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Title

Efficacy of a free-play intervention to increase physical activity during childcare: a randomised controlled trial

Abstract

The primary aim of this study was to assess the efficacy of a childcare based intervention in increasing child physical activity by allowing children unrestricted access to outdoor areas for free-play when structured activity is not taking place. A randomised controlled trial was conducted in six childcare services. Intervention services provided children unrestricted access outdoors for active free-play, while control services provided their usual scheduled periods of outdoor play. Consent was obtained from 231 children. Child moderate to vigorous activity (MVPA), the primary trial outcome, was assessed via accelerometer at baseline and 3 months post baseline. Intervention effects were examined using Generalised Linear Mixed Models. Controlling for child age, gender and baseline outcome measure, at follow-up there were no significant differences between groups in minutes of MVPA in-care (mean difference: 4.85; 95% CI: -3.96, 13.66; $p=0.28$), proportion of wear time in-care spent in MVPA (mean difference: 1.52%; 95% CI: -0.50, 3.53; $p=0.14$) or total physical activity in-care (mean difference in counts per minute: 23.18; 95% CI -4.26, 50.61; $p=0.10$), nor on measures of child cognition ($p=0.45-0.91$). It was concluded that interventions addressing multiple aspects of the childcare and home environment might provide the greatest potential to improve child physical activity.

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Childcare services

Preschool

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Intervention

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Introduction

In young children, adequate physical activity has been shown to be associated with healthy weight, bone and skeletal health, motor skill development and improved psychosocial wellbeing [1, 2]. Research also suggests that physical activity may improve child cognitive development. For example a recent study found preschool children that were adherent to the recommendations of the Australian 24-hour movement guidelines performed better on tests of emotional understanding [3]. As such, promoting physical activity in early childhood is recommended to support child health [4]. Centre-based childcare services have a particularly important role to play in providing opportunities for child activity, as in developed countries, childcare services provide access to a large proportion of this population for extended periods [5]. Furthermore, accreditation processes and best practice guidelines for the childcare sector recommend services create environments that are supportive of child physical activity [6].

Evidence for the effectiveness of interventions, which focus on building the capacity of childcare service staff to implement structured physical activities with children, is equivocal [7]. Modifying opportunities for children to engage in unstructured outdoor free-play, however, has been suggested as a promising opportunity to improve child physical activity [8]. In many childcare services, opportunities for children to engage in outdoor free-play is restricted to scheduled periods during the day [9]. A recent randomised trial found that increasing the number of scheduled periods children are allowed outdoors to play can significantly improve child moderate-to-vigorous physical activity (MVPA) while in care [10]. A likely explanation for these findings is provided by epidemiological studies demonstrating that children's activity during care is characterised by short, intense bouts of activity of between 3-15 minutes during the start of outdoor play periods [11-14].

Allowing children to move freely between indoor and outdoor areas of childcare may support them to more frequently use outdoor spaces and so benefit from more frequent bouts of physically active play. In Australia, such a model of childcare operation is consistent with

national quality standards for the sector that encourage childcare services to allow children flexible use of outdoor spaces when not undertaking a structured activity [6]. Despite this policy alignment and the potential to improve child physical activity, a recent systematic review identified no previous trials examining the impact of providing such access to outdoor environments for children [7].

In this context, the primary aim of this exploratory study was to assess the efficacy of a childcare based intervention in increasing child physical activity by allowing children access to outdoor areas for free-play when a structured activity is not taking place. The primary outcome of the trial was child MVPA while in care. Secondary outcomes included the proportion of time children spent in MVPA in care, total child physical activity in care, and child cognitive function.

Methods

The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (reference ACTRN12616001008415). Ethical approval to conduct the study was obtained from the Hunter New England (reference 15/11/18/4.03) and the University of Newcastle (reference H-2016-0088) Human Research Ethics Committees. The research is reported in accordance with the requirements of the CONSORT Statement for cluster trials [15].

Design and setting

An exploratory parallel arm, cluster randomised controlled trial was conducted in six centre-based childcare services in the Hunter region of New South Wales, Australia from August to December 2016.

Participant eligibility and recruitment procedures

Childcare services

To be eligible to participate in the trial, centre-based childcare services (defined as long day care services or preschools) were required to have an enrolment of at least 25 children aged between 3 to 6 years, be located within the Hunter region of New South Wales, Australia, and provide scheduled periods of outdoor play for children. Childcare services catering solely for special needs populations, or those participating in other physical activity interventions were excluded from participating in the trial. Service managers from a convenience sample of 73 childcare services across the study region were sent study information prior to telephone contact to assess eligibility and to invite study participation among eligible services. Recruitment continued until six eligible services consented to participate.

Children and parents

Informed parental consent was required for participation in the data collection component of the study. Children were eligible to participate if they were aged between three and six years and attended childcare between 9 am and 3 pm on one or more days per week. Children with an intellectual or physical impairment that may have impacted on their physical activity capacity or prevented them from complying with data collection protocols were excluded. Parents were invited to provide consent for: i) their child to wear an accelerometer on each day of attendance at childcare (from arrival to 3 pm) over one week (to assess the primary trial outcome) ; ii) their child to wear an additional accelerometer outside of care hours (e.g. at home) over one week (to assess if any increases in child activity at care were displaced during out of care hours); iii) their child to complete an assessment of cognitive function; and iv) their own participation in a computer-assisted telephone interview.

Parents were recruited using evidenced-based strategies recommended to increase child research participation in education settings and previously applied in the childcare setting by the research team [16-19]. Specifically, i) study information and consent forms, including institutional logos and a contact number for more information, were distributed to parents via the childcare service; ii) recruitment packs were also handed directly to parents during child

drop off or pick up from the services during which time research staff could respond to questions or concerns regarding participation; iii) reminder letters were sent to parents approximately 1-2 weeks after initial information packs were distributed; and iv) study co-ordinator was employed to monitor recruitment rates and oversee recruitment strategies.

Randomisation and allocation

Following the completion of baseline data collection, childcare services were randomly allocated via a block randomisation procedure to either the intervention or control condition by an independent statistician using a random number function in a 1:1 (intervention: control) ratio. Randomisation of services was stratified by the socioeconomic status of the area where the service was located based on evidence of an association between service locality and service physical activity policies and practices [20]. Services were not blind to study allocation.

Intervention group

Within a six-hour day (9 am-3 pm), intervention services provided unrestricted access to outdoor areas of the service, to allow children the opportunity to engage in active free-play. The only time when an opportunity for outdoor free-play was not available for children was when structured indoor or outdoor activities were scheduled (for example, structured physical activity, circle time, meal time, rest time or indoor-seated learning activity time). At all other times, children were free to move between indoors and outdoors areas as they wished. All other service activities remained unchanged. Intervention services were provided with access to an early childhood education specialist if they required support or advice to make changes to their operations to implement the intervention and were visited prior to the day of data collection to ensure that the intervention had been implemented.

Control group

Participating services randomised to the control group continued with their usual scheduled periods of outdoor free-play for children.

Data collection and measures

Baseline data collection occurred between August and September 2016. Follow-up data collection occurred approximately three months post-baseline between November and December 2016.

Service characteristics

At baseline, a telephone interview was conducted with participating service managers to assess: service days and hours of operation; type of service (pre-school or long day care service); postcode; number of three to six year old children enrolled; and years the service had been in operation. The items used to assess service characteristics have been used in other Australian surveys of childcare services conducted by the research team [21, 22] and are intended to provide contextual information to assess the external validity of the study findings.

Child and parent characteristics

At baseline, parents provided information on their child's age, sex, residential postcode, and usual number of days per week attending childcare on the child consent form. Consenting parents also completed a computer-assisted telephone interview to collect parent demographic information using items from the New South Wales Population Health Survey [23]. Such data were used to describe the trial sample, and undertake sub-group analyses.

Primary trial outcome: Minutes of MVPA in care

The primary trial outcome was the number of minutes children spent in MVPA from the time that children arrived at care until 3 pm across one week (five days). MVPA was assessed using Actigraph GT3X+ accelerometers using recommended cut-points [24] and used data for each day a child attended care (ranging from one to five days). Accelerometers were worn by the children during the core hours of service operation (from arrival through to 3 pm).

Accelerometer data were collected every day for one week (five days in total) of the data collection period at baseline and follow-up. Two trained data collectors attended services to fit and collect accelerometers. Accelerometers were placed above the iliac crest at the hip of each child using an elasticised band and were fitted as they arrived at the childcare service, and removed at 3 pm (or earlier if the child departed the service). Assenting children wore an accelerometer each day (up to five days) that they attended at childcare. While not a trial outcome, for descriptive purposes, among all parents consenting for their children to wear a second accelerometer at home, physical activity outside of care was assessed to examine any potential compensatory intervention effects in children's physical activity period on the days that children attended care. These children had their 'in care' accelerometer removed at 3 pm on each day of attendance (or earlier if they departed the service for the day), but continued to wear the 'out of care' accelerometer.

Secondary trial outcomes

Proportion of time spent in MVPA in care (% MVPA)

The proportion of time children spent in MVPA in care was assessed, adjusted for wear time.

Total child activity in care (counts per minute)

Total child activity in care, assessed via counts per minute collected in 5-second epochs [25] was also included as a secondary outcome. Counts per minute were calculated from the total activity counts recorded divided by the total time the accelerometer was worn.

Other physical activity measures

Total minutes of physical activity in care; total minutes engaged in activity at various intensities (vigorous, moderate, light activity) as well as time spent sedentary were also assessed. Cut points described by Pate [24] were used to classify physical activity intensities and periods of sedentary behaviour. These measures were included for descriptive purposes, are not trial outcomes, and were not prospectively registered.

Child cognitive function

Child cognitive function was measured using three tests from the validated Early Years Toolbox that uses games to assess inhibition, visual-spatial working memory, and cognitive flexibility/shifting [26]. The tests were delivered via iPad-based games with built-in verbal instructions for children. Specifically the Early Years Toolbox 'Go/No-Go' task evaluated the ability to inhibit a dominant behavioural response in response to a less frequently presented 'no-go' stimulus; the 'Mr Ant' task assessed visual-spatial working memory, or the amount of visual information that concurrently can be activated in the mind; and a card sorting task was used to measure children's ability to disengage and re-direct attention. Data collectors administered the three tests to children once during their attendance at childcare on the days of field data collection. Data collectors ensured that the child understood the instructions for each test and gave clarification where needed. Tests were conducted in a quiet private location.

Service free-play schedule and physical activity policies, practices and environment

At baseline and follow-up, observations at childcare services were conducted by trained data collectors (not blind to group allocation) across one week (five days) to record the duration, timing and frequency of indoor and outdoor free-play, to i) assess the degree to which intervention and control services were implementing a free-play schedule that adhered to the study protocol; and ii) identify other changes in potential prognostic factors to aid interpretation of trial findings. Data collectors also gathered information regarding the childcare service physical activity policies, practices and environment using a modified version of the validated Environment and Policy Assessment and Observation instrument (EPAO) [27]. Information on minimum and maximum daily temperatures was obtained from the local meteorological bureau website [28] and daily UV index retrieved from the Australian Radiation Protection and Nuclear Safety Agency website [29]. Such factors have been associated with child physical activity in

care [30, 31] and have been included to aid the interpretation of trial findings and to provide contextual information to enable assessments of broader generalisability.

Statistical analyses

All statistical analyses were performed using SAS (version 9.3) statistical software. All statistical tests were two tailed with an alpha value of 0.05.

Descriptive statistics were used to describe the service, child, and parent characteristics of intervention and control group participants at baseline. Service socioeconomic characteristics were determined using service postcodes, which were classified as being in the top or bottom 50% of New South Wales according to the Socio-economic Indices for Areas (SEIFA) [32]. Geographic characteristics of the service locality were classified as either urban or rural according to the Australian Statistical Geography Standard [33].

Minutes of MVPA were determined using age-specific child-validated equations (cut points) [24]. Accelerometer data were cleaned using Meterplus software, with 20 minutes of consecutive zero minutes classified as non-wear time. The valid wear time for children when attending childcare was classified as at least 50% of wear time during the childcare day. Days classified as invalid were removed from the dataset.

Generalised Linear Mixed Models (GLMM), to take account of the clustering of individual children within services, were used under an intention to treat framework to test for a difference in mean minutes of MVPA between groups over time. The GLMM included terms for group (intervention or control), and the interaction of group and time, and controlled for child age and sex and baseline outcome value (for the primary outcome this was MVPA). The same approach was used to test for a difference between groups over time in the proportion of time children spent in MVPA in care (adjusted for wear time) and total child physical activity in care (assessed via counts per minute collected in 5 second epochs in care) and other child physical

activity measures. Analysis was performed using all available (complete case analysis) data as well as an analysis using multiple imputation for missing data. Multiple imputation was performed on missing values at either baseline or follow-up using the MI Procedure in SAS [34]. Any compensatory behaviour in activity occurring outside care changes between groups in mean minutes of MVPA was assessed using all available valid data. Subgroup analysis for the primary trial outcome was undertaken for age, sex, and baseline physical activity levels (classified as higher or lower based on the median MVPA value of children at baseline). Child cognitive function was also analysed using GLMM, adjusting the clustering of individual children within services, the baseline value of the outcome, and controlled for child age and sex.

Results

Sample

Figure 1 shows the participation of services, children, and parents throughout the trial. Six service managers consented for their service to participate in the study. Of the 350 eligible children, consent was obtained for: i) 231 (66.0%) to wear an accelerometer on each day of attendance at childcare; ii) 128 (36.6%) to wear an additional accelerometer outside of care hours; and iii) 231 (66.0%) to complete an assessment of cognitive function. Trial outcome data was not collected during periods of inclement weather. As such, data was collected for 14 of the 15 days planned (5 days per service) within control services and 14 of 15 days among intervention services at baseline. At follow-up data was collected for 14 of 15 days within control services and 13 of 15 days within intervention services. Of the 221 eligible parents, 165 (74.7%) provided consent to participate in the computer-assisted telephone interview. For the primary trial outcome (minutes of MVPA in care), 206 children (89.2%) provided valid accelerometer data at baseline and 174 (75.3%) at follow-up.

Service, child, and parent characteristics

For most characteristics, baseline service, child, and parent characteristics by intervention and control group were similar suggesting baseline equivalence was achieved via randomisation for most characteristics. All services were open five days, and five of the six services were located in urban localities. Only one service was located in a rural area, and was allocated to the intervention group. The proportion of boys in the sample ranged from 52-61% between intervention and control groups, the mean age ranged from 4.0 – 4.1 years, and body mass index ranged from 16.1 to 16.3. In both groups, 44% of children were meeting physical activity guideline recommendations at baseline. However, children in the intervention group appeared more likely to be from higher income households (68% versus 46%) and have a parent with a University qualification (43% versus 25%) (Table 1).

Primary trial outcome: Minutes spent in MVPA in care

Adjusted differences in changes over time in child physical activity outcomes between groups are shown in Table 2. In both groups, mean minutes of MVPA reduced over time from baseline to follow-up. Analyses utilising complete case showed a mean difference of MVPA in care of 5.63 minutes (95% CI -8.25, 19.52; $p=0.32$) between groups, an effect that was non-significant. Multiple imputation for missing data found that, controlling for child age, gender and baseline values of the outcome measure, child minutes of MVPA at follow-up also did not differ significantly between groups (mean difference: 4.85; 95% CI -3.96, 13.66; $p=0.28$; ICC 0.069).

Among children with valid accelerometer data during the out of care period, children attending intervention services had lower mean minutes of MVPA during the out-of-care period on childcare days than children attending control services (adjusted difference between groups - 3.72; 95% CI -18.82, 11.38; $p=0.53$); however this difference was non-significant.

There were no significant subgroup interactions for the primary trial outcome by child sex, or baseline physical activity levels (Table 3). For the age specific analyses, the difference was

significant for 3 year olds compared to 5 year olds (adjusted mean minutes between subgroups -14.96; 95% CI -29.9, 0.01; $p=0.05$).

Secondary trial outcomes

Proportion of time spent in MVPA in care and total child activity in care (counts per minute)

Controlling for child age, gender and baseline values of the outcome measure, at follow-up, there were no significant differences in between groups on any of the trial secondary outcomes assessed using complete case or multiple imputation analyses. There was a non-significant 1.52 percentage increase (95% CI -0.50, 3.53; $p=0.14$,) in the proportion of wear time in care spent in MVPA for children attending intervention relative to control services at follow-up in multiple imputation analyses (Table 2). Similarly, measures of total physical activity (counts per minute) in care was also higher among children attending intervention relative to control services (mean difference in counts per minute: 23.18; 95% CI -4.26, 50.61; $p=0.10$) at follow-up in multiple imputation analyses, however the difference was not significant.

Other outcome measures

Controlling for baseline measure, child age, and gender there were no significant differences in change over time between groups at follow-up in the mean minutes children spent in care in vigorous, moderate, or light activity, or the time they spent sedentary (Table 2). In both groups, however, such measures of physical activity tended to decrease over time while sedentary time increased slightly between baseline and follow-up.

Child cognitive function

Controlling for child age, gender and baseline values of the outcome measure, there were no significant differences between groups at follow-up in any measure of child cognition including inhibition, visual spatial working memory and cognitive flexibility/shifting ($p=0.45-0.91$) (Table 4).

Service free-play schedule and physical activity policies, practices and environment

Overall, change over time in most measures of childcare physical activity policy, practice and environments were similar across both intervention and control groups during the study period. There were reductions in the mean number of times per day staff prompted to initiate child activity, (baseline: 7.3; follow-up 3.0) and provided positive statements about physical activity (baseline 8.0; follow-up 2.0) in the intervention group while the control group remained stable on these measures between baseline and follow-up (Table 5). Mean minutes of television viewing also increased in the intervention group (baseline 0.30; follow-up 10.56) and increased slightly in the control (baseline 0.17; follow-up 3.47).

Discussion

This is the first randomised trial to examine the impact on child physical activity of childcare service scheduling that allows children unrestricted access to outdoor areas across the day for free-play when structured activities are not taking place. The trial did not find statistically significant changes between groups in child MVPA levels or other secondary trial outcomes following the intervention. The findings suggest that additional intervention strategies may be required to achieve significant improvements in children's physical activity in this setting.

While non-significant, the effect size of the intervention in this study (approximately 5 minutes of MVPA over 6 hours) appeared lower than reported in the SPACE randomised trial where child MVPA improved by 1.28 minutes/hour following an eight week intervention incorporating the provision of four 30 minute opportunities for children to engage in outdoor free-play, portable play equipment and staff training in physical activity promotion [10]. Simply allowing children unrestricted access to either indoor or outdoor areas may not encourage active outdoor play among children who prefer indoor activities. If that is the case, having repeated set periods of outdoor free-play may be more efficacious in supporting MVPA by ensuring all

children are regularly exposed to outdoor space for activity play. Nonetheless, more comprehensive interventions in childcare that combine structured interventions with modifications to child opportunities to engage in free-play or that also target other environments influential to child activity, such as the home, may be required to achieve large shifts in population physical activity levels.

An alternative explanation for the findings is that a change in outdoor play opportunities may have adversely modified staff behaviours. Process data, for example, suggested that there were reductions in educator prompts and positive statements about child physical activity in the intervention group at follow-up compared with baseline, while such staff actions appeared relatively stable in the control group. As childcare service staff consistently report a lack of time and competing service priorities as barriers to engaging children in physical activity [35] such data may suggest that without set periods for outdoor free play programmed throughout the day, staff attention may be drawn from a focus on child physical activity during that time to other roles or responsibilities. As prompts and positive statements have been positively associated with child activity in childcare [36, 37], their relative reduction within interventions services may have reduced the potential impact of the intervention. Future studies should implement strategies such as the use of environmental stimuli and reminders for staff to facilitate child activity to mitigate this risk.

A number of studies have reported an association between child physical activity and cognitive function [3, 38, 39]. The findings of this trial found no meaningful between group differences on measures of child cognition. The intervention, however, did not significantly improve child activity, the hypothesised mechanism by which cognitive improvements would be facilitated. The brevity of the intervention period in the current study is also unlikely to have provided sufficient latency for physical activity mediated changes in child cognition. On measures of MVPA, the primary trial outcome, the study found some indication that the intervention may have a differential impact by subgroups including child age and sex. Previous research [40]

suggests that opportunity for outdoor play is particularly influential on the physical activity of boys [41-43], and on older children [37, 44, 45], and effect, which is suggested (although not significant for sex) by the magnitude of the non-significant subgroup interactions reported in this study. Future research to identify strategies that do not exacerbate physical activity differences between these groups in childcare are required.

The trial methods employed were rigorous, and included random assignment, the use of objective measures of physical activity outcomes in care, the inclusion of measures of physical activity outside of care to enable an assessment of any potential compensatory changes in physical activity occurring during this period, as well as prospective trial registration. Nonetheless, the trial findings need to be considered in the context of a number of limitations. Most importantly, the trial was an exploratory study and was not adequately powered to detect clinically meaningful changes in the primary trial outcome. Post hoc power analysis suggests that, with the same intra-class correlation (0.069), a standard deviation of 21 min/day, and an average of 34.33 children per service, a sample size of 22 services per group (1510 children in total) would have been required for the effect size found in this study (5.6 minutes) to reach statistical significance, with 80% power and alpha of 0.05. The study effect sizes, intra-class correlation, and retention rates provide important information for trialists to use to adequately power future trials examining similar interventions. The low participation rate also suggests that future studies employ more rigorous recruitment strategies to improve study participation and external validity of trial findings. The study was also conducted over a short time period in one region of Australia, which introduced seasonal differences in the baseline, and follow-up periods. The within group reductions in physical activity and the small increases in sedentary time observed in both groups over time is likely the result of follow-up data collection occurring during the summer months where hotter ambient temperatures may hinder physically active play. Future studies conducted in different jurisdictions, with different climates and operational contexts, and which track child activity over extended periods of

follow-up to assess longer-term effects would also address important evidence gaps not dealt with in this study.

Conclusion

Improving child physical activity through childcare setting-based interventions has proven a considerable challenge to-date. Changing the childcare operational procedures and scheduling to allow children unrestricted access to outdoor areas to engage in free-play did not significantly improve child physical activity during care in this trial. Comprehensive interventions that address multiple aspects of the childcare and home environment may provide the greatest potential to improve child physical activity in this setting.

References

1. Timmons, B.W., et al., *Systematic review of physical activity and health in the early years (aged 0-4 years)*. Appl Physiol Nutr Metab, 2012. **37**(4): p. 773-92.
2. Carson, V., et al., *Systematic review of the relationships between physical activity and health indicators in the early years (0-4 years)*. BMC Public Health, 2017. **17**(S5).
3. Cliff, D.P., et al., *Adherence to 24-Hour Movement Guidelines for the Early Years and associations with social-cognitive development among Australian preschool children*. BMC Public Health, 2017. **17**(Suppl 5): p. 857.
4. World Health Organization, *Consideration of the evidence on childhood obesity for the Commission on Ending Childhood Obesity: Report of the ad hoc working group on science and evidence for ending childhood obesity*. 2016: Geneva, Switzerland.
5. OECD, *Starting Strong 2017 Key OECD Indicators On early childhood education and care*. 2017: Paris.
6. ACECQA, *Guide to the National Quality Standard*. 2017: Sydney, NSW.
7. Finch, M., et al., *Effectiveness of centre-based childcare interventions in increasing child physical activity: a systematic review and meta-analysis for policymakers and practitioners*. Obes Rev, 2016. **17**(5): p. 412-28.
8. Ward, D., et al., *Interventions for increasing physical activity at child care*. Medicine & Science in Sports & Exercise, 2010. **42**(3): p. 526-34.
9. Tandon, P.S., B.E. Saelens, and D.A. Christakis, *Active Play Opportunities at Child Care*. Pediatrics, 2015. **135**(6): p. e1425-e1431.
10. Tucker, P., et al., *Impact of the Supporting Physical Activity in the Childcare Environment (SPACE) intervention on preschoolers' physical activity levels and sedentary time: a single-blind cluster randomized controlled trial*. Int J Behav Nutr Phys Act, 2017. **14**(1): p. 120.
11. Pate, R.R., et al., *Physical activity in preschool children with the transition to outdoors*. J Phys Act Health, 2013. **10**(2): p. 170-5.
12. Pate, R.R., et al., *Directly observed physical activity levels in preschool children*. J Sch Health, 2008. **78**(8): p. 438-44.

13. Timmons, B., P. Naylor, and K. Pfeiffer, *Physical activity for preschool children-how much and how?* Applied Physiology, Nutrition and Metabolism, 2007. **32**(Supplement. 2).
14. Verbestel, V., et al., *Within- and between-day variability of objectively measured physical activity in preschoolers.* *Pediatr Exerc Sci*, 2011. **23**(3): p. 366-78.
15. Campbell, M.K., et al., *Consort 2010 statement: extension to cluster randomised trials.* *BMJ*, 2012. **345**: p. e5661.
16. Wolfenden, L., et al., *Obtaining active parental consent for school-based research: a guide for researchers.* *Aust N Z J Public Health*, 2009. **33**(3): p. 270-5.
17. Wolfenden, L., et al., *Randomized controlled trial of a telephone-based intervention for child fruit and vegetable intake: long-term follow-up.* *Am J Clin Nutr*, 2014. **99**(3): p. 543-50.
18. Wyse, R., et al., *A cluster randomized controlled trial of a telephone-based parent intervention to increase preschoolers' fruit and vegetable consumption.* *Am J Clin Nutr*, 2012. **96**(1): p. 102-10.
19. Finch, M., et al., *A cluster randomized trial of a multi-level intervention, delivered by service staff, to increase physical activity of children attending center-based childcare.* *Prev Med*, 2014. **58**: p. 9-16.
20. Wolfenden, L., et al., *Physical activity policies and practices of childcare centres in Australia.* *J Paediatr Child Health*, 2011. **47**(3): p. 73-6.
21. Finch, M., et al., *Impact of a population based intervention to increase the adoption of multiple physical activity practices in centre based childcare services: a quasi experimental, effectiveness study.* *Int J Behav Nutr Phys Act*, 2012. **9**(1): p. 101.
22. Jones, J., et al., *Dietary intake and physical activity levels of children attending Australian childcare services.* *Nutrition & Dietetics*, 2017. **74**(5): p. 446-453.
23. NSW Government. *NSW Population Health Survey 2014 - Questionnaire.* 21/01/2016]; Available from: <http://www.health.nsw.gov.au/surveys/child/Pages/default.aspx>.
24. Pate, R.R., et al., *Validation and calibration of an accelerometer in preschool children.* *Obesity (Silver Spring)*, 2006. **14**(11): p. 2000-6.
25. Vale, S., et al., *Preschool children physical activity measurement: importance of epoch length choice.* *Pediatr Exerc Sci*, 2009. **21**(4): p. 413-20.
26. Howard, S.J. and E. Melhuish, *An Early Years Toolbox for Assessing Early Executive Function, Language, Self-Regulation, and Social Development: Validity, Reliability, and Preliminary Norms.* *J Psychoeduc Assess*, 2017. **35**(3): p. 255-275.
27. Ward, D., et al., *An instrument to assess the obesogenic environment of child care centers.* *Am J Health Behav*, 2008. **32**(4): p. 380-6.
28. Bureau of Meteorology. *Latest Weather Observations for New South Wales.* 2016 12/12/2016]; Available from: <http://www.bom.gov.au/nsw/observations/nswall.shtml#HUN>.
29. Australian Radiation Protection and Nuclear Safety Agency. *Ultraviolet radiation index.* 2016 17/01/2017]; Available from: <https://www.arpsa.gov.au/services/monitoring/ultraviolet-radiation-monitoring/ultraviolet-radiation-index>.
30. Harrison, F., et al., *The changing relationship between rainfall and children's physical activity in spring and summer: a longitudinal study.* *Int J Behav Nutr Phys Act*, 2015. **12**: p. 41.
31. Boldemann C, et al., *Impact of preschool environment upon children's physical activity and sun exposure.* *Preventive Medicine*, 2006. **42**(4): p. 301-308.

32. ABS. 2033.0.55.001 - *Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2011* 2013 21/06/2017]; Available from: <http://www.abs.gov.au/ausstats/abs@.nsf/mf/2033.0.55.001>.
33. ABS. 1270.0.55.005 - *Australian Statistical Geography Standard (ASGS): Volume 5 - Remoteness Structure, July 2011* 2013 21/06/2017]; Available from: <http://www.abs.gov.au/ausstats/abs@.nsf/mf/1270.0.55.005?OpenDocument>.
34. White, I.R., et al., *Strategy for intention to treat analysis in randomised trials with missing outcome data*. *Bmj*, 2011. **342**: p. d40.
35. Hesketh, K.R., R. Lakshman, and E.M.F. van Sluijs, *Barriers and facilitators to young children's physical activity and sedentary behaviour: a systematic review and synthesis of qualitative literature*. *Obes Rev*, 2017. **18**(9): p. 987-1017.
36. Nicaise, V., D. Kahan, and J.F. Sallis, *Correlates of moderate-to-vigorous physical activity among preschoolers during unstructured outdoor play periods*. *Preventive Medicine*, 2011. **53**(4-5): p. 309-315.
37. Gubbels, J.S., et al., *Interaction between physical environment, social environment, and child characteristics in determining physical activity at child care*. *Health Psychology*, 2011. **30**(1): p. 84.
38. Palmer, K.K., M.W. Miller, and L.E. Robinson, *Acute exercise enhances preschoolers' ability to sustain attention*. *Journal of Sport and Exercise Psychology*, 2013. **35**(4): p. 433-437.
39. Becker, D.R., et al., *Physical Activity, Self-Regulation, and Early Academic Achievement in Preschool Children*. *Early Education and Development*, 2013. **25**(1): p. 56-70.
40. Tonge, K.L., R.A. Jones, and A.D. Okely, *Correlates of children's objectively measured physical activity and sedentary behavior in early childhood education and care services: A systematic review*. *Prev Med*, 2016. **89**: p. 129-39.
41. Stephens, R.L., et al., *Peer Reviewed: Relationship Between Child Care Centers' Compliance With Physical Activity Regulations and Children's Physical Activity, New York City, 2010*. *Preventing chronic disease*, 2014. **11**.
42. Pate, R.R., et al., *Physical activity in preschool children: comparison between Montessori and traditional preschools*. *Journal of School Health*, 2014. **84**(11): p. 716-721.
43. Van Cauwenberghe, E., et al., *Efficacy and feasibility of lowering playground density to promote physical activity and to discourage sedentary time during recess at preschool: A pilot study*. *Preventive Medicine*, 2012. **55**(4): p. 319-321.
44. Pagels, P., C. Boldemann, and A. Raustorp, *Comparison of pedometer and accelerometer measures of physical activity during preschool time on 3- to 5-year-old children*. *Acta Paediatr*, 2011. **100**(1): p. 116-20.
45. Grontved, A., et al., *Personal characteristics and demographic factors associated with objectively measured physical activity in children attending preschool*. *Pediatr Exerc Sci*, 2009. **21**(2): p. 209-19.

Table 1: Baseline child, parent, and service characteristics

	Intervention	Control
Child characteristics		
Number of children*	101	105
Boys (n, %)	54, 52.4%	65, 60.8%
Age of child (mean, SD years)	4.0, 0.7	4.1, 0.7
Days per week attending childcare (mean, SD)	2.50, 0.96	2.55, 1.05
Country of birth - Australia (n, %) **	58, 95.1%	61, 100%
BMI (kg/m ²)**	16.1, 2.3	16.3, 2.6
Parent characteristics		
Number of parents***	61	61
Mother (n, %)	49, 80.3%	52, 85.3%
Age 30-39 years (n, %)	31, 50.8%	40, 65.6%
University qualification (n, %)	26, 42.6%	15, 24.6%
Married or living in a relationship (n, %)	53, 86.9%	47, 78.3%
Household income >\$80,000 per year (n, %)	40, 67.8%	28, 45.9%
Country of birth – Australia (n, %)	52, 85.3%	56, 91.8%
Usual physical activity (n, % meeting national physical activity guidelines)	27, 44.3%	27, 44.3%
Service characteristics		
Number of services	3	3
Service operates 5 days per week (n, %)	3, 100%	3, 100%
Hours of operation (mean, SD)	9.8, 1.3	10.5, 1.3
Number of 3-6 year old children enrolled (mean, SD)	66.3, 1.5	60.7, 27.5
Type of service (n, %)		
Pre-school	2, 66.7%	1, 33.3%
Long day care service	1, 33.3%	2, 66.7%
Service geographical location (n, %)		
Urban	2, 66.7	3, 100
Rural	1, 33.3	0
Service socio-economic area (n, %)		
Top 50% of New South Wales	1, 33.3	1, 33.3
Bottom 50% of New South Wales	2, 66.7	2, 66.7

*All children who had valid in care accelerometer data at baseline

**Denominator is children who had valid in care accelerometer data at baseline and had a parent complete the baseline computer-assisted telephone interview

***Parents (only one) of children who had valid in care accelerometer data at baseline

Table 2: Changes in daily physical activity outcomes between groups from baseline to 3-month follow-up

	Intervention		Control		Intervention-Control Complete case		Intervention-Control Multiple imputation	
	Baseline n=101	Follow-up n=89	Baseline n=105	Follow-up n=97	Adjusted difference between groups (95% CI)	p-value	Adjusted difference between groups (95% CI)	p-value
Primary trial outcome								
Minutes of physical activity in care (mean, SD)								
Moderate-to-vigorous physical activity	62.23 (22.12)	58.34 (21.69)	53.14 (20.71)	47.32 (18.76)	5.64 (-8.25, 19.52)	0.32	4.85 (-3.96, 13.66)	0.28
Secondary trial outcomes								
Total minutes of physical activity in care (mean, SD)								
Total physical activity in care	123.52 (32.95)	117.87 (33.06)	109.39 (33.35)	99.99 (30.69)	10.16 (-11.98, 32.29)	0.27	8.58 (-5.60, 22.76)	0.24
Percentage of wear time in care spent in moderate-to-vigorous physical activity (% , SD)								
% moderate-to- vigorous physical activity	17.19 (5.63)	16.19 (5.59)	15.84 (5.17)	13.62 (4.67)	1.51 (-1.57, 4.60)	0.25	1.52 (-0.50, 3.53)	0.14
Counts per minute in care (mean, SD)								
Counts per minute	208.71 (67.42)	204.41 (68.27)	183.50 (68.46)	165.53 (59.82)	26.75 (-16.09, 69.59)	0.16	23.18 (-4.26, 50.61)	0.10
Other measures*								
Vigorous physical activity	23.96 (11.42)	22.76 (10.94)	19.65 (10.21)	17.62 (9.59)	2.56 (-4.18, 9.29)	0.35	2.30 (-1.94, 6.54)	0.29
Moderate physical activity	38.28 (11.86)	35.59 (11.63)	33.49 (11.65)	29.71 (10.01)	3.49 (-4.11, 11.09)	0.27	2.89 (-2.03, 7.82)	0.25
Light physical activity	61.29 (13.28)	59.52 (13.10)	56.25 (14.78)	52.66 (13.59)	5.01 (-3.84, 13.86)	0.19	4.21 (-1.71, 10.12)	0.16
Sedentary time	237.63 (40.56)	241.23 (40.98)	225.39 (50.18)	243.26 (41.57)	-4.66 (-24.95, 15.63)	0.56	-4.88 (-19.36, 9.59)	0.51

* Included for context only and are not prospectively registered trial outcomes

Table 3: Changes in physical activity between groups from baseline to 3-month follow-up by subgroup (age, sex, and baseline physical activity)

		Intervention		Control		Intervention-Control	
		Baseline n=101	Follow-up n=87	Baseline n=105	Follow-up n=93	Adjusted difference between groups (95% CI)	p-value
Minutes of moderate-to-vigorous physical activity in care (mean, SD)							
Age	3 years	55.87 (19.63)	50.66 (17.23)	44.08 (16.84)	50.59 (15.45)	-14.96 (-29.9, 0.01)	0.05
	4 years	64.30 (23.23)	62.07 (23.84)	54.89 (22.50)	46.33 (19.98)	3.12 (-9.32, 15.56)	0.58
	5 years*	64.57 (21.38)	56.02 (16.45)	58.48 (18.79)	46.66 (19.75)		
Sex	Males	70.81 (19.36)	67.27 (19.64)	59.75 (21.30)	51.71 (21.30)	5.93 (-6.82, 18.68)	0.27
	Females*	53.13 (21.37)	48.34 (19.56)	43.24 (15.31)	41.07 (12.10)		
Baseline physical activity	Higher	74.96 (15.29)	65.23 (20.02)	70.99 (14.44)	57.65 (21.15)	2.68 (-10.26, 15.61)	0.60
	Lower*	37.25 (10.13)	38.17 (12.18)	39.19 (9.40)	43.62 (20.94)		

*Denotes subgroup level used as a reference for the interaction estimate

Table 4: Changes in child cognitive function between groups from baseline to 3-month follow-up

	Intervention		Control		Intervention-Control	
	Baseline	Follow-up	Baseline	Follow-up	Adjusted difference between groups (95% CI)	p-value
Inhibition (mean, SD)	0.57 (0.20)	0.66 (0.22)	0.53 (0.22)	0.61 (0.21)	-0.02 (-0.22, 0.06)	0.45
Visual-spatial working memory (mean, SD)	1.68 (0.92)	1.82 (0.86)	1.57 (0.85)	1.76 (0.81)	-0.02 (-0.36, 0.33)	0.91
Cognitive flexibility/ shifting (mean, SD)	5.95 (3.61)	7.33 (3.25)	6.96 (2.95)	7.43 (3.29)	-0.26 (-1.68, 1.15)	0.63

Table 5: Changes in service free-play schedule and physical activity policies, practices and environment between groups from baseline to 3-month follow-up

		Intervention		Control	
		Baseline n=3	Follow-up n=3	Baseline n=3	Follow-up n=3
Staff delivery of structured physical activity	Total occasions (mean, SD)	1.1 (1.6)	0.88 (1.4)	1.2 (1.2)	1.32 (1.3)
	Total minutes (mean, SD)	24.38 (14.4)	23.43 (18.2)	17.36 (14.8)	19.77 (10.1)
Staff delivery of fundamental movement skill development activities	Total occasions (mean, SD)	1.0	0	1.0	0
	Total minutes (mean, SD)	9.0 (1.73)	0	7.3 (2.5)	0
Staff role modelling of physical activity and delivery of verbal prompts	Number of times staff participated in physical activity (mean, SD)	6.7 (1.2)	5.0 (1.4)	3.0	2.0
	Number of times staff prompted to initiate or increase physical activity (mean, SD)	7.3 (0.6)	3.0	2.7 (2.9)	2.50 (2.1)
	Number of times staff provided positive statements about physical activity (mean, SD)	8.0 (1.7)	2.0 (1.4)	2.7 (0.6)	3.0 (2.8)
Small screen recreation and sedentary time	Total minutes of television viewing (mean, SD)	0.30 (1.0)	10.56 (15.1)	0.17 (0.7)	3.47 (15.1)
	Services with any observed seated time exceeding 30 minutes (n, %)	14(7 3.7)	10 (58.8)	11 (61.1)	17 (89.5)
Physical activity equipment	Number of portable physical activity equipment items indoors (mean, SD)	0.67 (1.2)	1.33 (0.58)	1.67 (1.15)	3.00 (1.00)
	Number of portable physical activity equipment items outdoors (mean, SD)	9.00 (1.0)	9.00 (1.0)	8.67 (0.6)	9.33 (0.6)
Policy	Services with written physical activity policy (n, %)	1 (33.3)	2 (66.7)	2 (66.7)	2 (66.7)
Playground size	Outdoor playground size (metres squared, mean, SD)	522.91 (91.9)	501.58 (193.0)	399.90 (112.6)	398.54 (109.6)
Weather	Minimum temperature (degrees Celsius, mean, SD)	10.33 (3.2)	17.83 (2.7)	8.16 (3.5)	15.32 (2.4)
	Maximum temperature (degrees Celsius, mean, SD)	21.72 (3.1)	29.95 (4.4)	23.53 (1.8)	31.41 (4.9)

	UV index (mean, SD)	4.74 (0.9)	9.82 (0.9)	5.22 (0.9)	9.58 (0.6)
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