Impact of "JolinchenKids - fit and healthy in daycare" on children's objectively measured physical activity: A cluster controlled study

Berit Brandes, Christoph Buck, Marvin N. Wright, Claudia R. Pischke, Mirko Brandes

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Corresponding author
Berit Brandes

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Abstract (200 words)

Background: To evaluate a multi-component health promotion program targeting preschoolers' physical activity (PA).

Methods: PA of children from 23 German daycare facilities (DF; 13 intervention, 10 control) was measured via accelerometry at baseline and after 12 months. Children's sedentary time, light PA, and moderate-to-vigorous PA (MVPA) was estimated. Adherence was tracked with paper-and-pencil calendars. Mixed model regression analyses were used to assess intervention effects.

Results: PA data were analyzed from 183 (4.2 ± 0.8 years, 48.1% boys) children. At follow-up, children in DF groups with more than 50% adherence to PA intervention components showed an increase of nine minutes of MVPA per day (β=9.28, 95% Confidence interval [CI]: -0.16; 18.72) and a 19 minute decrease in sedentary time (β=-19.25, 95% CI: -43.66; 5.16) compared to the control group, whereas children's PA of those who were exposed to no or less than 50% adherence remained unchanged (MVPA, β=0.34, 95% CI: -13.73; 14.41; sedentary time, β=1.78, 95% CI: -26.54; 30.09). Notable effects were found in children with migration background.

Conclusion: Only small benefits in PA outcomes were observed after one year. A minimum of 50% adherence to the intervention seems to be crucial for facilitating intervention effects.

Abbreviations

AOK	General Local Health Insurance
EE	Energy expenditure
BMI	Body mass index
CI	Confidence interval
DF	Daycare facility
LPA	Light physical activity
MET	Metabolic equivalent
MIN	Minutes
MVPA	Moderate-to-vigorous physical activity
PA	Physical activity
SB	Sedentary behavior
SD	Standard deviation
WHO	World Health Organization

Introduction

Regular physical activity (PA) is associated with improved cardiometabolic health and psychosocial development throughout the life course. [1-5] While the health benefits of PA for school children, youth and adults are well known, there is a growing body of evidence on the health benefits of regular PA in early childhood. This growing body of research suggests that in young children (under the age of five years), higher levels of PA are associated with improved bone and skeletal health, adiposity, motor development, cognitive development, psychosocial, and cardiometabolic health. [6-8] Furthermore, it is known that an active lifestyle is, to a great extent, learned during the first years of life and tends to persist into adulthood. [9,10] However, the frequency and duration of PA necessary to achieve these health benefits are still unclear. In children, MVPA is positively associated with higher levels of locomotor skills [11] and inversely associated with skinfold thickness and waist circumference. [12] MVPA and reduced sitting times also have been shown to make an important contribution to children's physical, mental and cognitive development. [13-15] In order to achieve health effects, the World Health Organization (WHO) therefore recommends for children of three to four years of age to spend at least 180 minutes (min) in a variety of types of physical activities at any intensity, of which at least 60 min is moderate-to-vigorous PA (MVPA). [16] To date, 50 percent of children under the age of six years in Germany do not reach the recommended amount of MVPA per day. [17] Therefore, the promotion of PA and the reduction of sedentary behavior (SB) in young children are major public health targets. Less is known about the contribution of light PA (LPA). Poitras et al [18] analyzed the relationship between different PA intensities and health indicators during the early years of childhood and came to the conclusion that relationships with health outcomes were more consistent and robust for higher (e.g., MVPA) versus lower (e.g., LPA) intensity PA.

There is consensus among experts in the field of PA promotion that offering as much PA as possible to children is important [6,7] and that all intensities of PA should be considered in future research aimed at examining the health benefits of PA in children and youth. [18] Hence, government bodies internationally recommend at least 180 min of light, moderate or vigorous PA (LMVPA or total PA) per day. [19-21] According to the German National Recommendations for Physical Activity and Physical

Activity Promotion [19] these 180 min of PA may consist of structured and unstructured PA whereby structured PA is intentionally directed by an adult (e.g. bean bag games) and unstructured PA is an activity that is started by the child itself (e.g. playing tag or riding a bike). Furthermore, avoidable sitting times should not exceed 30 min per day at this young age. [19]

A recent meta-analysis of PA interventions for preschool-aged children found a small to moderate effect on total PA (overall PA) and a moderate effect on MVPA. [22] The greatest effects for MVPA were identified for interventions that were of short duration, were offered in an early-learning environment, were led by teachers, involved outdoor activity, and incorporated unstructured activity. [22] In Germany, approximately 93% of children between the ages of three and six years attend a daycare facility (DF). [23] Due to the high number of children attending daycare and the amount of time children spend at DFs, they can be considered a key setting for early health promotion.

Recently, the health insurance AOK (General Local Health Insurance) developed and implemented the *JolinchenKids – Fit and Healthy in Daycare* intervention for children at DFs in Germany. In this multi-component health promotion program, children's dietary and PA habits and their mental well-being are addressed. It is also aimed at promoting health among DF staff and fostering parental participation. The protocol of the intervention trial, the *JolinchenKids – Fit and Healthy in Daycare* study, including details on the design, sample size, methods, and intervention content can be found elsewhere. [24] The objective of the present study was to evaluate the effect of the PA promotion module of this program on objectively measured PA in a subsample of children from the *JolinchenKids – Fit and Healthy in Daycare* study. In detail, we hypothesized that participation in the PA intervention module would increase objectively measured light PA and MVPA (min per day) and decrease SB compared to the control group.

Methods

Study design and participants

This study is based on data from a nationwide cluster controlled trial which was performed in rural and urban municipalities in Germany to evaluate effects of the *JolinchenKids – Fit and Healthy in Daycare* intervention. [24] In Germany, daycare covers children age three to five (or six) before they enter formal education at an elementary school. The intervention program *JolinchenKids – Fit and Healthy in Daycare* therefore targets three-to-six year-old preschoolers. Due to organizational reasons, it was not feasible to randomly allocate DFs to either intervention or delayed intervention control conditions. Therefore, this study was planned as a cluster controlled trial with a non-random allocation procedure. Ethical approval was obtained by the Medical Association in Bremen (HR/ RE – 522, April 28th, 2016) and the study was registered at the German Clinical Trials Register (DRKS00011065). Recruitment of DFs took place in September until December 2016. [24] Only DFs that were organized in groups and that took care of at least 14 children aged three to five years were included. Full information on the inclusion criteria can be found elsewhere. [24] For the recruitment, from two lists, one containing DFs that wanted to start program implementation in 2016 (intervention DFs) and one containing DFs that wanted to start with program implementation after completion of this study (waitlisted control DFs), a random selection of DFs was contacted via mail and invited to participate in the study. In addition to the invitation letter, DFs received a short questionnaire. Further information on the short questionnaire and the inclusion criteria can be found elsewhere. [24] This questionnaire was used to later match intervention and control DFs. Of those DFs that were interested in participating in the study, DFs that were deemed eligible and that had a matching DF assigned to them were asked to choose up to two DF groups to take part in the study. The sample size for this study was calculated based on the primary outcome of this study, objectively measured PA. Briefly, we estimated that a total of 360 children at 24 DFs (about 15 children per DF) would be required for our study which is explained in further detail in the study protocol. [24] For the collection of objectively measured PA data, 23 DFs (13 intervention DFs, 10 control DFs) of a total number of 62 DFs enrolled in the *JolinchenKids – Fit and Healthy in Daycare* study, were randomly chosen. At those DFs, parents of children of the two kindergarten groups were invited to have their child participate in the study and were asked for informed consent. Children with written parental informed consent were informed

144 appropriately and asked for verbal consent. Children with verbal consent were asked to wear
145 accelerometers for 24 hours on seven consecutive days at baseline and at follow-up.

146 Between October and December 2016, baseline measurements were performed followed by a post-
147 intervention assessment between September and December 2017. The same two study nurses who had
148 been previously trained by two researchers collected data at both time points. After baseline
149 assessment, program implementation started at intervention DFs providing training sessions to
150 kindergarten teachers and distributing intervention materials provided by the AOK. Control DFs did
151 not receive the intervention and continued with their usual routine but were offered the same training
152 and materials after the post-intervention assessment at intervention DFs.

153 *Intervention*

154 *JolinchenKids - fit and healthy in daycare* was comprised of five modules, three focusing on children,
155 one on parental participation, and one on promoting health among DF staff. Program implementation
156 was based on the Public Health Action Circle [25] and included the four steps: (1) needs analysis, (2)
157 module selection, (3) module implementation, and (4) evaluation. DFs were free to choose which
158 modules they wanted to implement and could implement several modules in parallel.

159 The PA module of the *JolinchenKids - Fit and Healthy in Daycare* intervention included the provision
160 of instructions for PA games and for creating areas in the DF which allowed children to engage at least
161 one hour of active play per day. The PA module of the intervention aimed at (1) providing children
162 with a wide range of opportunities to develop positive movement experiences so that they could
163 develop a positive attitude towards movement, (2) integrating one hour of PA into the everyday
164 routine at DFs by DF staff, and (3) using a card box that included exercises targeting five motoric
165 areas (strength, endurance, perception, coordination and, mobility) for establishing daily exercise
166 routines that could be used at any point in time by DF staff together with the children. Further aims
167 were to increase outdoor movement, to initiate parental participation, and the provision of newsletters
168 to parents informing about program activities. DF staff was trained in a workshop led by experts in the
169 field of PA. Further information about the program and the intervention components of the other four
170 modules can be found elsewhere. [24]

171 *Outcome measures*

172 To date, the majority of studies use accelerometers which are commonly worn on a waist belt, aligned
173 with the right anterior axillary line and worn the entire day for up to seven days to estimate habitual
174 PA. [26] But compliance among young children has been shown to be better when using wrist-worn
175 accelerometers compared to hip-worn devices. [27] We therefore measured both PA and SB with the
176 wrist-worn GENEActiv device (Activinsights Ltd., Kimbolton, UK). This accelerometer includes a
177 triaxial acceleration sensor (ADXL345) with a ±8-g dynamic range, is light weight and waterproof and
178 has recently been validated as a PA measurement tool in young children. [28,29] All accelerometers were
179 initialized according to the manufacturer's guidelines and operated with 100Hz. All children were
180 requested to wear the accelerometer on their left wrist where it was attached directly to the skin with a
181 Tyvek tape. Parents were instructed via a letter that the device had to be worn by children for seven
182 consecutive days for 24 hours each day and were asked to fill out a daily log book to track periods of
183 non-wear. Parents received several Tyvek tapes for replacement. After one week of wear time, parents
184 returned the accelerometer and the log book to the DF staff. Each of the 23 participating DFs collected
185 the accelerometers and log books and sent them back to the study center.

186 Height was measured to the nearest 1 cm using a stadiometer (Seca® type 213 stadiometer, Invicta
187 Plastics Ltd, Leicester, UK). Body weight was measured to the nearest 0.1 kg. While being measured,
188 children were allowed to wear normal clothes. The body mass index (BMI) was calculated as weight
189 in kilograms divided by body height in meters squared. Children were classified as
190 underweight/normal or overweight/obese, according to age- and sex-specific cut-offs derived from
191 centile curves by Cole and Lobstein. [30] At baseline and at follow-up, a questionnaire was used to
192 gather information on sociodemographic characteristics of children. Information on education
193 available from either one or both parents/legal guardians was used to classify parental education into
194 low, medium, and high according to Lampert et al. [31] Highest parental education was considered in the
195 analyses taking the maximum parental education from either one or both parents/legal guardians. Data
196 on migration background were compiled based on information on the country of birth and the
197 nationality of both parents. Children were classified as having a one- or two-sided migration

198 background, if they had one or both parents who had immigrated to Germany and/or parents who were
199 not German citizens, respectively. [32] To categorize the level of urbanity, children at DFs from
200 municipalities with more than 20,000 inhabitants were classified as urban whereas those at DFs from
201 municipalities with fewer than 20,000 inhabitants were classified as rural.

202 *Process evaluation data*

203 To assess intervention dose and adherence, intervention DFs were provided with a paper-and-pencil
204 calendar to track implementation progress at individual DF groups from baseline to follow-up. In these
205 calendars, DF staff documented module choices, as well as module-specific activities implemented
206 during each week. For the PA module, the calendar covered the weekly amount of time (in min) spent
207 on working with PA games from the card box and whether one hour of PA was integrated into the
208 daily routine of DF groups.

209 To quantify the intervention dose for the PA module, we considered a time frame of 40 weeks (i.e. one
210 year excluding holidays) during which the module could be implemented. Further, essential
211 components were distinguished from additional components. For example, conducting one hour of PA
212 games was considered essential and counted as one point, while any additional ten min spent on PA
213 games was counted as 1/6 additional points for each week. The weekly sum of points for the PA
214 module was added up for all 40 weeks and then divided by 40 to compute the percentage of adherence.
215 Lastly, the percentage of adherence for all DF groups at intervention DFs was categorized into 0 - 50%
216 and more than 50% of adherence. Because the total number of points depended on the reported
217 duration of implementation, sometimes an adherence above 100% was calculated.

218 *Data analysis*

219 Accelerometer data were downloaded using GENEActiv v.2.2 software (Activinsights, Cambs, UK)
220 and saved in raw format. Raw data files were then processed in R 3.4.3 [33] using the software package
221 GENEAread (version 2.0.6). To remove sleeping data, all data between the hours of 7pm and 7am
222 were excluded from the analysis. As in other studies [34,35], accelerometer non-wear time was estimated
223 on the basis of the standard deviation and value range of each accelerometer axis, calculated for

moving windows of 60 min with 15-min increments to identify periods between initialization and attachment of the device and periods where the device was not worn. A time window was classified as non-wear time if, for at least two of the three axes, the standard deviation was less than 13.0 mg (1 mg = 0.00981 m/s^2) or if the value range was less than 50 mg. [34] By using a 60-min time window, the method aims to detect periods of monitor non-wear time lasting for more than one hour which are the periods that would most impact summary measures. Further, using this time window ensured that short periods of inactivity were not confused with non-wear time. [35] Only data of children with a wear time of at least eight hours per day on at least three weekdays and one weekend day were included in the analysis as previously outlined by DuBose et al. [36]

Time spent at various intensities of movement (e.g. SB, LPA, MVPA) was derived from estimated energy expenditure (EE) values as follows: sedentary (<7 kJ/min), light (7-10 kJ/min), and moderate-to-vigorous (>10 kJ/min). As there is no consensus in the literature with regard to cutoffs for SB, LPA, and MVPA, we used the data provided by Roscoe et al [28] and converted Kcal values for different activities to KJ values to derive cutoffs. In their discussion, Roscoe et al [28] state that in their study "Lego" was classified as SB. From that, we classified "slow walk" as LPA and "fast walk" as MVPA. EE was predicted using a random forest machine learning model trained on preschoolers in a previous validation study. [29] For total PA, time spent on LPA and MVPA was summed up. The average of time spent on SB, LPA, MVPA, and total PA over weekdays and weekend days was calculated to represent daily time spent on SB, LPA, MVPA, and total PA.

Descriptive statistics (i.e. mean and standard deviation; SD) or percentage of categories, were calculated for the baseline and follow-up assessment. Descriptive statistics of time spent on SB, LPA, MVPA, and total PA are shown as means and SD (intervention vs. control).

We investigated the effect on time spent on SB, LPA, MVPA, and total PA between baseline (T0) and follow-up after one year (T1) between intervention and control group by using linear mixed models. We modelled fixed effects for intervention group and time to investigate overall group and time effects, as well as an interaction of group and time to identify the intervention effect. Due to the flexibility of mixed models, we were able to use data of participants at baseline without observations

at follow-up and accounted for repeated measurements by means of a random effect on the residual side. All models were adjusted for accelerometer wear time, sex, age, and migration background of the children, as well as for household income, highest educational level of parents and urbanity of the DF. In a further step, all models were also stratified by migration background of children and urbanity of the DFs. Based on the process evaluation data, effects on time spent on SB, LPA, MVPA, and total PA were estimated, depending on adherence to the PA module. The adherence categories were used considering control and intervention group at baseline as the reference, while investigating changes in the control group at T1, and the two categories of module adherence. Significance level was set to $\alpha = 0.05$, but analyses were not adjusted for multiple testing. Statistical analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, North Carolina, USA) and particularly the GLIMMIX procedure to estimate linear mixed models.

Results

Participant recruitment and sample size is illustrated in Figure 1. At baseline and at follow-up, accelerometers were handed to 232 and 175 children at 23 German DFs (ten control DFs, 13 intervention DFs), respectively. Fourty-nine children (21.1%) and 24 children (13.7%) had to be excluded due to (1) a loss of the device, (2) a wear time violation, or (3) incomplete answers in the parental questionnaire at baseline and at follow-up, respectively. Resulting samples sizes at baseline and at follow-up were 183 children (n=94 intervention, n=89 control) and 144 children (n=67 intervention, n=77 control), respectively, which were included in the analyses.

*****Figure 1 here*****

Children's characteristics at baseline are shown in Table 1. Children were comparable between groups in terms of migration background, household income, and accelerometer wear time. However, at baseline, the percentage of parents with a low educational background and the prevalence of overweight and obesity was higher in the intervention group compared to controls (Table 1).

***** Table 1 here *****

Table 2 presents the results of the linear mixed models, as well as study characteristics of PA outcome variables for baseline and follow-up. At baseline, children at intervention DFs spent slightly fewer min on total PA (244 vs. 251 min), LPA (174 vs. 178 min), and MVPA, (70 vs. 73 min), and slightly more min on SB (378 vs. 372 min), on average per day, compared to children from the control group (Table 2). With regard to the intervention effect at follow-up, children at intervention DFs spent 8 min more on MVPA (β=8.20, 95% Confidence interval [CI]: -0.39; 16.79) and 11 min more on LPA (β=10.83, 95% CI: -7.25; 28.91) compared to children of the control group. Regarding SB, we found a decrease of 20 min in the intervention group at follow-up (β=-20.30, 95% CI: -42.81; 2.21) compared to the control group. Results of further analyses stratified by migration background are presented in Table 3. In the subsample of children with migration background, we found an increase of 29 min of time spent on MVPA in favour of the intervention group (β=28.60, 95% CI: 6.08; 51.11, Table 3). Intervention effects stratified by urbanity can be found in Table 4.

With regard to the adherence to the PA module, at follow-up, for two thirds of the 67 children who were enrolled at intervention DFs, an adherence of more than 50% to the PA module was reported by DF staff. One third of children at intervention DFs participated in the PA module which was implemented with an adherence below 50%. All intervention DFs from rural areas reached an intervention adherence of more than 50% whereas only two-third of intervention DFs from urban areas reached this adherence level.

Children at DF groups with >50% adherence displayed an increase of 9 min of time spent on MVPA (β=9.28, 95% CI: -0.16; 18.72) compared to children at control DFs whereas in children at DF groups with 0-50% adherence to the PA module this increase was not seen (β=0.34; 95% CI: -13.73; 14.41, Table 5).

***** Table 2-5 here *****

Discussion

The purpose of this study was to evaluate the effects of the PA module of a multi-component intervention program on objectively measured PA in German preschoolers. Our results indicate that

participation in this intervention module only lead to small effects in objectively measured time spent on MVPA, total PA and SB over the course of one year. Similarly, no intervention effect on proxy-reported PA was found in the previous analysis based on the total sample including all 62 DFs participating in the trial. [37]

Despite small and favorable effects in PA outcomes, our study did not show a substantial increase of PA in the entire study population. Limited or null intervention effects in this study do not imply that the PA module itself did not have a positive impact on children's PA, as DFs were free to choose this module and to implement other modules in parallel. Unfortunately, in our study sample, only slightly more than half of the intervention DFs reached an intervention adherence of more than 50% with regard to the PA module. A substantial intervention effect was found comparing high adherence to no to low adherence DFs. Our results therefore indicate that intervention effects were strongly related to implementation level and are in line with those reported in a systematic review of 500 studies analysing the effects of interventions for primary prevention and health promotion targeting children and adolescents. Based on the findings of the review, the authors reached the conclusion that higher levels of implementation are often associated with better outcomes. [38]

Another problem is that DFs often simultaneously implement other programs. Process evaluation data of the pilot trial suggest that most of the programs that were running in parallel also targeted physical activity, healthy eating, and mental wellbeing. They were mainly national programs, such as *Faustlos, Stark durch Gefühle,* and *TigerKids*. [39]This was also the case during the study period of the full trial (not reported here) and might have hindered a more extensive implementation of *JolinchenKids – Fit and Healthy in Daycare* due to time constraints in the daily routine of intervention DFs. Furthermore, we did not monitor the implementation of health promoting programs at control DFs during the study period which may have led to an increase of PA in children at control DFs.

The manual of *JolinchenKids – Fit and Healthy in Daycare* provides concrete instructions regarding the implementation of single activities (e.g., via card boxes to engage children in active play). However, current intervention materials lack detailed information about which dose is required for obtaining health effects and DF staff need to acquire knowledge of the contents of the materials on

their own. Hnatiuk et al [40] report in their recent review that workshops delivered to childcare staff which provide opportunities for hands-on experience were deemed important for the success of preschool-based PA interventions because these hands-on opportunities seem to be a crucial factor to encourage staff skills in promoting PA.

While *JolinchenKids* promoted active play without a special focus on MVPA, which is in line with national recommendations for PA in this age group, we did not find an increase in time spent in LPA in favor of the intervention group. Findings are in line with those of a recent meta-analysis of PA interventions for preschoolers where small to moderate effects on total PA and a moderate effect on MVPA are reported. [22] Yet, it is unclear why stronger effects are seen for MVPA. Possibly, we did not see any changes in LPA because baseline values were already high suggesting that our study involved a sample of already active children.

Another finding of our study was that intervention effects were more pronounced in the subsample of children enrolled at DFs in rural areas. Our data suggest that all rural intervention DFs reached an intervention adherence of more than 50% whereas only two-thirds of intervention DFs from urban areas achieved more than 50% intervention exposure. Possibly, DFs in urban areas were not able to implement several of the components of the PA module. Research suggests that PA interventions in the preschool setting that involve outdoor activities are more effective [22] and at intervention DFs from urban areas the promotion of outdoor activities may have been more difficult compared to those in rural areas due to a lack of space in German cities. Intervention contents should therefore be revised to ensure that all DFs, regardless of geographic location, can achieve a sufficiently high level of implementation.

Interestingly, children with a migration background who showed notably lower PA outcomes at baseline substantially benefited from the intervention, presumably due to a kind of compensation effect. However, little is known about the PA behaviours and habitual routines of families in leisure time and particularly on weekends. [41] The PA program of the *JolinchenKids* intervention was aimed at bringing behavioural change also into the family. However, in this study we did not specifically evaluate changes in PA in the family setting. To evaluate this specific intervention goal, further studies

356 should combine accelerometry with PA diaries to gather more contextual insights into children's
357 habitual PA and especially into children's PA outside of DF.

358 Several strengths and limitations of this study need to be considered. A strength of the study is that we
359 conducted a cluster-controlled study including 23 DFs all over Germany and that intervention and
360 control DFs were matched by organizational characteristics of DFs and parents' socio-demographic
361 characteristics (e.g., education, income, percentage of parents receiving subsidies, also see [37]). Further,
362 we used accelerometers to objectively measure PA in a subsample of DFs of the original study, instead
363 of using parental reports which resulted in inconsistent effects in previous studies. [42] The machine
364 learning model to predict energy expenditure from accelerometer data that we used in our study has
365 recently been shown to be valid under free-living conditions. [43] The use of linear mixed models
366 allowed for a flexible analysis of the available data, handling loss-to-follow-up, while adjusting for
367 confounders on the individual-level. A limitation of the study is, however; that we were not able to
368 objectively assess PA in the originally planned sample size and the statistical analyses were thus
369 underpowered. Furthermore, characteristics of the DFs included in the subsample showed some
370 differences in socio-demographic indicators (e.g. percentage of parents with a low educational
371 background: 10.6% at intervention DFs, 4.5% at control DFs) and in the prevalence of overweight and
372 obesity (11.7% at intervention DFs, 1.1% at control DFs) even though those were randomly chosen
373 from the total sample of the JOKITA study in which the matching seemed to have worked well. In
374 addition, children in the intervention group were slightly less active with regard to baseline data than
375 children in the control group. Generally, the prevalence of overweight and obesity was relatively low
376 in our sample (6.6%) whereas the prevalence of overweight and obesity in German children below the
377 age of ten, according to data from a large study, is much higher (16.5%) [44], suggesting some selection
378 bias in the participation at the individual level. Lastly, despite evidence that habitual PA of
379 kindergarten staff is associated with health indicators, such as weight status, in kindergarten children
380 [45], this association was not examined in our study. However, descriptive information regarding socio-
381 demographic characteristics, health behaviors, and health literacy of the daycare staff implementing
382 the intervention at the intervention DFs are reported elsewhere. [39]

Conclusion

Despite small and favorable effects in PA outcomes, our study did not demonstrate a substantial increase of PA in the entire study population. An increase of 29 min in time spent on MVPA favoring the intervention group and children with a migration background supports the notion that socially disadvantaged groups which are often underrepresented in interventions for health promotion can be reached in the preschool setting and can benefit from these interventions. The preschool setting seems to be appropriate for the provision of PA intervention program preferably encouraging higher adherence. Hence, public health policies should focus on the integration of PA promotion as an integral part of health education policies in preschools.

Ethics approval and consent to participate

Ethical approval was obtained from the Medical Association in Bremen (HR/ RE – 522, April 28th, 2016). Parents were fully informed about the study and gave written informed consent for their children. All children were informed appropriately and asked for oral consent. The study is also registered at the German Clinical Trials Register: DRKS00011065 (25).

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Competing interests

The authors declare no conflict of interest or financial interests. The results of the present study do not constitute endorsement by the American College of Sports Medicine. The results of the study are presented clearly, honestly, and without fabrication, falsification, or inappropriate data manipulation.

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Author's contribution

BB wrote the manuscript, contributed to the design of the study and the assessment battery, coordinated the data collection, and analysed the data. CB and MNW were responsible for statistical modelling, contributed to the data analysis and critically revised the manuscript. CP designed the study and assessment battery, coordinated the study, and critically revised the manuscript. MB participated in the accelerometer data collection, provided methodological support throughout the study, and critically revised the manuscript. All authors read and approved the final version of the manuscript.

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566 **Tables**

567 Table 1 Baseline characteristics.

Characteristics	Intervention	Control
Children	(n=94)	(n=89)
Boys (%)	46.8	49.4
Age (mean years SD)	4.1 ± 0.8	4.3 ± 0.8
Accelerometer weartime		
Hours/day (mean SD)	10.4 ± 0.6	10.2 ± 0.5
Migration background (%)		
No migration background	75.5	75.3
One-sided or two-sided	21.3	20.2
Missing	3.2	4.5
Highest educational level of the parents (%)		
Low	10.6	4.5
Medium	54.3	75.3
High	27.7	20.2
Missing	7.4	0
Household income (%)		
<2000€	18.1	13.5
2000-3000€	23.4	28.1
>3000€	48.9	50.6
Missing	9.6	7.9
Urbanity (%)		
≤ 20.000 inhabitants	44.7	51.7
> 20.000 inhabitants	55.3	48.3
Body-mass-index (%)		
Normal weight	88.3	98.9
Overweight/obese	11.7	1.1
Missing	0	0

568 Note: SD standard deviation

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576 Table 2 Intervention effects on primary outcomes.

(N=278 observations)					
Characteristics	Assessment period Mean(SD)		Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)
	Baseline	Follow-Up	Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline
MVPA (min/day)					
Intervention	70.2 (23.8)	80.1 (27.4)	0.80 (-6.0; 7.6)	-4.02 (-12.0; 4.0)	8.20 (-0.4; 16.8)
Control	73.0 (31.9)	75.5 (27.7)			
LPA (min/day)					
Intervention	173.9 (36.7)	182.9 (48.6)	2.94 (-11.0; 16.9)	-8.01 (-21.8; 5.8)	10.83 (-7.3; 28.9)
Control	178.0 (48.5)	173.8 (51.6)			
SB (min/day)					
Intervention	378.7 (59.9)	364.4 (69.9)	-2.18 (-19.7; 15.4)	12.55 (-6.0; 31.1)	-20.30 (-42.8; 2.2)
Control	362.2 (60.8)	369.3 (67.2)			
Total PA (min/day)					
Intervention	244.2 (51.3)	263.0 (63)	2.18 (-15.4; 19.7)	-12.55 (-31.1; 6.0)	20.30 (-2.2; 42.8)
Control	251.1 (63.8)	249.3 (71.4)			

577 Note: Min minutes; SD standard deviation; CI confidence interval; All models were adjusted for age, sex and migration
578 background of the children, education and income of the parents, GENEActiv weartime, and urbanity

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Table 3 Intervention effects, stratified by migration background.

	Migration background (N=58 observations)			No migration background (N=220 observations)		
Characteristics	Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)	Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)
	Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline	Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline
MVPA (min/day)						
Intervention	-23.5 (-41.5; -5.4)	-2.3 (-21.2; 16.7)	28.60 (6.1; 51.1)	6.09 (-1.1; 13.3)	-5.71 (-14.5; 3.1)	5.78 (-3.3; 14.8)
Control						
LPA (min/day)						
Intervention	-22.4 (-57.7; 12.9)	-0.3 (-32.6; 32.0)	33.84 (-13.0; 80.7)	8.08 (-7.2; 23.4)	-12.87 (-28.4; 2.7)	10.00 (-9.9; 29.9)
Control						
SB (min/day)						
Intervention	44.8 (-2.7; 92.3)	1.4 (-42.9; 45.7)	-60.1 (-122.6; 2.4)	-12.8 (-31.4; 5.9)	19.1 (-1.6; 39.7)	-16.7 (-40.6; 7.3)
Control						
Total PA (min/day)						
Intervention	-44.8 (-92.3; 2.7)	-1.4 (-45.7; 42.9)	60.1 (-2.4; 122.6)	12.8 (-5.9; 31.4)	-19.1 (-39.7; 1.6)	16.7 (-7.3; 40.6)
Control						

Note: Min minutes; CI confidence interval; All models were adjusted for age and sex of the children, education and income of the parents, GENEActiv weartime, and urbanity.

Table 4 Intervention effects, stratified by urbanity.

	Rural < 20.000 inhabitants (N=131 observations)			Urban > 20.000 inhabitants (N=147 observations)		
Characteristics	Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)	Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)
	Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline	Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline
MVPA (min/day)						
Intervention	3.6 (-7.1; 14.4)	-5.2 (-17.7; 7.2)	11.8 (-1.5; 25.1)	0.2 (-9.3; 9.7)	-1.3 (-12.6; 10.0)	3.8 (-8.6; 16.2)
Control						
LPA (min/day)						
Intervention	-0.1 (-23.5; 23.3)	-25.2 (-47.2; -3.2)	18.6 (-11.5; 48.8)	7.4 (-10.2; 25.1)	7.4 (-11.5; 26.2)	4.4 (-19.0; 27.7)
Control						
SB (min/day)						
Intervention	-3.8 (-33.0; 25.4)	30.8 (0.0; 61.6)	-31.3 (-67.9; 5.3)	-6.8 (-29.7; 16.2)	-6.3 (-30.8; 18.2)	-7.6 (-37.9; 22.8)
Control						
Total PA (min/day)						
Intervention	3.8 (-25.4; 33.0)	-30.8 (-61.6; -0.0)	31.3 (-5.3; 67.9)	6.8 (-16.2; 29.7)	6.3 (-18.2; 30.8)	7.6 (-22.8; 37.9)
Control						

Note: Min minutes; CI confidence interval; All models were adjusted for age, sex, and migration background of the children, education and income of the parents, and GENEActiv weartime.

Table 5 Intervention effects, stratified by intervention dose.

(N=266 observations)				
Characteristics	Number observations	Time difference β (95% CI)	Group difference β (95% CI)	Group-by-time interaction β (95% CI)
		Ref.: Baseline	Ref.: Control	Ref.: Control*Baseline
MVPA (min/day)				
PA Module > 50% adherence		1.3 (-5.6; 8.1)	-4.7 (-12.8; 3.5)	9.3 (-0.2; 18.7)
PA Module 0-50% adherence				0.3 (-13.7; 14.4)
Control				
LPA (min/day)				
PA Module > 50% adherence		3.0 (-11.0; 17.0)	-9.4 (-23.4; 4.7)	8.2 (-11.5; 27.8)
PA Module 0-50% adherence				1.8 (-26.5; 30.1)
Control				
SB (min/day)				
PA Module > 50% adherence		-2.8 (-20.3; 14.7)	14.5 (-4.4; 33.4)	-19.3 (-43.7; 5.2)
PA Module 0-50% adherence				1.8 (-26.5; 30.1)
Control				
Total PA (min/day)				
PA Module > 50% adherence		2.8 (-14.7; 20.3)	-14.5 (-33.4; 4.4)	19.3 (-5.2; 43.7)
PA Module 0-50% adherence				1.3 (-34.5; 37.0)
Control				

Note:CI confidence interval; MVPA moderate-to-vigorous physical activity; min minutes; LPA light physical activity; SB sedentary behaviour; PA physical activity;All models were adjusted for age, sex, and migration background of the children, education and income of the parents, GENEActiv weartime, and urbanity.

Figures

Figure 1: Participant flow chart.