

SMARTFAMILY2.0: A refined mobile health intervention to promote physical activity and healthy eating in a family setting - A randomized-controlled trial

Janis Fiedler, Kathrin Wunsch, Sebastian Hubenschmid, Harald Reiterer, Britta Renner, Alexander Woll

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SMARTFAMILY2.0: A refined mobile health intervention to promote physical activity and healthy eating in a family setting – A randomized-controlled trial

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Abstract

Background: Many mobile health (mHealth) apps focus on promoting physical activity (PA) and healthy eating (HE). However, there is limited empirical evidence regarding their effectiveness in initiating and sustaining behavior change, particularly among children and adolescents. Considering that behavior is influenced by social contexts, it is essential to take core settings like family dynamics into account when designing mHealth apps.

Objective: The purpose of this study was to further develop and refine the SMARTFAMILY app targeting PA and HE in a collective family-based setting by enhancing design and usability, as well as by adding gamification aspects, health literacy, and just-in-time adaptive interventions (JITAI) to the first version of the app.

Methods: The SMARTFAMILY2.0 app, based on behavior change theories and techniques, was developed, implemented, and evaluated. The app was used in a collective family setting, with family members using it individually and cooperatively. In a cluster-randomized controlled trial, the intervention group (IG) used the app for three consecutive weeks, while the control group (CG) received no treatment. Primary outcomes included physical activity (PA) measured through self-reports and accelerometry, as well as self-reported fruit and vegetable intake (FVI) for health eating (HE). Secondary outcomes included intrinsic motivation, behavior-specific self-efficacy, and the Family Health Climate (FHC). A follow-up assessment (T2) was conducted four weeks after the post-measurement (T1) to assess intervention effects. Multilevel analyses were performed in R, considering the hierarchical structure of individuals (level 1) within families (level 2).

Results: Overall, 55 families (28 CG, n = 105; 27 IG, n = 104 participants) were recruited for the study. Three families (3 KG, n = 12) chose to drop out of the study due to personal reasons before T0. Overall, no evidence for meaningful and statistically significant increases in PA was observed in favour of the IG our physically active sample. However, the app elucidated positive effects in favor of the intervention group for FVI diary (T0-T1; p = .031), joint PA (T0-T1 and T0-T2; p < .026), and joint family meals (T0-T1; p = .004).

Conclusions: The SMARTFAMILY2.0 trial evaluated a mHealth intervention designed to promote PA and HE within families. Despite incorporating a theoretical foundation, several behavior change techniques based on family life and gamification and JITAI features, the intervention did not significantly increase PA levels among physically active participants. FVI intake, joint PA, and joint meals were improved within the intervention group. Previous studies on digital health interventions have produced mixed results, and family-based mHealth interventions remain rare, with limited focus on whole-family behavior and randomized controlled trials. To enhance intervention effectiveness, future app development could consider incorporating even more advanced features and should focus on inactive participants. Further research is needed to better understand intervention engagement and tailor mHealth approaches for primary prevention efforts. Clinical Trial: The study is registered with the

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Original Research

SMART*FAMILY*2.0: A refined mobile health intervention to promote physical activity and healthy eating in a family setting – A randomized-controlled trial

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Trial registration

The study is registered with the German Clinical Trials Register under the registration number DRKS00010415.

Conflicts of interest

All authors declare they do not have any conflicts of interest. Authors/evaluators are distinct from the developers/sponsors of the intervention.

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SMART*FAMILY:* family-based mHealth intervention for physical activity and healthy eating

Abstract

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Conclusion: The SMART*FAMILY*2.0 trial evaluated a mHealth intervention designed to promote PA and HE within families. Despite incorporating a theoretical foundation, several behavior change techniques based on family life and gamification and JITAI features, the intervention did not significantly increase PA levels among physically active participants. FVI intake, joint PA, and joint meals were improved within the intervention group. Previous studies on digital health interventions have produced mixed results, and family-based mHealth interventions remain rare, with limited focus on whole-family behavior and randomized controlled trials. To enhance intervention effectiveness, future app development could consider incorporating even more advanced features and should focus on inactive participants. Further research is needed to better understand intervention engagement and tailor mHealth approaches for primary prevention efforts.

Keywords: mobile application; telemedicine; behavior change; health behavior; family; primary prevention; exercise; diet, food and nutrition; randomized controlled trial; accelerometer; wearable electronic devices; social-cognitive determinants; just-in-time adaptive intervention; digital intervention

SMART*FAMILY:* family-based mHealth intervention for physical activity and healthy eating

Abbreviations: PA: physical activity, HE: healthy eating, IG: intervention group, CG: control group, SF: SMART*FAMILY*, FHC: Family Health Climate, FVI: fruit and vegetable intake; EMA: ecological momentary assessment; JITAI: just-in-time adaptive intervention; mHealth: mobile Health, app: application; BLE: Bluetooth Low Energy, BCT: behavior change technique

SMART*FAMILY:* family-based mHealth intervention for physical activity and healthy eating

Introduction

Background

The health benefits of sufficient physical activity (PA), reduced sedentary behavior (SB) including screen time, and healthy eating (HE) are manifold [1–4] and include benefits regarding all-cause mortality, cardiovascular function, cancer, and metabolic and mental health among others [3,5–7]. Hence, engaging in different health behaviors should be emphasized from young ages onwards. Guideline adherence is only high for PA in preschool children [8], but the older the children get, it becomes less likely that they sufficiently engage in PA [9–11]. Adherence to screen time guidelines is generally low [12,13], and children are known to make frequently unhealthy food choices [14–17]. It has been observed that the majority of children and adolescents (81%) and a significant proportion of adults (23%) do not meet the recommended levels of PA and HE, specifically in terms of fruit and vegetable intake (FVI), globally [18]. Research has shown that there is a dose-response relationship, meaning that even small increases in PA and/or HE can have positive effects on the physiological and psychological health of children and adolescents [19] and adults [2,20–23].

A promising way to achieve sustainable behavior change is to create interventions that target children and adolescents, as longitudinal studies showed that behavioral patterns in childhood and adolescence have a low-to-moderate influence on PA patterns in adulthood [24–29]. As children and adolescents are strongly dedicated to siblings and parents, social contexts like the family context need to be involved in intervention development, as health behaviors are affected by social relations and ties [30,31]. By implementing the family context into the intervention design, HE [32] and PA [33,34] can be facilitated more sustainably by targeting variables of daily family life like common meals [35–37]. Results of intervention studies also indicate that social support is significantly associated with the continuation of exercise programs [38–42] as well as participation in weight-loss interventions [43–45]. Therefore, both parents and their children can benefit from a behavior change intervention at the family level.

To deliver such interventions and individualize them to the different needs of participants, mobile health (mHealth) technologies are upcoming developments [46]. Smartphone-based applications (apps) in particular are promising to change health behavior and be cost-effective on a large scale [47-49]. Recent reviews and metaanalysises provide preliminary evidence for the effectiveness of app-based health behavior change [50-52]. Here, certain facets are related to intervention effectiveness [53], including a theoretical foundation and behavior change techniques (BCTs, [54]) like goal setting, self-monitoring, social support [55,56], implementing the intervention in a social context [30,57] and the tailoring of interventions to participants needs [50,52,58]. These aspects were already included in the SMARTFAMILY1.0 trial [59]. Based on current literature, this app was further developed by revising user interface and usability and by adding and consolidation several other features that have been shown to positively influence intervention effectiveness, like gamification [60], physical literacy [61,62], further BCTs [54], momentary assessments (EMA) [63] and just-in-time interventions (JITAIs) [64]. Recent developments in technology, mobile sensing, and wireless communication enable researches to deliver JITAIs [64,65] at the most promising time for behavior change and adapt them in real time to sensor or

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participant input. The evidence for these interventions is preliminary but promising to maximize effectiveness while minimizing participant burden [59,66,67].

Overall, there is a lack of randomized-controlled mHealth studies targeting both, children and adults within a social system aiming at health behavior change of more than one behavior [68] that use important key facets of effective interventions like BCTs and a theoretical foundation and incorporate JITAIs [65,69,70].

Objective

The SMARTFAMILY2.0 trial aimed at refining the existing mHealth intervention app [59] that incorporates the family as a social system. Here, additional BCTs, gamification features, physical literacy aspects and a JITAI were integrated and the functionality and design of the app was improved. As before, the behavior of children and parents was targeted within the SMARTFAMILY2.0 app to induce family- and individual-based behavior changes. For more details and the complete study protocol see [71]. A positive influence of the refined mHealth intervention on PA variables steps and MVPA and the HE variable FVI in the whole family was hypothesized.

Methods

Study Design

The study was conducted and described according to the corresponding study protocol and the CONSORT-EHEALTH checklist [72]. A graphical representation of the SF2.0 trial is depicted in Figure 1. Outcome evaluations were conducted at three time points: baseline (T_0) , immediately after the 3-week intervention (or absence of intervention) phase (post; T_1), and four weeks after the post-measurement (follow-up; T_2). Participants were cluster-randomized into one of two groups: an intervention (IG) or a waiting-control group (CG). Given that the study protocol is freely accessible, the study design and measurements will be described very briefly. For a comprehensive overview, please consult the study protocol [71].

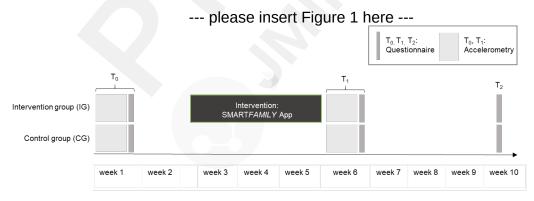


Figure 1. Detailed study design.

All eligible members of each family attended an initial visit to the research facility, during which they were provided with detailed instructions on how to utilize various tools that would be used throughout the study. These tools encompassed accelerometers, which recorded levels of PA, as well as paper diaries for monitoring behavior over time. This procedure was changed to online instructions and mailing of the material during the study due to Covid-19 restrictions. At the end of this initial phase, participants also responded to inquiries about their habits and behaviors

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during the preceding week, serving as a baseline measurement. This information was subsequently shared with intervention participants to enable them to establish family goals based on this starting point.

Participants assigned to the intervention group were given specially designed smartphones embedded with our "SMARTFAMILY2.0" app. The development of the app followed an iterative approach, incorporating feedback from the prior app, the target audience and domain experts. Insights from previous research conducted as part of the SMARTACT project and behavioral theories also informed the app's creation. The programming of the applications was undertaken by the Human-Computer Interaction Workgroup at the University of Konstanz, as a component of the SMARTACT project. To ensure equitable access to technology, study personnel provided all participants with study smartphones. Families were thoroughly briefed on the app's functionality, with a study manual distributed to aid their comprehension, and study staff were available to address any queries or concerns that arose. Moreover, the accelerometers worn by participants were wirelessly synchronized with the smartphones via Bluetooth low-energy connections.

During the onset of the three-week intervention, families in the intervention group were instructed to establish collective weekly goals related to PA and HE. These objectives encompassed achieving a specific step count, engaging in appropriate levels of moderate/vigorous PA, planning enjoyable family activities, sufficient FVI, and having joint family meals. Families were instructed to collaborate in formulating these goals based on their previous performance as assessed during the baseline evaluations. To facilitate this process, the goals for the entire family were set on a single smartphone, and the app sent notifications every Sunday to prompt the setting of new goals. During the initial explanation by study staff, participants were encouraged to strive for progressively more ambitious yet attainable goals based on their past behaviors. As part of the program, participants regularly reviewed and adjusted their goals to ensure they remained challenging yet manageable, fostering ongoing improvement. The app-based intervention also incorporated a just-in-time adaptive intervention [64,65], delivered by a coach, which prompted users to engage in physical activity after prolonged periods of inactivity. Inactivity was defined as one hour with less than 100 steps and less than 2 minutes with >2 metabolic equivalents (MET) during waking hours. Additionally, the coach provided daily progress updates towards the goals, motivational messages, up to 5 informational and entertaining facts per day, and ecological momentary assessments regarding sleep quality and core affect. Participants in the non-intervention control group did not receive any materials or communication during the intervention period. All smartphones were collected after the conclusion of the intervention period. Consequently, the intervention group did not have access to the app during the T₁ measurement or thereafter.

The app included 14 BCTs [54] for the intervention group and no BCT for the control group. Intervention BCTs were: behavioral goal-setting, prompt review of behavioral goals, prompt self-monitoring of behavior, provide feedback on performance, plan social support/social change, prompt identification as role model/position advocate, set graded tasks, shaping, prompt rewards contingent on effort or progress toward behavior, provide rewards contingent on successful behavior, barrier identification/problem solving, teach to use prompts/cues, and prompt review of behavioral goals.

After the intervention or control period ended, participants proceeded to undergo two

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additional testing sessions (T_1 and T_2). Throughout the entire process, strict adherence to ethical standards was maintained, and measures were implemented to safeguard personal data. The research study employed a single-blind design, whereby participants were unaware of their group assignment. Furthermore, prior to implementation, the survey instruments underwent thorough evaluation to ensure user-friendliness and technical reliability.

Eligibility Criteria and Ethical Approval

Households consisting of at least one adult caregiver and one child older than ten years of age living together were invited to participate. In cases where applicable, additional siblings - including younger siblings - were also welcome to join the project. All participants were required to possess basic proficiency in operating mobile devices, have the physical capability to engage in physical activity independently, and effectively communicate in German. Prior to the commencement of the study, all participants, including minors, parents, or legal guardians, provided informed written consent. The research study received full ethical approval from both the University of Konstanz and the Karlsruhe Institute of Technology. The study adhered to the guidelines outlined in the Helsinki Declaration.

Randomization and Blinding

This study employed a cluster-randomized controlled design to compare two distinct groups: an Intervention Group (IG) that received the intervention and a Control Group (CG) that did not receive any treatment. Families who provided consent were randomly assigned to either group using a straightforward allocation scheme suitable for cluster trials (following 58). While participants in the IG were aware of the mHealth aspects of the study, participants in the CG were informed about their contribution to an epidemiological examination of physical activity and overall health. To ensure accurate and reliable measurements, all participants wore accelerometers for one week twice over a ten-week duration. Additionally, participants completed various questionnaires during this period.

Participants

Participants were recruited in schools, school holiday programs, music schools, and sports clubs, via personal communication, newspapers, and email distribution lists of the Karlsruhe Institute of Technology. Overall, 55 families (28 KG, n = 105; 27 IG, n = 104 participants) were recruited for the study. Three families (3 KG, n = 12) chose to drop out of the study due to personal reasons before T_0 .

Measurements

Physical activity measures

Device-based measured physical activity (accelerometry)

The study employed hip-worn 3-axial accelerometers (Move 3/Move 4, Movisens GmbH, Karlsruhe, Germany) placed on the right hip to continuously capture PA data. These accelerometers are recognized scientific research instruments, featuring a measurement range of ±16 g, an output rate of 64 Hz, physical dimensions measuring 62.3 mm x 38.6 mm x 11.5 mm, and weighing 25 g. Custom epoch lengths of 10 seconds were used to summarize the raw data recorded at 64 Hz. The choice of an epoch length of 10 seconds was based on the belief that shorter epoch lengths are more suitable for estimating vigorous PA and assessing PA in children due to their intermittent movement behavior [59,60]. The validity of a previous

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accelerometer version (Move 2), which utilizes similar digital signal processing techniques as the Move 3/Move 4 models, has been established and considered accurate for assessing steps [73] and energy estimation [74,75] in adults. Participants received instructions and demonstrations from a study instructor regarding the proper handling of the accelerometers. They were directed to wear the accelerometers throughout their waking hours and remove them only during activities such as showering, swimming, or certain sports involving bodily contact to minimize the risk of injuries. The outcomes measured using the accelerometer in this study were MVPA (>3.0 MET) and steps for all participants. MET values were calculated based on activity class determined by acceleration and barometric signals, which informed the estimation model. The model combined movement acceleration, altitude change, and demographic information to estimate MET values [75]. To be included in the analysis, accelerometer data needed to meet certain criteria. This included a minimum wear time of at least 8 hours per day for at least 4 of the 7 days during the measured week. Non-wear time was calculated in 30-second intervals using an algorithm that incorporated accelerometry and temperature signals over a 10-minute window. This algorithm distinguished between wear time, non-wear time, and sleep. as described elsewhere [64]. Valid measurements were determined by calculating the average of MVPA and steps per valid day and multiplying it by 7 to estimate the total minutes per week.

Self-reported physical activity

At the conclusion of each week of measurement, all participants were requested to complete the German version of the Global Physical Activity Questionnaire (GPAQ) [76]. This questionnaire asked participants to retrospectively report their activities during the previous week. To calculate the results for this study, we multiplied the reported number of days engaged in moderate physical activity (related to work, travel, and recreation) and vigorous physical activity (related to work and recreation) by the reported duration of each activity per day. We then added the values for moderate and vigorous physical activity to obtain the total minutes of MVPA per week. Additionally, a physical activity diary was utilized for all participants at time points T_0 and T_1 . However, the results from the diary were not included in the current analysis due to non-comparability with other measures [77,78]. Both parents and children were instructed to independently complete their respective questionnaires and diaries.

Fruit and vegetable intake

The assessment of FVI involved two methods. Firstly, a single item in the questionnaire asked participants to report the total amount of fruits and vegetables consumed in the previous week [79]. Secondly, a detailed description of food consumption during time points T_0 and T_1 weeks was recorded in a diary. This included information such as the time of the meal, the ingredients, portions of FVI, and whether the meal was consumed within the family or alone.

Secondary Outcomes

Demographics

In the T_0 questionnaire, demographic information of the participants was collected, including sex, age, height, and weight.

Health status

Perceived general health was assessed using a single Item [79].

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Intrinsic Motivation Toward Physical Activity

According to the Self-Determination Theory, the assessment of activity-related self-determination was conducted using the Behavioral Regulation in Exercise Questionnaire (BREQ-2) [80]. BREQ-2 assesses the manifestation of the five different regulation modes by the Self-Determination Theory, reflected by the subscales of amotivation (4 items), external (4 items), introjected (3 items), identified (4 items), and intrinsic (4 items) regulations. Responses were made on a 4-point Likert scale, ranging from (0) 'not true', (1) 'rather not true', (2) 'rather true' to (3) 'true'. For the purpose of analysis, a relative autonomy index (RAI) was constructed based on the subscales of the questionnaire. The RAI provides an assessment of the extent to which respondents perceive themselves as self-determined. To calculate the index, each subscale score was multiplied by its assigned weighting, and the weighted scores were then summed. A higher, positive RAI score indicates a higher level of relative autonomy, while a lower, negative score suggests a greater level of controlled regulation.

Intrinsic Motivation Toward Healthy Eating

The Regulation of Eating Behavior Scale [81] was used to assess dietary-related intrinsic motivation. The dimension "integated regulation" was omitted, resulting in a total of 5 subscales, coded from 0-3. A sum score was built analogous to the BREQ-2.

Intention

Intention towards PA and FVI as well as intention to use an app for PA and HE were assessed using single items [82].

Self-efficacy for Physical Activity and Healthy Eating

In order to assess activity-related self-efficacy and dietary-related self-efficacy, the study employed health-specific self-efficacy scales. These scales consisted of five items for each behavior-related dimension [83]. Participants were asked how certain they are to handle different health-specific barriers. Responses were given on a 4-point Likert scale, ranging from (1) very uncertain, (2) uncertain, (3) certain to (4) very certain. A sum score was built for both scales.

Family Health Climate

To assess shared perceptions and cognitions regarding health behaviors, the study utilized the Family Health Climate Scale (FHC) [84]. This scale consists of two separate scales: the FHC-PA scale and the FHC-nutrition (NU) scale. FHC-PA contains 14 items, which are assigned to the three subscales of value (5 items), cohesion (5 items), and information (4 items). FHC-NU includes 17 items, comprising the four subscales of value (4 items), cohesion (5 items), consensus (3 items,) and communication (5 items). Responses for each dimension were scored on a 4-point Likert Scale ranging from (0) 'not true', (1) 'rather not true', (2) 'rather true' to (3) 'true'. Sumscores were built for both scales.

Joint Physical Activity and Meals within the family

Joint PA and NU were assessed using a single item that inquired about the number of activities and meals in which the entire family participated during the previous week. The mean value per family was calculated and used for the analysis.

Statistical Analysis

The analyses were run with different packages of R [85] and RStudio [73]. The package 'ggplot2' was used for visualizations [86] following the instructions of Allan

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and colleagues [87]. Mixed models were calculated using the package 'ImerTest' [88] with participants (level 1) nested in families (level 2) to acknowledge the hierarchical structure of the data. The result tables of the regression analyses were generated using the package 'sjPlot' [89]. Here, seven final models were calculated, one with each measurement method and outcome parameter (1 steps, 2 MVPA, 2 FVI intake per week, 1 joint PA, 1 joint NU) as dependent variables. Assumptions were checked using the visualization of the 'performance' package [90]. A hierarchical approach was used for the inclusion of the control variables and the model fit was assessed with the Akaike information criterion (AIC) for sensitivity analysis.

The predictor group (i.e. control = 0, intervention = 1) x time (dummy coded with T_0 as reference for T_1 and T_2) was included in the models to evaluate the interaction effect (main effect) of the intervention on the seven outcome parameters. To assess sensitivity regarding the additional variables, the secondary outcome parameters self-efficacy, intention, intention for app use, intrinsic motivation, and the family health climate were added either referring to PA or FVI depending on the outcome and the control variables health status, population (adult = 0, children = 1), sex (0 = male, 1 = female) and non-wear time per week - only for the device-based measured PA models - were tested for the inclusion in the random effect models. Additionally, the inclusion of random slopes and random intercepts were evaluated based on the model fit. The level of statistical significance was set a priori to $\alpha < .05$

Results

Data availability and participant characteristics

In total, 52 families (n=96 adults, 49/51% female/male, and n=101 children, 47/53% female/male) participated in the study. Technical issues with the application during the intervention, insufficient wear time of the accelerometer (i.e. less than 4 days with more than 8 hours wear time), and missing data for the self-reported items led to the inclusion of a different number of participants for each calculated model (depending on the outcome variables, see Appendix B/C). Participant characteristics of the 52 families separated by group (control vs. intervention), population (children vs. adults), and sex (male vs. female) are displayed in Table 1. Descriptive results for all included outcomes and predictors can be found in Table 2.

--- please insert Table 1 here ---

Table 1. Participant characteristics of the 52 families included in the SMARTFAMILY2.0 trial. Displayed are the means and standard deviations (SD) of the parameters age and BMI divided by group (control or intervention), population (children and adults), and sex (male and female).

group populati		cor	ntrol		intervention				
on	cł	nild	ac	dult	cl	nild	adult		
sex	male	female	male	female	male	female	male	female	
	25	25	23	20 (47	29	22	26	27	
m	(50%)	(50%)	(53%)	%)	(57%)	(43%)	(49%)	(51%)	
	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean	
	(SD)	(SD)	(SD)	(SD)	(SD)	(SD)	(SD)	(SD)	
	11.5	10.4	45.1	46.4	11.4	12.1	45.0	46.7	
age	(3.64)	(2.58)	(5.92)	(6.09)	(2.73)	(3.63)	(5.11)	(4.98)	
ВМІ	18.9	17.9	24.3	27.2	17.2	18.5	23.5	27.1	

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(3.68) (3.19) (3.86) (4.51) (3.12) (2.82) (3.66) (3.66)

SMARTFAMILY: family-based mHealth intervention for physical activity and healthy eating

--- please insert Table 2 here ---

Table 2. Descriptive results of the 52 families included in the SMART FAMILY 2.0 trial. Displayed are the means and standard deviations (SD) of the device-based measured parameters steps, moderate to vigorous physical activity (MVPA), and non-wear time (nwt) and the self-reported parameters moderate to vigorous physical activity measured by the global physical activity questionnaire (GPAQ MVPA), fruit and vegetable intake measured by a single item questionnaire (FVI quest) and by diary (FVI diary) and the secondary outcomes health status (health), intrinsic motivation towards nutrition (M intrinsic NU), intention to change physical activity and nutrition with an application (int app PA/NU) and physical activity (M intrinsic PA), intention towards changing physical activity (int PA), nutrition (int NU), and the family health climate (FHC NU and FHC PA), and self-efficacy for physical activity (self-efficacy PA) and healthy eating (self-efficacy NU) as well as joint physical activities (joint PA) and joint family meals (joint NU) divided by group (control or intervention), and population (children and adults). RAI = relative autonomy index.

Group	Control								Interv	ention
	Т0		T1		T2		Т0		T1	
population	child	adult	child	adult	child	adult	child	adult	child	adult
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Steps (counts/week)	57000 (26200)	55700 (17800)	64100 (23000)	54600 (17100)	_	_	64600 (25900)	54000 (14500)	61300 (24100)	49800 (20100)
MVPA (minutes/week)	579 (346)	621 (236)	729 (351)	631 (221)	_	_	651 (358)	644 (177)	587 (311)	572 (205)
nwt (minutes/week)	4990 (538)	4330 (671)	4810 (660)	4380 (596)	_	_	4920 (535)	4400 (561)	4990 (700)	4540 (600)
GPAQ MVPA (minutes/week)	988 (1020)	980 (1230)	1200 (1020)	995 (860)	1430 (954)	1410 (1270)	1160 (1380)	725 (687)	1170 (1080)	869 (644)
FVI diary (portions/week)	20.7 (14.5)	20.1 (11.6)	18.0 (11.8)	19.7 (10.8)	_	_	21.5 (13.1)	20.5 (10.0)	22.0 (13.3)	24.0 (10.1)
FVI quest (portions/week)	19.3 (11.0)	15.8 (11.8)	17.5 (11.2)	17.0 (12.2)	19.2 (12.2)	16.8 (9.96)	20.9 (14.7)	17.8 (11.3)	20.0 (15.1)	20.7 (11.3)
health	4.20 (0.808)	3.70 (0.803)	4.17 (1.11)	3.79 (0.645)	4.33 (0.816)	3.79 (0.592)	4.26 (0.828)	3.91 (0.946)	4.11 (1.04)	4.00 (0.799)
M intrinsic PA (RAI)	35.3 (14.1)	32.8 (18.8)	35.6 (13.0)	35.5 (17.4)	36.2 (14.7)	40.2 (12.9)	34.7 (14.7)	36.4 (12.6)	32.3 (18.4)	34.9 (13.5)
M intrinsic NU (RAI)	9.86 (19.7)	20.0 (17.9)	8.94 (19.1)	2.90 (11.7)	12.5 (20.6)	23.5 (18.9)	11.6 (19.0)	22.0 (15.7)	10.5 (20.7)	5.34 (10.5)

int PA	1.94	2.44 (1.22)	1.96	2.10	2.18	1.94	2.08	2.11	1.98	2.04
	(1.02)		(0.932)	(1.25)	(1.07)	(0.886)	(0.997)	(0.934)	(0.917)	(0.922)
int NILL	2.78	2.72	2.66	2.81	2.73	2.74	2.57	2.79	2.37	2.88
int NU	(0.840)	(0.854)	(0.939)	(0.890)	(0.719)	(0.790)	(0.855)	(0.793)	(0.878)	(0.761)
int and DA	2.68	3.19 (1.20)	2.96	3.00	2.94	3.35	3.10	3.47	3.09 (1.24)	3.04
int app PA	(1.49)		(1.28)	(1.27)	(1.46)	(1.30)	(1.47)	(1.26)		(1.24)
int one NIII	2.28	2 72 (1 22)	2.38	2.88	2.55 [^]	2.85 [^]	2.96	2.94 [′]	2.80 (1.31)	2.58 [^]
int app NU	(1.23)	2.72 (1.32)	(1.24)	(1.25)	(1.30)	(1.28)	(1.39)	(1.25)		(1.13)
FHC NU	51.6	51.7 (7.01)	50.0	51.0	51.5	51.1	50.6	51.6	48.8 (9.52)	50.0
	(7.41)		(8.39)	(7.08)	(7.46)	(7.30)	(8.06)	(8.82)		(8.88)
FHC PA	39.0	39.7 (7.63)	38.6	38.7	39.2	40.1	38.2	38.2	38.5 (7.54)	36.9
	(7.92)		(8.03)	(7.32)	(8.37)	(7.35)	(7.91)	(8.33)		(7.78)
self-efficacy NU (RAI)	Ì2.0 ´	12.9 (4.23)	12.0	13.0	ì2.7 [°]	Ì2.8 ´	Ì3.4 [°]	Ì3.6 ´	12.5 (3.67)	14.2 ´
	(3.52)		(3.22)	(3.19)	(4.13)	(2.97)	(3.52)	(2.84)		(2.95)
self-efficacy PA (RAI)	Ì3.6 ´	12.8 (3.53)	13.5	12.7	12.6	13.2	14.6	Ì4.0 ´	13.4 (3.22)	Ì3.0 ´
	(3.71)		(3.11)	(3.35)	(3.53)	(3.11)	(2.71)	(3.04)		(3.25)
joint PA	2.00 ´	1.84 (2.85)	3.69	3.03	5.12	3.58 [^]	Ò.96Ó	ì.19 ´	2.07 (5.20)	3.08
	(3.40)		(5.31)	(4.00)	(8.24)	(3.72)	(1.48)	(1.78)	3.97 (5.29)	(4.15)
joint NU	7.52 [^]	7 52	9.96	9.54	ì3.5 [°]	Ì4.1 ´	8.20 ´	7.62 ´	0.00 (5.70)	9.83 [^]
	(4.39) 8.95 (4.26)	(3.13)	(2.78)	(6.00)	(4.64)	(5.54)	(4.67)	9.32 (5.79)	(5.16)	

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All control variables (except non-weartime for MVPA and steps, and population for FVI diary) improved the model fit based on AIC and were therefore included in the final sensitivity models with the exception of the joint models where only population improved the model fit. Random slopes were not supported by the data but random intercepts were used for all models. Sensitivity analysis showed no difference in patterns for the effectiveness of the intervention (see Appendix C, Tables 1-7). Therefore, only the main models are reported. Data and code are available at the Open Science Framework: https://osf.io/3gtja/

Effect of the intervention on physical activity

Results of the linear mixed models indicate significant main effects for the interaction of group with time in device-based-measured MVPA between T_0 and T_1 in favor of the control group (p = .016, β = -0.50). Steps show no significant main effect but the β point in the same direction as for device-based measured MVPA. Self-reported MVPA with the GPAQ reveals no significant interaction of group x time but a significant time effect between T_0 and T_2 (p = .008, β = 0.21). For all main results see Appendix B, Tables 1-3. Figures 2 and 3 display the descriptive results for the device-based measured PA outcomes MVPA and step count. As displayed by the grey dotted lines in Figure 2, both mean and median values are clearly above the recommendation for MVPA [4] for both children (i.e. 60 minutes per day on average, 420 minutes / week) and adults (i.e. 150 minutes / week) in both groups and at both measurement periods. For steps, mean and median values are below the commonly used 10.000 steps/day (70.000 steps/week) goal [91,92] for all participants (see Figure 3).

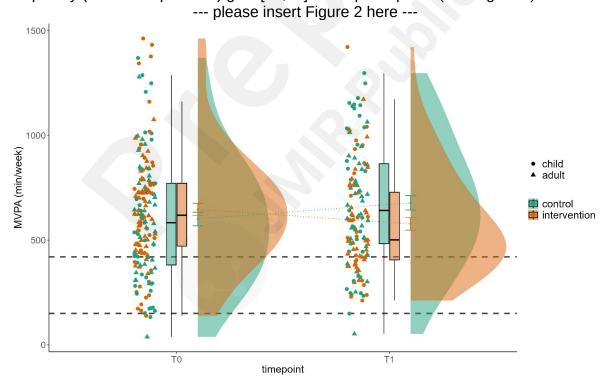


Figure 2. Interaction effect of group x time for device-based measured physical activity for the parameter minutes of moderate to vigorous physical activity per week (MVPA). Displayed is the mean MVPA (y-axis) of 180 participants during one week of baseline measurement (T_0) and one week of post-measurement after a 3-week intervention/waiting period (T_1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed lines represent the PA

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recommendations for children (420 min/week) and adults (150 min/week).

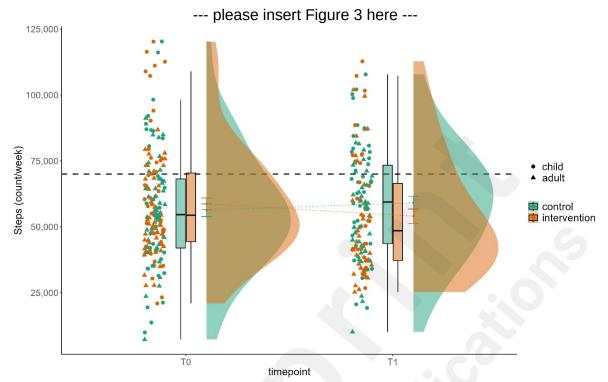


Figure 3. Interaction effect of group x time for device-based measured physical activity for the parameter steps per week (steps). Displayed is the mean step count (y-axis) of 180 participants during one week of baseline measurement (T_0) and one week of post-measurement after a 3-week intervention/waiting period (T_1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the commonly used step recommendation of 10.000 steps/day (70.000 steps/week).

Effect of the intervention on fruit and vegetable intake

Results of the linear mixed models indicate a significant interaction of group x time concerning FVI reported by the diary between T_0 and T_1 in favor of the intervention group (p = .031, β = -0.35). There is no significant main effect for FVI assessed via questionnaire (see Appendix B, Tables 4-5). Figure 4 displays the descriptive results for self-reported FVI per week assessed by the questionnaire. Here, both mean and median values are clearly below the recommended FVI of 5 portions per day (35 portions/week) [93].

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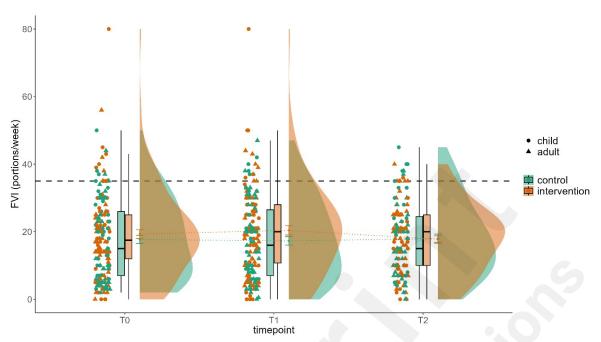


Figure 4. Interaction effect of group x time for the parameter fruit and vegetable intake per week (FVI) assessed by questionnaire. Displayed is the mean fruit and vegetable intake (y-axis) of 197 participants related to the week of baseline measurement (T_0), the week of post-measurement after a 3-week intervention/waiting period (T_1), and the week of follow-up measurement (T_2) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the recommondation for daily FVI of 5 portions (35 portions/week).

Effect of the intervention on joint Physical Activity and Meals

Results of the linear models indicate a significant effect for group x time for both T_0 to T_1 (p = .026, β = 0.18) and to T_2 (p = .008, β = 0.29) in favor of the intervention group for joint PA. Regarding joint meals, a significant group x time interaction was found for T_0 to T_1 in favor of the IG (p = .004, β = 0.14), and a significant group x time interaction was found for T_0 to T_2 in favor of the CG (p < .001, β = -0.34). Additionally, all four time effects were significant with a β between 0.21 and 1.20. All results are displayed in Appendix B, Tables 6 and 7.

Discussion

The SMART*FAMILY*2.0 trial evaluated the effectiveness of a refined mHealth intervention to increase PA and HE in a family setting. Extending previous research, the behavior of children *and* parents was targeted to induce individual behavior changes that are anchored in daily family life. Moreover, besides a theoretical foundation, several BCTs were additionally included which contribute to the fulfillment of basic psychological needs according to the self-determination theory [94]. Overall, there was no significant intervention effect of our app for PA, independent of measurement method, but for FVI as measured by diary. However, participants were not able to maintain this effect four weeks after intervention cessation. The explorative results for joint PA point to a potential effectiveness of the collaborative mHealth intervention.

PA and HE

Regarding PA results it is noteworthy that an interaction effect occurred for device-

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based measured MVPA in favour of the control group, and the same tendency was found in the steps measure. On the first sight this seems arbitrary. However, a closer look to the data reveals that the sample was already highly active at baseline, however coincidentially just as low regarding their FVI. Regarding guideline adherence, participants exceeded the recommended amount of 420 minutes of MVPA per week by 180 minutes on average, but simultaneously deceeded the recommended amount of 35 portions of fruits and vegetables by 15 (diary) or 17.5 (questionnaire). Whereas our sample can be classified as being highly active in an (inter-) national comparison [95] [94], they cannot be classified as equally healthy regarding their eating behavior. In a germanwide representative sample, 17% (7%) of 6- to 11-year-olds and 20% (23%) of 12- to 17-year-olds reached the recommendation on fruit (vegetable) consumption [14,96]. Our intervention was able to evoke a positive intervention effect on FVI based on diaries, as there was enough room for improvement in contrast to PA levels. Surprisingly, this effect was not present in FVI assessed via questionnaires. This elucidades the need to interpret findings with caution regarding measurement accuracy and construct validity. Research shows that the same construct measured with different methods is likely to lead to different results [97,98], and a comparison within the current data shows a limited comparability between device-based and self-reported measures[77,78]. Additionally, a secondary data analysis on the JITAI within the intervention group of this study points to promising results concerning physical activity enhancement in the subsequent hour after a prolonged period of inactivity [66]. This points to the importance of considering the timeframe and aim of the intervention as this enhancement on an hour to hour analysis that is also important for health benefits [99] is not detectable if considering pre-posttest analyses on a weekly level. Moreover, the different findings regarding PA and FVI supports the notion that both health behaviors must be viewed and targeted independently in interventions, as they do not seem to be related.

In contrast to MVPA and step findings, joint PA within the family revealed a positive intervention effect, i.e. our app supported the families to be active together. This results show that it is of importance to interpret the quality of PA in addition to the amount and intensity. Studies have found the positive influence of social interaction for habit formation [100,101]. Hence it is of high importance to facilitate family events of PA to teach children and adolescents the fun and enjoyment of PA in social groups. For joint meals, however, the effect of T_0 to T_1 was in favor of the IG, and for T_0 to T_2 was in favor of the CG, but an increase over time was observable in all groups.

Taken together, the hypothesis that HE would increase due to the intervention was supported by diary data. For PA, no or even a partially reversed intervention effect could be detected. However, this is in line with previous digital health studies also revealing heterogeneous results with a majority of studies finding at least some significant benefit of interventions [50,53]. However, it needs to be noted that the current sample was exceedingly high in their amount of PA, however coincidentially just as low regarding their FVI.

Family-based interventions

Research on mHealth interventions for families is scarce, particularly those involving randomized controlled trials (RCTs). Existing studies often focus on digital interventions between parents and children, but the results are mixed and sometimes combined with non-digital approaches. These studies tend to emphasize children's behavior rather than considering the entire family [102,103]. A recent review

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highlighted the effectiveness of digital interventions in preventing childhood obesity, with only two of the included studies specifically addressing mobile health interventions [104]. In one study, an app for self-monitoring weight and goal-setting led to greater weight reduction compared to standard care after 6 months in children with obesity [105]. Another study aimed to enhance fundamental movement skills in 3- to 6-year-olds and observed improvements after a 2-month intervention period [106]. However, not all studies reported positive effects. Of the seven studies included in another review [107], two pilot studies reported significant improvements in PA, three studies found evidence for some improvements in PA measures, e.g. collaborative PA of children and parents, and the remaining two studies found no evidence for an effect. Interestingly, one study found that adolescent dropout rates were more than 12 times higher when parents stopped using the application. In this regard, analyzing family-behavior and dyadic relationships will be a promising approach for future investigations. Studies suggest that family meal practices and values can support HE [108] [101] and that the frequency of shared family meals is significantly related to nutritional health in children and adolescents [31]. The current results do not support the assumption that joint PA or joint meals (i.e. some kind of "guality time" within the family) impacts quantitative PA or HE behavior. However, it needs to be acknowledged that joint PA was rather low in our sample (only about 1 joint activity per week), and the enjoyment of PA or attitude towards PA were no outcome variables in the current trial.

Strengths and limitations

The main strengths of the SMARTFAMILY2.0 intervention are that (1) it collaboratively targets the family, (2) it is designed as a cluster randomized controlled trial, (3) it is theorybased, and (4) it incorporates 14 different BCTs, four more than the prior version of the app. Further, (5) the goalsetting in the app is ad libitum selected by the family to fit their schedule and preferences with guidance from the results of the first measurement week. This empowers the families to set self-selected goals which have been found to increase motivation and adherence [109,110]. In this recent app version, (6) JITAIs were included to change behaviour when participants were most prone to [64-66], and (7) gamification features were expanded through an avatarized coach, asking questions for (8) ecological momentary assessment, providing support with goal-setting challenges and providing health literacy information. Another strength regarding the evaluation is (9) that multiple outcome measures of self-reported and device-based measured PA were considered. This is important as these measures are known to yield different results, and including multiple measurement tools improves the plausibility of the results [77,111]. Last, using (10) advanced statistical methods to consider the nested structure of the data by applying multilevel analyses enhanced the accuracy of the results, as it considered the variance based on the clustering of participants in families.

Some limitations have to be acknowledged. Regarding our sample, family sizes and ages within families have been very diverse while the required sample size by the a priory power analysis of 52 families and 156 participants has been met [71]. However, there is a lack of knowledge about how these composite family structures interfere with results regarding behavior change or the accomplishment of healthy lifestyles. For example, it might be assumed that older parents might be more aware of healthy food choices, as they consider healthy nutrition as being more important for themselves than their younger counterparts [112]. Advanced paternal age is associated with increased risk, and younger paternal age with decreased risk of children's eating disorders [113]. A further restriction might be the age range, especially for children and adolescents. Since this study includes the whole family, children of different ages and with different needs and perceptions were addressed similarly by the app which might have affected intervention effects. Future interventions should aim to

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address the individual needs of the family members and tailor the intervention more specifically to the participants. Another important factor concerning the current sample, which could explain the lack of significant intervention effects for PA was probably the highly active sample with around 600 minutes of MVPA per week and person, which already fulfilled the guidelines of the World Health Organisation for PA [4]. This is in contrast to recent research about PA guideline fulfillment, which reliably reveals only small portions of participants fulfilling the PA recommendations, with lower amounts with increasing ages [9–11]. This skewness of our sample was also apparent regarding body composition and HE behaviour [114]. With BMIs between 17 and 19 in children, and between 23 and 27 in adults, our sample was of normal weight. Studies have shown that intervention effects can be expected to be higher on overweight or obese samples, both for HE and PA interventions [115]. This might be a probable explanation for the absence of intervention effects (i.e., there was no or only little room for improvement in our sample).

An additional aspect was that the participants had to use the provided smartphones instead of their own for equality and data security reasons, which can be burdensome. However, previous research showed no differences in engagement between participants with their own smartphones versus additional smartphones [116]. If a program aims for long-term sustainability beyond a scientific scope, the use of an additional phone must be considered very carefully.

Another potentially limiting factor is the comparably short duration of the intervention. Based on literature regarding behavior change theories (i.e. the transtheoretical model [117], an intervention duration of three weeks might not have been sufficient [50]. However, mHealth intervention studies even revealed significant behavior change effects with intervention durations of only one [118], two [119], and three weeks [120]. In a similar vein, a recent meta-analysis on mobile apps for diet showed that interventions with longer duration were not generally more effective [121].

Moreover, as we examined families in their natural setting, there are also practical constraints. In Germany, a continuous school period lasts a maximum of 6 to 8 weeks, followed by a vacation period. To conduct the core assessments including pre- and post-testing accelerometry (please see also Fig. 1, study design) during one continuous school period, an intervention period longer than three weeks was not feasible for the study design. Longer intervention periods would inevitably mean that there is a co-founding between the assessment period (school time vs. vacation). Furthermore, data was gathered during the Covid-19 pandemic. However, we did not test any participants within lockdown situation, i.e. where they were not allowed to leave the house. However, homeschooling and homeoffice might have influenced the results, both in children and adults. Especially in Germany, research showed that Covid-19 hightened the amount of PA in children and adolescents [111], depending on population density [122]. Independent of age, gender and country, however, a declining trend in PA was found [123].

Conclusion

Taken together, the evaluation of the SMART*FAMILY2.0* trial expands the existing body of evidence as it investigated the influence of a theory-based mHealth intervention targeting PA and HE in a collective family-based setting. Yet, no evidence for the effectiveness of the trial has been found for PA, but diary data of HE, and joint PA showed improvements due to app usage. The finding regarding PA, might be attributable to an initially active and lean sample. Future evaluations of interventions should therefore also consider (1) methods that go beyond pre-post-follow-up designs to account for the timeliness and complexity of mHealth interventions, (2) recruiting participants of all activity- and weight levels, and (3) control for or restrict ages of children and parents.

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Figure Captions

Figure 1. Detailed study design.

Figure 2. Interaction effect of group x time for device-based measured physical activity for the parameter minutes of moderate to vigorous physical activity per week (MVPA). Displayed is the mean MVPA (y-axis) of 180 participants during one week of baseline measurement (T_0) and one week of post-measurement after a 3-week intervention/waiting period (T_1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed lines represent the PA recommendations for children (420 min/week) and adults (150 min/week).

Figure 3. Interaction effect of group x time for device-based measured physical activity for the parameter steps per week (steps). Displayed is the mean step count (y-axis) of 180 participants during one week of baseline measurement (T_0) and one week of post-measurement after a 3-week intervention/waiting period (T_1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the commonly used step recommendation of 10.000 steps/day (70.000 steps/week).

Figure 4. Interaction effect of group x time for the parameter fruit and vegetable intake per week (FVI) assessed by questionnaire. Displayed is the mean fruit and vegetable intake (y-axis) of 197 participants related to the week of baseline measurement (T_0), the week of post-measurement after a 3-week intervention/waiting period (T_1), and the week of follow-up measurement (T_2) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the recommendation for daily FVI of 5 portions (35 portions/week).

Appendix

Appendix A. Consort eHealth checklist.

Appendix B. Results of the main analyses.

Appendix C. Results of the sensitivity analyses.

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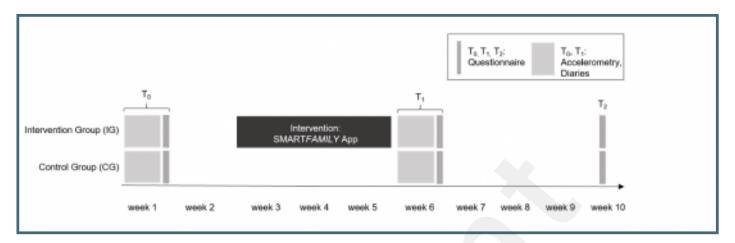
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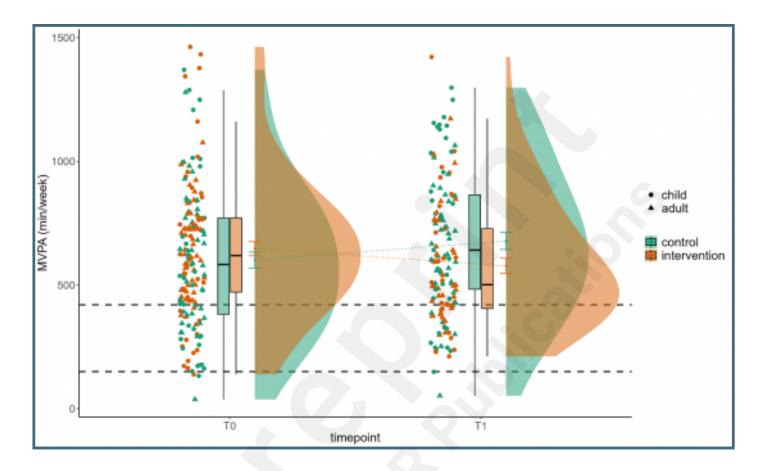
Supplementary Files

Figures

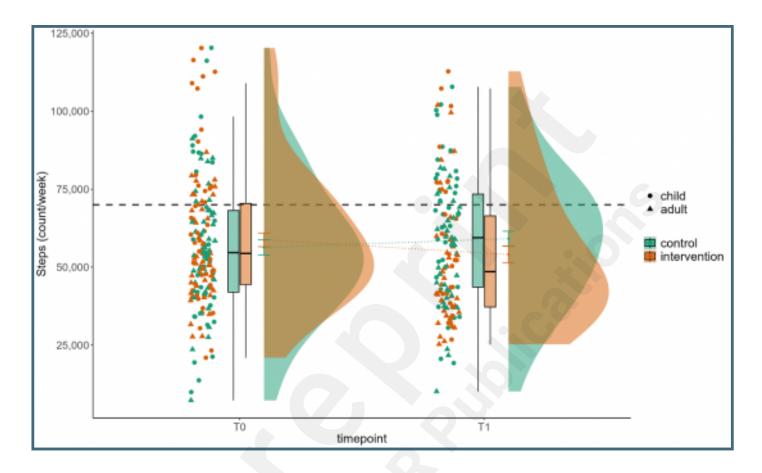
Detailed study design.



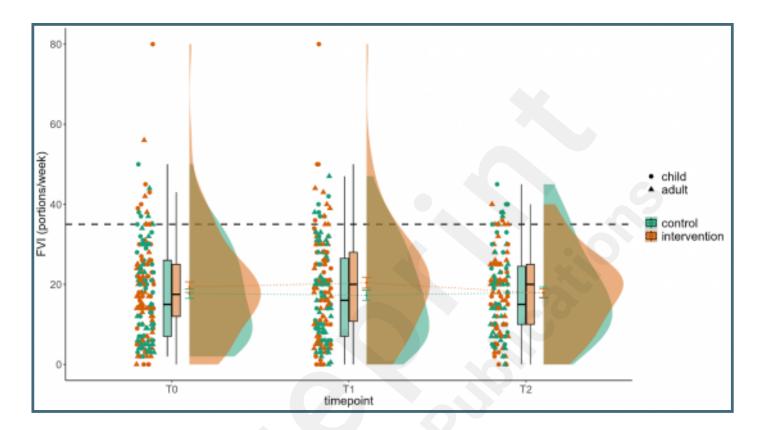
Interaction effect of group x time for device-based measured physical activity for the parameter minutes of moderate to vigorous physical activity per week (MVPA). Displayed is the mean MVPA (y-axis) of 180 participants during one week of baseline measurement (T0) and one week of post-measurement after a 3-week intervention/waiting period (T1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed lines represent the PA recommendations for children (420 min/week) and adults (150 min/week).



Interaction effect of group x time for device-based measured physical activity for the parameter steps per week (steps). Displayed is the mean step count (y-axis) of 180 participants during one week of baseline measurement (T0) and one week of post-measurement after a 3-week intervention/waiting period (T1) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the commonly used step recommendation of 10.000 steps/day (70.000 steps/week).



Interaction effect of group x time for the parameter fruit and vegetable intake per week (FVI) assessed by questionnaire. Displayed is the mean fruit and vegetable intake (y-axis) of 197 participants related to the week of baseline measurement (T0), the week of post-measurement after a 3-week intervention/waiting period (T1), and the week of follow-up measurement (T2) for the control group (green) and the intervention group (red), stratified by children and adults. The grey dashed line represent the recommendation for daily FVI of 5 portions (35 portions/week).



Multimedia Appendixes

Results of the main analyses.

URL: http://asset.jmir.pub/assets/b1a61d76349f3278e8e913f58a6af74c.pdf

Results of the sensitivity analyses.

URL: http://asset.jmir.pub/assets/f12352d24a014bcdb91f1e2f28991d41.pdf

CONSORT (or other) checklists

Appendix A. Consort eHealth checklist.

URL: http://asset.jmir.pub/assets/5690a0fb390ca2dd357035534152fbfb.pdf

TOC/Feature image for homepages

SmartFamily.

