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ABSTRACT

Purpose: We studied whether physical activity (PA) counseling for parents influenced the level of parental support of children's PA and leisure time PA in children of different levels of initial parental support. It was hypothesized that the initial level of parental support would moderate the intervention efficacy. **Methods:** Children (n = 44, Mage = 6.09 ± 1.17 years) and their parents (n = 61) randomized to an intervention group received counseling for six months. Children of the control group (n = 47, Mage = 6.12 ± 1.11 years) and their parents (n = 63) did not receive any counseling. Parental support was assessed using the Family Physical Activity Environment (FPAE) questionnaire and children's leisure time PA was recorded using triaxial accelerometers at baseline, at 6 months, and at 12 months. The efficacy of intervention was tested by linear mixed-effects modelling adjusting for confounding variables (Model 1), and additionally for children's participation in organized PA or sports (Model 2). **Results:** Parents within the lowest initial parental support intervention tertile significantly increased their support and their children's mean level of leisure time PA significantly improved compared to the corresponding controls during the counseling period. On the other hand, intervention was found to have an unfavorable influence especially in the PA of children of initially highly supportive parents. **Conclusion:** Targeting PA counseling for parents with low support of their children's PA could contribute to better family-based PA counseling efficacy.

Keywords: young children, physical activity behavior, family-based intervention, physical activity parenting

Parental Support and Objectively Measured Physical Activity in Children: a Year-Long Cluster Randomized Controlled Efficacy Trial

The role of physical activity (PA) in health is well documented already in childhood (Strong et al., 2005). PA may also play a crucial role in cognition (Tomporowski, Lambourne, & Okumura, 2011) as well as in psychosocial wellbeing (Timmons et al., 2012). Due to a high prevalence of inactivity among children (Spittaels et al., 2012) and a tracking of PA behavior over time (Telama et al., 2014), there is a need to identify feasible and effective strategies to influence the early formation of PA habits.

Leisure-time PA has been shown to be low and progressively decreasing during childhood (Telford et al., 2013). Family influence has been recognized as one of the most important predictors of children's overall, as well as leisure time, PA. Parental support of children's PA (Beets, Cardinal, & Alderman, 2010; Cleland et al., 2011; Edwardson & Gorely, 2010; Loprinzi & Trost, 2010; Rhodes et al., 2013), parents' perceived behavior control over children's PA (Rhodes et al., 2013), and parents' participation in PA with a child (Beets et al., 2010; Edwardson & Gorely, 2010) have all been linked to greater PA in children. However, parents' own PA level seems to be neither a prerequisite for children's PA nor is parents' own inactivity a primary barrier for children's PA (e.g., Iannotti et al. 2005; Yao and Rhodes 2015), but it is the case that physically active parents tend to more often support children's PA (Dowda et al., 2011; Loprinzi & Trost, 2010). Sedentary behavior, based on the limited research literature to date, does seem to associate between parents and their children (Jago, Fox, Page, Brockman, & Thompson, 2010) and activities performed together as a family are typically sedentary in nature (Thompson et al., 2010). Therefore, encouraging parental support for children's PA and

limiting co-participation in sedentary behaviors remain potential intervention strategies for affecting PA in children.

Direct involvement of parents (e.g., parents' presence at education sessions, parents' attendance and participation at counseling or training sessions or phone communication with parents) is known to be a cornerstone of family-based nutrition (Hingle, Connor, Dave, & Baranowski, 2010) and PA interventions (Brown et al., 2016; O'Connor, Jago, & Baranowski, 2009). Families are known to have heterogeneous work time demands and free time interests (Thompson et al., 2010), and this may be a reason why focusing on small-step and gradually increasing goal setting and encouragement have been shown to be key methods in family-based PA enhancement in children (Brown et al., 2016; Rodearmel et al., 2006). There is however very little support for the family-based PA intervention effectiveness on children's objectively measured PA (Metcalf, Henley, & Wilkin, 2012). Therefore, there is a great need for examining mechanisms, especially moderators and mediators, of the family-based PA interventions for better understanding how PA in children should be promoted in a family context (Brown et al., 2016; O'Connor et al., 2009).

We conducted a cluster-randomized controlled trial "A family-based tailored counseling to increase non-exercise physical activity in adults with a sedentary job and physical activity in their young children" (InPact, ISRCTN28668090) (Finni, Sääkslahti, Laukkanen, Pesola, & Sipilä, 2011). The InPact study was designed to help parents' to find ways to decrease sedentary behavior of their own and to increase PA in their children. PA counseling of the study was based on social cognitive theory (Bandura, 1986) and theory of planned behavior (Ajzen, 1985). The counseling was found to significantly decrease parents' muscle inactivity and to increase light muscle activity in short-term (Pesola et al., 2014). However, PA in children of the intervention

group declined statistically significantly compared to their control peers although the development of some domains of motor competence was positively associated with the counseling (Laukkanen, Pesola, Heikkinen, Sääkslahti, & Finni, 2015). Results suggested distinct counseling efficacy on parents and their children's PA behavior when treated at the same time, and this is why we decided to study the counseling efficacy on children's PA behavior in more detail.

Association between the parental support of children's PA and the children's PA is well documented but little is known of how to influence changes in these variables (Davison et al., 2013; O'Connor et al., 2009). We hypothesized that the initial level of parental support of children's PA moderates the efficacy of family-based PA intervention. We based the hypothesis on an assumption that parents who initially provide different levels of support (low or high) for their children's PA have different potentials for supporting the change in their children's PA behavior which may affect the counseling efficacy on their children's PA. Consequently, this study examined whether the family-based PA intervention, consisting of individually tailored face-to-face and phone counseling for the parents of children aged 4 to 7 years, influenced parental support of children's PA and objectively measured leisure-time PA in the children with the lowest and highest initial parental support. We aimed to complement interpretation of the intervention efficacy analyses by describing intervention evaluation separately from the view of parents with the lowest and highest initial parental support of children's PA.

Methods

The local ethics committee approved the study protocol (Dnro 6U / 2011) and all the parents signed a written informed consent form for their own and their children's participation in

the study. A checklist of the CONSORT 2010 Statement for reporting randomized trials (Moher et al., 2010) guided reporting of the methods and findings of this trial.

Cluster Randomization and Recruitment

We performed randomization and recruitment in a Scandinavian city with around 133,000 inhabitants living in a relatively small city center and topographically varied suburbs. Based on a city registry and recreational city map, we identified equivalent suburbs in the city in terms of amount of the children attending regional kindergarten(s) or day care center(s) (henceforth referred as day care center) and school(s), mean educational level of the region, and PA possibilities in natural landscapes. We then formed seven balanced counterpart regions (henceforth referred as "clusters", one to four day care centers or schools in each cluster) and randomized to either the intervention or the control cluster between these counterparts. Families were recruited from the intervention cluster regions to intervention group and from the control cluster region to control group. Contamination between the intervention and control groups was avoided by forming the balanced intervention and control regions on geographically opposite sides of the city. Figure 1 illustrates the enrollment and allocation, as well as measurement and analysis flow of the present study.

Figure 1 here.

Children attending less than 10 days a month in a day care center, and having a developmental disorder or other disorders delaying motor development we excluded from the study. Because the intervention was not only aimed at affecting behavior of children's but also their parents', there were exclusion criteria also for parents. Accordingly, we excluded parents sitting less than 50% of their work time or having chronic diseases, and pregnant parents. We accepted families including both parent(s) and a child and fulfilling the study criteria for the

study. We recruited participants between April 2011 and April 2012. Altogether 35 and 36 children and their parents of the intervention and control groups begun in the study between May 2011 and December 2011, respectively. In addition, 16 children and their parents from both randomized groups begun in the study between January 2012 and May 2012, respectively.

Tailored Counseling

Theoretical Framework. Behavior change techniques based on social cognitive theory (Bandura, 1986) and the theory of planned behavior (Ajzen, 1985) were systematically used by researchers in the counseling process. Description of the behavior change techniques utilized is reported elsewhere (Laukkanen et al., 2015) and detailed here briefly. We utilized altogether 9 behavior change techniques in the counseling process: providing instruction (I), providing information on consequences (IC), prompting identification as a role model (IRM), providing general encouragement (GE), providing information about others approval (IOA), prompting intention formation (IF), progressive goal setting (PGS), prompting barrier identification (BI) and self-evaluation (SE). This process comprised of a lecture (I, IC, IRM, GE, IOA), individual face-to-face counseling (GE, IF) and goal setting (PGS) given in a university seminar class in two weeks after the baseline measurements, and phone consultation (GE, PGS, BI, SE) at 2 and 5 months after the baseline. The researchers (AL, male, approx. 30-years old, engaged; AP, male, approx. 30-years old, married; TF, female, approx. 40-years old, married and a parent of 2 children) received orientation on good practices in PA counseling before the study.

Lecture. In the approximately 30 min lecture given by one of the researcher's (AL), one hour of moderate to vigorous PA (MVPA) at leisure time each day was encouraged to be targeted in the children (I). This target was justified by the research evidence indicating the high proportion of children not achieving even a half (Spittaels et al., 2012) of the nationally

recommended level of two hours of MVPA each day (Sosiaali- ja terveysministeriön oppaita, 2005) and by the assumed health and developmental benefits due to increased PA (IC). Specific arguments related to the associations found between PA and health, motor competence and cognitive functioning. We encouraged parents to give children possibilities for PA in everyday leisure time, and also to enable PA in non-built environments such as heaths, forests, and hills (Sallis, Prochaska, & Taylor, 2000) (GE). We encouraged efforts increasing PA especially in winter time as this has been generally known to be a more inactive season in northern countries (Carson & Spence, 2010). We emphasized the meaning of role modeling in PA by providing examples where parents act as role models for their children, e.g. situations when they spend time with their children and they have to choose between lift and stairs or between bicycling and taking a car (IRM). During the lecture, opinions on and approval of restricting PA in children (e.g., for the sake of convenience) were discussed by parents and researchers (IOA).

Face-to-Face Discussion. After the lecture, individual face-to-face discussion took place. Following a fidelity checklist, a researcher asked a parent to describe their families' leisure-time and PA habits at leisure time. Next, the same researcher encouraged the parent, first, to identify contexts where PA in their children could be feasible to be enhanced, and second, to set small-step goals aiming at increasing PA in the child(ren) (GE, IF). The small-step goals set were, for instance, "I will let my child to walk to the day care center with me" or "We will go outdoors as a family". Every goal was set on the scale from 1 to 4 depending on the frequency of the intended implementation (1: randomly, 2: once or twice a week, 3: three to four times a week, 4: daily). Gradually progressing goal-setting was recommended so that the baseline goals set would be likely achievable and they could be progressively raised later in the phone consultations

(PGS). The goals set were written into an agreement form which was signed by the parent and the researcher.

Phone Consultation. We enhanced compliance with the goal implementation by phone consultations at two months and five months after the face-to-face counseling (GE). Compliance with the goals and perceived barriers for implementation of goals were discussed and possible modifications to the goals were suggested (PGS, BI). Furthermore, we promoted self-evaluation of the compliance by a question "Did you do your best to achieve the goal?" and by asking answer on a scale between 1 and 5 (1: not at all, 2: a little, 3: moderately, 4: relatively well, 5: fully) (SE). Implementation of the goals was reinforced by monthly emails for the first six months. Parents were instructed to continue the children's PA promotion after the reinforced intervention period.

Parental Support

We used the Family Physical Activity Environment (FPAE) questionnaire for determining the parental support of children's PA (Cleland et al. (2011). The test-retest reliability of the questionnaire has been found good in 5-6 and 10-12-years old Australian children (ICC = .81 – .90). The FPAE was translated into the mother tongue of the study participants by an informed translator and by an uninformed one (Beaton, Bombardier, Guillemin, & Ferraz, 2000). The two independent translations were compared in the second phase of the translation process, and via the consensus of the translators, a synthesized version of the questionnaire was formed. In the third phase, the translated questionnaire was pretested for its clarity of language and suitability for the local culture by five experts in different fields (physical education, exercise physiology, kinesiology, and health science). We chose three sections consisting of altogether seven items from the FPAE to represent the rate of parental

support on children's PA. Each section consisted of two separate items considering the parental support the father, and secondly, the mother has provided to the child. We saw this classification suitable as the legal guardians of the children involved in this study were all either mothers or fathers. The first section, family participation in PA, was assessed by the following items: "Evaluate how often *father / mother* participates in physical activity with your child, such as moving and playing games". Moreover, the first section included a third item: "Evaluate how often you do physical activity, such as cycling, walking, playing outdoors or indoors, hiking, playing games, together as a family". The second section, direct support on child's PA, was assessed as follows: "Evaluate how often *father / mother* provides support for your child's participation in physical activity, such as take him / her to PA hobby or training, provide money for participation, buy sports clothing / equipment". The third section, reinforcement for PA, was assessed by the following items: "Evaluate how often *father / mother* praises your child for participating in PA, such as say positive things to him / her for being physically active". Parents were asked to evaluate the frequency of support regarding the youngest child of the family participating in the study on a six-step scale for each item (1 = never, 2 = less than once per week, 3 = 1 – 2 times per week, 4 = 3 – 4 times per week, 5 = 5 – 6 times per week, 6 = daily). We asked the same parent to fulfill the FPAE questionnaire in each time at baseline, 6 months, and 12 months.

Assessment of Leisure-Time Physical Activity, Anthropometrics and Socioeconomic status

Leisure-Time PA. Children's PA was measured with triaxial X6-1a accelerometers with a dynamic range of ± 6 g (Gulf Coast Data Concepts Inc., Waveland, MS, USA) at baseline, 6 months, and 12 months for six consecutive days at a time. For analysis we accepted recordings that contained day care center or school time and leisure time longer than seven hours a day (420

min) on at least three days per measurement point (at minimum two weekdays and one weekend day, for more see Penpraze et al., 2006). Because the intervention focused on time the parents spend with their children, we examined changes in PA during leisure time. Based on diaries completed by the parents, leisure-time PA was recorded on average for 5.86 ± 1.51 hr / day (minimum 3.19 hr / day, maximum 9.87 hr / day, referring to out of school or day care center hours) during 3.35 ± 0.79 weekdays. On average, 1.81 ± 0.39 weekend days with a mean of 11.25 ± 1.43 hr / day (minimum 7.08hr / day, maximum 15.64 hr / day) were recorded and analyzed. Hence, the measured total leisure-time PA was on average similar between weekdays and weekend days (19.6 hr vs. 20.4 hr). We calculated average counts per min (henceforth CPM), indicating the mean level of PA (Cardon & De Bourdeaudhuij, 2008), for the leisure time at each measurement point. Also, time (min) spent at sedentary, light and MVPA intensities were calculated on the basis of validated cut-off points (van Cauwenberghe, Labarque, Trost, De Bourdeaudhuij, & Cardon, 2011). We weighted PA data measured on weekdays' leisure time by 5 / 7 and on weekend days' leisure time by 2 / 7. We assessed children's participation in organized PA or sports by asking from the parents whether their child participating in this study is involved in an organized PA or sports out of the day care center or school time. The answer was coded as "yes" or "no".

Anthropometrics and Socioeconomic Status. We measured height and body weight in the laboratory at 6 months and calculated body mass index (kg / m^2). The highest achieved educational level was used as a measure of socioeconomic status (SES) and we asked parents to evaluate it on the scale from zero to four (0 = elementary school, 1 = secondary school, 2 = high school, 3 = vocational or intermediate degree, 4 = polytechnic or university degree). A mean of the highest educational level of parent(s) was calculated and used for analyses. Besides, to

describe the SES among parents of the study sample, a dichotomous variable of "higher level education" (value 4) and "no higher level education" (values 0 – 3) was formed.

Intervention Evaluation

Goals set by parents in the intervention group during the face-to-face counseling and in the phone counselings 1 and 2 were categorized according to how PA in children was aimed to be enhanced. Altogether we formed 5 categories (PA with family, PA with peers, PA outdoors, PA in the backyard or in the neighboring area, PA indoors) covering 97 – 100% of all the goals set. Proportion of the goal categories among parents of the lowest and highest initial parental support tertiles was then calculated in relation to the total frequency of the goals in the corresponding tertile and in the certain counseling time. We performed similar protocol for evaluating the most common barriers for goal implementation perceived by the parents in the phone counselings. We conducted evaluation of the perceived barriers separately for those considering weekdays and weekend days. During a common feedback session in the end of the study, we asked parents to rate the order of importance of the counseling tools. We evaluated the counseling tool the more important the more often it was rated as the most important intervention tool by the parents.

Statistical Analysis

We found internal consistency for all seven of the FPAE items to be good after testing Cronbach's alpha at baseline (0.83), 6 months (0.79), and 12 months (0.83). Pairwise correlations ranged from low to moderately high between all seven items at different measurement points (baseline, 6 months, and 12 months) ($0.334 < r < 0.718$), and removal of any of the items would not have increased the consistency of the questionnaire. Therefore, we calculated a sum factor of all seven selected FPAE items (mean 24.62 ± 0.88, 23.81 ± 1.02 and

23.39 ± 0.96 at baseline, 6 months and 12 months, respectively) and used it as a parental support factor for further analysis.

We formed tertiles of low and high initial parental support for examining the parental support as a moderator of the intervention efficacy. The use of tertiles was aimed to facilitate the drawing of conclusions and practical implications of the study. The tertiles were formed by selecting the lowest and highest thirds (33 %) of the intervention and control families based on the sum factor of the FPAE at baseline. There were higher FPAE sum factor scores among the intervention group compared to the control group, and a one more family was included to the highest intervention tertile and a one less to the highest control tertile for achieving a statistical balance between the tertiles. The level of initial parental support was therefore statistically equal between the children in the lowest tertiles of intervention (n = 15, mean 2.77 ± 0.33, min. 2.14, max. 3.14, range 1) and control (n = 16, mean 2.74 ± 0.37, min. 1.86, max. 3.14, range 1.29), and between the children in the highest tertiles of intervention (n = 16, mean 4.51 ± 0.46, min. 4.0, max. 5.71, range 1.71) and control (n = 14, mean 4.42 ± 0.55, min. 3.57, max. 5.14, range 1.57). We tested the intervention efficacy on changes in parental support and PA using the whole sample (n = 91) and tertiles of parental support.

We tested differences between the intervention and control groups and the tertiles of parental support in background characteristics by an independent samples t test (age of child and parent(s), height, weight, BMI, log transformed PA variables, measurement length of PA per day, parental support items and sum score), the Mann-Whitney U test (measurement days of PA), and a chi-square (X^2) test (participation to organized PA or sports, higher level education, being single parent, answerer's sex of FPAE). We calculated the Cohen's d for indicating the

effect sizes (ES) of the statistically significant differences in the background variables and they were interpreted as small when ES ≥ 0.2, medium when ES ≥ 0.5 and large when ES ≥ 0.8.

We analyzed the efficacy of intervention with linear mixed-effects model fit by restricted maximum likelihood using the Statistical Package for the Social Sciences (SPSS; IBM SPSS Statistics 22). Analysis of the counseling efficacy was initially based on a three-level hierarchy where children (n = 91) were nested within families (n = 85) and families were nested within randomized clusters (n = 14). The children, families and clustered samples were considered in the models as random grouping effects. However, we found the effect of family level and clustered samples to be insignificant and they were therefore left out from the final models and tests examining the counseling efficacy. The Group × Time interaction formed a base for all autoregressive covariance models (AR1) examining the efficacy of intervention on, first, parental support, and second, on the mean level and specific intensities of PA in children with different levels of initial parental support between baseline and 12 months. Based on this interaction, we calculated mean change from baseline to 6 months and mean difference between groups in these time intervals. We entered theory-based confounding variables (answerer's sex to FPAE, BMI, total number of children in the family, age of mother and father, SES, age and sex of a child, temperature of the measurement month, season started in the study, participation to organized PA or sports, measurement length of PA per day, measurement days of PA and with regard to parental support models also mean level of PA) one by one into the unadjusted Group × Time model. We entered all variables significantly interacting with the unadjusted model into the adjusted mixed effect models.

Model 1 examining the intervention efficacy on parental support was adjusted (in the order of statistical significance) for child's age, PA in leisure time, and average temperature of

the measurement month. When we examined the intervention efficacy on PA, we adjusted Model 1 for temperature of the measurement month, the child's sex, and the sex of the parent answering the parental support questionnaire. Furthermore, we found the child's participation in organized PA or sports to be a nearly significant confounding variable when examining the intervention efficacy on parental support and a significant variable when examining the efficacy on PA. However, interpretation of the interaction between participation in organized PA or sports and the intervention efficacy on PA can be complex. Therefore, we applied model 2 when examining the intervention efficacy on parental support and on PA by adjusting apart from other covariates for participation in organized PA or sports. Finally, we performed a three-way interaction of Group × Time × Sex in an unadjusted and adjusted models with the whole sample and separately considering the tertiles of parental support for examining whether the intervention efficacy on parental support or PA differed between the sexes of the children.

We reported means, confidence intervals (CI) and *p*-values for statistically significant findings with respect to mixed models. A logistic regression was used to identify significant predictors for dropping out of the study. All predictor variables were entered in the model simultaneously. We set the level of significance to $p < .05$ for all analyses.

Results

Baseline Characteristics of Parental Support Tertiles

According to the whole study sample's initial parental support (mean 3.52 ± 0.82), parents supported their children in PA approximately two to three times per week. Table 1 shows the frequency of parental support among the tertiles. Initial parental support was higher ($F(1, 59) = 4.19$, $p < .001$, ES = 0.89) among the intervention and control tertiles of the highest parental support (mean 4.47 ± 0.50, corresponding to four to five times a week of parental support)

compared with the lowest parental support tertiles (mean of sum factor 2.76 ± 0.35, corresponding to less than once a week up to once a week of parental support). The mothers of the intervention group were significantly younger ($F(1, 69) = 8.47$, $p = .001$, ES = 0.37) and participated more in PA with their children ($F(1, 89) = 6.20$, $p = .02$, ES = 0.25) than mothers of control children did. Additionally, girls in the lowest tertile of parental support were significantly older ($F(1, 29)$, $p = .045$, ES = 0.35) than the boys were.

Tables 1, 2 and 3 here.

The mean level of leisure-time PA at baseline was 567.70 ± 188.0 CPM and on average 421.87 ± 66.82, 23.88 ± 9.15 and 27.96 ± 14.19 minutes of the free time per day was spent at the intensity levels of sedentary, light and MVPA, respectively. While boys were generally more active ($F(1, 89) = 1.58 – 6.09$, $p = .001 – .007$, ES = 0.27 – 0.35) than girls in all PA measures at the baseline, the difference between genders was significant among the tertile of the lowest parental support ($F(1, 29) = 1.63 – 5.65$, $p = .011 – .037$, ES = 0.39 – 0.41) but not among the tertile of the highest parental support. On the other hand, girls were significantly older than boys ($F(1, 89) = 1.42$, $p = .045$, ES = 0.21) in general. On average, 63% of the children participated in organized PA or sports at baseline and the prevalence of participation generally showed an increasing trend over time, with a few exceptions: the children of the lowest intervention tertile showed a decreasing trend of participation from baseline (53.3%) to 6 months (38.5%) and an increasing trend to 12 months (80%), while children of the highest control tertile showed a decreasing trend of participation from baseline (84.6%) to 6 months (71.4%) and 12 months (66.7%).

Those families who dropped out of parental support measurements after baseline had more children ($F(1, 89) = 0.009$, $p < .001$, ES = 0.71) than families who continued for the full

year. There were no other significant predictors for dropping out. In general, parents of the children included in the analyses more often had a university or polytechnic degree when compared with the mean of the whole recruitment region (84% / 35%) and were less often single parents (4% / 27%).

Efficacy of Intervention on Parental Support

Parental support declined in the intervention and control groups with time, but this overall decline was not statistically significant nor did the change differ between groups (Table 2). A significant decline in parental support took place within the highest initial parental support tertile of the intervention group from baseline to 6 months (unadjusted mean -0.59, CI -0.96 – -0.20, p = .004; Model 1 mean -0.44, CI -0.84 – -0.05, p = .03; Model 2 mean -0.52, CI -1.02 – -0.01, p = .046) and to 12 months (unadjusted mean -0.57, CI -1.01 – -0.14, p = .011; Model 1 mean -0.43, CI -0.86 – -0.00, p = .048) and within the corresponding control tertile from baseline to 12 months (unadjusted mean -0.72, CI -1.16 – -0.29, p = .002; Model 1 mean -0.65, CI -1.11 – -0.19, p = .006; Model 2 mean -0.63, CI -1.13 – -0.13, p = .015). The decrease in parental support did not differ between the highest intervention and control group tertiles. On the other hand, parental support increased significantly within the lowest intervention support tertile from baseline to 6 months (unadjusted mean 0.29, CI 0.04 – 0.53, p = .021; Model 1 mean 0.27, CI 0.03 – 0.52, p = .032; Model 2 mean 0.33, CI 0.06 – 0.61, p = .018), although this change was not significant either when compared with the corresponding control tertile. The three-way interaction of Group × Time × Sex indicated no differences between sexes in the intervention efficacy on parental support.

Efficacy of Intervention on Physical Activity

The control group had an increasing, yet insignificant, trend in the mean level of PA and

MVPA during the study year in comparison to the intervention group (Tables 2 and 3). However, children in the lowest intervention tertile of initial parental support significantly increased the mean level of PA between baseline and 6 months (unadjusted mean 160.17, CI 56.27 – 264.06, *p* = .003; Model 1 mean 154.07, CI 41.69 – 266.44, *p* = .008; Model 2 mean 192.90, CI 76.90 – 308.89, *p* = .002) and this change was also significant compared to the lowest control tertile (unadjusted mean 160.30, CI 15.68 – 304.93, p = .030; Model 2 mean 173.24, CI 16.18 – 330.31, p = .031). The mean level of PA increased in that case approximately by 29 % in children of the lowest intervention tertile between the baseline and 6 months. At the same time period, time spent at MVPA significantly increased within the lowest intervention tertile of parental support (unadjusted mean 12.32, CI 2.62 – 22.01, *p* = .014; Model 1 mean 11.50, CI 1.07 – 21.92, *p* = .031; Model 2 mean 15.09, CI 4.46 – 25.72, p = .006) although this change was not significant compared to the corresponding control tertile. On the other hand, children in the highest control tertile significantly decreased the time spent sedentary compared to the corresponding intervention tertile between the baseline and 6 months (Model 2 mean 79.80, CI 6.39 – 153.20, *p* = .034). Additionally, mean level of PA significantly increased within the highest control tertile of parental support between the baseline and 12 months (Model 1 mean 106.90, CI 8.37 – 205.43, *p* = .034). Although found statistically insignificant, there was an increasing trend of MVPA in favour of the highest control tertile compared to the highest intervention tertile from baseline to 12 months' follow-up. The three-way interaction of Group × Time × Sex indicated no differences between the sexes in the intervention efficacy on PA.

Intervention Evaluation

The initial goals set by the parents in the lowest and highest tertiles concerned PA with family (27% / 30% set this goal), PA with peers (21% / 12%), PA outdoors (19% / 28%), PA in

the backyard or in the neighboring area (18% / 28%) and PA indoors (12% / 2%), respectively. The goals remained relatively stable both in the lowest and highest support tertiles, although the frequency of the goals for PA with peers showed an increasing trend in the phone consultations at 2 months (25% / 14%) and at 5 months (24% / 18%) among the parents of the lowest and the highest tertiles, respectively. We found the compliance rate of phone consultations to be generally high in both the lowest and the highest tertile parents at 2 months (95 % / 92 %) but there was a decreasing trend to 5 months (74 % / 83 %). Parents of the lowest and highest support tertiles and who were reached once or twice for the phone consultations perceived being busy and other tasks (40% / 19% of all barriers), weather (30% / 24%), either their own or their children's tiredness (20% / 33%), and sickness (10% / 19%) as the most common barriers against meeting the goals on weekdays. Correspondingly, being busy and other tasks (55% / 53%), tiredness (27% / 11%), weather (0% / 21%), and sickness (9% / 16%) were most often mentioned as barriers among the lowest and highest tertile parents for meeting the goals on weekend days. Parents perceived face-to-face counseling (32%) as the most useful intervention tool in general followed by feedback from measurements (25%), counseling lectures (21%), phone consultations (7%), printed material (4%), emails (4%), and the project website (0%). However, parents of the lowest intervention tertile perceived the face-to-face counseling and feedback from measurements clearly more often as the most important tool compared to the parents of the highest tertile (44 % vs 14 % and 33 % vs 21 %, respectively). On the other hand, 14 % vs 0 % of parents of the highest and lowest tertiles rated the phone counseling as the most important intervention tool, respectively.

Discussion

Even though parental support has been documented as a key variable interacting with PA behavior in children (Beets et al., 2010; Edwardson & Gorely, 2010; Loprinzi & Trost, 2010), there is a lack of knowledge of how to affect parental support of children's PA for enhancing PA in children (Brown et al., 2016; O'Connor et al., 2009). Family-based PA counseling was previously shown to negatively influence the children's MVPA (Laukkanen et al., 2015), and this study aimed to examine whether the initial level of parental support of children's PA moderated the intervention efficacy on the parental support and objectively measured PA in the children. We hypothesized that the initial parental support of children's PA would moderate the intervention efficacy because parents with low or high initial level of parental support probably have different potential to benefit from the tailored counseling. The novel finding of this study relates to the children with lowest parental support at baseline who significantly increased their objectively measured mean level of leisure time PA during the counseling period in the intervention group when compared with their control peers. Importantly, parental support provided to these children significantly increased within the lowest intervention tertile, although this change was not significant compared to the corresponding control tertile. This study showed that the unfavorable intervention influence found on children's MVPA (Laukkanen et al., 2015), may be partly explained by allocation of the counseling to initially highly supportive parents. Overall, the findings suggest that initial parental support may be a significant moderator of family-based PA intervention efficacy on children's objectively measured PA.

The mean level (2 – 3 times per week) and declining trend of parental PA support along the child's age are equivalent with the findings in Australian children with the same measurement tool (Cleland et al., 2011). A unique finding of the present study was that the initial level of parental support on child's PA was found to moderate the efficacy of family-based PA

intervention on children's objectively measured PA. Parents who reported the lowest baseline level of PA support were also the ones who seemed to be the most sensitive for the PA counseling. Although regression to the mean probably explains part of the increase of parental support in the lowest tertiles (both intervention and control), the increase was significant only within the lowest intervention tertile. In contrast, we found individual counseling not to be an influential procedure for positively affecting parents of the highest support tertile. One explanation for the common inefficacy of family-based PA interventions on affecting the objectively measured PA in children (Metcalf et al., 2012; O'Connor et al., 2009) may be therefore actually the lack of potential for change in parents support of children's PA. This is because without an appropriate screening, family-based PA interventions may be overrepresented by parents with high initial support of their children's PA, a fact which may attenuate the intervention efficacy. Thus, efficacy of family-based PA counseling on 4-7-years old children's PA should be further researched in parents belonging to the lowest third when it comes to the validated measure of support of their children's PA.

Promoting parental support in childhood would be important for maintaining the level of PA across the childhood to adolescence (Kahn et al., 2008). Earlier evidence is stating that this would be important especially in girls (Davison & Jago, 2009). We found intervention efficacy to be independent of children's sex at the present study, so the family-based PA counseling may offer a suitable tool for enhancing parental support in both girls and boys. Additionally, it is important to note that regardless of the low absolute level, the positive change in parental PA support can have a meaningful influence on the children's PA behavior. The 29% increase of PA in children of the lowest intervention tertile in the end of the counseling period can be seen practically meaningful as the mean level of PA in all children at the present (567.70 ± 188.0) was

found relatively low compared to the level of 701 CPM reported in 4-5-years old children elsewhere (Cardon & De Bourdeaudhuij, 2008).

Interestingly, we found the changes of participation in organized PA or sports to have an opposite trend compared to the objectively measured PA in children at the present study. Children of the lowest initial parental support intervention tertile declined participation in organized PA between the baseline and 6 months, at the same time when the parental support showed an increasing trend and their measured PA was found to significantly increase compared to the control peers. It can be speculated that the increase of physically active family time and encouragement for PA in contrast to the declined participation in organized PA or sports contributed to the increase of measured PA in these children. Further, we found children of the highest control tertile to decline participation in organized PA or sports during the study year, at the same time when their measured PA increased compared to the corresponding intervention peers. It may be that the parents of the intervention group who already provided a high support on their child's PA found organized PA or sports as an only feasible way to further enhance PA in their children, a solution which was found to negatively influence measured PA in their children.

Future Directions of Family-Based Physical Activity Interventions

Behavioral theories (e.g. Bandura, 1986), as well as quantitative (e.g., Telford et al., 2013; Cleland et al., 2011) and qualitative (Thompson et al., 2010) research evidence state family to be a primary context for enhancing habitual PA in children. With the exception of some promising findings, attempts to enhance PA in children via the family context have been inefficient (Brown et al., 2016; Davison et al., 2013; Metcalf et al., 2012; O'Connor et al., 2009; van Sluijs et al., 2011). Consequently, there is a great need to find efficacious and well-detailed

family-based PA intervention methods, and on the other hand, to reveal those of found inefficacious. This study suggests that affecting parental support of children's PA would be a key factor in family-based PA interventions. It could be crucial to allocate the family-based PA counseling on the basis of initial parental support level as it may be an important moderator of the intervention efficacy. Influence of the family-based PA counseling on the parental PA support should be further examined in fully powered efficacy trials with optimal and highly controlled PA counseling circumstances, and if found consistently efficacious, in fully powered effectiveness trials, e.g. in community-based lifestyle programs.

It has been shown that perceived control over supporting a child in PA may be a primary outcome to focus on in family-based PA interventions. Although the attitude towards providing support for children's PA is a strong correlate of the intention of providing support on child's PA, especially the parent's perceived confidence on supporting PA has been shown to associate with the child's PA (Rhodes et al., 2013). Therefore, it can be assumed that the mode of delivery may play a crucial role in the PA intervention counseling. Almost half of parents in the lowest initial parental support tertile rated the individually tailored face-to-face counseling as the most important intervention tool at the present study. It is possible that the confidence on providing support on child's PA was best promoted through individual face-to-face discussions where a parent had a possibility to freely and without a feeling of hurry to tell a researcher about, e.g. the barriers against PA promotion. Although direct involvement of parents has been generally shown to be a key for successful PA and nutrition programmes (Hingle et al., 2010; O'Connor et al., 2009), there is a need to find both efficacious and efficient (i.e. cost-effective) ways of promoting parental support on child's PA. Therefore, research on alternative methods to face-to-face PA counseling and on an optimal combination of face-to-face counseling and other

intervention delivery methods are needed. In more detail, there is a need to examine ways to effectively support behavior change of PA parenting via general encouragement, progressive goal setting and other behavior change techniques which have a solid social cognitive theory basis on the behavior formation.

Parental support on children's PA may not be well explained by volitional intention (Rhodes et al., 2013). Parents of the present study reported similar barriers against PA promotion than parents of 10-11-years old children in the United Kingdom (Thompson et al., 2010). However, the barriers reported were somewhat different between the lowest and highest tertiles of parental support in the present study. Although individualization of PA intervention is most likely important, it would be beneficial to further research the challenges parents providing low support on their children's PA systematically face in everyday family life. Besides, positive intervention influences were found among the lowest parental support tertile during the 6 months lasting counseling period but not during the follow-up period. Therefore, it is likely that these families would need continuous reinforcement for maintaining the intended behavior.

Study Limitations and Strengths

When evaluating the contributions of this study, there are several aspects that should be considered. The Family Physical Activity Environment (FPAE) questionnaire used in the present study has been validated (Cleland et al., 2011) but not in the country where the present study was conducted. However, we performed careful translation into the local language and suitability testing for the local culture and the translated questionnaire was found to have an acceptable internal consistency. Second, the intervention efficacy analyses were hindered by the small number of participants in the tertiles of lowest and highest initial parental support. Therefore, the results of the present study should be confirmed by larger and fully powered interventions. Third,

the findings of the study should be generalized to the population with care, because the families randomized in this study represented mainly highly educated families. Regardless, it is important to note that the intervention efficacy was seen in the children with the lowest initial parental support. It can therefore be assumed that the intervention strategies used could be transferred to the families of children with lower parental support regardless of socioeconomic status but further examination would be needed.

The strength of the present study was accelerometer-derived PA assessment in children, which enables objective assessment of the changes in habitual PA. Moreover, a study design with a six-month reinforced intervention period followed by a six-month follow-up period was sufficient to enable observations in changes of long-term behavior. This element of the design is important because the focus in lifestyle interventions should be primarily on long-term behavior changes, which may take a long time to realize.

What Does This Article Add?

Family involvement has been proposed to be a primary component when intervening with children's PA (Brown et al., 2016; O'Connor et al., 2009; van Sluijs et al., 2011). However, family-based PA interventions have not been successful in increasing objectively measured PA in children (Metcalf et al., 2012), suggesting that more research is needed on how to successfully involve families in PA interventions with children. Parental support has been found to be a consistent correlate of children's PA, and the present study showed that individually tailored counseling for parents led to positive short-term changes in parental support and objectively measured PA in children aged 4 to 7 years who had the lowest parental support level initially. Therefore, identifying and counseling parents who provide their children with low support could be an efficacious way to enhance PA in children at least in the short-term. On the other hand,

family-based PA interventions may not positively affect PA in children with a high initial level of parental support.

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Table 1. Background characteristics of the study participants for analysis.

	All		*Lowest parental support tertile*		*Highest parental support tertile*	
	Means ± SD (range)		*Means ± SD (range)*		*Means ± SD (range)*	
Variables	*Intervention*	*Control*	*Intervention*	*Control*	*Intervention*	*Control*
Children (*n*)	44	47	15	16	16	14
Girls (*n*)	21	26	8	10	8	7
Age (years)	6.09 ± 1.17 (3.71)	6.12 ± 1.11 (3.48)	**6.53 ± 1.26 (3.59)#**	**6.36 ± 1.19 (3.48)#**	5.89 ± 1.18 (3.42)	6.14 ± 1.18 (3.42)
Height (cm)	112.21 ± 8.71 (34.1)	113.91 ± 7.79 (28.4)	117.14 ± 8.22 (18.1)	114.26 ± 7.75 (20.1)	110.94 ± 7.52 (25.6)	111.1 ± 5.36 (16)
Weight (kg)	20.08 ± 3.47 (14.8)	20.31 ± 3.16 (10.2)	20.95 ± 4.24 (11.2)	20.13 ± 3.62 (10.2)	19.73 ± 3.15 (10)	19.73 ± 2.48 (7)
BMI	15.88 ± 1.2 (4.35)	15.6 ± 1.16 (3.9)	15.17 ± 1.48 (4.35)	15.32 ± 1.3 (3.9)	15.96 ± 1.06 (2.92)	15.95 ± 1.12 (2.5)
Participates to organized PA (%)	60.5	65.2	53.3	68.8	62.5	84.6
Parents involved in the study (*n*)	61	63	19	21	23	17
Mother (*n*)	38	33	13	12	15	8
Age	**34.9 ± 4.11 (20)***	38.82 ± 5.61 (19)	35.77 ± 5.56 (20)	39.92 ± 5.52 (19)	33.67 ± 2.42 (9)	39.5 ± 5.76 (17)
Higher level education (%)	82	72	80	81.3	75	57.1
Single parent (*n*)	1	3	0	1	1	1
Father (*n*)	23	30	6	9	8	9
Age	37.22 ± 5.16 (23)	39.64 ± 5.36 (20)	39.84 ± 7.63 (21)	41 ± 4.28 (15)	35.63 ± 4.41 (11)	41.45 ± 6.31 (16)
Higher level education (%)	55	66	33.3	62.5	56.3	57.1
Single parent (*n*)	0	0	0	0	0	0
Parental support on PA						

Answerer sex female (%)	72.7	53.2	80	62.5	75	57.1
Father participates in PA with a child	3.48 ± 1.21 (5)	3.11 ± 1.05 (5)	2.53 ± 0.64 (2)	2.63 ± 0.81 (3)	4.25 ± 1.13 (3)	3.86 ± 1.24 (4)
Mother participates in PA with a child	**3.64 ± 1.13 (4)***	3.13 ± 0.88 (4)	2.93 ± 0.46 (2)	2.63 ± 0.62 (2)	4.25 ± 1.24 (4)	3.64 ± 1.09 (4)
PA together as a family	3.61 ± 1.13 (4)	3.38 ± 1.08 (4)	2.87 ± 0.64 (2)	2.56 ± 0.52 (1)	4.63 ± 1.03 (3)	4.36 ± 0.93 (3)
Father provides support for PA	3.27 ± 1.09 (5)	3.23 ± 1.22 (5)	2.4 ± 0.64 (2)	2.69 ± 0.8 (3)	4.06 ± 1.13 (3)	4.43 ± 1.35 (5)
Mother provides support for PA	3.23 ± 1.06 (5)	3.3 ± 1.02 (5)	2.47 ± 0.75 (3)	2.75 ± 0.69 (3)	3.75 ± 1 (4)	4.14 ± 1.17 (4)
Father praises for PA	3.95 ± 1.38 (4)	3.72 ± 1.38 (5)	2.87 ± 0.75 (2)	2.81 ± 0.75 (3)	5.25 ± 1.19 (3)	5.07 ± 1.15 (4)
Mother praises for PA	4.23 ± 1.2 (4)	4.04 ± 1.31 (4)	3.33 ± 0.62 (2)	3.13 ± 0.81 (3)	5.37 ± 0.89 (3)	5.43 ± 0.76 (2)
Mean of parental support	3.63 ± 0.82 (3.58)	3.42 ± 0.82 (3.29)	2.78 ± 0.33 (1)	2.75 ± 0.38 (1.29)	4.51 ± 0.47 (1.72)	4.42 ± 0.56 (1.58)

Note. Data are presented as mean ± SD and range (in parentheses) from baseline measurements, except height, weight and BMI (kg/m2) for children, which are presented from midline measurements. Scale for parental support on PA is 1 to 6.

Statistically significant differences at the level of $p < .05$ between intervention and control groups (*) and between sexes (#). Statistically significant values are shown in bold.

Table 2. Changes in parental support and mean level of physical activity within and between intervention and control support tertiles.

		Unadjusted mean (SD)		*p-value*	*MODEL 1*	*p-value*	*MODEL 2*	*p-value*
					Adjusted change between groups		*Adjusted change between groups*	
					(95% CI)		*(95% CI)*	
Outcome	*Time (months)*	*Intervention*	*Control*					
Parental support								
All	0	3.63 (0.82)	3.42 (0.81)					
	6	3.46 (0.61)	3.31 (0.83)	.102	0.07 (-0.19 to 0.32)	.612	0.04 (-0.23 to 0.32)	.751
	12	3.45 (0.70)	3.21 (0.80)	.915	0.10 (-0.23 to 0.44)	.543	0.08 (-0.26 to 0.43)	.635
Lowest parental support tertile	0	2.77 (0.33)	2.74 (0.37)					
	6	**3.04 (0.41)|ǂǂ**	2.90 (0.75)	.411	0.23 (-0.08 to 0.55)	.146	0.28 (-0.06 to 0.62)	.107
	12	2.95 (0.38)	2.78 (0.77)	.871	0.11 (-0.30 to 0.53)	.581	0.56 (-0.37 to 0.48)	.796
Highest parental support tertile	0	4.51 (0.46)	4.42 (0.55)					
	6	**3.92 (0.56)|ǂǂ**	4.20 (0.55)	.244	-0.22 (-0.80 to 0.36)	.450	-0.29 (-0.98 to 0.40)	.400
	12	**3.96 (0.74)|ǂ**	**3.68 (0.71)|ǂǂ**	.623	0.22 (-0.39 to 0.82)	.475	0.20 (-0.45 to 0.86)	.541
Mean level of physical activity								
All	0	590.93 (217.24)	519.82 (134.27)					
	6	645.81 (252.31)	538.59 (158.91)	.510	62.91 (-170 to 44.89)	.363	49.01 (-71.65 to 169.68)	.976
	12	557.66 (156.19)	561.10 (176.41)	.165	-69.67 (-185.66 to 46.33)	.158	-32.88 (-160.94 to 95.19)	.092
Lowest parental support tertile	0	515.81 (155.68)	531.82 (151.49)					
	6	**666.49 (310.57)|ǂǂ**	528.85 (199.35)	**.030**	157.27 (-18.0 to 332.54)	.091	**173.24 (16.18 to 330.31)**	**.031**
	12	531.84 (133.21)	521.36 (146.08)	.856	-2.25 (-211.78 to 207.28)	.969	-3.22 (-212.63 to 206.18)	.824

Highest parental support tertile	0	577.43 (132.58)	543.59 (135.62)					
	6	614.93 (238.31)	592.52 (99.67)	.939	-92.12 (-231.77 to 47.54)	.077	-57.39 (-220.52 to 105.74)	.415
	12	560.69 (162.40)	**638.91 (190.21) ł**	.198	-65.02 (-207.30 to 77.263)	.145	-65.44 (-223.92 to 93.03)	.144

Note. Mean level of physical activity = mean accelerometer counts per minute at leisure time. 0 months = baseline.

| Within group change from baseline statistically significant at the level of $p < .05$ (unadjusted model).

ł Within group change from baseline statistically significant at the level of $p < .05$ (model 1).

ǂ Within group change from baseline statistically significant at the level of $p < .05$ (model 2).

Statistically significant values are shown in bold.

Table 3. Changes in daily minutes spent at different physical activity intensities within and between intervention and control support tertiles.

		Unadjusted mean (SD)		*p-value*	*MODEL 1*	*p-value*	*MODEL 2*	*p-value*
					Adjusted change between groups		*Adjusted change between groups*	
					(95% CI)		*(95% CI)*	
Outcome	*Time (months)*	*Intervention*	*Control*					
Sedentary								
All	0	414.64 (71.83)	428.63 (61.77)					
	6	407.84 (75.44)	419.06 (60.03)	.721	0.94 (-29.41 to 31.30)	.951	4.84 (-27.53 to 37.20)	.768
	12	398.65 (67.11)	412.42 (67.02)	.871	-0.84 (-37.82 to 36.15)	.964	1.96 (-36.11 to 40.02)	.919
Lowest parental support tertile	0	440.30 (55.05)	439.52 (74.63)					
	6	423.40 (64.98)	440.46 (54.45)	.405	-14.71 (-62.44 to 33.02)	.537	-22.21 (-72.91 to 28.49)	.381
	12	419.28 (61.53)	425.15 (64.26)	.792	-7.35 (-69.80 to 55.10)	.815	-3.06 (-68.08 to 61.96)	.925
Highest parental support tertile	0	385.36 (63.63)	407.95 (64.77)					
	6	412.44 (86.18)	375.64 (58.31)	.097	53.45 (-10.71 to 117.61)	.100	**79.80 (6.39 to 153.20)**	**.034**
	12	379.13 (69.53)	395.51 (58.10)	.889	1.73 (-64.04 to 67.51)	.958	5.90 (-63.90 to 75.69)	.866
Light								
All	0	24.28 (9.67)	23.50 (8.72)					
	6	24.92 (10.44)	23.38 (8.62)	.753	-1.81 (-5.77 to 2.14)	.366	-0.64 (-4.90 to 3.62)	.766
	12	25.57 (10.25)	23.60 (7.89)	.684	1.49 (-3.32 to 6.31)	.541	0.90 (-4.04 to 5.84)	.719
Lowest parental support tertile	0	25.13 (12.49)	25.23 (11.78)					
	6	27.24 (14.19)	22.74 (10.29)	.105	4.43 (-1.55 to 10.41)	.142	5.82 (-0.36 to 12.00)	.064
	12	28.53 (10.28)	24.47 (9.92)	.362	4.30 (-3.94 to 12.53)	.300	3.53 (-4.85 to 11.91)	.402

Highest parental support tertile	0	22.28 (7.04)	24.87 (7.17)					
	6	23.33 (8.50)	25.74 (7.46)	.941	-2.79 (-10.66 to 5.07)	.477	-1.26 (-10.43 to 7.92)	.784
	12	34.41 (10.77)	26.42 (7.62)	.899	-1.33 (-8.96 to 6.29)	.728	-2.38 (-10.47 to 5.70)	.557
MVPA								
All	0	30.32 (15.57)	25.74 (12.53)					
	6	33.69 (20.49)	27.91 (17.84)	.782	-5.12 (-13.08 to 2.83)	.205	-1.81 (-10.07 to 6.46)	.666
	12	27.10 (13.12)	28.46 (13.68)	.167	-6.36 (-15.44 to 2.71)	.168	-7.52 (-16.66 to 1.62)	.106
Lowest parental support tertile	0	27.33 (13.69)	27.77 (14.58)					
	6	**39.02 (27.21)|ǂ‡**	30.56 (21.89)	.178	6.54 (-7.77 to 20.85)	.363	10.55 (-3.8 to 24.95)	.147
	12	27.54 (12.12)	25.24 (13.25)	.854	-0.35 (-17.99 to 17.29)	.969	-1.46 (-19.13 to 16.21)	.869
Highest parental support tertile	0	27.92 (10.73)	26.05 (14.22)					
	6	30.0 (16.18)	28.26 (9.72)	.912	-6.59 (-16.79 to 3.61)	.198	-3.14 (-15.53 to 9.25)	.610
	12	25.33 (12.71)	33.52 (14.97)	.131	-9.04 (-20.28 to 2.20)	.113	-10.31 (-22.39 to 1.78)	.093

Note. 0 months = baseline. MVPA = moderate to vigorous physical activity intensity.

| Within group change from baseline statistically significant at the level of $p < .05$ (unadjusted model).

ǂ Within group change from baseline statistically significant at the level of $p < .05$ (model 1).

‡ Within group change from baseline statistically significant at the level of $p < .05$ (model 2).

Statistically significant values are shown in bold.

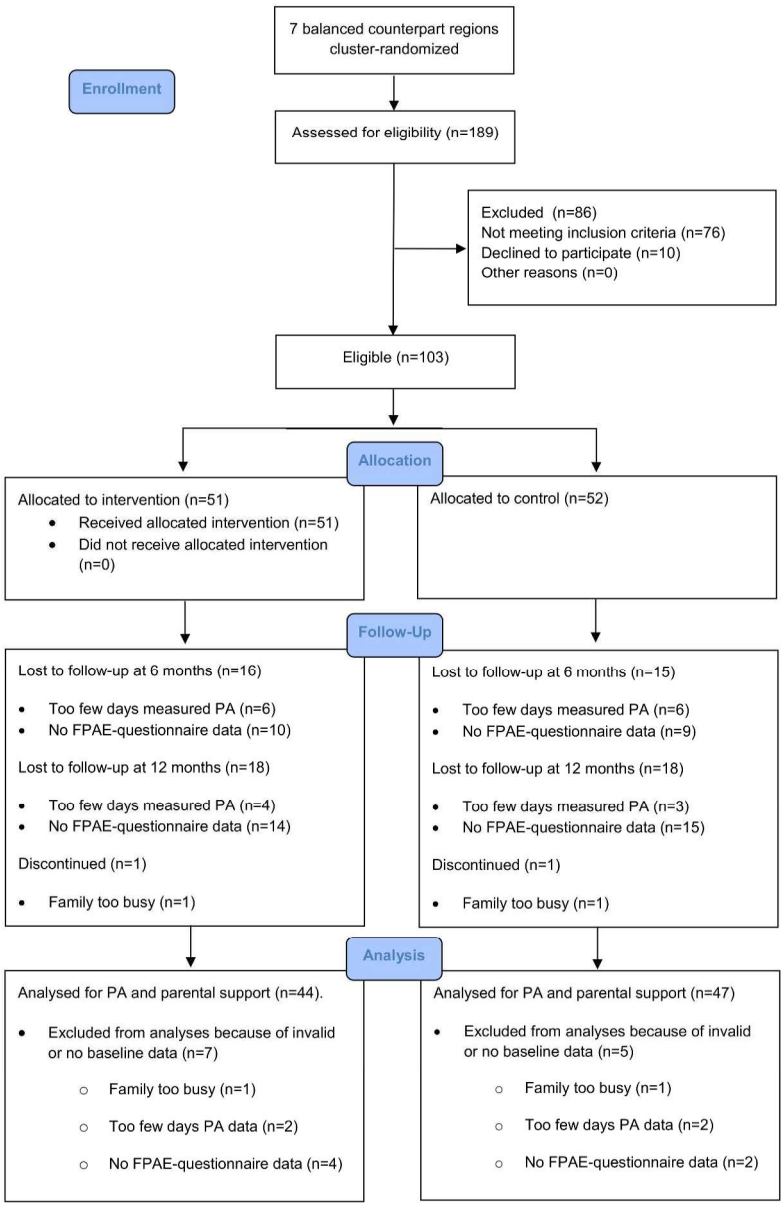

Figure 1. Flow of the study participants

250x385mm (600 x 600 DPI)