Title: A cluster randomized trial of a multi-level intervention, delivered by service staff, to increase physical activity of children attending center-based childcare.

Authors names and affiliations:

Meghan Finch ^{1,2§}, Philip J. Morgan³, Megan Freund^{1,2,4}, Jannah Jones¹, John Wiggers^{1, 2, 4}, Luke Wolfenden²

¹ Hunter New England Population Health, Newcastle, NSW, Australia.

² School of Medicine and Public Health University of Newcastle, Newcastle, NSW, Australia

³ School of Education, & Priority Research Center in Physical Activity and Nutrition, University of Newcastle, Newcastle, NSW, Australia

⁴ Hunter Medical Research Institute, Newcastle, NSW, Australia

[§]Corresponding author: Meghan Finch

Locked Bag 10, Wallsend NSW 2287, AUSTRALIA

Tel: +61 2 4924 6131 Fax: +61 2 4924 6215

Email: meghan.finch@hnehealth.nsw.gov.au

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1. Abstract

Objective

To evaluate the impact of a multi-level intervention on the physical activity levels of 3-5 year old children attending center-based childcare services.

Method

The trial was conducted in New South Wales Australia in 2010 in 20 centers with 459 children. The intervention, included: fundamental movement skill sessions; structured activities; staff role modelling; limiting small screen recreation and sedentary time; and an activity promoting physical environment. Control services continued with usual routines. Physical activity during care was assessed using pedometers at baseline and at six months after baseline. Intervention implementation was assessed via observation of staff physical activity practices and audits of service environment and policy.

Results

Mean step counts at baseline and follow-up were 17.20 (CI 15.94-18.46) and 16.12 (CI 14.86-17.30) in the intervention group and 13.78 (CI 12.76-14.80) and 13.87 (CI 12.57-15.17) in the control group (p=0.12). Intervention services showed significantly greater increases in the total minutes that teachers led structured activities, relative to control group services (p=0.02).

Conclusion

The intervention showed no significant effect on child step counts per minute despite increasing time that staff delivered structured activity which is likely to be attributable to difficulties experienced by service staff in delivering a number of intervention components.

2. Introduction

Adequate physical activity for preschool age children (age three to five), promotes bone health, is protective against obesity and contributes to social, psychological and fundamental motor skill development (Burgi F et al., 2011; Janz KF et al., 2010; McWilliams C et al., 2009; Metallinos-Katsaras et al., 2007; Oliver M et al., 2007; Reilly JJ et al., 2008; Ward D, 2010). The United States National Association for Sport and Physical Education have recommended that three to five year old children should engage in at least 60 minutes of structured physical activity per day (National Association for Sport and Physical Education, 2002). Australian physical activity recommendations advise that children aged three to five participate in a minimum of three hours of physical activity per day (Australian Government Department of Health and Ageing, 2010). Compared with these recommendations, research suggests that children are not adequately physically active (Colley R et al., 2013; Okely AD et al., 2009). For example a systematic review of 39 studies from seven countries (United States, Scotland, Finland, Australia, Chile, Estonia, Belgium) found that overall, only 54 percent of two to six year old children participated in moderate to vigorous physical activity for at least 60 minutes per day (Tucker P, 2008).

Center-based childcare services represent a unique opportunity to deliver interventions to increase young children's physical activity levels. They provide access to a significant proportion of the population under five years, often for prolonged periods (Story M et al., 2006). Research also suggests that young children are not sufficiently active during attendance at care (Boldemann C et al., 2006; Bower et al., 2008; Dowda M et al., 2009; Raustorp A et al., 2012). A number of service characteristics have been associated with increased child activity, providing a potential target for physical activity interventions. Specifically, delivery of structured physical activities (Bower et al., 2008; Ward D et al., 2010), fundamental movement skill programs (Cliff D et al., 2009; Williams H et al., 2008); limiting small screen recreation opportunities (Dowda M et al., 2009; Okely AD et al., 2008); staff involvement in, and verbal prompting of children's active play (Cashmore A and Jones S, 2008; Gubbels J et al., 2011); having a physical activity policy (Bower et al., 2008; Trost SG et al., 2010); and adequate availability of portable play equipment (Bower et al., 2008).

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Experimental research examining the effectiveness of such interventions, however, is limited (Ward D, 2010). Published systematic reviews (Kreichauf S et al., 2012; Trost SD, 2011; Ward D et al., 2010) together with more recent trials have identified just nine randomized controlled trials of physical activity interventions delivered in center-based childcare that have assessed physical activity using objective measures (Alhassan S et al., 2012; Alhassan S et al., 2007; Binkley T and Specker B, 2004; Cardon G et al., 2009; Eliakim A et al., 2007; Fitzgibbon ML et al., 2011; Jones RA et al., 2011; Reilly JJ et al., 2006; Trost SG et al., 2008). Interestingly, these trials have examined interventions targeting relatively few of the many center-based characteristics associated with increased child physical activity. Two of the nine trials assessed environmental interventions including the addition of outdoor free play time (Alhassan S et al., 2007) and the inclusion of portable equipment and playground markings (Cardon G et al., 2009). Both failed to demonstrate a significant effect on child physical activity. The remaining seven trials focused on increasing child participation in structured teacher led activities (such as group games, gross motor or fundamental movement skill development programs) (Alhassan S et al., 2012; Eliakim A et al., 2007; Fitzgibbon ML et al., 2011; Jones RA et al., 2011; Reilly JJ et al., 2006; Specker B and Binkley T, 2003; Trost SG et al., 2008) with four of these reporting a significant intervention effect (Eliakim A et al., 2007; Fitzgibbon ML et al., 2011; Specker B and Binkley T, 2003; Trost et al., 2008). A common feature of effective interventions was the frequency of structured activity provided to children, with three of the four providing such activities on a daily basis (Eliakim A et al., 2007; Specker B and Binkley T, 2003; Trost SG et al., 2008). In contrast, interventions providing structured activities less frequently (2-3 days per week) did not yield improvements to children's physical activity (Jones RA et al., 2011; Reilly JJ et al., 2006).

Interventions which are effective and can be implemented by existing childcare service staff, as opposed to external experts or additional staff, have particular public health appeal as they are not reliant on external staff or experts or constrained by additional costs associated with their employment. In this context, and given the limited scope of previous interventions we sought to evaluate the impact of a multi-level intervention, delivered by childcare service staff, on the physical activity levels of 3–5 year old children attending center-based childcare. We hypothesized that children in services assigned to the intervention group would exhibit higher

step counts per minute than children in services where usual care was provided. We also sought to measure intervention implementation, acceptability and any unintended adverse effects of the intervention on child injury.

3. Methods

Design and setting

A detailed protocol for the trial has been published elsewhere (Finch M et al., 2010). The cluster wait-list randomized controlled trial (see Figure 1) was conducted in a sample of eligible long day care center-based childcare services (providing care for a minimum of eight hours a day) in three local government areas of New South Wales (NSW), Australia from March to October 2010. All trial outcomes reported in this article were registered with the Australian New Zealand Clinical Trials Registry (ACTRN1261000087055). The study was approved by the Hunter New England Area Human Research Ethics Committee (approval No.06/07/26/4.04) and University of Newcastle Human Research Ethics Committee (approval No.20100038).

Participants and recruitment

Recruitment was conducted from January to February 2010.

Long day care services

To be eligible to participate in the trial, services were required to have at least 25 enrolled children aged between three and five years. A total of 70 childcare services in the study region served as the sampling frame.

Children

Children aged three to five years attending participating services were eligible for the study if they attended on the day of the week nominated by the Authorized Supervisor for baseline data collection.

Randomization and allocation

After the completion of service recruitment, a statistician not associated with the project allocated services to either the intervention or control condition using block randomization performed in a

1:1 ratio in randomly sequenced blocks of two, four or six by a computerized random number function in Microsoft Excel. Randomization of long day care services was stratified by socioeconomic status based on evidence of an association with service adoption of physical activity promoting practices (Wolfenden L et al., 2010), with such status being determined by the postcode in which the service was located (Australian Bureau of Statistics, 2008). Services were informed of group allocation via a letter after baseline data collection.

Intervention

The multi-level intervention, designed using social ecological models of health behaviour Change (Stokol, 1992) aimed to influence children's physical activity behaviour through the manipulation of mediators across the social, physical and organisational environment of the childcare services (Stokols D, 1996; Trost SG et al., 2010). Specifically the intervention targeted staff instructional practices and interactions with children (social), service physical activity policy and programming (organisational) and the characteristics and equipment available within play space (physical environment). The social ecological framework has been identified as a suitable conceptual model for the design of physical activity interventions (King AC et al., 2002) and has been applied when describing correlates of children's physical activity behaviours (Okely AD et al., 2008; Sallis JF et al., 1993). Furthermore, school-based interventions grounded in such social ecological theory have been found to be effective in increasing physical activity levels of children by altering instructional practices and the environment (Pate RP et al., 2005). The intervention was delivered over a four month period and comprised of the following components:

- 1. *Daily structured fundamental movement skill development sessions:* The 20 minute session included a warm up activity, an age and developmentally appropriate teacher led game focusing on one or more fundamental movement skill, and a cool down activity.
- 2. Increased opportunities each day for children to participate in physical activity: Service staff were asked to, over the course of the usual day, program and opportunistically initiate physically active structured teacher led activities such as movement based group or circle time (where children participate in dance and group active games) and modifying planned activities to incorporate active movement such as during transitions between routine activities (e.g. children performing a locomotor skill on their way to lunch).

- 3. *Staff role modeling of active play and delivery of instructional practices:* All staff were asked to participate with children during active child initiated free play (role modeling) and provide verbal guidance (prompts to extend active play) and encouragement (positive statements about children's activity) during each free-play period.
- 4. *Limiting children's small screen recreation and sedentary time:* Staff were asked to limit the amount of time children spent watching or using electronic media whilst at the service and limit time children spent sitting still to periods of less than 30 minutes at a time (except when eating meals or sleeping).
- 5. Providing children with a physical activity promoting indoor and outdoor physical environment: Services were asked to make more readily available their existing activity promoting resources and portable equipment to children in indoor and outdoor areas (for example ball and batting play equipment, skipping roles, hula hoops, tumbling mats, twirling play equipment and climbing frames). Services were also encouraged to include, photos, books and posters promoting physical activity within the service.

Strategies to support intervention implementation

Strategies employed to support intervention implementation by service staff are described in detail elsewhere (Finch M et al., 2010). In brief, they included a 6 hour training workshop for service staff (a choice of four sessions were made available on different dates and days of the week in order to maximise the opportunity for attendance by staff in intervention services), provision of resources and instructional materials, delivery of follow-up support (two telephone support calls and a two hour service visit over the four month intervention period), performance feedback on service implementation of intervention components via a project newsletter on two occasions, incentives (entered into a draw to win Au\$500 vouchers for educational toys and resources) for the development of a physical activity policy, and having reliable and credible opinion leaders (qualified early childhood teachers,who are respected experts in the field of physical activity and early childhood) deliver the training and follow-up support.

Control group services

Services allocated to the wait list control group did not receive the intervention or any intervention support or materials during the study period and were offered the intervention after collection of all follow-up data.

Data collection procedures and measures

Baseline data collection occurred between March-April 2010 and post intervention follow-up data were collected six months later (September-October 2010).

Service, parent and child characteristics

Service operational information was collected from the Authorized Supervisor via a telephone interview during service recruitment and environmental and additional staffing and child number data were assessed by field data collection staff on the day of baseline data collection. Measures include: socioeconomic status of the area based on service postcode location (Australian Bureau of Statistics, 2006), number of years in operation, total number of three to five year old children enrolled, number of children enrolled to attend on the day of data collection, number of university trained teaching staff, number of room staff working on the day, number of staff per child on day, outdoor play area (m²) and fixed play equipment in the outdoor environment. Fixed play equipment includes balancing surfaces (balance beams, boards etc.), basketball/netball hoop, climbing structures, sandpit, see-saw, slides, swinging equipment (swings, rope etc.), tricycle or bike track, tunnels, trampoline or vegetable garden. The observation also identified the presence of portable and fixed play equipment in indoor and outdoor areas.

Parent and child demographic information were assessed via a brief parental self report survey included with the child consent form. Measures obtained included: parental education level; socioeconomic status of residence based on postcode; child age, sex and Aboriginal and/or Torres Strait Islander status; number of days spent at long day care each week; and time children spend being physically active and participating in small screen recreation during weekdays outside of care hours.

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Child step counts

Child physical activity was measured using pedometers (model Yamax SW200 and SW7000). Step counts during attendance at care were recorded between 9 am and 3 pm on the same day of the week at both baseline and follow-up. Craig et al as part of a large nationally representative survey of pedometer-determined physical activity in youth including children, reported that one day of pedometer monitoring yielded a valid representation of steps per day relative to the whole week in terms of both reliability (ICC = 0.79) and validity (relative absolute percent error [APE]) = <10%) (Craig CL et al., 2010). Pedometers measure vertical oscillations of body movement (Louie L and Chan L, 2003), and provide a total count of accumulated movements over the data collection time period (McKee DP et al., 2005) and are suitable for assessing accumulated time spent being physically active (Oliver et al., 2007). Pedometry has been shown to be a reliable and valid measure of physical activity in preschool age children (age 3-5 years) (Cardon G and De Bourdeaudhuij I, 2007; Louie L and Chan L, 2003; McKee DP et al., 2005; Oliver et al., 2007) and has been used in intervention studies assessing child physical activity levels attending centre based care (Boldemann C et al., 2006; Eliakim A et al., 2007). Participant burden associated with wearing a pedometer is minimal (Pate et al., 2010), reactivity is minimal (Craig CL et al., 2010) and pre-school age children are comfortable with the contact required to collect the data (by pedometer) (McKee DP et al., 2005). Pedometers were attached by trained research staff to the clothing of children above the right hip and in line with the right knee (Boldemann C et al., 2006; Cardon G and De Bourdeaudhuij I, 2007; McKee DP et al., 2005). Each participant's count was reviewed to identify possible malfunctioning, or resetting. All research staff involved in data collection were blind to group allocation. Step counts per minute were calculated, with data being considered valid if the pedometer had not malfunctioned, been reset and was worn for at least three hours.

Implementation of intervention

Implementation of intervention policies and practices were measured in intervention services through an observational audit based on the physical activity component of the Environment and Policy Assessment Observation (EPAO) (Ward D et al., 2008b). The EPAO and has been used in both descriptive and intervention studies (McWilliams C et al., 2009; Ward D et al., 2008b) and

has reported high inter-observer agreement (87.3%) (Ward D et al., 2008b). The EPAO was conducted by two trained research staff at baseline and follow-up over a six hour observation period in the indoor and outdoor play area of each service between the core service hours of 9 am to 3pm on the day that children's physical activity was measured. This included a 10 minute interview with Authorized Supervisors. Such assessments were also conducted in controls services to describe secular changes. For both groups, the EPAO assessed the number of occasions and total minutes that children participated in: fundamental movement skills sessions; physically active structured (teacher led) activities; and small screen recreation. The number of minutes of seated time and number of times such activities exceeded a 30 minute period were assessed as were the number of times staff: delivered prompts to increase child activity; made positive statements to encourage activity; and joined in children's active play. The observation also identified the presence of physical activity displays, books and posters, a written physical activity policy and portable play equipment in indoor and outdoor areas. Portable play equipment included ball play equipment, climbing structures (ladders, frames), floor play equipment (tumbling mats, carpet squares), jumping play equipment (skipping ropes, hula hoops), parachute, push/pull toys that require the children to stand when playing (wagon, scooters, prams), riding toys (tricycles, cars), rocking and twisting toys (rocking horse), sand/water play toys (buckets, scoops, shovels), slides, twirling play equipment (ribbons, scarves, batons), batting equipment (foam bats, light weight cricket bats), foot prints (stones, bricks, tiles, wood blocks), aiming equipment (portable goals, poles with baskets, targets), mini trampolines, balancing equipment, trucks and cars.

Intervention acceptability and reach

Data regarding intervention group staff acceptability of the intervention resources was collected via a written survey completed at follow-up for intervention group services. Data regarding uptake of training by services (reach) was sourced from program records which were collected by research staff during implementation. Acceptability of the resources, training and overall program was assessed by asking staff to respond to a Likert scale including 'strongly agree, agree,

disagree, strongly disagree" for the following items; The information in the Guide is easy to understand; The information in the Guide is appropriate to the long day care setting ; The information in the Activity Handbook can be applied in the long day care setting ;The information in the Activity Handbook is easy to use; Children found the activities from the Handbook enjoyable; The activities in the Handbook were age and developmentally appropriate. The Activity Cards are easy to use; Children found the activities in the cards enjoyable; The activities in the handbook were age and developmentally appropriate. In regards to training and overall satisfaction, the following items were similarly assessed: I would recommended the training to other childcare staff; The information covered in the training was useful; I learned new information at the training that I could apply in my day to day practice; The children attending our service benefited from participation in the program I benefited from participation in this program; I would recommended the program to other childrens' services staff. Reach was assessed using the total number of staff at each service eligible to attend training.

Adverse events

Information on adverse events was assessed via interview with Authorized Supervisors in both intervention and control groups at baseline and follow-up. Adverse events were assessed by asking Authorized Supervisors "What was the number of injuries recorded at your service" in the month of data collection at baseline (March 2010) and follow-up (August 2010).

Temperature

Baseline data was collected- collected during autumn and follow up collected during winter/spring. Information on minimum and maximum daily ambient temperature (degrees celcius) were obtained from local meteorological data each data collection day during baseline and follow-up data. The average of the minimum and maximum temperatures was then calculated for each data collection period.

Sample size and power calculations

Assuming a step count per minute of 17 among children attending control services and an intraclass correlation of 0.1 (Reilly JJ et al., 2006) it was calculated that recruiting 350 children from 20 long day care services would provide a sample of 280 participants (140 per group) at the final follow-up data collection. This was based on the assumption that services cared for 30 children aged three to five years per day on average (Unpublished data), an estimated child participation rate of 60% and 20% attrition at follow-up. Such a sample size was sufficient to detect a difference between the intervention and control groups of four step counts per minute with 80% power at the 0.05 significance.

Analysis

All statistical analyses were performed with SAS (version 9.2) statistical software. All statistical tests were two tailed with an alpha value of 0.05. Mean, standard deviation, and percentages were calculated to describe the parent and child demographic and service characteristics of intervention and control groups at baseline. Step counts were converted to a rate per minute based on wear time (Boldemann C et al., 2006; Cardon G et al., 2009; McKee DP et al., 2005). The analysis of the step count data was completed using a generalised linear mixed model, which is a hierarchical model with random intercept terms for long day care centre and for children nested within centres. Such analyses account for the correlation between pre and post measures and adjust for clustering within centres. The outcome in the model was the childs' step count with predictors of time, group and an interaction term for time by group. The coefficient of the interaction term is an estimate of the differential change between groups. The analysis used all available participants with data for both time points. A sensitivity analysis imputed step-counts forwards or backwards as a substitute for missing data where participants had consented but were unavailable on the day of data collection at either baseline or follow-up. Intervention effect on staff practices, organizational policy, environment and adverse events were estimated using logistic regression. The logistic regression models included terms for time, group (intervention or control group) and the interaction of time and group. Results are described as mean and standard deviation (SD) or as a count. Acceptability data was calculated using the percentage of staff that reported either 'strongly agree' or 'agree' to each item. Reach was calculated by determining the

mean number of eligible staff per service attending training and reporting the percentage that attended of the total eligible staff.

4. Results

Figure 1 describes the participation of services and participants in the trial. Of the 537 eligible children, consent was obtained for 459 (84%) to participate in baseline and follow-up data collection. Of these 348 (65%) were available at baseline to wear the pedometers and 328 (61%) provided valid data. At follow-up 317 (59%) of the original 459 children were available to wear pedometers and of these 294 (55%) had valid data.

Service, parent and child characteristics

Service and participant characteristics by intervention and control group are shown in Table 1. A higher percentage of control group services were located within areas of higher socioeconomic classification (90 vs 60%) and reported being in operation for more years than services in the intervention group (20 vs 8 years). The control group also had a higher proportion of parents in residing in areas of higher socioeconomic classification (82 vs 65%) and a higher proportion of children of Aboriginal or Torres Strait Islander background (4.6 vs 2.9%).

Child step counts

The between group analysis comparing rate of change in mean child step counts per minute from baseline to follow-up were non-significant p=0.12. Specifically mean child step counts in the intervention group at baseline and follow-up were 17.20 (CI 15.94-18.46, and, 16.12,(CI 14.86-17.30) and in the control group were 13.78 (CI 12.76-14.80), and 13.87 (CI12.57-15.17 8) (Table 2). This non-significant result remained for the sensitivity analysis when children's step counts per minute at baseline and follow-up were imputed for missing data at both time points (p=0.07).

Implementation of intervention

Table 3 shows the results for implementation of intervention components by group over time. Relative to the control group, intervention group services showed significantly greater increases in total minutes that staff were observed to deliver structured activities (p=0.02). There were no other significant between group differences in the prevalence of supportive practices, policy or environmental characteristics.

Acceptability and reach

Staff reported high satisfaction with the program overall (93%-98%), and the resources(60-100%). With unanimous satisfaction reported for the training (100%) All intervention services had staff attend the training workshop with an average of 3.5 staff members attending from each service, representing 41% (n=34) of all intervention service staff. The range of staff participation in the workshop for intervention services was 18-100%.

Adverse events

At baseline the injury rate per month was 0.18 (CI0.09-0.27) in the intervention group and 0.12 (CI 0.04-0.20) in the control group. At follow-up the injury rate per month for the intervention group was 0.17 (CI0.08-0.27) and 0.11 (CI 0.03-0.19) in the control group. When comparing groups the was no significant difference observed in the injury rate per month (p=0.85).

Temperature

During the baseline data collection period the mean ambient minimum temperature was 18.7 and mean maximum temperature was 26 degrees celcius. During follow up data collection period the mean minimum temperature was 11.9 and mean maximum temperature 20 degrees celcius.

5. Discussion

This randomized controlled trial sought to assess the impact of a multi-level intervention delivered by existing childcare service staff to increase objectively measured child physical activity in care. The trial is novel in regard to the number of childcare physical activity promoting characteristics it sought to change and in reporting of both child physical activity behaviours and observational data to assess intervention implementation, potential unintended adverse effects, and intervention acceptability. Such factors which together haven't been reported in previous randomized trials in this setting. The findings indicate that while the intervention increased the amount of time staff spent delivering structured activities and was considered highly acceptable, it showed no significant effect on child step counts per minute during care.

A number of factors may have contributed to this result. First, at both time points mean child step counts per minute were higher (+3.42, +2.25) in the intervention group compared to the control group limiting scope for further increases. There is also the potential that differences between groups in the service level characteristics assessed or other environmental characteristics that were not assessed in this study such as playground topography (trees, shrubbery, and broken ground) (Boldemann C et al., 2006) may have acted as confounding factors. Future studies randomizing a greater number of services will reduce the risk of confounding. Intervention implementation data also provides potential explanation of the trial results. Although observational data indicated that intervention services provided significantly more time for structured physical activity compared with control group services, the duration of structured activity in both groups was relatively high and greater than the 20 minutes of daily structured activity which has characterized other effective interventions (Eliakim A et al., 2007; Specker B and Binkley T, 2003; Trost SG et al., 2008). Previous research has found that while structured activities delivered by external experts or research staff are effective in improving child physical activity (Binkley T and Specker B, 2004; Eliakim A et al., 2007), those which have been delivered by usual childcare service staff have tended to be ineffective (Alhassan S et al., 2012; Jones RA et al., 2011; Reilly JJ et al., 2006). While the intervention delivered in this trial targeted a number of physical activity promoting characteristics beyond structured activity, most of the intervention elements did not improve, reducing the capacity to influence child activity level.

Several factors may have also have limited the effectiveness of the intervention implementation strategies and could be considered as opportunities for enhancing future interventions which rely on delivery by existing service staff. First, the trial included only one day of staff training, at which less than half of all intervention service staff attended with representation by one centre as low as 18%. Providing training on site, or offering multiple opportunities for staff to attend professional development opportunities at times convenient for staff may maximise the number of service staff appropriately trained to deliver the intervention. Second, follow-up support involved just two follow-up telephone contacts and a two hour site visit. By comparison, other successful interventions delivered by staff have been characterized by up to three staff training sessions held on site, and, greater frequency of follow-up (weekly on-site visits) (Fitzgibbon ML

et al., 2011; Trost SG et al., 2008). Third, the intervention was delivered over a relatively short period (four months). Early childhood educational research suggests that prolonged periods of ongoing support (at least 12 months), is required for the embedding of new and complex teaching practice change in this setting (Mitchell L and Cubey P, 2003).

The measure of child physical activity used in this study did not assess the context in which children were active, how many were engaged in activities, type or intensity of activity (Pate et al., 2010), or fundamental movement skill ability. It is possible that the intervention may have had an impact on these factors without increasing accumulated step counts. In addition, the analysis was conducted using a minimum wear time of three hours which could be accumulated from any part of the six hour data collection period including scheduled seated times (e.g eating meals) and sleep times. However analysis using available data for a wear time of five hours or greater show similar trends to the 3 hour data. In addition as part of the EPAO observation we collected information on eating and sleeping times for participating services. A review of this data suggests that centre routines within the observation period allocated time for seated morning tea and lunch, and a sleep time. As such the analysis using the five hour wear time data would have accounted for such routines, and based on these results, suggests that they did not influence step count data.Future studies, however would benefit from being able to restrict analysis to specific time periods to account for this variation.

The findings of this trial highlight the challenges faced by policy makers and practitioners interested in promoting child physical activity in center-based childcare and corroborates the experience of other researchers reporting challenges with childcare service staff delivered interventions (Finch M et al., 2012; Hardy L et al., 2010; Ward D et al., 2008a). Physical activity interventions in this setting are only of benefit if they are able to be implemented to a level sufficient to influence child physical activity. In contrast to the findings of this study, Trost and colleagues (2008) and Fitzgibbon and colleagues (2011), who provided multiple staff training sessions (including one on-site) and weekly on-site individual meetings with staff (Fitzgibbon ML et al., 2011; Trost SG et al., 2008) reported sound intervention implementation and

significant intervention effects. This demonstrates that with sufficient support childcare service staff are able to deliver effective interventions.

Strengths of this study include its use of a randomized controlled design, broad inclusion criteria, use of an objective measure of physical activity and assessment of intervention implementation by direct observation, recommended as the gold standard for environmental assessments (Ward D et al., 2008a). However, several limitations are important to consider. Child step counts were assessed on one day, which while shown to give a valid representation of steps per day relative to a whole week in population studies of children (Craig CL et al., 2010), represent the minimum standard for reliability. Craig et al as part of a large nationally representative survey of pedometer-determined physical activity in youth including children aged from 5-19 years, reported that one day of pedometer monitoring yielded a valid representation of steps per day relative to the whole week in terms of both reliability (ICC = 0.79) and validity (relative absolute percent error [APE] = <10%) (Craig CL et al., 2010). This information in combination with strong findings of non-reactivity (Craig CL et al., 2010), evidence that younger children demonstrate smaller variation in physical activity levels (Trost SG et al., 2000), and that variability is less during week days (McNamara E et al., 2010) suggest that one day of data collection was sufficient to reliably assess young children's physical activity during a weekday in center based care setting. None-the-less, the internal validity of the findings would have been improved with the addition of multiple days. Further, the use of pedometers, rather than accelerometers or direct observation methods precluded examination of the impact of the intervention on activity intensity, type and context. Finally, another limitation of this study is the follow-up period which did not enable us to assess implementation following the formal intervention period.

6. Conclusion

The findings of this trial provide an important contribution to the limited literature regarding physical activity interventions to increase young childrens' physical activity delivered in the childcare setting. The intervention failed to show an impact on child step count per minute despite increasing time that staff delivered structured activity which is likely to be attributable to

difficulties experienced by service staff in delivering a number of intervention components. Such findings highlight the need for future research to focus on identifying strategies which more effectively support staff implementation of physical activity interventions in this setting.

Title: Figure 1: CONSORT diagram

Author's contributions

First author MFinch led the development of this manuscript. Authors LW and MFinch, conceived the intervention. Authors LW, MFinch, JW, PM, MF designed the research and advised on implementation of the intervention and secured funding. MFinch, LW and JJ conducted the research. All authors contributed to, read and approved the final version of this manuscript.

Conflict of Interest

The authors declare that they have no conflict of interests.

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The trial was conducted in New South Wales, Australia from March-October 2010

At baseline	Intervention	Control	
Service characteristics			
Number	20	20	
Seifa in top half of state %	60.0	90.0	
Years of operation mean (std)	7.8 (4.44)	20.0 (10.1)	
Children enrolled – overall mean (std)	64.3 (21.2)	58.5 (25.4)	
Children enrolled - on day of collection mean (std)	30.6 (7.21)	27.1 (9.60)	
Number of Tertiary qualified staff -mean (std)	1.7 (1.5)	1.6 (1.2)	
Number of children in class observed-mean (std)	21 (5.5)	19 (7.0)	
Number of staff working on survey day-mean (std)	3.1 (0.6)	3.1 (0.9)	
Number of children per staff member-mean (std)	6.6 (1.3)	6.2 (2.1)	
Outdoor play area size (m2) -mean (std)	435 (233)	342 (81)	
median (min, max)	395 (78, 806)	334 (234, 534)	
Number of types of fixed play equipment -mean (std)	3.3 (1.3)	3.3 (2.1)	
median (min, max)	3.0 (1.0, 5.0)	2.5 (1.0, 7.0)	
Parent Characteristics			
Consenting parent has university qualification (%)	50.0	51.0	
Parent residential area socioeconomic classification in top half of state	65.0	82.0	
Child characteristics ^a			
Number of children	172	156	
Age of child (%) 3 years	37.0	35.0	
4 years	57.0	61.0	
5 years	5.3	3.9	
Male (%)	54.0	60.0	
Aboriginal or Torres Strait Islander (%)	2.9	4.6	
Days a week the child usually attends (%)			
1 day	3.5	13.0	
2 days	45.0	41.0	
3 days	31.0	27.0	
4 days	9.7	17.0	
5 days	11.0	2.6	
Time child spends being physically active outside childcare (%)			
Zero/none	0.8	0.9	
1-30 mins	14.4	9.8	
31-120 mins	54.0	66.0	
121-180 mins	12.0	12.0	
Greater than 3 hours	18.0	12.0	
Time child spends watching TV, video, DVD or computer games outside childcare (%)			
Zero/none	3.8	5.2	
1-30mins	25.4	25.0	

Table 1: Service, parent and child characteristics by group

28.0	28.0
28.0	27.1
	28.0

^a All children who had valid pedometer data at baseline

Table 2: Pedometer step counts by group

		Step count per minute (Std)							
		Intervention	95%CI	Control	95% CI	ICC ^c	Effect size	t-value	P value
^a Main analysis	Baseline	17.20 (7.33) N=172	15.94-18.46	13.78 (5.61) N=156	12.76-14.80	0.23			
	Follow-up	16.12 (6.22) N=125	14.86- 17.38	13.87 (6.25) N=120	12.57-15.17	0.23	1.39	1.56	0.12
^b Sensitivity analysis	Follow-up	16.09 (6.76) N= 218	15.06-17.12	13.85 (6.07) N=197	12.87-14.83		1.28	1.85	0.07

Data collected in New South Wales, Australia in March-April, and September-October 2010

^a all children with valid data at both time points with no imputation ^b all children with valid data at both time points and imputing both forwards and backwards to that those that only have data for one time point have their data imputed for the other (BOCF)

^c Intra-class correlation coefficient based on anova

Table 3: Implementation of intervention policies and practices

		Intervention (N=10)		Control (N=10)		
Observed practice and policy	Measure	baseline	Follow-up	baseline	Follow-up	Interaction P-Value ^a
Fundamental movement skill development activity sessions	Total occasions, Mean (std)	0.00	0.80	0.10	0.30	0.07
		(0.00)	(0.92)	(0.32)	(0.48)	
	Total minutes, Mean (std)	0.00	4.30	1.70	2.50	0.24
		(0.00)	(6.09)	(5.38)	(4.84)	
Staff delivery of structured physical activity	Total minutes of structured physical activity Mean (std)	23.67 (6.03)	52.40 (45.29)	37.80 (13.33)	27.00 (1.41)	0.02
Staff role modeling of active play	Number of times staff participated in active	4.90	6.30	5.30	3.70	0.08
and delivery verbal prompts	play, Mean (std)	(3.84)	(4.16)	(5.62)	(4.60)	
	Number of times staff prompted to initiate or	6.40	5.40	12.90	9.80 (13.46)	0.75
	increase physical activity, Mean (std)	(5.52)	(5.52)	(13.15)		
	Number of times staff provided positive	9.20	10.90	17.80	7.40	0.07
	statements about physical activity, Mean (std)	(6.96)	(17.19)	(15.49)	(9.75)	
Limiting small screen recreation	Total minutes of television viewing, Mean	0.00	0.00	6.90	12.00 (37.95)	0.29
and sedentary time	(std)	(0.00)	(0.00)	(21.82)		
	Number of services with any observed seated time exceeding 30 minutes	4	4	6	3	0.34
	Total minutes of seated time, Mean (std)	39.17 (41.27)	45.71 (25.82)	52.11 (27.82)	45.80 (27.44)	0.56
Physical activity promoting resources and materials	Number of posters, pictures or displayed books about physical activity, Mean (std)	2.33	4.25	1.00 (.)	9.33 (10.21)	0.20
		(2.31)	(2.06)			
Portable equipment	Number of portable play equipment items indoors, Mean (std)	0.50	0.20	0.50	0.30	0.77
		(0.53)	(0.63)	(0.71)	(0.48)	
	Number of portable play equipment items	0.50	0.20	0.50	0.30	0.77
	outdoors, Mean (std)	(0.53)	(0.63)	(0.71)	(0.48)	
Policy	Number of services with a written physical activity policy	3	5	2	6	0.50

Data collected in New South Wales, Australia in March-April, and September-October 2010

^a The interaction p-value is to see if there is a different effect of the intervention over time on the outcome.