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Early Childhood Educators' Fear of Injury Risks Limits Movement and Physical Activity for Children—A Risk in Itself!

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Abstract: Many children spend a large proportion of their waking hours in early childhood education and care (ECEC). Movement and physical activity (PA) are crucial for children's development and sustainable health. The competence to manage and assess risks starts early in life and can be improved through opportunities for challenging PA. The aim of this study was to investigate ECEC educators' experiences and perceptions of injury risks in ECEC and examine their reasoning about teaching movement and PA, and experiences of any restrictions and prohibitions of movement and PA. Eighteen ECEC educators were interviewed. The qualitative content analysis revealed three themes with adherent sub-themes: *Responsibility for the children* (*Caretaking* and *Empathy); Fear of being accused* (*Fear of being exposed* and *Fear of being irresponsible in the work team); Low competence in movement (Low expectations of children* and *Perceived poor personal movement skills).* The study concluded that educators' fear of injury risks limits the children's movement and PA occasions. The educators' perceived poor personal motor skills and low fitness combined with their perceived low competence to teach movement limit the possibility for the children to develop their motor skills, which in turn might affect the children's physical literacy for sustainable health.

Keywords: early childhood education and care; risk; injury; physical activity; movement; motor skills; teaching; educators; child's perspective

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1. Introduction

As more children attend early childhood education and care (ECEC) and are engaged in it, it plays a crucial role in shaping their sustainable and healthy development and preparing them for the future. In Sweden, about 94 percent of children aged one to five years attend ECEC [1]. Children's outcomes in ECEC are suggested to be foundational aspects of learning and development [2], which are important for later learning [3]. ECEC is a well-suited arena for developing movement skills [4] as well as developing risk management. The competence to manage and assess risks starts early in life and can be improved through opportunities for challenging physical activity (PA) [5], which involves inherent risk [6]. PA is defined as any bodily movement produced by the skeletal muscles that increases energy expenditure [7].

According to the rights of the child [8], parents, educators, caregivers, and society should stand up for children's right to participate in decisions that affect them. This includes children's right to be physically active and to develop fundamental movement skills (FMS) [9,10]. Many adults worry that children will injure themselves in PA, which leads to banning physically active play and challenging movement. They are focused on the risk of acute physical injury and seem to be unaware of other dangers that may occur as a result of restricting PA [11], such as weight gain or other health problems [12,13].

Early childhood is a crucial period for developing and strengthening movement skills because the brain is developing and adapting to motor skill learning at the same time. Children who do not engage in activities that enrich their movement skills in early childhood risk being unable to achieve their full potential for motor control, which is essential for

maintaining physical fitness and sustainable health in the future [14] (Myer et al., 2015). Furthermore, low levels of PA and poor FMS significantly increase the risk of injury [15,16]. Children develop the ability to perceive and appraise risks as they learn to avoid injury while exploring the environment and learning what their bodies and skills are capable of [17]. The concept of physical literacy is described as the motivation, confidence, physical competence, knowledge, and understanding to value and take responsibility for engagement in PA for life [18]. Physical literacy is not restricted to the development of motor skills in early childhood; rather, it is characterized by a broad variety of forms of PA and is relevant throughout life [19]. Insufficient motor skills from childhood can lead to both avoidance of PA and low ability to avoid injury in adolescence and adulthood [20–23].

Child development is enhanced when significant adults allow children to explore their surroundings, experiment, try new things, accept challenges, and take risks. Risky play can be thrilling and exciting forms of physical play that involve uncertainty [24], but also involve a risk of injury, which ends up in conflict with society's contemporary discourse to protect children from all risks of physical injury to the extent that not even minor injuries such as bruises are tolerated [25].

ECEC educators should implement teaching for preschoolers' sustainable learning [26]. The professional functioning of ECEC educators valued in the ECEC sector was assessed in terms of expertise, deliberation, recognition, responsiveness, and integrity [27]. Opportunities for the development of movement skills and risk management depend on knowledge and motivation among educators [4]. Many ECEC educators perceived that it was difficult and challenging to get toddlers physically active [28]. Teacher-guided and teacher-led movement was shown to increase children's PA levels [29]. During a movement project, the participating ECEC educators detected their insufficient pedagogical content knowledge to teach movement and PA, and that teaching was often replaced with free play [30].

The aim of this study was to investigate ECEC educators' experiences and perceptions of risks of PA-related injury in ECEC and investigate their reasoning about teaching movement and PA and experiences of any restrictions and prohibitions of movement and PA in ECEC.

2. Materials and Methods

2.1. Procedure

Data was collected using individual interviews with a semi-structured approach with the aim of exploring the educators' experiences and perception of teaching children's movement skills and PA and risks connected to movement and PA. A semi-structured interview guide was used to gather data from a variety of perspectives [31]. The length and depth of the interviews varied according to the participants' engagement in the interview, but they lasted between 30 and 90 min. The interviews consisted of a series of open questions. The questions were evaluated in a pilot study before their use in the final interviews. The participants in the pilot study were ECEC educators with the same qualifications and experience as the participants in the final study. The questions were discussed in the pilot study to ensure they were relevant and understandable.

The interviews were conducted at the interviewees' workplaces by the same interviewer, and the same central questions were raised, but with the possibility for the interviewees to develop their answers in a broad manner. The interviewer created a conversational climate to get the interviewees to share their thoughts and experiences [32]. The 18 educators were individually interviewed, based on the principle of saturation [33]. The interviews were fully performed with all 18 educators. The saturation principle meant that no additional data were found after the performed interviews. Already after 14 interviews, the recognition of answers was high, whereby similar instances could repeatedly be seen [34].

2.2. Participants

Interviews were carried out with 18 ECEC educators, 17 females and one male, working in five preschools in municipalities with 10,000 to 95,000 inhabitants in southern Sweden.

The five selected preschools represented both the private and the public sectors. The educators were 11 preschool teachers and seven day-care assistants with five to 38 years of work experience in ECEC. The two groups of ECEC staff worked in teams with children's education. In the following text, they are all referred to as educators. Years of work experience differed among the preschool teachers and day-care assistants, but all had a minimum of five years of work experience in ECEC. Informed consent was obtained from all the educators.

2.3. Analysis

The analysis of the transcribed interviews was derived as a conventional coding process in five steps [35]: familiarization, generating themes and sub-themes, reviewing themes, defining and naming the themes, and presentation of findings [36,37]. The techniques of both thematic [37] and qualitative content analysis [38] were found to be meaningful in this explorative study with a focus on movement, PA, and perceived risks [39]. The meaningful units were condensed and coded into themes and sub-themes relevant to the research questions.

The *child's perspective(s)* and *children's perspective(s)* described by Sommer et al. (2013) were used as the point of departure in this study. *Child's perspective(s)* refers to adults viewing children's situations from the children's reality, while *children's perspective(s)* represents children's own experiences, perceptions, and understandings of their life-world [40]. When ECEC educators were interviewed in this study, *the child's perspective* was used. This means that the adult (the educator) uses their own experiences and knowledge from, for example, their own upbringing, education, professional, and family life, and tries to put themselves in the child's situation to assess for themselves what is in the child's best interests. The children were not personally involved in this study.

2.4. Ethics

The study was conducted in accordance with the ethical principles for research involving human subjects, and all procedures in the study were in accordance with the Declaration of Helsinki and the Swedish law on research ethics (SFS 2003:460). The study was approved by the Regional Ethical Review Committee in Lund (Dnr 2017/555). The participants were informed about the study, its voluntariness, and its confidentiality, and written informed consent was obtained from all participants. The participants did not receive any benefits for their participation.

3. Results

The study resulted in a rich body of material based on the varying experiences and perceptions of the educators. The analysis revealed three themes with adherent sub-themes.

1. Responsibility for the children included the sub-themes Caretaking and Empathy.
2. Fear of being accused included the sub-themes Fear of being exposed and Fear of being irresponsible in the work team.
3. Low competence in movement included the sub-themes Low expectations of children and Perceived poor personal movement skills.
4. Examples of condensed meaningful units from the analysis of the interviews are presented in Table 1.

Table 1. Themes with associated sub-themes identified in the analysis of interviews with ECEC educators, as well as examples of condensed meaningful units.

Themes	Sub-Themes	Examples of Condensed Meaningful Units
Responsibility for the children	Caretaking	A sense of responsibility toward the parents.
		Everything must be safe.
	Empathy	It is horrible when children get injured.
		Personally suffer when children get injured.
Fear of being accused	Fear of being exposed	Afraid of being seen publicly in a negative light.
		Afraid of parents' criticism.
	Fear of being irresponsible in the work team	Afraid of colleague's opinions.
		Afraid of employer's opinions/losing the job.
Low competence in movement	Low expectations of children	Young children have limited motor skills.
		Young children cannot cope with risks.
	Perceived poor personal movement skills	Own poor motor skills.
		Own fitness not sufficient to be active.

3.1. Responsibility for the Children

The content analysis revealed two adherent sub-themes, *Caretaking* and *Empathy*, which are presented below.

3.1.1. Caretaking

The educators experienced that caring for the children was important and they were afraid that the children would get hurt in ECEC. The fear was related to the children's PA. The possibility of getting injured in other types of activities was ruled out. They saw themselves as educators but argued that due to the children's young age, care and nurturing were paramount. Safety and protecting the children from injury were perceived as basic in caretaking. One of the educators summarized that there had not been many injuries in the years she had been working, but she believed that sometimes children did collide, trip, and hurt themselves, but she did not attach much importance to that. There had been occasions when children had knocked out teeth and had to see a dentist or had suffered cuts that had to be stitched. She did not see herself as an anxious person who held the children back, but over the years she had colleagues who were more like that.

> *The safety of the children is vital. We are different in the staff group, but in terms of safety, we are probably pretty much in agreement, even if I sometimes think that some of my colleagues are too cautious with the children.* (J)

The responsibility toward the parents was important and the teachers were afraid of having to tell them that children had injured themselves in preschool. Many educators emphasized their responsibility for the children's safety in ECEC, which for them also meant that it would be risk-free.

The parents believe that we take care of the children, so it is very important to do so and keep the children from any risks. (A)

The educators felt they had large groups of children to take care of and that it was difficult to be the leader of a group of physically active children. They preferred to let the children do crafts or to be in smaller groups, so it was easier to maintain order and discipline. Even if they had the opportunity to organize smaller groups for movement it was perceived as time-consuming and to lead a group of ten to 15 children was perceived as difficult to handle, so organized movement activities were mostly excluded from the daily work.

They seem to be so many when they are mobile. They are everywhere and I am worried that I will fail to keep order. I perceive that when they are moving and become excited, they don't listen to me. (F)

When asked about the children's motor skills at different ages, the educators hesitated in their responses. They said that they had not thought about it. However, they stated that many children have poor motor skills and they thought that parents carried the children up to a late age. The educators thought that the children should receive much more training in motor skills at home. When it came to motor skills training in ECEC, they perceived that they had difficulties finding time for it and said there were not enough staff.

It is probably because of staff shortages that we cannot offer what we want. I think we would like to offer it if we had more educators. (J)

When the compensatory assignment for ECEC was discussed, they were not sure that the assignment included motor development. Some educators thought the compensatory assignment was exclusively dedicated to language development.

Overall, the educators reflected that they took a cautious approach regarding the importance of taking care of the children in different ways. They said that they were very much aware of the individual variations and prerequisites among children. When it came to movement skills, they were unsure. The educators thought they delivered good caretaking which included preventing injuries by banning movements they perceived as risky. The bans, for example on climbing trees, included all children and were not adapted to the children's different abilities.

3.1.2. Empathy

Some of the teachers said that they felt very uncomfortable when children were injured, and they personally experienced pain when caring for children who had been hurt. They empathized with the children and emphasized the need to prevent injuries to avoid the unpleasant feeling. They did not associate this feeling of discomfort with their profession; instead, they saw it as an integral part of their personal nature. While they felt similarly at home with their own children, the intensity of this emotion was heightened in their work at the preschool, where they were responsible for other parents' children. This combination of protective instincts and professional responsibility led some teachers to act overprotectively, which restricted the possibility for movement and PA for children.

I want the children to move but I think it is so terrible if they are injured so, so . . . I often nag them to stop and tell them to do something calmer instead. (N)

3.2. Fear of Being Accused

The adherent sub-themes Fear of being exposed and Fear of being irresponsible in the work team are presented below.

3.2.1. Fear of Being Exposed

When asked about how often they had witnessed children getting injured in ECEC, the educators reported that it did not happen very frequently. They referred to knocked-out teeth, wounds, broken arms or legs, and some occasional concussions, but overall, they

perceived that injuries did not commonly occur. In case of any accident, they called the parents and let them know, but many of the educators described the fear they felt when they had to tell the parents.

> *I fear that something will happen. If something happens and I must tell the parents. It does not happen often, but I still think about it all the time.* (K)

The educators recalled headlines in the media discussing children getting hurt at preschool. They believed it would be a catastrophe if they were to be involved in an incident that made headlines. They cited examples of media reports where children had fallen from play structures at preschool and broken bones, and they found it terrible. Nowadays, events easily become media focal points, and scapegoats are sought. There was a fear of explaining to the parents if a child was injured in ECEC and they also feared what the parents could publish in social media and might also forward to traditional media. They felt it was important to be extremely cautious when it came to children's movement and PA, especially since that is where injuries occur, as summarized by one of the educators.

> *It is in physically active play that they suffer injury. It never happens in any other activity. I cannot recall any other accidental situation.* (F)

3.2.2. Fear of Being Irresponsible in the Work Team

The educators did not want to be perceived as poor work team members. Allowing children to engage in risky play or movements that might lead to injury could be seen as acting irresponsibly in the work team. Even though individual educators wanted to let children explore various movements such as climbing trees and give them more freedom during play, they perceived that this approach was disapproved of by some colleagues within the team. The collegial mindset of approved harmless activities took over and those who advocated more adventurous and challenging activities were in the minority and adapted to the cautious attitude of the work team.

> *Yes, we have plenty of rules. Rules that restrict. Rules like only one child on the swing even if it is possible to have four, no climbing in trees and so on. Sometimes I perceive that the rules are invented just because we should have rules. I do not want to follow all the constructed rules, but the others in the work team think they are so important, so I must adapt.* (N)

Various restrictions and prohibitions to prevent children from engaging in activities perceived as risky were implemented, and it was seen as the educators' responsibility to enforce these local rules.

> *We cannot let the older children climb because then the little kids come, and they can't do it and fall. So, we must stick to the rules for all.* (M)

3.3. Low Competence in Movement

The adherent sub-themes *Low expectations of children* and *Perceived poor personal movement skills* are presented below.

3.3.1. Low Expectations of Children

Overall, the educators had low expectations regarding children's motor skills and ability to move. Several educators perceived that today's children are unaccustomed to PA. The educators experienced that more children than before struggled to keep up when the group of children moved short distances at low speed.

> *We walk only short distances today because many children have difficulty walking. They are not used to walking. We have electric box bikes in which we can transport six children at a time which is practical for them and for us.* (M)

They perceived it was difficult to teach movement and PA, and when the question of ECEC's compensatory mission arose, they hesitated about whether it also was applicable

to motor skills and PA. Typically, they focused on language and mathematical abilities to bridge gaps among children before starting school.

> *Somersaults? No, I do not think so many preschool children here can do that. Do they learn in ECEC? No, I do not know how to teach it and not my colleagues either*. (A)

The educators doubted that children could assess risks in movements and PA. They thought that children forget everything when they are physically active.

> *The children are too young and cannot see any risk. We must tell them all the time not to do dangerous things.* (B)

3.3.2. Perceived Poor Personal Movement Skills

Some of the educators argued that it was unreasonable for them to expect children to perform tasks they could not do themselves. They found it difficult to teach motor skills because the children were mobile and ran away. They found it even more difficult to know what to teach when it came to motor skills. When asked about learning specific movements like the somersault or wheel (spinning around by going sideways from standing, via a handstand, back to standing again), they said that they were not able to teach it because of their own low motor skills. Even those educators that had trained gymnastics themselves in the past and knew how to do it were not sure if they could teach it in ECEC in front of their colleagues.

> *I do not know why I do not teach it. Actually, I have been a gymnast, but in ECEC . . . I do not know what my colleagues will think if I teach children to do gymnastics.* (M)

Activities including motor learning were excluded to a high degree according to the educators. If any teaching in movement was done in ECEC, it was mostly very basic skills such as balancing on one foot, jumping on equal footing, crawling, etc. in the form of play without any instructions. The teaching sessions were unusual, and movement was mostly in the form of free play, but if any teaching was carried out, it concerned the same basic exercises that were done by the children, irrespective of age. Most of the educators said they were supervisors when the children had free play and that they seldom or never did any PA themselves. Even those educators who said they enjoyed PA stated that they could not demonstrate movements to the children. When asked if it was embarrassing to demonstrate movements in front of the children, they said it was not, but in front of their colleagues it was embarrassing because they felt they were not good at doing movements. Consequently, it resulted in no teaching and the children's motor skills learning occurred in free play if the children initiated it themselves. A few educators sometimes ran with the children during games, but most of the educators never did any PA because of what they described as their low fitness and poor motor skills. They did not want to show their shortcomings in front of their colleagues.

> *Normally we go out once a day if it is not raining too much. Once a week we walk to an open place where the children can run. We don't train anything special with the children. I have lousy fitness; well, my colleagues are not fit either so . . . no training.* (I)

4. Discussion

The aim of this study was to investigate ECEC educators' experiences and perceptions of risks of PA-related injury in ECEC and also to investigate their reasoning about teaching movement and PA and experiences of any restrictions and prohibitions of movement and PA in ECEC.

The findings from the interview study with preschool educators are discussed in relation to the three research questions under the headlines: *Educators' perceptions of risk for PA-related injuries in ECEC; Educators' description of risk elimination; Educators' perceptions of teaching children movement and PA.*

4.1. Educators' Perceptions of Risk for PA-Related Injuries in ECEC

The educators perceived risks for injury when the children were physically active, while they did not perceive any risks for injury in other activities in ECEC. Children are at an inherent injury risk while participating in PA, but not when engaged in sedentary activities. The perceptions of PA-related injuries varied among the educators and seemed to be derived from their individual experiences of PA, their own motor skills, and their perceived leadership skills. The situation of having responsibility for other people's children, as well as influences from the collegial group dynamics affected the educators' perceptions of risks in movement and PA in ECEC. Thus, socially constructed factors were involved in the educators' feelings of risk [41], but a perceived lack of professional experience and pedagogical content knowledge in movement and PA [30] was also involved in the educators' feelings of being unable to practically handle mobile children when teaching movement. The feeling of insecurity led them to mostly refrain from teaching the children to move and also led to them introducing movement bans. This was especially noticeable indoors, but also outdoors. Other studies have shown that children in ECEC spend more time indoors where PA is not promoted [42], and outdoor time occurs less frequently than scheduled [43]. The outdoor time is usually spent in free play [30].

The educators admitted that PA mostly occurred during free play and that organized PA occurred quite rarely. They controlled the risks in free play by supervising the children and by setting up rules for where and how the children were allowed to play. Other studies have shown that most injury prevention efforts focus on the sports setting, but that many children sustain an injury during unorganized PA [6]. PA in ECEC mostly seems to occur during unorganized free play where little or no instruction in motor learning takes place. Motor learning incorporates a variety of skill-enhancing movements into a developmentally appropriate intervention, which may provide an optimal method for the promotion of injury-free PA as a long-term lifestyle choice [44] for health [45]. Improved motor competence and improved physical fitness developed in childhood [46] facilitates the establishment of desired behaviors and habits that may carry over into adulthood [47]. If no motor learning takes place, the children risk missing the best period in their lives to acquire basic vital movement patterns [14].

The educators perceived the group sizes of children as large and therefore troublesome to manage in movement and PA. Movement and PA in large groups lead to risks for injury according to the educators. At the same time, they perceived organizing smaller groups from the large group as time-consuming and therefore this was not done. Other studies showed that children are organized into smaller groups only to a limited extent during ECEC [48,49] and children spend most of the time in large groups.

4.2. Educators' Descriptions of Risk Elimination

The educators in our study participated in teamwork and the group dynamics affected their stance regarding actions. Any educator's fear of injury affected the whole team and resulted in constructions of local rules to eliminate risks of injury. The construction of such rules often appeared after any incident, but also without the occurrence of any incident. The rules were often based on someone's concern that something might happen. The rules meant banning diverse kinds of physically active play, but also meant there was a low frequency of sessions of teaching movement and PA. The educators were eager to protect the children from injuries but their excessive zeal to make everything safe might have been counterproductive for resilience. Children's safe risk-taking offers learning experiences that help them to solve problems and develop an understanding of limits and boundaries, and that foster resilience and enhance learning [50]. Physical literacy developed in childhood is vital for a healthy adolescence and adulthood [51]. Excessive risk elimination is a risk that can lead to children easily becoming injured because they cannot assess risks themselves. They might also risk having poorly developed motor skills to cope with everyday situations both in childhood and during the rest of their lives. Physical

literacy is important for realizing the key role that the embodied dimension plays in life and affords an essential possibility to realize our potential as healthy humans [52].

4.3. Educators' Perceptions of Teaching Children Movement and PA

The educators' feelings of low competence and insecurity in teaching movements led them to mostly refrain from teaching the children to move but also led to them to introduce rules that banned movement. This was especially noticeable indoors but also outdoors. Preschoolers engage in little PA during their stay in ECEC. Children showed higher PA levels on days with structured movement sessions compared to those without, and the contribution of the structured sessions to PA levels was higher than that of free play [53].

The educators in our study perceived that it was difficult to arrange structured movement sessions because of low competence in teaching movement but also because of low personal fitness. This is troublesome as they do not follow the directives of the curriculum [54] as a result of personal shortcomings. The educators had low expectations of children's competence to assess risks, but also low expectations of children's motor skills, which resulted in limited challenges for the children. Expectations of children's achievement and the subsequent effects of such expectations have received attention for decades. Many factors play a role in shaping how educators form expectations of students and how students form expectations of themselves and their potential [55]. If educators' expectations of children are low, the children will not have elevated expectations of themselves either. The perception of low physical competency levels is itself a risk factor. Half-hearted movements or hesitant entry into situations involving body contact increase the risk of injuries [56]. Poor motor skills and low physical capacity levels lead to negative psychological outcomes and increased risk of injury [57].

The educators' fear of being accused and exposed in the media if children were injured in PA held them back from promoting PA. There is an inherent risk of injury in PA. However, the medically treated injury incidence rate was reported to be low, between 0.15 and 0.27 injuries per 1000 h of PA [6]. The low incidence rate should not be a reason to ignore the risk of injury, but there is a need to find a balance between healthy PA and an acceptable risk of injury. It is important to address this complexity and try to optimize interventions so that children can participate in activities that enhance motor skills. ECEC needs educators with pedagogical content knowledge of movement and PA to balance the desirable healthy PA and risk awareness. Instruction and adequate teaching in movement and PA is vital for motor development, not only activities in free play. The number of injuries related to unorganized PA in free play was shown to be higher than the number of injuries reported in organized movement activities [6]. Teacher-led sessions in movement increased children's PA levels [29]. In a review of studies performed in the ECEC setting, most of the studies call for further professional development of early childhood teachers specific to PA [58]. ECEC should be educational and involve training in fundamental motor skills [59] to increase physical literacy and physical self-efficacy [60], which could prevent injuries and promote lifelong PA. Empowering ECEC educators to serve as role models for all healthy behaviors may benefit sustainable wellness [61]. Thus, well-educated movement educators are a prerequisite for ECEC.

4.4. Strengths and Limitations

The strengths of this study are worth mentioning, but also the limits. Overall, the design of qualitative research has methodological considerations. It is always a crucial question regarding what type of conclusions can be drawn from interview studies. The study highlights the thoughts and perceptions of the 18 educators. The study focused on the educators' descriptions of their perceptions and experiences, which limits the generalizability. It is the nature of exploratory qualitative research to adopt a narrow focus to obtain in-depth contextual data.

The content analysis was thoroughly conducted, and the study findings were checked by a selection of participating educators during and after the analysis. There are limitations

concerning content and thematic analysis, but also strengths [37]. The study used the *child's perspective(s)* described by [40] Sommer et al. (2013) as the point of departure. The other part of the theory, *the children's perspective(s),* was not present as only the educators participated, and the children's voices were silent. Future studies should focus on the children's voices.

5. Conclusions

The educators' fear of injury risks limits the children's movement and PA occasions in ECEC. The educators' perceived poor personal motor skills and low fitness which combined with their perceived low competence to teach movement limit the possibility for the children to develop their motor skills, which in turn might affect children's physical literacy for sustainable PA and health later in life. As most children spend a substantial proportion of their waking hours in ECEC, educators are important for promoting, teaching, and modeling children's movement and PA. The risk is that educators through movement bans spread their fear of PA-related injury and aversion to movement, which could have negative consequences from a health perspective.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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