Chapter 3

Design of the iPlay-study
Systematic development of a physical activity-related injury prevention programme for primary school children

Abstract

Health benefits of physical activity in children are well known. However, a drawback is the risk of physical activity-related injuries. Children are at particular risk for these injuries, because of a high level of exposure. Because of the high prevalence of physical activity injuries and the negative short- and long-term consequences, prevention of these injuries in children is important. This article describes how we systematically developed a school-based physical activity-related injury prevention programme using the intervention mapping (IM) protocol. IM describes a process for developing theory- and evidence-based health promotion programmes. The development can be described in six steps: (i) perform a needs assessment, (ii) identify programme and performance objectives, (iii) select methods and strategies, (iv) develop programme; (v) adopt and implement, and (vi) evaluate.

First, the results of the needs assessment showed the injury problem in children and the different risk factors for physical activity-related injuries. Based on the results of the needs assessment the main focus of the injury prevention programme was described. Second, the overall programme objective of the injury prevention programme was defined as reducing the incidence of lower extremity physical activity-related injuries. Third, theoretical methods and practical strategies were selected to accomplish a decrease in injury incidence. The theoretical methods used were active learning, providing cues and scenario based risk information, and active processing of information. The practical strategy of the injury prevention programme was an 8-month course about injury prevention to be used in physical education classes in primary schools. Fourth, programme materials that were used in the injury prevention programme were developed, including newsletters for children and parents, posters, exercises to improve neuromotor fitness, and an information website. Fifth, an implementation plan was designed in order to ensure that the prevention programme would be implemented, adopted and sustained over time. Finally, an evaluation plan was designed. The injury prevention programme is being evaluated in a cluster randomised controlled trial with more than 2,200 children from 40 primary schools throughout the Netherlands. The IM process is a useful process for developing an injury prevention programme. Based on the steps of the IM we developed an 8-month injury prevention programme to be used in physical education classes of primary schools.
**Introduction**

Regular physical activity has many health benefits, for example it lowers the risk of obesity, coronary heart disease and osteoporosis\(^1\). A drawback of increased physical activity levels is the risk of physical activity-related injuries. Sports are the leading cause of injury and hospital emergency room visits in adolescents\(^4,5\). Although most physical activity-related injuries are not life threatening, the occurrence of physical activity-related injury can result in pain, disability, school absence, absence from physical activities, and sometimes in dysfunction in the short and long term. Therefore, prevention of physical activity-related injuries is essential. Emery (2005)\(^6\) showed in a review that injury prevention strategies in children could reduce the risk of physical activity-related injuries. However, the literature has some limitations and is based primarily on observational studies for specific injuries and specific sports\(^7\). Few studies on school-based physical activity-related injury prevention strategies have been published. Of these, only one study was a randomized controlled trial\(^8\). Measures to prevent physical activity-related injuries should generally be based on knowledge about the incidence and severity of the injury problem, aetiological risk factors, and mechanisms contributing to the risk of sustaining such injuries\(^9\).

Because to our knowledge a proper school-based physical activity-related injury prevention programme in children does not exist and evidence on effectiveness is lacking, development and evaluation of such a programme is necessary. An injury prevention programme can be developed using the intervention mapping (IM) protocol\(^10,11\). IM describes a process for developing theory- and evidence-based health promotion programmes, and

![Figure 3.1: Steps of the Intervention Mapping process]^10.]

**Step 1:** Needs Assessment

**Step 2:** Define suitable programme objectives

**Step 3:** Select theory-based intervention methods and practical strategies

**Step 4:** Produce programme components and materials

**Step 5:** Design an implementation plan

**Step 6:** Design an evaluation plan
Design of the iPlay-study involves a systematic process that prescribes a series of six steps: (i) performing a needs assessment, (ii) defining suitable programme objectives, (iii) selecting theory-based intervention methods and practical strategies, (iv) producing programme components and materials, (v) designing an implementation plan; and (vi) designing an evaluation plan (see figure 1.1). Collaboration between the developers, the users of the intervention and the target population is a basic assumption in the IM process. This article describes in detail the development of a physical activity-related injury prevention programme for children by using the steps of the IM process. Step 6 of the process describes in detail how to evaluate the effectiveness of such a programme.

Perform a needs assessment
Prior to the development of an injury prevention programme for children, the injury problem and the risk factors for injuries in children should be assessed from literature and focus group interviews. In order to gain insight into the needs of the target population, a focus group interview with 23 physical education (PE) teachers from 12 secondary schools was carried out.

The injury problem
Injuries cause children unnecessary suffering and pain in the short term. Individuals who have experienced macro trauma or injuries to joints may be at risk of accelerated development of (secondary) osteoarthritis in later life. Moreover, it is suggested that injuries sustained at a young age have a negative influence on participation in physical activities and sports. Data from the period 2000–2004 revealed that in the Netherlands 1.5 million injuries are reported each year and 51% of these injuries are medically treated. The injury incidence in children aged 0–17 years is 1.3 (95% CI 1.2, 1.4). The absolute number of injuries in the Netherlands increases for both sexes until the age of 12 years. Above this age, injuries in boys increase considerably until the age of 16 years. The highest number of injuries in girls is registered at 14 years of age. The most frequently injured body parts are the lower extremities. The ankle is the most affected part of the body (20%), followed by the knee (18%)\textsuperscript{17}. Although sport participation in children has increased (children aged 6-11 years: 88% in 1991 to 93% in 2003; children aged 12–19 years: 84% in 1991 to 93% in 2003), membership of sports clubs has decreased (children aged 6–11 years: 76% in 1991 to 74% in 2003; children aged 12–19 years: 77% in 1991 to 71% in 2003)\textsuperscript{18}. There are a large number of children who participate in organized team sports, but a growing number of children are attracted to non-organized sports activities and individual sports. There seems to be a trend for individualization, and children nowadays are attracted to sports other than traditional sports in a sport club\textsuperscript{19}. The literature shows that most physical activity-related injuries occur during non organized sports activities and leisure time\textsuperscript{20-22}. Data from a nationwide survey in the Netherlands showed that school absence occurs in 7% of the...
children who sustained a sports injury, and the mean duration of school missed by these children was 8 days. This means that 0.02% of the total population who visit school and participate in sports are absent from school one or more days. With a mean duration of 8 days, the total school absence due to sports injuries can be calculated at 794,000 days a year. In addition, 22% of the people who sustained an injury were also absent from physical activities. The economic consequences of physical activity-related injuries in children are not known, but direct medical costs, e.g. medical treatments as a result of all injuries, were estimated at €170 million and indirect medical costs, e.g. work or school absence, were estimated at €420 million.

**Table 3.1: Risk factors for physical activity-related injuries in children.**

<table>
<thead>
<tr>
<th>Extrinsic risk factors</th>
<th>Intrinsic risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sport played (contact/no contact)</td>
<td>(Aerobe) fitness level</td>
</tr>
<tr>
<td>Level of play (recreational/elite)</td>
<td>Preparticipation sport-specific training</td>
</tr>
<tr>
<td>Position played</td>
<td>Flexibility</td>
</tr>
<tr>
<td>Weather</td>
<td>Strength</td>
</tr>
<tr>
<td>Time of season / time of day</td>
<td>Joint stability</td>
</tr>
<tr>
<td></td>
<td>Biomechanics</td>
</tr>
<tr>
<td></td>
<td>Balance/proprioception</td>
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<tr>
<td></td>
<td>Psychological/social factors</td>
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</tbody>
</table>

Risk factors for injuries are factors that increase the potential risk for injury and include extrinsic risk factors (i.e. weather, field conditions) and intrinsic risk factors (i.e. age, conditioning). Identification of risk factors can be used as a leading guide for preventive measures. However, it is clear that injuries are caused mostly by a combination of factors. Table 3.1 shows the most important risk factors for injuries in children. Based on the literature, the aim of our injury prevention programme should be to prevent injuries in school children. A prevention programme to prevent physical activity-related injuries embedded in PE classes in schools will reach all the children who are physically active – not only children in sport clubs. Physical activity-related injuries are defined as injuries occurring during organized sports activities, leisure time activities and PE class.
Focus group interviews
In order to gain insight into the needs of the target population and in order to be able to design a feasible intervention programme, focus group interviews were held. Five individual interviews and two focus group interviews were performed with 23 PE teachers from 12 secondary schools. In the Netherlands, children go to primary school until the age of 12 years, followed by attendance at secondary school. The interviewed secondary school PE teachers generally agreed there is a great diversity in physical fitness and neuromotor fitness in children in the first grade of secondary schools. Their common opinion was that these inter-individual differences are an important contributing factor to physical activity-related injuries in children. Asking the interviewed PE teachers about the causes of the noted diversity in neuromotor fitness, and particularly about possible solutions, they argued that an intervention programme should focus on primary school children. In primary schools, children receive regular PE classes. Unfortunately, these regular PE classes are not always supervised by certified PE teachers (due to economic reasons, the child’s regular teacher often provides the PE classes). However, the regular teachers usually do not incorporate injury prevention aspects in their PE classes; as general injury prevention lessons are not given in primary schools, it is likely that a preventive intervention in this setting can lead to maximum improvement. In addition, the PE teachers in secondary schools said they were hesitant and not motivated to incorporate our preventive intervention in their PE classes, because they already incorporated their own injury prevention in their PE classes. Because the PE teachers in secondary schools argued that the intervention programme should focus on primary schools since injury prevention lessons are already given in secondary schools, a shift from secondary school children to primary school children was made. From the focus group interviews with the PE teachers we also learned that, in general, the PE teachers were rarely confronted with injuries, and they were unaware of a sports injury problem among their pupils. From the interviews it became clear that raising injury knowledge in children, teachers and parents should be an important objective for our intervention programme.

Define suitable programme objectives
This step provides the foundation for the programme by specifying who and what will change as a result of the intervention. The overall objective of our intervention programme was to reduce the incidence of lower extremity physical activity-related injuries in primary school children. In order to achieve this overall objective, several risk-reduction behaviours and interpersonal environment ‘sub-objectives’ were defined that focus on children, parents and PE teachers. The underlying assumption of the risk-reduction behavioural sub-objectives is that if an intervention reduces the prevalence of risk factors, it will reduce the prevalence of physical activity-related injuries. Furthermore, the presence or absence of support from important others (e.g. parents, PE teachers) within the individual’s
immediate interpersonal environment may have an influence on the performance of the injury-preventing behaviour\textsuperscript{24}. The sub-objectives used in our preventive measure are: (i) children take fewer injury-related risks, (ii) parents create a safe physical activity environment for their children outside PE classes, (iii) and teachers include injury prevention into their usual teaching routine.

Performance objectives were defined on the basis of the programme objectives and describe what the participants in this programme need to do to perform the desired injury-preventing behaviour. The performance objectives for each programme objective are presented in table 3.2.

\textit{Table 3.2:} Performance objectives for the four different programme objectives.

<table>
<thead>
<tr>
<th>Programme objective 1: Children will take fewer injury related risks</th>
<th>Programme objective 2: Parents will create a safe PA environment outside PE classes</th>
<th>Programme objective 3: PE teachers will include injury prevention into their usual teaching routine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance objective 1</td>
<td>Children learn the consequences of an injury</td>
<td>Parents learn the consequences of an injury</td>
</tr>
<tr>
<td>Performance objective 2</td>
<td>Children learn which risk factors cause injuries</td>
<td>Parents learn which risk factors cause injuries</td>
</tr>
<tr>
<td>Performance objective 3</td>
<td>Children gain insight into their own injury risk behaviour</td>
<td>Parents gain insight into the injury risks during the child’s leisure time physical activities</td>
</tr>
<tr>
<td>Performance objective 4</td>
<td>Children form strategies to reduce their injury risk.</td>
<td>Parents form strategies to reduce the injury risk during the child’s leisure time physical activities</td>
</tr>
<tr>
<td>Performance objective 5</td>
<td></td>
<td>Parents gain insight into the child’s risk behaviour</td>
</tr>
<tr>
<td>Performance objective 6</td>
<td></td>
<td>Parents form strategies to reduce child’s the risk behaviour</td>
</tr>
</tbody>
</table>

Select theory-based intervention methods and practical strategies

The third step of the IM process is the selection of theory-based intervention methods and practical strategies to effect changes in the health behaviour of individuals, and to change organizational and societal factors to alter the environment.

A ‘method’ can be described as a theoretically derived technique used to influence (determinants of) injury-preventing behaviour, and a ‘strategy’ as a practical way of organizing and delivering the intervention method\textsuperscript{12,25}.
Theory-based intervention methods

Preventive measures should target one or more of the risk factors mentioned earlier (table 3.1). A potentially modifiable risk factor for injuries in children is wearing appropriate protective equipment and footwear during physical activities. To decrease this risk factor, injury-preventing behaviour should be addressed. Injury-preventing behaviour is an indirect causal factor for injuries. Therefore, improving this behaviour could be a method to decrease injury incidence and injury severity. To change injury-preventing behaviour, knowledge of determinants of behaviour is necessary. We applied the attitude, social influence and self-efficacy (ASE) model for behaviour change. The ASE model is based on the theory of planned behaviour and the social learning theory. This model postulates that intention, the most proximal determinant of behaviour, is determined by three conceptually independent constructs: attitude, social influence and self-efficacy. To change injury preventing behaviour and finally decrease injury incidence, our programme tries to improve attitude, social influence, self-efficacy and intention towards wearing appropriate protective equipment and footwear during organized physical activities, leisure time activities and PE classes (see figure 3.2).

In addition, a second potentially modifiable risk factor for injuries in children is dimensions of neuromotor fitness (e.g. flexibility, strength and balance/proprioception). Neuromotor fitness and sport specific skills have an impact on sports injuries. There is some evidence that improving certain dimensions of neuromotor fitness can decrease injuries. However, this evidence is found in sport-specific studies (see figure 3.2).

Theoretical methods are general techniques for influencing changes in determinants of behaviour. In our programme the following methods will be used: active learning, pro-

Figure 3.2: Hypothetical model that was used for the iPlay-programme.
viding cues and scenario-based risk information, and active processing of information. The related theories for the adopted methods are the persuasion communication matrix, elaboration likelihood, social cognitive theory, theories of information processing, and a precaution adoption process model.

**Practical strategies**
The next step is to translate the methods into practical strategies that can be used in a preventive measure. Knowledge is a basis for many different determinants of behaviour, but giving children information will not lead directly to behavioural change. However, behavioural determinants like attitude are based partly on knowledge. The practical strategy that is used to deliver information in order to increase attitude, social influence, self-efficacy and neuromotor fitness is an 8-month course about injury prevention. The communication channels are a course manual for teachers, newsletters for children and parents, posters for children, an exercise programme during PE lessons for children, and an interactive website. The newsletters can be made especially for children or parents, and the willingness to receive a newsletter is usually good. In addition, posters can be effective in calling attention to a campaign and they provide continuous exposure to the children. Table 3.3 gives an overview of the determinants, methods, theories and strategies to reach the programme objectives.

**Interpersonal environment**
Changing determinants of behaviour is almost always embedded in one or more environmental levels. A child participating in physical activities is in an environment with par-

<table>
<thead>
<tr>
<th>Determinants</th>
<th>Methods</th>
<th>Theory</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude</td>
<td>Active learning</td>
<td>Persuasion communication matrix</td>
<td>Newsletter delivered to children and parents to improve knowledge</td>
</tr>
<tr>
<td>Social influence</td>
<td>Cues</td>
<td>Elaboration likelihood</td>
<td>Posters exposed to children in the classroom to improve knowledge</td>
</tr>
<tr>
<td>Self efficacy</td>
<td>Scenario based risk information</td>
<td>Social cognitive theory</td>
<td>Course manual for teachers</td>
</tr>
<tr>
<td>Neuromotor fitness</td>
<td>Active processing of information</td>
<td>Theories of information processing</td>
<td>Short circuit training to improve neuromotor fitness during PE classes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Precaution adoption process model</td>
<td>Website accessible for children, parents and teachers</td>
</tr>
</tbody>
</table>
ents and PE teachers, therefore parents and PE teachers should also be involved in the intervention programme. Parents are very important in creating a safe physical activity environment outside PE classes. They should encourage their children to play safe, and they are important as role models for their children. The influence of parental rules and pressure has been found to have a strong effect on the use of protective equipment. PE teachers are very important in creating a safe physical activity environment during PE classes. In order to prevent injuries in PE classes it is important that teachers include injury prevention into their usual teaching routine. If PE teachers include injury prevention into their teaching routines, they will teach children how to prevent injuries during physical activities, not only during PE classes, but also outside school.

**Produce programme components and materials**

The task in this step of the IM process is to translate methods and practical strategies into programme components and materials. Our injury prevention programme as a whole is not specified for any specific type of sport. It addresses the most common injuries and preventive measures in general and includes the programme components and materials outlined below.

**Newsletters**

Monthly newsletters are produced for both children and parents. The aim of the newsletters is to increase knowledge and awareness about injury prevention. The monthly newsletters consist of information about injury prevention, self-evaluation tests and puzzles on a specific topic. By providing a monthly newsletter, new information will be given each month in a motivational way. It is believed that this will remind all involved each month of the task of preventing injuries.

**Posters**

Eight different posters (A1 size, i.e. 594x840mm) show the highlights of the content of the newsletters. The posters contain important and clear messages about injury prevention and are very colourful and have humorous cartoon images in order to make the posters attractive to children. They are displayed in the classroom, so that the children are able to see the posters continuously.

**Exercises to improve neuromotor fitness**

A short training circuit is performed at the beginning and the end of each PE class, twice a week. This circuit consists of exercises aimed at the improvement of neuromotor fitness (i.e. strength, speed, balance/coordination and flexibility). The exercises are developed on the basis of exercises from ‘active childhood-healthy life’, exercises from ‘Basisdocument Bewegingsonderwijs’, and exercises from a programme to prevent lower limb injuries in youth sports. Table 3.4 gives examples of the exercises that are done during the PE classes.
Website
The website (www.iplaystudy.nl) contains general information about injury prevention for children, parents and PE teachers, who can view the newsletters online, and children can check their solutions to the newsletter puzzles. Additionally, various instruction videos and photos are displayed to illustrate for PE teachers how to teach the exercises.

Pretesting the 8-month course
Pilot testing of programme strategies and materials with intended implementers and recipients is an important part of step 4.
Teachers and children of six primary schools were informed about the programme in full detail. Teachers were asked for their comments on the topics and timing of the different modules of the 8-month course via a focus group interview. With the exception of a few minor comments, all interviewed primary school teachers were positive about the programme and believed the programme to be feasible and effective. Children responded in a comparable way and were very enthusiastic about the monthly newsletters and posters. Although the programme also targets parents, for practical reasons they were not asked for their comments about the 8-month course. However, the positive response of teachers and children led us to believe that the programme will be widely accepted in its current form.

Pretesting exercise programme
The exercise programme to improve neuromotor fitness was pretested in two different primary schools, involving three PE teachers. Teachers were asked specifically for their comments on the feasibility of the exercises, the level of intensity, the degree of difficulty of the exercises and the clarity of the manual. Some exercises were perceived as too difficult or taking too much time. Additionally, the teachers advised delivery of the exercises in a more competitive and playful way. Exercises were adapted as suggested by the PE teachers. The teacher’s manual was considered to be very clear.

Table 3.4: Examples of the iPlay-programme of exercises used to prevent injuries

<table>
<thead>
<tr>
<th>Strength</th>
<th>Coordination</th>
<th>Speed</th>
<th>Flexibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forward jumps</td>
<td>Passing the ball (one leg stance)</td>
<td>Shuttle run</td>
<td>Flexibility hamstring</td>
</tr>
<tr>
<td>Squats to 80 degree of knee flexion</td>
<td>Skate jumps</td>
<td>Race course</td>
<td>Flexibility calf muscle</td>
</tr>
<tr>
<td>Hand wrestling in push up stand</td>
<td>Pushing each other off balance (one leg stance)</td>
<td>Spirits from different start positions</td>
<td>Flexibility biceps femoris</td>
</tr>
</tbody>
</table>
Design an implementation plan
This step focuses on the design of an implementation plan, in order to ensure that an injury prevention programme will be implemented, adopted and sustained over time. The intervention programme is a ‘ready to use’ preventive measure so it can be implemented directly in PE lessons, if proven effective. The Royal Association of Teachers of Physical Education (KVLO) and the Academy for PE Teachers’ Education will then play an important role in the implementation. The KVLO controls the standards and continuity of physical education in the Netherlands, and has a wide array of implementation channels. Thereby, the KVLO will be an important channel through which the preventive programme can be implemented not only by today’s PE teachers, but also by the PE teachers of the future. Another channel that plays an important role in successful implementation is the academic school where PE teachers are educated. The KVLO and the Academy for PE Teachers’ Education have been involved in the study from the very beginning and have participated in the IM process. By using IM, the programme was tailored to the wishes of the end users. In doing so, the practical and logistical issues of implementation have been minimized.

Design an evaluation plan
Through effect and process evaluation, IM planners can determine whether decisions were correct at each mapping step. To evaluate the effect of the intervention, the decrease in injury incidence will be analysed in a cluster randomized controlled trial. The primary research questions addressed are: “What is the effect of the injury prevention programme on lower extremity physical activity-related injury incidence and severity?” and “What is the cost effectiveness of this programme?” The secondary research question is: “What is the effect of the injury prevention programme on the improvement of knowledge, (determinants of) injury-preventing behaviour and neuromotor fitness?”

Sample Size
A difference in the incidence of acute lower extremity injuries of 7% between the intervention and control group after 8 months is considered clinically relevant. To detect a difference of 7% in the incidence of lower extremity physical activity-related injuries with a power of 90% and a alpha of 5%, 500 children per group (intervention/control) are needed in an evaluation study. However, in order to perform multi-level analyses taking into account a cluster randomization design (schools as randomization level) – with an intra-cluster correlation coefficient of 10% and a dropout rate of 20% – a total of 2,280 children from 40 schools are required at baseline.

Recruitment of primary schools
The evaluation will be carried out in Dutch primary schools. From the 7,000 primary schools throughout the Netherlands, 520 primary schools are randomly selected from a
database and invited by means of an information flyer. Inclusion criteria for the primary schools are: (i) being a regular primary school, (ii) giving PE lessons twice a week, and (iii) being willing to appoint a contact person for the duration of the study. A flowchart of the recruitment of primary schools is given in figure 3.3.

Recruitment of children and their parents
The children and parents from the participating schools receive an information letter about the study design. All children are eligible for inclusion in the study. The parents receive a passive informed consent request: this consent procedure assumes that the parents consent, unless the researcher is contacted by means of a telephone call or by sending an email.

Randomisation
Schools serve as randomisation units to avoid spill over of the intervention within schools. A stratified randomisation is performed based on geographic location (urban/suburban) and professional status of the PE teacher (certified/ uncertified), resulting in four strata. From each stratum, schools are randomly allocated to the intervention or control group.
by a computerized random number generator. Before the school year starts, the primary schools are informed about the group (intervention/control) they are assigned to.

**Primary outcome measures**

*Injury definition and registration*

Throughout the school year, PE teachers record physical activity-related injuries continuously. They are instructed to question children explicitly every week about whether they have been injured as a result of physical activities (including non-organized events) in the past week. The injury definition, as described by van Mechelen et al. (1992)\(^9\), is used where a physical activity-related injury is any injury as a result of participation in PE class, sport activities or leisure time activities with one or more of the following consequences: the child (i) has to stop the physical activity and/or (ii) cannot (fully) participate in the next planned physical activity (applies also to planned leisure time physical activities) and/or (iii) cannot go to school the next day and/or (iv) needs medical attention ranging from onsite care (e.g. first-aid personnel) to personal care (e.g. physiotherapist or sports physician). In case of an injury, the child is asked to complete an injury registration form. The injury registration form collects information on injury type, injury location, direct cause of the injury and activity performed at the time of injury. Injury incidence refers to the number of new injuries during a particular period of time (e.g. 1 year). One method to express incidence rates is to calculate the incidence of injuries in relation to exposure (in days, hours or sport event). To determine time at risk for physical activity-related injuries, all children complete a questionnaire in the classroom twice a year. This questionnaire collects information on exposure time (sports and leisure-time participation).

*Cost effectiveness*

In order to evaluate the cost effectiveness of the preventive measure, all parents from children who sustain a physical activity-related injury receive a cost diary. The cost diary is a log in which parents register all (para-) medical treatment (including use of medication), absence from school and sport activities, and other discomfort from the moment of injury onwards, until full recovery. From these cost diaries, direct and indirect costs resulting from the sustained injury can be calculated for use in the economic evaluation.

**Secondary outcome measures**

Knowledge, injury-preventing behaviour, behavioural determinants and neuromotor fitness are measured at baseline (start of the school year) and follow-up (end of the school year).

*Questionnaires*

Children are requested to complete a questionnaire in the classroom. The children take home the questionnaire to their parents, who are asked to complete their questionnaire and return
Knowledge about injury prevention is measured with one question on self-reported improvement in knowledge of how to prevent physical activity-related injuries, as well as a knowledge test including nine multiple-choice questions about injury prevention in general. Behavioural determinants are assessed with the following constructs: attitude, social influence, self-efficacy and intention. The injury-preventing behaviour is defined as wearing appropriate protective equipment and footwear during organized physical activities, leisure time and PE class. Attitude towards the injury-preventing behaviours is assessed with three questions. Social influence is assessed with questions regarding social norm, modelling of friends, and modelling of parents. Self-efficacy is assessed with two questions relating to the child's perception of their ability to perform injury-preventing behaviour. Intention and behaviour towards wearing protective equipment and appropriate shoes during organized physical activities, leisure time and PE class are assessed with one question. All answers on the questions are given on a five-point Likert scale varying from always (1) to never (5) or totally agree (1) to totally do not agree (5). All questions are positively formulated.

We pretested the questionnaires on comprehensibility, (lack of) clarity and practical applicability in 54 children and their parents. Based on the results of the pre-test, we changed some questions to increase comprehensibility, deleted excessive text messages and shortened the questionnaire to decrease completion time.

**MOPER fitness test**

Neuromotor fitness is assessed with the MOtor PERformance (MOPER) fitness test. Supervised by a research assistant, groups of 3–4 children perform seven test items of the MOPER fitness test (bent arm hang test, 10 x 5m run test, plate tapping test, leg lift test, sit and reach test, arm pull test and standing high jump test), and they are asked to perform all test elements as well as possible. For practical reasons, we decided to exclude the 6-minute endurance run. For an extensive description of the MOPER fitness test items, see Leyten et al. (1982). In addition, children perform the flamingo balance test, which has been described in the EUROFIT test. To be able to complete all tests during one PE class we shortened the flamingo balance test to 30 seconds instead of 1 minute as the original flamingo balance test protocol indicates. All test items are performed barefoot to rule out the effect of footwear on the test results. Body height and weight are also measured. Body height is measured in metres to the nearest centimetre with a portable stadiometer (Seca 214, Leicester Height Measure; Seca GmbH & Co, Hamburg, Germany). Asking the subject to stand straight, with the heels together and looking straight ahead standardizes positioning of the body. Body weight is measured to the nearest 0.1 kg with a digital scale (Seca 770; Seca GmbH & Co, Hamburg, Germany). During the body height and weight measurements, children wear only underwear.
Design of the iPlay-study

Statistical analysis
The effects of the intervention will be assessed using multilevel regression analysis. This statistical technique takes into account the dependency of observations of different children from the same school. Analyses will be adjusted for baseline values and, if necessary, for other confounders. The economic evaluation will be assessed using mean direct (i.e. medical costs), indirect (i.e. costs for absence from school/work) and total costs from the cost diaries. Because costs are generally not normally distributed, 95% confidence intervals for the differences in mean costs will be obtained by bias-corrected and accelerated bootstrapping. Differences in costs and differences in injury incidence will be included in a cost-effectiveness ratio, which estimates the additional costs to prevent one physical activity-related injury.

Process evaluation
A process evaluation is included to monitor programme implementation, which will gain insight into the relationship between specific programme elements and programme outcomes. The injury prevention programme will be evaluated with the use of the RE-AIM (reach, effectiveness, adoption, implementation and maintenance) framework. All PE teachers, children and parents assigned to the intervention group are asked to complete the process evaluation questionnaire.

Discussion and conclusions
Regular physical activity has many health benefits, but also increases the risk of physical activity-related injuries. This paper describes how to develop and evaluate a preventive measure using the IM protocol. To our knowledge, this is the first time this has been done in the injury prevention field. Although this strategy has never been used before in this field, the underlying systematic ‘evidence-based’ process and the contribution of the field of practice make the IM method likely superior to any other method for developing an injury prevention programme. The IM protocol provides a valuable checklist for the development of an intervention programme. However, it is a rather time-consuming process. The research on determinants, definition of suitable performance objectives, moving back and forth between the IM steps, and the pretesting of materials required much time. This makes it sometimes difficult to apply the IM process according to the full instructions. The results of the evaluation study will be published elsewhere. Preliminary analysis clearly indicates that the iPlay study resulted in a significant decrease in injury incidence in the intervention group. Moreover, the results of the evaluation study will help to gain more insight into the effects of school-based injury prevention programmes.

Reference List


Design of the iPlay-study


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