Chapter 7

Effectiveness of a school-based physical activity-related injury prevention programme; a cluster randomised controlled trial

Abstract

Objective: To study the effects of a school-based injury prevention programme on physical activity-related injury incidence and severity.

Design: Cluster randomised controlled trial performed from January 1, 2006 through July 31, 2007.

Setting: Forty Dutch primary schools.

Participants: A total of 2,210 children (aged 10-12 years).

Intervention: Schools were randomised to receive either the regular curriculum or an intervention programme that targeted physical activity-related injuries.

Outcome measure: Incidence and severity of physical activity-related injuries per 1,000 hours of physical activity participation.

Results: A total of 100 injuries in the intervention group and 104 injuries in the control group were registered. Non-response at baseline or follow-up was minimal, only 8.7%.

The Cox regression analyses adjusted for clustering showed a small non-significant intervention effect on total (HR=0.81;95%CI:0.41-1.59), sport club (HR=0.69;95%CI:0.28-1.68) and leisure time injuries (HR=0.75;95%CI:0.36-1.55). However, physical activity appeared to be an effect modifier. In those who were less physically active, the intervention had a larger effect. The intervention reduced the total and leisure time injury incidence (HR=0.47;95%CI:0.21-1.06 and HR=0.43;95%CI:0.16-1.14; respectively). Sport club injury incidence was significantly reduced (HR=0.23;95%CI:0.07-0.75).

Conclusion: We found a substantial and relevant reduction in physical activity-related injuries, especially in children in the low active group, because of the intervention. This school-based injury prevention programme is promising, but future large scale research is needed.
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Introduction
The health benefits of regular physical activity in children are widely known and include a decrease in cardiovascular risk factors, enhanced bone health and reduction of the risk of obesity and type 2 diabetes mellitus. Participation in physical activity, however, also increases the risk of adverse effects such as injuries and with the current focus on a physically active lifestyle, increasing numbers of physical activity-related injuries can be expected. Although most physical activity-related injuries in children are not life threatening, they may coincide with direct pain, short-term disability, school absence and long-term consequences such as osteoporosis in later life, all of which lead to high direct and indirect costs. Moreover, children may lose their enthusiasm for participating in physical activity because of negative associations with injuries. Given the consequences and costs of physical activity-related injuries, prevention of such injuries in children is an important Public Health issue.

Although the magnitude of paediatric injuries has been shown in several studies, most preventive research within the sports injury field has been performed in adults. Moreover, a great part of the physical activities of a child consists of leisure time activities other than sports, and the risks associated with such a wider spectrum of physical activity has hardly been investigated. Previously performed prevention studies concentrated on specific sports and/or specific injuries. To the best of our knowledge, intervention studies with regard to the effectiveness of school-based physical activity-related injury prevention programmes in children are lacking. The objective of this study is to evaluate the effects of a school-based injury prevention programme on physical activity-related injury incidence density (IID) and injury severity.

Methods
Design and participants
The Injury Prevention Lessons Affecting Youth (iPlay) study was designed as a cluster randomised controlled trial. In January 2006, a total of 520 of 7,000 Dutch primary schools located in urban and suburban areas were randomly invited to participate in the study. Inclusion criteria for the schools were (i) being a regular primary school, (ii) giving physical education classes twice a week, and (iii) being willing to appoint a contact person for the duration of the study. All children in grades 5 and 6 (aged 10-12 years) from the participating schools were eligible to participate in the study. Parents of the participating children received a passive informed consent form that explained the nature and procedures of the study. If parents and/or their child(ren) did not want to participate they could withdraw. The Medical Ethics Committee of VU University Medical Centre approved the study design, protocols, and informed consent procedures.
The iPlay-intervention

The iPlay-programme was developed according to the Intervention Mapping protocol. This protocol describes a structured approach for the design of theory- and evidence-based health programmes. The 8-month iPlay-programme focused on both children and parents. Each month children received a newsletter aimed at improving knowledge, attitude, and self-efficacy towards the prevention of physical activity-related injuries. Each month parents also received a newsletter, aimed at improving knowledge about injury prevention, that suggested strategies to reduce injury risk for their child. In addition to the newsletters, posters that addressed the main topics with regard to injury prevention were continuously displayed in the classroom. The iPlay-website contained all sorts of interactive information for children, parents and physical education teachers.

In addition, 5-minute exercises were given at the beginning and end of each physical education class. These exercises were aimed at improving strength, speed, flexibility and overall coordination. During the first physical education class strength and coordination exercises were performed. During the next PE class speed and flexibility exercises were performed. Teachers were able to choose from 5 different speed, strength, coordination and flexibility exercises. A more detailed description of the exercises is described in the article by Collard et al. (2009).

A teachers’ manual contained all the information about the iPlay-programme, including schedule, explanation of the exercises, and newsletter topics. The intervention focused in particular on prevention of lower extremity physical activity-related injuries because those are the most common.

Outcome measures

The objective of this study was to evaluate the effect of the iPlay-intervention on physical activity-related injury incidence density (IID) (number of injuries per 1,000 hours of sport participation) and injury severity.

Demographics

At the start (September 2006) and end (June 2007) of the school year all children completed a questionnaire in the classroom. The baseline questionnaire collected information on demographic variables such as age, gender, ethnicity, and socio economic status (SES). Children were classified as being of western or non-western ethnicity on the basis of the definition used by the Central Bureau of Statistics. Children with at least 1 parent born in Turkey, Africa, Latin America, or Asia were classified as non western immigrants. Children with at least 1 parent born in Europe, North America, Oceania, Indonesia, or Japan were classified as western immigrants. Socioeconomic status (SES) was assessed using the highest level of maternal education, which was self-reported via a questionnaire for parents and ranged from 1 (no qualification) to 8 (Master’s degree).
Anthropometrics
Body height was measured in meters with a portable stadiometer (Seca 214, Leicester Height Measure; Seca GmbH & Co, Hamburg, Germany). Body weight was measured in kilograms, with a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany). Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared, and we used the age-specific and gender-specific cut-off points to determine weight status.

Exposure time
The questionnaire also included questions about frequency and duration of sports club and leisure time activities during the last week. If the last week was not a regular week (because of vacation or sickness, for example) children were asked to complete the questions for a regular week. Sports activities were defined as organised activities on sports clubs. Leisure time physical activity was defined as unorganised physical activity during leisure time.

Exposure to physical education classes - twice a week for 45 minutes - was multiplied by the intervention duration in weeks, taking the regular school holidays into account. Individual exposure to sports activities and leisure time physical activity was derived from the baseline and follow-up questionnaires. From these data the mean weekly exposure was calculated, which was multiplied by the number of intervention weeks. Finally, a correction factor of 0.8 was used to account for seasonal effects on physical activity participation throughout the school year. Although chosen arbitrarily, this correction factor is in line with decreased physical activities during wintertime as found in previous studies. Weekly leisure time physical activity exposure was missing for 35 children. There were no missing data with regard to exposure to sports participation.

Physical activity-related injuries
Every week physical education teachers asked the children whether they were injured as a result of physical activity in the past week. In case of an injury, children completed an injury registration form. This form collected information on injury type, location, direct cause and activity performed at the time of the injury (i.e. physical education class, sports, or leisure time physical activity).

We adapted the injury definition as described by van Mechelen et al. (1992). A physical activity-related injury is any injury as a result of participation in physical education class, sport activities, or leisure time physical activity with 1 or more of the following consequences: the child (i) has to stop the PA and/or, (ii) cannot (fully) participate in the next planned PA and/or, (iii) cannot go to school the next day and/or, (iv) needs medical attention (e.g. from providers ranging from first aid personnel to general physicians or physiotherapists). Reported physical activity-related injuries that did not meet this injury
definition were excluded from the analyses.
The severity of physical activity-related injuries was categorized on sporting time lost (no sporting time lost versus 1 or more days of sporting time lost). Using a cost-diary, parents of the injured child reported sporting time lost.

Randomisation
Before baseline measurements and after all schools were enrolled, a randomisation was performed using a computerized random number generator, with stratification for geographic location of the school (urban or suburban) and professional status of the physical education teacher (certified or uncertified). Randomisation took place at the school level. The researchers informed the schools of the allocation before the start of the school year. The intervention group received the iPlay-programme during 1 school year, whereas the control group followed the regular curriculum. The control group received 2 information sheets with information about the iPlay-study and the measurements but no information about injury prevention. Participants and researchers were not blinded to group allocation.

Statistical analysis
The IID was calculated for total physical activity participation and for 3 different modalities of physical activity-related (i.e. physical education classes, leisure time, and sports activities). The IID is reported as the number of new injuries per 1,000 hours of physical activity participation, using exposure time of each individual until the first injury. The number of injuries divided by the total time-at-risk is the preferred measure of incidence because it can accommodate variations in the exposure time of individuals. If a child had multiple injuries, only the first injury was considered in the analysis. Because the unit of allocation was schools, we performed a multilevel Cox proportional hazard regression analysis, using Stata statistical software, version 10 (Stata Corp, Chicago, Illinois), to estimate the hazard ratio’s (HRs) and 95% confidence intervals (CIs). Schools were used as cluster levels. To analyse the difference in injury severity (injured children with sporting time lost) between the intervention and control groups a multilevel logistic regression was performed using Stata statistical software, version 10. All analyses were adjusted for ethnicity, SES, and BMI. We checked for possible effect modification by gender, grade of urbanization, ethnicity, BMI-class and PA exposure time.

Results
Participants
A total of 2,210 children (aged 10-12 years) from 40 primary schools throughout the Netherlands were invited to participate in the study. All children were willing to participate, except for 2 children in the control group who refused to participate.
Figure 7.1 outlines the complete flow of participants from recruitment (January 2006)
through the last follow-up contact (July 2007). Reasons for not completing the baseline or follow-up exposure were mostly school absence because of illness or having a medical appointment (e.g. dentist/orthodontist). Data from 8 children were excluded from analysis because those children completed the questionnaire incorrectly. Eventually, data from 1,015 children in the intervention group and 996 children in the control group were analyzed. All analyses were performed according to the intention-to-treat analysis. There were no deviations from the protocol as planned and no reported adverse effects.

Table 7.1 presents baseline characteristics of the study population. The mean (SD) age of the children was 10.7 (0.8) years. At baseline, children in the intervention group reported

Figure 7.1: Flow of participants from recruitment through the last follow-up contact.
Table 7.1: Baseline characteristics in intervention and control children.

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>Intervention group N=1015</th>
<th>Control group N=995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) (y)</td>
<td>10.7 (0.8)</td>
<td>10.7 (0.8)</td>
</tr>
<tr>
<td>Gender No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>495 (49)</td>
<td>493 (50)</td>
</tr>
<tr>
<td>Girls</td>
<td>520 (51)</td>
<td>503 (50)</td>
</tr>
<tr>
<td>BMI, mean (SD) (kg/m²)</td>
<td>17.7 (2.7)</td>
<td>18.1 (3.1)</td>
</tr>
<tr>
<td>BMI class * No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal weight</td>
<td>819 (81)</td>
<td>779 (78)</td>
</tr>
<tr>
<td>Overweight and obese</td>
<td>142 (14)</td>
<td>170 (17)</td>
</tr>
<tr>
<td>Unknown</td>
<td>54 (5)</td>
<td>47 (5)</td>
</tr>
<tr>
<td>Ethnicity No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Western</td>
<td>849 (84)</td>
<td>727 (73)</td>
</tr>
<tr>
<td>Non-western</td>
<td>121 (12)</td>
<td>229 (23)</td>
</tr>
<tr>
<td>Unknown</td>
<td>45 (4)</td>
<td>40 (4)</td>
</tr>
<tr>
<td>SES No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>492 (48)</td>
<td>386 (39)</td>
</tr>
<tr>
<td>High</td>
<td>331 (33)</td>
<td>364 (36)</td>
</tr>
<tr>
<td>Unknown</td>
<td>192 (19)</td>
<td>246 (25)</td>
</tr>
<tr>
<td>Physical activity, mean (SD) (min/wk)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical education class</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Organised sports</td>
<td>145 (131)</td>
<td>131 (132)</td>
</tr>
<tr>
<td>Leisure time</td>
<td>320 (168)</td>
<td>287 (173)</td>
</tr>
<tr>
<td>All</td>
<td>559 (231)</td>
<td>511 (232)</td>
</tr>
</tbody>
</table>

*a using cut-off values described by Cole et al.20 Abbreviations: BMI, Body Mass Index; SES, socioeconomic status

significantly more physical activity (mean (SD), 559 (231) minutes/week) than children in the control group (mean (SD), 511 (232) minutes/week). Children in the intervention group reported an especially large number of activities during leisure time. In addition, children in the control group were more often from a non western ethnic background and tended to have a higher BMI.

Effects on physical activity-related injury incidence
The total number of physical activity-related injuries registered during 1 school year in the intervention and control groups was 100 and 104, respectively. Table 7.2 summarises the number of injuries and the IID in the intervention and control group for total physical activity-related injuries and the different modalities of physical activity and
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The IID for total physical activity participation was 0.38 (95%CI:0.31-0.46) in the intervention group compared with 0.48 (95%CI:0.38 - 0.57) in the control group. The Cox regression analyses showed a non-significant intervention effect on total injuries after adjustment for clustering (HR=0.81; 95%CI:0.41-1.59). When we considered the different modalities of physical activity, small non significant effects on injuries during sport and leisure time activities were found, HR=0.69 (95%CI:0.28-1.68) and HR=0.75 (95%CI:0.36-1.55); respectively.

Table 7.2: Effect of the iPlay-intervention on physical activity injury incidences.

<table>
<thead>
<tr>
<th>Number of injuries</th>
<th>Injury rate (injuries per 1,000 exposure hours)</th>
<th>Hazard ratio (HR*) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control group</td>
<td>Intervention group</td>
</tr>
<tr>
<td><strong>Total PA injuries</strong></td>
<td>104</td>
<td>100</td>
</tr>
<tr>
<td><strong>Sports club injuries</strong></td>
<td>40</td>
<td>44</td>
</tr>
<tr>
<td><strong>Leisure time injuries</strong></td>
<td>48</td>
<td>40</td>
</tr>
<tr>
<td><strong>PE class injuries</strong></td>
<td>22</td>
<td>24</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; HR, Hazard Ratio; PA, physical activity; PE, physical education.

Table 7.3: Effect of the iPlay-intervention on physical activity injury incidence density for high active and low active children.

<table>
<thead>
<tr>
<th>Injury rate (injuries per 1,000 exposure hours)</th>
<th>Hazard ratio (HR) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Control group</strong></td>
<td>Intervention group</td>
</tr>
<tr>
<td><strong>Total PA injuries</strong></td>
<td>0.43 (0.31 - 0.54)</td>
</tr>
<tr>
<td><strong>Sports club injuries</strong></td>
<td>0.53 (0.30 - 0.76)</td>
</tr>
<tr>
<td><strong>Leisure time injuries</strong></td>
<td>0.33 (0.20 - 0.46)</td>
</tr>
<tr>
<td><strong>PE class injuries</strong></td>
<td>0.65 (0.28 - 1.02)</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; HR, Hazard Ratio; iPlay, Injury Prevention Lessons Affecting Youth; PA, physical activity; PE, physical education.

* Multilevel Cox-regression adjusted for ethnicity, socioeconomic status and body mass index

* Significant difference between intervention and control group (p<0.05)
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After adjustment for clustering, we found not only wider 95% CIs but also a change in point estimates. Thus, the cluster effect in our study was much higher than expected. Looking at the data, we observed a large difference in IID between schools with different physical activity exposure times. Therefore, we performed subgroup analyses for high active and low active children.

High active versus low active group
Children who reported less than 414 minutes per week of physical activity (median) were categorized as low active. Children who reported 414 or more minutes per week of physical activity were categorised as high active.
Table 7.3 summarizes the IID for the intervention and control groups and the effect of the iPlay-programme on IID for the high active and low active group.
In the low physically active group, effects of the iPlay-programme were much larger, with a 50% reduction in total injuries (HR=0.47; 95%CI:0.21-1.06) and an even more than 50% reduction for sport injuries (HR=0.23; 95%CI:0.07-0.75) and leisure time injuries (HR=0.43; 95%CI:0.16-1.14).

Effects on severity of the injuries
Figure 7.2 shows the percentages of injured children with sporting time lost in the intervention and control groups for total, sports club, leisure time, and PE class injuries.
Children in the intervention group reported fewer severe injuries than those in the control group. The multilevel logistic regression analyses showed that there was no significant difference between the intervention and control group in the percentage of children with sporting time lost.

Discussion
Effects on injury incidence density and severity
The iPlay-study was the first study, to our knowledge, to evaluate a school-based PA injury prevention programme. In the literature there are some studies that evaluate school-based intervention programmes, but most of these studies focus on injury prevention in general (e.g. bike and pedestrian safety, falls, poisoning, and fire burns) or on sport-specific injury prevention (e.g. high-school basketball).
Our school-based injury prevention programme showed a reduction in IID and injury severity in primary school children aged 10-12 years. The reduction was not significant in the total group because of the unexpectedly large cluster effects.
In the low active group the intervention effect was much larger. However, because of the smaller sample size this effect was not significant. A significant effect was found for sport club IID. Children in the intervention group had approximately 3 times less risk for a sport club injury than children in the control group.
Comparison with literature

To our knowledge, only 1 study focused especially on school-based prevention of PA injuries in children\textsuperscript{25}. This controlled experimental study evaluated an injury prevention programme designed for children aged 12 to 20 years. It showed a minor reduction in injury incidence rates.

\textbf{Figure 7.2}: Percentages injured children with sporting time lost in intervention and control group for total, sport club, leisure time and PE class injuries and the Odds ratio’s (OR) with 95%CI. Please note that the OR does not approximate RR.
Strength and limitations of the study

One strength of the present iPlay-study is the large sample size, including more than 2,200 children from 40 different primary schools. The intervention-programme was developed according to the Intervention Mapping protocol and tailored to the needs and possibilities of the target population. This is an important element for a successful community-based programme. Moreover, the intervention-programme appeared easily implementable, was time-efficient, and fit the regular school curriculum. The study population was a good representation of the Dutch population as a whole.

Last but not least, an important strength of this study is that all physical activity-related injuries that resulted from sports activities, physical education class, and leisure time physical activity were registered in a school setting. Often injuries are only recorded through medical channels, which will result in a large percentage of serious injuries, whereas less serious injuries will be underreported. Thus, only part of the total injury problem is revealed: the “tip-of-the-iceberg” phenomenon. In this study both serious and less serious injuries as a result of participation in organized and unorganized physical activity were reported.

A drawback of the study is that physical activity-related injuries were registered by means of self-report. Self-report of physical activity-related injuries leaves open the possibility that some injuries were missed. To report physical activity-related injuries as adequately as possible, all physical education teachers were informed about the definition of a physical activity-related injury and they were contacted frequently by telephone or e-mail in an attempt to minimize underreporting.

Exposure time was also self-reported because this was the only feasible means of collecting exposure data in such a large sample. In this study, exposure time was assessed at the start and end of the school year. Weekly registration of exposure time would have been preferable. However, this was not feasible. This method of self-reported exposure might have resulted in a slight overestimation of actual exposure to leisure time physical activities and sports.

Another limitation of the study is that the participants and research-assistants were not blinded. Blinding of participants and research-assistants is important to prevent bias, but in a trial like this blinding is difficult to attain.

Generalizability

Only 9% of all 520 invited schools agreed to participate. Non-response of primary schools in this study was 71%. Of total primary schools, 20% of the primary schools indicated that they did not want to participate, mostly because of lack of time. Schools that did not want to participate were not different than participating schools with regard to geographic location (urban versus rural). Comparison of the participating schools and non participating schools on other variables than geographic location is not possible because information with regard to those variables is lacking.
Conclusions
Our findings are encouraging for the prevention of physical activity-related injuries in children. Although our findings were not statistically significant, we found a substantial and relevant reduction in physical activity-related injuries because of the iPlay-intervention, especially in the children from the low active group. Therefore we believe that this school-based injury prevention programme is promising, but future research is needed.

Reference List


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