Prospective associations between screen media use and physical activity in preschool children: Findings from the Motor Skills in PreSchool (MIPS) study

- *Statistical analysis plan*

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Background

Time spent using screen-based media devices is ubiquitous in everyday life of children and adults of the 21st century. Rapid technological development and market introduction of handheld screen-based devices, such as smartphones and tablets, to consumers all over the world, has changed the way and the amount of time humans interact with electronic media. To the extent that self-report depicts screen time habits accurately, evidence suggests that British children and youth (8-18 years) engage in four hours and 45 minutes of screen time a day on average, as a main activity or while engaging in other activities (1). Furthermore, results from the same study indicate a pronounced increase in screen time from 2010 to 2015 in British children (1) and data from North America suggests an increase in computer use during leisure hours from 2001 to 2016 in most age groups (2). Based on a 2018 survey of 3660 school children in Denmark, 24% of boys and at least 19% of girls aged 13 and 15 spend at least four hours each weekday watching movies, tv-series, Youtube-movies or entertainment shows (3). Also, 88% of adult Danes report using the internet as part of their daily routine (4). Clearly, adults and children spend much of their leisure time engaging in some form of entertainment-based screen media.

In the mainstream media and in the general population, there is much discussion about whether use of screen media carries a risk to our mental well-being and physical health. According to a 2016 Technical report from The American Academy Pediatrics, screen-based media use includes some beneficial effects, such as improved knowledge acquisition at an early age, access to important information and creating enhanced opportunities for communication (5). However, there is also evidence which suggest that screen media use has a negative relationship with children and adolescents' sleep (6), as well as multiple other aspects of health, including adiposity, unhealthy dietary pattern, symptoms of depression, a poor quality of life (7) and decreased physical activity (8). Of concern may be the effect of excessive screen time in childhood on children's physical activity habits.

Physical activity in children below five years has been associated with numerous health benefits, including improved motor skills and cognitive development, cardiometabolic health, decreased adiposity (9), and possibly increased psychosocial health (10). Also, some evidence suggests that childhood physical activity habits track to some degree into young adulthood (11) which furthermore underlines the importance of physical activity at an early age. Therefore, preschool years appear to be an important time to establish healthy physical activity habits to support a healthy physical, psychological, and social development throughout childhood. Thus, it is very important to understand the physical activity behavior of young children, as well as map which factors it is associated with.

The relation between screen time usage and device-based assessment of physical activity in pre-school children is still poorly understood. Most cross-sectional analyses investigating this relation have found no association (12-16), while two found inverse associations (17, 18) and one found a counter-intuitive positive association (in girls only) (16). Of these, six are studies of correlates (12-14, 16, 17, 19). Statistical model building in these investigations is not necessarily based on variable selection in order to analyze the relation between screen time and physical activity with appropriate adjustment for confounding. For this reason, over-, under- or inappropriate statistical correction may at least partly explain somewhat conflicting findings. No prospective analyses of observational data using objective measures of physical activity have been published in this age group. Results from two randomized controlled trials, whose interventions aimed to decrease screen time in preschool children, have been published (20, 21). In Epstein et. al. 2008 (20), a tv-reduction intervention did result in significant change in device-based assessment of physical activity, in 4-7 year old children. In the pilot randomized controlled trial by Hinkley et. al. 2015, including 2-3-year-old children, a screen media use reduction intervention did not result in change in accelerometry-derived physical activity, either (21). Overall, there are clear gaps in our knowledge of the relation between screen media use and physical activity in preschool children,

including a lack of evidence from prospective observational investigations. Furthermore, to the best of our knowledge no studies, in any child age group, have investigated the relationship between screen media use and its relation to specific everyday activities.

The Motor Skills in PreSchool (MIPS) study was initiated in 2016 and included preschool children (3-6 years of age) attending preschools in the Municipality of Svendborg, in Denmark. A subset of the preschools included an intervention component, whose aim was optimization of motor skills. In this study, the children's screen media use was assessed via questionnaire and physical activity was assessed using two Axivity AX3 (Axivity Ltd., Newcastle upon Tyne, United Kingdom) triaxial accelerometers - one placed at the hip and one at the lower back - at both baseline and at 18-month follow-up. In addition, data on relevant covariates was also collected (22). Most of the longitudinal physical activity literature involves a single baseline measurement of PA, linked to e.g. questionnaire-based data or health/mortality records data. Having data on both exposure and outcome at baseline and follow-up renders more detailed longitudinal assessments possible. Furthermore, daily schedule (proxy based on reporting by parents and pedagogical personnel) information on the children introduces the possibility of domain-specific analyses of physical activity, as we can time annotate the data into different sections of the children's daily routine. Therefore, data from MIPS can be an important data resource to investigate the direction of the relationship between screen media use and physical activity, in preschool children. Utilizing data from MIPS could help in closing some of the gaps in knowledge in this field acknowledged above.

Aims of the proposed study

- The primary aim is to investigate the relationship between changes in screen media use with changes in non-sedentary time (time, min/day, spent in activities other than lying and sitting) during leisure (outside nursery) from baseline to 18-month follow-up.
- The secondary aim is to investigate the relationship between changes in screen media use and time (min/day) spent in specific daily activities (lying, sitting, moving, standing, walking, and running) and changes in moderate-to-vigorous intensity physical activity during leisure.

Overall data processing and statistical analyses plan

Accelerometry

Time spent in distinct activity types (sitting, moving, standing, biking, running, walking, and lying down) are determined from the acceleration measured with the thigh worn device using the method proposed by Skotte et. al. (2014) (23) using 1-second epochs. In this study, the method was validated with adults in a standardized field test and demonstrated a sensitivity >95% and specificity >99% for all activities. Also, during almost six days of measurement in free-living, sensitivity and specificity were 98% and 93%, respectively, for classification of sitting time (23). Child specific decision thresholds for the method were developed using an internally conducted study (publication in preparation). The results indicate high sensitivity and specificity of measurement. Non-sedentary time is defined based on this method and includes all activities, including standing, other than sitting and lying. We will analyze non-sedentary time as the amount per day (total amount per six days divided by six). In addition, time spent within physical activity intensity domains (sedentary, light, moderate and vigorous) will be estimated using ActiGraph counts generated with the waist worn device (24) using 10-second epochs. The cut-points defining intensity domains are determined using pre-school specific accelerometer cut-points (25).

Based on the child's daily schedule data during physical activity assessment, we will separate physical activity performed according to time of sleep (including naptime in preschool), leisure, and preschool hours. If data schedule is missing, we will impute using data from preceding or following days, where data is available. If no data on nocturnal sleep time is not available from daily schedules, typical sleep hours reported in the baseline questionnaire, will be employed. Because schedules are completed at both baseline and follow-up physical activity assessment, we will be able to employ time-specific data on sleep time. This is necessary, as sleep patterns most likely have changed from baseline to follow-up, i.e. 18 months later, when the children are that much older.

Statistical analyses

To address the primary objective, we will analyze changes in screen time (based on weighted averages of typical weekday and a typical weekend day) as continuous variable, as well as using four categories of screen time; those who consistently, i.e. at both baseline and 18-month follow-up, have high screen time; those who initially had high screen time but moved to having low screen

time at 18-month follow-up; those who initially had low screen time but moved to the high screen time category; and, lastly, those consistently had low screen time. High screen time will be defined as being above the 1-hour recommendation by WHO for daily sedentary screen time (9). However, the median baseline screen time will used as a cut-off, if an inspection of the data distribution deems this more appropriate. The secondary objective of the study proposal will be addressed using the same treatment of the exposure variable, as in the primary objective.

To address possible clustering of preschool children's non-sedentary time within their respective preschools a multilevel modelling approach will be used to assess the relation of screen time with physical activity. We will employ a linear mixed-effect model, where the random effect (random intercept) of preschool will be included. A crude model (only adjusting for age, sex, and intervention arm) and a multivariable adjusted model will be computed. Although the main effect of intervention will be computed in our statistical model, this will not be presented in the paper. This remains to be true even in the unlikely event that an editor or reviewer request this information from us.

According to a proposed Directed Acyclic Graph of the relation between screen time and physical activity (appendix 1), to analyze the direct relation (close all backdoor confounding paths) we could adjust for the child's age, both the child's and the parents' chronic disease status, gender, the child's mental well-being, number of siblings, whether the child has access to his or her own garden, as well as parents' screen media use habits and the household socio-economic-status. Of several minimally adjustment sets, this set of variables is chosen as questions pertaining to these variables were posed in the questionnaires included in MIPS. We will also adjust for baseline non-sedentary time to into account that one's initial levels may be related to the degree of change in screen time and independently predict changes in non-sedentary, over time. If some variables exhibit large amounts of missing data, these may not be included in the main model. Rather, they will be included in a sensitivity analysis and missing data will be imputed (see later). If variables exhibit lack of variation, they may be excluded from the main analysis, and, instead, including in a sensitivity analysis.

First, it is well-established that males and females have different health behaviors. Thus, it is important to investigate potential sex differences between changes in screen time and changes in non-sedentary time during leisure. Secondly, socio-economic-status may to some extent reflect parent resources. Resources may to some extent dictate whether parents have the capacity to consistently encourage their children to perform more daily physical activity, even though their children have plentiful screen time. Thus, the extent to which parents can mitigate the risk of physical inactivity with increasing screen time, may differ depending on available physical and mental resources. It is, for this reason, important to investigate whether the relationship between changes in screen time and changes in non-sedentary differ depending on the socio-economic group which the parents report membership. Lastly, related to the above, the number of immediate siblings may also encourage physical activity, through e.g. an invitation to play activities. Such encouragement may be absent in only children. Overall, effect modification of gender, socio-economic status proxy (parent education) and number of siblings (single-child/having siblings only two years younger or older than oneself/having siblings more than two years younger or older than oneself) will be tested using the likelihood ratio test (comparing a model with and a model without the respective interaction term). We will conduct these analyses only in the analyses included in the primary aim.

Supplementary analysis of the primary analysis

- The analyses included in the primary aim will be parsed (via stratification) onto weekdays and weekend days. The purpose of this is to investigate whether the strength of the relationship between changes in screen time and changes in non-sedentary time during leisure differ, depending on the day of week (typical weekday or typical weekend day).

Sensitivity analyses of the primary analysis

- In the MIPS study, the accelerometers were mounted to the children's skin using adhesive tape at baseline and using belts at 18-month follow-up. Cross-sectional analysis of the relation between screen time at baseline and follow-up, with non-sedentary time at baseline and follow-up, respectively. The purpose of this is to investigate whether we have reasons to suspect that methodological issues relating to the modality of accelerometry, might impact the computation of amount of participation in daily activities and time spent at distinct activity types. These investigations will be conducted in children who are five at baseline and who are five at 18-month follow-up (two separate cohorts), i.e. in subsets of the data. We will also compare the amount of wear time at the two time points.
- We will also conduct an analysis where we limit the exposure variable to baseline screen time (i.e. not changes in screen time) and relate this to changes in non-sedentary time during leisure. In the analyses included in the primary aim, concerns regarding reverse causality may be raised, which we will attempt to address in this analysis. This approach assumes that to some extent screen time habits are relatively constant in the 18 months that follow.

- To address the possibility of bias from missing data, e.g. from loss to follow-up (not participating in follow-up examination) or other reasons, we will compute, based on the models from the primary aim, where we impute data on covariates and exposure variable using Multiple Imputation Chained Equations. A mixed-effect model including beta-coefficient and 95% confidence intervals will be computed based on 20 datasets. Our a priori assumption is that missing data is missing at random (MAR).

We will check all the linear mixed effect models for the basic statistical assumptions, which underlie the integrity of the models. We will visually assess normality of residuals, linearity of each independent variable to the dependent variable, homogeneity of variance of the residuals, as well as check that means from the fixed effect of the cluster groups are not correlated with the effects associated with the cluster variable groups.

The statistical analyses will be conducted using Stata IC 16 (Statacorp) with an α=0.05 (two-sided testing).

Data storage

The data will be stored it on a PF-folder, on a University server. A PF folder is a type of folder which meets the requirements of the General Data Protection Regulation (including logging of user folder activity) for storage of sensitive data. The data will be deleted when the study has been finalized in accordance with the legal agreement established with SDU Research and Innovation.

Variables proposed

Variable	*Variable names*	*Baseline (Autumn 2016)*	*Follow-up (Spring 2018)*
Child variables			
All variables on the child's screen media use habits	screen_morning_bl screen_evening_bl screen_workhour_bl screen_workmin_bl screen_weekhour_bl screen_weekmin_bl tv_workhour_bl tv_workmin_bl tv_weekhour_bl tv_weekmin_bl screenrules_bl (only baseline) screenrule_control_bl (only baseline)	x	x
Child's age/date of birth	birthdate	x	
Child's gender	gender	x	
Child's height	height_ant	x	
Child's weight	weight_ant	x	
Child country of birth	childnative_bl childnativeother_bl	x	
Number of siblings	cohabchildren_bl	x	
Age of siblings	sib1birthDatofelt_bl sib2birthDatofelt_bl sib3birthDatofelt_bl sib4birthDatofelt_bl sib5birthDatofelt_bl sib6birthDatofelt_bl	x	
Wake and sleep times of the child (baseline survey data)	wakeworkday_bl wakeworkdaywhen1_bl wakeworkdaywhen2_bl sleepworkday_bl sleepworkdaywhen1_bl	x	

	sleepworkdaywhen2_bl wakeweekend_bl wakeweekendwhen1_bl wakeweekendwhen2_bl sleepweekend_bl sleepweekendwhen1_bl sleepweekendwhen2_bl		
Wake, sleep and nap time according to daily schedule registrations	Provided by LGO	x	x
Child's chronic disease state	genhealth_bl inhealth_bl inhealthtype_bl psydiag_bl psydiagtx_bl	x	
Type of home and whether the child has access to his/her own garden	houseown_bl housetype_bl housetypeother_bl garden_bl		
Child's mental wellbeing (Strengths and difficulties questionnaire – total score)	complete_triv_paed16au complete_triv_paed18sp	x	x
Immediate family (including father and mother) musculoskeletal disease	famill_bl famill_pain_bl famill_rharth_bl famill_osarth_bl famill_other_bl famill_none_bl famill_othertx_bl	x	
Kindergarten	key_kindergarten	x	
Intervention/randomization arm	?	x	
Accelerometry-derived physical activity data	Provided by JCB	x	x
Parent/caregiver variables			
Biological mother's country of birth	motnative_bl	x	
Biological father's country of birth	fatnative_bl	x	
Mother's education	motedu_bl		
Father's education	fatedu_bl		
All variables on the mother's screen media use habits	screenmot_workhour_bl screenmot_workmin_bl screenmot_weekhour_bl screenmot_weekmin_bl	x	
All variables on the father's screen media use	screenfat_workhour_bl screenfat_workmin_bl screenfat_weekhour_bl screenfat_weekmin_bl	x	

Publication plan

A manuscript will be written based on the results of the current study and submitted to a peer-review journal. The journal that the journal will be submitted to is not decided at this point. The results of the current investigation will be submitted independently of

the direction of the findings, including non-significant results. All authors list above will be included as authors of the manuscript, unless an author chooses not to take part in the study.

Appendix 1 – Suggested Directed Acyclic Graph of causal relation between screen media use and non-sedentary time in preschool children (SES: Socio-economic-status, P: Parental, ST: Screen time, PA: Physical activity)

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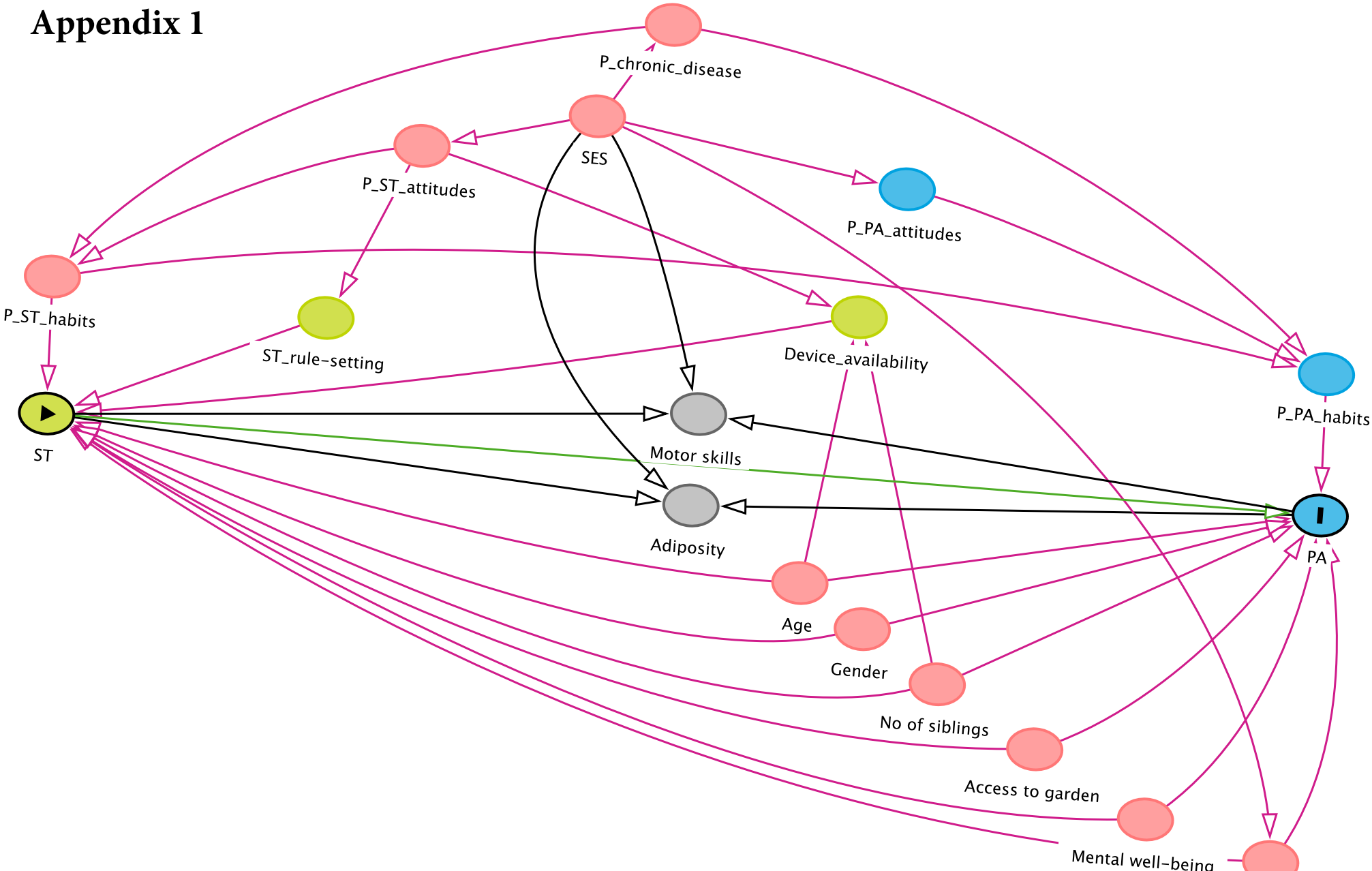
Appendix 1


P_chronic_disease
SES
P_ST_attitudes
P_PA_attitudes
P_ST_habits
ST_rule-setting
Device_availability
P_PA_habits
ST
Motor skills
Adiposity
PA
Age
Gender
No of siblings
Access to garden
Mental well-being