Physical fitness in preschool children: Correlates and intervention effects

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# Summary

## Summary

Children's physical fitness has decreased over the last decades. At the same time, the prevalence of overweight and obesity in children has increased dramatically. For public health, these trends are alarming because overweight and a decrease in aerobic fitness are already in children associated with increased cardiovascular risks. In addition, the interaction between poor fitness, low physical activity and high BMI leads to a vicious circle. Preschool time corresponds to the time of the adiposity rebound, a critical period for the development of overweight and obesity. Therefore, the preschool setting seems to be particularly relevant in the establishment of a healthy lifestyle and a healthy weight.

This research is based on the Ballabeina Study, a multidimensional lifestyle intervention aimed at increasing aerobic fitness and reducing BMI in preschool children. The cluster-randomized trial was conducted in German and French speaking regions of Switzerland with a high migrant population. The intervention targeted four lifestyle behaviors during one school year: an increase in physical activity, a balanced nutrition, sufficient sleep and a reduction in media use. For this thesis, cross-sectional and longitudinal measures of physical fitness (aerobic fitness, agility, static balance and dynamic balance), body composition (BMI, BMI-group and body fat) and cognition (attention and spatial working memory) were assessed and analyzed. In addition, the effects of the intervention on physical fitness in preschool children were evaluated. The thesis first describes the study design. The following publications focus on the physical fitness of preschoolers, on correlates and intervention effects.

The cross-sectional results showed that already in preschoolers, normal weight children performed significantly better in different dynamic fitness tests assessing aerobic fitness, agility and dynamic balance compared to their overweight counterparts. The differences in aerobic fitness and agility were more pronounced in older preschoolers compared to the younger ones. In the longitudinal analysis, the relationship between aerobic fitness, agility and balance with memory and attention was investigated. Higher baseline physical fitness was related to a better spatial working memory and attention at baseline, and to some extent also to their future improvements over the following 9 months. Contrary to this finding, higher baseline memory and attention levels were not associated with improvements in aerobic fitness or motor skills over the following 9 months. The dominant direction regarding the longitudinal association between measures was the relationship of physical fitness with future cognitive performance. The study also showed that the Ballabeina intervention was successful in increasing aerobic fitness and agility but not balance in the general population. Subgroup analysis revealed that overweight and low fit children benefitted at least equally from the intervention compared to their normal weight and normal fit peers.

This research has shown that physical fitness can be increased in children over one school year with a multilevel and multidimensional lifestyle intervention. Although coordination was not improved as a result of the intervention, the findings of this study are of great value, because aerobic fitness is the

physical fitness component that is most strongly associated with health related outcomes. This research was also able to show, that differences in physical fitness between normal weight and overweight children are more pronounced in older compared to younger preschoolers. It seems that the vicious circle of overweight and low physical fitness begins to manifest itself at this age. Therefore it is important to start with interventions already in preschoolers and to support children with low physical fitness starting at a young age. This might help to reduce the ongoing epidemiological trend of overweight and low fitness in children and the development of cardiovascular risk factors in the coming years. It is encouraging that overweight and low fit children can benefit equally from the intervention compared to their normal weight and normal fit peers. With respect to the cognitive abilities, our data was able to contribute to the emerging field of brain fitness and highlights the importance of promoting physical education in school. In conclusion, Ballabeina offers an effective school-based intervention program to increase fitness and reduce adiposity in both, the general population as well as the risk groups of overweight and/or low fit children.

Zusammenfassung

(German summary)

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In den letzten Jahrzehnten konnte ein Rückgang der körperlichen Leistungsfähigkeit bei Kindern beobachtet werden. In der gleichen Zeit stieg die Prävalenz von Übergewicht und Adipositas an. Für die öffentliche Gesundheit sind diese Trends beunruhigend, weil eine tiefe Fitness und Adipositas bereits im Kindesalter mit erhöhten kardiovaskulären Risiken im Zusammenhang stehen. Dazu kommt, dass eine schlechte Fitness, eine tiefe körperliche Aktivität und Übergewicht sich gegenseitig beeinflussen und zu einem Teufelskreis führen können. Das Kindergartenalter ist eine kritische Zeit für die Entwicklung von kindlichem Übergewicht, deshalb scheint der Kindergarten in der Vermittlung eines gesunden Lebensstils von besonderer Bedeutung zu sein.

Diese Forschungsarbeit basiert auf der Ballabeina Studie, einer Lebensstilintervention zur Steigerung der aeroben Fitness und zur Reduktion des BMI bei Kindergartenkindern. Die «cluster»-randomisierte Studie wurde in der deutsch- und der französischsprachigen Region der Schweiz durchgeführt. Die städtischen Settings waren geprägt durch einen hohen Anteil an Kindern mit einem Migrationshintergrund. Die einjährige Intervention zielte ab auf der Vermittlung von vier Lebensstilverhalten: mehr körperliche Aktivität, ausgewogenere Ernährung, weniger Medienkonsum und ein gesundes Schlafverhalten. Für die vorliegende Arbeit wurden Querschnitts- und Longitudinaldaten zur körperlichen Fitness (aerobe Fitness, Agilität, statisches und dynamisches Gleichgewicht), zur Körperzusammensetzung (BMI, Gewichtsstatus und Anteil Körperfett) und zur Kognition (Aufmerksamkeit und visuelles Arbeitsgedächtnis) erfasst und ausgewertet. Zusätzlich wurde der Interventionseffekt auf die körperliche Fitness der Kinder evaluiert. Die erste Publikation beschreibt das Studiendesign. Die darauf folgenden Arbeiten konzentrieren sich auf die körperliche Fitness von Kindergartenkindern, auf Korrelationnen und Interventionseffekte.

Die Resultate der Querschnittanalyse zeigten, dass normalgewichtige Kinder in verschiedenen dynamischen Fitnessparametern bereits im Kindergarten signifikant bessere Leistungen zeigen als übergewichtige Kinder. Bei den älteren Kindergartenkindern waren die Unterschiede in der aeroben Fitness und im Hindernislauf (Agilität) grösser als bei den jüngeren. In den Längsschnittanalysen wurden die Zusammenhänge zwischen aerober Fitness, Agilität und Gleichgewicht untersucht. Bessere körperliche Fitness zu Beginn der Studie stand im Zusammenhang mit einem besseren visuellen Arbeitsgedächtnis und mit einer gesteigerten Aufmerksamkeit ebenfalls zu Beginn der Studie aber zum Teil auch mit einer besseren kognitiven Leistung neun Monate später. Dagegen standen die Gedächtnisund Aufmerksamkeitsleistung zu Beginn der Studie nicht im Zusammenhang mit der späteren körperlichen Fitness. Das bedeutet, dass der positive Zusammenhang zwischen der körperlichen Fitness und der späteren kognitiven Leistung die dominante Richtung dieser Verbindung ist. Die Analyse der Interventionsstudie zeigte positive Effekte in der Erhöhung der aeroben Leistungsfähigkeit und der Agilität, aber keine Verbesserung des Gleichgewichts. In der Analyse der Untergruppen konnte gezeigt werden, dass übergewichtige Kinder und Kinder mit einer tiefen Fitness mindestens gleich stark von der Intervention profitierten, wie ihre normalgewichtigen und fitten Altersgenossen.

Diese Arbeit zeigt, dass die körperliche Fitness bei Kindern mit einem intensiven und vielseitigen einjährigen Programm signifikant gesteigert werden kann. Obwohl in der Koordination keine Interventionseffekte erzielt werden konnten, sind diese Resultate bedeutend, weil die aerobe Fitness für die Gesundheit die wichtigste Fitnesskomponente darstellt. Die Unterschiede in der Fitness zwischen den Normalgewichtigen und den Übergewichtigen waren bei den älteren Kindern verglichen mit den jüngeren grösser. Übergewicht und reduzierte Fitness scheinen sich also bereits im Kindergartenalter in einem Teufelskreis zu manifestieren. Deshalb ist es wichtig bereits im Kingergarten mit Interventionen zu starten und Kindern mit einer tiefen Fitness möglichst früh Unterstützung zu bieten. Es ist erfreulich, dass gezeigt werden konnte, dass von der Lebensstilintervention auch übergewichtige Kinder und Kinder mit einer tiefen Fitness profitieren können. Die Daten in Bezug auf die kognitiven Fähigkeiten tragen zum noch wenig untersuchten Feld der «brain fitness» bei und unterstreichen den Nutzen der Bewegungsförderung im Kindesalter. Zusammengefasst bietet Ballabeina eine effektive Schulintervention zur Steigerung der körperlichen Fitness und zur Reduktion von Adipositas. Die Intervention war erfolgreich in der allgemeinen Bevölkerung, erreichte aber auch übergewichtige Kinder oder Kinder mit einer tiefen Fitness, die zur kardiovaskulären Risikogruppe gehören. Physical fitness in preschool children: correlates and intervention effects

Introduction

## 1. Introduction - Physical fitness and body composition in children

## 1.1. Epidemiology

Children's physical fitness has decreased over the last decades.<sup>1-3</sup> Large population studies of 6- to 19-year-old children from 27 countries demonstrate a decline in aerobic fitness of 0.4% per year between 1970 and 2003.<sup>1</sup> Likewise, general physical fitness has also declined by around 10% from 1975-2000 as demonstrated in a cohort of 6- to 17-year-old children in Germany.<sup>3</sup> Similar results have been found in Canada comparing data from 1981 and 2007-2009.<sup>2</sup> In the same time the prevalence of overweight and obesity in children has increased and despite a possible recent stabilization, represents a great public health concern.<sup>4</sup> Already in young children, a reduced aerobic fitness<sup>5-7</sup> and overweight or obesity<sup>8</sup> are associated with cardiovascular risk factors. In addition, low fitness, decreased physical activity and overweight can influence each other, leading to a vicious circle<sup>9</sup> that further complicates treatment efforts. Preschool is a critical time for the adiposity rebound<sup>10</sup> and the development of overweight and obesity. Therefore, the preschool setting seems to be particularly relevant in the establishment of a healthy lifestyle and a healthy weight. We therefore carried out a schoolbased multidimensional cluster randomized controlled trial (Ballabeina) to increase aerobic fitness and reduce BMI in preschool children. Within this huge research field, I was particularly interested in correlates of physical fitness such as the relationship of physical fitness with overweight or with cognitive performance. In my main research questions, I assessed, whether physical fitness in young children can be modulated by a lifestyle intervention in the preschool setting and whether high-risk groups of overweight and low fit children benefitted equally from the intervention compared to their normal weight and normal fit counterparts.

Physical fitness is a multifaceted concept and there are several different definitions of physical fitness and its related components depending on the scientific field in which one operates. «Physical fitness», «exercise» and «physical activity» are different terms describing different concepts. Unfortunately, these terms are often confounded.<sup>11</sup> In this research thesis, the focus is set on physical fitness, however, as these terms are often used interchangeably in the literature,<sup>11</sup> it is sometimes difficult to make a clear distinction. Measuring weight categories in children is also challenging because of sex differences and the BMI changes associated with age.<sup>12</sup> I will therefore spend a first chapter of this work on the terminology of physical fitness and body composition.

## 1.2. Physical fitness and body composition

Physical fitness can be defined as "a set of attributes that people have or achieve that relates to the ability to perform physical activity"<sup>13</sup> or exercise training.<sup>13</sup> In the field of public health, the most frequently cited components of physical fitness fall into two groups: one related to health and the other related to motor skills (Figure 1).<sup>14</sup>



In the definition of Pate<sup>14</sup> and Caspersen et al.<sup>11</sup> that was later used by other authors,<sup>15</sup> body composition (sometimes also called morphological fitness) is a component of physical fitness. However, in the current research it is often necessary to make a difference between the morphological component and the cardiorespiratory and motor components, as these concepts are analyzed in detail. In the present work we will therefore use the terms **physical fitness (aerobic fitness, agility, balance)** and **body composition (BMI, BMI-group, body fat)** separately (Figure 2), as has been done in other studies.<sup>16</sup> In response to our publications, some reviewers stated that the term «physical fitness» should be defined in terms of four components: aerobic fitness, muscular strength, muscular endurance and flexibility and that agility and balance were not part of physical fitness. As we did not find any references to back up this position, we based our methodology on the above mentioned definition of Pate et al.,<sup>14</sup> in our opinion the most appropriate concept in our scientific field. However, to meet the feedback of these reviewers, we additionally separated the term **physical fitness** into **aerobic fitness** and into **motor skills (agility, balance)** in the respective publications (Figure 2). The following to chapters will give an overview over the assessed measures. Further information can be found in the study design paper **(publication 1)**.

**Aerobic fitness** 

Motor skills

- Physical fitness:
- aerobic fitness (20m shuttle run test)
- agility (obstacle course)
- static balance (balance platform)
- dynamic balance (balance beam)
- ➔ Body Composition:
- BMI (kg/m<sup>2</sup>)
- BMI-group (Overweight, normal weight)
- body fat (skinfolds, waist circumference, bioimpedance analysis)

**Figure 2** Physical fitness and body composition measures of the current study.

#### 1.2.1. Physical fitness

#### a) Aerobic fitness

In the study underlying this thesis, the 20 m shuttle run test was used to assess aerobic fitness:

Aerobic fitness reflects the overall capacity of the cardiovascular and respiratory systems to supply oxygen during sustained physical activity, as well as the ability to carry out prolonged exercise.<sup>17,18</sup> Aerobic fitness tests often measure the maximal oxygen consumption (VO<sub>2max</sub>) as an indicator of aerobic fitness. In epidemiological studies involving young people, the most common test for an indirect assessment of aerobic fitness has been the 20m shuttle run test.<sup>19</sup> Aerobic fitness and cardiorespiratory fitness or endurance refer to the same concept and can be used interchangeably.<sup>20</sup>

## b) Motor skills

The skill-related fitness consists of those components of physical fitness that have a relationship with enhanced performance in sports and motor skills. There is a confusing amount of possibilities to assess motor skills. However, these tests are often part of a larger test battery and reliability and validity information about the specific skill related domains like balance or agility are often lacking. In the basic study of this research, we have assessed the following skill-related fitness measures:

- Agility corresponds to the ability to rapidly change the position of the entire body in space with speed and accuracy.<sup>11</sup> Agility tests measure a combination of speed, strength, spatial orientation and memorization of a specific sequence of actions.<sup>21</sup> In general, mostly obstacle courses are used to test agility. The Illinois test is considered a standard test for agility in school children (children have to run a 10 m long zig-zag run without knocking the cones over).<sup>21</sup> The «Allgemeiner Sportmotorische Test für Kinder (AST 6-11)» also describes an agility test.<sup>22</sup> This obstacle course includes jumping over, crawling under or turning around obstacles like benches and marking coins. In fact it is very similar to the test we used in the present study, but the one we've chosen for the preschoolers is easier (shorter and less complicated).<sup>23,24</sup>
- **Balance** relates to the maintenance of equilibrium while stationary (static balance) or moving (dynamic balance). Balance tests measure the postural control and mostly include task on gaits, balance platforms or balance beams (with or without dual-task conditions or perturbations). Static balance can be assessed on one or on two legs and with open or closed eyes.<sup>25</sup> In the study underlying this research both, static and dynamic balance have been assessed. Due to the young age of the children tests were performed with open eyes and without dual-task conditions or perturbations.

## 1.2.2. Body composition

Body composition relates to the relative amount of muscle, fat, bone and other vital parts of the body. The measures used to assess body composition are for example body mass index (BMI) or body fat.<sup>11</sup>

- The **body mass index (BMI)**, calculated as the weight in kilograms divided by the square of the height in meters (kg/m<sup>2</sup>) can be used as a continued variable or to classify children as over-weight or obese.
- **Overweight and obesity** are defined as an abnormal or excessive fat accumulation that may impair health.<sup>26</sup> The World Health Organization proposed an international classification of weight status categories in adults based on BMI cut-off points independent of age and sex where underweight is considered as BMI < 18.5, normal weight as  $18.5 \le BMI < 25$ , overweight as  $25 \le$ BMI < 30 and obese as BMI  $\ge$  30.<sup>27</sup> In children, age- and gender-specific BMI percentiles are used to report weight categories<sup>28</sup> but there is no standard for weight categories in children applied worldwide. Several BMI precentiles based on national<sup>29,30</sup> or international<sup>12,31</sup> data have been developed. Depending on the reference population(s) and the year the percentiles have been established, different BMI-values correspond to the cut-offs of overweight and obesity. For most BMI-centile curves, the respective 90th and 97th percentiles serve as respective cut-offs for overweight and obesity, except for the United States references of the Centers for Disease Control and Prevention (CDC)<sup>32</sup> were the cut-offs used are the 85th and the 95th percentiles. National percentiles are known to be more sensitive than the international ones.<sup>33,34</sup> We therefore use the national percentiles in the publications 2 and 5. However, to ensure the international comparison, the percentiles of the International Obesity Task Force (IOTF)<sup>12</sup> have been used in publication 4 although they have been criticized not to respect gender differences. For simplicity, the term «overweight» is used for overweight and obesity, unless stated otherwise.
- There are several methods to measure **body fat.** Waist circumference is a measure of central body fat. To assess total body fat, the skinfold thickness or bioimpedance analysis can be used in large epidemiological studies as they are well correlated with dual energy x-ray absorptiometry (DXA).<sup>35-38</sup> Percent body fat can be calculated based on the skinfold thickness according to different formulas. The formulas of Slaughter, Deurenberg and Dezenberg<sup>35,39,40</sup> are validated in preschool children. The calculation of percent body fat with this method has a prediction error of 3–5%.<sup>39,40</sup> Percent body fat can also be calculated based on bioimpedance analysis according to validated formulas for children.<sup>36,37,41</sup> The coefficient of variation between different bioelectrical impedance analysis measurements was less than 1.5% and for the calculation of fat-free mass it was 5.8%.<sup>37</sup>

## 1.3. Correlates of physical fitness

Physical fitness is important for children's health, affecting the cardiorespiratory, hematocirculatory, musculo-sceletal, psychoneurological and endocrine-metabolic systems.<sup>42,43</sup> In contrast to adults, the association between physical fitness with numerous health benefits in children cannot directly be documented with morbidity or mortality data.<sup>44</sup> Therefore, studies in children are mostly restricted to examining surrogate markers. For example overweight/obesity, high blood pressure, elevated blood lipids and fatness are used to indicate a higher risk for cardiovascular disease (CVD).<sup>44</sup> The relationships with CVD risk factors are the most extensively studied benefits of physical fitness,<sup>44</sup> possibly due to the importance of CVD as a cause of mortality in the developed world.<sup>45</sup> Different dimensions of physical fitness such as aerobic fitness, muscular strength and motor skills are related to the below mentioned benefits, but aerobic fitness is most strongly related to different health aspects in children.<sup>44</sup> In general, many of the studies on the relationship between physical fitness and health in children have been large-scale, cross-sectional population surveys, and more large longitudinal studies are needed.<sup>46,47</sup> It is therefore important to keep in mind that the mentioned relationships are based on limited pediatric data, although there are stronger adult data, and sound physiological and psychological principles that underline the assumptions in children.<sup>46</sup>

- Childhood obesity: In school children, strong relationships between obesity (a CVD risk factor) and low physical fitness, particularly low aerobic fitness, have been found in cross-sectional<sup>42,48-53</sup> and in longitudinal studies.<sup>54-57</sup> The relationship in younger children is less clear. Aerobic fitness is also positively associated with other CVD risk factors (see below), and seems to protect particularly overweight and obese children from CVD risk factors.<sup>7,58,59</sup>
- Other CVD risk factors: Today it is known that CVD often starts in childhood, even though the clinical symptoms of this disease do not become apparent until much later in life.<sup>60-62</sup> Cross-sectional and longitudinal studies in children show a strong inverse relationship between physical fitness (especially aerobic fitness) and the prevalence of other CVD risk factors<sup>42,47,48</sup> such as dyslipidemia, glucose intolerance or high blood pressure. Longitudinal studies show mostly moderate relationships between low aerobic fitness and later CVD risk factors.<sup>47,57,63-65</sup> The mentioned relationships are stronger when several risk factors are analyzed concomitantly, either in the form of clustering<sup>66</sup> or when using the definition of the metabolic syndrome.<sup>67,68</sup> In addition, exercise intervention studies have shown significant beneficial effects on CVD risk factors.<sup>69-71</sup>
- Bone mineral mass: Bone mass is a key determinant of fracture risk. Maximizing bone mineral mass during childhood and adolescence may contribute to fracture risk reduction during adolescence and possibly in the elderly.<sup>72</sup> Several studies in preadolescent children<sup>72-79</sup> many of them exercise interventions<sup>73-77</sup> demonstrate a positive relationship between physical activity training and a gain in bone mineral mass. Weight-bearing physical activities<sup>72</sup> such as jumping and training in muscular fitness or speed/agility<sup>42</sup> seem to have a positive effect on skeletal health.
- Chronic diseases: In the US, about 6.5% of all children suffer from a chronic disease.<sup>80</sup> Effects of physical fitness on children and adolescents with chronic diseases such as rheumatism, arthritis, asthma, cystic fibrosis, diabetes or cancer have not been studied adequately.<sup>81,82</sup> Children with chronic diseases are not always but often less fit then healthy children partly due to decreased physical activity (deconditioning), partly due to direct consequences of the dis-

ease or the therapy.<sup>83-88</sup> If no contraindications are present, aerobic fitness, muscular fitness and functional mobility enhancements are recommended in children with chronic diseases in order to compensate their reduced fitness, to attenuate fatigue and/or to improve their quality of life.<sup>81,83,86-88</sup> Similarly, in children that have successfully survived a disease, enhancement of physical fitness is recommended, to compensate deficits as quickly as possible.<sup>86</sup>

- Mental health: There are some studies indicating that improvement in aerobic fitness has short-term and long-term positive effects on depression, anxiety, mood status and self-esteem.<sup>42,89</sup> Better studied are the positive associations between physical activity and depression,<sup>90</sup> anxiety<sup>90</sup> and self-esteem.<sup>91</sup> However, as data are derived mainly from cross-sectional and quasi experimental studies, conclusions about causality are dare.<sup>87</sup>
- Cognitive performance: Cross-sectional studies show that higher physical fitness (mainly aerobic fitness, but also motor skills such as balance or agility), might be related to cognitive benefits in children. <sup>92-95</sup> However, longitudinal relationships are less clear.<sup>95</sup>

In addition to its benefits, physical activity and exercise training aiming to improve physical fitness carry inherent risks such as accident injuries or overload damage. The roles and responsibilities of teachers, parents, sports governing bodies and coaches in this matter are considerable and the risks and benefits must be carefully balanced. To date, it seems that the benefits of physical fitness are clearly predominant.<sup>44</sup>

In the context of the current research I will in the following focus on the relationship of physical fitness with overweight as one of the most relevant health issues and on the relationship of physical fitness with cognition as an underinvestigated topic of growing importance.

#### a. Physical fitness and childhood overweight/obesity

The most frequent negative short term consequences of childhood obesity are psychological morbidity and the clustering of CVD risk factors, NAFLD (non-alcoholic fatty liver disease) etc.<sup>96</sup> Similarly, type 2 diabetes and the metabolic syndrome in youth have increased concomitantly to the increase in childhood obesity.<sup>97</sup> In the long term, childhood obesity often persists into adulthood and cardiovascular and general morbidity/mortality is increased.<sup>98,99</sup> Additionally, the socioeconomic impact of obesity in adolescence and young adulthood is considerable.<sup>96</sup>

In school children, strong relationships between obesity and low physical fitness, particularly low aerobic fitness, have been found in cross-sectional<sup>42,48-50</sup> and longitudinal studies.<sup>54-56</sup> One cross-sectional study reported associations between abdominal and total adiposity and lower limb explosive strength, abdominal endurance strength and speed/agility<sup>100</sup> and a longitudinal study between the sum of four skinfolds and motor skills.<sup>101</sup> In prepubertal primary school children, differences between normal weight and overweight/obese children have been found in aerobic fitness,<sup>102-104</sup> while differences in motor skills are more controversial.<sup>53,104,105</sup> In preschool children it is even less clear, if differences in physical fitness between normal weight and overweight/obese children already exist. Only few studies have been performed and most of them are small and their results are inconclusive.<sup>106,107</sup> In addition, they only measure motor skills in this young age group, while differences in aerobic fitness have not been studied. Therefore, it remains unknown whether the vicious circle of low fitness and overweight begins already during the preschool years. In the cross-sectional analysis of the **publication 2** this issue will be addressed to find out if the preschoolers of the Ballabeina Study show BMI-group-related differences in their physical fitness including aerobic fitness, agility and balance.

#### b. Physical fitness and cognitive performance

Ten years ago, first data revealed that motor and cognitive development in children may be more interrelated than previously appreciated.<sup>108</sup> There currently exists considerable pressure of schools to enhance cognitive performance.<sup>109</sup> In this context, the observed decrease in children's physical fitness over the last years<sup>1,3</sup> has fuelled the debate about a possible relationship between physical fitness and cognitive development in children. Cross-sectional relationships of aerobic fitness with measures of cognitive performance such as attention and working memory have been found in preadolescent schoolchildren.<sup>110-112</sup> Additionally, data from recent cross-sectional studies demonstrate that not only aerobic fitness, but also other domains like motor skills (e.g. balance, agility, ball skills) may be related to cognitive performance.<sup>113-117</sup> While cross-sectional studies point towards a positive relationship between aerobic fitness and/or motor skills with cognitive performance,<sup>92,113-118</sup> longitudinal data<sup>118,119</sup> and intervention studies<sup>92,118</sup> are few and more inconclusive.<sup>118</sup> Furthermore, there is a general lack of information in young children. Of the few studies in preschoolers<sup>113,114,117</sup> one presents controversial results<sup>117</sup> and one was of a poor design (i.e. no adjusting for sex and age).<sup>114</sup> In addition, they did not assess the relationship of aerobic fitness with cognition. Three hypotheses how exercise may affect cognitive performance have been put forward:<sup>120</sup> (1) increase in oxygen saturation based on an increased blood flow and angiogenesis, (2) increase in brain neurotransmitters like serotonin and norepinephrine facilitating information processing and (3) regulation of neurotrophins such as different growth factors. Recent studies in rodents support additionally the concept of a stimulation of neurogenesis in the hippocampus and the subventricular zone.<sup>121</sup> This might be important for lasting and cumulative network adaptations.<sup>121</sup> It is assumed that a similar mechanism could work in humans. The publication 3 of the current research investigates a possible cross-sectional and longitudinal relationship of different domains of physical fitness (aerobic fitness, agility and balance) with attention and spatial working memory in young children. A focus will thereby be set on the question whether the relationships vary according to the different investigated domains.

## 1.4. Determinants of physical fitness

Physical fitness is influenced by genetic factors and lifestyle factors such as physical activity and nutritional behavior.<sup>122</sup> Genetic contributions to fitness are important but probably account for less of the variation observed in fitness than is due to (non-transmissible) environmental factors, principally physical activity.<sup>123</sup> Physical activity is associated with sex (male), parental overweight (inverse), physical activity preferences, intention to be active, perceived barriers (inverse), previous physical activity, healthy diet, program/facility access, and time spent outdoors.<sup>124,125</sup> Physical activity is also determined by genetic and environmental factors. Additionally, physical activity might also be influenced by physical fitness through different mechanisms such as an improved physiological condition for physical activity or an increased self-efficacy when being physically active.<sup>126</sup> For most individuals, increases in physical activity produce increases in physical fitness, although the amount of adaptation in fitness to a standard exercise dose varies widely and is under genetic control.<sup>127</sup> In children, however, this relationship is not as clear as in adults, probably due to the complexity of assessing physical activity in children. At present we know that the association between physical activity and aerobic fitness is related to the intensity of physical activity.<sup>42</sup> Increased levels of vigorous (rather than light/moderate) physical activity seem to be positively related to aerobic fitness in children in cross-sectional and longi-tudinal data.<sup>128-130</sup> Some data indicate also a relationship between physical activity and motor skills.<sup>130</sup>

Due to the strong link between physical activity as a behavior and physical fitness as a set of attributes, it is obvious that it might be difficult to make a clear distinction between benefits of physical activity and physical fitness. Physical activity and lifestyle interventions mostly have the objective to increase physical fitness, probably because physical fitness is easier to assess.

#### 1.5. Intervention studies to improve physical fitness

In the preschool setting, eight randomized controlled lifestyle or physical activity interventions have been performed,<sup>134-141</sup> but only some of them assessed physical fitness measures like aerobic fitness<sup>134,135</sup> or motor skills.<sup>137,138</sup> In the study of Eliakim et al.,<sup>134</sup> 54 preschool children completed a 14-week combined dietary behavioral physical activity intervention and were compared to 47 age matched controls.<sup>134</sup> The physical activity intervention consisted of an exercise training of 45 min at six days of the week. Twice a week the training was directed by a professional youth coach. The rest of the week physical activity was coordinated by the preschool teacher and the training was then divided into three 15 min sessions. The lessons were held indoors and/or outdoors and were based on circuit training. Endurance type activities accounted for most of the time spent in training, with attention also given to coordination and flexibility skills. Children were additionally encouraged by the study staff to reduce sedentary activities and to increase their after school physical activity. Physical fitness was assessed using a 600 m run before and at the end of the 14-week program. The same authors published in 2011 the results of a randomized school-based intervention on nutrition and physical activity knowledge and preferences.<sup>135</sup> This intervention lasted one school year and 376 intervention and 349 control children participated in the study. The physical intervention was very similar to the previous study. This time, fitness was assessed by use of the 10 m shuttle run test, as the standard 20 m shuttle run was not feasible due to space restraints. However, no data were given regarding the correlations between both tests in general and specifically in this age group. All over, the physical activity

interventions of both studies were comparable to the Ballabeina Study. In terms of measurements, Ballabeina used the 20 m shuttle run for aerobic fitness and also assessed skill-related fitness measures such as agility and balance. There also exist three exercise intervention studies from Japan, each consisting of 16 to 57 preschoolers,<sup>142-144</sup> though it is unclear from their reports if these studies are randomized controlled studies. Their intervention lasted 6 to 14 months and comprised a daily morning run (six days per week) of 750 to 1500 m as part of the regular preschool curriculum. Before, during and after the training, a running test was performed.

In general, data about the effect of physical activity or lifestyle interventions on young children's fitness are rare as well as the knowledge about how to conceptualize an effective lifestyle intervention. We therefore carried out a multidimensional lifestyle intervention to increase aerobic fitness and reduce BMI in preschool children (Ballabeina). Ballabeina is the Rhaeto-Romanic meaning of «see saw» or «swing» and stands for a children's life in balance but also in drive. This cluster-randomized trial was conducted in August 2008 to June 2009 in 40 preschool classes in the German and French speaking regions of Switzerland (with a high migrant population). The intervention targeted four lifestyle behaviors during one school year: an increase in physical activity, a balanced nutrition, sufficient sleep and a reduction in media use. The main outcome measures were aerobic fitness and BMI as primary outcomes and percent body fat, waist circumference, motor agility, balance, physical activity, eating habits, media use, sleep, psychological health and cognitive abilities as secondary outcomes. The study was mainly founded by the Swiss National Science Foundation and the Health Promotion Switzerland. In **publication 4** of this research the effects of Ballabeina on the general preschool population are analyzed and discussed.

To our knowledge, no previous population-based intervention study in school or preschool children has specifically addressed if the intervention is equally effective in high-risk groups of overweight or low fit children. There are, however, programs and studies focusing on treatment of childhood overweight.<sup>145-147</sup> Counseling in primary care, i.e. by family practitioners, has shown only modest results.<sup>148-151</sup> Comprehensive intensive behavioral interventions in specialized medical centers yielded mostly positive short-term results with some evidence for persistence of effects.<sup>148,152</sup> A big disadvantage of the treatment is that only about 10% of obese children and adolescents seek weight loss treatment.<sup>146</sup> In Switzerland, around 200 obese children and adolescents benefit yearly from specialized obesity programs, while 60'000 obese would be in need for therapy.<sup>153</sup> Additionally, the studied programs are mostly interdisciplinary interventions. Based on the need for effective strategies to reduce body fat and increase fitness in overweight and/or low fit children, we investigated in **publication 5** whether the high-risk groups of overweight and low fit children benefitted equally from the intervention compared to their normal weight and normal fit peers.

## 1.6. Aim of the research

The main focus of the Ballabeina Study was to describe the development and effectiveness of a lifestyle intervention aiming at increasing aerobic fitness and decreasing BMI in Swiss preschool children. The publications summarized in this thesis focus on physical fitness in preschoolers, their correlates and intervention effects.

- The **publication 1** describes the study design and provides detailed information about its background and methods.
- Does the vicious circle of low fitness and overweight already begin during the preschool years? Based on this question, the cross-sectional analysis of the **publication 2** discusses BMI-group-related differences in different measures of physical fitness (aerobic fitness, agility, balance) of preschoolers.
- The literature indicating a relationship between physical fitness and cognitive performance is still scarce and especially lacking in young children. The **publication 3** assesses if there exist cross-sectional and/or longitudinal relationships between different physical fitness measures and memory and attention in preschoolers.
- The findings on benefits of physical fitness are of limited use, if we do not have successful intervention strategies to increase physical fitness. The **publication 4** focuses on the effectiveness of the Ballabeina intervention in increasing physical fitness measures such as aerobic fitness, agility and balance in preschoolers.
- Based on the need for effective strategies to reduce adiposity and increase fitness in high-risk groups such as overweight and/or low fit children, we assessed in the subgroup analysis of publication 5 whether high-risk groups of overweight and low fit children benefit equally from the Ballabeina intervention compared to their normal weight and normal fit peers.

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## **Publication 1**

## Influence of a lifestyle intervention in preschool children on physiological and psychological parameters (Ballabeina): study design of a cluster randomized controlled trial

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## Study protocol

## Influence of a lifestyle intervention in preschool children on physiological and psychological parameters (Ballabeina): study design of a cluster randomized controlled trial

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#### Abstract

**Background:** Childhood obesity and physical inactivity are increasing dramatically worldwide. Children of low socioeconomic status and/or children of migrant background are especially at risk. In general, the overall effectiveness of school-based programs on health-related outcomes has been disappointing. A special gap exists for younger children and in high risk groups.

Methods/Design: This paper describes the rationale, design, curriculum, and evaluation of a multicenter preschool randomized intervention study conducted in areas with a high migrant population in two out of 26 Swiss cantons. Twenty preschool classes in the German (canton St. Gallen) and another 20 in the French (canton Vaud) part of Switzerland were separately selected and randomized to an intervention and a control arm by the use of opaque envelopes. The multidisciplinary lifestyle intervention aimed to increase physical activity and sleep duration, to reinforce healthy nutrition and eating behaviour, and to reduce media use. According to the ecological model, it included children, their parents and the teachers. The regular teachers performed the majority of the intervention and were supported by a local health promoter. The intervention included physical activity lessons, adaptation of the built infrastructure; promotion of regional extracurricular physical activity; playful lessons about nutrition, media use and sleep, funny homework cards and information materials for teachers and parents. It lasted one school year. Baseline and post-intervention evaluations were performed in both arms. Primary outcome measures included BMI and aerobic fitness (20 m shuttle run test). Secondary outcomes included total (skinfolds, bioelectrical impedance) and central (waist circumference) body fat, motor abilities (obstacle course, static and dynamic balance), physical activity and sleep duration (accelerometry and questionnaires), nutritional behaviour and food intake, media use, quality of life and signs of hyperactivity (questionnaires), attention and spatial working memory ability (two validated tests). Researchers were blinded to group allocation.

**Discussion:** The purpose of this paper is to outline the design of a school-based multicenter cluster randomized, controlled trial aiming to reduce body mass index and to increase aerobic fitness in preschool children in culturally different parts of Switzerland with a high migrant population.

Trial Registration: Trial Registration: clinicaltrials.gov NCT00674544

#### Background

Obesity is considered to be a global epidemic by the World Health Organization [1]. The marked increase in childhood obesity is alarming and already present in preschool children reaching 26 % in 2- to 5-year old children and to 37 % in 6- to 11-year old children [2]. In Switzerland there is a prevalence of overweight and

obesity of around 20 % and 23 % in 6- to 12-year old boys and girls [3]. The prevalence of overweight/obesity and of physical inactivity is especially increased in children of low socioeconomic status (SES) [4] and/or children of migrant background [5, 6].

Obese children are at increased risk to become obese adults [7, 8] and this tracking becomes stronger the closer the child gets to adult status [9]. Yet, overweight preschool children have an over fivefold risk to be overweight at age twelve years compared with normal weight preschoolers [8]. Childhood obesity is already associated with cardiovascular disease risk factors [10-13] as well as other complications [7, 8] and is an independent predictor of coronary heart disease in adulthood [14].

The main environmental causes attributed to the enormous increase in body fatness in the last few decades are an increase in energy intake through food and a decrease in energy expenditure through a decrease in physical activity (PA) and/or an increase in sedentary behaviour [15]. One of the most important contributors to sedentary behaviour is media use (TV, PC, game use) [16] which is also related to energy intake [16]. Another postulated factor associated with obesity and insulin resistance is a lack of sleep [17]. Social, cultural and economic factors also influence energy balance.

In the last years, cross-sectional and longitudinal data have shown that the increased intake of foods with high fat or sugar content [18], high energy snacks, sweets and sugar-added beverages is associated with increasing BMI [18-20]. In addition, over the last 20 years, aerobic fitness has decreased by around 8 % in children from developed countries [21]. In contrast to aerobic fitness, there are no population-level objective data on temporal changes in total PA. However, some data indicate that children have become less physically active or less engaged in sports participation in the last years [22, 23]. Nowadays, 3- to 5-year old children monitored with accelerometers spent around 80 % of their time in activities of <1100 counts/min [24], which is considered to be sedentary behaviour or at most light PA [25]. In children, physical inactivity and reduced aerobic fitness are associated with increasing prevalence of cardiovascular risk factors [26-28] even independently of weight status [28, 29].

As the great majority of obesity treatment studies show a lack of selected and longstanding effectiveness [30], primary prevention is absolutely essential. But shortand long-term studies in recent reviews show only small or no positive effects in BMI, SF and/or PA [31-34]. Implementing successful studies or projects is even more difficult in children from families of less advantaged SES and/or migrant background [34, 35]. Although the period between the ages four and seven (the timing and the magnitude of the so called obesity rebound) has been suggested as a crucial time for development of overweight and obesity in children, there is a lack of studies in younger children [34]. For these reasons, we developed a study to assess the effect of a multidisciplinary lifestyle intervention on BMI and aerobic fitness by focusing on a young age group (preschoolers) and on children of migrant background (Ballabeina – Kinder im Gleichgewicht / enfants en équilibre). Ballabeina is Rhaeto-Romanic and means swing, teeter-totter, seesaw. This name of the study stands for a life in drive but also in balance.

#### **Theoretical model**

Causes for overweight and obesity are multifaceted and prevention is difficult and complex. In the last years, social models of health promotion have been increasingly used to study complex interactions [36, 37], as simple interventions are unlikely to work on their own and the development of effective preventive interventions requires strategies that affect multiple settings simultaneously [38]. Ballabeina is based on the social ecological model [36] (figure 1), that includes concentric rings that influence lifestyle patterns. The "psychobiologic core" of the model represents the genetic, physiologic, and socio-cultural forces that shape ones identity (individual child). This core is surrounded by the microsystem, the immediate environments with which a child interacts (parents, siblings, teachers, peers, etc.). The exosystem includes environments with which the child doesn't usually directly interact, but that can still affect the child (school boards, etc.). The macrosystem includes the broad societal settings under which the other cycles function (culture, history, social norms, economic system, etc.). For preschooler, the two main influence factors are the family and the teachers [39]. That's why the main intervention targets included these settings. The program promotes a healthy lifestyle by positively influencing personal, behavioral, and environmental factors. On the one side the intervention program transferred knowledge about adequate PA, nutrition and healthy food selection, reduced media use and proper sleep. On the other side



#### Figure 1: Ecological Model

Bronfenbrenner's Ecological Model describing the environmental influences on a child, with permission from [39].

the intervention also seeked to change the behavior of the child by increasing skills like motor abilities and augmenting daily PA. In addition the children and parents learned in a practical way strategies to change their nutritional behavior according to five nutrition messages (see below). The teachers achieved competencies by implementing PA and nutrition lessons in the preschool. On the environmental level, the built infrastructure (in- and outdoor in preschool) was adapted to enhance the child's natural behaviour to move and to explore. Participation of the children in extracurricular sport activities (club, etc.) in their neighbourhoods was promoted. The Ballabeina team also collaborated with the school boards, the building authorities and the school health services.

#### Methods/Design

#### Study objectives

The aim of the study was to evaluate the effects of a multidisciplinary multilevel lifestyle intervention in preschool children (aged 4- to 6-years) during one schoolyear in a multicenter cluster randomized controlled trial. The study included 40 randomly selected preschool classes and was conducted in the French (canton Vaud, VD) and in the German (canton St. Gallen, SG) part of Switzerland, focusing on areas with a high prevalence of migrant children.

#### Main outcomes

Primary outcomes:

- BMI
- Aerobic fitness (20 m shuttle run)
- Secondary outcomes:
- Total (sum of four SF, bioelectrical impedance) and central (waist circumference) body fatness
- Other motor abilities (obstacle course, balance platform, balance beam)
- PA and sleep duration (accelerometry and questionnaires), media use, nutritional behaviour and food intake of the child and the family (all questionnaires)
- General health (child and family), health-related quality of life, presence of hyperactivity (all questionnaires)
- Cognition tests (testing attention and spatial working memory ability)

Null-hypothesis: Potential differences in the primary outcomes between the INT and the CON groups at the end of the intervention will be entirely due to chance.

#### Study Design

Figure 2 shows a flow diagram of the recruited population. It was performed in two (SG & VD) out of 26 Swiss cantons. The German (SG) and the French (VD) parts of Switzerland represent two culturally distinct regions with different school and preschool systems. Classes from SG and VD were therefore separately selected



- 10 single preschool classes
- 3 single preschool classes, 2x2 classes in one school, 1x3 classes in one school
- 4 single preschool classes, 2x3 classes in one school.

Figure 2: Participants flow chart

and randomized after agreement of the school directors and the school health services of both cantons. The city of St. Gallen and the Lausanne area were chosen due to a high prevalence (i.e. at least 40 %) of children of migrant background. Migrant background was defined as at least one parent born out of Switzerland. The prevalence of 40 % was chosen as the school board estimated that in large adjacent areas with a high prevalence of a migrant population, 40-70 % of children were of migrant background. For the selection and randomization opaque envelopes were used. For practical reasons, and to reduce an effect of contamination, preschool classes integrated in the same school building were randomized into the same group.

For all children an informed consent from a parent or a legal representative was necessary in order to participate in the study. Of the 727 children visited the chosen preschools, consent was obtained from parents/legal representatives for 655 (343 in the INT and 312 in the CON, participation rate: 90.1 %).

The study was approved by the cantonal ethical committees of St. Gallen and Vaud.

#### Need assessment, preplanning and pilot studies

In a first step a broad state of the art of health promoting projects in Swiss preschools [40-44] and a requirement analysis (knowledge, existing offers and barriers) was done. Teachers, health professionals and migrant experts were interviewed and asked to respond to a structured questionnaire. We also interviewed parents of migrant background with special emphasis on nutrition and PA behaviours (Jörg R, unpublished license of

Table 1: Overview of the different pilot studies:

diploma, University of Basel). We performed qualitative interviews and designed and distributed questionnaires about their health perception, individual needs and attitudes towards offers in five preschool classes. Physical education classes were visited and analyzed. Based on this analysis, we determined content and transmission of information, as well as the extracurricular offers. We then performed different pilot studies (**table 1**) before the beginning of the main intervention.

#### Intervention

The intervention was developed with input from exercise physiologists, preschool and primary school teachers, paediatricians, dieticians, psychologists and various stakeholders including experts for migrant families). The intervention focused on four topics: PA, nutrition, media use and sleep duration and was primarily applied at the level of the teachers, children and parents. All INT classes proceeded according to the same curriculum i.e. workshops, lessons, home activities, offers of extra-curricular activities, adaptation of the built infrastructure. The teachers were coached by trained health promoters (HP). These were physical education teachers who were further trained by a dietician and a physician. Theses HP intervened on the level of the teachers, the children, the parents and the local community. The CON group continued to follow their usual school curriculum which included one 45 min physical education lesson taught by the classroom teachers and one 45 min rhythmic lesson (given by a rhythmic specialist) for the French part of the study. Children were blinded to the existence of INT classes.

Pilot studies evaluating the intervention (PI)	ו (PI) Pilot studies evaluating the measurements (PM)	
11/2006: Testing of 10 PA home activity cards in 5 pre- school classes for 4 weeks. Evaluation by teachers and parents (questionnaires).		
5/2007: Testing of 2 further PA and 2 nutrition home activi- ty cards in 4 preschool classes. Evaluation by teachers and parents (questionnaires).		
11/2007: Testing of daily PA and weekly nutritional lessons with their home activity cards during 3 weeks in 1 pre- school class. Evaluation by teachers and parents (ques- tionnaires).	Feasibility and selection of tests	
	11/2007: Evaluation of 10 motor ability tests in one pre- school class and selection of 4 of them by a team of sports scientists. Evaluation of the anthropometric measurements and the cognitive tests.	
	Feasibility and reliability of tests	
	4/2008: Evaluation of the 4 motor ability tests in 2 pre- school classes. Test-retest reliability of the balance plat- form test (static balance) and the anthropometric mea- surements.	
	Reliability of motor ability tests	
	6/2008: Test-retest reliability of the "obstacle course" test (combined motor ability) and the balance beam test (dy-namic balance) 1 preschool class.	

The teachers and the parents, however, knew about the intervention arm. Participants, parents and school personnel, including classroom teachers, were informed that the intervention would promote their children's health, but were unaware of the main objectives.

#### Teachers:

Prior to the intervention, the teachers took part in two afternoon workshops on the four topics (PA, nutrition, media use and sleep). In these workshops the teachers learned how to work with the lessons, the homework cards, the new PA infrastructure material. During the study, regular informal exchanges between the teachers and the HP took place and two formal meetings were organized.

#### Children:

*PA lessons:* PA lessons were given four times a week including 40 min lessons and 5 min cool down. In the beginning, one of the four lessons was given by the HP with the regular classroom teachers attending these lessons. After four months of intervention, the HP reduced their contribution to twice a month while the remaining lessons were taken over by the preschool teachers. All PA lessons were prepared by an exercise physiologist. The lessons took place in or around the preschool and once a week in the gym. Training of coordination and endurance was performed as described in **figure 3**. Additional sports equipment for the lessons such as balls, skipping ropes was offered and organized. Adherence to the PA lessons was assessed by regular classroom teachers.



#### Figure 3: Model for the physical lessons

The physical activity lessons focused on coordination and endurance, but their distribution within one 40 min lesson changed over the period of the study.

Nutrition, media use and sleep lessons: The intervention on healthy balanced nutrition included weekly 45 min nutrition lessons, where the children learned balanced nutrition and healthy nutritional behaviour in a playful way. These lessons were developed and prepared by a dietician. The lessons were based on five messages i.e. "drink water", "eat fruit and vegetables", "eat regularly", "make clever choices", "turn your screen off when you eat" [42] that were transmitted in the form of a nutrition disk, developed in collaboration with the Swiss Society for Nutrition [45]. Each message was taught during a two-weeks period and was presented in two cycles over the year. Each message was described on a funny card which was taken at home with a task to implement the message at home (see below). During two additional weeks, lessons about sleep were implemented.

*Infrastructural changes:* The infrastructures of the preschool were adapted, in coordination with the building department to ensure the insurance guidelines for prevention of accidents.

*Extracurricular activities:* This included an additional weekly PA lesson (e.g. clubs). Where there was no offer of inexpensive all-round weekly PA lessons a weekly extracurricular lesson from a new national PA program [46] was offered.

#### Children and parents:

PA and nutrition home activities: Sixteen PA and five nutrition cards were developed by professional PA teachers/nutritionists in collaboration with Health Promotion Switzerland [43]. The children got every other week a new PA or a nutrition activity card at home. These cards include specific PA tasks to be done at home. Some of these activities focused on a team work, which should promote the integration of other family members. A text on the backside of the card included simple information and practical hints to the parents. A CD with specific music for most PA cards was created to increase pleasure and define the minimal time the activity should be performed.

*Events:* Toward the end of the intervention, a morning event was organized, where children and parents participated together in a fun program while implementing the main messages of the study.

#### Parents:

Information evenings: The HP organized two information evenings in each preschool. During the first information evening the HP informed about the study, the intervention, the testing and the informed consent. This information evening was performed also for the CON classes. On the second information evening, the HP presented the nutrition disk, informed about the five nutrition and media use messages and discussed possibilities and barriers of implementation. A third information evening performed by a dietician discussed the possibility of healthy nutrition that is cheap, tasty and can be easily and rapidly prepared.

*Information booklet:* In a short booklet, parents got informed about: (1) details of the intervention (2) practical hints to increase PA for children and for adults (3) existing PA offers for preschooler in the neighbourhood (4) the material, the children need at home for the home activities (5) the nutrition disc and (6) recommendations for a healthy mid-morning snack.

With the second information event the parents received the nutrition disc (offered in ten languages) and two other booklets about cooking and eating ("Gemeinsam Kochen und Essen", Cleven-Becker-Stiftung, 2008) and about PA in daily life ("Bewegung ist Leben", Bundesamt für Sport BASPO, 2008), offered in eight languages

#### Measurements

Measurements at baseline and at the end of the intervention were accomplished during a time period of five weeks (beginning both times in SG). **Table 2** gives an overview about all measurements taken. The measurements were collected in three teams: anthropometry/concentration/memory (tested in the preschool class), motor abilities (tested in the gym) and PA (accelerometry). These teams worked parallel in different classes. With few exceptions the local teams did not change between the two testing periods. The main investigators for SG and VD were trained together to minimize inter-observer variability. Research assistants were blinded to group allocation. If a child was sick, BMI was measured few days later and questionnaires were distributed.

#### Anthropometry and body composition:

Standing height was determined and body weight was measured using an electronic scale (Seca, Basel, Switzerland; accuracy 0.05 g). Waist (midway between the iliac crest and the lowest border of the rib cage) and hip circumference (at the largest circumference) were measured by a flexible tape. SF thickness was measured in triplicate to the nearest 0.5 mm with Harpenden calipers (HSK-BI, British Indicators, UK) calibrated to exert a pressure of 10 g/cm<sup>2</sup> to the skin. Four sites (triceps, biceps, subscapular and suprailiac) were measured based on standard procedures [47]. The same four investigators took all measurements. Percent body fat was calculated according to the formulas of Slaughter, Deurenberg and Dezenberg [48-50] validated in preschool children [51, 52]. The calculation of % body fat with this method has a prediction error of 3-5 % [48, 49]. The intra- and interobserver correlations in the pilot study (n=21) using Spearman rank correlation analyses were r=0.95 (p<0.001) and r=0.90

(p<0.001), respectively for waist circumference and r=0.98 (p=0.001) and r=0.96 (p=0.001), respectively for the sum of four SF. Bioelectrical impedance was measured by a 4-polar single frequency device (RJL Systems, Model 101A; Detroit, MI, USA). The unit was calibrated prior to each testing day using a 500 ohm resistor provided by the company. Measurements were taken based on standard procedure[53]. If the distance from the proximal to the distal electrode was less than 5 cm in small children, the proximal electrode was located more proximal until the distance of 5 cm was attained. Percent body fat was calculated based on validated formulas [52, 54, 55]. The coefficient of variation between different bioelectrical impedance analysis measurements was less than 1.5 % and for the calculation of fat-free mass it was 5.8 % [52].

#### Motor abilities:

Shuttle run test: The maximal multistage 20 m shuttle run test (20-MST) was used to assess aerobic fitness [56]. The test measures aerobic capacity by running forth and back for 20 m with an initial running speed of 8.0 km/h and a progressive 0.5 km/h increase of the running speed every minute that is indicated by a sound. The maximal performance was determined when the child was twice in series more than 3 m behind the given time or the child decided itself to stop because of exhaustion. The 20-MST has been found to be reliable (test-retest r=0.73-0.93) [56-58], a valid measure of maximum oxygen consumption as measured by treadmill testing (r=0.69-0.87) [57-61], and sensitive to changes in 6- to 16-year old children [61]. Some formal adoptions were made due to the very young age of the children by marking tracks on the floor to prevent the children from running curves and by an adult running with the children to provide the adequate pace.

Table 2: Overview of the measurements:	
Anthropometry and body composition	PA, nutritional intake and behaviour, media use, sleep duration
Height	Accelerometers, questionnaires*
Weight	Food frequency questionnaire*
Waist and hip circumference	
Skinfold thickness (triceps, biceps, subscapular,	Psychosocial health
suprailiacal)	General health of the child and the family*
Bioelectrical impedance (4-Polar)	Health-related quality of life (HRQOL)*
	Signs of Hyperactivity (SDQ)*
Motor ability	
Shuttle run test (aerobic fitness)	Cognition tests
Balance platform (static balance)	Attention (KHV-VK)
Balance beam (dynamic balance)	Spatial working memory ability (IDS)
Obstacle course (combination)	
* evaluated by a total of two questionnaires (one for life	estyle parameters, general and psychosocial health, one food
frequency questionnaire)	

Balance platform: Static postural control was measured in accordance to a standardized protocol [64] on a balance platform (GKS 1000®, IMM, Mittweida, Germany). The balance platform consisted of four sensors measuring displacements of the center of pressure (COP) in medio-lateral and anterior-posterior direction. Data acquisition was monitored (40 Hz) for 25 sec [64]. A balance-pad (Airex balance Pad, Airex, Aalen-Ebnat, Germany) was put on the balance platform, increasing the difficulty of the test. Postural sway was collected measuring the displacement of the COP. The smallest total length of two trial was used for further analysis. For experimental testing, children were asked to stand barefoot, with a 2 cm distance between both heels and feet placed in a 30° angle on the balance-pad, where coloured foot prints were placed. Hands were placed on the hips. After a test-stand for five seconds and a break while children descended from the force plate, the two trials were collected. The intraobserver testretest correlation for the total length between the two attempts in the pilot study (n=40) using Spearman rank correlation analyses was r=0.73 (p<0.0001).

Balance beam: According to Keogh (1965) balance beams are a suitable tool for testing dynamic balance in children [65]. In pilot testing we observed that balancing backwards was too difficult for children aged 4to 6-years but balancing forward on a 3 cm wide balance beam was feasible and discriminated between children with high and low motor skills. We therefore included balancing barefoot forward on a 3 m long and 3 cm wide balance beam. The number of successful steps on the beam were counted until the child's foot touched the floor. Children performed three trials. The mean of the best two trials was calculated and used for further analyses. The intra- and interobserver correlation between the two better attempts in a pilot study (n=15) using Spearman rank correlation analyses were r=0.84 (p<0.01) and r=0.97 (p<0.01), respectively.

#### Physical activity:

PA was assessed by an accelerometer (MTI/CSA 7164, Actigraph, Shalimar, FL, USA). The accelerometers were constantly worn around the hip over five days at baseline and at the end of the intervention (both summertime) in the INT and in the CON group. The sampling epoch was set at 15 sec. This instrument has been shown to be valid across different activities in 3-to 5-year old children with a Pearson correlation coefficient between  $VO_2$  (ml/kg per min) and Actigraph counts/15 sec of r=0.82 [66].

#### Questionnaires:

**Table 3** gives an overview of the two used questionnaires [67-74]. The reliability of a semi-qualitative food frequency questionnaire was tested in three classes assessing nutritional behaviour and food intake of preschool children of predominantly migrant background (Ebenegger, V. manuscript in preparation). Items were chosen from different food frequency questionnaires [67-69] adapted to the Swiss situation and the age group. This food frequency questionnaire was also filled in for each sibling aged two years or older.

Table 3: Ov	verview of	the quest	ionnaires:
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General Health Questionnaire

- PA and participation in sports clubs of the child and the family [73]
- media use and sleep duration [74] of the child and its siblings
- General health of the family members
- Parental height and weight
- Socioeconomic data (i.e. education, origin, nationality and cultural integration)
- health-related quality of life (HRQOL)\* [70]
- presence of a hyperactive behavior with the Strengths and Difficulties Questionnaire (SDQ)\*\* [71]

\* HRQOL was measured by the German version of the PedsQL 4.0TM (Pediatric Quality of Life Inventory) Generic Core Scales (U.S. Copyright Registration No. TXu 856-101) with a parent proxy-report, containing four scales (Physical, Emotional, Social, School) and 23 items. The psychometric properties of the PedsQL 4.0TM justify application in a healthy child population [70]. \*\* The presence of hyperactive behaviour was evaluated with the Strengths and Difficulties Questionnaire (SDQ) [71]. The parent proxy-form comprised the hyperactivity/inattention scale consisting of five items. Validity has been demonstrated in healthy children and adolescents [72].

Food frequency questionnaire (adapted from [67-69])

- Nutritional behavior (i.e. if and where (i.e. home, day care) the meals were eaten, eating while watching television, eating alone)
- Intake of 15 different categories of food during the last 4 weeks (subdivided into nutriments)

#### Cognition tests:

To measure attention ability, the *Konzentrations-Handlungsverfahren für Vorschulkinder* (KHV-VK) [75] was applied. Test material consists of 44 cards with familiar pictures, which had to be sorted into four different boxes. Sorting time and error quote allowed quantitative and qualitative statements on attention. The test has been validated in a preschool population and age specific norms are available. Test-retest reliability was r=0.88 [75].

Spatial working memory ability was measured by a subtest taken from the Intelligence and Development Scales (IDS) [76]. Thereby geometrical forms had to be memorized and identified. Significant correlations to related measures confirmed construct validity (i.e. HAWIK-IV Working memory scale: r=0.52) and the test-retest reliability was r=0.48 [77, 78].

#### Evaluation

All evaluation measures were developed as defined in the CONSORT guidelines [79]. We will evaluate the intervention with regard to primary and secondary outcome measures. We will also perform a process evaluation to assess the appreciation the feasibility and the subjective effectiveness of the program by teachers (questionnaires and semi-qualitative interviews) and parents (questionnaires).

#### Data analysis

Baseline comparability of INT and CON schools will be assessed using descriptive statistics and two sample t test for continuous and  $\chi^2$  test for categorical variables. If necessary, variables will be logarithmically transformed before analyses. As a primary prevention program, the intervention was designed to target the entire sample. Effects are expected and intended to occur throughout the entire distribution of adiposity and aerobic fitness in the sample - not just around a defined threshold. Thus, for purposes of establishing the efficacy of this intervention, it is most appropriate to compare the full distributions of BMI and aerobic fitness between INT and CON groups. Therefore, to test the primary hypotheses, accounting for the design with classes as the unit of randomization, mixed linear models will be used, with change in BMI and aerobic fitness as the dependent variable, study arm as the factor of interest and age, sex, language region (German vs. French part of Switzerland) and baseline BMI or aerobic fitness, respectively, as covariates. The same analytic approach will also be used for all secondary outcome variables. Potential interactions of intervention with sex or age will be tested for each outcome. Data will be analyzed according to intention to treat.

With an average class size of 18, we assumed that 13 children per class would participate in both shuttle runtests (due to non-participation, attrition, moving, sickness on the testing day). A total number of 40 classes would then provide enough power to detect a true intervention effect of half an inter-subject standard deviation at the usual significance level of 0.05 with a probability of 0.9, provided that the standard deviation

of the random class effect does not exceed 25 % of the inter-subject standard deviation (i.e., corresponding to an intra-class correlation of about 0.06).

The following subgroups will be also investigated: Normal weight and overweight/obese children, children with low baseline fitness, children with migrant background and Swiss children, children of low socioeconomic background.

## Discussion

We achieve to develop a concise and appropriate protocol for the development and implementation of a multilevel lifestyle intervention aiming to prevent weight gain and to increase aerobic fitness in a high-risk preschool population with a high percentage of migrant background. We believe that the inclusion of stakeholders such as teachers, parents and school directors from the very beginning, the extended preplanning inlcuding testing and evaluation of the intervention material and the theory-driven multilevel approach will improve the likelihood of a successful intervention.

The purpose of this paper was to outline the design of a multicomponent multilevel school-based multicenter cluster-randomized, lifestyle intervention trial aiming to reduce BMI and to increase aerobic fitness in 4- to 6year old preschool children in culturally different parts of Switzerland with a high prevalence of migrant children. We aim to offer information and a solid base for a further adaption and larger implementation of prevention programs focusing on preschool children that are adapted to children of low SES and migrant background. Results of the intervention will be available in 2010.

## **Competing interests**

None of the authors has any competing financial interests.

## Authors' contributions

JJP, SK and LZ designed the study. JJP was the principal investigator and is guarantor. JJP, SK, IN, FB, VE, AN, TH and PM established the methods and questionnaires. IN, FB, VE and JP were the main coordinators of the study. IN, FB, VE, UM, AN, PM and JJP conducted the study. CS and PM gave statistical and epidemiological support. IN wrote the article under the assistance of JJP and got additional help from SK and PM. JJP obtained the funding, with the assistance of SK and LZ. All authors provided comments on the drafts and have read and approved the final version.

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## **Publication 2**

# BMI-Group-Related Differences in Physical Fitness and Physical Activity in Preschoolers: a Cross-Sectional Analysis

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### Research article

## BMI-Group-Related Differences in Physical Fitness and Physical Activity in Preschoolers: a Cross-Sectional Analysis

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### Abstract

We investigated age- and BMI-group-related differences in aerobic fitness (20m shuttle run), agility (obstacle course), dynamic (balance beam) and static balance (balance platform) and physical activity (PA, accelerometers) in 613 children (age  $5.1 \pm 0.6$  years). Normal weight (NW) children performed better than overweight (OW) children in aerobic fitness, agility and dynamic balance (all p<0.001), while OW children had a better static balance (p<0.001). BMI-group-related differences in aerobic fitness and agility were larger in older children (p for interaction with age=0.01) in favor of the NW children. PA did not differ between NW and OW (p>0.1), but between NW and obese children (p<0.05). BMI-group-related differences in physical fitness can already be present in preschoolers.

Keywords: child, cross-sectional Studies, overweight, psychomotor performance

### Background

The high prevalence of childhood overweight and obesity remains of great public health concern, despite a possible recent stabilization (Ogden, Carroll, Curtin, Lamb, & Flegal, 2010). The increasing overweight has been shown to be associated with a concomitant decrease in physical fitness (Tomkinson & Olds, 2007; Tremblay et al., 2010). Though fitness is also genetically determined, data from large cohorts also reveal the importance of environmental factors. These cohort studies of 6- to 19-year-old children from 27 countries demonstrated a decline in aerobic fitness of 0.4% per year between 1970 and 2003 (Tomkinson & Olds, 2007). Likewise, also general physical fitness has declined by around 10% from 1975-2000 as demonstrated in a cohort of 6- to 17-year-old children in Germany (Bös, 2003). In contrast to physical fitness, there are no population-level studies on changes in objectively measured physical activity (PA) over the last decades, although some data indicate that children have become less physically active (Andersen & van Mechelen, 2005). These different trends are alarming as already in young children obesity (Speiser et al., 2005), physical inactivity and a reduced aerobic fitness (Andersen et al., 2006; Kriemler et al., 2008; Weiss et al., 2004) are all associated with cardiovascular risk factors. They cause immediate and long-term related health and psychosocial consequences (Freedman et al., 2005; Speiser et al., 2005). In addition, low fitness, decreased PA and obesity can influence each other leading to a vicious circle (Pietilainen et al., 2008). This vicious circle complicates any treatment efforts. In adolescents, BMI-group-related differences in physical fitness are well documented. Except for some domains like flexibility, normal weight (NW) adolescents perform better than overweight or obese (OW) adolescents (Bovet, Auguste, & Burdette, 2007; Deforche et al., 2003; Okely, Booth, & Chey, 2004). Data collected in prepubertal primary school children also demonstrate BMI-group-related differences in aerobic fitness (Eisenmann, DuBose, & Donnelly, 2007; Hussey, Bell, Bennett, O'Dwyer, & Gormley, 2007; Korsten-Reck et al., 2007), while differences in coordinative tasks are more controversial (Graf et al., 2004; Korsten-Reck et al., 2007; Okely et al., 2004). To this date, only few studies have been performed in preschoolers. These studies demonstrated certain BMI-group-related differences in motor skills (Bappert, Woll, & Bös, 2003; Mond, Stich, Hay, Kraemer, & Baune, 2007), although their findings have not been replicated in an another study (De Toia et al., 2009). It is also debated, if there already exist BMI-grouprelated differences in PA in this young age group: one report has found a relationship between objectively measured PA and OW in a small sample of children (Metallinos-Katsaras, Freedson, Fulton, & Sherry, 2007), but the results were less consistent in another study (Trost, Sirard, Dowda, Pfeiffer, & Pate, 2003). It is unclear whether the vicious circle of low fitness, decreased PA and obesity begins already during the preschool years and there is a lack of studies in preschoolers examining both fitness and PA in the same population. We therefore investigated if BMI-grouprelated differences in physical fitness (Molnar & Livingstone, 2000) and in PA were present in 4- to 6-year-old

children and whether possible deficits are more pro-

nounced in older preschool children.

### Methods

The study was performed in late summer 2008 using cross-sectional analyses of 40 randomly selected urban kindergarten classes from two Swiss cantons (St. Gallen, SG and Vaud, VD). The study was approved by the cantonal ethical committees of SG and VD and written informed consent was obtained from a parent or legal representative for 655 of the initially selected 727 children (participation rate: 90%). The current database includes 613 children (94% of the participating children, 84% of the initial population) with valid BMI and fitness test data.

### Anthropometry

Standing height was determined and body weight was measured using an electronic scale (Seca, Basel, Switzerland; accuracy 0.05 g). BMI was calculated as weight (kg)/height (m)<sup>2</sup>. Children were classified into two BMI-groups (NW < 90th and OW  $\ge$  90th percentile). Some additional analyses were performed between NW (< 90th) and obese children ( $\ge$  97th percentile). All used cut off points are based on the Swiss national percentiles (Prader, Largo, Molinari, & Issler, 1989), as national percentiles are known to be more sensitive than the international ones (Reilly, 2002; Reilly et al., 2009).

### Physical fitness (Molnar & Livingstone, 2000)

Shuttle run test. Aerobic fitness was assessed by the multistage 20 m shuttle run test (Leger, Mercier, Gadoury, & Lambert, 1988). The test measures aerobic capacity by running back and forth for 20 m with an initial running speed of 8.0 km/h and a progressive 0.5 km/h increase of the running speed every minute indicated by a sound. The maximal performance was determined when the child could no longer follow the pace or the child stopped because of exhaustion. The test results were expressed as the number of stages completed (one stage corresponds approximately to the running time of one minute). The 20 m shuttle run test has been found to be a reliable in 6-to 16-year-old children (test-retest r=0.73-0.93) (Leger et al., 1988) and valid measure of maximum oxygen consumption

as measured by treadmill testing (r=0.69-0.87) (van Mechelen, Hlobil, & Kemper, 1986). Due to the young age of the children, some formal adaptations of the original test were made by marking tracks on the floor for each individual child and by having an adult running with the children until the end of the test to provide adequate pace. In a pilot study testing these adaptations (Kriemler S, unpublished data), scores were measured twice for children aged 4- to 6 years (n=20) and test-retest reliability was r=0.84 (p<0.001).

Obstacle course. Agility was assessed by an obstacle course that measured a combination of speed, strength, spatial orientation and memorization of a specific sequence of actions (Sheppard & Young, 2006). This obstacle course was designed for 3- to 6year-old children and described by Vogt (1978) and Kunz (1993) (Kunz, 1993; Vogt, 1978). It includes running 1 m from a marking cone to a transversally positioned bench, jumping over the bench (36 cm high, 28 cm wide), crawling back under this bench and running back to the marking cone three times in a row as fast as possible. The test was assessed by the time needed to complete the obstacle course and was measured in seconds. Each child had two attempts and the faster one was used for further data analysis. The interobserver correlation and the test-retest reliability in our pilot study (n=14) were r=0.99 (p<0.01) and r=0.82 (p<0.01), respectively.

Balance beam. Dynamic balance was tested by balancing forward barefoot on a 3 m long and 3 cm wide balance beam (Malina, Bouchard, & Bar-Or, 2004). As an outcome measure, the consecutive successful steps on the beam were counted until the child's foot touched the floor or until the maximum of eight successful steps was reached. Children performed three trials and the mean of the best two trials was calculated and used for further analyses. The interobserver correlation and the test-retest reliability between the two better attempts in our pilot study (*n*=15) were *r*=0.97 (*p*<0.01) and *r*=0.84 (*p*<0.01), respectively.

Balance platform. Static balance was measured in accordance with a standardized protocol (Kapteyn et al., 1983) on a balance platform (GKS 1000®, IMM, Mittweida, Germany). The balance platform consisted of four sensors measuring displacements of the center of pressure in medio-lateral and anterior-posterior direction. Data acquisition was monitored at 40 Hz for 25 s (Kapteyn et al., 1983). A balance-pad (Airex balance Pad, Airex, Aalen-Ebnat, Germany) was put on the balance platform in order to increase difficulty of the test. Postural sway was collected measuring the displacement of the centre of pressure in millimeters. The smallest total displacement length of two trials was used for further analysis. The intraobserver test-retest correlation for the total length between the two attempts in our pilot study (n=40) was r=0.73 (p<0.0001).

	Preschool children								
	Age 4 <i>n</i> =112 (18%) Age 5 <i>n</i> =313 (51%)		Age 6 <i>n=</i> *	188 (31%)					
	NW <i>n</i> =87 (78%)	OW n=25 (22%)	NW <i>n</i> =255 (81%)	OW <i>n</i> =58 (19%)	NW <i>n</i> =148 (79%)	OW <i>n</i> =40 (21%)	Overall <i>p</i> for BMI- group <sup>2</sup>	Overall <i>p</i> for age group <sup>3</sup>	Interaction <sup>4</sup>
Age [years]	4.3 ± 0.1	4.3 ± 0.1	5.1 ± 0.3	5.0 ± 0.3	$5.9 \pm 0.2$	5.9 ± 0.2	0.5	<0.001	0.6
Height [cm]	105.9 ± 4.4	107.5 ± 3.5	110.5 ± 4.6	112.4 ± 4.2	115.4 ± 4.9	119.0 ± 5.4	<0.001	<0.001	0.2
Weight [kg]	17.5 ± 1.9	20.2 ± 1.5	18.6 ± 2.0	22.8 ± 2.5	19.9 ± 2.3	26.1 ± 3.5	<0.001	<0.001	<0.001
BMI [ka/m <sup>2</sup> ]	15.5 ± 0.8	17.4 ± 0.6	15.2 ±	18.0 ± 1 4	14.9 ± 1 0	18.3 ± 1.5	<0.001	<0.001	<0.001

Table 1: Characteristics of the 613 children (girls n=305, boys n=308) according to age- and BMI-group<sup>1</sup>

*Note.* NW, normal weight; OW, overweight. Data are shown as means ± SD. Variables were analyzed using ANCOVA. <sup>1</sup> Swiss national percentiles.

<sup>2</sup>Adjusted for age-group, sex, preschool class (cluster) and, in case of significance, BMI-group\*age group interaction.

<sup>3</sup> Adjusted for BMI-group, sex, preschool class (cluster) and, in case of significance, BMI-group\*age group interaction.

<sup>4</sup> BMI-group\*age group interaction.

### **Physical activity**

PA was measured over six consecutive days with an accelerometer (GT1M, Actigraph, Florida, USA), which was programmed to save data in 15 s intervals (epochs) as proposed for this age group (Niederer et al., 2009; Pate, Almeida, McIver, Pfeiffer, & Dowda, 2006). The CSA/Actigraph is the most commonly used motion sensor in children and has a good reproducibility, validity and feasibility (de Vries, Bakker, Hopman-Rock, Hirasing, & van Mechelen, 2006). This particular type of PA assessment has been shown to be valid across different activities in 3- to 5-year-old children (Pate et al., 2006) with a Pearson correlation coefficient between VO<sub>2</sub> (ml/kg per min) and Actigraph counts/epoch of r=0.82 (Pate et al., 2006). The accelerometers were worn around the hip. To consider data as valid, at least three days of recording (two weekdays and one weekend day) (Trost, Pate, Freedson, Sallis, & Taylor, 2000) with a minimum of 6 h valid registration per day were needed. Correlation between 6 and 10 h recording was r=0.92 (p< 0.001, n=502). Sequences of at least 10 min of consecutive zero values were removed and interpreted as accelerometer not worn (Baguet, Stratton, Van Praagh, & Berthoin, 2007). Data from monitored days were extrapolated by weighing weekdays and weekends (5:2) (Niederer et al., 2009). Average physical activity (PA) level, moderate-vigorous physical activity (MVPA) and vigorous physical activity (VPA) were chosen as PA markers. Average PA levels were expressed as counts per minute (cpm, total counts recorded divided by total daily wearing time). MVPA and VPA were based on published cut-offs for preschool children (Pate et al., 2006): ≥420 counts/epoch for MVPA and ≥842 counts/epoch for

VPA. Data are expressed as the number of epochs/hour above this cut-off. Valid PA data were received from 517 of 613 (84%) children with valid BMI and fitness data. Children without valid PA data were comparable for age, sex, migrant status and parental education. As differences in daily monitored time between groups were negligible and non-significant, we did not adjust for monitoring time (mean time of monitoring  $10.9 \pm 1.2$  h/day).

### Statistical Analysis

Descriptive analyses were presented as mean ± standard deviation, as all variables were normally distributed. To examine age- or BMI-group-related differences in the outcome parameters anthropometry, physical fitness and PA, one-way analysis of covariance (ANCOVA) adjusting for sex and preschool class was used. For age-group differences a further adjustment for BMI-group and for BMI-group differences a further adjustment for age-group were made. We also tested interactions between age- and BMI-group. Differences in physical fitness were further adjusted for average PA. To assess differences in PA between NW and obese children, the same analyses were done with these two BMI-groups. Within each age group, BMIgroup-related differences in physical fitness and in PA were also calculated using ANCOVA adjusting for sex and preschool class and *p*-values were assessed after Bonferroni correction for the 3 age subgroups. Differences in age, sex, migrant status and parental education between children with and without valid PA data were calculated using ANCOVA adjusting for preschool class. Significance was set at p<0.05 and all analyses were performed using STATA version 11.0 (Statacorp, College Station, TX, USA).

	Preschool children									
	Age 4 <i>n</i> =112 (18%)		Age 4 <i>n</i> =112 Age 5 <i>n</i> =313 (18%) (51%)		Age 6 (31	Age 6 <i>n</i> =188 (31%)				
	NW <i>n</i> =87 (78%)	OW <i>n</i> =25 (22%)	NW <i>n</i> =255 (81%)	OW <i>n</i> =58 (19%)	NW <i>n</i> =148 (79%)	OW <i>n</i> =40 (21%)	Overall <i>p</i> for BMI- group <sup>2</sup>	Overall <i>p</i> for age group <sup>3</sup>	Effect size (η²)	Interaction <sup>4</sup>
Aerobic fitness [stages]	2.0 ± 1.2	2.2 ± 1.0	3.0 ± 1.3	2.5 ± 1.0	3.8 ± 1.4	2.9 ± 1.2	<0.001	<0.001	0.34	0.01
Agility [s]	22.1 ± 5.6	21.4 ± 5.3	18.9 ± 3.9	21.3 ± 4.9	17.2 ± 3.5	19.9 ± 3.7	<0.001	<0.001	0.25	0.01
Dyn. balance [steps]	1.5 ± 1.3	1.4 ± 1.2	2.4 ± 1.5	1.7 ± 1.0	3.1 ± 2.0	2.5 ± 1.3	<0.001	<0.001	0.19	0.3
Static balance [mm]	1036 ± 182	1007 ± 370	987 ± 237	860 ± 126	881 ± 115	827 ± 145	<0.001	<0.001	0.41	0.7
Average PA <sup>5</sup> [counts/min]	712 ± 139	725 ± 153	740 ± 181	682 ± 130	745 ± 165	704 ± 167	0.3	0.2	0.23	0.6
MVPA <sup>5</sup> [epochs/ hour ≥420 counts]	34.6 ± 8.7	35.4 ± 7.9	35.7 ± 9.5	33.5 ± 8.1	36.1 ± 9.5	33.7 ± 8.0	0.3	0.4	0.22	0.5
VPA <sup>5</sup> [epochs/ hour ≥842 counts]	8.9 ± 3.4	9.1 ± 3.1	9.7 ± 4.1	8.4 ± 3.7	10.2 ± 9.1	9.1 ± 3.6	0.1	0.06	0.21	0.5

Table 2: Physical fitness and physical activity of the children (girls n=305, boys n=308) according to age- and BMIgroup<sup>1</sup>

*Note.* NW = normal weight; OW = overweight; PA = physical activity; MVPA = moderate-vigorous PA; VPA = vigorous PA. Data are shown as means  $\pm$  SD. Variables were analyzed using ANCOVA.

<sup>1</sup> Swiss national percentiles.

<sup>2</sup>Adjusted for age-group, sex, preschool class (cluster) and, in case of significance, BMI-group\*age group interaction.

<sup>3</sup>Adjusted for BMI-group, sex, preschool class (cluster) and, in case of significance, BMI-group\*age group interaction.

<sup>4</sup> BMI-group\*age group interaction.

<sup>5</sup> mean time of monitoring 10.9 ± 1.2 hours/day.

### Results

Of the 613 children (age  $5.2 \pm 0.6$  yrs; 49.8% female), 20.1% were OW according to the Swiss national percentiles (Prader et al., 1989).

**Table 1** shows the anthropometric characteristics of the children according to age- and BMI-group. OW children were taller than their NW counterparts. Differences in BMI between NW and OW children were larger in older children (BMI-group\*age group interaction p<0.001).

**Table 2** shows the results of the physical fitness and the PA of the children according to age- and BMIgroup. In the full sample of participants, older children performed better than younger children in all physical fitness tests (p<0.001). Significantly better results for NW compared to OW children were found in aerobic fitness, agility and dynamic balance (all p<0.001), while OW children performed better than NW children in static balance. Differences in aerobic fitness between NW and OW children were larger in older children (p=0.01 for BMI-group\*age group interaction, **table 2** and **figure 1**). Among the 4-year-olds, OW children performed similarly to NW children (p=0.4), while among 6-year-olds, the OW children reached 0.9 stages less than the NW (p=0.006), corresponding to a 24% lower fitness. A similar age effect was found for the obstacle course (agility test): among the 4-year olds the OW children were as fast as the NW (p=0.3), but running time was increased by 2.7 s or 16% in the 6year-old OW children compared to their NW counterparts (p<0.001).

PA was not different between the age groups except that older children tended to spend more time in vigorous PA (p=0.06). There were also no BMI-grouprelated differences in either of the PA parameters (all p≥0.1). However, obese children (≥97<sup>th</sup> percentile, n=47) had lower average and vigorous PA compared to NW children (average PA (cpm): mean difference -55, 95% CI -5 to -105, p=0.049; vigorous PA (epochs/hour ≥ 842 counts): mean difference -1.3, 95% CI -0.1 to -2.5, p=0.02).

BMI-group-related differences in physical fitness were not or only minimally altered after further adjustment for average PA (p<0.001 for aerobic fitness and static balance, p=0.002 for agility and dynamic balance).

Boys performed better in the aerobic fitness (p=0.03) and the agility test (p=0.001) and were more physically active (p≤0.001 for average PA, MVPA and VPA). Girls performed better in static balance (p<0.001). There were no sex-related differences in dynamic balance (p=0.1).



Figure 1: Results of aerobic fitness and agility tests of normal weight and overweight/obese children NW=normal weight, OW=overweight. Data are presented as means  $\pm$  standard error. Overall differences for aerobic fitness and agility between BMI- and age groups were significant (all *p*<0.001) with a significant interaction between BMI-group and age group (\*both *p*=0.01).

### Discussion

Our data show that NW preschool children performed better in all dynamic fitness tests, while OW children had a better static balance. Within the preschool population, BMI-group-related differences in aerobic fitness and agility were larger in older preschoolers. PA did not differ between NW and OW children.

This study adds important information regarding BMIgroup-related differences in physical fitness in preschoolers, as few studies have been performed in this age group (Bappert et al., 2003; De Toia et al., 2009; Mond et al., 2007) and their results are controversial. One preschool study (De Toia et al., 2009) observed no differences among NW and OW children. However, other studies in preschoolers (Bappert et al., 2003; Mond et al., 2007) and first graders (Graf et al., 2004) found a significantly better physical fitness among NW children compared to their OW counterparts. Interestingly, the more dynamic the test was, the larger were the found differences (Bappert et al., 2003). The reasons for the discordant results between those studies are not entirely clear since similar fitness tests were used. De Toia et al. (2009) hypothesized, that the different results might be due to the fact that the performance differences may become apparent at a certain age and subsequently increase with age (De Toia et al., 2009). To confirm this hypothesis, longitudinal studies in this age group are needed, but our crosssectional data would be consistent with this hypothesis. Quite substantial differences in aerobic fitness, agility and dynamic balance were found between NW and OW children across the entire age group of preschoolers. However, for aerobic fitness and agility, these differences were larger in the older age groups. In the youngest age group, we found no differences at all. It is also possible that the moment of appearance of BMIgroup-related differences in physical fitness may also depend on the selected fitness tests.

The larger performance deficit of the OW children in the older age groups might be due to a more pronounced overweight in these groups. Indeed we could observe that the weight differences were more pronounced in the older children. This might have conseguences in their biomechanical and physiological function. Additionally, it is possible that a deconditioning caused by a reduced physical activity may also play a role, as many (Klesges, Klesges, Eck, & Shelton, 1995; Moore, Nguyen, Rothman, Cupples, & Ellison, 1995) but not all (Metcalf, Voss, Hosking, Jeffery, & Wilkin, 2008) longitudinal studies have shown associations between PA and BMI or body fat in young children. However, adjusting for PA in our study did not or only minimally alter the relationship between the BMI-group and physical fitness. Similarly, we did not find differences in PA between OW and NW children, but differences were apparent between normal weight and obese children. Though not consistent, the few existing studies in preschoolers tend to show differences in PA between NW and OW children (Jimenez-Pavon, Kelly, & Reilly, 2009; Metallinos-Katsaras et al., 2007; Trost et al., 2003). As the cut-off for OW in the Swiss national percentiles is lower compared to most other national or international percentiles, different BMI cut-offs may contribute to the discordant results, as in this age group, differences may be predominantly observed at higher BMI's. In addition, the lower number of children with valid accelerometer data might have contributed to a lower statistical power in our cohort. Bailey et al. (1995) reported that the median duration of low and medium intensity activities of 6 to 10 year-old children was 6 s and of high intensity activities only 3 s with 95% lasting less than 15 s (Bailey et al., 1995). Based on these findings it could be possible, that even 15 s epochs may not be sufficient to assess more intense PA. Differences in PA between NW and obese (and possibly also OW) children may in turn, lead to a lower fitness and additional deconditioning and favor a further increase in weight.

Physical fitness is partially determined by genetics, but it is also evident, that nongenetic factors contribute in a major way to the familial resemblance observed in fitness (Teran-Garcia, Rankinen, & Bouchard, 2008). These factors include lifestyle factors shared among family members such as diet, physical activity behavior or television viewing time. This gives practitioners and professionals the possibility to intervene by influencing the children's environment with targeted programs. Our data show that such a program aiming to increase physical fitness and decrease overweight should start in young children because BMI-group-related differences in physical fitness are noticeable already in preschoolers. These differences could otherwise aggravate a vicious circle between low PA, fitness and obesity.

The effects of increased body mass on static and dynamic balance in prepubertal children are still a matter of debate. Some studies in schoolchildren have found that OW children had poorer performances in static (Deforche et al., 2009) and dynamic (Deforche et al., 2009; Hills & Parker, 1991) balance compared to their NW counterparts. In the current study, OW children showed a worse dynamic balance than their NW peers, while they performed better in static balance. Aside from the possibility that the simple mass-related inertia of OW children could explain the better static balance, other reasons can only be speculated. Compared to other static (i.e. unilateral stand) or dynamic balance tests, our static bilateral test might have been not challenging enough and thus other factors like concentration, calmness or the urge to move might have become relevant in these still young children. A similar observation was made by Deforche et al. (2009): they found no differences between NW and OW preschool children in a static balance test on a force plate but did find differences in a static test on a narrow and raised balance beam. The latter may be more challenging and more dependent on daily PA experiences (Deforche et al., 2009)

An important strength of this study is the comprehensive assessment of both objectively measured PA and different fitness tests including aerobic fitness, agility, static and dynamic balance in a relatively large preschool population. Assessing both fitness and PA in the same cohort allows us to show that in this young age group, BMI-group-related differences can be manifest and guite pronounced without large differences in PA. In addition, the possibility of further dividing the sample in three age groups provided the opportunity to have a closer look at this very critical preschool period. The relatively low sample size of OW children in the subgroup of 4-year olds could potentially contribute to the lack of differences in the fitness tests. However, if anything, OW 4-year-old children did perform better than NW children in aerobic fitness and agility but fitness deficits of the OW were found in the 5 and the 6 year olds. Like any cross-sectional study, we are limited by the design that does not allow investigation of the cause-effect relationships. A limitation of the fitness tests is that the shuttle run test was not validated

against a more direct measure of maximal oxygen consumption in children below the age of six. However, the test-retest reliability in our pilot was good and we think that a "fitness ranking" of the children was nevertheless possible. One might also criticize the use of BMI instead of body fat. We had done the analyses, using sex and age-group adjusted quartiles of % body fat calculated by bioimpedance analysis (corresponding to the 25% children in the OW group) and had gotten very similar results. We chose to use only the BMI-data as in clinical practice and in the majority of studies in this field, BMI-related cut-offs are most frequently used, and adding data regarding % body fat would not have yielded any additional information. Finally, we do not know what PA epoch size represents children's PA the best (McClain, Abraham, Brusseau, & Tudor-Locke, 2008)

We conclude that BMI-group-related differences in physical fitness are already present in preschool children and the differences are more pronounced in older preschoolers. Screening not only for overweight but also for physical fitness deficits enables professionals to provide early and targeted support. This might help to reduce the physical fitness gap between NW and OW children and the subsequent development of a vicious circle.

### Author Note

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## **Publication 3**

# Relationship of aerobic fitness and motor skills with memory and attention in preschoolers (Ballabeina): A cross-sectional and longitudinal study

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### Research article

## Relationship of aerobic fitness and motor skills with memory and attention in preschoolers (Ballabeina): A cross-sectional and longitudinal study

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### Abstract

**Background:** The debate about a possible relationship between aerobic fitness and motor skills with cognitive development in children has recently re-emerged, because of the decrease in children's aerobic fitness and the concomitant pressure of schools to enhance cognitive performance. As the literature in young children is scarce, we examined the cross-sectional and longitudinal relationship of aerobic fitness and motor skills with spatial working memory and attention in preschool children.

**Methods:** Data from 245 ethnically diverse preschool children (mean age: 5.2 (0.6) years, girls: 49.4%) analyzed at baseline and 9 months later. Assessments included aerobic fitness (20 m shuttle run) and motor skills with agility (obstacle course) and dynamic balance (balance beam). Cognitive parameters included spatial working memory (IDS) and attention (KHV-VK). All analyses were adjusted for age, sex, BMI, migration status, parental education, native language and linguistic region. Longitudinal analyses were additionally adjusted for the respective baseline value.

**Results:** In the cross-sectional analysis, aerobic fitness was associated with better attention (r=0.16, p=0.03). A shorter time in the agility test was independently associated with a better performance both in working memory (r=-0.17, p=0.01) and in attention (r=-0.20, p=0.01). In the longitudinal analyses, baseline aerobic fitness was independently related to improvements in attention (r=0.16, p=0.03), while baseline dynamic balance was associated with improvements in working memory (r=0.15, p=0.04).

**Conclusion:** In young children, higher baseline aerobic fitness and motor skills were related to a better spatial working memory and/or attention at baseline, and to some extent also to their future improvements over the following 9 months.

Trial Registration: Trial Registration: clinicaltrials.gov NCT00674544

### Background

The debate about a possible relationship between aerobic fitness and motor skills with cognitive development in children has recently re-emerged, because of the decrease in children's aerobic fitness [1] and the concomitant pressure of schools to enhance cognitive performance [2]. In preschoolers, the focus is preferentially set on the advancement of cognitive parameters such as working memory and attention. Both working memory and attention have been shown to be important predictors of academic achievement [3, 4].

Despite the beneficial health effects, time for physical education or sports activities is often limited by budget

cuts or the abundance of alternative out-of-school offers [5]. These trends may already affect the level of activity and subsequent aerobic fitness in young child-ren.

It has been suggested that motor and cognitive development may be more interrelated than has previously been appreciated [6]. The cerebellum is not only important for motor but also for those cognitive functions, that are related to the dorsolateral prefrontal cortex [6]. Currently, there are three hypotheses based on data in rodents and humans explaining how exercise may affect cognitive parameters [7]: (1) increase in oxygen saturation based on an increased blood flow and angiogenesis, (2) increase in brain neurotransmitters like serotonin and norepinephrine facilitating information processing and (3) regulation of neurotrophins such as different growth factors. Additionally we know from studies in rodents, that exercise stimulates neurogenesis in the hippocampus and the subventricular zone [7] which may be important for lasting and cumulative network adaptations [8].

Studies in primate and adult humans have shown a relationship between aerobic fitness and cognitive performance [7]. These findings have been recently confirmed in a study including more than one million adolescents [9], where aerobic fitness was positively associated with intelligence at baseline and changes in aerobic fitness between age 15 and 18 years independently predicted intelligence at age 18 [9]. Similar cross-sectional relationships between aerobic fitness and measures of cognitive performance such as attention and working memory have been found in preadolescent schoolchildren [10-12], while there are no data in preschoolers. However, while aerobic fitness is considered to be the main parameter responsible for cognitive benefits in adults, data from recent crosssectional studies in preadolescent children demonstrate that not only aerobic fitness, but also other domains like motor skills (e.g. balance, agility, ball skills) seem to be related to cognitive benefits in children [13-17]. Furthermore, exercises involving specific mental processing including executive functions might be more prone to trigger global cognitive development in children than aerobic exercises alone [18, 19].

But research in children shows generally mixed results. While cross-sectional studies point towards a positive relation between aerobic fitness and/or motor skills with cognitive performance [12-18, 20], longitudinal data [18, 21] and intervention studies [18, 20] are few and more inconclusive [18]. Tomporowski and colleagues assume different causes in the sometimes contradictory results of the studies in children [18]: Lack of sensitivity of the selected tests to evaluate motor and cognitive performance, substantial differences among populations in the different studies and effect dependency according to age and developmental level. They also postulate that specific types of exercise training may facilitate cognitive performance more than others. Other causes for the contradictory results might be that some of the studies were limited by self reported or subjectively assessed data [21], measures of aerobic fitness or motor skills often restricted to one domain [12, 14, 17], analyses not adjusted for age and sex [14] and that other confounder variables like BMI or socioeconomic status were only rarely taken into account [21, 22]. Thus, more comprehensive cross-sectional and longitudinal analyses are needed. In preschoolers, studies are particularly rare [13, 14, 17] and controversial [17] and there is a lack of longitudinal data.

We therefore comprehensively assessed the crosssectional and longitudinal relationships of aerobic fitness and motor skills (agility, dynamic balance) with two different cognitive parameters (spatial working memory and attention) in a sample of ethnically diverse Swiss preschool children controlling for sociocultural characteristics and for BMI. Based on the literature, our hypothesis was that higher aerobic fitness and better motor skills in young children would be related to better memory and attention at baseline and to their improvements over 9 month. We also hypothesized that the relationship would vary according to the investigated domains.

### Methods

We analyzed data from a randomized controlled trial (Ballabeina Study, clinicaltrials.gov NCT0067454; [23]), involving preschoolers from the German (St. Gallen) and French speaking part (Vaud) of Switzerland [23]. Children were assessed both at baseline (summer 2008) and 9 months later. Children from the 20 control classes were used for these analyses. They did not receive any intervention and were not at the same schools as the intervention classes. The study was approved by the cantonal ethical committees of St. Gallen and Vaud and written informed consent from the parents or legal representatives was obtained for 312 of the initial 367 control children (participation rate: 85%). The current database focuses on those 245 children (79% of the 312 participating children) with aerobic fitness and cognitive data at both time points. Compared to children whose parents consented but who did not have a complete valid dataset (n=67), the 245 children in the current analysis were 0.2 years older (p=0.02) and more likely to have parents of low educational level (44 vs. 26%, p=0.02). Otherwise they did not significantly differ regarding sex, BMI, baseline aerobic fitness, motor skills and cognitive and sociocultural characteristics. Complete information about sociocultural characteristics was available for 217 of 245 children so that the adjusted analyses were done with this reduced sample.

### Aerobic fitness and motor skills

The tests of aerobic fitness, agility and dynamic balance were assessed in a gym during a time period of 45-50 minutes. After a standardized warm up, children were divided in two groups: One performed first the obstacle course and then the balance beam test and vice versa. For both motor skill tests, children were divided in groups consisting each of three to four children headed by a trained researcher. Altogether, three groups of children were concomitantly performing the obstacle course and three groups the balance beam test. Both motor skill tests were performed individually. Afterwards, the shuttle run test was performed in two consecutive groups consisting each of 6-11 children. All outcomes were measured by specially trained researchers.

Shuttle run test. Aerobic fitness was assessed by the multistage 20 m shuttle run test [24]. The test measures aerobic capacity by running back and forth for 20 m with an initial running speed of 8.0 km/h and a progressive 0.5 km/h increase in the running speed every

minute indicated by a sound. The maximal performance was determined when the child could no longer follow the pace or stopped because of exhaustion. The test results were expressed as stages (one stage corresponds approximately to the running time of one minute). The 20 m shuttle run test has been found to be a reliable (test-retest r=0.73-0.93 (p<0.05) in 6-to 16-year-old children) [24] and valid measure of maximum oxygen consumption as measured by treadmill testing (r=0.69-0.87, p<0.05) [25]. Due to the young age of the children, some formal adaptations of the original test were made by marking tracks on the floor for each individual child and by having an adult running with the children until the end of the test to provide adequate pace. In one of our pilot studies testing these adaptations, scores were measured twice for children aged 4- to 6 years (n=20) and test-retest reliability was r=0.84 (p<0.001).

Obstacle course. Agility was assessed by an obstacle course that measured a combination of speed, strength, spatial orientation and memorization of a specific sequence of actions [26]. This obstacle course was designed for 3- to 6-year-old children by Vogt and modified by Kunz [27]. It includes running 1 m from a marking cone to a transversally positioned bench, jumping over the bench (36 cm high, 28 cm wide), crawling back under this bench and running back to the marking cone three times in a row as fast as possible. The test was assessed by the time needed to complete the obstacle course and was measured in seconds. Each child had two attempts and the faster one was used for data analysis. The interobserver correlation and the test-retest reliability in our pilot study (n=14) were *r*=0.99 (*p*<0.01) and *r*=0.82 (*p*<0.01), respectively. Balance beam. Dynamic balance was tested by balancing forward barefoot on a 3 m long and 3 cm wide balance beam [28]. As an outcome measure, the consecutive successful steps on the beam were counted until the child's foot touched the floor or until the maximum of eight successful steps was reached. Children performed three trials and the mean of the best two trials was calculated and used for further analyses. The interobserver correlation and the test-retest reliability between the two better attempts in our pilot study (n=15) were r=0.97 (p<0.01) and r=0.84 (p<0.01), respectively.

### Spatial working memory and attention

The tests of spatial working memory and attention were assessed in the preschool setting along with the anthropometric measurements. For the cognitive parameters, children were tested individually in a separate room close to their classroom. All outcomes were measured by specially trained researchers.

IDS. To measure spatial working memory performance, a validated subtest for preschoolers that has been taken from the Intelligence and Development Scales (IDS) [29] was applied. Thereby geometrical forms had to be memorized and recognized from a new set of forms including color as distractor. In the first step, one colored geometrical form on a picture was shown that had to be memorized and recognized on a following picture where altogether three forms were shown. Thereby the color of the form changed between the two pictures. Over the following steps the number of forms that had to be memorized within one set of forms rose continuously up to the children's limit. The child had to point at the correct form(s). For every correct set of forms, children received one point. The test was stopped after three consecutive wrong answers. The sum of points was used for further analysis. Significant correlations to related measures confirmed construct validity (i.e. HAWIK-IV Working memory scale: r=0.52) and the test-retest reliability was r=0.48 [30].

*KHV-VK.* To measure attention performance, a validated test for preschoolers ("Konzentrations-Handlungsverfahren für Vorschulkinder (KHV-VK)") was applied [31]. The test material consisted of 44 cards with familiar pictures, which had to be sorted into four different boxes. On each card, 12 different small items were visible. Thereby, children had to recognize if among these 12 items, they saw a tree, a hair comb,

Table 1: Descriptive characteristics of the 245 children (girls n=121, boys n=124) at baseline and follow up							
	Baseline	Follow up	<i>p</i> -value				
Age and anthropometry							
Age [years], mean (SD)	5.2 (0.6)						
BMI [kg/m²], mean (SD)	15.8 (1.6)	15.9 (1.7)	0.05				
Sociocultural characteristics							
Migration background <sup>1</sup> , yes / no [%]	79 / 21						
Foreign language spoken at home, yes / no [%]	41 / 59						
Low parental education <sup>2</sup> , yes/no [%]	44 / 56						
Physical fitness							
Agility [s], mean (SD)	19.2 (4.5)	16.6 (3.2)	<0.001				
Aerobic fitness [stages], mean (SD)	3.0 (1.4)	4.5 (1.7)	<0.001				
Dynamic balance [steps], mean (SD)	2.4 (1.7)	3.0 (2.0)	<0.001				
Cognition							
Spatial working memory [no. of points], mean (SD)	3.6 (2.0)	4.8 (1.7)	<0.001				
Attention score [standard nine values], mean (SD)	10.4 (2.3)	11.0 (2.1)	<0.01				
Mixed linear regression analyses with preschool class (clus	ter) as random factor. S	oiteiveb brehnete D	n's seconds				

Mixed linear regression analyses with preschool class (cluster) as random factor. SD, standard deviation; s, seconds. <sup>1</sup> at least 1 parent born outside Switzerland vs. no parent born outside Switzerland

<sup>2</sup> at least 1 parent with no education beyond mandatory school (9 year) vs. middle or high parental

both or neither of both items. The cards had to be sorted as fast as possible in the four respective boxes showing the same pictures of these items: "a picture of a tree", "a picture of a hair comb", "a picture of both" and "a picture without any items". Total attention score was based on sorting time and error quote. Published test-retest reliability was r=0.88 [31].

### Covariates

*BMI.* Body height and weight were measured using standardized procedures [23]. BMI was calculated as weight  $(kg)/height (m)^2$ .

Sociocultural characteristics. To assess migrant status and parental education, parents filled in a general questionnaire regarding their sociocultural characteristics. Parents were defined as migrant if they were born outside of Switzerland [32]. Their educational level was recorded as the respective highest grade of school completed (5 levels). Low educational level was defined as no education beyond mandatory school (9 years) [33]. For analyses, migrant status and low parental education were divided into two categories (at least one vs. no migrant parent / at least one vs. no parent with low education). Children were also categorized into two groups according to the language most frequently spoken at home (native language): French/German (local official languages) vs. other native languages. Due to school legislation, no information could be obtained on economic status.

### Statistics

All analyses were performed using STATA version 11.0 (Statacorp, College Station, Tx, USA). Differences in age, sex and outcome parameters between children with and without complete data were assessed using the unpaired t-test for continuous and the  $\chi^2$ -test for binomial variables. All testing was two-tailed and at a significance level of 0.05. For descriptive analyses, measures of BMI, sociocultural characteristics, aerobic fitness, motor skills, spatial working memory and attention are presented as means (standard deviations, SD). To assess the relationships between aerobic fitness, motor skills, cognitive parameters and the measured confounder variables that are hypothesized to influence aerobic fitness, motor skills and/or cognitive parameters (e.g. age, sex, BMI, sociocultural characteristics like migration status, parental education, native language and linguistic region), we used correlation analyses for continuous confounder variables and ttests for binomial variables. To assess longitudinal changes of all measures, mixed linear regression models were computed. To account for potential clustering of data within preschool classes, all performed regression analyses included respective random intercepts. To assess the cross-sectional and longitudinal relationship of aerobic fitness and motor skills with memory and attention, we used mixed linear regression models with the cognitive parameters as outcome and aerobic fitness/motor skills (predictor) as fixed

Table 2: Cross-sectional relationship between baseline aerobic fitness and motor skills with cognition (n=245).								
	Aerobic fitness [stages]							
-	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>				
Spatial working memory [no. of points]								
Unadjusted model <sup>1</sup>	0.30	0.12 to 0.47	0.001	0.22				
Adjusted model <sup>2</sup>	0.12	-0.08 to 0.33	0.246	0.08				
Attention score [standard nine values]								
Unadjusted model <sup>1</sup>	0.19	-0.09 to 0.47	0.850	0.10				
Adjusted model <sup>2</sup>	0.25	0.02 to 0.49	0.036	0.15				
	Agility [s]							
_	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>				
Spatial working memory [no. of points]								
Unadjusted model <sup>1</sup>	-0.12	-0.17 to -0.06	<0.001	-0.27				
Adjusted model <sup>2</sup>	-0.07	-0.13 to -0.02	0.013	-0.17				
Attention score [standard nine values]								
Unadjusted model <sup>1</sup>	-0.10	-0.16 to -0.02	0.008	-0.18				
Adjusted model <sup>2</sup>	-0.11	-0.19 to -0.03	0.005	-0.20				
		Dynamic bala	nce [steps]					
	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>				
Spatial working memory [no. of points]								
Unadjusted model <sup>1</sup>	0.17	0.02 to 0.3	0.024	0.14				
Adjusted model <sup>2</sup>	0.02	-0.13 to 0.17	0.792	0.02				
Attention score [standard nine values]								
Unadjusted model <sup>1</sup>	0.27	0.01 to 0.53	0.774	0.13				
Adjusted model <sup>2</sup>	0.06	-0.11 to 0.24	0.452	0.06				

Mixed linear regression analyses with preschool class (cluster) as random factor.

<sup>1</sup> not adjusted

<sup>2</sup> adjusted for sex, age, BMI, migration status, parental education, native language and linguistic region

<sup>3</sup> partial correlation coefficient between outcome and predictor variable.

<sup>95%</sup>CI, 95% confidence interval; β-Coeff., β-Coefficient; s, seconds

factor. In the longitudinal analysis, we additionally adjusted for baseline memory and attention to assess the association between baseline aerobic fitness/motor skills and the prospective change in cognitive parameters. In a second step ("adjusted model"), we adjusted cross-sectional and longitudinal analyses for the potential confounder variables. For better understandability and comparability, the results of mixed linear models were also expressed in the form of partial correlation coefficients. These coefficients were computed by first regressing outcome and predictor variables of interest against the covariates of the underlying model and then correlating the resulting residuals. Conversely, the same regression and correlation analyses were performed with aerobic fitness/motor skills as the outcome and cognitive parameters as predictor variables. Potential interactions with sex were tested. As no sex interactions were found, we did not stratify analyses by sex.

### Results

The **characteristics of the sample** at baseline and at follow up are shown in **Table 1**. 78% of the children had a migrant background and the most frequent migrant countries or regions were: Portugal, Africa, Asia, Turkey, Albania and "rest of Europe". Aerobic fitness, motor skills, spatial working memory and attention

improved over the 9 months. Analyses between the confounder variables and the outcome measures showed that aerobic fitness, motor skills and cognitive parameters were related to age ( $p \le 0.002$ ), while only aerobic fitness and motor skills were related to BMI (all p < 0.01). Aerobic fitness, motor skills and both cognitive parameters differed according to sociocultural characteristics (p < 0.05 for differences according to either migration status, parental education, native language and/or linguistic region). Baseline and follow up values were correlated as following: aerobic fitness (r=0.76), agility (r=0.71), dynamic balance (r=0.33), working memory (r=0.42), attention (r=0.31), all p < 0.001.

In the cross-sectional analyses (Table 2), aerobic fitness was positively related to attention in the adjusted analyses. The relationship of **aerobic fitness** with working memory, however, did not remain significant after adjustment. A shorter time in the obstacle course (increased level of **agility**) was related to better performance in working memory and in attention before and after adjustment. The relationship of **dynamic balance** with working memory did not remain significant after adjustment.

In the **longitudinal analyses (Table 3)**, baseline aerobic fitness was associated with improvements in attention. The relationship of an increased level of baseline agility with improvements in memory and in attention

Table 3: Longitudinal relationship between b	aseline aerobic fitness and motor skills with changes in cognition 9
month later (n=245).	

month later ( <i>n</i> =245).								
		Aerobic fitnes	ss [stages]					
	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>				
Spatial working memory [no. of points]								
Unadjusted model <sup>1</sup>	0.1	-0.03 to 0.24	0.136	0.1				
Adjusted model <sup>2</sup>	0.08	-0.09 to 0.24	0.366	0.06				
Attention score [standard nine values]								
Unadjusted model <sup>1</sup>	0.29	0.11 to 0.47	0.002	0.19				
Adjusted model <sup>2</sup>	0.25	0.03 to 0.48	0.029	0.16				
	Agility [s]							
	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>				
Spatial working memory [no. of points]								
Unadjusted model <sup>1</sup>	-0.05	-0.09 to -0.01	0.020	-0.15				
Adjusted model <sup>2</sup>	-0.04	-0.09 to 0.01	0.100	-0.11				
Attention score [standard nine values]								
Unadjusted model <sup>1</sup>	-0.07	-0.14 to -0.005	0.036	-0.14				
Adjusted model <sup>2</sup>	-0.05	-0.12 to 0.03	0.241	-0.09				

	Dynamic balance [steps]					
_	β-Coeff.	95% CI	<i>p</i> -value	r <sup>3</sup>		
Spatial working memory [no. of points]						
Unadjusted model <sup>1</sup>	0.17	0.06 to 0.28	0.002	0.20		
Adjusted model <sup>2</sup>	0.13	0.01 to 0.25	0.035	0.15		
Attention score [standard nine values]						
Unadjusted model <sup>1</sup>	0.13	-0.02 to 0.3	0.081	0.12		
Adjusted model <sup>2</sup>	0.05	-0.11 to 0.22	0.518	0.05		

Mixed linear regression analyses with preschool class (cluster) as random factor.

95%Cl, 95% confidence interval; β-Coeff., β-Coefficient; s, seconds

<sup>1</sup> adjusted for baseline cognitive performance

<sup>2</sup> adjusted for sex, age, BMI, migration status, parental education, native language, linguistic region and baseline cognitive performance

<sup>3</sup> partial correlation coefficient between outcome and predictor variable.

over nine months did not remain significant after adjustment. However, baseline dynamic balance was associated with improvements in spatial working memory before and after adjustment.

In case of a loss of significance, this was not due to the lower sample size in the adjusted model. The relationships of aerobic fitness and motor skills with working memory were mostly attenuated by the age of the children, and the ones with attention by parental education and by BMI. In contrast to the above mentioned relationships, baseline memory and attention were not associated with any improvements in aerobic fitness or motor skills, neither before nor after adjustment (all p> 0.1).

### Discussion

### Main results

These analyses addressed both the cross-sectional and longitudinal relationships of aerobic fitness and motor skills with spatial working memory and attention in preschool children. Aerobic fitness and motor skill measures were positively associated with current working memory and/or attention after adjustment for BMI and sociocultural characteristics, and to some extent also with their future improvements over the following 9 months. Thereby, the relationship varied if aerobic fitness, agility or balance were investigated: The crosssectional results were most consistent for agility where both physical and cognitive resources are required.

## Relation of baseline aerobic fitness and motor skills with baseline memory and attention

In our cohort, aerobic fitness and motor skills were positively related to current cognitive parameters. The findings concerning the motor skill measures complement two existing cross-sectional studies in preschoolers that show similar relationships [13, 14]. One previous study that failed to show a relationship between motor skills and cognition had a small sample size (n=36 children) [17] compared to the other two (n=85 and 295) [13, 14]. However, none of the preschool studies assessed aerobic fitness and they did not adjust for BMI or sociocultural characteristics. As our data demonstrate, it is important to account for these confounders.

# Relation of aerobic fitness and motor skills with improvements in memory and attention over 9 month

Our longitudinal analysis showed that baseline aerobic fitness and motor skills were related to some improvements in cognitive parameters. However, the relationships were not always consistent with the crosssectional results and were sometimes attenuated after controlling for confounders. One possible explanation is that the positive relation of aerobic fitness or motor skills with memory or attention might be set earlier for certain parameters with no further amplification of differences during the preschool years. It might be, that there are sensitive periods, during which aerobic fitness and motor skills have a stronger impact on cognitive parameters. And possibly the time period of nine month is too short to detect a relation between two measures, which are both strongly associated with other factors. One previous longitudinal study has been performed in young children that assessed the relationship of reported motor performance between birth and age 4 to cognitive parameters at age 6 [21]. This study found that motor performance accounted for a significant proportion of the variance of cognitive parameters. However, they did not control for baseline cognitive parameters and thus could not assess longitudinal changes. Additionally, motor performance was only reported, but not measured.

## Relations according to aerobic fitness and motor skills

Concerning aerobic fitness, the present study has found a cross-sectional relationship of aerobic fitness with attention in the adjusted analyses. In the longitudinal analyses, aerobic fitness was consistently related to improvements in attention. This would indicate that high fitness in preschool children might have beneficial effects on attention in the following years. These longitudinal data are in line with a cross-sectional study done by Hillman and his colleagues, which revealed that aerobic fitness in school children was associated with accuracy and speed (both measured in our attention task) in a stimulus discrimination task [12]. However, in contrast to the predominantly adult literature, we did not find a consistent relationship between aerobic fitness and memory. In accordance with previous reviews [18, 19], we conclude that factors that influence cognitive development in children might probably differ from those in adults and that the relationship of aerobic fitness with cognitive performance might evolve over time.

Of the domains assessed in the present study, **agility** was most consistently related to both cognitive measures in the cross-sectional analyses. Agility was tested through an obstacle course that measured a combination of speed, strength, spatial orientation and memorization of a specific sequence of actions. This kind of resource-demanding test involves both physical and cognitive resources [26] which could explain the correlation with both cognitive measures. Similar results have been found in a study with sport games which are also considered to require both physical and cognitive resources [34].

We found a relationship of **dynamic balance** with working memory that got more consistent when analyzed longitudinally, possibly due to maturation and neural adaptations that occur in young children. No association was found between dynamic balance and attention. These results coincide with cross-sectional findings in preschoolers with and without learning disabilities, where the authors did not find a positive relation of dynamic and static balance with global aspects of cognition, but with working memory [35]. Both the balance and the memory task do not include speed in their evaluation which might be one reason for the found relationship.

### **Confounder variables**

In our population, some associations were attenuated or did not remain significant after adjustment for different confounder variables. In another longitudinal study [21] and in a cross-sectional study in older children [36] the adjustment for sociocultural characteristics attenuated [36] or strengthened [21] the relationships between physical fitness/motor skills and academic achievement or cognitive parameters. This underlines the importance to take those confounders into account.

## Relation of baseline memory and attention with improvements in aerobic fitness or motor skills

In contrast to the relationships mentioned above, we did not find any associations of baseline memory and attention with improvements in aerobic fitness and motor skills, neither before nor after adjustment. This lack of longitudinal relationship has not been previously investigated and adds to our understanding regarding the dominant direction of the relationship between those measures.

### **Strength and Limitations**

We included a comprehensive and objective assessment of aerobic fitness, two different motor skill measures and two cognitive parameters in a relatively large sample of preschool children. An important strength of this study is the cross-sectional and longitudinal design in the same population, which is novel for this young age group. This also gives a hint about the direction of the observed relationships despite the relatively short follow-up period. Although we did not directly measure academic achievement, attention and working memory may play a crucial role in key learning areas for children at the beginning of formal education [37]. For example, measures of working memory at school entry have been found to provide excellent predictors of children's success in national assessments of scholastic abilities up to 3 years later [38]. Unfortunately, the test-retest reliability of the spatial working memory task is with r=0.48 quite low. Another limitation is the use of an indirect measurement of VO<sub>2</sub> to test aerobic fitness. This may have diluted the relationship between aerobic fitness and cognitive parameters. However, the test had a good reproducibility in our pilot and laboratory tests would not have been feasible in this epidemiological approach. In this age group, it can be hypothesized that tests conducted in the preschool setting may better reflect performance levels in real-life than assessments in more experimental settings [39].

### Conclusions

Based on our results, higher performance in aerobic fitness and motor skills in preschoolers seems to be related to improved spatial working memory and/or attention. Based on neurophysiological approaches, we cautiously suggest that structural and functional modifi-

cations might explain the relationship of aerobic fitness and motor skills with cognitive parameters found in our study. Baseline measurements were to some extent also related with improvements in memory and attention over nine month. Based on our results we suggest that exercises involving specific mental processing including executive functions are most suitable to trigger global cognitive development in young children. Further studies should measure the longer-term impact of increasing aerobic fitness and/or motor skills as well as the impact of different domains on specific cognitive parameters. Our data contribute to the emerging field of brain fitness and highlight the importance of a promotion of physical education.

### **Competing interests**

The authors declare that they have no competing interests.

### Authors' contributions

IN was implicated in the more detailed conception of the study, responsible for the performance of the aerobic fitness and motor skills tests in half of the children, had a main job in the data collection, analyzed and presented all data, wrote the initial manuscript and all its revisions. SK was of major assistance in the conception of the project, the choice of the aerobic fitness and motor skills tests and the physical activity measurements as well as the presentation of the data. JG supported us in the analysis and the interpretation of the results as well as in revising the manuscript giving inputs of a psychologist. One of the cognitive tests used (IDS), was provided to us from her research group. TH helped in the choice and performance of the cognitive tests, contributed in the data collection and assisted in presentation of the data. JB supported the team in the neurocognitive aspects, in the data collection and in the presentation of the data. CS assisted in the conception of the study and gave epidemiological and statistical assistance. JP is the project leader for the design, implementation, analysis and presentation of the data, the draft and all revisions of the manuscript. All authors read and approved the final manuscript.

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### **Publication 4**

# Effect of a multidimensional lifestyle intervention on fitness and adiposity in predominantly migrant preschool children (Ballabeina): a cluster randomised controlled trial

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Research article

# Effect of a multidimensional lifestyle intervention on fitness and adiposity in predominantly migrant preschool children (Ballabeina): a cluster randomised controlled trial

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We declare that we have no conflict of interest.

### Abstract

**Objective:** To test the effect of a multidimensional lifestyle intervention on aerobic fitness and adiposity in predominantly migrant preschoolers.

**Design:** Cluster randomised controlled single blinded trial (Ballabeina Study) over one school year; randomisation was performed after stratification for linguistic region.

**Setting:** 40 preschool classes in areas with a high migrant population in the German and French speaking regions of Switzerland.

**Participants:** 652 of the 727 preschool children had informed consent and were present for baseline measures (mean age 5.1 years (SD 0.7), 72% migrants of multicultural origins). No children withdrew, but 29 had moved away.

**Intervention:** The multidimensional culturally tailored lifestyle intervention included a physical activity programme, lessons on nutrition, media use and sleep, and adaptation of the built environment of the preschool and lasted from August 2008 to June 2009.

**Main outcome measures:** Primary outcomes were aerobic fitness and BMI. Secondary outcomes included percent body fat, waist circumference, motor agility, balance, physical activity, eating habits, media use, sleep, psychological health, and cognitive abilities.

**Results:** Compared with controls, children in the intervention group had an increase in aerobic fitness at the end of the intervention (adjusted mean difference: 0.32 stages [95% CI 0.07 to 0.57], p=0.01), but no difference in BMI (-0.07 kg/m2 [95% CI -0.19 to 0.06], p=0.31). Relative to controls, children in the intervention group had beneficial effects in percent body fat (-1.1% [-2.0 to -0.2], p=0.02), waist circumference (-1.0 cm [-1.6 to -0.4], p=0.001), and motor agility (-0.54 sec [-0.90 to -0.17], p=0.004). There were also significant intervention benefits in reported physical activity, media use and eating habits, but not in the remaining outcomes.

**Conclusions:** A multidimensional intervention increased aerobic fitness and reduced body fat, but not BMI in predominantly migrant preschoolers.

Trial Registration: clinicaltrials.gov Identifier: NCT00674544

### Introduction

Adiposity and low aerobic fitness in children are associated with a clustering of cardiovascular risk factors.<sup>1</sup> The high prevalence of childhood obesity<sup>2</sup> and low fitness<sup>3 4</sup> represents a major public health burden. Thereby, children with migrant and/or socially disadvantaged background are disproportionately affected.<sup>5 6</sup> Few prevention programmes exist in these populations and they are generally less effective.<sup>7-9</sup> Therefore, there is a large demand for innovative and effective prevention measures that target this high-risk group to avoid the potential widening of health inequalities.

We had previously performed a physical activity (PA) intervention in elementary schoolchildren that decreased adiposity and increased aerobic fitness.<sup>10</sup> Indeed, most prevention studies have been performed in schoolchildren, but few of them reported successful results.<sup>11 12</sup> Focusing on younger children has the ad-

vantage to tackle a period where the basis for a healthy lifestyle is still being established. In addition, the preschool period (four to six years) corresponds to the time of the adiposity rebound which is thought to be critical for obesity development.<sup>13</sup> However, little research has been devoted to preschool children. Further, the combined effects of a health-promoting study on aerobic fitness, different adiposity measures, and diverse lifestyle behaviors have never been assessed appropriately.

Existing trials have focused on PA and/or nutrition, but the determinants of obesity and healthy lifestyle behaviors are multiple and inherently complex and interlinked.<sup>14</sup> Therefore, the Ballabeina study was designed to focus on several potentially modifiable lifestyle behaviors implicated in the development of childhood obesity or low fitness such as PA, nutrition, media use and sleep. The main purpose of this multidimensional cluster randomised controlled trial was to increase aerobic fitness and reduce BMI in predominantly migrant preschool children of multicultural origin.

### Methods

### Study design, setting and participants

The Ballabeina study is a cluster-randomised controlled trial conducted in 40 randomly selected public preschool classes in areas with a high migrant population from two different sociocultural and linguistic regions in Switzerland. The detailed design of the study protocol has been previously described.15 The study was conducted in the German (city of St. Gallen, canton SG; 70'000 inhabitants) and the French (urban surroundings of Lausanne, canton VD; 50'000 inhabitants) speaking regions of Switzerland during the school year 2008/09. The preschool setting was chosen as all children in Switzerland attend preschool.

Preschool classes were the unit for randomisation and intervention. Eligibility criteria for the preschool classes included a >40% prevalence of migrant children (defined as at least one parent born outside of Switzerland16 17) and no participation in any other prevention project.

### **Randomisation and blinding**

Randomisation of classes (1:1) was performed separately for the German (SG, n=20) and French (VD, n=20) speaking parts. Classes were randomised with the use of opaque envelopes. For practical reasons, and to minimise contamination, preschool classes integrated in the same school building were randomised into the same group. Recruitment took place between November 2007 and January 2008. Selection and randomisation took place between February and March 2008 and were performed by a person from the School Health Services who was not involved in the study. Teachers, parents, and children were informed that the intervention aimed to promote children's health, but were unaware of the main objectives of the study. Specially trained researchers measured outcomes and were blinded to group allocation. Contact persons and organisers (IN, FB, VE) were unblinded, and therefore not involved in measuring outcomes.

### Intervention

The rationale, the pilot studies, focus groups and the intervention methods have been previously described in more detail.<sup>15</sup> The intervention lasted one school year (end of August to mid-June 2009) and was based on the following four lifestyle behaviors: PA, nutrition, media use and sleep. The study was designed to intervene at the individual (children, teachers, and parents) and environmental (school curriculum and built environment of the preschool) level and focused on changes in education, attitudes and behavior, and on providing social support. To be culturally tailored, norms and needs were evaluated in different pilot studies and focus groups, information translated as needed, recommendations kept simple and short using many pictures and a focus was set on practical exercises. Trained health promoters intervened on the level of the teachers (workshops, visits with hands-on training, assistance in the adaptation of the built environment), parents (events in collaboration with the teachers) and children (PA lessons).

### Children

Children participated in a PA programme consisting of four 45 minute sessions of PA per week. The PA lessons aimed to increase aerobic fitness and coordination skills; they were designed to be playful and organised into themes (e.g. "Clown, Spiderman"). The lessons took place in or around the preschool classroom and once a week in the gym. Health promoters taught one PA lesson/week which was reduced to twice a month after four months. The remaining lessons were provided by the regular preschool teacher. Additionally, there were 22 lessons on healthy nutrition, media use, and sleep. Positive and culturally-independent nutritional messages were based on the five recommendations of the Swiss Society of Nutrition ("drink water", "eat fruit and vegetables", "eat regularly", "make clever choices", "turn your screen off when you eat").18 In addition, healthy snacks during recess and healthy treats for anniversaries were promoted. In May 2009, a Ballabeina event was organised with games implementing the main messages of the intervention. Stickers that were pasted on a poster in the classroom illustrated the advancement of the programme. Regardless of consent, participation in the intervention was mandatory for all children. Additional information about the intervention material is provided elsewhere.<sup>18 19</sup>



### Figure 1: Trial profile of clusters

INT=Intervention classes, CON=Control classes

\*Inclusion criteria included a >40% prevalence of migrant children and no participation in any other prevention project. †Reasons for refusals were lack of interest or time (of the director or the teacher) or health problems of the teacher.

### Teachers

Teachers participated in two workshops to learn about the content and the practical aspects of the intervention and in one informal meeting to exchange their experiences. Teachers received the prepared intervention lessons several weeks in advance.

### Parents

Parents participated in three interactive information and discussion evenings about promotion of PA, healthy food, limitation of TV use and importance of sufficient sleep. Further support was provided by brochures, funny cards, worksheets, and PA exercises that children brought home. Information leaflets were provided in 10 different languages and native speakers of the main foreign languages were available to answer questions. Participation of children in extracurricular activities was also encouraged, but not verified.

### Environmental factors

Besides curricular changes, the built environment of the preschool was adapted to promote PA. Thereby, fixed and mobile equipment such as climbing walls, hammocks, balls, cords, or stilts were installed or provided in and around classrooms, including a "movement corner".

### **Control group**

The control group did not receive any intervention and continued their regular school curriculum which in-

cluded one 45 min PA lesson per week in the gym; for the French part, one additional 45 min rhythmic lesson per week was provided corresponding to their regular curriculum. Parents of the control group participated in one information and discussion evening. No financial incentives were provided for either intervention of control group.

### **Objectives and outcomes**

We tested the efficacy of the intervention by comparing participants allocated to intervention group with those in the control group at the end of the intervention.15 Measurements were performed before (August 2008) and at the end of the intervention (June 2009). All primary and secondary outcomes were measured less than two weeks apart and are reported at the individual child level. Physical fitness outcomes were assessed in the gym and adiposity outcomes and cognitive abilities in a separate room close to the classroom. All outcomes were measured by specially trained researchers and the tests in the preschool were supervised by a medical doctor. Additional details on the pre-specified outcomes and pilot studies evaluating the feasibility and test-retest validity of the measures in this population have been previously reported.15



Figure 2: Trial profile of participants.

\*BMI at follow-up was also measured in four control and one intervention child that had moved away. †Bioelectrical impedance analysis. ‡Measured by accelerometry. §Attention and spatial working memory. || Reported PA, sleep duration and media use. ¶Assessed by parental questionnaires. \*\*Completion of all questions related to the five messages of the Swiss Society of Nutrition (used to calculate a sum score). One child with cerebral palsy was excluded from fitness testing.

*Primary outcomes* included BMI and aerobic fitness. Body height and weight were measured by standardised procedures.15 Aerobic fitness was assessed by the 20 m shuttle run test, where children run back and forth for 20 m with an initial running speed of 8.0 km/h and a progressive 0.5 km/h increase of the running speed every minute.20 Results were expressed as stages, one stage corresponding to the running time of one minute. 8-10 children took the test at one time and each child had a researcher assigned who was checking adequate test procedures. In an unpublished pilot study in this population, test-retest reliability was r=0.84 (n=20, p<0.001).

Secondary outcomes included additional adiposity and fitness measures.15 Overweight was defined according to cut-offs of the International Obesity Task Force (IOTF).21 Bioelectrical impedance analysis was performed using a 4-polar single frequency device (RJL Systems, Model 101A; Detroit, MI, USA) and percent body fat calculated based on a validated formula for children in this age group.22 Sum of four skinfolds (triceps, biceps, subscapular and suprailiac) was measured triplicate to the nearest 0.5 mm with Harpenden calipers (HSK-BI, British Indicators, UK).23 Waist circumference was measured with a flexible tape in midway between the iliac crest and the lowest border of the rib cage. Motor agility (obstacle course) and dynamic balance (balance beam) were tested individually within groups of three to four children. The obstacle course includes the time needed for running 1 m from a marking cone to a transversally positioned bench, jumping over the bench (36 cm high, 28 cm wide), crawling back under this bench, and running back to the marking cone three times in a row as fast as possible.24 25 Dynamic balance included the num-

Secondary outcomes also included PA measured by accelerometry (MTI/CSA 7164, Actigraph, Shlimar, FL, USA) and reported PA, eating habits, media use, sleep duration, guality of life and cognitive abilities (attention and spatial working memory).15 Accelerometers were consistently worn around the hip over five days at baseline and at the end of the intervention (both summertime) using a sampling epoch of 15 sec/seconds. Eating habits were assessed by the parents with a semi-qualitative food frequency questionnaire.16 28 Healthy eating habits were defined according to the five recommendations of the Swiss Society of Nutrition.16 18 Each recommendation further included two subtopics. For example, for the first recommendation, one topic was the encouragement of water drinking and the second topic the reduction of sweetened drinks. For each topic, we built quartiles of responses, as the values of the respective topics had different codings. Thereby, binary variables were created (coding one for the healthiest quartile vs. zero for the others). The binary variables were further summed up to create a general healthy eating score. "Healthy eaters" thus corresponded to the highest guartile of their recommendations. As numbers with the same values were put into the same category, the number of "healthy eaters" does not exactly correspond to 25%. Other lifestyle characteristics like reported PA29, media use (TV viewing and video games playing), sleep duration,30 health related quality of life (PedsQL 4.0),31 and sociocultural characteristics were assessed by a general health questionnaire that was filled out by the parents. "Active children" were defined as those who answered to be "more" or "much more" active than their peers of the same sex and age.29 Parental migrant status was determined by their country of birth16 17 and the educational level as the highest grade of school completed (five levels). Parental low educational level was defined as education (mandatory school

years) of at most 9 years. For descriptive analyses, migrant status and low parental education were divided into three categories (no parent migrant/with low education, one parent migrant/with low education, both parent migrant/with low education). Children were also categorised into two groups according to the language most frequently spoken at home (native language): French/German vs. foreign language. Due to school legislation, no information could be obtained about economic data (i.e. earning, wages). To test attention, children had to sort 40 cards with familiar pictures into four different boxes32 and sorting time (quantitative dimension) and number of correct cards (qualitative dimension) were assessed. To test spatial working memory, an increasing number of geometrical forms which became more and more complex had to be memorised and then recognised from a new set of figures including colors as distractors.33 Process evaluation of the implementation in the preschool was performed by the health promoters and at home through parental questionnaires.

### Statistical methods

All analyses were performed using STATA version 11.0 (Statacorp, College Station, Tx, USA). With an average class size of 18, we assumed that, on average, 13 children per class would participate in both shuttle run tests (due to non-participation, attrition, moving, sickness on the testing day). We calculated that a total number of 40 classes would provide 90% power for detecting a true intervention effect of half an intersubject standard deviation at the significance level of 0.05, provided that the standard deviation of the random class effect does not exceed 25% of the intersubject standard deviation (i.e., corresponding to an intra-class correlation of around 0.06). We hypothesised a corresponding effect size for change in BMI and shuttle run performance.

Analyses were performed on an intention to treat basis, using individual children data but adjusting for clustering of outcomes within school classes. Data are described by mean ±SD or percentages. Intervention effects were estimated using mixed linear and logistic regression models, adjusting for baseline outcomes, age, sex, sociocultural and linguistic region (German vs. French part of Switzerland) as covariates. Results of logistic regression analyses are presented as odds ratios with 95% confidence intervals. Potential modifications of intervention effects by sex or age were tested and were all found to be non-significant. No pvalue adjustment for parallel comparisons was made because the focus was on effect estimation and there is considerable correlation between the outcome and the predictor variables considered.

Table 1: Baseline characteristics of children accord	ling to experimenta	al group	

	Total	Intervention	Control
Number of children	652	343	312
Girls (%)	50	48.8	51.2
Age, yr (mean, SD)	5.2 (0.6)	5.2 (0.6)	5.2 (0.6)
French versus German part of Switzerland (%)	51.2	51.5	51.0
Parental low educational level (%)*			
None of the parents	61.9	64.6	58.9
One parent	21.3	21.5	21.1
Both parents	16.8	13.9	20
Speaking mainly foreign language at home (%)†	39.5	37.5	41.8
Parental migrant status (%)‡			
None of the parents	27.8	31.0	24.1
One parent	24.5	22.3	27
Both parents	47.8	46.8	48.9
Most frequent migrant regions (%)§			
Former Yugoslavia	24.2	27.9	20.1
Portugal	17	19	14.9
Rest of Europe	31	26.3	36.2
Africa	12.1	12.1	12.1
Rest of the World¶	15.7	14.7	16.7

Data were provided by parental questionnaires. \*At most 9 years of education. †Any other language than German or French. ‡Born outside of Switzerland. §According to country of birth of the father. Analogous numbers were obtained for the country of birth of the mother. || Predominantly Mediterranean and Eastern Europe. ¶Predominantly Asia, Middle East and South America.

### Results

### Participant flow

Figures 1 and 2 show the flow charts of the trial profile. A total of 40 preschools (727 children) entered the study and were randomly assigned to group (20 interventions, 20 controls) after stratification for sociocultural and linguistic region. Informed consent was obtained from 655 children (participation rate: 90%), and 652 were examined at baseline. A sample of 342 children received the intervention. None of the 40 preschools left the study and 9 children of the control and 18 of the intervention group had moved away by the end of the year.

### **Baseline data**

Children's baseline characteristics are presented in table 1. Of the participating children, 72% had at least one parent and 48% had two parents born outside of Switzerland. We noted no differences in baseline characteristics and outcome variables between the intervention and control group (all p $\ge$ 0.2).

### Outcomes

Data on outcomes are presented in tables 2 and 3. There was a significant higher increase in aerobic fitness in the intervention compared to the control group. Thereby, the adjusted mean difference versus the control group corresponded to 11% of the mean baseline values. Although no group difference in BMI at follow-up was found (table 2), children in the intervention group showed reductions in percent body fat and the sum of four skinfolds and lower increases in waist circumference than control children, with intervention effects being in the order of 5%, 10% and 2% of the respective mean baseline values. They also showed a more pronounced improvement in motor agility (time to perform an obstacle course), but not in static or dynamic balance. There were also significant beneficial intervention effects on reported PA, eating habits and media use. There was no intervention effect for the prevalence of overweight, measured PA, sleep duration, cognitive abilities and quality of life (table 3).

### Process Evaluation

A total of 20 (out of 20) evaluation feedbacks of teachers and 297 (out of 342) of parents in the intervention group were obtained over the course of the study. Most of the teachers (95%) attended both workshops and the informal meeting. The majority of PA and nutrition lessons were implemented as planned (95±6% for PA and 88±14% for nutritional lessons). In 85% of the classes, the built environment in or around the preschool was adapted. 85% of parents came to at least one of the three information evenings and over 90% of parents reported having seen the PA and nutrition cards with the home exercises. According to parental report 75 and 80% of the children had done the nutrition and the PA exercises on the cards or worksheets at home and 89 and 92% had liked the respective cards.

Table 2: Adiposity and physical fitness outcomes. Baseline and postintervention values are unadjusted means (SD) unless stated otherwise.

	Base	eline	Postinte	rvention	Adjusted differer	nce at fo	llow-up
	Intervention	Control	Intervention	Control	Coefficients or Odds Ratio (95% CI)*	p value	ICC
Physical fitness							
Aerobic fitness (shuttle run, stages)	2.9 (1.3)	2.9 (1.4)	4.6 (1.7)	4.3 (1.7)	0.32 (0.07 to 0.57)	0.01	0.07
Agility (obstacle course, seconds)	19.4 (4.6)	19.3 (4.4)	16.2 (2.8)	16.7 (3.2)	-0.54 (-0.90 to -0.17)	0.004	<0.01
Dynamic balance (balance beam , steps)	2.4 (1.6)	2.3 (1.7)	3.1 (2.2)	2.9 (2.0)	0.2 (-0.21 to 0.60)	0.35	0.05
Static balance (balance platform, total length, mm)	941 (925)	953 (226)	875 (137)	857 (128)	19.4 (-9.1 to 48.0)	0.18	0.10
Adiposity							
BMI (kg/m <sup>2</sup> )	15.6 (1.4)	15.8 (1.6)	15.7 (1.5)	15.8 (1.7)	-0.07 (-0.19 to 0.06)	0.31	0.05
Overweight (BMI ≥90th percentile, %)†‡	10.5	13.0	11.0	14.9	0.65 (0.32 to 1.32)	0.23	<0.01
Percent body fat§	23.7 (6.3)	23.6 (6.8)	23.2 (6.2)	24.1 (6.7)	-1.1 (-2.02 to -0.20)	0.02	0.18
Sum of four skinfolds (mm)	27.3 (8.1)	26.6 (9.2)	25.7 (7.5)	28.4 (11.1)	-2.78 (-4.35 to -1.2)	0.001	0.28
Waist circumference (cm)	52.8 (4.2)	52.8 (4.3)	53.3 (4.1)	54.3 (4.9)	-1.0 (-1.6 to -0.42)	0.001	0.12

ICC=intercluster correlation. CI=confidence interval.

\*Change estimates and 95% CIs are the differences between intervention and control group with preschool class as the unit of randomisation and after adjustment by mixed linear or logistic models for the baseline value, age, sex, and language region. †In case of logistic regressions, data are presented as OR (95% CI). ‡Cut-offs of the International Obesity Task Force (IOTF). §Bioelectrical impedance analysis. Samples sizes for each time point (baseline, postintervention and both) are provided in Figure 2.

### Adverse events

No injuries or other adverse events have occurred during PA lessons in the intervention classes.

#### Discussion

### Main findings

We employed a multidimensional school-based intervention in predominantly migrant preschoolers in two sociocultural and linguistic different regions in Switzerland. The intervention included a physical activity programme, lessons on nutrition, media use and sleep, and adaptation of the built environment of the preschool. Using approaches designed to target a multicultural population, we observed improvements in aerobic fitness, but no changes in BMI. The intervention also lead to beneficial effects in percent body fat, the sum of four skinfolds, waist circumference, and motor agility. Respective intervention effect sizes of the mean baseline values were 11% for aerobic fitness and 5-10% for body fat. Fitness and body fat are both important health determinants. Their observed improvements point to a combined effect of several potentially modifiable determinants, especially as reported PA, eating habits, and media use showed beneficial changes.

### Strengths and limitations

A novelty of the current study is the focus on young migrant children of multicultural origins in Europe, a population at high risk for obesity development.6 Further strengths are the multidimensional approach, the main focus on adiposity and on fitness, the comprehensive assessment, the high participation rate and the rigorous implementation. The inclusion of sleep as part of a lifestyle intervention represents an innovative concept. According to age, sleep durations of 10-10.5 hours per night have been suggested to protect against obesity.34 35 Sleep duration was not influenced by this intervention. However, sleep at baseline might have been sufficient for the large majority of preschoolers, as only 5% slept less than 10 hours per night. Based on our results, future intervention should consider to specifically focus on these high-risk children. The effect of lifestyle on psychological health and cognitive abilities in young children has been previously debated, but not investigated in a randomised design. We therefore included the assessment of those parameters in our school-based intervention. Neither of both measures improved which raises questions regarding their direct link or the need for other approaches. For example, in order to achieve significant neurocognitive benefits, the PA intervention may need to be more intense, or contain more tasks that specifically demand both physical and cognitive resources.

	Base	eline	Postinte	rvention	Adjusted difference at follow           Coefficients or           Odds Ratio         p $(95\% Cl)^*$ value         h $(-51.5 \text{ to } 26.9)$ $0.54$ 0 $1.7$ $0.01$ < $(1.1 \text{ to } 2.6)$ $0.04$ < $(-12.3)$ $0.04$ < $(1.1 \text{ to } 2.6)$ $0.04$ < $(1.02 \text{ to } 3.6)$ $-13.4$ $0.03$ 0 $(-25.0 \text{ to } -1.7)$ $0.03$ 0         0 $(-20.90 \text{ to } 0.1)$ $0.97$ 0         0 $(-27.0 \text{ to } 19.1)$ $0.98$ 0         0 $(-27.0 \text{ to } 19.0)$ $0.87$ 0         0		low-up
		Control	later entire	Control	Coefficients or Odds Ratio	р	100
	Intervention	Control	Intervention	Control	(95% CI)*	value	ICC
Lifestyle characteristics							
Total physical activity (cpm)	724 (166)	729 (165)	817 (186)	820 (215)	-12.3 (-51.5 to 26.9)	0.54	0.05
Active children (%)†‡	44.8%	49.0%	53.1%	43.7%	1.7 (1.1 to 2.6)	0.01	<0.01
Healthy eaters (%)†§	26.4%	21.4%	24.3%	12.4%	1.9 (1.02 to 3.6)	0.04	<0.01
Media use (TV & computer, min/d)	65.6 (60.0)	69.1 (63.1)	64.9 (53.0)	81.7 (74.5)	-13.4 (-25.0 to -1.7)	0.03	0.06
Sleep duration (hrs/d)	10.9 (0.6)	10.9 (0.6)	10.9 (0.6)	10.8 (0.6)	0.002 (-0.09 to 0.1)	0.97	0.03
Cognitive abilities and quality of life							
Attention (KHV-VK, duration in min)	5.9 (1.9)	5.9 (1.6)	5.5 (1.5)	5.6 (1.6)	-4.0 (-27.0 to 19.1)	0.98	0.07
Attention (KHV-VK, correct cards)	29.2 (10.4)	28.5 (11.0)	34.8 (5.8)	34.7 (5.6)	0.05 (-0.89 to 0.99)	0.87	0.03
Spatial working memory (IDS)	3.7 (2.0)	3.6 (2.0)	4.8 (1.7)	4.6 (1.7)	0.11 (-0.31 to 0.54)	0.58	0.03
Quality of life (PedsQL, total score)	82.5 (11.0)	82.1 (10.8)	81.5 (11.6)	80.3 (10.4)	1 (-0.57 to 3.1)	0.17	0.02

Table 3: Outcomes in lifestyle characteristics, cognitive ability, and quality of life. Baseline and postintervention values are unadjusted means (SD) unless stated otherwise.

ICC=intercluster correlation. CI=confidence interval. Cpm=count per minute. KHV-VK=Konzentrations-Handlungsverfahren für Vorschulkinder [Concentration test for preschoolers]. IDS=Intelligence and Development Scales. PedsQL=Pediatric Quality of Life Inventory.

\*Change estimates and 95% CIs are the differences between intervention and control group with preschool class as the unit of randomisation and after adjustment by mixed linear or logistic models for the baseline value, age, sex, and language region. †In case of logistic regressions, data are presented as OR (95% CI). ‡Reported by parents to be more active than other children of the same age and sex (Lipid Research Questionnaire). §Correspond to the healthiest quartile of the dietary recommendations of the Swiss Society of Nutrition (Food frequency questionnaire). Samples sizes for each time point (baseline, postintervention and both) are provided in Figure 2.

A limitation of this study is the use of an indirect measurement of VO2 to test aerobic fitness. However, the shuttle run test had a good reproducibility in our pilot trial and laboratory tests would not have been feasible in this epidemiological study. We opted for BMI as our primary outcome in view of a possible implementation strategy including simple and cost-effective measurement tools. However, BMI did not change. A more intense intervention within the preschool setting outside of a research project would not be feasible, but possibly a more extensive involvement of parents, the community and policies.36 On the other side, given the low overweight prevalence at baseline, one could challenge the need to lower BMI. In addition, more specific measurements of body fat may be necessary to measure the effect of a PA intervention in a general non-obese population37 which is consistent with our own results regarding central and total body fat. We found no intervention effect on measured PA. Despite this finding, increases in PA throughout the year are likely to have occurred in view of the improvements in aerobic fitness and motor agility which were manifest in the absence of any BMI-changes. Furthermore, the lack of effect on measured PA might be in part explained by the large intraindividual variability of PA,38 its low measurement precision regarding the extensive use of "gliding activities" on bikes, scooters or roller skates,39 and the fact that the follow-up measurements had to take place at

the end of the school year, when the intervention was diluted by other end-of-the year events. Of particular note is that 8 of the 20 control classes indeed had their sports week during their follow-up PA assessment. Another limitation is that the study lacks a long-term assessment of the observed effects. Ideally, a further continuation of this programme into advancing school years should be pursued and its long-term effects evaluated.

### Comparison to other studies

Previous trials had demonstrated no or very limited success when intervening in **migrant** or socially disadvantaged children.<sup>7 8 40</sup> In the current study, the many in-school activities and their mandatory nature and the cultural adaptations most likely played a major role for achieving beneficial effects.<sup>41</sup>

In preschoolers, there exist eight RCTs aiming to reduce either BMI,<sup>9 34 42-47</sup> and/or body fat<sup>42 46 47</sup>. Of those, one focused on television viewing,<sup>47</sup> the others on physical activity with our without a nutritional intervention, but none was multidimensional. Overall, two studies, combining PA with nutritional interventions, demonstrated beneficial effects.<sup>42 43</sup> One was a small, very intense PA intervention (270 min/week) over 14 weeks.<sup>42</sup> The other, performed in a population with a high baseline prevalence of overweight of over 30%, was less intensive, but included parents with the help of weekly newsletters and homework assignments that were linked to financial incentives.<sup>43</sup> PA in our intervention was rather intense, amounted to 180 min/week and was complemented by home exercises. As addressed in previous studies,<sup>48</sup> a high intensity and parental inclusion may be two important factors to achieve an effect on adiposity in this age group and a more multidimensional approach might be favorable. Two previous RCTs in preschoolers have assessed effects on aerobic fitness, but both lack methodological quality using either a 600 m run or a 10 m shuttle run test.<sup>40 42</sup> Similarly to our results, the only other preschool study that used accelerometers, did not find an intervention effect on PA.<sup>34</sup>

### Implications and generalisability

Aerobic fitness predicts reduced morbidity and mortality in adults49-51 and is associated with a more beneficial cardiovascular risk profile in children.5210 52 As aerobic fitness in children predicts future PA53 it may help to sustain achieved intervention effects. Therefore, and in view of a substantial decrease in children's fitness of 10% over the last 20 years,3 4 the improvements in aerobic fitness in favor of the intervention group are most relevant.

The spread of non-communicable diseases presents a global crisis and affects particularly individuals who are poor which raises already existing inequalities.54 As response to this crisis, a strong focus on primary prevention has been defined as a Public Health priority, encouraging interventions in young children.54 The preschool age is thought to be a critical time for the development of overweight and obesity.13 This was also evident in our study in which the prevalence of overweight, particularly of the control group, started to increase at the end of the study period. The study took place in two sociocultural and linguistic different parts of Switzerland which reflect the broader situation in Europe including more "northern and southern" cultural regions. This and the multicultural origins of the migrant populations suggest the intervention to be more universally applicable within Europe. Based on the few successful preschool interventions,42 43 additional approaches to enhance parental collaboration such as combining school-based interventions with interventions in the health setting and community actions and complementing such programmes with wider environmental and policy intervention should be further evaluated in future studies.

In conclusion, our approaches to target a multicultural population of preschoolers did not change BMI, but resulted in improvements in aerobic fitness and body fat, both important health determinants. Currently, some of the Cantonal Health promotion programmes in Switzerland are implementing several modules of the Ballabeina intervention. Further dissemination of this programme could contribute to reduce some aspects of the burden of chronic diseases and of the health inequalities that have risen as a consequence of social inequities.

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### What is already known on this subject:

Obesity and low fitness are disproportionally prevalent in migrant children.

Prevention programmes in this particular multicultural population are scarce, mostly ineffective and even nonexistent in preschoolers.

As obesity is caused by various lifestyle behaviors, there is a need to evaluate multidimensional interventions.

### What this study adds:

A multidimensional culturally tailored lifestyle intervention programme improved fitness and body fat in predominantly migrant children.

The preschool age is a critical period to start prevention studies.

**Contributors:** JJP and SK designed the study. JJP was the principal investigator and is guarantor. JJP, SK, LZ, IN, FB, VE, AN, CS, and PM established the methods and questionnaires. IN, FB, VE and JP were the main coordinators of the study. IN, FB, VE, LZ, AN, PM and JJP conducted the study. CS and PM gave statistical and epidemiological support. JJP wrote the article with the support of SK, PM, FB and IN. JJP obtained the funding, with the assistance of SK and LZ. All authors provided comments on the drafts and have read and approved the final version.

All authors, internal and external, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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**Ethical approval:** The study was approved by both ethical committees of the cantons involved in the study (SG and VD) and written informed consent was given by a parent or legal representative of each child. **Data sharing:** No additional data available.

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## **Publication 5**

# Benefits of a lifestyle intervention in adiposity and fitness in overweight and low fit preschoolers (Ballabeina)

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in submission

### Research article

# Benefits of a lifestyle intervention in adiposity and fitness in overweight and low fit preschoolers (Ballabeina)

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### Abstract

**Background:** Overweight (OW) and low fit children represent cardiovascular high-risk groups that are difficult to reach. We investigated whether OW ( $\geq 90^{th}$  national percentile) and low fit (lowest sex- and age-adjusted quartile of aerobic fitness) children benefitted equally from a multidimensional school-based lifestyle intervention compared to their normal weight and normal fit counterparts.

**Methods:** Cluster randomized controlled trial with 40 preschool classes from the French and German speaking parts of Switzerland. The intervention lasted from August 2008 to June 2009 and included a playful physical activity program and lessons on nutrition, media use and sleep which also included parents. Primary outcomes were changes in BMI and aerobic fitness; secondary outcomes were changes in sum of four skinfolds (SF), waist circumference and motor agility. Modification of intervention effects by BMI-group and fitness-group was tested by interaction terms.

**Results:** In the total sample (n=652, mean age 5.2±0.6 yrs), the intervention reduced SF thickness and waist circumference and improved both physical fitness outcomes. Compared to their counterparts, OW children (n=130) had more beneficial effects on waist circumference (p for interaction = 0.001) and low fit children (n=154) on all three adiposity outcomes (all p for interaction  $\leq$  0.03). The intervention effects on both fitness outcomes were not modified by BMI- or fitness-group (all p for interaction  $\geq$ 0.2).

**Discussion:** This comprehensive multidimensional intervention was at least equally effective in high-risk preschoolers and represents a promising option for OW and low fit children.

Key words: overweight prevention, anthropometry, physical fitness, children

Trial Registration: clinicaltrials.gov Identifier: NCT00674544

### Introduction

Overweight (OW) (1), obesity (2) and low aerobic fitness in children are associated with a clustering of cardiovascular risk factors (3). High BMI (4) and low fitness (5-7) represent a major public health burden. There is a need for effective strategies to reduce OW and obesity and to increase fitness to minimize physical and psychosocial consequences (8).

Interventions regarding childhood obesity range from obesity prevention to treatment of established obesity and its complications (9). Treatment interventions are individually oriented and usually delivered either in specialized or in primary care settings (9). Counseling in primary care, i.e. by family practitioners, has shown only modest results (10-13). Comprehensive intensive behavioral interventions in specialized centers yield mostly positive results (10, 14). However, in many countries interdisciplinary therapy programs in specialized centers are expensive and only paid for the most severely affected children. In addition, only the more motivated children and families participate in such programs and access is difficult in more remote areas, further limiting a population-wide accessibility. Low physical fitness is also a cardiovascular risk factor and important for children's health (15). Aerobic fitness
tends to track in children (16, 17) and has been shown to predict future physical activity (PA) (18, 19). Thus, low fitness might lead to low PA, which in turn might negatively influence fitness even more (19). Still, to our knowledge, there are no interventions in groups of low fit children.

Both obesity and low fitness prevention include population-oriented and individual approaches. Populationoriented approaches, like environmental and policy changes, reach a large number of subjects at low costs and they are critical for reaching the least-advantaged population segment (9). Individually oriented prevention approaches focus on children at high-risk of becoming OW (9). While there are many data on approaches for overweight children (9-13), no data exists for low fit children. School-based prevention programs include both environmental and individual components, transmit a healthy lifestyle to all children and could thus automatically reach normal weight/normal fit and OW/low fit children.

Interventions should start early, if possible at preschool age (20). In the preschool setting, there are eight randomized controlled trials (21-28) but, to the best of our knowledge, none of them investigated modification of intervention effects by BMI and/or fitness group.

We had recently demonstrated in a randomized controlled trial, that a multidimensional lifestyle intervention reduced body fat and enhanced aerobic fitness in a general population of preschool children (Puder et al. 2011, in submission). Based on the need for effective strategies to reduce adiposity and increase fitness in OW and/or low fit children, we investigated whether these high-risk groups benefitted equally from the intervention compared to their normal weight and normal fit counterparts.

### Methods and procedures

### Participants and study design

The Ballabeina study is a cluster-randomized controlled trial conducted in 40 randomly selected public preschool classes in areas with a high migrant population from two different sociocultural and linguistic regions in Switzerland. The design of the study has been previously described (29). The study was conducted in the German (city of St. Gallen, SG; 70'000 inhabitants) and the French (urban surroundings of Lausanne, VD; 50'000 inhabitants) speaking regions of Switzerland during the school year 2008/09. The preschool setting was chosen as all children in Switzerland attend preschool. Preschool classes were the unit for randomization and intervention. Randomization of classes (1:1) was performed separately for the German (SG, n=20) and French (VD, n=20) speaking parts. Classes were randomized by a person from the School Health Services with the use of opaque envelopes. Eligibility criteria for the preschool classes included a >40% prevalence of migrant children (migrant background was defined as at least one parent born outside of Switzerland) and no participation in any other prevention project. The study was approved by both cantonal

ethical committees and a parent or legal representative of each child provided written informed consent.

Teachers, parents, and children were informed that the intervention aimed to promote children's health, but were unaware of the main objectives of the study. Specially trained researchers measured outcomes and were blinded to group allocation. Contact persons and organizers were not blinded, and therefore not involved in measuring outcomes.

### Intervention

Rationale, pilot studies, focus groups and intervention methods have been previously described in more detail (29). The intervention lasted one school year (end of August to mid-June 2009) and was based on the following four lifestyle behaviors: physical activity (PA), nutrition, media use and sleep. The study was designed to intervene at the individual (children, teachers, and parents) and environmental (school curriculum and built environment) level and focused on changes in education, attitudes and behavior, and on providing social support.

Children: Children participated in a PA program consisting of four 45 minute sessions of PA per week. The PA lessons aimed to increase aerobic fitness and motor skills; they were designed to be playful and organized into themes (e.g. «Clown», «Spiderman»). The lessons took place in or around the preschool classroom and once a week in the gym. Health promoters gave initially one PA lesson/week which was reduced to twice a month after four months. The remaining lessons were provided by the regular preschool teacher. Additionally, there were 22 lessons on healthy nutrition, media use, and sleep. Nutritional messages were based on the recommendations of the Swiss Society of Nutrition («drink water», «eat fruit and vegetables», «eat regularly», «make clever choices», «turn your screen off when you eat», http://www.sgessn.ch/fileadmin/pdf/600-medien\_presse/40-bilder/ Ernaehrungsscheibe/Ernaehrungsscheibe\_englisch.

pdf). Healthy snacks during recess and healthy treats for anniversaries were promoted. Regardless of consent, participation in the intervention was mandatory for all children.

**Teachers:** Teachers participated in two workshops to learn about the content and the practical aspects of the intervention and in one informal meeting to exchange their experiences. Teachers received the prepared intervention lessons several weeks in advance and were supported by visits of health promoters and by hands-on trainings.

**Parents:** Parents participated in three interactive information and discussion evenings about promotion of PA, healthy food, and limitation of TV use. Further support was provided by brochures, funny cards, worksheets, and PA exercises that children brought home. Information leaflets were provided in ten different languages and native speakers of the main foreign languages were available to answer questions. Participation of children in extracurricular activities was also encouraged, but not verified.

**Environmental factors:** Besides curricular changes, the built environment was adapted to promote PA. Thereby, fixed and mobile equipment such as climbing walls, hammocks, balls, cords, or stilts were installed or provided in and around classrooms, including a «movement corner».

**Control group:** The control group did not receive any intervention and continued their regular school curriculum which included one 45 min PA lesson per week in the gym; for the French part, one additional 45 min rhythmic lesson per week was provided corresponding to their regular curriculum. Parents of the control group participated in one information and discussion evening. No financial incentives were provided for either intervention of control group.

#### Outcomes

We tested if the efficacy of the intervention (comparing participants allocated to intervention group with those in the control group) was modified by BMI or fitness of the children. Measurements were performed before (August 2008) and at the end of the intervention (June 2009). All primary and secondary outcomes were measured less than two weeks apart and are reported at the individual child level. Except for the questionnaires, all data were collected in the classroom or at the gym. Additional details of the outcomes have been reported (29).

*Primary outcomes* included BMI and aerobic fitness. Body height and weight were measured by standardized procedures (29). BMI was calculated as weight (kg)/height (m)<sup>2</sup>. **Overweight** (BMI ≥90<sup>th</sup> percentile, including obesity unless stated otherwise) was defined according to the Swiss National Percentiles (30). **Aerobic fitness** was assessed by the multistage 20 m shuttle run test (31), where children run back and forth for 20 m with an initial running speed of 8.0 km/h and a progressive 0.5 km/h increase of the running speed every minute until they could not keep up the predefined pace (31). Results were expressed as stages, one stage corresponding approximately to the running time of one minute. 8-10 children took the test at one time and each child had a researcher assigned who was checking adequate test procedures. In a pilot study in this population, test-retest reliability was r=0.84 (n=20, p<0.001). Low fitness was defined as the lowest sex and age adjusted quartile in aerobic fitness.

Secondary outcomes included additional adiposity measures (sum of four skinfolds (SF), waist circumference) and an obstacle course as an additional fitness measure (motor agility). Sum of four SF (triceps, biceps, subscapular and suprailiac) was used as a measure of body fat and measured triplicate to the nearest 0.5 mm with Harpenden calipers (HSK-BI, British Indicators, UK) (32). Waist circumference was measured with a flexible tape in midway between the iliac crest and the lowest border of the rib cage. Motor agility was assessed by an obstacle course that measured a combination of speed, strength, spatial orientation, and memorization of a specific sequence of actions (33). It was tested individually within groups of three to four children. The obstacle course includes running 1 m from a marking cone to a transversally positioned bench, jumping over the bench (36 cm high, 28 cm wide), crawling back under this bench, and running back to the marking cone three times in a row as fast as possible.

In a parental questionnaire, we asked for information about migration background and parental education. Low parental education was defined as at least one parent with no education beyond mandatory school (9 years).

28 / 72

38 / 62

76 / 24

40 / 60

17 / 84

57 / 43

73/27

37 / 63

v3. normarney						
	Overweight <sup>a</sup> (n=130)	Normal weight <sup>a</sup> (n=519)	p-value	Low fit <sup>b</sup> (n=154)	normal fit <sup>b</sup> (n=462)	p-value
Age [years]	5.2 ± 0.6	5.2±0.6	0.904	$5.3 \pm 0.6$	5.1 ± 0.6	0.016
Girls [%]	53.9	48.8	0.268	46.1	51.3	0.296
BMI [kg/m2]	18.0 ± 1.3	15.1 ± 0.9	<0.001	16.1 ± 2.0	15.6 ±1.3	0.001

22 /78

49/51

72 / 28

35 /65

0.003

0.039

0.116

0.008

35 / 65

59/41

80 / 20

48 / 52

Table 1: Baseline characteristics according to BMI-group (overweight vs. normal weight) and fitness-group (low vs. normal fit)

Data are shown as mean ± SD.

French versus German part of Swit-

Migration background<sup>c</sup>, yes / no [%]

Low parental education<sup>d</sup>, yes / no [%]

Overweight<sup>a</sup>, yes / no [%]

Low fit<sup>b</sup>, yes / no [%]

zerland [%]

<sup>a</sup> Swiss National Percentiles (Prader et al. Helv Paediatr Acta 1989;52:1-125). <sup>b</sup> Low fit ≤ 25th percentile, normal fit >25th percentile in baseline aerobic fitness (20m shuttle run test). <sup>c</sup> At least 1 parent born outside Switzerland vs. no parent born outside Switzerland. <sup>d</sup> At least 1 parent with no education beyond mandatory school (9 years) vs. middle or high parental education.

0.003

< 0.001

0.143

0.430

	Base	Baseline Follow		v-up				Inter-
	Intervention	Control	Intervention	Control	(95% CI)	n	p-value	action <sup>b</sup>
BMI (kg/m2)								
Overweight	17.8 (1.2)	18.2 (1.5)	17.7 (1.4)	18.2 (1.7)	-0.12 (-0.43 to 0.19)	127	0.46	0 501
Normal weight	15.1 (0.9)	15.2 (0.9)	15.2 (1.0)	15.3 (1.0)	-0.05 (-0.19 to 0.08)	499	0.42	0.521
Sum of four SF (mm)								
Overweight	36.7 (10.9)	37.6 (13.3)	33.2 (10.1)	40.1 (16.2)	-3.63 (-6.45 to 081)	106	0.01	0.00
Normal weight	25.1 (5.3)	23.8 (4.6)	23.8 (5.1)	25.5 (6.9)	-2.46 (-3.91 to -1.01)	452	0.001	0.08
Waist (cm)								
Overweight	58.1 (4.7)	58.2 (4.9)	58.0 (4.9)	60.1 (5.6)	-2.19 (-3.18 to -1.20)	121	<0.001	0.004
Normal weight	51.6 (2.9)	51.4 (2.7)	52.1 (2.9)	52.8 (3.3)	-0.67 (-1.24 to -0.11)	471	0.02	0.001
Shuttle run (stages)								
Overweight	2.6 (1.8)	2.5 (1.1)	4.3 (1.6)	3.8 (1.2)	0.40 (-0.01 to 0.82)	117	0.06	0.00
Normal weight	3.0 (1.4)	3.0 (1.5)	4.8 (1.7)	4.5 (1.7)	0.30 (0.03 to 0.56)	451	0.029	0.60
Obstacle course (s)								
Overweight	21.4 (4.9)	20.2 (4.2)	17.3 (2.7)	17.6 (3.3)	-1.03 (-1.92 to -0.14)	116	0.023	0.40
Normal weight	18.8 (4.4)	19.0 (4.5)	16.0 (2.8)	16.5 (3.1)	-0.42 (-0.81 to -0.02)	443	0.041	0.18

Table 2: Intervention effect (Intervention vs. Control) and interaction between intervention and BMI on adiposity and fitness outcomes

SF=skinfolds, CI=Confidence Interval

<sup>a</sup> Adjusted difference in changes between intervention and control group. Data shown as regression coefficients (95% confidence interval) adjusted for baseline value, age, sex, and language region. <sup>b</sup> p-value for interaction term intervention-group x BMI-group.

### Statistical analysis

Analyses were performed on an intention to treat basis at the child's level, but adjusting for clustering of outcomes within school classes. All children with valid BMI or valid shuttle run at baseline were included in the analysis (n=652). Data were described by means ±SD or percentages. All comparisons between intervention arms (intervention group vs. control group) were done using mixed linear and logistic regression models with preschool class (cluster) as random factor. Effect estimates were adjusted for age, sex, linguistic region (German vs. French part of Switzerland) and baseline outcomes as covariates. BMI-group (OW/normal weight children) and fitness-group (low fit/normal fit children) were pre-specified groups (29). To determine whether the intervention effect was modified by BMI-group and fitness-group, we used interaction terms (intervention arm x BMI-group and intervention arm x fitness group). In addition, we also tested if the intervention was modified by obesity (BMI ≥97th percentile/normal weight children). In a secondary analysis, all effects were also stratified by BMI-group or fitness-group to obtain separate point estimates for the respective subgroups.

As prevalence of low fitness differed according to BMIgroup and prevalence of OW differed according to fitness-group, we also adjusted in a second step the BMI-group model for fitness and the fitness-group model for BMI.

We further adjusted both models for parental education. This was not done in the initial model as parental education was missing for 129 children.

As the study was not designed to make statistical inferences on such interactions, we report these results as explorative analyses (29). No p-value adjustment for parallel comparisons was made because the focus was set on effect estimation and there is considerable correlation between the main outcomes and between predictor variables considered.

### Results

**Table 1** shows the baseline characteristics according to BMI-group (OW vs. normal weight) and fitness group (low vs. normal fit) adjusted for preschool class (cluster). In the total group, 20% were OW (including 10.5% obese) and 80% were normal weight, while 25% were low fit and 75% normal fit. Intervention and control groups were very similar in outcome measures at baseline and this also held true for the major subsamples (OW and normal weight or low fit and normal fit children) (cf. Table 2). OW and normal weight as well as low fit and normal fit children in general, however, differed significantly in all baseline measures of adiposity and fitness (all p≤0.001). In contrast the prevalence of low parental education did not differ according to BMI- or fitness-group.

In the total sample (n=652, mean age  $5.2\pm0.6$  yrs), the intervention reduced SF and waist circumference and improved both physical fitness outcomes.

# Intervention effects on adiposity and physical fitness outcomes modified by BMI

The intervention effects on adiposity outcomes were partially modified by BMI **(Table 2)** with a more beneficial effect on waist circumference in OW compared to normal weight children (p for interaction 0.001), but no significant interactions for BMI (p for interaction 0.5) and sum of four SF (p for interaction 0.08). The intervention effects on the physical fitness outcomes were not modified by BMI-group (p for interaction  $\geq 0.1$ ).

	Base	eline	Follow-up		Adi changes <sup>a</sup>			Inter-
	Intervention	Control	Intervention	Control	(95% CI)	n	p-value	action <sup>b</sup>
BMI (kg/m2)								
Low fit	16.0 (1.8)	16.2 (2.3)	16.0 (1.8)	16.3 (2.3)	-0.26 ( -0.46 to -0.03)	146	0.014	0.027
Normal fit	15.6 (1.3)	15.6 (1.3)	15.6 (1.4)	15.7 (1.4)	-0.02 (-0.17 to 0.12)	446	0.853	0.027
Sum of four SF (mm)								
Low fit	29.6 (10.9)	30.2 (14.3)	27.3 (9.1)	31.5 (16.4)	-5.04 (-7.4 to -2.70)	135	<0.001	0.001
Normal fit	26.7 (7.0)	25.5 (6.3)	25.1 (6.8)	27.5 (8.6)	-2.30 (-3.9 to -0.80)	397	0.003	0.001
Waist (cm)								
Low fit	54.0 (5.3)	54.2 (6.1)	54.0 (5.3)	55.7 (6.8)	-1.62 (-2.73 to -0.51)	141	0.004	0.026
Normal fit	52.5 (3.7)	52.4 (3.4)	53.2 (3.6)	53.9 (4.1)	-0.76 (-1.32 to -0.90)	422	0.009	0.020
Shuttle run (stages)								
Low fit	1.8 (0.7)	1.5 (0.6)	3.6 (1.3)	3.1 (1.3)	0.12 (-0.26 to 0.61)	140	0.422	0.240
Normal fit	3.3 (1.2)	3.4 (1.3)	5.0 (1.7)	4.8 (1.6)	0.36 (0.10 to 0.63)	431	0.007	0.310
Obstacle course (s)								
Low fit	19.8 (3.8)	21.8 (5.7)	17.1 (3.0)	18.2 (3.8)	-0.20 (-1.03 to 0.63)	138	0.637	0.467
Normal fit	19.2 (4.8)	18.4 (3.6)	15.9 (2.7)	16.2 (2.9)	-0.59 (-1.00 to -0.19)	422	0.004	0.407
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Table 3: Intervention effect (Intervention vs. Control) and interaction between intervention and fitness on adiposity and fitness outcomes

SF=skinfolds, CI=Confidence Interval

<sup>a</sup> Adjusted difference in changes between intervention and control group. Data shown as coefficients (95% confidence interval) adjusted for baseline value, age, sex, and language region. <sup>b</sup> *p*-value for interaction term intervention-group x BMI-group.

Subgroup analyses revealed that the intervention effects on SF and waist circumference were significant in both BMI-groups with effect sizes being 9% and 3.8% of the mean baseline values for the OW and 10.0% and 1.3% for the normal weight children. The intervention effects on agility were significant in both BMI-groups with effect sizes of 5.0% relative the mean baseline value for the OW and of 2.2% for the normal weight children. The intervention effects on aerobic fitness were significant in the normal weight group and marginally non-significant in the OW group with effect sizes of 15.4% for the OW and of 10.0% for the normal weight children, respectively.

### Intervention effects on adiposity and physical fitness outcomes modified by fitness

The intervention effects on adiposity outcomes were partially modified by fitness-group **(Table 3)** with more beneficial effects on BMI, sum of four SF and waist circumference in low fit compared to normal fit children (all p for interaction  $\leq 0.03$ ). The intervention effects on the physical fitness outcomes were not modified by the fitness-groups (p for interaction  $\geq 0.3$ ).

Subgroup analyses revealed that the intervention effects on BMI were only significant in the low fit group; the effects on sum of four SF and waist circumference were significant in both fitness-groups. The effect sizes were 1.6% of the mean baseline value for BMI, 16.9% for sum of four SF and 3.0% for waist circumference in the low fit children and 0.1%, 8.8% and 1.4% in the normal fit children. Concerning the fitness changes, the intervention effects were only significant in the normal fit children. The effect sizes for aerobic fitness and agility were 7.5% and 1.0% in the low fit and 10.6% and 3.1% in the normal fit children.

Adjusting the BMI-group model for aerobic fitness and the fitness-group model for BMI did not alter our results except that the interaction between intervention and BMI on sum of four SF got significant in favor of the OW group (p for interaction = 0.04). Similarly adjusting for a low parental education level, did not change the results except for the same above mentioned relation (p for interaction = 0.04). Using the obese instead of the OW subgroup to compare with normal weight children did not alter the results except for one measure: The intervention showed a more beneficial effect on the sum of four SF in obese compared to normal weight children (p for interaction 0.01). The intervention effect on OW prevalence was not modified by the fitness and the intervention effect on the prevalence of low fitness was not modified by the BMI (both p > 0.2, data not shown).

## Discussion

The effect of this multidimensional intervention on adiposity and fitness in preschoolers was partially modified by BMI and fitness: OW or low fit children showed at least as beneficial effects as their normal weight and normal fit counterparts. For some adiposity measures, they benefitted even more from the intervention. In the total sample, the intervention led to a reduction in body fat and waist circumference and an improvement in aerobic fitness and agility, while BMI remained unchanged (Puder et al. 2011, in submission).

It is of high importance to learn more about the effects of school-based interventions not only in the whole population, but also in high-risk children like those with increased BMI or low fitness. Even in children, OW and low fitness are associated with cardiovascular risk factors such as dyslipidemia, insulin resistance, inflammation, increased blood pressure and body fat (15, 34, 35). Additionally, some cross-sectional findings indicate that high levels of aerobic fitness in OW children are associated with lower CVD risk factors (3, 36). Unfortunately, lifestyle interventions in OW and obese children in primary care settings have yielded limited success (10-12). Though comprehensive intensive behavioral interventions in specialized centers yield mostly positive results (10, 37, 38), this approach is very expensive and the accessibility to the affected families and children is limited (10, 38, 39). In Switzerland, around 200 children and adolescents benefit yearly from specialized obesity programs, while 60'000 obese are in need for therapy (39). Additionally, dropout rates are substantial in primary care (40) and specialized centers (38) showing attrition rates over 12 months of up to 46% (38). So, the advantages of school-based programs such as accessibility, low attrition and the relatively low costs should not be ignored. For example, in our intervention, no child had left the study except for the 27 children (4%) who had moved away (Puder et al. 2011, in submission). Additionally, school-based interventions avoid that OW or low fit children are being treated separately and thus potentially feel discriminated.

Although the adiposity rebound at age 4-6 years is considered crucial for the development of obesity, there are actually few school-based lifestyle intervention studies in preschoolers. Eight RCTs to reduce adiposity have been performed in this age group (21-28) and two lead to a reduced BMI and/or body fat (22, 24). Two of these RCTs assessed aerobic fitness (21, 22) and two others motor skills (23, 26), all demonstrating some beneficial effects. However, while few studies show data stratified by BMI-group, none of the existing studies in preschoolers (or in school children) had investigated modification of intervention effects by BMI and/or fitness group. The intervention program of Nemet et al. (21) stratified their effects on aerobic fitness for OW and obese children (BMI-group) and showed that the improvements in fitness were also observed in the high-risk groups. For reasons of feasibility, they adopted the originally validated 20 m shuttle run test and performed a 10 m shuttle run test to measure aerobic fitness. Bayer et al. (26) stratified their analysis by BMI-group, but only presented stratified data for lifestyle behavior but not motor skills or anthropometric measures (26). To our knowledge, reviews or metaanalyses including preschool- and school-based lifestyle interventions did not include results in the highrisk groups of OW or low fit children (i.e.(41)).

One could assume that in view of their excess body fat, OW children may lose weight and body fat more easily compared to normal weight children; likewise, low fit children might more easily increase their physical fitness performance compared to normal fit children, who already perform on a satisfying level. Both groups might thus benefit more from a given «intervention dose» than normal weight and normal fit children. Yet, despite many efforts, population data indicate that the prevalence of overweight and obesity remains high (4) and that physical fitness level decreases (5-7).

In the current study, the intervention effects on **adiposity measures** were at least equally or more beneficial in OW and low fit children compared to their counterparts. Specifically, OW children showed an even more beneficial intervention effect on waist circumference and low fit children showed a more beneficial effect on BMI, SF thickness and waist circumference. Furthermore, subgroup analyses in these high-risk groups revealed that the intervention effects were significant in adiposity measures although sample sizes were obviously much smaller. This is of high importance as adiposity is a major cardiovascular risk factor in all children (42) and children who are additionally less fit have a combined risk for later cardiovascular disease (43). The intervention effects on both fitness outcomes were equally beneficial in OW and low fit children compared to their normal weight and normal fit peers, as the effect was not modified by BMI or fitness. The exploratory subgroup analyses in the small sized high-risk groups, however, revealed that the intervention effect on fitness measures was significant or borderline significant in the OW and not significant in the LF children and effect sizes pointed toward a similar conclusion.

Several characteristics of the study might have helped to achieve the generally positive results in the high-risk subgroups. The playful and fun multidimensional intervention focusing on physical activity, nutrition, media use and sleep approached children and parents in a «positive way» focusing on health promotion and not on prevention of OW or low physical fitness. This might have contributed to increase motivation, even in the high-risk groups. With the mandatory curriculum for all children, the Ballabeina program created new social norms for all. A focus was set on the transfer effect from the preschool to the child's home. Parenting skills were additionally endorsed by two parental evenings and one workshop. As children were young, baseline differences in fitness performance and weight were not as pronounced as among older children (44), which facilitated the physical activity intervention for teachers. Nevertheless, different activity levels were offered to accommodate children according to their fitness and teachers were trained in several workshops to stimulate children based on their individual performance level. Therefore, discrimination or stigmatization of children might have been minimized. These points together could have led to the result that also OW and low fit children have been reached by the intervention. Despite this, the group of the low fit children seemed to have benefitted least from the intervention regarding the physical fitness outcomes in terms of absolute effects. Several hypotheses might explain the observation of these exploratory subgroup analyses. Moderate or vigorous intensity seems to be needed (15, 19) to increase physical fitness, which might be less attractive or too strenuous for low fit children. Second, the physical fitness outcome measures could have been insufficiently sensitive or motivation dependent, which could have led to a more pronounced benefit for the normal fit children. Lastly, our intervention methods to reach the low fit children might not have worked well enough for the physical activity part. Interestingly, the low fit children showed more beneficial effects on adiposity outcomes compared to their normal fit counterparts.

Indeed, as low fit children were more often OW, they might possibly have a higher potential to lose body fat. And even though low fit OW children might show a certain resistance to increasing physical fitness, other aspects of the intervention like the promotion of a balanced nutrition might have specially caught their interest or the interest of their parents.

Strengths and limitations: A novelty of the current analysis is the investigation on a high-risk population of OW and low fit children. Additional strengths are the use of a stringent RCT-design in accordance with CONSORT guidelines, the relatively large study population and the high participation rate. In the current study, the broad range of in-school activities and their mandatory nature most likely played a major role for achieving beneficial effects in these high-risk children. A limitation of this study is the use of an indirect measurement of VO<sub>2</sub> (20 m shuttle run test) to test aerobic fitness. Additionally, the shuttle run is not validated for children younger than six years. However, the shuttle run test had a good reproducibility in our pilot trial and laboratory tests would not have been feasible in this epidemiological study. From a statistical point of view the unequal sizes of complementary subgroups (i.e. OW vs. normal weight or low vs. normal fit children) is a limitation for estimating effect modification. As the study was not powered to perform subgroup analyses, these analyses were of exploratory nature.

In conclusion, the results of this multidimensional study in preschoolers indicate that the intervention effect on body fat and fitness was at least as successful in OW compared to normal weight children and in low fit compared to normal fit children. This is important as these two subgroups of children are at increased risk of developing cardiovascular diseases and are difficult to be reached for effective treatment. «Ballabeina» offers a school based intervention program to reduce adiposity and increase fitness in the general population that also targets OW and low fit children. This offers a promising public health approach for the general preschool population, but particularly for those who are most in need.

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Physical fitness in preschool children: correlates and intervention effects

# Discussion

## 3. General discussion and conclusions

This thesis first describes the study design of Ballabeina. The following publications focus on the physical fitness of preschoolers, correlates to overweight and cognitive performance and intervention effects. The cross-sectional results showed that already in preschoolers, normal weight children performed significantly better in different dynamic fitness parameters such as aerobic fitness, agility and balance compared to their overweight counterparts. In the cross-sectional and longitudinal analyses of the publication 3, the relationship between aerobic fitness, agility and balance with memory and attention was investigated. Particularly agility but also aerobic fitness and dynamic balance were related to improved spatial working memory and/or attention. To some extent, baseline physical fitness was also related to future improvements in cognitive performance over the following 9 months. The analysis also showed that the intervention of the Ballabeina Study was successful in increasing aerobic fitness and agility but not balance in the general population. Of particular interest is the subgroup analysis of the fifth publication, showing that overweight and low fit children benefitted at least equally from the intervention compared to their normal weight and normal fit peers regarding body fat and physical fitness.

### Intervention effect on physical fitness

The multidimensional intervention increased agility and aerobic fitness but not balance in preschoolers. The publication of the intervention results shows that the Ballabeina children of the intervention group achieved a more significant improvement in aerobic fitness and in agility compared to the children of the control group. In the static and dynamic balance tests, no intervention effects were found. Although coordination was not improved as a result of the intervention, the findings of this study are of great value, because aerobic fitness is the physical fitness component that is most strongly associated with health related outcomes.<sup>1</sup> There are several points that might have been crucial for the success of the intervention. Compared to other lifestyle interventions, the physical activity curriculum was very intensive with a clear increase in the intensity of the aerobic components throughout the intervention year. The many in-school activities and their mandatory nature most likely played a major role for achieving beneficial effects.<sup>2</sup> A multilevel approach seems to be important in lifestyle interventions.<sup>3</sup> The Ballabeina Study coped with this by intervening on the individual and the environmental level (i.e. physical activity lessons in the preschool, intensive work with teachers and parents, adaptation of the built environment around the preschool, funny homework cards to support the transfer from preschool to home). Especially parental involvement is crucial in this age group<sup>4</sup> and this aspect could still be intensified in the future implementation of Ballabeina. A key factor of the intervention concept might have been the trained health promoters that gave physical activity lessons (initially once a week, then twice a month) and coached teachers and parents. The fact that we did not achieve any intervention effect on static and dynamic balance was somehow surprising as the physical activity lessons and the new school equipment focused also on balance. However, to the end of the intervention, aerobic fitness exercises were intensified at the expense of balance exercises. This could have diluted possible results. Additionally, based on our experience with the measures of static and dynamic balance we assume that measurements might have been not precise enough. The limitations regarding the validity of our measures are discussed below.

Four previous RCTs in preschoolers have assessed physical fitness.<sup>5-8</sup> Two of the studies assessed aerobic fitness and the physical activity programs were similar to our program.<sup>5.6</sup> But, both studies lack in methodological quality. Nemet et al.<sup>5</sup> showed an intervention effect on aerobic fitness in their children but they reported also an absolute decrease in aerobic fitness in the control group. This seems questionable after one entire school year, in terms of the development of the children and also in comparison to the results of our study, in which also the control children improved their aerobic fitness clearly. Additionally, the study group modified the 20m shuttle run test and used the same pacer but reduced the running distance to 10 m.<sup>5</sup> Unfortunately, the correlation to the standard 20 m shuttle run, particularly in this population, is not known. In a previous study, the same author group showed a significant intervention effect in a 600 m run, but also in this study the control children needed at post intervention 6 s more to run the distance at the end of the intervention.<sup>6</sup> Of the two studies assessing motor skills, Bayer et al.<sup>7</sup> showed no significant intervention effects in a fundamental movement skills score. As previous trials are few and show partially clear methodological limitations, the findings of the Ballabeina Study add important information to the current literature.

## Physical fitness and overweight

BMI-group-related differences in physical fitness can already be present in preschoolers, the Ballabeina Study, however, was at least equally effective in high-risk preschoolers and represents a promising option for overweight and low fit children. The cross-sectional analyses of the baseline data showed, that normal weight children performed significantly better in the three dynamic motor tests compared to their overweight counterparts. Differences were found in tests requiring mobility and agility and overweight children might have been disadvantaged by their higher body mass. It is also possible, that overweight children might have less experience in doing such tasks, based on a reduced physical activity. Nevertheless, these tasks reflect the fitness tasks that children perform during their daily activities. The differences in aerobic fitness and agility were more pronounced in older children compared to younger ones. Therefore it is important to start with interventions already in preschoolers and to support children with low physical fitness starting at a young age. This might help to reduce the ongoing epidemiological trend of overweight and low fitness in children and the development of cardiovascular risk factors in the coming years. In this context, it was interesting to investigate the intervention effect in overweight children. An often heard criticism of practitioners on lifestyle intervention is that the intervention reaches primarily those who are not affected of overweight and low fitness. The interaction and subgroup analyses, however, demonstrated that the intervention was at least equally successful in overweight as in normal weight children and in low fit as in normal fit children. Thus Ballabeina offers an effective school based intervention program to reduce overweight and increase fitness also in the risk groups of overweight and/or low fit children. Nemet et al.<sup>5</sup> stratified their analysis for overweight and obese children and showed that the improvements in fitness were observed also in overweight as well as in obese children.

### Physical fitness and cognition

Higher baseline physical fitness was related to better cognitive abilities at baseline, and to some extent also to their future improvements over the following 9 months. However, the intervention did not achieve significant cognitive benefits. The cross-sectional and longitudinal data of the Ballabeina Study indicate, that higher baseline physical fitness was related to a better spatial working memory and attention at baseline, and to some extent also to their future improvements over the following 9 months. Contrary to the above mentioned relationships, baseline memory and attention were not associated with any subsequent improvements in aerobic fitness or motor skills over the following 9 months. The dominant direction regarding the longitudinal association between measures was the relationship of physical fitness with future cognitive performance. This adds important information to the previous primarily cross-sectional data in children. In this regard it is interesting to also have a look at the intervention effects on the cognitive parameters. There was no significant intervention effect for changes in attention and spatial working memory, which is somehow contradictory to the cross-sectional and longitudinal results. To achieve significant cognitive benefits, the physical activity intervention might possibly need to be aligned differently. In the cross-sectional data it has been shown that a high agility was most consistent related to both cognitive parameters. Agility combines speed, strength, spatial orientation and memorization of a specific sequence of actions. It might be possible that an intervention should contain more tasks including both physical and cognitive resources like it is required in agility tasks. And finally the intervention was possibly too short and/or not intensive enough to achieve significant structural and functional modifications in the neurophysiological structure. Further studies should measure the impact of different domains on specific cognitive parameters with a focus on tasks requiring physical and cognitive resources. Based on these findings, targeted interventions to improve cognitive parameters should be tested. Nevertheless, our data contribute to the emerging field of brain fitness and the cross-sectional and longitudinal data highlight the importance of a promotion of physical education.

## Strength and limitations of this research

Strengths of the Ballabeina study in general are the used stringent RCT-design in accordance with CONSORT guidelines, the relatively large study population and the high participation rate. A further strength is the comprehensive and objective assessment of different fitness tests including aerobic fitness, agility, static and dynamic balance. Also other measurements like body composition and cognitive performance were based on objective tests.

However, the present data also have their limitations: Although lifestyle interventions in young children are needed,<sup>3</sup> there are not many objectively measured, valid and reliable fitness tests for preschoo-

lers. Fitness tests for relatively large populations should be objective, standardized, reliable and valid, constructed to test a large number of subjects and motivate the children to participate. The 20 m shuttle run test meets all these criteria<sup>9,10</sup> and is one of the most widely used aerobic fitness tests,<sup>11</sup> although it is an indirect measure of VO<sub>2</sub>max. Unfortunately, the 20 m shuttle run test is not validated for children below age six. However, the shuttle run test had a good reproducibility in our pilot trial (testretest: r=0.84, p<0.0.001, n=20). With respect of this limitation, we did not estimate the VO<sub>2</sub>max from the result of the test and did not compare the results with standard values but used the raw data to compare the children within the study. To meet the children's age, some formal adaptations of the original test were made by marking tracks on the floor for each individual child and by having an adult running with the children until the end of the test to provide adequate pace. This is not unusual as Ruiz et al. (2006) mentioned in their article about fitness assessment in children that in most studies adaptation of the tests has been made according to local/national, social, cultural or environmental considerations and/or budget issues. We had similar difficulties to find age-adapted adequate tasks to test agility and dynamic balance. Both tests have not been published as validated and reliable tests and are not part of known international test batteries. Nevertheless, both tests are very similar to known and partially validated and reliable tests or subtests in older children.<sup>12,13</sup> Furthermore, test criteria were objective and standardized and both tests had a good reproducibility in our pilot study (test-retest was r=0.82 (p<0.01, n=14) for agility and r=0.84 (p<0.01, n=15) for dynamic balance). Compared to other static (i.e. unilateral stand) or dynamic balance tests, our static bilateral test might not have been challenging enough and thus other factors like concentration, calmness or the urge to move became relevant in these young children. Reproducibility in the static balance test was r=0.73 (n<0.01, n=40)). Overall, test results of maximal tests in young children, even of the validated ones, should probably always be interpreted with caution, as many influence factors like motivation and cognitive development may have influenced the results and fluctuations in these factors are probably more prevalent compared to older children or to adults. Test experiences with such young children should be collected and used to develop efficient systems for large-scale collection of health-related fitness. In a further physical activity intervention study we would probably measure the intensity of the physical activity intervention at different time points during the year. Additionally, we would measure heart rate of the children during the 20m shuttle run test. However, we would need to be attentive if the transmitters of the heart rate monitors would bother these young children and thus influence the results. From a statistical point of view there are the limitations of unbalanced distributions between the normal fit and the low fit group in the subgroup analyses and between the overweight and the normal weight group in the cross-sectional and the subgroup analyses. Then, the study was initially not powered to do subgroup analyses. To meet this point, we interpreted results of the subgroup analyses in the sense of explorative analyses, rather than a firm scientific conclusion.

## Implications for practitioners and future research

The improvements in aerobic fitness in favor of the intervention group are relevant as recent observational studies have found an alarming decrease in children's fitness over the last 30-40 years of about

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-0.5% per year.<sup>14,15</sup> Aerobic fitness has an important health impact.<sup>11,16-24</sup> Physical activity interventions in schoolchildren have been shown to be successful in improving the cardiovascular risk profile. <sup>25,26</sup> Furthermore, aerobic fitness in children can predict future physical activity<sup>27</sup> and may thus help to sustain achieved intervention effects. Schools can improve children's health and should therefore adapt their curricula in favor of more health- and physical education. In preschools, this is easier to implement compared to the more competitive school environment. Future lifestyle interventions should assess longer term effects on aerobic fitness and motor skills and evaluate advanced approaches to enhance parental collaboration such as events for children and their parents in the health setting. Additionally, wider environmental community actions and policy interventions should be tested in further analysis.

The preschool time is thought to be a critical time for the development of overweight and obesity.<sup>28</sup> This research has shown that also the physical fitness gap between normal weight and overweight children is bigger in older compared to younger preschoolers. Screening not only for overweight but also for physical fitness deficits enables professionals to provide early and targeted support. The Ballabeina modules represent a possibility to increase physical fitness in normal weight as well as in overweight children. This might help to reduce this mentioned performance differences between normal weight and overweight children and the ongoing epidemiological trend of overweight, low physical fitness and development of cardiovascular risk factors in the coming years.

Concerning the cognitive performance, our data is able to contribute to the emerging field of brain fitness and highlights the importance of promoting physical education in school. We cautiously suggest that exercises involving specific mental processing including executive functions are most suitable to trigger global cognitive development in young children. However, this should be confirmed and the impact of different domains on cognitive parameters should be further analyzed in future studies.

Interventions are one of the cornerstones of childhood obesity research and prevention studies are crucial. Ballabeina was successful in several important areas. Nevertheless, Ballabeina was a very intense intervention and in its intensity (particularly for the preschool teacher), it is not feasible to be implemented on a population-wide basis. Currently, as a consequence of the study, individual modules will now be implemented in Swiss preschools within 9 of 26 cantons that participate in the «Purzel-baum project» (around 500 preschools). Compared to more intense and rigorous designs of research interventions, this practical project is widely accepted by teachers and parents and the feasibility is guaranteed. Their effects are not known (yet), but smaller effects are to be expected. However, the scientific results of the Ballabeina Study support the acceptance of these individual modules. Additionally, the fact, that Ballabeina was conducted in two different settings differing in language and culture, increases the acceptance of the modules in the different sociocultural regions of Switzerland. Another dilemma lies in the question if an intervention should focus on one dimension (e.g. physical activity) or be multidimensional. Obesity is a multifactorial, multidimensional disease, but multidimensional

sional interventions may be too complex and their message may get diluted. In the literature, there

exists data favoring both types of interventions, thus focusing on one<sup>29,30</sup> or multiple lifestyle factors.<sup>31-</sup> <sup>33</sup> More detailed analysis of process evaluations and mediation analysis, two aspects that have been previously neglected, may help to tease out the best combination of intervention parts.

# Conclusion

This research has shown that physical fitness in preschool children can be increased over a school year with a multilevel and multicomponent lifestyle intervention. Preschool level seems to be a crucial time point to start with interventions, as the vicious circle of overweight, low physical activity and fitness manifest itself at this age. Thereby, overweight children showed significantly lower fitness performances compared to normal weight children. Importantly, overweight and low fit children benefited at least as much from the Ballabeina intervention as their normal weight and normal fit counterparts. Fitness is not only important for physical but also for mental health, we therefore looked for this respective correlates and we found a cross-sectional and longitudinal relationship between physical fitness and cognitive performance. Agility was most consistently related to memory and attention in the cross-sectional analyses. An intervention effect on attention and spatial working memory of the children could not be demonstrated. However, there was also no negative effect of our lifestyle intervention on cognitive parameters despite a daily physical activity lesson that was implemented instead of more academic lessons. Overall, this research made an important contribution to the understanding of the relations of physical fitness with anthropometric or cognitive parameters and added a successful prevention strategy to combat low fitness in children to the scientific world.

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About the author

# About the author

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Address	Im Kugelfang 4, CH-4102 Binningen
Date of birth	4.02.1981
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# Education

Since 2007	PhD in Public Health, Institute of Exercise and Health Sciences, University			
	Basel			
	PhD thesis «Physical fitness in preschoolers: Correlates and intervention ef-			
	fects»			
	Supervisors:	PD Dr. Jardena J Puder, University of Lausanne		
		PD Dr. Susi Kriemler, University of Basel		
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September 2007	Master degree in Exercise and Health Sciences, University of Basel			
	Master thesis: «Movement- and nutrition tasks for children. Evidence-based			
	approaches to promote physical activity in children»			
	Supervisors:	PD Dr. Lukas Zahner, University of Basel		
		PD Dr. Susi Kriemler, University of Basel		
2001 – 2002	Training at UBS (1	8 months), graduate with a diploma.		
September 2000	General qualification	on for university entrance		
	Kantonsschule Tro	ogen (AR)		

# Employment

Research	
2007 - 2011	PhD Project at the Institute of Exercise and Health Sciences, University of
	Basel, Supervisors: PD Dr. Jardena J Puder, PD Dr. Susi Kriemler
2006 - 2008	Student assistant and project management «Kidz-Box» Institute of Exercise
	and Health Sciences, University of Basel
	Supervisor: Dr. Lukas Zahner, ISSW University of Basel

# Teaching

2011	Physical education, Gymnasium Münchenstein (6 hours for 10 week)
2011	Physical education, Gymnasium Oberwil (18 hours in total)
2008	Docent track and field, Institute of Exercise and Health Sciences, University
	of Basel
2007 - 2010	Training for preschool teachers as part of the project «Purzelbaum»
Others	
2008	Course expert «J+S Kids»
2004-2006	Student assistant, Institute of Exercise and Health Sciences, University of
	Basel (administration) (20%)
2002-2004	Bank assistant UBS (20%)
2001-2002	Bank assistant UBS (100%)

# Honorary Functions

Since 2010	Board member of the Sport Group TV Bottmingen (Youth leader)
Since 2010	Board member of the Sport Group TV Bottmingen (kids leader)
1998 – 2002	Board member of the Sport Group TV Teufen (Track and field leader)

# **Peer-Reviewed Original Publications**

- Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Hartmann T, Meyer U, Schindler Ch, Nydegger A, Marques-Vidal P, Puder JJ Influence of a lifestyle intervention in preschool children on physiological and psychological parameters (Ballabeina): study design of a cluster randomized controlled trial, *BMC Public Health* 9:94; 2009
- Ebenegger V, Marques-Vidal P, Nydegger A, Laimbacher J, Niederer I, Bürgi F, Giusti V, Bodenmann P, Kriemler S, Puder JJ Independent contribution of parental migrant status and educational level to adiposity and eating habits of preschool children, *European Journal of Clinical Nutrition*, in press
- 3. Bürgi F, Meyer U, **Niederer I,** Ebenegger V, Granacher U, Marques-Vidal P, Kriemler S, Puder JJ Sociocultural determinants of adiposity and physical activity in preschool children, *BMC Public Health,* in press
- 4. **Niederer I**, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Granacher U, Marques-Vidal P, Puder JJ BMI-related differences in motor abilities and physical activity in preschoolers (Ballabeina), *Research Quarterly for Exercise and Sport*, in press
- Niederer I, Kriemler S, Gut J, Hartmann T, Schindler Ch, Barral J, Puder JJ Relationship of physical fitness with cognitive performance in preschoolers: A cross-sectional and longitudinal study ("Ballabeina"), *BMC Pediatrics*
- Ebenegger V, Marques-Vidal P, Kriemler S, Nydegger A, Zahner L, Niederer I, Bürgi F, Puder JJ Differences in Aerobic Fitness and Lifestyle Characteristics in Preschoolers according to their Weight Status and Sports Club Participation, *Obesity Facts*, submitted
- 7. Puder JJ, Marques-Vidal P, Schindler C, Zahner L, **Niederer I,** Bürgi F, Nydegger A, Kriemler S Effect of a multidimensional lifestyle intervention on fitness and adiposity in predominantly migrant preschool children (Ballabeina): a cluster randomised controlled trial, *BMJ*, submitted
- 8. **Niederer I**, Bürgi F, Ebenegger V, Marques-Vidal P, Schindler C, Nydegger A, Kriemler S, Puder JJ Benefits of a lifestyle intervention in adiposity and fitness in high-risk subgroups of preschoolers (Ballabeina), *Obesity*, in submission

# Conference abstracts as first author

- Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Granacher U, Marques-Vidal P, Puder JJ The relationship between sex and obesity on motor skills in preschool children: "The Ballabeina study", 1<sup>st</sup> Annual Meeting of the Swiss Association of Sports Sciences (SGS), Bern, 02/09
- \*Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Granacher U, Marques-Vidal P, Puder JJ The relationship between sex and obesity on motor skills in preschool children: "The Ballabeina study", oral presentation, 9th Annual Meeting of the Society for Pediatric Sports Medicine, Köln, Germany, 02/09
- Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Granacher U, Marques-Vidal P, Puder J Bodyweight and migration-related differences in motor abilities in preschool children "Ballabeina" (Abstract No 383), 14th annual congress of the European College of Sport Science (ECSS), Oslo, Norway, 06/09
- 4. \*Niederer I, Kriemler S, Marques-Vidal P, Zahner L, Bürgi F, Ebenegger V, Hartmann T, Meyer U, Schindler Ch, Nydegger A, Puder JJ A multifactorial approach to prevent adiposity and improve fitness in preschool children (in Switzerland): cluster-RCT (the Ballabeina Study), oral presentation & award, 2e congrès annuel de la Société suisse des sciences du sport (4S), Zurich, Switzerland, 3/10
- \*Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Marques-Vidal P, Puder JJ BMI-related differences in motor abilities and physical activity in preschoolers (Ballabeina study), oral presentation, 2e congrès annuel de la Société suisse des sciences du sport (4S), Zurich, Switzerland, 3/10
- 6. \*Niederer I, Kriemler S, Zahner L, Bürgi F, Ebenegger V, Granacher U, Marques-Vidal P, Puder J BMI-related differences in motor skills increase with age in preschoolers (Ballabeina, oral presenta-

tion), Physical activity & health among 0-6 y.o. children, Epinal, France, 5/10, Science & Sports 2010 (25), 26-32

- Niederer I, Hartmann T, Barral J, Marques-Vidal P, Kriemler S, Puder JJ Motor ability and cognition in preschool children (Ballabeina): a cross-sectional and longitudinal analysis, 2nd joint meeting North American Society of Pediatric Exercise Medicine (NASPEM)–Pediatric Work Physiology (PWP), Ontario, Canada, 09/10
- \*Niederer I, Bürgi F, Ebenegger V, Schindler Ch, Marques-Vidal P, Kriemler S, Puder JJ Effect of a lifestyle intervention on adiposity and fitness in high-risk subgroups of preschoolers (Ballabeina): a cluster-randomized trial, oral presentation, 3e congrès annuel de la Société suisse des sciences du sport (4S), Lausanne, Switzerland, 2/11
- Niederer I, Bürgi F, Ebenegger V, Schindler Ch, Marques-Vidal P, Kriemler S, Puder JJ Effect of a lifestyle intervention on adiposity and fitness in high-risk subgroups of preschoolers (Ballabeina): a cluster-randomized trial, SGIM 3 - Endokrinologie und Metabolismus, oral presentation, 79th Annual Meeting of the Swiss Society for Internal Medicine, Lausanne, Switzerland 5/11

# Awards

- Award of the Society of Pediatric Sports Medicine 2009 (for the presentation of the mentored PhD student Iris Niederer: "The relationship between sex and obesity on motor skills in preschool children: The Ballabeina study", 200 Euro)
- Award of the Swiss Society of Sports Medicine ("2. Preis der Nachwuchspreise der Schweizerischen Gesellschaft für Sportmedizin") 2010 (for the presentation of the mentored PhD student Iris Niederer: "A multifactorial approach to prevent adiposity and improve fitness in preschool children (in Switzerland): cluster-RCT (the Ballabeina Study)", 250 CHF)