-being.

Objective: This protocol outlines the design of a study investigating the effectiveness of the Screen-Free Time with Friends intervention aimed to promote more time face-to-face with peers and reduce recreational screen media use among children aged 9-11 years.

Methods: The study is conducted as a cluster-randomized controlled trial involving children aged 9–11-year-old and their parents from 18 schools in Denmark. Schools are randomized (1:1) to either a control or an intervention group. The intervention includes five core components: (1) curricular activities, (2) two family meetings, (3) a brief parent exercise, (4) a development program for after-school clubs, and (5) two community workshops. It is designed to allow local adaptation while maintaining fidelity to the core components. The primary outcome—children's time spent face-to-face with peers during leisure - is assessed at T0 (baseline), T0+[6–10 months], and T0+[13-15 months] (follow-up). Secondary outcomes including screen media use, physical activity, social relations, and well-being are measured at baseline and follow-up. A comprehensive process evaluation explores implementation, context, and mechanisms of change.

Results: The project was funded in July 2020. Schools were recruited from July 2023 to January 2024, while children and parents were recruited from November 2023 to April 2024. At baseline, 685 children were enrolled at the participating schools, with 343 (50%) having at least one parent enrolled in the questionnaire. Baseline data were collected from December 2023 to June 2024, and follow-up data from March to August 2025. As of September 2025, data analysis has not yet commenced, and no study results are currently available. Findings are expected to be published by the end of 2025.

Conclusions: This paper presents the protocol for a cluster-randomized controlled trial evaluating the Screen-Free Time with Friends intervention, designed to increase face-to-face interaction and reduce recreational screen use among children aged 9-11 years. Regardless of the findings, this study will generate important knowledge about the intervention's potential effectiveness, complemented by insights into how, why, and under what circumstances it may lead to meaningful changes. These insights can assist municipalities, schools, after-school clubs, community stake-holders, and parents in shaping everyday environments that foster children's face-to-face interaction and encourage balanced screen use. Furthermore, the findings may inform policy decisions, guide the development of new initiatives, and inspire future research into practical, real-world interventions that

support meaningful and enriching leisure experiences for children. Clinical Trial: ClinicalTrials.gov, ID: NCT06163495, Registered 17/11/2023.

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Original Manuscript

Screen-Free Time with Friends: Study protocol for a Cluster-Randomized Controlled Trial to Promote Face-to-Face Interaction with Peers and Reduce Recreational Screen Use among Children Aged 9–11 Years

Protocol version 1.0

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Abstract

Background: Children's leisure time has changed in recent decades, with more time spent on screen media and less time face-to-face with peers - potentially affecting their physical and mental well-being.

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Conclusion: This paper presents the protocol for a cluster-randomized controlled trial evaluating the Screen-Free Time with Friends intervention, designed to increase face-to-face interaction and reduce recreational screen use among children aged 9-11 years. Regardless of the findings, this study will generate important knowledge about the intervention's potential effectiveness, complemented by insights into how, why, and under what circumstances it may lead to meaningful changes. These insights can assist municipalities, schools, after-school clubs, community stakeholders, and parents in shaping everyday environments that foster children's face-to-face interaction and encourage balanced screen use. Furthermore, the findings may inform policy decisions, guide the development of new initiatives, and inspire future research into practical, real-world interventions that support meaningful and enriching leisure experiences for children.

Trial registration: ClinicalTrials.gov, ID: NCT06163495, Registered 17/11/2023.

Keywords: Social interaction; Interpersonal relations; Digital media use; Screen time; Physical activity; Mental health; Well-being; Child; Community participation; After-school programs

Introduction

In modern society, the use of screen media among children and adolescents has increased rapidly in the recent years (1). Although digital technologies offer several advantages, including enhanced communication and educational opportunities, increasing evidence points to the potential negative impact of increased screen media use among children and adolescents (2-4). Excessive screen use has been associated with a range of adverse physical and mental health outcomes, including obesity, emotional and cognitive difficulties, reduced well-being, and elevated risk of lifestyle-

related health issues (2-4). One potential explanation for these negative effects is that excessive screen use may disrupt essential aspects of healthy development, including sleep, physical activity, and face-to-face interactions with peers and family members (3, 5, 6). In Denmark, time spent in physical, face-to-face interaction with friends has declined markedly. In 2009, 72% and 71% of Danish 11-year-old boys and girls, respectively, spent time face-to-face with friends more than once a week (7). In 2021, the proportion had decreased to 40% of the boys and 60% of the girls (7). Another Danish study demonstrated that the amount of 11-year-old children spending time after school with friends four-five days/week has decreased from 54% in 1988 to 19% in 2022 for girls and from 58% to 24% for boys (8). This decrease in face-to-face interactions with peers has also been shown internationally (9).

Face-to-face interaction and play are essential for children's development, fostering social and emotional skills, creativity, and problem-solving abilities (10). In contrast, time spend alone has been associated with increased risk of anxiety, depression, poor friendship quality, and school difficulties (11). Moreover, children are more likely to engage in physical activity when spending time with friends (12, 13). The decline in peer face-to-face interaction - alongside a rise in recreational screen use - may further reflect mutually reinforcing behaviors (14) that together contribute to the low levels of physical activity observed among Danish children, as shown in a recent Danish report based on accelerometer measurements (15). Collectively, these trends pose a serious risk to both the physical and mental well-being of children.

Consequently, there is growing concern about the amount of time children spend on recreational, solitary screen use and how this may affect their physical and mental well-being. In response, the Screen-Free Time with Friends intervention was developed to explore whether promoting face-to-face interaction as an alternative to recreational screen use can influence key aspects of children's

leisure-time behavior and well-being.

This cluster-randomized controlled trial (RCT) examines the effectiveness of the Screen-Free Time with Friends intervention on several outcomes including recreational face-to-face interactions and screen media use among children aged 9-11 years. In addition, a comprehensive process evaluation assesses the implementation, contextual influences, and potential mechanisms of change. Overall, this study will provide robust evidence on the potential effectiveness of the intervention, along with insights into how, why, and under what circumstances it may lead to meaningful changes. This protocol outlines the methodology and procedures for conducting the cluster-RCT in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist and is registered in clinicaltrials.gov (NCT06163495).

Methods

Feasibility Trial

From February to November 2023, we conducted the Screen-Free Time with Friends Feasibility Trial including three schools, the related after-school club and the local community from three different municipalities in Denmark (www.clinicaltrials.gov ID: NCT05480085) (16, 17). The purpose of this study was to assess the feasibility of the intervention, recruitment procedures, and data collection plan to identify elements requiring refinement prior to conducting the cluster-RCT outlined in this protocol. Overall, stakeholders and participants in the feasibility trial expressed strong support for the study's aims and found the intervention activities meaningful, while also highlighting areas that needed improvement. Insights from the feasibility study have informed key refinements to the

intervention design, recruitment strategy, and data collection procedures (17, 18). These adjustments have been implemented and are reflected in the protocol for the Screen-Free Time with Friends cluster-RCT presented here.

Study design and participants

To evaluate the Screen-Free Time with Friends intervention, we conduct a cluster-RCT involving children aged 9-11 years from public schools across Denmark. The initial recruitment target was 18 schools, based on sample size calculations using our primary outcome: time spent with peers (in minutes). We anticipated a total of 1080 eligible 3rd-grade children, assuming an average of 2.5 classes per school and 24 students per class. With an expected participation rate of approximately 80%, we aimed to enroll 864 children at baseline. Accounting for an estimated 15% dropout or missing data rate, we projected an average of 41 children per school (cluster) in the final analytical sample, resulting in a total sample size of approximately 738 children. Drawing on a previous Danish school-based study from our research group (19), we assumed a coefficient of variation in cluster size of 0.24 and an intra-cluster correlation coefficient of 0.07. Additionally, based on findings from the feasibility trial, we estimated a correlation of 0.67 between baseline and follow-up measurements, and a standard deviation of 38 minutes per day in both the intervention and control groups. To control for type I error due to the small number of clusters, we lowered the alpha level to 0.025 in the power calculation. This adjustment was made in anticipation of applying the Satterthwaite correction for mixed linear models, as recommended for small-sample cluster trials (20). Under these assumptions, the study is powered at 80% to detect a statistically significant mean difference of 13.5 minutes per day or more between the intervention and control groups at follow-up. A difference of 13.5 minutes per day corresponds to approximately 1.6 additional hours of peer

interaction per week, roughly equivalent to one extra weekly after-school playdate or an extra organized extracurricular activity, which we consider an effect size of relevance.

Schools are randomized by an independent statistician in a 1:1 ratio to either an intervention or a control group, balancing on the following criteria: 1) number of students in 3rd grade, 2) school-level parents' ethnicity, 3) school-level parents' education level, and 4) building coverage. A covariate-constrained randomization procedure is applied (21) to optimize the balance in school-level covariates between the intervention and control groups, thereby reducing the likelihood of substantial differences in child baseline characteristics. Data on school-level covariates is sourced from the Danish Ministry of Children and Education (22). The statistician communicates the allocation results to the research team in two rounds, after the respective schools have completed their baseline assessments. Following randomization, after-school clubs and local community stakeholders affiliated with the schools in the intervention group are recruited to participate in the intervention. The respective school, after-school club, and local community will hereafter be referred to as an intervention school district. Intervention school districts implement the intervention program, consisting of five core components: 1) curricular activities; 2) two family meetings; 3) a brief exercise for parents; 4) an after-school club developmental program and 5) two workshops in the local community, while school districts randomized to the control group continue with their usual practices.

Recruitment

To recruit schools for the cluster-RCT, school leaders are contacted via the municipality or directly by a member of the research team. Schools are eligible if they meet the following criteria: 1) the

school must have an after-school or youth club (or similar) within walking distance, 2) the after-school club's leader and staff must be willing to develop the club by participating in an after-school development program facilitated by Ungdomsringen. Ungdomsringen is a Danish non-governmental organization that supports the development of youth clubs and educational environments through training, networking, and practice-based resources. No additional inclusion or exclusion criteria are applied, as the aim was to include a representative sample of children and parents from the participating 3rd grade classes.

Children and parents

In collaboration with a representative from the school, the research team recruits children and parents from 3rd grade at the participating schools. Based on the results from the feasibility trial (17), the strategy for informing and recruiting parents was carefully designed, incorporating multiple methods of communication and several reminders via Aula, which is an electronic communication platform at the school, to encourage parents to enroll in the study. Initially parents receive written information about the project along with a short video presentation of the project. In addition, the project is introduced to the children during school hours. Each child receives a keychain featuring the project logo, along with written information to take home and share with their parents. Parents are informed about this presentation via Aula. Lastly, parents are invited to an in-person information meeting at the school. At the information meeting, the project is comprehensively explained, and parents receive detailed written information along with the opportunity to ask questions.

After-school club staff

Following randomization, the contact information of the after-school club leaders in the

intervention school districts is shared with Ungdomsringen. Ungdomsringen is responsible for the remaining practical planning of the after-school club development program, including the coordination of the three workshops with the leader and staff. The implementation of the program is planned with close consideration of each club's schedule and preferences. Based on insights from the feasibility study, clubs with only a few staff members are merged with other clubs to optimize the workshop process and foster greater knowledge sharing.

Local stakeholders

To support the recruitment of participants for the local workshops, a local ambassador is recruited in each of the nine intervention school districts. The ambassador should represent the local community and possess knowledge of children's leisure activities and opportunities in the area. The ambassador is invited to an initial meeting - either online or in person, depending on their preference - and receives informational materials, including a video outlining the aim and overall content of the two local workshops. The ambassador is responsible for recruiting 15-18 local stakeholders who are engaged in or committed to promoting children's leisure time activities in the local area (e.g., representatives from the local sports club, church, or local politicians). The research team provides support as needed throughout the recruitment process.

Ethics

The study was approved by the Research Ethics Committee at the University of Southern Denmark on June 15, 2022 (22/29625), and an updated version of the study protocol was approved on October 2, 2023. Parental written consent is required for their child to participate in the physical

activity measurement, while the remaining assessments only require school approval. However, parents may formally withdraw their child from all assessments prior to data collection. On the day of measurement, if a child indicates that they do not wish to participate, their decision is respected. Parents must register for the project to receive the questionnaires.

Intervention development and program theory

The Screen-Free Time with Friends intervention is the result of a comprehensive and systematic development process, guided by the Medical Research Council (MRC) framework for developing complex interventions (23) and inspired by the process outlined Hawkins et al. (24).

To inform the development of the intervention, scientific literature, national and international reports, and formative qualitative work with children, parents, school and after-school club staff - involving both interviews and observations - were initially collected and analyzed. A key insight from this process was the need to shift the focus away from individual responsibility and instead develop an intervention that supports children by shaping the surrounding context. It also became clear that a one-size-fits-all approach would be insufficient, as local needs and conditions vary considerably in terms of e.g., problem perceptions, norms, infrastructure, community engagement, and available resources. Therefore, the intervention was designed with flexible - yet clearly defined - components to allow for local adaptation. For example, parents, after-school staff, and local stakeholders are actively involved in identifying key action areas that reflect local needs and conditions, in line with recommendations for developing context-specific interventions (25).

A wide range of stakeholders contributed to shaping the overall structure of the program - including researchers, practitioners, and organizations working with screen use and children's leisure time.

For example, an expert-generated systems map provided valuable insights into the multiple factors influencing children's leisure activities and helped identify key leverage points for intervention, thereby informing the development of the intervention's overall framework (23).

The final program protocols were developed in close collaboration with national organizations, including Ungdomsringen, Just Human, a non-profit foundation dedicated to promoting mental health and well-being among children and young people, and researchers with knowledge and experience in approaches inspired by Group Model Building (26).

The program theory (Figure 1) illustrates how the core components of the intervention (i.e., family meetings, brief exercise, curricular activities, after-school development program and local workshops) are expected to lead to changes in change mechanisms such as increased parent-child communication, social support, and awareness of screen behavior. These mechanisms are hypothesized to influence behavioral outcomes (e.g., increased face-to-face interaction with peers, reduced screen time) and, in the long term, contribute to improved child well-being. The model also highlights the importance of implementation fidelity, contextual adaptability, and participant engagement in achieving desired outcomes.

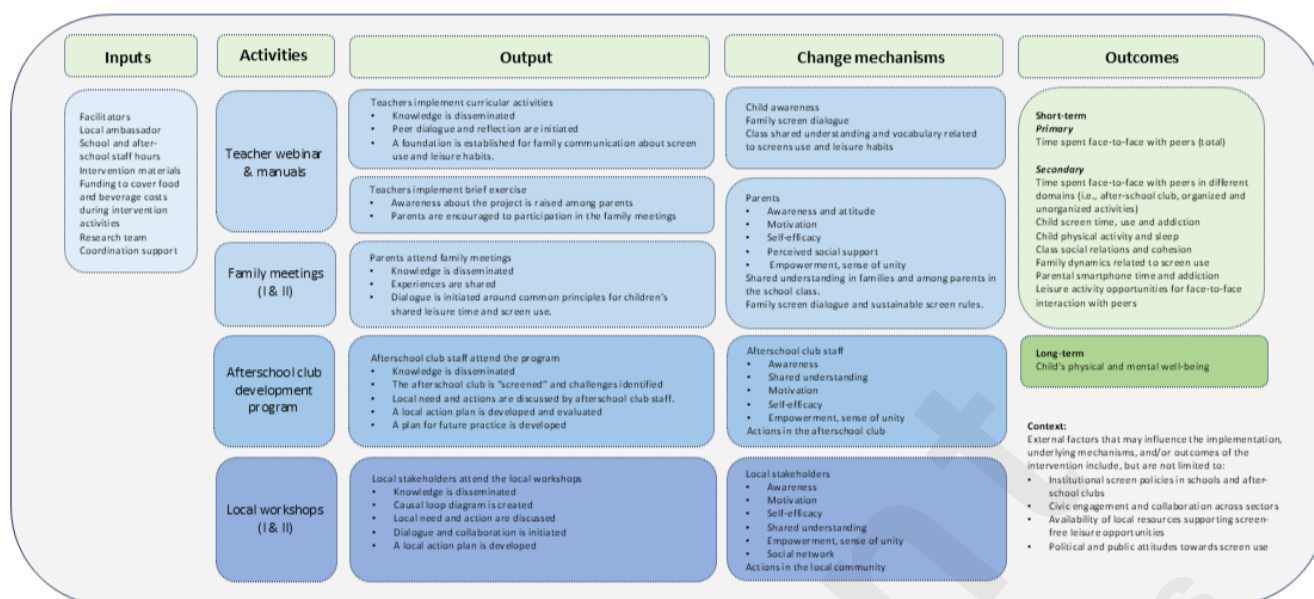


Figure 1: The program theory of the Screen-Free Time with Friends intervention.

Intervention content and implementation strategies

The intervention consists of five core components comprising: 1) curricular activities targeting 9-11-year-old children in each school class; 2) two family meetings targeting parents from each school class; 3) a brief exercise for parents, focusing on screen media dilemmas - included in the regular parental meeting at the start of 4th grade, 4) a developmental program targeting after-school club staff and; 5) two workshops in the local community targeting local stakeholders. Schools initiate and complete the intervention activities at different time points, depending on the timing of their allocation. Figure 2 illustrates an example of the intervention's implementation in a single intervention school district.

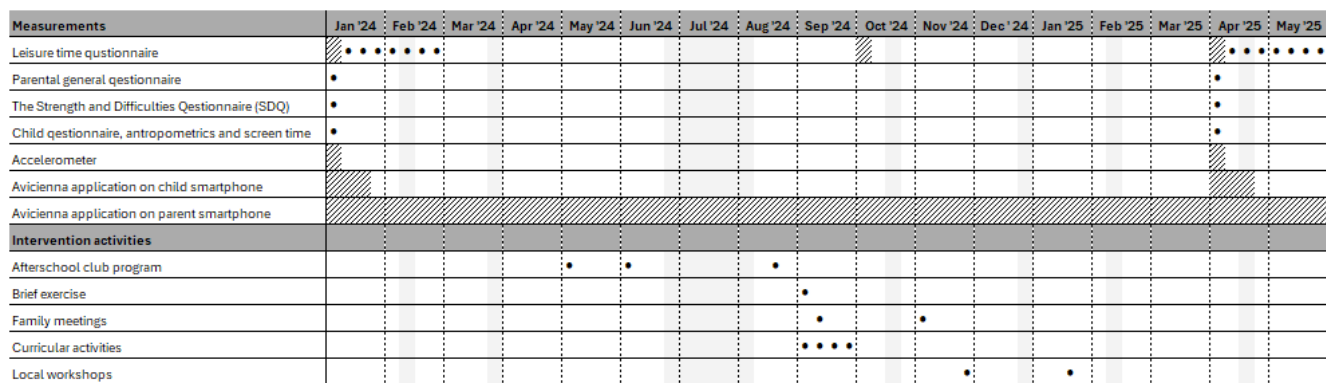


Figure 2. Example timeline showing the scheduling of data collection and intervention activities in a single intervention school district. A dot represents one measurement or intervention activity. Bars with diagonal lines indicate measurement periods lasting seven consecutive days per week (e.g., accelerometer data collection). School holidays are represented by solid light grey bars.

Parents, schoolteachers, and after-school club staff in each intervention school district receive a video and written materials explaining the full intervention program prior to intervention start. A school representative is invited to an initial meeting with a member of the research team, where details about the family meetings and curricular activities are presented.

The school representative receives invitations to the family meetings and is responsible for ensuring that these are distributed to all relevant parents. They also receive information about a brief exercise for parents to conduct during the regular parental meeting at the start of 4th grade, and it is their responsibility to ensure that teachers carry out the exercise.

To ensure effective implementation of the curricular activities, participating teachers are invited to a webinar introducing the materials. The webinar also offers an opportunity for teachers to ask questions related to both the material and the family meetings. The after-school club leader is contacted by Ungdomsringen to coordinate the implementation of the after-school club development program. In addition, the school representative is encouraged to recruit a local

community representative - someone familiar with children's leisure activities and opportunities in the area. A video and written information explaining the purpose of the local community workshops, along with an invitation and registration link, are sent to both the school and community representative. They are encouraged to share this information broadly within the local community to recruit participants for the local workshops. The research team also supports the recruitment of both the community representative and local stakeholders. All family meetings, local workshops, and after-school club workshops are facilitated by trained staff provided by the project.

Intervention component 1: Curricular activities for children

The curriculum activities include activities addressing screen media use and leisure time. The teaching material consists of videos, posters, workbooks, sheets, and reflection and dialogue tasks, which take place in groups or as a whole class. The program is structured into four modules comprising a total of seven lessons (45 minutes/lesson), as outlined in Table 1. Teachers receive a printed teacher's manual, a booklet outlining the theory and key concepts behind the material, and five posters to put up in the classroom. Teachers are encouraged to take breaks during the sessions to discuss with the children what they have read and learned while working through tasks in the workbooks. Additionally, teachers should use the provided videos and posters as tools for fostering dialogue during and after the lessons. Teachers are expected to implement the material from all modules but are welcome to spread it over more than seven lessons. The material must be completed prior to the second family meeting - and no later than the autumn break in Oct 2024 - as selected responses from the children are used as input for the meeting. The curricular activities aim to foster a shared understanding and vocabulary related to screen use and leisure habits within the class, and to lay the foundation for communication between children and their parents on these

matters.

Module	Lesson	Title	Aims	Curricular activities
1	1-2	Social communities and leisure time	The students develop an understanding of the importance of maintaining a good balance between different activities throughout the day. The students become able to reflect on their own leisure time activities and screen use, and understand that these factors affect their well-being	A video that can be used to introduce the module. The video depicts situations related to academic content. Posters depicting: 1) How participation in different communities and activities affects us and 2) The balance of activities in one's daily life. Exercise "Swipe" (with movement): Questions are displayed on the smartboard and read aloud by the teacher. Children move either to the right (yes) or to the left (no). Responses are collected - to be used for the second family meeting. Exercises (workbook): Knowledge about social communities and how participation in different communities and activities affects us. Focus on the balance of activities in one's daily life. Exercise "What would you prefer?" (worksheet): A checklist where students choose what they prefer from two statements. Responses are collected - to be used for the second family meeting.
2	3-4	Digital and analog communication	The students gain an understanding of digital and analog communities and communication.	A video that can be used to introduce the module. The video depicts situations related to academic content. Exercise (worksheets): Differences between digital and analog communication. Group work (3-4 students): Reflection and dialogue about various digital communication situations/cases. Class discussion and development of "the class's top 3 tips for think before you text".
3	5-6	Critical sense in the digital world	The students develop a certain degree of critical awareness and a conscious and reflective approach towards the digital environment. The students understand the importance of involving their parents in their digital lives.	A video that can be used to introduce the module. The video depicts situations related to academic content. Posters depicting "The Critical Code." "The Critical Code" consists of two points: 1) "Pause and think" and 2) "Involve an adult". Exercises (workbook): Text and tasks that introduce "critical awareness in the digital world" and "The Critical Code,". Concepts such as algorithms and tech giants are introduced. Parents are described as superheroes who are ready to help - also in the digital world. Group work (3-4 students): Reflection and dialogue about different cases, using "The Critical Code". Can also be done collectively with the whole class.
4	7	Summary	The students reflect on what they have worked on and learned in the three previous modules.	Reflection on what students have worked on and learned, revisiting the three videos, posters and key concepts from modules 1, 2, and 3. Encouragement to revisit later in the school year. Exercise (worksheet): The worksheet is divided into 3 sections, each illustrating the three modules. Each section includes a small reflection exercise where students must draw/write what they have learned, worked on, or concluded in the three modules. The students are to take the worksheet home and go through it with their parents.

Table 1: Description of the curricular activities targeting children aged 10-11 years.

Intervention component 2: Family meetings for parents

Within each class, children and parents are invited to two family meetings. The family meetings comprise a workshop for parents, that combines education and dialogue between parents, while children engage in fun and interactive activities. The overall goal of these meetings is to support parents in fostering balanced and sustainable leisure habits - both within the class community and at home - with particular attention to screen use. Building on the Social Cognitive Theory (27) and Social Support Theory (28) the meetings provide parents with a possibility to share experiences and foster dialogue helping parents gain strategies and confidence to address digital challenges effectively. An essential aspect of the meetings is to foster collective decision-making on key issues relevant to the specific class, which could be (in)appropriate screen content, online gaming, or social media use. By aligning on these matters, the goal is to reduce social pressure, strengthen unity, and promote the development of more sustainable rules (29, 30).

The first family meeting focuses on screen-related aspects within the family, while the second meeting addresses children's screen use within the class. As part of the second meeting, data collected from the children during the curricular activities (Table 1) is presented to the parents to ground the discussions in the children's real-life experiences and perspectives. This includes the children's responses from the "Swipe" exercise (Table 1, module 1), offering insights into, for example, how many children report having profiles on various social media platforms and how many report having screen rules at home. In addition, selected answers from the "What would you prefer?" exercise (Table 1, module 1) are shared - such as whether children prefer to spend one hour on a screen or playing outside with others for one hour, and whether they rather play online with friends or be together with them face-to-face. Evidence-based knowledge is shared through slides referencing research and recent reports as well as videos featuring expert statements.

Workshops are led by a trained facilitator provided by the project. All materials are freely available online following the meeting.

Activities for the children are conducted by staff from the after-school club or sport science students from the University of Southern Denmark, coordinated by the research team in collaboration with the school based on their preferences. These activities, along with a concluding shared dinner, are included as part of the intervention to support and encourage parent participation by making attendance as convenient as possible.

Intervention component 3: Brief exercise for parents

In Denmark, a class-wide parent-teacher meeting is held at the beginning of each school year. During this meeting in 4th grade, parents take part in a brief teacher-led exercise focusing on screen media dilemmas. An example of a dilemma is: "Your daughter Signe is 11 years old and wants to create an Instagram account. She tells you that almost everyone else in her class has one, and she's seen how they share photos and play games on the platform. You're aware that Instagram's official age limit is 13". The primary goal is to raise awareness about the project and encourage parents to participate in the upcoming family meetings.

Intervention component 4: Development program for after-school club staff

The development program consists of three workshops conducted within the after-school club setting. The program is developed in collaboration with Ungdomsringen, who facilitates the program.

The development program is inspired by principles of action learning (31), applied in a condensed,

iterative format referred to as a 'mini action learning cycle'. This means that the after-school club staff are expected to develop their own practice based on specific, real-life challenges and dilemmas they have experienced. In this way, the issues addressed during the process are directly relevant to their everyday practice, supporting ownership of the change process.

During the workshops, after-school club staff are supported in investigating identified challenges and preparing small actions to be implemented in their everyday practice. In the following session, their experiences and observations become the basis for systematic reflection, knowledge sharing, and the development of new insights - insights that can inform further actions. As part of the program, the after-school club staff are introduced to knowledge, tools and methods that enable them to continue developing their practice - even after the formal conclusion of the development program. The overall aim of the program is to increase participation in the after-school club and reduce dropout rates from 3rd to 4th grade. To achieve this, the program seeks to enhance staff self-efficacy and motivation for developing the club, foster a shared understanding of current practices across key themes, and strengthen empowerment and a sense of unity among the club's staff.

Intervention component 5: Community workshops for local stakeholders

The last intervention component comprises two workshops in the local community. A local ambassador and 15-18 local stakeholders are recruited from the local community, representing parents, schoolteachers, after-school club personnel, local politicians, and others relevant to children's leisure time (representatives from e.g., local sports clubs, library, church etc.). With support from the research team, the local ambassador is responsible for planning the two workshops, which are led by trained facilitators. The workshops are based on the Group Model

Building methodology, aiming to foster a shared understanding of the problem by collaboratively developing a system dynamics model grounded in diverse stakeholder perspectives (32). Group Model Building has been shown to enhance problem understanding, strengthen stakeholder engagement and confidence in systems thinking, and foster consensus for action (26, 33, 34).

In the first workshop, stakeholders identify key factors and collaboratively develop a visual representation of the system using Causal Loop Diagrams, illustrating various factors that influence children's face-to-face interactions with peers during leisure time in the local area—and how these factors are interconnected. The purpose of the system map is to help stakeholders understand the system's dynamics and enable system-level change (35). During the second workshop, and based on the system map, stakeholders identify existing actions and prioritize key leverage points for intervention. Local actions are then outlined, and action groups are formed based on individuals' interest, motivation, and capacity to drive change within the specific area. The overall goal of the workshops is to increase opportunities for children to engage in face-to-face leisure activities with peers. This is supported by strengthening the participants' self-efficacy and motivation to create local opportunities, building shared awareness of the challenge that children spend more time on screens and less together in person, and fostering empowerment, a sense of unity, and supportive social networks to take collective action.

Effectiveness evaluation measures

All outcome measurements are conducted at all 18 schools at baseline (T0) and again after 13-15 months. In addition, the leisure time activity questionnaire—which includes the primary outcome of time spent face-to-face with peers - is administered at T0 + [6-10 months]. An overview of the measurements is provided in Table 2. Below, outcomes related to the primary target group—

children and their parents - are detailed, encompassing both primary and secondary outcomes as part of the effectiveness evaluation.

Outcome	Target	Measurement	Data source	Time points
Time spend face-to-face with peers (total) Time spend face-to-face with peers (domains) Solitary screen use	Child	Leisure time activity questionnaire	Parent-report	T0, T0+7-9 mo and T0+14 mo
Total screen media use Screen media addiction Smartphone addiction Family dynamics related to screen use	Child Parent Family	General parental questionnaire	Parent-report	T0 and T0+14 mo
Physical activity Sleep	Child	Axivity AX3 triaxial accelerometer	Device-based	T0 and T0+14 mo
Smartphone time	Parent	Avicienna application	App-based	T0 and T0+14 mo
	Child	Built-in screen time tracking features (iOS/Android)	Device-based (retrieved by research team)	
Wellbeing	Child	The Strengths and Difficulties Questionnaire	Teacher/pedagogue-report	T0 and T0+14 mo
Social relations Class cohesion	School class	Child questionnaire	Child-report (during school hours)	T0 and T0+14 mo

Table 2. Overview of outcomes, measurement methods, time points, and information on data source and target (i.e., the person or group the outcome concerns). The table presents the outcomes assessed at each timepoint, along with the corresponding measurement methods. For each outcome, the table specifies who the outcome concerns (target) and how data were collected (data source). For example, when parents report on their child's screen use, the child is the target, and the data source is specified as parent-report. For subjective measures, the respondent is indicated; for digital measures, the source is specified (e.g., app-based or device-based).

Primary outcome

Children's time spend face-to-face with peers

To assess the primary outcome, children's face-to-face time with peers during leisure, parents receive an SMS-based leisure time activity questionnaire about their child's leisure activities for seven consecutive days, followed by once-weekly messages for seven weeks, during both the baseline and follow-up periods. Midway they receive the same questionnaire for seven continuous days. The questions cover the amount of time children spend in after-school clubs, organized leisure activities (e.g., sports or crafts), and unorganized time with peers such as playdates. Total face-to-face interaction time with friends during leisure is calculated as the sum of these three categories.

Secondary outcomes

Children's time spend face-to-face with friends in different domains

As a secondary outcome, children's time spent face-to-face with peers—based on the SMS-based leisure time activity questionnaire—is categorized into distinct time domains: after-school club, organized activities, and unstructured time with peers. This categorization serves two purposes: first, to explore whether changes occur within specific domains independently, offering insight into where potential effects may be most pronounced; and second, to examine whether—and to what extent—shifts in time allocation between domains contribute to the overall result.

Children's solitary screen use

As part of the SMS-based leisure time activity questionnaire, parents are asked to report children's time spent using screen media devices (including smartphone, tablet, television, computer, etc.)

alone. Screen time is defined as “alone” when the child is using a screen without others in the same room being actively involved in the activity. For example, online interaction with others still qualifies as alone time, whereas shared use - such as interacting together on a tablet - does not.

Child smartphone time, total screen media use and addiction

Parents are asked to install an app on their child's smartphone, if the child owns one (<https://avicennaresearch.com/>). The application objectively monitors smartphone use over three weeks at both baseline and follow-up by logging screen activation and deactivation events. In addition, the research team retrieves data on children's smartphone time from the past week as part of the assessment battery conducted during school hours at both baseline and follow-up.

To assess children's overall screen media use, parents are asked - within the general parental questionnaire - to report on various aspects of their child's screen habits, including screen use before bedtime. This section is based on a modified version of the SCREENS-Q (36). Additionally, the same questionnaire asks parents to report on their child's screen media addiction using the Problematic Media Use Measure Short Form (PMUM-SF) (37). The PMUM-SF is a validated 9-item parent-report scale designed to capture addictive-like patterns of screen media use in children aged 4 to 11 years, based on criteria reflecting impaired control, preoccupation, withdrawal, and family conflict. Parents rate each item on a 5-point Likert scale ranging from “never” to “always,” with higher scores indicating greater levels of problematic media use.

Children's physical activity and sleep

Children's physical activity and sleep are assessed using Axivity AX3 triaxial accelerometers (<https://axivity.com/product/ax3>) worn at the thigh using two adhesive patch 24 hours/day for seven

consecutive days at baseline and follow-up (38). Time spent in different intensity domains of physical activity, physical activity types, and sleep metrics is determined using the appropriate algorithms such as those developed by Brønd et al. (39). Preparation of the accelerometers and download of data will be conducted using the OmGui software (<https://github.com/digitalinteraction/openmovement/wiki/AX3-GUI>).

Child well-being

Child well-being is assessed using the Strengths and Difficulties Questionnaire (SDQ) for teachers consisting of 25 items focusing on emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behavior at baseline and follow-up (40, 41). In addition, as part of the child questionnaire, children are asked to complete Cantril's Ladder (42), a widely used single-item measure of global life satisfaction. The ladder presents a visual scale from 0 to 10, where 0 represents the worst possible life and 10 represents the best possible life. Children are asked to indicate where on the ladder they feel they currently stand, providing an indicator of their overall well-being.

School class, social relations and cohesion

To assess peer relationships and social structures within the school class, children are asked - as a part of the child questionnaire - to indicate which classmates they spend the most time with during recess and leisure activities. This data is used to construct sociograms, enabling analysis of social networks, including indicators such as centrality, mutual connections, and potential social isolation (43). In addition, children will report on perceived class cohesion.

Parent smartphone time and addiction

As for the children, parents are asked to download an application (<https://avicennaresearch.com/>) to their own smartphone to track smartphone use. This application objectively monitors smartphone time throughout the intervention period by logging the timing of screen activation and deactivation events. Smartphone addiction is self-reported using the smartphone addiction scale – short version (SAS-SV) at baseline and follow-up (44). The SAS-SV is a validated 10-item questionnaire designed to assess symptoms of problematic smartphone use, including daily-life disturbance, withdrawal, tolerance, and preoccupation. Each item is rated on a 6-point Likert scale ranging from “strongly disagree” to “strongly agree,” with higher scores indicating greater risk of smartphone addiction.

Family dynamics related to screen media use

As a part of the general parental questionnaire, parents are asked to report on the frequency of conflicts in the family related to screen media use.

Process evaluation

A comprehensive process evaluation is conducted, guided by the framework of Moore et al. (45) and the underlying program theory (Figure 1). This evaluation will aid the interpretation of intervention outcomes and enhance understanding of how, why and under what conditions the intervention may/may not be effective. The process evaluation will explore three key domains: (1) implementation, (2) mechanisms of change, and (3) context, as recommended by Moore et al. (45)

Implementation is assessed through questionnaires administered to those responsible for delivering each intervention component (i.e., facilitators of family meetings, local workshops, the after-school club development program, and teachers implementing the curricular activities). Furthermore, participants are asked to complete questionnaires immediately after participating in each respective intervention component, except for the curricular activities and the brief exercise. These questionnaires provide data on reach (extent of participation), fidelity (delivery as intended), dose delivered, and adaptations made to fit local contexts. This together will enable us to understand how the intervention was implemented and received across different settings.

To investigate mechanisms of change, we assess changes in mechanisms identified in the program theory (Figure 1), including, but not limited to, parental awareness and attitude, family screen dialogue, family screen rules and perceived social support. Mechanisms are assessed at multiple time points, depending on the component: before, immediately after, and at follow-up for the local workshops and the after-school club program; and immediately after and at follow-up for the family meetings and the educational material. To obtain a more nuanced understanding, semi-structured interviews are also conducted in some cases. For example, to capture a more complete picture of actions initiated as a result of the local workshops and after-school club program, we plan to interview at least one participant per local workshop or after-school club.

To gain an understanding of the different contexts in which the intervention is implemented, we explore contextual factors (e.g., organizational structures, local resources, and existing practices) that may influence implementation and outcomes. This data is collected through interviews and questionnaires targeting key informants (i.e., representatives of the local community, school and after-school club).

Based on insights from the feasibility study and in alignment with the recommendations by Moore et al. (45), we recognize the need for a flexible, multi-method approach in the collection of qualitative data. Accordingly, to realistically conduct a comprehensive process evaluation, open-ended questionnaires are sometimes used instead of interviews when participants decline to take part or when resources are limited.

Data management

Questionnaire data is collected using SurveyXact, except for the data from children, which is obtained through the system Klassetrivsel (www.klassetrivsel.dk, Skolevisioner ApS, Ry, Denmark). This platform enables the collection of information for assessing peer relationships and social structures within the school class and offers the option of having questions read aloud. All data—including questionnaire responses, audio recordings and transcriptions from interviews, and data from objective measurements - will be extracted and securely stored on servers hosted by the University of Southern Denmark. Data will be stored in its raw form, and no statistical analyses will be conducted until the study is completed.

Analysis

To evaluate the effectiveness of the intervention, between-group differences from baseline to follow-up will be analyzed using mixed-effects regression models, incorporating school-level random effects to account for cluster dependency. Imbalanced covariates will be included in analyses to adjust for potential baseline differences between groups. Primer analyses will be conducted using

intention-to-treat principles and hypothesis tests will be two-sided, conducted at a statistical significance level of $\alpha = 0.05$. Process evaluation data will include both quantitative and qualitative sources. Quantitative process data (e.g., on fidelity, reach, and dose delivered) will primarily be analyzed descriptively. Qualitative data will be analyzed thematically to identify patterns in participants' experiences, contextual influences, and potential unanticipated and anticipated change mechanisms. Process data will be used to support interpretation of outcome findings and where relevant, to explore variation in effects across settings. Statistical analyses will be conducted using Stata or R, and qualitative data will be managed and coded in NVivo.

Results

The current cluster-RCT was funded in July 2020 as part of a larger project that also included a formative qualitative study, an intervention development process, and a feasibility study (16, 17). For this cluster-RCT, schools were recruited from July 2023 to January 2024, and children and parents were recruited from November 2023 to April 2024. At baseline, 685 children were enrolled at the participating schools (Table 3). During the study period, 50 transferred to non-participating schools, while 32 were newly enrolled at participating schools, resulting in 667 children being enrolled at the participating schools at follow-up. In addition, two children moved between schools within the study. All children participated in most of the measurements unless they were actively withdrawn by their parents or absent from school on the day the measurements were conducted. Table 3 provides further details about the participant groups, including the number of children with consent to participate in the physical activity measurements, as well as the number of children with at least one parent who voluntarily enrolled to complete questionnaires and install the Avicenna app.

Participating children	Baseline, n (%)	Follow-up, n (%)
Number of children enrolled at the participating schools	685 (100%)	667 (100%)
Number of children <i>not</i> withdrawn by parents	675 (99%)	642 (96%)
Number of children with consent to participate in accelerometer measurements	366 (53%)	372 (56%)
Number of children with ≥ 1 parent enrolled in questionnaire	343 (50%)	351 (53%)

Table 3. Participation status of children and parents at baseline and follow-up (n, %).

Baseline data were collected from December 2023 to June 2024. Schools were randomized in March 2024, with allocation results communicated to the research team in two rounds (Round 1: 7 schools; Round 2: 11 schools). The scheduling and implementation of the intervention activities ran from March–May 2024, when the children were in 3rd grade (ages 9–10), to March 2025, when they completed 4th grade (ages 10–11). The exact timing of intervention activities varied by school district, as scheduling was coordinated with schools, after-school clubs, and local communities to ensure feasibility. Follow-up data collection took place from March 2025 to August 2025. A study timeline is presented in Figure 3 (46).

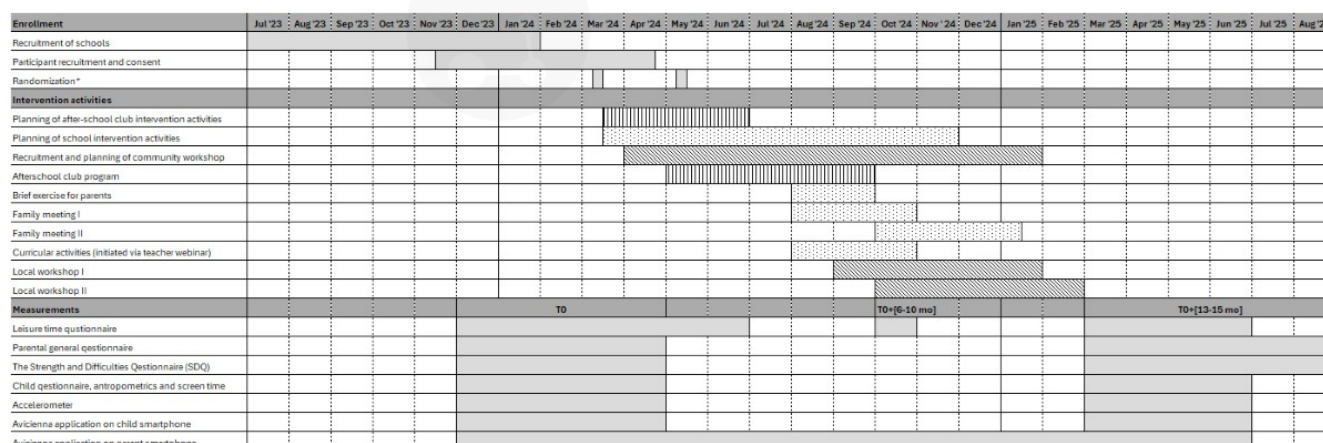


Figure 3. Overview of recruitment, intervention activities, and measurements. Patterns indicate the settings in which intervention activities are planned or implemented: vertical lines = after-school club; dots = school; diagonal lines = local community. *The randomization of schools was conducted in March 2024; however, the allocation results were communicated to the research team in two rounds: Round 1 (7 schools) and Round 2 (11 schools).

Dissemination of results

As of September 2025, data analysis has not yet commenced, and no study results are currently available. Findings on the primary outcome - time spent face-to-face with peers - and on the implementation of the intervention are expected to be published by the end of 2025. Results will be disseminated regardless of outcome through peer-reviewed scientific journals and presentations at relevant scientific conferences. Summaries will also be shared with participating schools and families in lay language. There are no publication restrictions, and the investigators retain full authority over the dissemination of findings.

Discussion

This paper describes the study protocol for the Screen-Free Time with Friends cluster-RCT. The study aims to evaluate the effectiveness of the pragmatic intervention program on a range of outcomes, including - but not limited to - time spent face-to-face with friends, child screen time, classroom social relationships and cohesion, family dynamics related to screen use and physical activity among children aged 9–11.

As children's leisure time behaviors are shaped by a variety of factors (47-53), the Screen-Free Time with Friends intervention is developed with a systemic perspective combining family meetings, curricular activities, development of the after-school club and an opportunity for local stakeholders to address the diverse aspects influencing children's face-to-face interactions and screen use. The family meetings aim to support and empower parents with strategies to facilitate more face-to-face interaction, and less screen use within the family unit and with peers, while the programs for both after-school club staff and local stakeholders aim to create supportive environments conducive to face-to-face interaction.

In recent years, both public discourse and scientific literature have increasingly highlighted the importance of parental dialogue and consensus - such as the development of shared principles for children's screen use - as a potential strategy to address the negative aspects associated with children's screen use (29, 30). However, despite growing recognition of the need for coordinated parental action, few studies have provided concrete, structured approaches or evaluated their feasibility in school settings. The family component of the Screen-Free Time with Friends intervention offers a structured and scalable approach to this challenge. The accompanying process evaluation will generate valuable insights into how this component functions in practice and will thereby contribute to both the scientific evidence base and future practical initiatives to support coordinated parental engagement in managing screen use among 9-11-year-old children.

In Denmark, structured after-school clubs play a central role in children's leisure time (54) and provide inclusive spaces for peer socialization. Most public schools transition children from one type of after-school club to another between grades 3 and 4 (ages 9-11 years). While 94% of children are enrolled in an after-school club in grade 0, participation drops to just 50% by grade 4 with the largest decline occurring between grades 3 and 4 (54, 55). As a result, more children begin spending

their afternoons alone at home. Increased participation in after-school clubs during the transition from grade 3 to 4 may help ensure that more children spend their leisure time in face-to-face interaction with peers rather than alone at home.

The after-school club component of the Screen-Free Time with Friends intervention provides a structured approach that may help reduce dropout between 3rd and 4th grade and increase participation on a daily basis. This, in turn, can support more children in spending time together in face-to-face social settings rather than being alone at home, which has been found to be associated with higher screen use (14). However, to make this approach scalable, additional resources are needed to fund facilitator salaries and to provide time and support for staff to further develop their clubs-also beyond what is included in the three sessions.

The use of methods related to Group Model Building (GMB) at the local level has increasingly been applied to address complex public health challenges (26). In the current study, the local workshops are informed by the GMB methodology and build on insights from previous studies, including the Screen Free Time with Friends feasibility trial (16, 17). While the intervention includes only two workshops of three hours each - less time than typically reported in comparable GMB-based interventions (26) - findings from the feasibility trial suggest that even this relatively limited effort initiated concrete local actions in communities that completed both workshops (17). However, civic engagement and volunteer participation are under pressure in Danish society, which may challenge workshop attendance and limit time and resources for follow-up activities. Our feasibility trial also indicated that it was not possible to implement the workshops successfully in all settings. Conducting this larger-scale trial will allow us to examine whether certain types of local contexts are less conducive to this approach. Moreover, the study will provide valuable insights into the critical

conditions for successful implementation - such as recruitment and participation, the role and capacity of the local ambassador, practical considerations, and the extent to which the research team or other formally paid staff need to support the process. These insights will be essential in understanding what is required for potential future implementation and scale-up of this approach, should it prove effective in fostering change at the community level.

During the feasibility trial, recruiting parents to sign up for the study proved challenging (17), which is critical for evaluating the intervention's effectiveness on outcomes - such as the primary outcome - that rely on data collected from enrolled parents and children. To address the challenge of enrolling parents in the study, the current cluster-RCT will implement several strategies. These include posting multiple messages on the school's online platform before and after the informational meeting, visiting classrooms to inform children directly, encouraging children to bring notes home to their parents, and increasing the project's visibility within the school through posters. In addition, informational video materials about the project are developed.

A limitation of the study may be the relatively short duration of the intervention period. A short timeframe may limit the potential to generate systemic changes that sufficiently influence children's behavior to produce measurable effects within the scope of a cluster-RCT. Therefore, the study also includes a process evaluation that, in addition to examining the implementation of the intervention, explores potential mechanisms of change. This will allow for a deeper understanding of whether the intervention initiates change that - although maybe not yet reflected in the primary outcomes - may, in line with the underlying program theory, lead to longer-term impacts. The findings will also inform future refinement, adaptation, or scaling of the intervention.

Taken together, this study will provide robust evidence regarding the potential effectiveness of the Screen-Free Time with Friends intervention. In addition, the process evaluation will offer insights into how, why, and under what circumstances the intervention may lead to meaningful changes, as well as practical understanding of the strategies and contextual factors influencing its implementation. These findings may support key stakeholders - such as municipalities, schools, after-school staff, community stakeholders, and parents - in shaping everyday environments that promote children's face-to-face interaction and reduce excessive solitary screen use. The insights may also inform policy decisions, guide the development of new or existing initiatives, and inspire future research into practical, real-world interventions that foster meaningful and enriching leisure experiences - ultimately supporting children's development and well-being.

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ChatGPT (OpenAI) was used for grammatical and language optimization of the manuscript. All AI-generated suggestions have been reviewed, edited, and approved by the authors.

Conflicts of interest

The authors declare no conflicts of interest.

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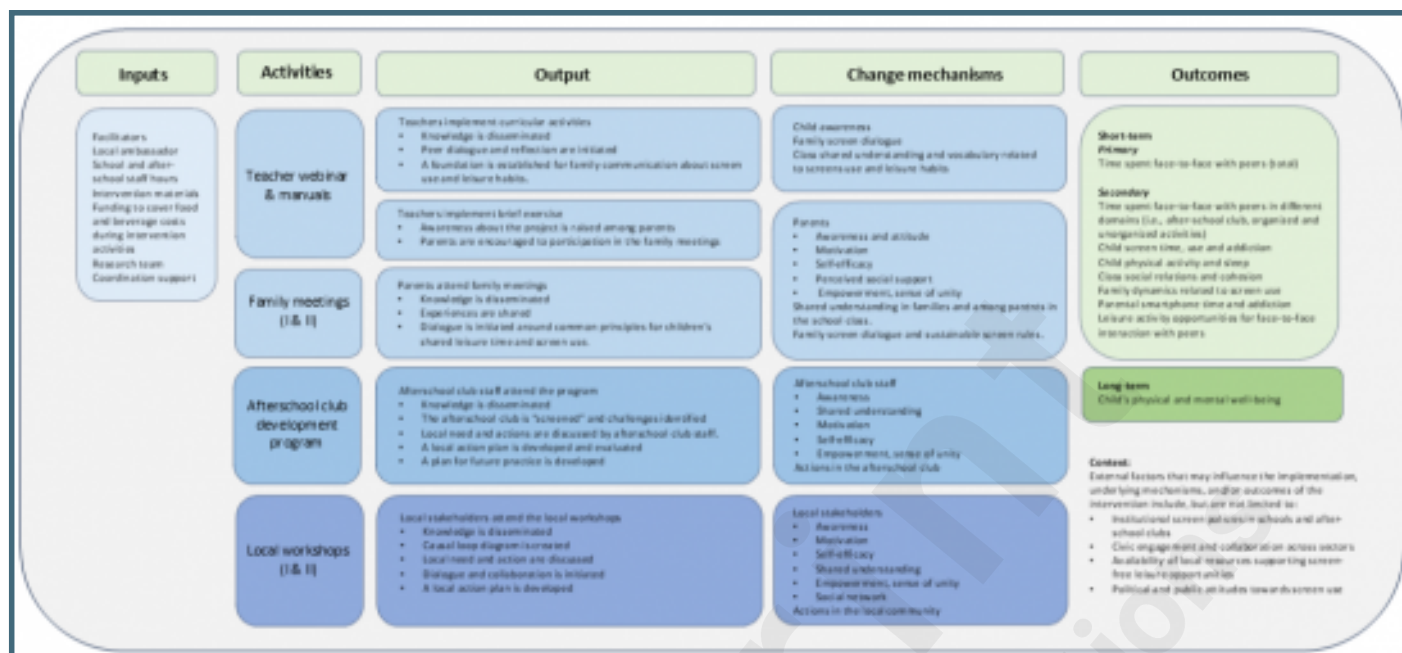
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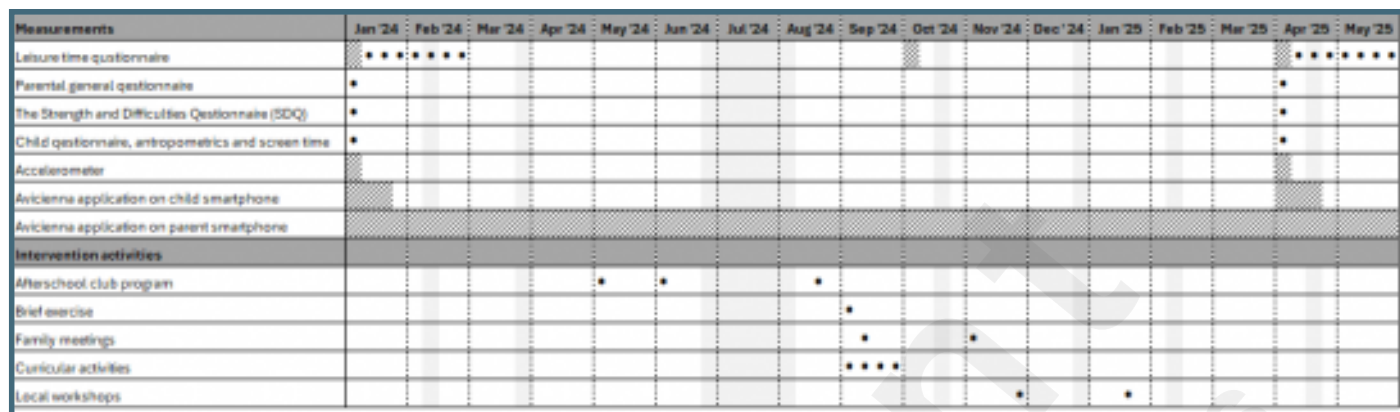
Supplementary Files

Figures

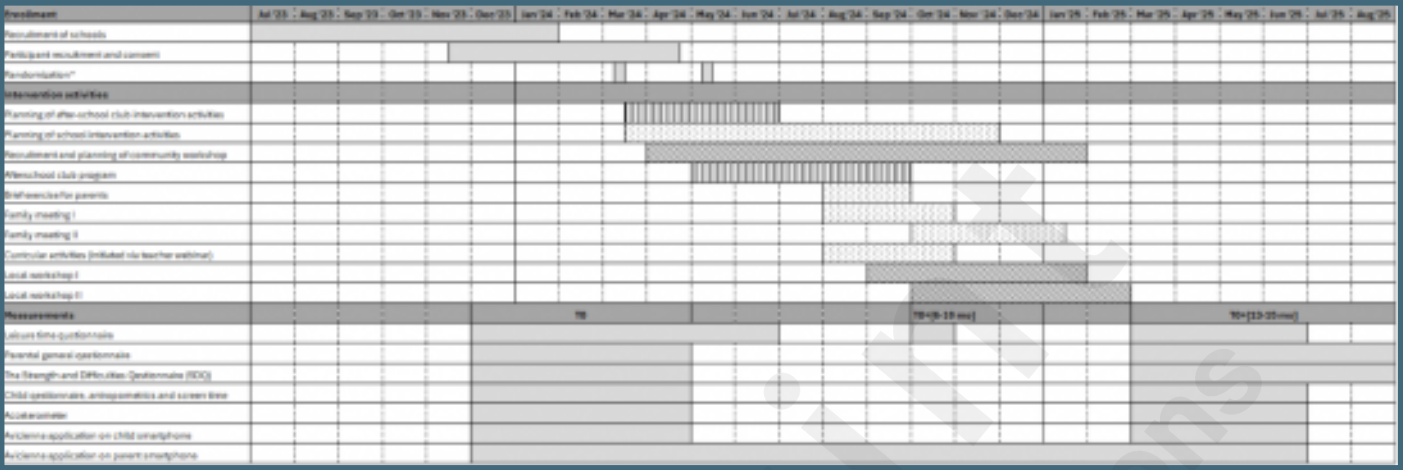
The program theory of the Screen-Free Time with Friends intervention.



Example timeline showing the scheduling of data collection and intervention activities in a single intervention school district. A dot represents one measurement or intervention activity. Bars with diagonal lines indicate measurement periods lasting seven consecutive days per week (e.g., accelerometer data collection). School holidays are represented by solid light grey bars.



Overview of recruitment, intervention activities, and measurements. Patterns indicate the set-tings in which intervention activities are planned or implemented: vertical lines = after-school club; dots = school; diagonal lines = local community. *The randomization of schools was conduct-ed in March 2024; however, the allocation results were communicated to the research team in two rounds: Round 1 (7 schools) and Round 2 (11 schools).



CONSORT (or other) checklists

SPIRIT checklist.

URL: <http://asset.jmir.pub/assets/313ed6253979d5ba04042e22a3fabae9.pdf>

