Physical activity to prevent obesity in young children: cluster randomised controlled trial


Abstract

Objective To assess whether a physical activity intervention reduces body mass index in young children.

Design Cluster randomised controlled single blinded trial over 12 months.

Setting Thirty six nurseries in Glasgow, Scotland.

Participants 545 children in their preschool year, mean age 4.2 years (SD 0.2) at baseline.

Intervention Enhanced physical activity programme in nursery (three 30 minute sessions a week over 24 weeks) plus home based health education aimed at increasing physical activity through play and reducing sedentary behaviour.

Main outcome measure Body mass index, expressed as a standard deviation score relative to UK 1990 reference data. Secondary measures were objectively measured physical activity and sedentary behaviour; fundamental movement skills; and evaluation of the process.

Results Group allocation had no significant effect on the primary outcome measure at six and 12 months or on measures of physical activity and sedentary behaviour by accelerometry. Children in the intervention group had significantly higher performance in movement skills tests than control children at six month follow-up (P = 0.0027; 95% confidence interval 0.3 to 1.3) after adjustment for sex and baseline performance.

Conclusions Physical activity can significantly improve motor skills but did not reduce body mass index in young children in this trial.

Trial registration Current Controlled Trials ISRCTN36363490.

Introduction

Obesity in children has increased dramatically in recent years. It has adverse health consequences, and there is an urgent need for population based interventions aimed at prevention. Systematic reviews have reported a dearth of high quality evidence from randomised controlled trials: most older intervention studies were short term, often underpowered, and had other weaknesses such as failure to include a control group. More recent interventions have usually been unsuccessful. Only a single long term randomised controlled trial reported as being of high quality in systematic reviews found benefits to the intervention (attributed to reduced time spent watching television). Despite the need for trials in obesity prevention in children, a systematic review to the end of 2003 identified only six ongoing trials, most of which were focused on adolescent girls from minority groups in the United States.

In 2001 in Scotland at least 10% of children aged 4-5 and 20% of children aged 11-12 were obese (body mass index ≥ 95th centile). Children in Scotland establish a physically inactive lifestyle before school entry. As many young children now attend preschool education (>90% in Scotland), the nursery provides population based opportunities for prevention of obesity. In a pilot study we found that an enhanced physical activity programme in nursery was a promising means of preventing obesity. We therefore tested the hypothesis that a physical activity intervention would reduce body mass index, expressed as a standard deviation score. We carried out a cluster randomised controlled trial to avoid contamination between intervention and control participants. Design, conduct, and reporting followed guidance from the CONSORT statement on cluster randomised controlled trials.

Participants and methods

Nurseries and children

In 2002 we invited 124 nurseries to participate in the movement and activity Glasgow intervention in children (MAGIC) trial. Eligible nurseries had at least 12 children in their preschool year. We randomly selected 36 of the 104 nurseries willing to participate. To ensure comparability of intervention and control groups, nurseries were stratified and pairs of nurseries randomly selected from the same stratum, one randomly allocated to intervention and one to control. Stratification was carried out simultaneously according to three characteristics that might have affected the intervention or study outcomes: type of nursery (school, class, extended day, private sector); size of nursery (area and number of children); and socioeconomic status of the area. All families with children in their preschool year attending the 36 nurseries were invited to participate. Parents gave informed written consent to participation.

Intervention

The intervention had nursery and home based elements and is described in detail elsewhere (www.gla.ac.uk/developmental/research/activities/Exercise%20&%20Metabolism/Magic/index.html).

Nursery element—The nursery based element was an enhanced physical activity programme consisting of three 30 minute sessions of physical activity each week over 24 weeks. To deliver the intervention two members of staff from each intervention nursery attended three training sessions. A researcher unblinded to allocation (AW) carried out a
Research

monitoring visit to assess implementation. The nursery based
element of the intervention was intended to increase levels of
physical activity and children's fundamental movement skills\(^{10}\)
and meet the requirements of the "physical development and
movement" component of the nursery curriculum in Scotland.
Nurseries experience several barriers to meeting this curriculum
requirement, including lack of space, and limited competence of
staff in physical education.\(^{15-17}\) The nursery element of the inter-
vention was also intended to be inexpensive and therefore gen-
eralisable (capital cost < £200, £297, £377).

Home element—The home based element of the intervention
had two parts: each participating family received a resource pack
of materials costing £16 (€24, $30), with guidance on linking
physical play at nursery and at home, and two simple health edu-
cation leaflets (one on opportunities for increasing physical
activity, summarising our recent evidence that levels of physical
activity in preschool children in Glasgow were low;\(^{18}\) the second
encouraged families to seek opportunities to reduce the time
spent watching television). For six weeks during the intervention,
each intervention nursery also displayed posters focused on
increasing physical activity through walking and play.

Control group—In the control group, nurseries continued with
their usual curriculum and headteachers agreed not to enhance
their physical development and movement curriculum.

Objective and outcome measures
We tested the efficacy of the intervention by comparing nurser-
ies allocated to intervention with those in the control group at six
months after the start of the intervention (when all children were
still in their final year at nursery) and 12 months after the start
(when 99% of children had gone to school). All primary and sec-
ondary outcomes were measured less than one week apart in
pairs of nurseries, and outcome data were analysed and
presented at the cluster (nursery) and child level.

Primary outcome measure—Our primary outcome was body
mass index expressed as a standard deviation score.\(^{19}\) This was
calculated at baseline and at six months (mean 24 weeks, SD 2)
and 12 months after the start of the intervention (mean 52
weeks, SD 4). To obtain the score LK, who was blinded to group
allocation, measured height to 0.1 cm and weight to 0.1 kg in
duplicate using a portable stadiometer (Leicester Height
Measure, Child Growth Foundation, London) and portable
scales (TANITA 300GS, Cranlea, Birmingham) with children in
light indoor clothing and no shoes.

Secondary outcome measures—We measured habitual levels of
physical activity and sedentary behaviour objectively over six
days with accelerometer at baseline and at six months\(^{15-17}\) using
the CSA/MIT WAM-7164 accelerometer (Manufacturing Tech-
nology, Fort Walton Beach, FL, USA). Activity data were summa-
rised as total physical activity (accelerometer count per minute)
and proportion of waking hours in moderate or vigorous physi-
cal activity (accelerometer count > 3200 per minute)\(^{20-22}\) and in
sedentary behaviour (no trunk movement; accelerometer count
< 1100 per minute).\(^{23}\) Because accelerometers and staff time
were limited, in nurseries with more than 15 participating
children we randomly selected up to 15 children per nursery for
accelerometry. We objectively assessed performance in funda-
mental movement skills at baseline and six months using the
movement assessment battery, which has high validity and
reliability in preschool children.\(^{27}\) The battery provides a global
motor skills score of 0-15, which is a composite of performance
in jumping, balance, skipping, and ball exercises. AF carried out
all assessments and was blinded to group allocation.

Sample size and power
We originally intended to recruit a sample large enough to detect
a reduction in standard deviation score of 0.25 with power 80%
at a significance of 5%. Making conservative assumptions about
the variance of the paired difference in the standard deviation
score, the correlation within nurseries (and hence the loss of effi-
ciency because of clustering), and the attrition rate at 12 months,
we set out to recruit at least 400 children from at least 30 nurser-
ies. As we were able to exceed these numbers, post hoc analysis
suggests we had power of 80% to detect a reduction in score of
just 0.125.

Sequence generation and blinding
All 36 participating nurseries were allocated to group in advance
in one operation with stratified random sampling. Allocations
were concealed by carrying out randomisation of the 36 nurser-
ies at the same time and informing the liaison researcher and
nurseries together.

The researchers who made the outcome measures were
blinded to nursery allocation with the exception of the
statistician who carried out the allocation (JHM) and the contact
between the research team and nurseries (AW).

Statistical analysis and evaluation
We used multi-level (or hierarchical) modelling for all statistical
analysis (MLwiN version 1.10), the iterative generalised least
squares method for model fitting; and Wald tests to obtain P val-
ues. We analysed and compared baseline and later results using
two level models, level 1 being the individual child and level 2 the
nursery (cluster). To achieve approximate normality of errors at
both levels, we transformed mean accelerometer count in counts
per minute and proportion of time spent in moderate or vigor-
ous physical activity by taking the natural logarithm. The modell-
ing for each variable at baseline began by entering the random
effects at nursery and child level (which are required because of
the cluster design) along with five fixed effects: an "intercept"
term, a slope with respect to age (years), a slope with respect
to date of baseline activity measurement (days from start of study),
and "dummy" variables for female sex and intervention group.
For all the outcome variables that were not derived from
measurements of physical activity we introduced a sixth
term—namely, a slope with respect to log counts per minute. The
modelling of the fixed effects proceeded in a backward stepwise
manner until we obtained a final model in which all fixed effects
were significant. P values were obtained for retaining the effect
in the model, at the point at which it was a candidate for removal;
this is in the final model for the effects that are significant, but in
an intermediate model (not shown) for the other effects. For the
random effects, variance components, and their estimated stand-
ard errors are listed. We calculated the intraclass correlation
to compare the variation between clusters to the total variation; this
is measured on a scale from 0 to 1, with a value close to 0 indicat-
ing that the clusters were all "similar."

The modelling of follow-up data at six and 12 months
proceeded in a similar manner, with the follow-up measurement
itself (rather than the difference between follow-up and baseline)
being used as the response. The fixed effects included an "inter-
cept," slopes with respect to the corresponding measurement at
baseline and age at measurement, and "dummy" variables for
female sex and intervention group. In models where the
response was not derived from physical activity, we included a
slope with respect to log (mean counts per minute) at six months
as a further fixed effect. Where the effects of a "dummy" variable
and slope were both significant, the interaction term between
them was considered for the final additive model as another
were attending 153 different primary schools. 504 (93%) were available at the 12 month follow-up, when they available at the six month follow-up (while still in nursery) and not available because of absence (n = 29) or non-compliance (n = 7). Table 1 shows characteristics of the children. Figures 1 and 2 show the flow of nurseries and children through the trial.

![Flow of nurseries though study (study cluster)](image)

Fig 1 Flow of nurseries though study (study cluster)

fixed effect. In no case was such an interaction significant at the usual 5% significance level.

We assessed the process of implementation of the intervention by requesting that nurseries record each session of physical activity delivered and attendance by children. We also ensured that nursery staff distributed home based equipment and educational materials to all participating families in the intervention group.

**Results**

Thirty six nurseries and 545 children entered the trial. Consent was obtained for the participation of 581 children, but 36 were not available because of absence (n = 29) or non-compliance (n = 7). Table 1 shows characteristics of the children. Figures 1 and 2 show the flow of nurseries and children through the trial. All 36 participating nurseries remained in the trial to its completion. Of the 545 children entered at baseline, 481 (88%) were successful in 424. We attempted six month accelerometry in only 420 (86% of the children in 285. We obtained data on fundamental movement skills in 489 children at baseline, of whom 355 were available, with successful (six day) accelerometer achieved in 285. We obtained data on fundamental movement skills in 489 (90%) children at baseline and 420 (86% of the children measured at baseline, 77% of entire sample) at six months.

**Outcomes, estimation, and evaluation**

From the modelling of baseline data, sex was the only fixed effect to enter the model for baseline standard deviation score, the mean score being 0.20 (95% confidence interval 0.03 to 0.36, P = 0.02) lower for girls than for boys.

From the modelling of baseline data, sex was the only fixed effect to enter the model for baseline standard deviation score, the mean score being 0.20 (95% confidence interval 0.03 to 0.36, P = 0.02) lower for girls than for boys.

Table 2 shows summary statistics for outcome variables at follow-up. The intraclass correlations were ≤ 0.11, indicating less clustering of final results than expected. The correlation between measurements at baseline and six months was so high that we included the baseline measurement in the final model for every outcome variable.

Group (intervention v control) was not a significant effect in the model for standard deviation score at six months (P = 0.87) or at 12 months (P = 0.90) nor was any other fixed effect significant at either time point. Group was not significant for modelling log counts per minute (P = 0.18) or percentage of time spent sedentary (P = 0.08) but was marginally significant for log percentage time in moderate or vigorous physical activity (the mean value being greater in the control nurseries by 0.1, 0.0 to 0.2, P = 0.05). In modelling the change in score for fundamental movement skills we found that girls improved more than boys, the average difference in improvement being 0.7 units (0.3 to 1.1, P = 0.001). There was a group effect for fundamental movement skills: children in the intervention nurseries improved their movement skills significantly more than children in the control nurseries, the average difference in improvement being 0.8 units (0.3 to 1.3 units).

At the nursery level, 83% of prescribed sessions of the physical activity programme were actually offered. At the level of the child, 71% of prescribed sessions were attended (lower quartile 57%, upper quartile 81%).

**Discussion**

Despite rigorous implementation, we found no significant effect of the intervention on physical activity, sedentary behaviour, or body mass index. Our results add considerably to the evidence base on prevention of childhood obesity because of the paucity of research in children and the serious limitations in study design that affected most previous interventions.\(^4\,\,^6\,\,^9\,\,^{10}\) Our intervention was intended to alter physical activity and sedentary behaviour, not diet. Interventions that have focused intensively on modification of just one or two behaviours have generally been the most promising\(^4\,\,^6\,\,^9\,\,^{10}\) and reduced physical activity or increased seden-
In the long term.

This is an important educational aim and may have other high in the pilot study. Our physical activity programme was implementation of the intervention in our study was apparently replicate these findings in the present study. Quantitatively, SD score=standard deviation score; cpm=accelerometry count per minute; MVPA=moderate-vigorous intensity physical activity.

studies, it is not ideal. while it is acceptable in trials of this kind and practical for large body mass index. The body mass index is multifactorial, and, physical activity to have any net impact on overall physical activ-

our intervention probably provided an inadequate “dose” of physical activity with the intervention, though we could not

To enhance generalisability of our intervention we randomly selected nurseries from those eligible and used an inexpensive intervention that met curriculum requirements and that the pilot study suggested was learned easily by staff and enjoyed by children.

Strengths and limitations

Our intervention probably provided an inadequate “dose” of physical activity to have any net impact on overall physical activity (as measured by accelerometry) or the more distal outcome of body mass index. The body mass index is multifactorial, and, while it is acceptable in trials of this kind and practical for large studies, it is not ideal. The home based element of the inter-

Changes in other behav-

objective outcome measures provided a rigorous test of the intervention. Some previous studies on obesity prevention that depended on subjective outcome measures have reported benefits to the intervention, but in many cases this was the result of biased self reporting.32

Conclusions

Time in nursery is limited and there is pressure on the curricu-

Successful interventions to prevent obesity in early childhood may require changes not just at nursery, school, and home but in the wider environment. Changes in other behaviours, including diet, may also be necessary. Further research is necessary to identify successful and sustainable interventions for prevention of obesity and promotion of physical activity in young children.

We thank Glasgow City Council for their encouragement, advice, and access to nurseries and primary schools. We are immensely grateful to the participating families, nurseries, and schools for their enthusiastic and highly motivated participation. This research was presented in abstract form at the annual meeting of the American College of Sports Medicine in June 2005.

Contributors: JRR was the principal investigator and is guarantor. JIR, AW, JHM, C, SG, and JYP designed the trial with CM, AF, and LK, who helped to refine study design and designed and carried out the outcome measures. JHM, C and RLC were responsible for statistical analysis and interpretation of the study, and all authors contributed to interpretation. JRR drafted the manuscript, and all authors critically revised it for scientific content and approved the final version.

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Ethical approval: Yorkhill Hospitals research ethics committee approved the research.


Table 1 Characteristics of nursery age children according to activity intervention aimed at reducing body mass index (BMI). Figures are means (SD) unless stated otherwise

<table>
<thead>
<tr>
<th></th>
<th>Boys</th>
<th>Girls</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample size</td>
<td>128</td>
<td>140</td>
<td>268</td>
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<tr>
<td>Age (years)</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>16.5</td>
<td>16.5</td>
<td>16.5</td>
</tr>
<tr>
<td>BMI SD score</td>
<td>0.50</td>
<td>0.29</td>
<td>0.39</td>
</tr>
<tr>
<td>No (%) overweight (BMI SD score ≥1.04)</td>
<td>35</td>
<td>27</td>
<td>62</td>
</tr>
<tr>
<td>No (%) obese (BMI SD score ≥1.64)</td>
<td>16</td>
<td>11</td>
<td>27</td>
</tr>
<tr>
<td>Total physical activity (cpm)</td>
<td>775</td>
<td>694</td>
<td>1329</td>
</tr>
<tr>
<td>Median (range) % monitored time sedentary</td>
<td>67.6</td>
<td>71.1</td>
<td>69.3</td>
</tr>
<tr>
<td>Median (range) % monitored time in MVPA</td>
<td>3.1</td>
<td>2.3</td>
<td>2.6</td>
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<tr>
<td>Fundamental movement skills score</td>
<td>7.8</td>
<td>8.0</td>
<td>7.9</td>
</tr>
<tr>
<td>Control</td>
<td></td>
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<tr>
<td>Sample size</td>
<td>145</td>
<td>132</td>
<td>277</td>
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<tr>
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<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>16.5</td>
<td>16.5</td>
<td>16.5</td>
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<tr>
<td>BMI SD score</td>
<td>0.50</td>
<td>0.29</td>
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<tr>
<td>No (%) overweight (BMI SD score ≥1.04)</td>
<td>34</td>
<td>27</td>
<td>61</td>
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<tr>
<td>No (%) obese (BMI SD score ≥1.64)</td>
<td>18</td>
<td>10</td>
<td>28</td>
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<tr>
<td>Total physical activity (cpm)</td>
<td>823</td>
<td>794</td>
<td>1613</td>
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<tr>
<td>Median (range) % monitored time sedentary</td>
<td>66.5</td>
<td>72.7</td>
<td>68.9</td>
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<td>Median (range) % monitored time in MVPA</td>
<td>3.1</td>
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<tr>
<td>Fundamental movement skills score</td>
<td>7.6</td>
<td>7.9</td>
<td>7.7</td>
</tr>
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</table>

SD score=standard deviation score; cpm=accelerometry count per minute; MVPA=moderate-vigorous intensity physical activity.

Table 2 Characteristics of nursery age children at follow-up according to activity intervention aimed at reducing body mass index (BMI). Figures are means (SD) unless stated otherwise

<table>
<thead>
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<th></th>
<th>Boys</th>
<th>Girls</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
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<td></td>
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<tr>
<td>Sample size at 6 months</td>
<td>110</td>
<td>121</td>
<td>231</td>
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<tr>
<td>BMI SD score at 6 months</td>
<td>0.51</td>
<td>0.42</td>
<td>0.46</td>
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<tr>
<td>BMI SD score at 12 months</td>
<td>0.41</td>
<td>0.40</td>
<td>0.41</td>
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<tr>
<td>Total physical activity (cpm)</td>
<td>841</td>
<td>792</td>
<td>1633</td>
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<tr>
<td>Median (range) % monitored time sedentary</td>
<td>64.8</td>
<td>68.5</td>
<td>67.0</td>
</tr>
<tr>
<td>Median (range)% monitored time in MVPA</td>
<td>3.8</td>
<td>3.7</td>
<td>3.7</td>
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<tr>
<td>Fundamental movement skills score</td>
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<td>11.8</td>
<td>11.5</td>
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<tr>
<td>Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample size at 6 months</td>
<td>134</td>
<td>116</td>
<td>250</td>
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<tr>
<td>BMI SD score at 6 months</td>
<td>0.52</td>
<td>0.32</td>
<td>0.43</td>
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<tr>
<td>BMI SD score at 12 months</td>
<td>0.54</td>
<td>0.31</td>
<td>0.43</td>
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<tr>
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<td>811</td>
<td>1630</td>
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<tr>
<td>Median (range) % monitored time sedentary</td>
<td>62.5</td>
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</table>

SD score=standard deviation score; cpm=accelerometry count per minute; MVPA=moderate-vigorous intensity physical activity.

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Research

What is already known on this topic

Many children are obese, even at preschool age

Preschool children typically have physically inactive lifestyles

Evidence on appropriate interventions for prevention of obesity in preschool children is lacking

What this study adds

A physical activity intervention had no effect on body mass index or habitual physical activity

The intervention improved movement skills, which may increase future participation in physical activity or sport

Alternative interventions to prevent obesity in young children are required

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12 Williamson A. Factors affecting the development of an appropriate curriculum to promote physical activity in 3-5 year old children in Glasgow pre five establishments. Glasgow: University of Glasgow, 1994. (MEd thesis.)

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